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Paper No. 55

STEPHEN S. SADACCA
LOCKHEED MARTIN CORPORATION
MAIL STOP WT-05
P.O. BOX650003
DALLAS TX 75265-0003

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JUN 28 2005

OFFICE OF PETITIONS

In re Application of
Monroe
Application No. 04/520,820
Filed: December 20, 1965
Attorney Docket No. 10919-16601
For: GUIDED MISSILE DEFENSE METHOD AND APPARATUS

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.137(b), filed March 3, 2005 (certificate of mailing date February 28, 2005), to revive the above-identified application.

This application became abandoned for failure to timely pay the issue fee within three (3) months of the mailing of the July 20, 2004 Notice of Allowance and Fee(s) Due. Accordingly, this application became abandoned on October 21, 2004. A Notice of Abandonment was mailed on January 13, 2005.

Applicant has submitted a proper reply in the form of the issue fee and a completed PTOL-85, an acceptable statement of the unintentional nature of the delay in responding to the July 20, 2004 Notice of Allowance and Fee(s) Due, a terminal disclaimer, and the petition fee.

The terminal disclaimed filed March 3, 2005 (certificate of mailing date February 28, 2005) under 37 CFR 1.137(c) has been entered and made of record. Effective September 8, 2000, 37 CFR 1.137(c)(1) has been added to state that a terminal disclaimer filed pursuant to this rule must dedicate to the public a terminal part of the term of any patent granted thereon equivalent to the lesser of: 1) the period of abandonment of the application; or 2) the period extending beyond twenty years from the date on which the application for the patent was filed in the United States, or, if the application contains a specific reference to an earlier filed application(s) under 35 U.S.C.

120, 121 or 365(c), from the date on which the earliest such application was filed. 65 Fed. Reg. 54,674 (2000). Accordingly, the period of the terminal disclaimer filed March 3, 2005 (certificate of mailing date February 28, 2005) will be equivalent to the lesser of period (1) or (2), as noted above, for this application.

The petition is **granted**.

This application is being forwarded to Publishing Division for processing into a patent.

Telephone inquiries concerning this matter may be directed to the undersigned at (571) 272-3230.

E. Shirene Willis

E. Shirene Willis
Senior Petitions Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

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FROM DIRECTORS OFFICE Paper no. 32

JAN 0 5 2007

TECHNOLOGY CENTER 3600

RICHARD S. SCIASCIA
OFC. OF NAVAL RESEARCH (CODE 320)
DEPT. OF THE NAVY
ARLINGTON VA 22217

In re Application of	:	DECISION ON REQUEST
William H. Fiden	:	TO WITHDRAW
SERIAL NO.: 05/626,674	:	HOLDING OF
FILED: October 28, 1975	:	ABANDONMENT
FOR: RADAR-COMPATIBLE		
DATA LINK SYSTEM		

The application was abandoned for failure to timely respond to the Office action mailed September 6, 2002 which included a 2 month period for response.

Petitioner asserts that a response was in fact timely-filed and presents a copy of the response with a certificate of mailing dated September 23, 2002 and a statement under 37CFR 1.8 (b)(3) signed by the person who signed the original Certificate of Mailing.

The evidence is sufficient to show timely receipt of the response.

The request to withdraw the holding of abandonment is GRANTED.

The application is being forwarded to the examiner for action on the response.

Donald T. Hajec

Director, T.C. 3600
703-306-4180

tht: 02-17-05

UNITED STATES PATENT AND TRADEMARK OFFICE

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RAYTHEON COMPANY
C/O DALY, CROWLEY, MOFFORD & DURKEE, LLP
354A TURNPIKE STREET
SUITE 301A
CANTON MA 02021

MAILED

NOV 18 2009

OFFICE OF PETITIONS

In re Application of	:	
George Spencer	:	
Application No. 05/879,642	:	DECISION ON PETITION
Filed: February 16, 1978	:	
	:	

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(b), filed March 29, 2001, resubmitted on August 1, 2005, to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned for failure to timely pay the issue fee on or before December 14, 2000, as required by the Notice of Allowance and Fee(s) Due, mailed September 14, 2000. Accordingly, the date of abandonment of this application is December 15, 2000. The Notice of Abandonment was mailed February 15, 2001.

The petition satisfies the requirements of 37 CFR 1.137(b) in that petitioner has supplied (1) the reply in the form of payment of the issue fee of $1,240, (2) the petition fee of $1,240; (3) a terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.27(d); and (4) a proper statement of unintentional delay.

37 CFR 1.137(b)(3) requires a statement that "the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional." Since the statement appearing in the petition varies from the language required by 37 CFR 1.137(b)(3), the statement is being construed as the required statement. Petitioner must notify the Office if this is not a correct reading of the statement appearing in the petition.

The application file does not indicate a change of address has been filed in this case, although the address given on the petition differs from the address of record. A change of address should be filed in this case in accordance with MPEP 601.03. A courtesy copy of this decision is being

mailed to the address noted on the petition. However, until otherwise instructed, all future correspondence regarding this application will be mailed solely to the address of record.

Telephone inquiries concerning this decision should be directed to Terri Johnson at (571) 272-2991.

This application is being referred to the Office of Data Management for processing into a patent.

Terri Johnson
Petitions Examiner
Office of Petitions

cc: **Donald F. Mofford**
Daly, Crowley & Mofford, LLP
275 Turnpike Street, Suite 101
Canton, MA 02021-2310

UNITED STATES PATENT AND TRADEMARK OFFICE

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AFLSA/JACN-P
1501 WILSON BLVD. SUITE 805
ARLINGTON, VA 22209

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NOV 13 2006

OFFICE OF PETITIONS

In re Application of :
KIRTCHIK :
Application No. 05/924,404 : DECISION ON PETITION
Filed: July 11, 1978 : TO WITHDRAW
Attorney Docket No. 11889 : FROM RECORD

This is a decision on the Request to Withdraw as attorney or agent of record under 37 C.F.R. § 1.36(b), filed August 3, 2006.

The request is **NOT APPROVED**.

A grantable request to withdraw as attorney/agent of record must be signed by every attorney/agent seeking to withdraw or contain a clear indication that one attorney is signing on behalf of another/others. A request to withdraw will not be approved unless at least 30 (thirty) days would remain between the date of approval and the later of the expiration date of a time to file a response or the expiration date of the maximum time period which can be extended under 37 C.F.R. § 1.136(a).

The request cannot be approved because there is no clear indication as to whether attorney is signing on behalf of himself or all attorneys of record.

The Office cannot approve the request at this time since the reasons provided do not meet any of the conditions under the mandatory or permissive categories enumerated in 37 CFR 10.40. Section 10.40 of Title 37 of the Code of Federal Regulation states, "[a] practitioner shall not withdraw from employment in a proceeding before the Office without permission from the Office[.]" More specifically, 37 CFR 10.40 states, "[i]f paragraph (b) of this section is not applicable, a practitioner may not request permission to withdraw in matter pending before the Office unless such request or such withdrawal is" for one the permissive reasons listed in 37 CFR 10.40(c). The reasons set forth in the request, "the office function of the attorney is being transferred", does not meet any of the conditions set forth in 37 CFR 10.40.

All future communications from the Office will continue to be directed to the above-listed address until otherwise notified by applicant.

Telephone inquiries concerning this decision should be directed to the undersigned at 571-272-7253.

Monica A. Graves
Petitions Examiner
Office of Petitions

cc: **DEPARTMENT OF THE AIR FORCE**
AFMC LO/JAZ
2240 B ST., RM. 100
WRIGHT-PATTERSON AFB, OH 45433-7109

UNITED STATES PATENT AND TRADEMARK OFFICE

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WILLIAM AUTON
US Air Force
ESC/JAZ
40 Wright St Bldg 1120
Hanscom Afb, MA 01731

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NOV 13 2006

OFFICE OF PETITIONS

In re Application of	:	
KIRTCHIK	:	
Application No. 05/924,406	:	DECISION ON PETITION
Filed: July 11, 1978	:	TO WITHDRAW
Attorney Docket No. 11,890	:	FROM RECORD
	:	

This is a decision on the Request to Withdraw as attorney or agent under 37 C.F.R. § 1.36(b) or 37 C.F.R. § 10.40 filed August 03, 2006.

The request is **NOT APPROVED**.

A review of the file record indicates that William G. Auton does not have power of attorney in this patent application nor is there any statement or evidence of record of employment in or otherwise being engaged in the proceedings in this patent application. Accordingly, the request to withdraw under 37 C.F.R. § 1.36(b) is not applicable.

All future communications from the Office will continue to be directed to the below-listed address until otherwise properly notified by the applicant.

Telephone inquires concerning this decision should be directed to Patricia Volpe at 571-272-6825.

P Volpe

Patricia Volpe
Petitions Examiner
Office of Petitions

cc: AFLSA/JACP
1501 WILSON BOULEVARD
ROOM 805
ARLINGTON, VA 22209

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON TX 77056

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NOV 1 9 2008

OFFICE OF PETITIONS

In re Patent No. 4,272,953	:	
Issue Date: June 16, 1981	:	
Application No. 05/954,838	:	DECISION ON PETITION
Filed: October 26, 1978	:	
For: REHEAT GAS TURBINE COMBINED	:	
WITH STEAM TURBINE	:	

This is a decision on the petition filed September 4, 2008 entitled "PETITION FOR REPLACEMENT LETTERS PATENT UNDER 37 C.F.R. § 1.182", for the above-identified patent.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

As authorized, the $400 fee for the petition under 37 CFR 1.182 has been assessed to petitioner's credit card account.

Telephone inquiries concerning this decision may be directed to the undersigned at (571) 272-3208. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Niomi Farmer in the Office of Data Management at (703) 308-9250, Ext. 139.

A copy of this decision is being faxed to the Office of Data Management for issuance of a duplicate Letters Patent.

Karen Creasy

Karen Creasy
Petitions Examiner
Office of Petitions

cc: Niomi Farmer, South Tower, 8th Floor, Room C23 (Fax No. (571) 270-9753)

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

William Squire
Carello, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein
6 Becker Farm Road
Roseland NJ 07068

Re: Patent Term Extension Application for U.S. Patent No. 4,291,708 #27

Dear Mr. Squire:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,291,708 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: T-Scan 2000

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Yeda Research and Development Co.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,291,708	:	INTERIM EXTENSION

Yeda Research and Development Co., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,291,708, filed an application for patent term extension under 35 U.S.C. § 156 on May 21, 1999. The term of the patent has been previously extended under 35 U.S.C. §§ 156(d)(5) and (e)(2) until November 2, 2000. The patent claims the medical device "T-Scan 2000" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on April 16, 1999. An extension of 1,826 days is requested.

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by FDA. Since the extended term of the patent expired before a certificate of patent term extension could be issued, an additional interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,291,708 is granted for a period of one year from the extended expiration date of the patent, until November 2, 2001.

JAN 30 2001
Date

Nicholas P. Godici
Nicholas P. Godici
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

JUL 9 2002

William Squire
Carella, Bryne, Bain, Gilfillan, Cecchi, Stewart & Olstein
6 Becker Farm Road
Roseland NJ 07068

Re: Patent Term Extension
Application for
U.S. Patent No. 4,291,708

Dear Mr. Squire:

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,291,708 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Health Assessment Policy Staff
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: T-Scan 2000®

FDA Docket No.: 98E-0851

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Yeda Research and Development	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,291,708	:	**INTERIM EXTENSION**

Yeda Research and Development, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,291,708, filed an application for patent term extension under 35 U.S.C. § 156 on May 21, 1999. An extension of five years is requested. The term of the patent has been previously extended under 35 U.S.C. §§ 156(d)(5) and (e)(2) until November 1, 2001. The patent claims the medical device "T-Scan 2000" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on April 16, 1999.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. On January 24, 2002 (67 Fed. Reg. 3501), FDA published the determination of the regulatory review period for purposes of patent term extension for "T-Scan 2000," but this determination has not yet been made final. Since the extended term of the patent expired before a certificate of patent term extension could be issued, an additional interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,291,708 is granted for a period of one year from the extended expiration date of the patent, i.e., until November 2, 2002.

JUL - 8 2002

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON TX 77056

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JUN 19 2008

OFFICE OF PETITIONS

In re Patent No. 4,314,442	:	
Issue Date: February 9, 1982	:	
Application No. 06/047,571	:	DECISION ON PETITION
Filed: June 11, 1979	:	
Attorney Docket No. CASE 1-A	:	

This is a decision on the petition under 37 CFR 1.182, filed May 20, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

The Office is in receipt of the $400 petition fee.

Telephone inquiries concerning this decision may be directed to the undersigned at (571) 272-3215. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Ms. Niomi Farmer, Office of Data Management, Phone: 703-308-9250 x129.

A copy of this decision is being faxed to Publishing Division for issuance of a duplicate Letters Patent.

Charlema Grant
Petitions Attorney
Office of Petitions

cc: Ms. Niomi Farmer, Office of Data Management, Fax: 571-270-9753.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
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Dr. Diana Hamlet-Cox
Intellectual Property for Incyte Corporation
1360 Porter Drive
Palo Alto CA 94304

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MAR 16 2009

OFFICE OF PETITIONS

In re Application of	:	
Tang et al.	:	
Application No. 06/308184	:	DECISION ON PETITION
Filing or 371(c) Date: 09/28/1981	:	
Patent Number: 6958725	:	
Issue Date: 10/25/2005	:	
Title of Invention:	:	
RADOME ABERRATION CORRECTING SYSTEM	:	

This is a Decision in response to the Petition Under 37 C.F.R. § 1.59(b) to Expunge Information Unintentionally Submitted in an Application, filed February 3, 2009.

This Petition is hereby **dismissed**.

Any further petition must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Request for Reconsideration of Petition under [insert the applicable code section]". This is **not** final agency action within the meaning of 5 U.S.C. § 704.

Background

Petitioner files the present petition to expunge the assignment record of the present patent. Petitioner provides that the Change of Name Recordation and Assignment of Assignors Interest were unintentionally submitted and would cause irreparable harm to the party in interest on whose behalf the information was submitted. Petitioner further states that the information requested to be expunged is not material information under 37 CFR 1.56.

Initially it is noted that in recording assignment (merger and change of name) documents, the Office does not determine whether the document is valid, nor does the Office determine the effect of the document. It is also noted that it is appropriate to file merger documents. The MPEP 314, Certificates of Change of Name or of Merger, provides

> Certificates issued by appropriate authorities showing a change of name of a business or a merger of businesses are recordable. Although a mere change of name does not constitute a change in legal entity, it is properly a link in the chain of title. Documents of

merger are also proper links in the chain of title. They may represent a change of entity as well as a change of name.

Regarding expungement of assignment records, the MPEP 323.01(d), Expungement of Assignment Records, states:

> Petitions to correct, modify or "expunge" assignment records are rarely granted. Such petitions are granted only if the petitioner can prove that:
> (A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
> (B) the integrity of the assignment records will not be affected by granting the petition.
>
> Even if a petition to "expunge" a document is granted with respect to a particular application or patent, the image of the recorded document will remain in the records of the Assignment Services Division at the same reel and frame number, and the image will appear when someone views that reel and frame number. The Office will, however, delete the links to the application or patent that was the subject of the petition, so that no information about the recorded document will appear when someone searches for that application or patent number in the Assignment Historical Database.

Here, Applicant has failed to demonstrate that the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief, <u>and</u> that the integrity of the assignment records will not be affected by granting the Petition.

The petition is dismissed without prejudice. Petitioner should file a request for reconsideration of petition and include the necessary showing.

Further correspondence with respect to this matter should be addressed as follows:

By mail:	Director for Patents PO Box 1450 Alexandria, VA 22313-1450
By FAX:	(571) 273-8300 Attn: Office of Petitions
By hand:	Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Telephone inquiries concerning this petition Decision should be directed to the undersigned at (571) 272-3232.

/Derek L. Woods/
Derek L. Woods
Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 24 2009
PATENT & TRADEMARK OFFICE

COMPLETED

Dr. Tamla Hamlet-Cox
Intellectual Property for Incyte Corporation
1360 Porter Drive
Palo Alto CA 94304

COPY MAILED

MAR 16 2009

OFFICE OF PETITIONS

In re Application of	:	
Tang et al.	:	
Application No. 06/308184	:	DECISION ON PETITION
Filing or 371(c) Date: 09/28/1981	:	
Patent Number: 6958725	:	
Issue Date: 10/25/2005	:	
Title of Invention:	:	
RADOME ABERRATION CORRECTING SYSTEM	:	

This is a Decision in response to the Petition Under 37 C.F.R. § 1.59(b) to Expunge Information Unintentionally Submitted in an Application, filed February 3, 2009.

This Petition is hereby **dismissed**.

Any further petition must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Request for Reconsideration of Petition under [insert the applicable code section]". This is **not** final agency action within the meaning of 5 U.S.C. § 704.

Background

Petitioner files the present petition to expunge the assignment record of the present patent. Petitioner provides that the Change of Name Recordation and Assignment of Assignors Interest were unintentionally submitted and would cause irreparable harm to the party in interest on whose behalf the information was submitted. Petitioner further states that the information requested to be expunged is not material information under 37 CFR 1.56.

Initially it is noted that in recording assignment (merger and change of name) documents, the Office does not determine whether the document is valid, nor does the Office determine the effect of the document. It is also noted that it is appropriate to file merger documents. The MPEP 314, Certificates of Change of Name or of Merger, provides

> Certificates issued by appropriate authorities showing a change of name of a business or a merger of businesses are recordable. Although a mere change of name does not constitute a change in legal entity, it is properly a link in the chain of title. Documents of

merger are also proper links in the chain of title. They may represent a change of entity as well as a change of name.

Regarding expungement of assignment records, the MPEP 323.01(d), Expungement of Assignment Records, states:

> Petitions to correct, modify or "expunge" assignment records are rarely granted. Such petitions are granted only if the petitioner can prove that:
> (A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
> (B) the integrity of the assignment records will not be affected by granting the petition.
>
> Even if a petition to "expunge" a document is granted with respect to a particular application or patent, the image of the recorded document will remain in the records of the Assignment Services Division at the same reel and frame number, and the image will appear when someone views that reel and frame number. The Office will, however, delete the links to the application or patent that was the subject of the petition, so that no information about the recorded document will appear when someone searches for that application or patent number in the Assignment Historical Database.

Here, Applicant has failed to demonstrate that the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief, <u>and</u> that the integrity of the assignment records will not be affected by granting the Petition.

The petition is dismissed without prejudice. Petitioner should file a request for reconsideration of petition and include the necessary showing.

Further correspondence with respect to this matter should be addressed as follows:

By mail:	Director for Patents PO Box 1450 Alexandria, VA 22313-1450
By FAX:	(571) 273-8300 Attn: Office of Petitions
By hand:	Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Telephone inquiries concerning this petition Decision should be directed to the undersigned at (571) 272-3232.

/Derek L. Woods/
Derek L. Woods
Attorney
Office of Petitions

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 17

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APR 21 2000

SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS

DANIEL SIXBEY
SIXBEY FRIEDMAN LEEDOM & FERGUSON PC
8180 GREENSBORO DRIVE SUITE 800
McLEAN VIRGINIA 22102

In re Patent No. 4,425,908 :
Issue Date: January 17, 1984 :
Application No. 06/314,005 :
Filed: January 17, 1984 :
Inventor: Morris Simon :

ON PETITION

This is a decision on the petition, filed September 21, 1999, under 37 CFR 1.378(e) requesting reconsideration of a prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-identified patent.

The request to accept the delayed payment of the maintenance fee under 37 CFR 1.378(b) is DENIED.

BACKGROUND

The patent issued January 17, 1984. The first and second maintenance fees were timely paid. Accordingly, the third maintenance fee due could have been paid during the period from January 17, 1995 through July 17, 1995, or with a surcharge during the period from July 18, 1995 through January 17, 1996. The above-identified patent expired as of midnight, January 17, 1996.

A petition under 37 CFR 1.378(b) to accept late payment of the first maintenance fee was filed November 10, 1998, and was dismissed in the decision of July 21, 1999.

STATUTE AND REGULATION

35 U.S.C. § 41(c)(1) states that:

> "The Commissioner may accept the payment of any maintenance fee required by subsection (b) of this section... after the six-month grace period if the delay is shown to the satisfaction of the Commissioner to have been unavoidable."

37 CFR 1.378(b)(3) states that any petition to accept delayed payment of a maintenance fee must include:

> "A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date, and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly."

OPINION

The Commissioner may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable"; 35 USC 41(c)(1).

Petitioner (Nitinol, the assignee) requests reconsideration in that (1) Nitinol relied upon the firm of Nixon & Vanderhye (Nixon) and its docketing system, as petitioner contends that Nixon's counsel constitutes petitioner's attorneys of record, for maintenance fee payments, (2) Nixon has been contacted by petitioner regarding this matter but has declined to offer information or assistance, (3) Nixon apparently contends that Nixon was engaged by petitioner solely for proceedings relating to the patent term extension request (filed in 1990), (4) counsel presenting the instant petition has represented petitioner for maintenance fee payments in other patents, but was not engaged for this patent. As such, petitioner asserts, the silence of Nixon should not operate to the detriment of Nitinol, and the patent reinstated.

Petitioner has not carried the burden of proof to establish to the satisfaction of the Commissioner that the delay was unavoidable.

Acceptance of late payment of a maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 USC 133 because 35 USC 41(c)(1) uses the identical language, i.e. "unavoidable delay". Ray v. Lehman, 55 f. 3d 606, 608-09, 34 USPQ2d 1786, 1787 (Fed. Cir. 1995)(quoting In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (Comm'r Pat.

1988)). Decisions on reviving abandoned applications have adopted the "reasonably prudent person" standard in determining if the delay in responding to an Office action was unavoidable. Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-515 (D.C. Cir. 1912); and Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141. In addition, decisions on revival are made on a "case-by-case basis, taking all the facts and circumstances into account." Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982). Finally, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay. Haines v. Quigg, 673 F. Supp. 314, 316-17, 5 USPQ2d 1130, 1131-32 (N.D. Ind. 1987).

Petitioner is reminded that it is the patentee's burden under the statutes and regulations to make a showing to the satisfaction of the Commissioner that the delay in payment of a maintenance fee is unavoidable. See Rydeen v. Quigg, 748 F. Supp. 900, 16 USPQ2d 1876 (D.D.C. 1990), aff'd 937 F.2d 623 (Fed. Cir. 1991)(table), *cert. denied*, 502 U.S. 1075 (1992); Ray v. Lehman, supra.

In determining whether a delay in paying a maintenance fee was unavoidable, one looks to whether the party responsible for payment of the maintenance fee exercised the due care of a reasonably prudent person. Ray, 55 F3d at 608-609, 34 USPQ2D at 1787. It is incumbent upon the patent owner to implement steps to schedule and pay the fee, or obligate another to do so. See California Medical Products v. Technol. Med. Prod., 921 F.Supp 1219, 1259 (D. Del. 1995). The patent owner must demonstrate that the patent had been docketed in a docketing system as would have been relied upon by a prudent and careful person with respect to that person's most important business. Id. In this regard, the record does not adequately show, as noted in the previous decision, that Nixon had ever been engaged by petitioner to track the maintenance fee payment, much less make the payment on behalf of petitioner. Even assuming in a light most favorable to petitioner that his patent term extension firm (Nixon) had assumed that obligation, reliance *per se* upon another to track and pay maintenance fees does not provide a petitioner with a showing of unavoidable delay within the meaning of 37 C.F.R. 1.378(b) and 35 U.S.C. 41(c). Id. Rather, such reliance merely

shifts the focus of the "reasonably prudent" inquiry from petitioner to the appointed representative. Id. Nevertheless, petitioner is bound by any errors that may have been committed by that representative. Id.

However, as petitioner has failed to establish who it had engaged to pay the maintenance fees, then petitioner had to have provided a showing that it had such steps in place as would be employed by a prudent and careful person, to ensure timely payment of the maintenance fees. Id. However, petitioner apparently took no steps on its own, as it believed, apparently through miscommunication, that it had appointed Nixon to undertake that obligation. In this regard, if Nixon had assumed the obligation to track and/or pay the maintenance fee, then petitioner would have been able to produce its own records to that effect, notwithstanding Nixon's silence.

Nevertheless, delay resulting from a lack of proper communication between a patentee and that patentee's representative(s) as to the responsibility for scheduling and payment of a maintenance fee does not constitute unavoidable delay within the meaning of 35 USC 41(c) and 37 CFR 1.378(b). See, In re Kim, 12 USPQ2d 1595 (Comm'r Pat. 1988). Specifically, delay resulting from a failure in communication between a patent holder and his representative regarding a maintenance fee payment is not unavoidable delay within the meaning of 35 USC 41(c) and 37 CFR 1.378(b). Ray, 55 F.3d at 610, 34 USPQ2d at 1789. That all parties failed to take adequate steps to ensure that each fully understood the other party's meaning, and thus, their own obligation in this matter, does not reflect the due care and diligence of prudent and careful persons with respect to their most important business within the meaning of Pratt, supra.

Petitioner is advised that delay resulting from a lack of awareness of the need to pay maintenance fees, or delay resulting from petitioner's lack of receipt of any maintenance fee reminder(s), or petitioner's being unaware of the need for maintenance fee payments, does not constitute "unavoidable" delay. See Patent No. 4,409,763, supra, *aff'd*, Rydeen v. Quigg, supra. See also "Final Rules for Patent Maintenance Fees," 49 *Fed. Reg.* 34716, 34722-23 (Aug. 31, 1984), reprinted in 1046 *Off. Gaz. Pat. Office* 28, 34 (September 25, 1984). Under the statutes and regulations, the Office has no duty to notify patentee of the requirement to pay maintenance fees or to notify patentee when the maintenance fee is due. While the Office mails maintenance

fee reminders strictly as a courtesy, it is solely the responsibility of the patentee to ensure that the maintenance fee is timely paid to prevent expiration of the patent. The failure to receive the Reminder does not relieve the patentee of the obligation to timely pay the maintenance fee, nor will it constitute unavoidable delay if the patentee seeks reinstatement under the regulation. Rydeen, Id. Moreover, a patentee who is required by 35 USC 41(c)(1) to pay a maintenance fee within 3 years and six months of the patent grant, or face expiration of the patent, is not entitled to any notice beyond that provided by publication of the statute. Id. at 900, 16 USPQ2d at 1876.

Furthermore, the Letters Patent contains a Maintenance Fee Notice that warns that the patent may be subject to maintenance fees if the application was filed on or after December 12, 1980. While the record is not clear as to whether petitioner ever read the Maintenance Fee Notice, petitioner's failure to read or remember the Notice does not vitiate the Notice, nor does the delay resulting from such failure to read the Notice establish unavoidable delay. Ray, 55 F.3d at 610, 34 USPQ2d at 1789. The mere publication of the statute was sufficient notice to petitioner. Rydeen, supra.

Petitioner is reminded that the Patent and Trademark Office must rely on the actions or inactions of duly authorized and voluntarily chosen representatives of the applicant, and applicant is bound by the consequences of those actions or inactions. Link v. Wabash, 370 U.S. 626, 633-34 (1962); Huston v. Ladner, 973 F.2d 1564, 1567, 23 USPQ2d 1910, 1913 (Fed. Cir. 1992); see also Haines v. Quigg, 673 F. Supp. 314, 317, 5 USPQ2d 1130, 1132 (D.N. Ind. 1987). Specifically, petitioner's delay caused by the mistakes or negligence of his voluntarily chosen representative does not constitute unavoidable delay within the meaning of 35 USC 133. Haines v. Quigg, supra; Smith v. Diamond, 209 USPQ 1091 (D.D.C. 1981); Potter v. Dann, 201 USPQ 574 (D.D.C. 1978); Ex parte Murray, 1891 Dec. Comm'r Pat. 130, 131 (Comm'r Pat. 1891). As such, assuming that petitioner had engaged Nixon for payment of the maintenance fees of the above identified patent, then it was incumbent upon petitioner to demonstrate, via a documented showing, that his duly appointed representative had docketed this patent for the first maintenance fee payment in a reliable tracking system. Id. However, petitioner has not been able to demonstrate that the patent was docketed for payment of the maintenance fees, or that Nixon had assumed that obligation on behalf of petitioner.

Even assuming that such a document(s) existed, and had been made of record, petitioner has also failed to demonstrate why petitioner's failure to diligently monitor Nixon's performance under the putative contract can reasonably be considered to constitute unavoidable delay. See Futures Technology Ltd. v. Quigg, 684 F.Supp. 430, 7 USPQ2d 1588 (E.D. Va. 1988). That is, petitioner's apparent failure to monitor Nixon's performance under the alleged contract, or diligently inquire of Nixon, or anyone else, including the PTO, into the status of the patent and maintenance fee payment, does not reflect the due care and diligence employed by a prudent and careful person with respect to their most important business, and as such, cannot demonstrate that the delay was unavoidable delay. Id. Rather, a prudent person takes diligent action to ensure that contracted services are timely performed as specified. Id. Note further in this regard, that the record does not present any invoice(s) from Nixon for services rendered with respect to tracking the maintenance fee payment, much less for the payment itself. The record lacks any showing that Nixon ever represented to petitioner that the maintenance fee had been paid, much less that petitioner ever paid Nixon for services rendered with respect to the maintenance fee payment. There is no showing from petitioner's records which were in *his* and not Nixon's possession, that petitioner, upon *timely* discovering that Nixon had not yet presented petitioner with an itemized bill for payment of the fee, diligently inquired of Nixon as to why that allegedly contracted service had not been timely discharged, in time to prevent expiration of the patent, or more diligently present a petition seeking reinstatement.

Even assuming, *arguendo*, that Nixon had been obligated in this matter, and further, that petitioner would not be bound by the mistakes or omissions of Nixon, diligence on the part of petitioner would still be essential to show unavoidable delay. See, Douglas v. Manbeck, 21 USPQ2d 1697, 1699-1700 (E.D. Pa. 1991), *aff'd*, 975 F.2d 869, 24 USPQ2d 1318 (Fed. Cir. 1992) (applicant's lack of diligence over a two and one half year period in taking any action with respect to his application, precluded a finding of unavoidable delay). However, the record lacks an adequate showing of petitioner's diligence in this matter during the entire period extending from the last date that the maintenance fee could have been timely filed (the one year period year that ended January 17, 1996), until the filing of the first petition on November 10, 1998, a period of almost three (3) years, which would be necessary to support a finding of

unavoidable delay. Id. Specifically, diligence on the part of the owner is necessary to show unavoidable delay when that owner's putative agent(s) fails to take timely and proper steps with respect to a proceeding before the Patent and Trademark Office. Futures, 684 F.Supp. 430 at 431, 7 USPQ2d at 1589. However, petitioner has not shown diligence with respect to any aspect of the payment of the maintenance fee for this patent. Petitioner's lack of due diligence with respect to this patent, for a period of time of almost three (3) years, overcame and superseded any omissions or commissions by his representative(s). Douglas, supra; Haines v. Quigg, supra. The delay was not unavoidable, because had petitioner exercised the due care of a reasonably prudent person, petitioner would have been able to act to correct the situation in a timely fashion. Haines v. Quigg, supra; Douglas, supra.

Petitioner's request for relief, notwithstanding the admitted lack of a showing from Nixon, cannot be favorably considered. it is brought to petitioner's attention that the requirement for a showing of unavoidable delay is a requirement of the statute (35 USC 41(c)), and, as such, the PTO lacks the authority or discretion to waive that requirement. See In Re Patent No. 4,409,763, 7 USPQ2d 1798, 1802 (Comm'r Pat. 1988), *aff'd*, Rydeen v. Quigg, 748 F. Supp. 900, 16 USPQ2d 1876 (D.D.C. 1990), *aff'd* 937 F.2d 623 (Fed. Cir. 1991)(table), *cert. denied*, 502 U.S. 1075 (1992). It follows that whatever principles might be enlisted by or on behalf of petitioner, such principles cannot properly be employed to offset the lack herein of an adequate showing of unavoidable delay. Rather, the decision of the PTO on the question of whether the delay herein was unavoidable *vel non* can only be based on the contents of the administrative record in this case. Douglas v. Manbeck, supra; Haines v. Quigg, supra. As noted above, the administrative record in this case lacks the necessary showing to meet petitioner's burden of proving that the entire delay herein was unavoidable. The record fails to adequately evidence that either petitioner or Nixon exercised the due care observed by prudent and careful men, in relation to their most important business, which is necessary to establish unavoidable delay. Pratt, supra. In the absence of a showing of the steps emplaced to pay the maintenance fees, then 37 CFR 1.378(b) does not permit acceptance of the belated fee.

As also noted in the previous decision, the PTO is simply not the forum for resolving a dispute between a patentee and his putative representative(s) regarding an unpaid maintenance fee. Ray,

supra. Moreover, there is no need in this case to determine the obligation between Nixon and petitioner, since the record fails to show that either Nixon or petitioner took adequate steps to ensure timely payment of the maintenance fee. See In re Patent No. 4,461,759, 16 USPQ2d 1883, 1884 (Comm'r Pat. 1990).

DECISION

The prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-identified patent has been reconsidered. For the above stated reasons, however, the delay in this case cannot be regarded as unavoidable within the meaning of 35 USC 41(c) and 37 CFR 1.378(b).

As stated in 37 CFR 1.378(e), no further reconsideration or review of this matter will be undertaken.

Since this patent will not be reinstated, the maintenance fees and the surcharge submitted by petitioner totaling $3860, have been credited to deposit account No. 19-2380. The $130 fee under 37 CFR 1.17(h) for requesting reconsideration (non-refundable) has been charged to the same account.

Lastly, the revocation and power of attorney filed with the instant petition has not been accepted as it lacks a certification under 37 CFR 3.73(b). If the request is renewed with a certification, it should be directed to the Office of Public Records, Dissemination Support Branch, Records Branch, at the PTO's usual mailing address. See MPEP 2560.

The patent file is being returned to the Files Repository.

Telephone inquiries regarding this decision should be directed to Petitions Examiner Brian Hearn at (703) 305-1820.

Manuel A. Antonakas, Director,
Office of Petitions

cc: NIXON & VANDERHYE
1100 NORTH GLEBE ROAD, 8th FLOOR
ARLINGTON VA 22201-4714

CC: SYLVIA BOYD
PO BOX 1050
CAMBRIDGE MA 02238

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COMMISSIONER FOR PATENTS
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Jeffrey J. Hohenshell
Senior Patent Attorney
Medtronic Cardiac Surgery Division
7601 Northland Dr.
Brooklyn Park, MN 55428

COPY MAILED

DEC 29 2005

OFFICE OF PETITIONS

In re Application of :
Wright, et al. : DECISION ON PETITION
Application No. 06/316,203 :
Filed: October 29, 1981 :
Docket No.: VCR-8 :

This is a decision on the petition under 37 CFR 1.137(b), filed November 3, 2005, and supplemented November 21, 2005, to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned August 18, 2005 for failure to timely submit the issue fee in response to the Notice of Allowance and Issue Fee(s) Due ("Notice") mailed May 17, 2005. The Notice set a three month statutory period for reply. Notice of Abandonment was mailed November 4, 2005.

A grantable petition pursuant to 37 C.F.R. § 1.137(b) must be accompanied by: (1) the required reply to the outstanding Office action or notice, unless previously filed; (2) the petition fee as set forth in 37 C.F.R. § 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional; and (4)any terminal disclaimer (and fee set forth in 37 C.F.R. § 1.20(d)) required pursuant to 37 C.F.R. § 1.137(c).

The instant petition has been reviewed and found in compliance with the provisions of 37 CFR 1.137(b). Accordingly, the failure to timely submit a proper reply to the Notice is accepted as having been unintentionally delayed.

This application will be forwarded to the Publications Division for further processing.

Telephone inquiries concerning this matter may be directed to the undersigned at (571) 272-3205.

Alesia M. Brown
Petitions Attorney
Office of Petitions

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Jeffrey J. Hohenshell
Metronic Cardiac Surgery Division
7601 Northland Dr.
Brooklyn Park, MN 55428

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APR 30 2007

OFFICE OF PETITIONS

In re Application of	:
Wright et al.	:
U.S. Patent No. 7,018,407	:
Issue Date: March 28, 2006	: Letter For
Application No. 06/316,203	: Certificate of Correction
Filed: October 29, 1982	:
For: VALVE HOLDER FOR TRICUSPID	:
HEART VALVE	:

The above-identified application has been forwarded to the undersigned for correction of the patent term extension information printed on the front page of the patent. In a telephone call with Jeffrey Hohenshell on April 27, 2007, it was confirmed that the Office would request a certificate of correction to correct the patent term extension information printed on the face of the patent. See 35 U.S.C. § 154(b)[1] and 37 C.F.R. § 1.701.

The Notice of Allowance and Issue Fee Due mailed on May 17, 2005, correctly indicated that the patent to issue from Application No. 06/316,203 was not eligible for a patent term extension, as the application was filed before June 8, 1995. The front page of the patent incorrectly indicates that the term of the patent is extended for 1109 days. Since the filing date was before June 8, 1995, the patent to issue from the application is eligible only for a 17-year term, which does not permit a patent term extension.

After mailing of this letter, the Office will issue a certificate of correction in order to rectify the error regarding the patent term extension information. See 35 U.S.C. 254 and 37 CFR 1.322. The Office will issue a certificate of correction deleting the patent term extension information.

Telephone inquiries with regard to this communication should be directed to the undersigned at (571) 272-7709.

Mark Polutta
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

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135 U.S.C. § 154 was amended by the "American Inventors Protection Act of 1999," which was enacted on November 29, 1999 as part of Public Law 106-113 (Consolidated Appropriations Act for Fiscal Year 2000). Since this amendment is effective May 29, 2000 and applies to applications filed on or after that date, the existing patent term adjustment provisions of 35 U.S.C. § 154 continue to apply to the above-identified application.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 7,018,407

DATED : March 28, 2006

INVENTOR(S) : Wright et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page,
[*] delete "Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1109 days."

NOTICE RE: CERTIFICATES OF CORRECTION

DATE : **January 2, 2001**

Paper No.: **24**

TO : Supervisor, Art Unit **1600** 1614

SUBJECT : Certificate of Correction Request in Patent No.: **4,420,639**

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

[X] 1. Would the change(s) requested, under 37 C.F.R. 1.323, correcting Applicant/Attorney's (A or Atty.) errors, constitute new matter or require reexamination of the application? **Note corrections to Related U. S. Application Data on PTOL 1050 form (stapled to CONTENTS page).**

[ ] 2. Would the change(s) requested, under 37 C.F.R. 1.323, correcting Applicant/Attorney's (A or Atty.) errors, materially affect the scope or meaning of the claims allowed by the examiner in the patent?

[ ] 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Should the change request be granted?

[ ] 4. With respect to the change(s) requested, correcting Office and/or printing (O, Off, C, and/or P) errors, should the patent read as shown in the certificate of correction?

[ ] 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO PALM LOCATION. 7580, CERTIFICATES OF CORRECTION BR, PARK 3 -922, Thank you

Cecelia Newman

Lead Legal Instrument Examiner
Tel. No. 305-8228

PLEASE CHECK THE BOX(ES) BELOW CORRESPONDING TO THE BOXES CHECKED FOR QUESTION(S) ABOVE AND RETURN FILE TO: PALM LOCATION 7580, CERT. OF CORREC. BR., PK 3 - 918

DATE:

The decision regarding the change(s) requested in the certificate of correction is shown below.

[ ] 1.YES	[X] NO	[ ] Comments below
[ ] 2.YES	[ ] NO	[ ] Comments below
[ ] 3.YES	[ ] NO	[ ] Comments below
[ ] 4.YES	[ ] NO	[ ] Comments below
[ ] 5.YES	[ ] NO	[ ] Comments below

[ ] Comments _____

Supervisor

1614
Art Unit

UNITED STATES PATENT AND TRADEMARK OFFICE

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WASHINGTON, D.C. 20231
www.uspto.gov

FEB 15 2001

James J. Sales
ELI LILLY AND COMPANY
Patent Division/jjs Lilly Corporate Center
INDIANAPOLIS IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,418,068

#19

Dear Mr. Sales:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,418,068 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: EVISTA
FDA Docket No.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Eli Lilly and Company	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,418,068	:	INTERIM EXTENSION

Eli Lilly and Company, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,418,068, filed an application for patent term extension under 35 U.S.C. § 156 on January 20, 1998. The original term of the patent is due to expire on April 3, 2001. The patent claims the active ingredient raloxifene hydrochloride in the human drug product "EVISTA" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on December 9, 1997. An extension of 1,103 days is requested.

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by FDA. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,418,068 is granted for a period of one year from the original expiration date of the patent, until April 3, 2002.

JAN 30 2001
Date

Nicholas P. Godici
Nicholas P. Godici
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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MAILED

MAR 1 5 2002

REEXAM UNIT

#22

James J. Sales
Eli Lilly and Company
Patent Division/jjs Lilly Corporate Center
Indianapolis IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,418,068

Dear Mr. Sales:

A order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,418,068 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: EVISTA®
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Eli Lilly and Company	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,418,068	:	**INTERIM EXTENSION**

Eli Lilly and Company, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,418,068, filed an application for patent term extension under 35 U.S.C. § 156. An extension of 1,103 days is requested, and an interim extension under 35 U.S.C. § 156(e)(2) has been previously granted for a period of one year. The patent is eligible for an extension of at least two years. The expiration date of the patent, as previously extended, is April 3, 2002. The patent claims the active ingredient raloxifene hydrochloride in the human drug product "EVISTA®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, as previously extended, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,418,068 is granted for a period of one year from the extended expiration date of the patent, until April 3, 2003.

MAR - 7 2002
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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DUANE MORRIS LLP
PO BOX 5203
PRINCETON NJ 08543-5203

COPY MAILED

AUG 06 2007

OFFICE OF PETITIONS

In re Application of Samuel M. Sherman Application No. 06/334,832 Filed: December 23, 1981 Attorney Docket No. RCA77153	: : : : :	ON PETITION

This is a decision on the petition to revive under 37 CFR 1.137(a), filed June 28, 2007.

The petition under 37 CFR 1.137(a) is **GRANTED**.

The above-identified application became abandoned for failure to reply to the Notice of Allowance mailed July 21, 2006. This Notice set a statutory period for reply of three (3) months for issue fee transmittal. No issue fee having been received, the application became abandoned on October 22, 2006. A Notice of Abandonment was mailed on May 21, 2007.

A grantable petition under 37 CFR 1.137(a) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(l); (3) a showing to the satisfaction of the Commissioner that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(a) was unavoidable; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required pursuant to 37 CFR 1.137(d). Decisions on reviving abandoned applications on the basis of "unavoidable" delay have adopted the reasonably prudent

person standard in determining if the delay was unavoidable:

> The word 'unavoidable' . . . is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business. It permits them in the exercise of this care to rely upon the ordinary and trustworthy agencies of mail and telegraph, worthy and reliable employees, and such other means and instrumentalities as are usually employed in such important business. If unexpectedly, or through the unforeseen fault or imperfection of these agencies and instrumentalities, there occurs a failure, it may properly be said to be unavoidable, all other conditions of promptness in its rectification being present.[1]

Moreover, a petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable."[2]

A review of the application reveals that the Notice of Allowance was returned as undeliverable due to an error on the part of the Office.

In view of the above, it is concluded that petitioner has met his burden of establishing that the delay was unavoidable.

Receipt of the petition fee, issue fee, and terminal disclaimer fee is acknowledged.

The matter is being forwarded to the Office of Patent Publication for processing into a patent.

Telephone inquiries concerning this decision should be directed to the undersigned at (571)272-3207.

Cliff Congo
Petitions Attorney
Office of Petitions

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[1] In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(quoting Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 USPQ 666, 167-68 (D.D.C. 1963), aff'd, 143 USPQ 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

[2] Haines v. Quigg, 673 F. Supp. 314, 316-17, 5 USPQ2d 1130, 1131-32 (N.D. Ind. 1987).

UNITED STATES PATENT AND TRADEMARK OFFICE

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#16

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DEC 3 1 2001
OFFICE OF PETITIONS

Charles E. Van Horn
Finngan Henderson Farabow Garrett & Dunner LLP
1300 I Street NW
Washington DC 20005

In re
Application for Patent Term Extension
U.S. Patent No. 4,386,085
For: MIFEPREX®

Dear Mr. Van Horn:

The above-identified patent has been extended under 35 U.S.C,. § 156(e)(2) for a period of one year. A copy of the order granting the interim extension is enclosed.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

FDA Docket No. 01E-0363
Attorney Docket No. 08292.001

UNITED STATES PATENT AND TRADEMARK OFFICE

In re The Population Council, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,386,085	:	**INTERIM EXTENSION**

On November 22, 2000, The Population Council, Inc., the owner of record of U.S. Patent No. 4,386,085, filed an application under 35 U.S.C. § 156(d)(1) for extension of the term of U.S. Patent No. 4,386,085. An extension of five years is requested. The patent claims the active ingredient, mifepristone, in the human drug product "MIFEPREX®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. The original term of the patent expires on January 8, 2002.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,386,085 is granted for a period of one year from the original expiration date of the patent.

DEC 28 2001
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

JAN 8 2003

Charles E. Van Horn
Finngan Henderson Farabow Garrett & Dunner LLP
1300 I Street NW
Washington DC 20005

Re: Patent Term Extension
Application for
U.S. Patent No. 4,386,085

Dear Mr. Van Horn:

A order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,386,085 for a period of one year is attached. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format (with updated contact information) for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Health Assessment Policy Staff
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MIFEPREX™ (mifepristone)

FDA Docket No.: 01E-0363

UNITED STATES PATENT AND TRADEMARK OFFICE

In re The Population Council, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,386,085	:	**INTERIM EXTENSION**

On November 22, 2000, The Population Council, Inc., the owner of record of U.S. Patent No. 4,386,085, filed an application under 35 U.S.C. § 156(d)(1) for extension of the term of the patent. An extension of five years is requested. An interim extension for a period of one year has already been granted. The patent claims the active ingredient, mifepristone, in the human drug product "MIFEPREX®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. The extended term of the patent expires on January 8, 2003.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, a second interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,386,085 is granted for a period of one year from the extended expiration date of the patent, until January 8, 2004.

JAN - 7 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

ofhical

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

MAR 1 5 2002

REEXAM UNIT

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WASHINGTON, D.C. 20231
www.uspto.gov

#23

David J. Josephic
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
Cincinnati OH 45202-2917

Re: Patent Term Extension
Application for
U.S. Patent No. 4,490,351

Dear Mr. Josephic:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,490,351 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: VITREON®
FDA Docket No.: 98E-0849

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Vitrophage, Inc. Request for Patent Term Extension U.S. Patent No. 4,490,351	: : :	**ORDER GRANTING** **INTERIM EXTENSION**

On November 22, 2000, Vitrophage, Inc., the owner of record of U.S. Patent No. 4,490,351, filed an application under 35 U.S.C. § 156(d)(1) for extension of the term of U.S. Patent No. 4,490,351. An extension of five years is requested. The patent claims a method of use of the approved device, perfluorophenanthrene ("VITREON®"). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product. The original term of the patent expires on March 15, 2002.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,490,351 is granted for a period of one year from the original expiration date of the patent, i.e., until March 15, 2003.

MAR - 7 2002
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
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MAR 13 2003

#24

David J. Josephic
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
Cincinnati OH 45202-2917

Re: Patent Term Extension
Application for
U.S. Patent No. 4,490,351

Dear Mr. Josephic:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,490,351 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: VITREON®
FDA Docket No.: 98E-0849

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Vitrophage, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,490,351	:	**INTERIM EXTENSION**

Vitrophage, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,490,351, filed an application under 35 U.S.C. § 156(d)(1), requesting an extension of five years. The original expiration date of the patent was March 15, 2002, and an interim extension of one year has previously been granted pursuant to 35 U.S.C. 156(e)(2), extending the patent to March 15, 2003. The patent claims a method of use of the approved device, perfluorophenanthrene ("VITREON®"). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product. The term of the patent, as previously extended, expires on March 15, 2003.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, a second interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,490,351 is granted for a period of one year from the extended expiration date of the patent, i.e., until March 15, 2004.

MAR 11 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON, TX 77056

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NOV 12 2008
OFFICE OF PETITIONS

In re Patent No. 4,507,914	:	
Issue Date: April 2, 1985	:	
Application No. 06/416,275	:	ON PETITION
Filed: September 9, 1982	:	
Attorney Docket No. RICE/0004	:	

This is a decision on the petition under 37 CFR 1.182, filed September 4, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **granted**.

The Office of Data Management is directed to issue duplicate Letters Patent.

A copy of this decision is being forwarded to the Office of Data Management for issuance of the duplicate Letters Patent.

The patent file is being referred to the Files Repository.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3226. Any questions concerning issuance of the duplicate Letters Patent should be directed to Niomi Farmer at (703) 308-9250 ext 119.

Andrea Smith
Petitions Examiner
Office of Petitions

cc: Niomi Farmer, P/OPPD, South Tower 8th Floor, Room C23
FAX No. (571) 270-9753

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 27 2008

Dianna Goldenson
Darby & Darby
805 Third Ave.,
New York, NY 10022-7513

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,560,766

DECISION DENYING APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 4,560,766

This is in response to the application for extension of the term of U.S. Patent No. 4,560,766 ("the '766 patent") under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on August 30, 2000, the request for interim extension filed on February 5, 2007, and the request for reconsideration, filed on September 28, 2007. The application was filed by Lonza Inc. ("Applicant"). Extension is sought based upon the premarket review under § 409 of the Federal Food, Drug, and Cosmetic Act of the food additive known as Dantobrom®RW/Dantochlor®RW, which was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 30, 2000. Because the application for patent term extension ("PTE application") was not timely filed, Applicant's request for extension of the patent term of the '766 patent is **DENIED**, the request for interim extension is **DENIED**, and its request for reconsideration is **DENIED**. Additionally, the four interim extensions previously granted under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

A. Decision

1. For Purposes of Patent Term Extension for a Food Additive, Permission for Commercial Marketing or Use is Under the FFDCA and Occurs When the Food Additive Regulations Are Amended

Applicant argues that the patented product Dantobrom®RW/Dantochlor®RW required regulatory review under the FFDCA as administered by FDA and under FIFRA as administered by the Environmental Protection Agency (EPA). Applicant argues that because additional regulatory review was required under FIFRA, the approval by FDA, in the form of amending the food additive regulations, did not amount to permission to commercially market or use Dantobrom®RW/Dantochlor®RW.

It is understood that the Federal Register notice which amended the food additive regulations to provide for the safe use of Dantobrom®RW/Dantochlor®RW as a slimicide in the manufacture of paper and paperboard intended to contact food, also indicated that further regulatory review under FIFRA may be required. However, even if additional regulatory review by another government agency was required the statutory language of § 156(d)(1) is clear as to

when the sixty day period begins for submitting an application for patent term extension. The specific statutory language in section 156(d)(1) states:

> To obtain an extension of the term of a patent under this section, the owner or record or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted <u>within the sixty day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred</u> for commercial marketing or use.

(Emphasis added.)

The word "permission" cannot be read in a context that excludes "under the provision of law under which the applicable regulatory review period occurred." Thus, whether Applicant could commercially market or use Dantobrom®RW/Dantochlor®RW based solely on FDA amending the food additive regulations is irrelevant to determining compliance with the requirement that an application for patent term extension be submitted within the sixty day period beginning on the date the product (here, Dantobrom®RW/Dantochlor®RW) received "permission" for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred (here, Section 409 of FFDCA). In other words, further additional regulatory review by another government agency is irrelevant to determining compliance with the sixty day period set forth in § 156(d)(1) since the critical triggering event relates to permission under the provision of law under which the "applicable regulatory review period" occurred, which, for a food additive, is set forth in § 156(g)(2)(B)(i) and § 156(g)(2)(B)(ii). Although an additional regulatory review period may have been necessary to commercially market the product for its intended end use, a regulatory review period under FIFRA is not contemplated by the statute. Since the only regulatory review period relevant to triggering the sixty day window for submitting a PTE application for a food additive is in accordance with Section 156(g)(2)(B)(ii), the date which began the sixty day period for Dantobrom®RW/Dantochlor®RW is June 30, 2000 (the date of the Federal Register notice amending 21 C.F.R. § 176). Accordingly, since the PTE application was submitted on August 30, 2000, it is untimely and hence, the PTE application is **<u>DENIED</u>**.

2. Judicial Precedent Directed to NDA Approvals Is Applicable to Other Regulated Products Subject to a Regulatory Review Period as Defined in 35 U.S.C. § 156(g)

Applicant argues that the judicial precedent cited in the Notice of Final Determination-Ineligible, directed to NDA approvals where additional regulatory review by DEA, is not relevant to the additional regulatory review by EPA under FIFRA for Dantobrom®RW/Dantochlor®RW. The USPTO does not agree with this assessment. While it is true that FDA reviews and approves these types of products under different regulatory schemes, 21 C.F.R. § 314 for drug products and 21 C.F.R. § 171 for food additives, the statutory requirements under Section 156 for patent term extension for drug products and food additives are the same. For determining the amount of

term to be extended, Section 156(g)(1) indicates the regulatory review period for a drug product, Section 156(g)(2) indicates the regulatory review period for a food additive, and all other sections of § 156 are applicable across the board regardless of the type of product subject to regulatory review, i.e., paragraphs (a)(1)-(5) and paragraph (d)(1). Accordingly, as stated by the court in *Mead Johnson Pharm Group v Bowen*, 838 F.2d 1332 (D.C. Cir 1988) and *Unimed Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989), the approval which triggers the start of the sixty day period for submission of an application for patent term extension is the date on which the product received permission under the provision of law under which the applicable regulatory review period occurred. Even though the responsibility for regulatory review of certain food additives may involve both FDA and EPA, as pointed out by Applicant at page 4 of their request for reconsideration, the amount of extended term under § 156 for a food additive is based solely on regulatory review before the FDA. See 35 U.S.C. § 156(g)(2)(B).

3. No Objections Or Withdrawal Of Permission For Commercial Marketing Altered The End Of The Regulatory Review Period

Furthermore, Applicant argues that the statutory language of Section 156(g)(2)(B)(ii) indicates that the regulatory review period ends on the date that the food additive product can be commercially marketed, which in the case of Dantobrom®RW/Dantochlor®RW would have been after EPA approved the product under FIFRA. The USPTO does not agree with this argument. There are two circumstances in Section 156(g)(2)(B)(ii) indicating that the end of the regulatory review period is a date different than the issuance of a regulation. First, the statutory language indicates a change in the end date of the regulatory review period, "if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted." In the present regulatory review of Dantobrom®RW/Dantochlor®RW, no objections were filed with respect to the Federal Register publication of the amendment to the food additive regulations, so the end of the regulatory review period was not extended based on this statutory provision. Second, the statute indicates another possible change in the end date of the regulatory review period, "if commercial marketing was permitted and later revoked pending further proceedings as a result if such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted." In the present regulatory review of Dantobrom®RW/Dantochlor®RW, no objections were filed and commercial marketing was never revoked by FDA, as such the end of the regulatory review period was on the date of the Federal Register publication which amended the food additive regulations to include Dantobrom®RW/Dantochlor®RW. This is particularly relevant since the Federal Register publication triggers the sixty day period set forth in 35 U.S.C. § 156(d)(1). Because no objections or withdrawal of permission for commercial marketing altered the end of the regulatory review period of Dantobrom®RW/Dantochlor®RW, the date which triggered the sixty day window for submission of the PTE application is June 30, 2000. Therefore, the filing of the PTE application on August 30, 2000, was untimely and hence, the PTE application is **DENIED**.

B. Interim Extensions

1. Applicant's Pending Fifth Interim Extension Request Is Denied

Applicant filed for a fifth interim extension to extend the term of the '766 patent for another year because the '766 patent expired on February 9, 2007. Section 156(e)(2) of Title 35 provides for an interim patent term extension while an application's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. See Somerset Pharms., Inc. v. Dudas, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '766 patent will not expire before a certificate of extension is issued or denied since the Director has denied Applicants' PTE application under 35 U.S.C. § 156(d)(1) as explained herein. The second requirement is not met because the Director issued a negative eligibility determination, thus divesting him of authority to grant an interim extension. See Somerset, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); see also In re Alcon Labs. Inc., 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for extension). Accordingly, because Applicant's PTE is denied herein and because the '766 patent is not eligible for patent term extension, the Office must deny Applicant's pending fourth interim extension request.

2. The Previously Granted Interim Extensions of the '766 Patent Are Vacated

During the pendency of Applicant's PTE Application before the USPTO, the USPTO granted interim extensions under 35 U.S.C. § 156(e)(2), extending the '766 patent for a total of four years while the USPTO determined whether the '766 patent was eligible for patent term extension. Because the USPTO has concluded herein that the '766 patent is not eligible for a patent term extension, the interim extensions previously granted under section 156(e)(2) are vacated *ab initio*. See In re Alcon, 13 USPQ 2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (stating that "an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent

is eligible for extension); see also In re Reckitt, 230 USPQ 369 (Comm'r of Pat. & Trademarks 1986) (recognizing that if a patent is ineligible for a patent term extension, then any interim extension granted to maintain a patent during the eligibility review process would be invalid); U.S. Pat. & Trademark Off., Manual of Patent Examining § 2755.01 (8th ed. 2001, rev. Oct. 2005) ("Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under § 156(e)(2). . . . Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under § 156(e)(2).").

C. Conclusion

For the above-stated reasons, the applications for patent term extension under 35 U.S.C. § 156(d)(1) and § 156(e)(2) are **DENIED**. Applicant's request for reconsideration is **DENIED**; and the four interim extensions previously granted to Applicant under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*. This is a final agency decision.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755. E-mail inquiries should be directed to Mary.Till@uspto.gov.

Robert A. Clarke

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of Deputy Commissioner for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Dantobrom®RW/Dantochlor®RW
FDA Docket No.: 2001E-0096

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED

JAN 23 2007

CENTRAL REEXAMINATION UNIT

Nabeela R. McMillian
Marshall, Gerstein, & Borun, LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, IL 60606-6357

In re: Patent Term Extension
Application for
U.S. Patent No. 4,894,221

Dear Ms. McMillian:

This is in regard to the Renewed Requirement for Information of August 3, 2006, to which applicant responded on September 27, 2006.

Applicant is advised that the Power of Attorney is now accepted as in compliance with 37 CFR 3.73(b). The documents submitted with the response of September 27, 2006, together with documents previously submitted, establish a chain of title from the inventors to Sinclair Pharmaceuticals Limited, the present applicant for patent term extension.

In order to clarify the record, and to ensure that any Certificate of Extension that may eventually issue for this patent will reflect Sinclair Pharmaceuticals Limited as the owner, applicant is encouraged to file all relevant assignment and title documents, including those concerning change of corporate name, with the Assignment Division of the Office for recordation. Applicant should clearly indicate that the documents are being filed with regard to the '221 patent. It is noted that the assignment document submitted as Exhibit B with the response of September 27, 2006, although already on file with the Office, is not retrievable using either the patent number or the application number of the '221 patent because it was submitted to the Office with regard to a parent application.

An Order granting an interim extension of one year under 35 U.S.C. §156(e)(2) accompanies this letter. You will note that the Order was signed by Director Dudas on January 16, 2007.

Applicant is advised that the Office is currently awaiting confirmation by the Food and Drug Administration that DECAPINOL® Oral Rinse was subject to a regulatory review period within the meaning of 35 U.S.C. §156(g).

Any correspondence with respect to this matter should be directed as follows (NOTE NEW MAIL STOP):

Mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FAX: (571) 273-7754

Hand-carry: Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.

Kathleen Kahler Fonda

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly J. Friedman

re: DECAPINOL® Oral Rinse

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Sinclair Pharmaceuticals Limited	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,894,221	:	INTERIM EXTENSION

Sinclair Pharmaceuticals Limited, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,894,221, filed an application for patent term extension under 35 U.S.C. § 156 on June 17, 2005. The original term of the patent is due to expire on January 16, 2007. The patent claims a method of using 3-(4-propyl-heptyl)-4-(2-hydroxyethyl)morpholine (delmopinol), which is the active ingredient of the product DECAPINOL® oral rinse. That product was approved by the Food and Drug Administration for commercial marketing or use on April 18, 2005. An extension of five years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,894,221 is granted for a period of one year from the original expiration date of the patent.

1/16/07
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JAN 16 2008

Nabeela R. McMillian
Howrey LLP
C/O IP Docketing Dept.
2941 Fairview Park Dr., Suite 200
Falls Church, VA 22042-2924

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,894,221

Dear Ms. McMillian :

An order granting interim extension certificate under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,894,221 for a period of 1 year.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: Decapinol® Oral Rinse
FDA Docket No.: 2006E-0366

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Sinclair Pharmaceuticals Limited	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,894,221	:	INTERIM EXTENSION

Sinclair Pharmaceuticals Limited, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,894,221, filed an application for patent term extension under 35 U.S.C. § 156 on June 17, 2005. The extended term of the patent is due to expire on January 16, 2008. The patent claims a method of using 3-(4-propyl-heptyl)-4-(2-hydroxyethyl)morpholine (delmopinol), which is the active ingredient of the product DECAPINOL® oral rinse. That product was approved by the Food and Drug Administration for commercial marketing or use on April 18, 2005. An extension of five years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,894,221 is granted for a period of one year from the extended expiration date of the patent.

1/14/08
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Paper No. 31

ATTN: MAX D. HENSLEY
GENENTECH, INC.
460 POINT SAN BRUNO BLVD.
SOUTH SAN FRANCISCO, CA 94080

COPY MAILED

FEB 26 2002

OFFICE OF PETITIONS

ON PETITION

In re Patent No. 4,816,567 :
Issue Date: March 28, 1989 :
Application No. 06/483,457 :
Filed: April 8, 1983 :
Attorney Docket No. DT-2477 :

This is a decision on the petition filed February 7, 2002, to waive the rules and accept the correction of the assignee on the front page of the above-identified patent.

The petition is **granted**.

There is no indication that the person signing the present petition was ever given a power of attorney or authorization of agent to prosecute the above-identified patent. If the person signing the present petition desires to receive future correspondence regarding this patent, the appropriate power of attorney or authorization of agent must be submitted. While a courtesy copy of this decision is being mailed to the person signing the present petition, all future correspondence will be directed to the address currently of record until such time as appropriate instructions are received to the contrary.

This file is being forwarded to the Certificates of Correction Branch for issuance of the requested Certificate of Correction.

Telephone inquiries concerning this matter may be directed to the Certificates of Correction Branch at (703) 305-8309.

Christina T. Tartera

Christina T. Tartera
Petitions Attorney
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy
(703) 306-5589

cc: Sharon E. Crane
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON, TX 77056

COPY MAILED

OCT 3 1 2008

OFFICE OF PETITIONS

In re Patent No. 4,565,490	:	
Issue Date: January 21, 1986	:	
Application No. 06/486,336	:	DECISION ON PETITION
Filed: April 19, 1983	:	
Attorney Docket No.	:	

This is a decision on the petition under 37 CFR 1.182, filed September 4, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

As authorized, the $400 fee for the petition under 37 CFR 1.182 has been assessed to petitioner's deposit account.

Telephone inquiries concerning this decision may be directed to JoAnne Burke at (571) 272-4584. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Naomi Farmer in the Office of Data Management at (703) 308-9250, Ext. 129.

A copy of this decision is being faxed to Office of Data Management for issuance of a duplicate Letters Patent.

Ramesh Krishnamurthy

Ramesh Krishnamurthy
Petitions Examiner
Office of Petitions

cc: Naomi Farmer, South Tower, 8th Floor, Room C23 (Fax No. (571) 270-9753)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: September 4, 2008 Signature: /Jason C. Huang, Reg. No. 46,222/
(Jason C. Huang)

PATENT
RICE/0003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ivan G. Rice	§	Confirmation No.: 1570
	§	
	§	Group Art Unit: 3403
Serial No.: 06/486,336	§	
	§	Examiner: Louis J. Casaregola
Filed: April 19, 1983	§	
	§	
For: INTEGRATED GAS/STEAM NOZZLE	§	

PETITION FOR REPLACEMENT LETTERS PATENT UNDER 37 C.F.R. § 1.182

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Jason C. Huang, attorney for the patent holder Ivan G. Rice, respectfully request a replacement Letters Patent Grant for U.S. Patent No. 4,565,490, issued on January 21, 1986. The reason for this request is that the original Letters Patent Grant was irreparably damaged during discovery in a litigation matter.

The fee for this petition in the amount of $400.00, as set forth under 37 C.F.R. § 1.17(f) (fee code 1462), has been submitted with the filing of this petition.

Prior to the filing of this Petition, Ivan G. Rice has filed a completed Power of Attorney and Correspondence Address Indication Form. Pursuant to that Form, please address all correspondence relating to this Petition—including the replacement Letters Patent Grant in the event this Petition is granted—to the following address:

Jason C. Huang
Patterson & Sheridan, LLP
3040 Post Oak Blvd.,
Suite 1500
Houston, TX 77056

Your assistance in this matter is greatly appreciated.

Respectfully submitted, and
S-signed pursuant to 37 C.F.R. 1.4,

/Jason C. Huang, Reg. No. 46,222/
Jason C. Huang, Reg. No. 46,222
PATTERSON & SHERIDAN, LLP
3040 Post Oak Blvd. Suite 1500
Houston, Texas 77056
Telephone: (713) 623-4844
Facsimile: (713) 623-4846

06/486336 Examiner: CASAREGOLA, LOUIS GAU: 3403
Inventor: RICE , IVAN Classification: 415/114.000
Status: 150 - PATENTED CASE
Title: INTEGRATED GAS/STEAM NOZZLE
Start Date: End Date:

bib_fee report (1 items, not sorted)

Acct Date	Seq. Num.	Tran Type	Fee Code	Fee Amount	Mailroom Date	Payment Method
09/04/2008	13077	4	1462	$400.00	09/04/2008	CC

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

MAY 19 2003

#20

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

A certificate under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Health Assessment Policy Staff
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: RANEXA™ (ranolazine)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On March 5, 2003, patent owner Roche Palo Alto LLC timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine in the product RANEXA™. The application indicates that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (May 18, 2003), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for a period of one year from the original expiration date of the patent, i.e., from May 18, 2003, until May 18, 2004.

MAY - 9 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 22 2004

#22

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

Dear Mr. Isacson:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: RANEXA™ (ranolazine)
FDA Docket No:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On March 29, 2004, patent owner Roche Palo Alto LLC, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine (Ranexa™). The application indicates, and the Food and Drug Administration (FDA) has confirmed, that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2004), the term of the patent will be extended under 35 U.S.C. § 156(d)(5) for an additional year.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until May 18, 2005.

9/17/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN-02 2005

JUN - 2 2005

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

A certificate of interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. A notice regarding this interim extension will publish in the Federal Register on June 6, 2005. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: RANEXA™ (ranolazine)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On March 25, 2005, patent owner Roche Palo Alto LLC timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine in the product RANEXA™. The application indicates that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional period of one year as required by 35 U.S.C. § 156(d)(5)(C). Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2005), a third interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the original expiration date of the patent, i.e., from May 18, 2005, until May 18, 2006.

5/26/05

Date

Jon W. Dudas

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. 2005-P-064]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,567,264; ranolazine

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a third one-year interim extension of the term of U.S. Patent No. 4,567,264.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (571)272-7744; by mail marked to her attention and addressed to Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571)273-7744; or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On March 25, 2005, patent owner Roche Palo Alto LLC, timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine (Ranexa™). The application indicates, and the Food and Drug Administration (FDA) has confirmed, that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional period of one year as required by 35 U.S.C. § 156(d)(5)(C). Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2005), the term of the patent will be extended under 35 U.S.C. § 156(d)(5) for an additional year.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until May 18, 2006.

5/26/05
Date

Jon W. Dudas
Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 18 2006

Grant d. Green
Patent Law Department A2-250
Roche Palo Alto LLC
3401 Hillview Avenue
Palo Alto, CA 94304

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

Dear Mr. Green:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: RANEXA™ (ranolazine)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,567,264	:	INTERIM EXTENSION

Roche Palo Alto LLC, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,567,264, filed a fourth application for interim patent term extension under 35 U.S.C. § 156(e)(2) on March 14, 2006. The previously extended term of the patent is due to expire on May 18, 2006. The patent claims the active ingredient ranolazine, in the human drug product RANEXA™, which was approved by the Food and Drug Administration for commercial marketing or use on January 27, 2006. An interim extension of one year is requested. U.S. Patent No. 4,567,264 was previously extended three times for a period of one year each under 35 U.S.C. 156(d)(5).

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,567,264 is granted for a period of one year from the extended expiration date of the patent.

5/17/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 22 2004

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

Dear Mr. Isacson:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: RANEXA™ (ranolazine)
FDA Docket No:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On March 29, 2004, patent owner Roche Palo Alto LLC, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine (Ranexa™). The application indicates, and the Food and Drug Administration (FDA) has confirmed, that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2004), the term of the patent will be extended under 35 U.S.C. § 156(d)(5) for an additional year.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until May 18, 2005.

9/17/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 23 2003

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.go

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

OIPE JC98
JUL 02 2003
PATENT & TRADEMARK OFFICE

Dear Mr. Stepno:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
RECEIVED
JUN 26 2003
DOCKETED

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MEXORYL®
FDA Docket No.:

Additional enclosure: Courtesy copy of application for interim extension
No action required at this time.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.go

JUN 23 2005

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MEXORYL®
FDA Docket No.:

Additional enclosure: Courtesy copy of application for interim extension
No action required at this time.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A. Request for Patent Term Extension U.S. Patent No. 4,585,597	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On May 30, 2003, patent owner L'Oreal S.A. timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient (Mexoryl® SX (ecamsule)) in the product ANTHÉLIOS® SP Topical Cream (HELIOBLOCK® SX Cream), and the methods of use and manufacturing of the active ingredient. The application indicates that a New Drug Application for the human drug product ecamsule has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (June 16, 2003), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the original expiration date of the patent, i.e., from June 16, 2003, until June 16, 2004.

JUN 13 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

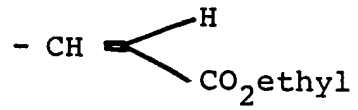
PATENT NO. : 4,585,597

DATED : April 29, 1986

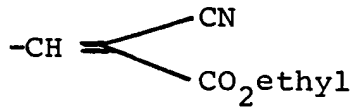
INVENTOR(S) : Gerard LANG et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7, Example 5, that portion of the formula reading



should read



Signed and Sealed this

Twenty-second Day of December, 1987

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

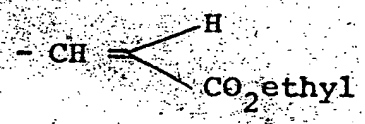
PATENT NO. : 4,585,597

DATED : April 29, 1986

INVENTOR(S) : Gerard LANG et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7, Example 5, that portion of the formula reading



should read

MAILING ADDRESS OF SENDER:
Fleit, Jacobson, Cohn & Price
1217 E Street NW
Washington, DC 20004-1998

PATENT NO. 4,585,597

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FORM PTO 1050 (REV. 3-82)

W241

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DATE: 05/23/03
PAGE: 00035

ACCESSION NUMBER 241-97-0330 BOX NUMBER 000~~061~~ 99 LOCATION 09-60-35-2-1

FOLDER TITLE 4585597

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DATE SEARCHED: SEARCHER:

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OLIPHANT BENNIE
U.S. PATENT & TRADEMARK OFFICE
FRANCONIA WAREHOUSE BUILDING 5A
6808 LOISDALE ROAD
SPRINGFIELD VA 22150
703-308-7400

SIGNATURE

DATE

00046395

RECEIPT OF RECORDS:

( )..REQUESTER PLEASE SIGN, DATE AND RETURN THIS FORM, FOR THE FILE ITEM(S) LISTED ABOVE ONLY IF THIS BOX HAS BEEN CHECKED BY THE RECORD CENTER.

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UNITED STATES PATENT AND TRADEMARK OFFICE

JUL - 6 2004

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,597	:	**INTERIM EXTENSION**

On April 30, 2004, patent owner, L'Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl™ SX (ecamsule) in the human drug product ANTHÉLIOS™ SP, a method of use of ecamsule, and a method of manufacturing ecamsule. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product ANTHÉLIOS™ SP (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The patent was previously extended for a term of one year.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 16, 2004), an interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2005.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.go

JUN 23 2005

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597.

Dear Mr. Stepno:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MEXORYL®
FDA Docket No.:

Additional enclosure: Courtesy copy of application for interim extension
No action required at this time.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A. Request for Patent Term Extension U.S. Patent No. 4,585,597	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On May 30, 2003, patent owner L'Oreal S.A. timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient (Mexoryl® SX (ecamsule)) in the product ANTHÉLIOS® SP Topical Cream (HELIOBLOCK® SX Cream), and the methods of use and manufacturing of the active ingredient. The application indicates that a New Drug Application for the human drug product ecamsule has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (June 16, 2003), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the original expiration date of the patent, i.e., from June 16, 2003, until June 16, 2004.

JUN 13 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 31 2006

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno :

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: ANTHÉLIOS® SP Topical Cream (Mexoryl® SX (Ecamsule))
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A. Request for Patent Term Extension U.S. Patent No. 4,585,597	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On May 17, 2005, patent owner, L'Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl® SX (ecamsule) in the human drug product ANTHÉLIOS® SP, a method of use of the active ingredient, and a method of manufacturing the active ingredient. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mexoryl® SX (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 16, 2005), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for an additional year, i.e., until June 16, 2006.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2006.

3/29/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN 13 2006

Norman Stepno
Buchanan Ingersoll, PC
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno :

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: ANTHÉLIOS® SP Topical Cream (Mexoryl® SX (Ecamsule))
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,597	:	**INTERIM EXTENSION**

On May 16, 2006, patent owner, L'Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl® SX (ecamsule) in the human drug product ANTHÉLIOS® SP (HELIOBLOCK® SX Cream), a method of use of the active ingredient, and a method of manufacturing the active ingredient. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mexoryl® SX (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 16, 2006), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for an additional year, i.e., until June 16, 2007.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2007.

6/12/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

SEP 27 2006

Norman Stepno
Buchanan Ingersoll, PC
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno :

A certificate of interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,585,597 up to June 10, 2007, or 1,455 days from the original expiration date of the patent.

Telephone inquiries regarding this communication should be directed to hte undersigned by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: ANTHÉLIOS® SP Topical Cream (Mexoryl® SX (Ecamsule))
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,597	:	**INTERIM EXTENSION**

L'Oreal S.A., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,585,597, filed an application for patent term extension under 35 U.S.C. § 156 on September 19, 2006. Three interim extensions have been granted for the patent under 35 U.S.C. § 156(d)(5), each for a period of one year. The extended term of the patent is due to expire on September 19, 2006. The patent claims the active ingredient Mexoryl® SX (ecamsule) in the human drug product, ANTHÉLIOS® SX Daily Moisturizing Cream with Sunscreen, a method of use of the active ingredient, and a method of manufacturing the active ingredient, which was approved by the Food and Drug Administration for commercial marketing or use on July 21, 2006. An extension of 1,455 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,585,597 is granted for a period of 1,455 days from the original expiration date of the patent, i.e., until June 10, 2007.

9/19/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED

SEP 22 2009

OFFICE OF PETITIONS

VENABLE LLP
P.O. BOX 34385
WASHINGTON DC 20043-9998

In re Application of Albert Dunn et al Application No. 06/531,939 Filed: September 7, 1983 Attorney Docket No. SB-186	: : : : :	ON PETITION

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(b), filed August 11, 2009, to revive the above-identified application.

The petition is **DISMISSED**.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition under 37 CFR 1.137(b)." This is **not** a final agency action within the meaning of 5 U.S.C. § 704.

The application became abandoned for failure to reply in a timely manner to the Office letter mailed December 15, 2006.

A grantable petition under 37 CFR 1.137(b) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.137(d). Where there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137 was unintentional, the Director may require additional information. See MPEP 711.03(c)(II)(C) and (D). The instant petition lacks item(s) (4).

The Office is in receipt of a Terminal Disclaimer submitted on August 11, 2009. However, the Terminal Disclaimer form is incomplete because no owner was provided. A proper Terminal Disclaimer is required.

Further correspondence with respect to this matter should be delivered through one of the following mediums:

By mail:	Mail Stop PETITIONS Commissioner for Patents Post Office Box 1450 Alexandria, VA 22313-1450
By hand:	Customer Service Window Mail Stop Petitions Randolph Building 401 Dulany Street Alexandria, VA 22314
By fax:	(571) 273-8300 ATTN: Office of Petitions
By internet:	EFS-Web www.uspto.gov/ebc/efs_help.html (for help using EFS-Web call the Patent Electronic Business Center at (866) 217-9197)

Any questions concerning this matter may be directed to the undersigned at (571) 272-3208.

/KOC/
Karen Creasy
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

VENABLE LLP
P.O. BOX 34385
WASHINGTON DC 20043-9998

MAILED

NOV 25 2009

OFFICE OF PETITIONS

In re Application of
Albert Dunn et al
Application No. 06/531,939
Filed: September 7, 1983
Attorney Docket No. SB-186

DECISION ON PETITION

This is a decision on the renewed petition under the unintentional provisions of 37 CFR 1.137(b), filed October 7, 2009, to revive the above-identified application.

The petition is **GRANTED**.

The petition satisfies the conditions for revival pursuant to the provisions of 37 CFR 1.137(b) in that (1) the reply, (2) the petition fee; and (3) the required statement of unintentional delay have been received. Accordingly, the reply to the Office letter mailed December 15, 2006, is accepted as having been unintentionally delayed.

The $140.00 fee for the Terminal Disclaimer submitted on October 7, 2009 is being credited to petitioner's deposit account no. 22-0261, since the fee was previously paid with the Terminal Disclaimer submitted on August 11, 2009.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3208.

This application is being referred to Technology Center AU 3662 for appropriate action by the Examiner in the normal course of business on the reply received October 7, 2009 and on August 11, 2009.

/KOC/
Karen Creasy
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 31 2006

David Gryte
Intervet Inc.
29160 Intervet Lane
Millsboro, DE 19966

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,770

Dear Mr. Gryte:

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,585,770 three times for a period of one year each, initially from October 12, 2003, to October 12, 2004, from October 12, 2004 to October 12, 2005, and from October 12, 2005, to October 12, 2006.

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Kery A Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE:
FDA Docket No.: docket no

UNITED STATES PATENT AND TRADEMARK OFFICE

In Hoechst Roussel Vet S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,770	:	**INTERIM EXTENSION**

On March 26, 2003, patent owner, Hoechst Roussel Vet S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,585,770. On March 31, 2004, patent owner, Hoechst Roussel Vet S.A., timely filed a second application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,585,770. On March 29, 2005, patent owner, Hoechst Roussel Vet S.A., timely filed a third application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,585,770. The patent claims the active ingredient, zilpaterol hydrochloride, in the animal drug product Zilmax®. The application indicates that an Investigational New Animal Drug Application for the animal drug product, Zilmax® (zilpaterol hydrochloride), has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (October 12, 2003), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for a period of one year to October 12, 2004, for an additional year to October 12, 2005, and for another additional year, i.e., until October 12, 2006.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,770, is granted for a period of one year from the original expiration date of the patent, i.e., until October 12, 2004; a second interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,770, is granted for an additional period of one year from the extended expiration date of the patent, i.e., until October 12, 2005; and a third interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,770, is granted for an additional period of one year from the extended expiration date of the patent, i.e., until October 12, 2006.

3/29/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 18 2006

Roger L. Browdy
Browdy and Neimark PLLC
624 Ninth Street NW
Suite 300
Washington DC 20001-5303

In Re: Patent Term Extension Application
for U.S. Patent No. 4,840,896

Dear Mr. Browdy:

An ORDER GRANTING INTERIM EXTENSION under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,840,896 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda by telephone at (571) 272-7754, or by e-mail at kathleen.fonda@uspto.gov.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: OVIDREL®
FDA Docket No.: 2005E-0256

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Genzyme Corporation	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,840,896	:	INTERIM EXTENSION

Genzyme Corporation, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,840,896, filed an application for patent term extension under 35 U.S.C. § 156 on November 20, 2000. The original term of the patent is due to expire on June 20, 2006. The patent claims the active ingredient choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG)), in the human drug product OVIDREL®, which was approved by the Food and Drug Administration for commercial marketing or use on September 20, 2000. An extension of 1,054 days was originally requested, but applicant's Request for Interim Extension Under 35 U.S.C. § 156(e)(2) of March 13, 2006, now requests an extension until April 28, 2009, (1,043 days) in view of the corrected regulatory period set forth in the Food and Drug Administration's (FDA) letter of February 24, 2006.

The initial USPTO review of the application to date indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. On March 15, 2006 (71 Fed. Reg. 50), the FDA published the determination of the regulatory review period for purposes of patent term extension for OVIDREL®, but this determination has not yet been made final. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,840,896 is granted for a period of one year from the original expiration date of the patent.

5/17/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL - 6 2004

Basil Krikelis
RatnerPrestia, Nemours Building
1007 Orange Street, Suite 1100
P.O. BOX 1596
WILMINGTON, DE 19899

Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of one year.

It is noted that the application for interim patent term extension was accompanied by a change of address for the patent, and a revocation of power of attorney. The address was requested to be changed to the address associated with Customer Number 31344, which is a slightly different address than above. Applications for patent term extension do not use the address associated with a Customer Number, since neither the Food and Drug Administration nor the Department of Agriculture have direct access to that database, so if the address associated with the application for patent term extension needs to be changed, applicant should submit a change of address specific to the application for patent term extension.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

On November 3, 2003, patent owner Arkion Life Sciences timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,600,706. The patent claims the method of making the animal feed product NSURE® (natamycin). The application indicates that an amended Food Additive Petition for the animal feed product has been filed and was undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The petition was granted by the Food and Drug Administration, and the regulations for food additives in feed and drinking water were amended to provide for the safe use of natamycin. See Food Additives Permitted in Feed and Drinking Water of Animals; Natamycin, 69 Fed. Reg. 19320 (April 13, 2004) (final rule).

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since regulatory review period continued beyond the expiration date of the patent (November 17, 2003, due to the terminal disclaimer disclaiming the term of the patent subsequent to the expiration date of U.S. Patent No. 4,536,494), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the expiration date of the patent, i.e., until November 17, 2004.

6/24/04
Date

Jon W. Dudas
Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. 2004-P-040]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,600,706; natamycin

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,600,706.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (703)306-3159; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Patent Ext., P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (703)872-9411, or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On November 3, 2003, patent owner Arkion Life Sciences timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,600,706. The patent claims the method of making the animal feed product NSURE® (natamycin). The application indicates that an amended Food Additive Petition for the animal feed product has been filed and was undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The petition was granted by the Food and Drug Administration, and the regulations for food additives in feed and drinking water were amended to provide for the safe use of natamycin. See Food Additives Permitted in Feed and Drinking Water of Animals; Natamycin, 69 Fed. Reg. 19320 (April 13, 2004) (final rule).

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since regulatory review period continued beyond the expiration date of the patent (November 17, 2003, due to the terminal disclaimer disclaiming the term of the patent subsequent to the expiration date of U.S. Patent No. 4,536,494), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the expiration date of the patent, i.e., until November 17, 2004.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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NOV 17 2004

Basil Krikelis
RatnerPrestia, Nemours Building
1007 Orange Street, Suite 1100
P.O. BOX 1596
WILMINGTON, DE 19899

Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (571)272-7744.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003 until November 17, 2004. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 348) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2005.

11/04/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

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Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2006.

10/18/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 30 2006

Basil Krikelis
McCarter & English
919 N. Market Street
PO Box 111
Wilmington DE 19801-3023

OK BK 11-9-06

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

Dear Mr. Krikelis :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NSURE®
FDA Docket No.: 2005E-0250

Attention: Beverly Friedman

RECEIVED
NOV 6 2006

RECEIVED NOV 6 2006

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences :
Request for Patent Term Extension : **ORDER GRANTING**
U.S. Patent No. 4,600,706 : **INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003, until November 17, 2004, and for a second year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2004, until November 17, 2005, and for a third year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2005, until November 17, 2006. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2007.

10/20/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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OCT 30 2006

Basil Krikelis
McCarter & English
919 N. Market Street
PO Box 111
Wilmington DE 19801-3023

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

Dear Mr. Krikelis :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NSURE®
FDA Docket No.: 2005E-0250

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003, until November 17, 2004, and for a second year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2004, until November 17, 2005, and for a third year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2005, until November 17, 2006. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2007.

10/20/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
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NOV 13 2007

Basil Krikelis
McCarter & English
Citizens Bank Center
919 N. Market Street, Suite 1800
P.O. Box 111
Wilmington, DE 19899

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156

This is in response to the application for extension of the patent term of U.S. Patent No. 4,600,706 (the '706 patent) filed under 35 U.S.C. § 156 in the United States Patent and Trademark Office (USPTO) on May 13, 2004, the request for reconsideration filed March 7, 2007, and the request for an interim extension of the '706 patent filed under 35 U.S.C. § 156(e)(2) on October 22, 2007. The application was filed by Arkion Life Sciences, Inc. (Applicant), the patent owner of record at the time application was filed. Extension was sought based upon the premarket review under § 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a food additive known by the tradename NSURE® which comprises natamycin. Because the Food and Drug Administration (FDA) and the PTO have determined that the approval of NSURE® (natamycin) does not constitute the first permitted marketing or use of natamycin under the provision of law under which the regulatory review period occurred, Applicant's requests for extension of the patent term of the '706 patent under 35 U.S.C. § 156(d)(1) and 35 U.S.C. § 156(e)(2) are **DENIED** and its request for reconsideration is **DENIED**. Additionally, the three interim extensions previously granted under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

A. Factual Background

In February of 1998, the FDA announced that Protein Technologies International filed a petition to amend the food additive regulations to provide for the safe use of a dry form of natamycin (pimaricin) as an antimycotic in food to inhibit mold spoilage. See Protein Technologies International; Filing of Food Additive Petition, 63 Fed. Reg. 6945 (Feb. 11, 1998). The FDA indicated that approval of a food additive occurs under section 409(b)(5) of the FFDCA (21 U.S.C. § 348(b)(5)). Id.

In December of 1998, the FDA amended the food additive regulation, 21 C.F.R. § 172.155, to provide for the safe use of a dry form of natamycin as an antimycotic on the surface of cuts and slices of cheese. See Food Additives Permitted for Direct Addition to Food for Human Consumption; Natamycin (Pimaricin), 63 Fed. Reg. 66014-15 (Dec. 1, 1998). Notably, the FDA acknowledged that natamycin was already used as an antimycotic agent for cheese when applied an aqueous solution by dipping or spraying. Id.

On April 13, 2004, the FDA approved the Food Additive Petition No. 2234 for NSURE® (natamycin) as an animal feed additive for use in broiler chicken feed to retard or inhibit the growth of *Aspergillus Parasiticus* fungi.

One month later, on May 13, 2004, Applicant filed an application to extend the term of the '706 patent (PTE Application) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO.[1] In its PTE Application, Applicant alleges that the '706 patent claims a method for using the product NSURE® (natamycin). Applicant likewise alleged that NSURE® (natamycin) "is currently subject to review under Section 409(b)(1) of the [FFDCA] (the act) (21 U.S.C. § 348(a))."

On November 17, 2004, the USPTO sent a letter to the FDA requesting assistance in determining the eligibility of the '706 patent for extension under 35 U.S.C. § 156(d)(1) based on the premarket review of NSURE® (natamycin). The USPTO indicated that it initially determined that the '706 patent was eligible for extension.

In a letter dated July 24, 2006, the FDA indicated that NSURE® (natamycin) had been subject to regulatory review period under section 409 of the FFDCA before its commercial marketing or use, but that the approval did not represent the first permitted commercial marketing or use of the active ingredient of NSURE® (natamycin) under 21 U.S.C. § 348, the provision of law under which the regulatory review period occurred. The FDA stated: "NSURE does not represent the first permitted commercial marketing or use of the food additive natamycin under 21 U.S.C. § 348, the provisions of law under which the regulatory review period occurred."

On September 7, 2006, the USPTO mailed a notice of final determination to Applicant, dismissing the PTE Application on grounds that not all of the requirements of 35 U.S.C. § 156 were satisfied. Specifically, in light of the FDA's letter, the USPTO explained that NSURE® (natamycin) did not constitute the first permitted commercial marketing or use of the product under the provision of law under which the regulatory review period occurred as required by 35 U.S.C. § 156(a)(5)(A).

On March 7, 2007, Applicant requested reconsideration of the dismissal, arguing that the provision of law under which the food additive petition for NSURE® (natamycin) was filed (i.e., 21 C.F.R. § 573) is a different provision of law than the provision of law that the FDA referenced

---

[1] The '706 patent expired by operation of law on November 17, 2003. However, Applicant filed a series of interim extension requests, which the USPTO granted, extending the term of the '706 patent on an interim basis pending completion of both FDA regulatory review process and the PTE application review. Specifically, Applicant filed its first interim extension request under 35 U.S.C. § 156(d)(5) on November 3, 2003, extending the '706 patent for one-year until November 17, 2004. It then filed three other interim extension requests, all under 35 U.S.C. § 156(e)(2), each extending the patent by one more year such that the patent will expire on November 17, 2007.

in its letter (i.e., 21 U.S.C. § 348).

On October 22, 2007, Applicant filed a fourth interim extension request under 35 U.S.C. § 156(e)(2) for the '706 patent.

B. U.S. Patent No. 4,600,706 Is Not Eligible for Patent Term Extension

Under 35 U.S.C. § 156(a), the term of a patent which claims a product shall be extended if six specific requirements are satisfied. Subparagraph (a)(5)(A) provides in pertinent part that "the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A) (emphases added).

Here, Applicant's product, NSURE® (natamycin), fails to meet the requirement of 35 U.S.C. § 156(a)(5)(A) because NSURE® (natamycin) does not represent the first permitted marketing or use of natamycin under the provision of law under which the regulatory review period occurred (i.e., 21 U.S.C. § 348). Applicant states in its PTE Application at page 3 that its feed additive "was subject to review under Section 409(b)(1) of the [FFDCA] (the Act) (21 U.S.C. § 348(a))." The FDA also pointed to 21 U.S.C. § 348 as being the applicable "provision of law" for the regulatory review period of NSURE® (natamycin) in its response to the USPTO's request for input. The USPTO, however, uncovered that natamycin (pimaricin) had been previously approved as a food additive under Section 409 of the FFCDA (21 U.S.C. § 348) for use as an antimycotic agent in cheese sometime before 1998. See 63 Fed. Reg. 6945. As a result, NSURE® (natamycin) plainly is not the first permitted marketing or use of natamycin under 21 U.S.C. § 348.

In its request for reconsideration, Applicant argues that the '706 patent is entitled to an extension under 35 U.S.C. § 156 because NSURE® (natamycin) was approved under 21 C.F.R. § 573, which although obtaining authority from 21 U.S.C. § 348, is a different provision of law than 21 U.S.C. § 348. Applicant is mistaken in its reading of 35 U.S.C. § 156(a)(5)(A). The phrase "provision of law" as used in 35 U.S.C. § 156(a)(5)(A) refers to the statutory provision under which the regulatory review period occurs for a particular class of products that is eligible for patent term restoration. It does not refer to a particular provision of a regulation, as argued by Applicant.

Section 156(g) of Title 35 and its implementing regulations confirm the USPTO's reading of 35 U.S.C. § 156(a)(5)(A). That is, 35 U.S.C. § 156(g) and its implementing regulations identify the statutory authorities under which regulatory review occurs for food and color additives.[2]

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[2] Notably, for all other classes of products for which patent term restoration is available, § 156(g) reflects statutory provisions under which regulatory review occurs: (i) section 505 of the FFDCA for new drugs; (ii) section 505 of the FFDCA and section 351 of the Public Health Service Act for licensed biologics; (iii) section 515 of the FFDCA for medical devices;

35 U.S.C. § 156(g) refers in general to the FFDCA for food additives and not to a regulation such as 21 C.F.R. § 573. The implementing regulations for 35 U.S.C. § 156(g), in turn, are more specific and refer to section 409 of the FFDCA. See 21 C.F.R. § 60.3(b)(9) (indicating that the provision of law for food additives is section 409 of the FFDCA).

For the foregoing reasons, the term of the '706 patent is not eligible for extension under 35 U.S.C. § 156 based upon the regulatory review period and approval of the product NSURE® (natamycin) as a feed additive.

C. Applicant's Pending Fourth Interim Extension Request Is Denied

Applicant filed a fourth interim extension application to extend the term of the '706 patent for another year because the '706 patent is due to expire on November 17, 2007. Section 156(e)(2) of Title 35 provides for an interim patent term extension while an applicant's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. See Somerset Pharms., Inc. v. Dudas, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '706 patent will not expire before a certificate of extension is issued or denied since the Director has denied Applicants' PTE application under 35 U.S.C. § 156(d)(1) herein as explained above. The second requirement is not met because the Director issued a negative eligibility determination, thus divesting him of authority to grant an interim extension. See Somerset, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); see also In re Alcon Labs. Inc., 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for

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and (iv) section 512 of the FFDCA for new animal drugs. Section 156(g) never mentions any regulations.

extension). Accordingly, because Applicant's PTE is denied herein and because the '706 patent is not eligible for patent term extension, the Office must deny Applicant's pending fourth interim extension request.

D. The Previously Granted Interim Extensions of the '706 Patent Are Vacated

During the pendency of Applicant's PTE Application before the USPTO, Applicant filed three previous interim extension requests under 35 U.S.C. § 156(e)(2). The USPTO granted each of the requests, extending the '706 patent for a total of three years while the USPTO determined whether the '706 patent was eligible for patent term extension. Because the USPTO has concluded herein that the '706 patent is not eligible for a patent term extension, the interim extensions previously granted under section 156(e)(2) are vacated *ab initio*. See In re Alcon, 13 USPQ 2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (stating that "an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent is eligible for extension); see also In re Reckitt, 230 USPQ 369 (Comm'r of Pat. & Trademarks 1986) (recognizing that if a patent is ineligible for a patent term extension, then any interim extension granted to maintain a patent during the eligibility review process would be invalid); U.S. Pat. & Trademark Off., Manual of Patent Examining § 2755.01 (8th ed. 2001, rev. Oct. 2005) ("Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under § 156(e)(2). . . . Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under § 156(e)(2).").

E. Conclusion

In sum, Applicant's requests for extension of the patent term of the '706 patent are **DENIED**; Applicant's request for reconsideration is **DENIED**; and the three interim extensions previously granted to Applicant under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

THIS DECISION MAY BE VIEWED AS A FINAL AGENCY ACTION.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till, Legal Advisor, at (571) 272-7755.

Robert A. Clarke

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane
Rockwall II Rm. 1101
Rockville, MD 20857

Attention: Beverly Friedman

Re: NSURE® (natamycin)
FDA Docket No. 2005E-0250

ExtAppCASE 4-12576

OIPE IAP89
SEP 13 2006
PATENT & TRADEMARK OFFICE

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being facsimile transmitted to the Patent and Trademark Office (571-273-7744) on the date shown below.

Peter J. Waibel		December 13, 2005
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT TERM EXTENSION
APPLICATION FOR
U.S. PATENT NO. 4,559,174
APPLICATION NO: 06/559,861
FILED: December 12, 1983

RECEIVED
SEP 18 2006
TECH CENTER 1600/2900

MS: Patent Ext.
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PATENT TERM EXTENSION APPLICATION FOR
U.S. PATENT NO. 4,559,174

[Sir] Ms. Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Ms. Ferriter,

As previously discussed, I am sending this fax to point out an error noted on the attached "Corrected Notice of Final Determination." The Notice indicates that the period of extension has been determined to be 1,500 days, not 1,739 days as previously erroneously calculated. On page 2 of the Notice, the Term Extended entry reflected the 1,500 days noted above, however, the Expiration Date of Extension is noted as September 21, 2007. This appears to be the extended expiration date based on the previous 1,739 days. Accordingly, it is believed that the Expiration Date of Extension based on 1,500 days is January 25, 2007. Correction prior to publication in the Official Gazette is respectfully request.

Should you require any additional information concerning this correspondence, you are invited to contact the undersigned by telephone.

Thank you.

Respectfully submitted,

Peter J. Waibel
Attorney for Applicant
Reg. No. 43,228
(862) 778-7951

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080

Date: December 13, 2005

P.

* * * COM[illegible]ICATION RESULT REPORT (DEC. 13. [illegible]5 9:58AM) * * *

FAX HEADER 1: NOVARTIS C. I. P. (973) 781-806
FAX HEADER 2:

RANSMITTED/STORED : DEC. 13. 2005 9:57AM

ILE MODE	OPTION	ADDRESS	RESULT	PAGE
326 MEMORY TX		USPTO	OK	4/4

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

ExtAppCASE 4-12576

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being facsimile transmitted to the Patent and Trademark Office (571-273-7744) on the date shown below.

Peter J. Walbel — Type or print name
Signature
December 13, 2005 — Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT TERM EXTENSION
APPLICATION FOR
U.S. PATENT NO. 4,559,174
APPLICATION NO: 06/559,861
FILED: December 12, 1983

MS: Patent Ext.
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PATENT TERM EXTENSION APPLICATION FOR
U.S. PATENT NO. 4,559,174

[Sir] Ms. Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Ms. Ferriter,

As previously discussed, I am sending this fax to point out an error noted on the attached "Corrected Notice of Final Determination." The Notice indicates that the period of extension has been determined to be 1,500 days, not 1,739 days as previously erroneously calculated. On page 2 of the Notice, the Term Extended entry reflected the 1,500 days noted above, however, the Expiration Date of Extension is noted as September 21, 2007. This appears to be the extended expiration date based on the previous 1,739 days. Accordingly, it is believed that the Expiration Date of Extension based on 1,500 days is January 25, 2007. Correction prior to publication in the Official Gazette is respectfully request.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

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OCT 2 2 2008
OFFICE OF PETITIONS

PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON TX 77056

In re Application of:	:	
Ivan G. Rice	:	
Pat. Num.: 4592204	:	
Issue Date: 06/03/1986	:	
Application No. 06/572548	:	ON PETITION
Filing or 371(c) Date: 01/20/1984	:	
Title of Invention: COMPRESSION	:	
INTERCOOLED HIGH CYCLE	:	
PRESSURE RATIO GAS GENERATOR	:	
FOR COMBINED CYCLES	:	

This is a decision on the Petition for Replacement Letters Patent Under 37 C.F.R. § 1.182," filed September 4, 2008.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

Questions concerning this decision may be directed to the undersigned at 571-232-3232. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Niomi Farmer, in the Office of Data Management at (703) 308-9250, Ext. 129.

A copy of this decision is being faxed to the Office of Data Management for issuance of a duplicate Letters Patent.

/Derek L. Woods/
Derek L. Woods
Attorney
Office of Petitions

CC: Niomi Farmer
South Tower 8th floor, Room C-32 (FAX 571-270-9753)

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Scott A. Williams
Corporate Patent Department
Pharmacia Corporation, Mail Zone O4E
800 N. Lindbergh Blvd
St. Louis MO 63167

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,559,332

#11

MAILED

APR 12 2004

REEXAM UNIT

Dear Mr. Williams:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,559,332 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the PSC Forms Download Website: http://forms.psc.gov/forms/FDA/fda.html (http://forms.psc.gov/forms/FDA/Fda-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: INSPRA™ (eplerenone)
FDA Docket No.: docket no

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Novartis AG	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,559,332	:	**INTERIM EXTENSION**

Novartis AG, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,559,332, filed an application under 35 U.S.C. § 156, requesting an extension of 1,218 days. The original expiration date of the patent is April 9, 2004. The patent claims the active ingredient eplerenone in the human drug product "INSPRA™" and a method of use of said product. The application indicates that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,559,332 is granted for a period of one year from the original expiration date of the patent, until April 9, 2005.

4/2/04
Date

Jon W. Dudas
Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Scott A. Williams
Corporate Patent Department
Pharmacia Corporation, Mail Zone O4E
800 N. Lindbergh Blvd
St. Louis, MO 63167

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,559,332

COPY MAILED

APR 08 2005

OFFICE OF PETITIONS

Dear Mr. Williams:

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,559,332 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Jerry J Dey for

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: INSPRA® (eplerenone)
FDA Docket No.: docket no

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Novartis Corporation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,559,332	:	**INTERIM EXTENSION**

On November 5, 2002, Novartis AG, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,559,332, filed an application under 35 U.S.C. § 156, requesting an extension of 1,218 days. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(e)(2), from April 9, 2004 until April 9, 2005. The patent claims the active ingredient eplerenone in the human drug product "INSPRA®" and a method of use of said product. The application indicates that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

A second interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,559,332 is granted for a period of one year from the extended expiration date of the patent, until April 9, 2006.

April 1, 2005
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APR -5 2006

Scott A. Williams
Pharmacia Corporation of Pfizer Inc.
Patent Department
P.O. Box 1027
St. Louis MO 63006

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,559,332

Dear Mr. Williams:

An interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,559,332 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:
http://www.fda.gov/opacom/morechoices/fdaforms/default.html
(http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at mary.till@uspto.gov by e-mail.

Kery A. Ries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: INSPRA® (eplerenone)
FDA Docket No.: 03E-0254

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Novartis AG	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,559,332	:	**INTERIM EXTENSION**

On November 5, 2002, Novartis AG, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,559,332, filed an application under 35 U.S.C. § 156, requesting an extension of 1,218 days. The patent was originally extended for a period of one year pursuant to 35 U.S.C. 156(e)(2) from April 9, 2004, until April 9, 2005, and extended again for a period of one year from April 9, 2005, to April 9, 2006. The patent claims the active ingredient eplerenone in the human drug product "INSPRA®" and a method of use of said product. The application indicates that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended date of expiration of the patent, interim extension of the patent term is appropriate.

A third interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,559,332 is granted for a period of one year from the extended expiration date of the patent, until April 9, 2007.

4/5/06
Date

Jon W. Dudas
Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

GREENBLUM AND BERNSTEIN PLC
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

COPY MAILED

NOV 19 2007

OFFICE OF PETITIONS

In re Patent No. 4,588,383	:	
Issued: May 13, 1986	:	
Application No. 06/605,593	:	ON PETITION
Filed: April 31, 1984	:	
Attorney Docket No. X25466.A09	:	

This is a decision on the petition under 37 CFR 1.182, filed July 9, 2007, requesting issuance of a duplicate Letters Patent for the above-identified application.

The petition is **GRANTED**.

The Publishing Division is directed to issue a duplicate Letters Patent.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3206. Any questions concerning issuance of the duplicate Letters Patent should be directed to Krystal Paige at (703) 308-9250.

A copy of this decision is being forwarded to Publishing Division for issuance of a duplicate Letters Patent.

Liana Walsh
Petitions Examiner
Office of Petitions

cc: Krystal Paige, P/OPPD, South Tower 8C41 (FAX 571-273-9756)

UNITED STATES PATENT AND TRADEMARK OFFICE

FEB 22 2006

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

John P. Isacson
Heller Ehrman LLP
1717Rhode Island Avenue N.W.
Washington, DC 20036

In Re: Interim Patent Term Extension Application for U.S. Patent No. 4,575,515

ORDER TO SHOW CAUSE WHY INTERIM EXTENSION SHOULD BE GRANTED

An application for interim extension of the patent term of U.S. Patent No. 4,575,515 under 35 U.S.C. § 156(d)(5) was initially filed in the United States Patent and Trademark Office on March 5, 2004. A subsequent request for interim extension of the patent term of U.S. Patent No. 4,575,515 under 35 U.S.C. § 156(d)(5) was filed on April 12, 2005. The application was filed by Dimethaid Research Inc. Extension is sought based upon the continuing premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename, PENNSAID®, having the active ingredient, diclofenac sodium and dimethyl sulfoxide as a medicinal ingredient. PENNSAID® has not yet been approved for commercial use and sale by the Food and Drug Administration (FDA).

A determination has been made that U.S. Patent No. 4,757,515 is **NOT** eligible for an interim patent term extension under 35 U.S.C. § 156(d)(5) based upon the continuing regulatory review period of PENNSAID®.

A response to the initial determination that PENNSAID® is **NOT** eligible for an interim patent term extension under 35 U.S.C. § 156(d)(5) may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. § 1.136. See 37 C.F.R. § 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate, and Applicant admits, that the active ingredient of PENNSAID® was approved prior to the ongoing regulatory review period for PENNSAID®. Diclofenac sodium was previously approved for commercial use or sale in many products, for example, as a delayed release oral tablet on July 28, 1988 (See the attached Orange Book listing for Diclofenac sodium). The medicinal ingredient of PENNSAID® is dimethyl sulfoxide. Dimethyl sulfoxide also has been previously approved for commercial use or sale in many products, for example, as a intravesical solution (RIMSO-50) prior to January 1, 1982 (See the attached electronic Orange Book search result for active ingredient "Dimethyl sulfoxide"). Because the approval of PENNSAID® **does not** represent the first permitted commercial marketing or use of either the active ingredient of the product or the medicinal ingredient, the patent is not eligible for patent term extension. See Arnold Partnership v. Dudas, 70 USPQ2d 1311 (CA FC 2004) (Patent term restoration statute, 35 U.S.C. §156, which does not permit extension of term for drug product patent unless applicant's permission to market product is "first permitted commercial marketing or use," is properly interpreted to apply to drug patent with two

active ingredients only if one of those active ingredients has not been previously marketed, since language of statute requires examination of patent's eligibility for extension on component-by-component basis, and is not susceptible of alternate reading that would allow extension for patent with two previously marketed active ingredients if combination thereof is new to marketplace).

The granting of an interim patent term extension under 35 U.S.C. § 156(d)(5) is premised on the Director determining that, except for permission to market, the patent is eligible for an extension under 35 U.S.C. § 156(a). This would require that the product for which interim patent term extension is sought meets the eligibility requirements of subsection (a)(1)-(5). In the present case, both the active ingredient and medicinal ingredient have been previously approved. Hence, PENNSAID® would be **INELIGIBLE** for patent term extension under 35 U.S.C. § 156(a) because it fails to comply with 35 U.S.C. § 156(a)(5), i.e., it is not the first permitted commercial marketing or use of a product under the provision of law under which such regulatory review period occurred.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the <u>first</u> permitted commercial marketing or use of the <u>product</u> under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 4,575,515 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the <u>active ingredient</u> of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the pending product PENNSAID is diclofenac sodium. As indicated in the Food and Drug Administration's "Orange Book," and as Applicant admits, the active ingredient diclofenac sodium had been approved for commercial marketing and use prior to the pending application for approval of the applicant's product. Furthermore, the prior approval of the active ingredient diclofenac sodium in VOLTAREN® by the Food and Drug Administration was under section

505(b) of the FFDCA, the same provision of law under which continuing regulatory review of the product PENNSAID® is occurring. Applying the definition of "product" provided in section 156(f) to the extension requirement of 35 U.S.C. § 156(a)(5)(A), applicant's product, PENNSAID®, does not qualify as the first permitted marketing or use of the active ingredient. Since the pending approval of PENNSAID® will not constitute the first permitted marketing or use of either the active ingredient, diclofenac sodium, or the medicinal ingredient, dimethyl sulfoxide, the patent is not eligible for patent term extension based upon the continuing regulatory review of PENNSAID®. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990); and Arnold Partnership, 70 USPQ2d 1311.

In view of the above, the term of U.S. Patent No. 4,575,515 is not eligible for interim extension under 35 U.S.C. § 156(d)(5) based upon the continuing regulatory review of the product PENNSAID® and the applications for interim patent term extension, filed March 5, 2004, and April 12, 2005, are dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755. E-mail inquiries should be directed to Mary.Till@uspto.gov.

Kery Fries

Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: PENNSAID®

Enclosure: Search Results from the electronic Orange Book: Dimethyl Sulfoxide
Listing in Orange Book: Diclofenac Sodium

505(b) of the FFDCA, the same provision of law under which continuing regulatory review of the product PENNSAID® is occurring. Applying the definition of "product" provided in section 156(f) to the extension requirement of 35 U.S.C. § 156(a)(5)(A), applicant's product, PENNSAID®, does not qualify as the first permitted marketing or use of the active ingredient. Since the pending approval of PENNSAID® will not constitute the first permitted marketing or use of either the active ingredient, diclofenac sodium, or the medicinal ingredient, dimethyl sulfoxide, the patent is not eligible for patent term extension based upon the continuing regulatory review of PENNSAID®. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990); and Arnold Partnership, 70 USPQ2d 1311.

In view of the above, the term of U.S. Patent No. 4,575,515 is not eligible for interim extension under 35 U.S.C. § 156(d)(5) based upon the continuing regulatory review of the product PENNSAID® and the applications for interim patent term extension, filed March 5, 2004, and April 12, 2005, are dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755. E-mail inquiries should be directed to Mary.Till@uspto.gov.

Kery Fries

Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

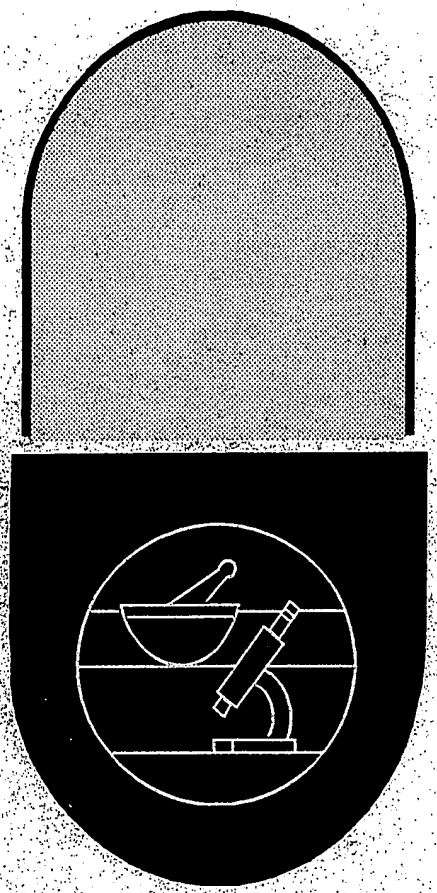
cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: PENNSAID®

Enclosure: Search Results from the electronic Orange Book: Dimethyl Sulfoxide
Listing in Orange Book: Diclofenac Sodium

3 0402 00187 4041



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

2000

DIAZEPAM

TABLET; ORAL

	VALIUM		
AB	+ ROCHE	10MG	N13263 006

DIAZOXIDE

CAPSULE; ORAL

	PROGLYCEM		
	+ BAKER NORTON	50MG	N17425 001

INJECTABLE; INJECTION

	HYPERSTAT		
	+ SCHERING	15MG/ML	N16996 001

SUSPENSION; ORAL

	PROGLYCEM		
	+ BAKER NORTON	50MG/ML	N17453 001

DICHLORPHENAMIDE

TABLET; ORAL

	DARANIDE		
	+ MERCK	50MG	N11366 001

DICLOFENAC POTASSIUM

TABLET; ORAL

	CATAFLAM		
AB	+ NOVARTIS	50MG	N20142 002 NOV 24, 1993
	DICLOFENAC POTASSIUM		
AB	INVAMED	50MG	N75229 001 NOV 20, 1998
AB	MYLAN	50MG	N75463 001 JUL 26, 1999
AB	TEVA	50MG	N75219 001 AUG 06, 1998
AB	WATSON LABS	50MG	N75152 001 NOV 27, 1998

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

	DICLOFENAC SODIUM		
AB	FALCON PHARMS	0.1% †	N20809 001 MAY 04, 1998
	VOLTAREN		
AB	+ CIBA	0.1%	N20037 001 MAR 28, 1991

TABLET, DELAYED RELEASE; ORAL

	DICLOFENAC SODIUM		
AB	CARLSBAD	25MG	N75185 002 NOV 13, 1998
AB		50MG	N75185 003 NOV 13, 1998
AB		75MG	N75185 001 NOV 13, 1998
AB	COPLEY PHARM	25MG	N74459 001 JUN 25, 1997
AB		50MG	N74459 002 JUN 25, 1997
AB		75MG	N74459 003 JUN 25, 1997
AB	GENEVA PHARMS	25MG	N74376 001 SEP 28, 1995
AB		50MG	N74376 002 SEP 28, 1995
AB		75MG	N74394 001 NOV 30, 1995
AB	MARTEC	50MG	N74986 001 FEB 26, 1999
AB		75MG	N74986 002 FEB 26, 1999
AB	NOVOPHARM	50MG	N74723 001 MAR 30, 1999
AB		75MG	N74390 001 AUG 15, 1996
AB	PUREPAC PHARM	50MG	N74514 001 MAR 26, 1996
AB		75MG	N74514 002 MAR 26, 1996
AB	ROXANE	25MG	N74391 001 JUN 29, 1995
AB		50MG	N74391 002 JUN 29, 1995
AB		75MG	N74391 003 JUN 29, 1995

† SEE SECTION 1.8 DESCRIPTION OF SPECIAL SITUATIONS

PRESCRIPTION DRUG PRODUCT LIST

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

	DICLOFENAC SODIUM		
AB	SIDMAK LABS NJ	50MG	N74432 002 JUL 29, 1999
AB		75MG	N74432 003 JUL 29, 1999
	VOLTAREN		
AB +		25MG	N19201 001 JUL 28, 1988
AB +		50MG	N19201 002 JUL 28, 1988
AB +		75MG	N19201 003 JUL 28, 1988

TABLET, EXTENDED RELEASE; ORAL

	VOLTAREN-XR		
+	NOVARTIS	100MG	N20254 001 MAR 08, 1996

DICLOFENAC SODIUM; MISOPROSTOL

TABLET, DELAYED RELEASE; ORAL

	ARTHROTEC		
+	SEARLE	50MG;0.2MG	N20607 001 DEC 24, 1997
+		75MG;0.2MG	N20607 002 DEC 24, 1997

DICLOXACILLIN SODIUM

CAPSULE; ORAL

	DICLOXACILLIN SODIUM		
AB	APOTHECON	EQ 250MG BASE	N61454 001
AB +		EQ 500MG BASE	N61454 003
		EQ 125MG BASE	N61454 002
AB	TEVA	EQ 250MG BASE	N62286 001 JUN 03, 1982
AB		EQ 500MG BASE	N62286 002 JUN 03, 1982
	DYCILL		
AB	SMITHKLINE BEECHAM	EQ 250MG BASE	N62238 001
AB		EQ 500MG BASE	N62238 002
	PATHOCIL		
AB	WYETH AYERST	EQ 250MG BASE	N50011 002

DICLOXACILLIN SODIUM

CAPSULE; ORAL

	PATHOCIL		
AB	WYETH AYERST	EQ 500MG BASE	N50011 003 MAR 28, 1983

POWDER FOR RECONSTITUTION; ORAL

	DICLOXACILLIN SODIUM		
AB +	APOTHECON	EQ 62.5MG BASE/5ML	N61455 001
	PATHOCIL		
AB	WYETH AYERST	EQ 62.5MG BASE/5ML	N50092 001

DICUMAROL

TABLET; ORAL

	DICUMAROL		
+	ABBOTT	25MG	N05545 003

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

	BENTYL		
AB +	HOECHST MARION RSSL	10MG	N07409 003 OCT 15, 1984
	DICYCLOMINE HCL		
AB	CHELSEA LABS	10MG	N85082 001 JUN 19, 1986
AB	HALSEY	10MG	N84505 001 OCT 21, 1986
AB	LANNETT	10MG	N84285 001
AB	MYLAN	10MG	N40319 001 SEP 07, 1999
AB	WEST WARD	10MG	N40204 001 FEB 28, 1997

INJECTABLE; INJECTION

	BENTYL		
AP +	HOECHST MARION RSSL	10MG/ML	N08370 001 OCT 15, 1984
	BENTYL PRESERVATIVE FREE		
AP	HOECHST MARION RSSL	10MG/ML	N08370 002 OCT 15, 1984
	DICYCLOMINE HCL		
AP	STERIS	10MG/ML	N80614 001 FEB 11, 1986

PRESCRIPTION DRUG PRODUCT LIST

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

AB	ZENITH GOLDLINE	30MG	N74168 001 MAR 03, 1995
AB		60MG	N74168 002 MAR 03, 1995
AB		90MG	N74168 003 MAR 03, 1995
AB		120MG	N74168 004 MAR 03, 1995

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
TIAMATE

+	HOECHST MARION RSSL	EQ 120MG HCL	N20506 001 OCT 04, 1996
+		EQ 180MG HCL	N20506 002 OCT 04, 1996
+		EQ 240MG HCL	N20506 003 OCT 04, 1996

DILTIAZEM MALATE; ENALAPRIL MALEATE

TABLET, EXTENDED RELEASE; ORAL
TECZEM

+	HOECHST MARION RSSL	EQ 180MG HCL;5MG	N20507 001 OCT 04, 1996

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE

AP	+ STERIS	50MG/ML	N80615 001
AP	+ WYETH AYERST	50MG/ML	N84316 001

DIMERCAPROL

INJECTABLE; INJECTION
BAL

+	AKORN	10%	N05939 001

DIMETHYL SULFOXIDE

SOLUTION; INTRAVESICAL
RIMSO-50

	RES INDS	50%	N17788 001

DINOPROSTONE

GEL; ENDOCERVICAL
PREPIDIL

+	PHARMACIA AND UPJOHN	0.5MG/3GM	N19617 001 DEC 09, 1992

INSERT, EXTENDED RELEASE; VAGINAL
CERVIDIL

+	CONTROLLED THERAP	10MG	N20411 001 MAR 30, 1995

SUPPOSITORY; VAGINAL
PROSTIN E2

+	PHARMACIA AND UPJOHN	20MG	N17810 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

AA		BARR	50MG	N80738 001
AA		CHELSEA LABS	50MG	N85083 001
AA		DANBURY PHARMA	25MG	N80728 001
AA			50MG	N80727 001
AA	+	GENEVA PHARMS	25MG	N80832 001
AA	+		50MG	N80832 002
AA		GLOBAL PHARM	25MG	N80807 001
AA			50MG	N80807 002
AA		HALSEY	25MG	N84506 001
AA		ICN	25MG	N80596 001
AA			50MG	N80592 001
AA		LNK	25MG	N87977 001 JAN 27, 1983
AA			50MG	N87978 001 JAN 27, 1983
AA		MK LABS	25MG	N83087 001
AA			50MG	N83087 002
AA		MUTUAL PHARM	25MG	N89488 001 JAN 02, 1987
AA			50MG	N89489 001 JAN 02, 1987

Search results from the "OB_Rx" table for query on "017788."

Active Ingredient:	DIMETHYL SULFOXIDE
Dosage Form;Route:	SOLUTION; INTRAVESICAL
Proprietary Name:	RIMSO-50
Applicant:	EDWARDS LIFESCIENCES
Strength:	50%
Application Number:	017788
Product Number:	001
Approval Date:	Approved Prior to Jan 1, 1982
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AT**
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through December, 2005

Patent and Generic Drug Product Data Last Updated: January 26, 2006

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN - 2 2005

JUN - 2 2005

JUN - 2 2005

Tom Moran
Cooley Godward LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,591,585

Dear Mr. Moran:

A certificate of interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,591,585 for a period of one year. A notice regarding this interim extension will publish in the Federal Register on June 6, 2005. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned at (571)272-7744.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: atamestan
FDA Docket No.: 02E-0097

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Schering Aktiengesellschaft	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,591,585	:	**INTERIM EXTENSION**

On May 4, 2005, Intarcia Therapeutics, Inc., on behalf of patent owner Schering Aktiengesellschaft, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,591,585. The patent claims the product atamestane. The application indicates that a New Drug Application for the human drug product atamestane has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional period of one year as required by 35 U.S.C. § 156(d)(5)(C). Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 18, 2005), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,591,585 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 18, 2006.

5/26/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. 2005-P-063]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,591,585; atamestane

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a second one-year interim extension of the term of U.S. Patent No. 4,591,585.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (571)272-7744; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Patent Ext., P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571)273-7744; or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On May 4, 2005, Intarcia Therapeutics, Inc., on behalf of patent owner Schering Aktiengesellschaft, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,591,585. The patent claims the product atamestane. The application indicates that a New Drug Application for the human drug product atamestane has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional period of one year as required by 35 U.S.C. § 156(d)(5)(C). Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 18, 2005), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,591,585 is granted for a period of one year from the expiration date of the patent, i.e., until June 18, 2006.

5/26/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 13 2006

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Ann M. Caviani Pease
Dechert LLP
P.O. Box 10004
Palo Alto, CA 94303-0961

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,591,585

Dear Ms. Caviani Pease:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,591,585 for a period of one year.

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: atamestan
FDA Docket No.: 02E-0097

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Schering Aktiengesellschaft	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,591,585	:	**INTERIM EXTENSION**

On May 9, 2006, patent owner, Schering Aktiengesellschaft through its exclusive licensee, Intarcia Therapeutics, Inc., timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,591,585. The patent claims the active ingredient atamestane, a method of use of the active ingredient, and a composition comprising the active ingredient. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product atamestane has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 18, 2006), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for an additional one year, i.e., until June 18, 2007.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,591,585 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 18, 2007.

6/12/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL - 6 2004

Tom Moran
Cooley Godward LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,591,585

Dear Mr. Moran:

A certificate of interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,591,585 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: atamestan
FDA Docket No.: 02E-0097

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Schering Aktiengesellschaft	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,591,585	:	**INTERIM EXTENSION**

On May 21, 2004, patent owner Schering Aktiengesellschaft, through its exclusive licensee BioMedicines Inc., timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,591,585. The patent claims the product atamestane. The application indicates that a New Drug Application for the human drug product atamestane has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since it is apparent that the regulatory review period will continue beyond the expiration date of the patent (June 18, 2004), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,591,585 is granted for a period of one year from the expiration date of the patent, i.e., until June 18, 2005.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. 2004-P-039]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,591,585; atamestane

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,591,585.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (703) 306-3159; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Patent Ext., P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (703) 872-9411, or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On May 21, 2004, patent owner Schering Aktiengesellschaft, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,591,585. The patent claims the product atamestane. The application indicates that a New Drug Application for the human drug product atamestane has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since it is apparent that the regulatory review period will continue beyond the expiration date of the patent (June 18, 2004), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,591,585 is granted for a period of one year from the expiration date of the patent, i.e., until June 18, 2005.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 27

TOWNSEND & TOWNSEND, KHOURIE & CREW
ONE MARKET PLAZA
STEUART STREET TOWER, 20TH FLOOR
SAN FRANCISCO, CA 94105

COPY MAILED

JAN 06 2000

SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS
ON PETITION

In re Application of Vorosmarthy :
Patent No. 4,976,732 :
Filed: September 12, 1984 :
Issued: December 11, 1990 :
Attorney Docket No. 2337(800000/ :

This is a decision on the petition filed September 14, 1999 (Certificate of Mailing date of September 9, 1999) under 37 CFR 1.378(c) to accept the unintentionally delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED.**

The patent issued December 11, 1990. The last day of the grace period for paying the 7.5 year maintenance fee was December 11, 1998. Therefore, since this petition was filed within twenty-four months after the six-month grace period provided in 37 CFR 1.362(e), this petition was timely filed under the provisions of 37 CFR 1.378(c).

Accordingly, the maintenance fee in this case is hereby accepted and the above-identified patent is hereby reinstated as of the mail date of this decision.

The file does not indicate a change of address has been submitted, although the address given on the petition differs from the address of record. If appropriate, a change of address should be filed in accordance with MPEP 601.03. A courtesy copy of this decision is being mailed to the address given on the petition; however, the Office will mail all future correspondence solely to the address of record.

This file is being forwarded to Files Repository.

Telephone inquiries should be directed to Petitions Attorney Steven Brantley at (703) 306-5683.

Beverly M. Flanagan
Supervisory Petitions Examiner
Office of Petitions
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Daniel J. Meaney, Jr.
P.O. Box 22307
Santa Barbara, CA 93121

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

NOV 29 2007

Andrew M. Douglas
Knobbe, Martens, Olson & Bear, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,976,732

DISMISSAL OF APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156(d)(5)

An application for extension of the patent term of U.S. Patent No. 4,976,732 under 35 U.S.C. § 156(d)(5) was filed in the United States Patent and Trademark Office on November 23, 2007. Extension is sought based upon the continuing regulatory review period under the Federal Food, Drug, and Cosmetic Act (FFDCA) of a medical device known by the tradename AcuFocus™ ACI 7000 corneal inlay. A determination has been made that U.S. Patent No. 4,976,732 is **NOT** eligible for patent term extension under 35 U.S.C. § 156(d)(5) based upon the continuing regulatory review period of AcuFocus™ ACI 7000 corneal inlay.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are applicable to this time period. See 37 CFR § 1.750.

The application for patent term extension seeks to extend U.S. Patent No. 4,976,732 under the statutory provisions of 35 U.S.C. § 156(d)(5) which govern interim extensions where a product claimed in a patent has not yet received approval for commercial marketing or use from the regulating agency. Here, the FDA has not approved the AcuFocus™ ACI 7000 corneal inlay for commercial marketing or use and their review of the AcuFocus™ ACI 7000 corneal inlay is continuing.

According to 35 U.S.C. 156(g), the term, "regulatory review period" includes a testing phase and an approval phase, see 21 C.F.R. § 60.22. Depending upon the type of product subject to regulatory review, the "testing phase" is defined in (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156. Similarly, depending upon the type of product subject to regulatory review, the "approval phase" is defined in (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) of subsection (g) of 35 U.S.C. § 156.

One of the requirements for an interim extension under 35 U.S.C. § 156(d)(5) is that the owner of record or his agent reasonably expects that the "approval phase" (recited in 156(d)(5)(A) as "the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii) and (5)(B)(ii) of subsection (g) of 35 U.S.C. § 156"), which must have **begun** for a product that is the subject of such patent where the regulatory review period, would continue beyond the expiration of the patent term. In other words, in order to be eligible for a interim extension under 35 U.S.C. § 156(d)(5) for the subject medical device, a Pre-Market Approval application (PMA) must have been filed under section 515 of the FFDCA for AcuFocus™ ACI 7000 corneal inlay. Specifically, the section 156(d)(5)(A) provides (in part):

> If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration date of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire.

35 U.S.C. § 156(d)(5)(A).

No PMA application under section 515 of the FFDCA for AcuFocus™ ACI 7000 corneal inlay has been filed. In fact, Applicant clearly admits (page 3 and 7) in their application materials in complying with 37 C.F.R. § 1.740(a)(3) and (11) that no PMA under section 515 of the FFDCA has yet been made or obtained and that a PMA under section 515 of the FFDCA is anticipated to be filed in February 2010. Since 35 U.S.C. 156(d)(5) requires that, in the case of medical devices, the product undergoing regulatory review be the subject of an application under section 515 of the FFDCA and applicant has admitted that such an application has not been made to FDA, the USPTO must dismiss Applicant's application for an interim extension under 35 U.S.C. § 156(d)(5) for U.S. Patent No. 4,976,732.

CONCLUSION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,976,732 is not eligible for extension of the patent term under 35 U.S.C. § 156(d)(5). AcuFocus™ ACI 7000 corneal inlay has not been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(d)(5)(B) as defined in 35 U.S.C. § 156(g)(3)(B)(ii). Accordingly, the application for extension of the patent term is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: AcuFocus™ ACI 7000
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

NOV - 5 2004

#20

Donald J. Bird
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Ave NW
Washington DC 20004

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,659,516

Dear Mr. Bird:

The Food and Drug Administration (FDA) recently communicated to the USPTO that the determination of the regulatory review period was not, in fact, final. As a result, the notice of final determination mailed September 16, 2004 is withdrawn. Once FDA's determination of the regulatory review period is final, a new notice of final determination of the length of the patent term extension will be mailed.

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,659,516 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: FASLODEX® (fulvestrant)
FDA Docket No.: 03E-0030

UNITED STATES PATENT AND TRADEMARK OFFICE

In re AstraZeneca UK Limited	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,659,516	:	**INTERIM EXTENSION**

On June 24, 2002, AstraZeneca UK Limited, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,659,516, filed an application under 35 U.S.C. § 156, requesting an extension of 1,165 days. The original expiration date of the patent is October 1, 2004. The patent claims the active ingredient fulvestrant in the human drug product "FASLODEX®." The application indicates, and the Food and Drug Administration (FDA) has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. FDA's determination of the regulatory review period of this product is not yet final.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,659,516 is granted for a period of one year from the original expiration date of the patent, until October 1, 2005.

10/26/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

PW

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DEC 5 2005

Donald J. Bird
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Ave NW
Washington DC 20004

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,659,516

Dear Mr. Bird :

An order granting Interim Extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,659,516 for a period of 1 year from the date of the previous interim extension. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:
http://www.fda.gov/opacom/morechoices/fdaforms/default.html
(http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to Mary Till by telephone at (571)272-7755, or at Mary.Till@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: FASLODEX® (fulvestrant)
FDA Docket No.: 03E-0030

UNITED STATES PATENT AND TRADEMARK OFFICE

In re AstraZeneca UK Limited	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,659,516	:	**INTERIM EXTENSION**

On June 24, 2002, AstraZeneca UK Limited, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,659,516, filed an application under 35 U.S.C. § 156, requesting an extension of 1,165 days. The original expiration date of the patent is October 1, 2004. The term of the patent has been previously extended to October 1, 2005. The patent claims the active ingredient fulvestrant in the human drug product "FASLODEX®." The application indicates, and the Food and Drug Administration (FDA) has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. FDA's determination of the regulatory review period of this product is not yet final.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,659,516 is granted for an additional period of one year from the extended expiration date of the patent, until October 1, 2006.

12/1/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

NOV - 5 2004

Teresa J. Welch
Michael Best & Friedrich LLP
P.O. Box 1806
One South Pinckney St.
Madison WI 53701-1806

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,555,364

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,659,516 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: Hectorol®
FDA Docket No.: 00E-1233

UNITED STATES PATENT AND TRADEMARK OFFICE

In re	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,555,364	:	**INTERIM EXTENSION**

On August 6, 1999, the Wisconsin Alumni Research Foundation, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,555,364, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The original expiration date of the patent is November 1, 2004. The patent claims the method of making doxercalciferol, the active ingredient in the human drug product "Hectorol®." The application indicates, and the Food and Drug Administration (FDA) has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,555,364 is granted for a period of one year from the original expiration date of the patent, until November 1, 2005.

10/29/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov
DIW Feb-07

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FEB 23 2007

OFFICE OF PETITIONS

FISH & RICHARDSON
2200 SAND HILL ROAD, SUITE 100
MENLO PARK, CA 94025

In re Patent No. 4,579,530 :
Issued: 1 April, 1986 :
Application No. 06/673,711 : ON PETITION
Filed: 21 November, 1984 :
Atty Docket No. P-48 :

This is in response to the deficiency fee payment filed pursuant to 37 CFR 1.28(c) on 4 October, 2005 (postcard date).

The Office apologizes for the delay in responding to the present petition.

The petition is **DISMISSED**.

37 CFR 1.28(c) states, "The deficiency is based on the amount of the fee, for other than a small entity, in effect at the time the deficiency is paid in full."

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

The petition cannot be granted because there are insufficient funds in counsel's deposit account to pay the stated fee deficiency of $1,945.00. Specifically, on 22 February, 2007, counsel's deposit account, No. 50-2734, contained a balance of $1,065.00. (See attached Deposit Account Maintenance printout).

37 CFR 1.25(a) states, in pertinent part, that an amount sufficient to cover all fees, services, copies, etc., requested must always be on deposit. Charges to accounts with insufficient funds will not be accepted.

As such, the fee deficiency under 37 CFR 1.28 cannot be accepted.

Petitioner should submit a renewed request under 37 CFR 1.28 accompanied by payment in the proper amount.

The address in the petition is different than the correspondence address. A courtesy copy of this decision is being mailed to the

address in the petition. All future correspondence, however, will be mailed solely to the address of record.

Small entity status will no longer apply.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-8300
Attn: Office of Petitions

By hand: Customer Service Window
Mail Stop Petition
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Telephone inquiries should be directed to the undersigned at (571) 272-3231.

D Wood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc: Michael P. Mazza, LLC
686 Crescent Blvd.
Glen Ellyn IL 60137-4281

Encl: Deposit Account Maintenance Screen

Deposit Account Maintenance

Deposit Account Window Help

Deposit Account

Number: 502734 **Balance Amount:** 1,065.00

Holder

Name: MICHAEL P. MAZZA, LLC

Address

Attention:

Street: 686 CRESCENT BLVD

Province:

City: GLEN ELLYN

State: IL **Postal Code:** 60137

Country: US

Telephone: 630-858-5071 **Fax:** 630-858-0373

Details

Category Code: NONGOVNMNT **Type:** REGULAR

Notification Amt: 0.00

Available Balance: 1,065.00

Status

Active Closed

DWOOD1 02/22/2007

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FEB 23 2007

OFFICE OF PETITIONS

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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DIW Feb-07

FISH & RICHARDSON
2200 SAND HILL ROAD, SUITE 100
MENLO PARK, CA 94025

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FEB 27 2007

OFFICE OF PETITIONS

ON PETITION

In re Patent No. 4,579,530 :
Issued: 1 April, 1986 :
Application No. 06/673,711 :
Filed: 21 November, 1984 :
Atty Docket No. P-48 :

This is in response to the deficiency fee payment filed pursuant to 37 CFR 1.28(c) on 26 February, 2007.

37 CFR 1.28(c) states, "The deficiency is based on the amount of the fee, for other than a small entity, in effect at the time the deficiency is paid in full."

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

The address in the petition is different than the correspondence address. A courtesy copy of this decision is being mailed to the address in the petition. All future correspondence, however, will be mailed solely to the address of record.

Small entity status will no longer apply.

Telephone inquiries should be directed to the undersigned at (571) 272-3231.

D Wood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc: ARNOLD TURK
GREENBLUM & BERNSTEIN
1950 ROLAND CLARKE PLACE
RESTON VA 20191

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Donald J. Bird
Morgan Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington DC 20004

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,911,932

MAR 20 2007

Dear Mr Bird :

A interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,911,932 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: VUSION™ Ointment
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Johnson & Johnson Consumer Companies, Inc.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,911,932	:	INTERIM EXTENSION

Johnson & Johnson Consumer Companies, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,911,932, filed an application for patent term extension under 35 U.S.C. § 156 on April 5, 2006. The original term of the patent is due to expire on March 27, 2007. The patent claims the human drug product VUSION™ Ointment, having the active ingredients miconazole nitrate, zinc oxide and white petrolatum, which was approved by the Food and Drug Administration for commercial marketing or use on February 15, 2006. An extension of 5 years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,911,932 is granted for a period of one year from the original expiration date of the patent.

3/15/07
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 2 0 2008

Donald J. Bird
Morgan Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington DC 20004

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,911,932

Dear Mr Bird :

A interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,911,932 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: VUSION®
FDA Docket No.: 2007E-0035

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Johnson & Johnson Consumer Companies, Inc.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,911,932	:	INTERIM EXTENSION

Johnson & Johnson Consumer Companies, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,911,932, filed an application for patent term extension under 35 U.S.C. § 156 on April 5, 2006. The extended term of the patent is due to expire on March 27, 2008. The patent claims the human drug product VUSION® Ointment, having the active ingredients miconazole nitrate, zinc oxide and white petrolatum, which was approved by the Food and Drug Administration for commercial marketing or use on February 15, 2006. An extension of five years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,911,932 is granted for a period of one year from the extended expiration date of the patent.

3/14/08
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES PATENT AND TRADEMARK OFFICE
MAILSTOP HATCH-WAXMAN PTE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

MAR 19 2009

Gregory T. Lowen
Morgan Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington, DC 20004

In re: Patent Term Extension
Application for.
U.S. Patent No. 4,911,932

DENIAL OF PATENT TERM EXTENSION APPLICATION FOR U.S. PATENT NO. 4,911,932

This is in response to the application for extension of the patent term of U.S. Patent No. 4,911,932 (the '932 patent) under 35 U.S.C. § 156, which was filed in the United States Patent and Trademark Office ("USPTO") on April 5, 2006. The patent term extension application ("PTE application") was filed by Johnson & Johnson Consumer Companies, Inc. ("Applicant"), the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of a human drug product known by the tradename Vusion®, which was approved for commercial marketing and use by the Food and Drug Administration ("FDA") on February 16, 2006.

A determination has been made that the '932 patent is **NOT** eligible for patent term extension based upon the regulatory review period of Vusion®. Therefore, Applicant's PTE application is **DENIED**.

FACTUAL BACKGROUND

1) On March 27, 1990, the USPTO issued the '932 patent to Charles E. Clum and David M. Isaacson; it was originally assigned to Johnson & Johnson Baby Products Company, now Johnson & Johnson Consumer Companies, Inc.

2) On February 16, 2006, the FDA approved New Drug Application ("NDA") No. 21-026, thereby granting permission for commercial marketing or use of Vusion® (miconazole nitrate, zinc oxide, and white petrolatum).

3) On April 5, 2006, Applicant filed a PTE application under § 156 to extend the term of the '932 patent based on the FDA regulatory review period of Vusion®.

4) On September 7, 2006, pursuant to the Memorandum of Understanding Between the USPTO and the FDA, *see* 52 Fed. Reg. 17830, May 12, 1987, the USPTO requested assistance from the FDA ("First USPTO Letter to FDA") in determining eligibility of the '932 patent for patent term extension based on the regulatory review period of Vusion®. The USPTO indicated in its letter that "the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, [it] note[d] that miconazole nitrate has been previously approved under section 505(b) of the Federal Food Drug and Cosmetic Act

(21 U.S.C. 355(b)) and was approved for marketing and use in several products before the approval of Vusion™." Thus, the USPTO asked the FDA to "confirm the approval of Vusion™, i.e., the other active ingredients of Vusion™, were subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use."

5) On December 19, 2006, Applicant filed a Request for Interim Extension pursuant to the provisions in § 156(e)(2).

6) On March 20, 2007, the USPTO granted an interim extension based on the regulatory review period for Vusion®.

7) On March 29, 2007, the FDA responded to the First USPTO Letter to FDA. The FDA indicated that Vusion® was subject to a regulatory review period within the meaning of § 156(g) as required by § 156(a)(4). The FDA further indicated that two of the active ingredients in Vusion® (miconazole nitrate and zinc oxide) do not represent the first permitted commercial marketing or use of the product as defined under § 156(f)(1). The FDA indicated that it has no record that the third active ingredient of Vusion®, white petrolatum, had been previously approved under section 505 of the FFDCA as an active ingredient in a drug product, but that it had been previously approved for commercial marketing as an inactive ingredient in drug products reviewed and approved under section 505 of the FFDCA. Finally, the FDA indicated that the NDA was approved on February 16, 2006, and that the submission of the PTE Application on April 5, 2006, was timely within the meaning of § 156(d)(1).

8) On June 12, 2007, the USPTO sent a second letter to the FDA ("Second USPTO Letter to FDA") requesting that the FDA determine the applicable regulatory review period pursuant to § 156(d)(2)(A).

9) On November 26, 2007, Applicant filed a Second Request for Interim Extension pursuant to the provisions of § 156(e)(2).

10) On March 20, 2008, the USPTO granted a second interim extension based on the regulatory review period for Vusion®.

11) On July 9, 2008, the USPTO reconsidered their determination that Applicant could rely on the third active ingredient, white petrolatum, for eligibility for patent term extension and issued an Order to Show Cause. In that Order, the USPTO found that white petrolatum was the only active ingredient in Vusion® not previously granted permission for commercial marketing or use under section 505 of the FFDCA that could serve as the basis for extension under § 156. Nevertheless, the USPTO found that the '932 patent did not claim white petrolatum, rendering the '932 patent ineligible for extension.

12) On September 8, 2008, Applicant responded to the Order to Show Cause.

13) On February 23, 2009, Applicant filed a Third Request for Interim Extension pursuant to the provisions of § 156(e)(2).

DECISION

The USPTO has considered the arguments made by Applicant in its Response to the Order to Show Cause and finds each to be unpersuasive. The USPTO will address Applicant's arguments in turn.

I. The Regulatory Review of Zinc Oxide as an Active Ingredient in Previously Approved Products Occurred under the Same Provision of Law under which VUSION® Was Reviewed

Applicant admits that zinc oxide was previously approved under section 505 of the FFDCA, but argues that the approvals are not under the same "provision of law" because there was no requirement for efficacy prior to the Drug Amendments of 1962.[1] Response to Show Cause Order at 6-7. In essence, Applicant contends that each version of the same statutory provision constitutes its own "provision of law," *i.e.*, that one statutory provision becomes a different statutory provision, at least for purposes of § 156, upon amendment. Additionally, Applicant argues that *Westwood Pharmaceuticals Inc. v. Quigg*, 1989 WL 205631; 13 U.S.P.Q.2d 2067 (D.D.C. 1989), although directly on point, was wrongly decided and would not be decided the same today "in view of FDA's more recent indication of the criticality of efficacy when considering the approval of a drug for commercial marketing or use." Response to Show Cause Order at 4. Applicant also contends that *Westwood* is distinguishable because the drug in that case contained a single active ingredient whereas its drug Vusion® contains three active ingredients. *Id.* Applicant is mistaken on all scores.

The starting point for statutory interpretation is the language of the statute itself. Statutory words are normally presumed to be used in their ordinary and usual sense, absent evidence to the contrary. *Caminetti v. United States*, 242 U.S. 470, 485 (1917). Section 156(a)(5)(A) states that patent term extension is available if the approval at issue is "the first permitted commercial marketing or use of the product under the *provision of law* under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A) (emphasis added). Section 156(g) identifies the applicable provisions of law for each class of products for which patent term extension is available. It specifically identifies section 505 of the FFDCA, codified at 21 U.S.C. § 355, for new human

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1 Pub. L. 87-781, 76 Stat. 780 (Oct. 1962). The Drug Amendment of 1962 amended section 505(b) of the FFDCA by inserting, immediately after the words "is safe for use", the words "and whether such drug is effective in use." The Drug Amendment of 1962 also amended section 505(d) to require that there be substantial evidence that the drug have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

drugs. That section has been the applicable provision of law under which drug products have been approved for commercial marketing or use since 1938. Nowhere does section 156 state or imply that amending any one of the identified statutory provisions renders it a new provision of law under which a patent term extension could be granted for a product that has already undergone regulatory review. Nor does Applicant point to any such statutory language. Thus, § 156 is clear on its face that the phrase "provision of law" means the statutory authority under which regulatory review occurs for a specific class of products, including any amendments to that statutory authority.

The legislative history supports the USPTO's interpretation of § 156. Congress gave no indication during the promulgation of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") that it intended to create a new opportunity for patent term extension on the basis of an amendment, even a significant one, of the federal statute governing regulatory review of a new drug product. Instead, the legislative history reveals that Congress was concerned that eligibility for patent term extension be limited to products that had been approved for the first time by the FDA, except in one instance specifically identified. According to a report by the House Committee on Energy and Commerce, accompanying H.R. 3605:

> Paragraphs (6) and (7)[2] describe two conditions which must be met by the product which is claimed in the product patent to be extended, or the use or manufacture of which is claimed in the use or process patent to be extended. First, the product must have been subjected to a regulatory review period under an applicable federal law, and approved, before the product was allowed to be commercially marketed. (The product which can be the subject of a patent extension is hereinafter referred to as the "approved product.") Second, with one exception, the approved product must have been approved for commercial marketing for the first time. The exception involves an approved product made under a patented process which primarily uses recombinant DNA technology. Such an approved product could have received its second approval for commercial marketing, but it must be the first time a product made by the claimed process has been approved.

H.R. Rep. No. 98-857, 98th Cong., 2d Sess., Part 1, 37-38 (1984), reprinted in 1984 U.S.C.C.A.N. 2670-1. This excerpt is significant for two reasons. First, there is a clear expression of Congressional intent to limit eligibility to the first approval of a product for commercial marketing. Specifically, eligibility was intended to be limited to a drug product that had been approved by the FDA for the first time. Second, Congress set forth only one exception to the general requirement that eligibility be based on the first approval. That exception was for products made from recombinant DNA. When Congress enumerates certain exceptions to a general prohibition, other exceptions are not to be implied absent contrary legislative intent. *Andrus v. Glover Constr. Co.*, 446 U.S. 608, 616-7 (1980).

Additionally, Congress was aware of the differences between the approval process for new drugs before 1962 and the approval process after 1962. According to the House report discussed

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2 Paragraphs (6) and (7) in this excerpt correspond to paragraphs (5)(A) and (5)(B) in § 156(a) as enacted.

earlier:

> Prior to 1962, the Federal Food, Drug and Cosmetic Act (FFDCA) required that all drugs be approved as safe before they could be marketed. The 1962 amendments required that all new drugs, generic and pioneer, must be approved as safe and effective prior to marketing.
>
> As a result of the 1962 amendments, FDA did two things regarding pre-1962 drugs. First, the agency created the Drug Efficacy Study (DESI) to determine if all pre-1962 drugs were effective. Second, FDA established a policy permitting the approval of a generic drug equivalent to a safe and effective pre-1962 pioneer drug.

H.R. Rep. No. 98-857, 98th Cong., 2d Sess., Part 1, 16 (1984), reprinted in 1984 U.S.C.C.A.N. 2649. Despite its awareness, Congress did not make or even mention any distinction between drugs approved before or after 1962 in enacting the patent term extension provisions of Title II of the Hatch-Waxman Act. By contrast, Congress stated that its purpose for Title I of the Hatch-Waxman Act was to change the approval process for generic drugs approved after 1962 as indicated from the same House report:

> The purpose of Title I of the bill is to make available more lost cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. Under current law, there is a generic drug approval procedure for pioneer drugs approved before 1962, but not for pioneer drugs approved after 1962.
>
> Title I of the bill generally extends the procedures used to approve generic copies of pre-1962 drugs to post-1962 drugs. Generic copies of any drugs may be approved if the generic is the same as the original drug or so similar that FDA has determined the differences do not require safety and effectiveness testing.

Id. at 2647-48. Thus, Congress presumably did not intend new drugs approved before 1962 to be treated differently from new drugs approved after 1962 for the purposes of eligibility for patent term extension under Title II. Had Congress intended to so do, it demonstrated via its alteration of the procedures for approval of a generic drug in Title I that it was capable of selecting words to affect a difference.

Case law likewise supports the USPTO's interpretation of § 156. In *Westwood,* the D.C. District Court addressed Applicant's argument here, *i.e.*, whether an amendment of section 505 of the FFDCA results in a new provision of law under which patent term extension becomes available again for an active ingredient originally approved before the amendment and then approved again after the amendment, and agreed with the USPTO's interpretation. More specifically, the applicant in *Westwood* obtained FDA approval for its drug having lactic acid as the active ingredient pursuant to Section 505 of the FFDCA and sought a patent term extension. *Westwood,* 13 USPQ 2d at 2068. The USPTO denied the extension on the ground that the *Westwood* applicant's drug was not the first permitted commercial marketing or use of lactic acid under the provision of law under which regulatory review occurred in light of the FDA's earlier approval of eight other drug product under Section 505 of the FFDCA containing lactic acid. *Id.* at 2069. In

challenging the USPTO's denial, the *Westwood* applicant argued that (i) section 505 of the FFDCA was amended by the Drug Amendments of 1962 incorporating effectiveness as a pre-condition for drug approval; rendering it a new provision of law from the pre-1962 version; and (ii) that its product was the first one approved under the effectiveness standard set forth in the 1962 amendments. *Id.* The court rejected the *Westwood* applicant's arguments, agreeing instead with the USPTO that an amendment does not produce a new provision of law for purposes of patent term extension eligibility. *Id.* It found that the agency's interpretation "is consistent with the statutory language and with the legislative history associated with this provision." *Id.* at 2068-69. Hence, the court deferred to the agency's interpretation. *Id.*

Applicant's attempt to circumvent *Westwood* on the grounds that it was wrongly decided then and that it would be decided differently today lacks merit. *Westwood* remains good law; it has not been overturned by the D.C. Circuit or Supreme Court. Nor has any court given any indication, even in *dicta*, that it would reach a different statutory interpretation for the meaning of "provision of law" than the *Westwood* court. Additionally, Applicant's factual distinction of *Westwood* is irrelevant. The D.C. District Court did not base its decision on the number of active ingredients in the drug product. Rather, the court based its decision on the construction of § 156 and its legislative history. *See id.* at 2069.

Taking the plain meaning of § 156 together with its legislative history and *Westwood*, the agency's interpretation of the statutory phrase "provision of law" means that the 1962 Drug Amendments to section 505 of the FFDCA did not result in a new provision of law, regardless of how that amendment changed the requirements of section 505. The pre-1962 version and the post-1962 version are but one "provision of law." A product approved for commercial marketing or use under the pre-1962 version cannot support a patent term extension later in time if given FDA approval for a different indication under the post-1962 version. Hence, the FDA's recent approval of zinc oxide under Section 505 of the FFDCA in Applicant's Vusion® drug product does not support the extension of the '932 patent since the FDA previously approved that compound under Section 505 of the FFDCA as an active ingredient in connection with a different drug product.[3]

II. The Plain Language of § 156(f) Requires that the USPTO Apply the Definition of Product in a Multi-Active Ingredient Drug Product to Each Individual Component of that Product

Applicant argues that Vusion® contains three active ingredients (zinc oxide, miconazole nitrate, and white petrolatum) that physically function together as a single indivisible entity. Response to Show Cause Order at 9-11. As such, Applicant asserts that *Arnold Partnership* is not applicable to the facts here. Applicant is mistaken; that case is directly on point to the present eligibility determination.

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3 Furthermore, in establishing two monographs for Over the Counter (OTC) products, one for skin protectant drug products and one for anorectal drug products, FDA evaluated information regarding the safety and effectiveness of zinc oxide in the two drug products subject to the two OTC monographs. *See* Skin Protectant Drug Products For Over-the –Counter Human Use, Establishment of a Monograph; Notice of Proposed Rulemaking, 43 Fed. Reg. 34628, 34641 (Aug. 4, 1978) and Anorectal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph, Proposed Rule, 45 Fed. Reg. 35576, 35635 (May 27, 1980). Copies attached hereto.

In *Arnold Partnership*, the applicant sought a patent term extension based upon the FDA approval of a product consisting of two active ingredients. The USPTO denied the extension on the grounds that both active ingredients had been previously marketed either alone or in combination with other active ingredients. The Federal Circuit affirmed the denial, interpreting § 156 to require eligibility determinations to be made on an ingredient-by-ingredient basis. *Arnold Partnership*, 362 F.3d at 1341. The Federal Circuit explained: "To extend the term of a patent claiming a composition comprising A and B, either A or B must not have been previously marketed. In other words, at least one of the claimed active ingredients must be new to the marketplace as a drug product." *Id.* Additionally, the Federal Circuit specifically rejected the argument that Applicant makes here, *i.e.*, that "the patent for combination drug product AB could receive an extension because the combination has not received prior approval, even though drug product A and drug product B have separate, prior approvals." *Id.* at 1342.

Because the two claimed active ingredients in Vusion®, zinc oxide and miconazole nitrate, have each been previously approved for commercial marketing or use under Section 505 of the FFDCA, Applicant fails to meet the eligibility requirement of § 156(a)(5)(A) under *Arnold Partnership* and thus its '932 patent is ineligible for a patent term extension.

III. Claim Construction of "Skin Care Composition" Does Not Inherently Require White Petrolatum

Applicant admits that white petrolatum is not explicitly recited in the claims of the '932 patent, but asserts that it is inherently included via the phrase "skin care composition," which appears in claim 1 and 2. Response to Show Cause Order at 11. Applicant's argument is unavailing. The skin care composition of claims 1 and 2 only require miconazole nitrate and zinc oxide. Those claims recite:

> 1. A skin care composition comprising as the active components (a) miconazole nitrate of the formula * * * and (b) zinc oxide; wherein the miconazole nitrate and zinc oxide are present in a ration of from about 1:60 to about 1:333.
>
> 2. The composition of claim 1 wherein the miconazole nitrate and zinc oxide are present in a ratio of about 1:60.

'932 patent, col. 8, ll. 24-44.

While the "comprising" transition phrase found in claim 1 leaves open the possibility that the skin care composition could contain additional components, there is nothing to suggest that it necessarily will do so. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (explaining that "comprising" is a term of art used in claim language to indicate that the named elements are essential, but that other elements may be added and still form a construct within the scope of the claim). Likewise, there is nothing to suggest that if the skin care composition of claim 1. contains an additional component that it will necessarily be white petrolatum. Further, that Examples IV and V in the specification list white petrolatum as a component in the skin care composition does not mean that claims 1 and 2 necessarily include that compound, contrary to

Applicant's argument. *See* Response to Show Cause Order at 11-13. Accordingly, because the '932 patent does not expressly claim white petrolatum and because the skin care composition of claims 1 and 2 does not necessarily require that compound, the USPTO finds that the '932 patent fails to satisfy the eligibility requirement of § 156(a), which provides the patent subject to extension must claim the product. *See* 35 U.S.C. § 156(a) (preamble).

IV. Vacatur of Interim Extensions Previously Granted under § 156(e)(2)

Applicant requests clarification with respect to the vacatur of the two earlier-granted interim extensions. Specifically, Applicant asserts that MPEP § 2775.01, cited in the Order to Show Cause, does not state that an interim extension *must* be vacated *ab initio*, but instead states that "where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension *may* be vacated *ab initio*." Response to Show Cause Order at 13 (emphasis added). Applicant also argues that Vusion® was granted three years of new product marketing exclusivity by the FDA and, as such, that there is no actual impact on the public until that exclusivity ends on February 16, 2009. *Id.* at 13-14.

With respect to the first point, the Office has reconsidered its position taken in the Order to Show Cause regarding vacatur of the two previous interim extensions granted to Applicant under § 156(e)(2). When the Office issued the two previous interim extensions, the Office determined at the time that the '932 patent was eligible for a patent term extension. As a result, the Office will not vacate the first previously-granted interim or the portion of the second previously-granted interim extension from March 27, 2008, to the date of this decision. However, since the Office has determined that the '932 patent is ineligible for a patent term extension, *see supra* § I-III, the Office vacates the portion of the second previously-granted interim extension covering the period from the date of this decision to March 27, 2009. Lastly, the Office notes that Applicant is correct that the MPEP § 2775.01 contains permissive "may" language rather than mandatory "must" language concerning the vacatur of an interim extension granted in error.

With respect to the second point, the protection afforded by new drug product marketing exclusivity is separate and distinct from patent protection. Accordingly, the expiration of the FDA exclusivity period is irrelevant to the propriety of a previously-granted interim extension under § 156(e)(2).

V. Applicant's Pending Third Interim Extension Request Is Denied

Applicant filed a third interim extension application to extend the term of the '932 patent for another year because the '932 patent is due to expire on March 27, 2009. Section 156(e)(2) provides for an interim patent term extension while an applicant's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire *before a certificate of extension is issued or denied* under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year *if he*

determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. *See Somerset Pharms., Inc. v. Dudas*, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '932 patent will not expire before a certificate of extension is issued or denied since the Director is herein denying Applicant's PTE application. *See infra*, § I-III. The second requirement is not met because the Director herein is issuing a negative eligibility determination, thus divesting him of authority to grant an interim extension. *Id.; see Somerset*, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); *see also In re Alcon Labs. Inc.*, 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for extension). Accordingly, since neither requirement for a interim extension under § 156(e)(2) is satisfied, the Office must deny Applicant's pending third interim extension request.

CONCLUSION

Applicant's PTE application is **DENIED**. The Office is **VACATING** the term of the second previously-granted interim extension from the date of this decision through March 27, 2009. Furthermore, Applicant's Third Request for Interim Extension is also **DENIED**.

THIS IS CONSIDERED A FINAL AGENCY DECISION.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Robert A Clarke

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: VUSION®
FDA Docket No.: 2007E-0035

UNITED STATES PATENT AND TRADEMARK OFFICE

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SEP 2 9 2008

OFFICE OF PETITIONS

In re Patent No. 4,638,628 :
Issue Date: January 27, 1987 :
Application No. 06/716,373 : ON PETITION
Filed: March 26, 1985 :
Attorney Docket No. RICE/0004 :

This is a decision on the petition under 37 CFR 1.182, filed September 4, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **granted**.

The Office of Data Management is directed to issue duplicate Letters Patent.

A copy of this decision is being forwarded to the Office of Data Management for issuance of the duplicate Letters Patent.

The patent file is being referred to the Files Repository.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3226. Any questions concerning issuance of the duplicate Letters Patent should be directed to Niomi Farmer at (703) 308-9250 ext 119.

Andrea Smith
Petitions Examiner
Office of Petitions

cc: Niomi Farmer, P/OPPD, South Tower 8th Floor, Room C23
FAX No. (571) 270-9753

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
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OCT 24 2005

Scott B. Markow
Fish & Richardson
1425 K Street, NW
11th Floor
Washington DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

Dear Mr. Markow:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year. A copy of the Federal Register Notice is also enclosed. The extension was published in the Federal Register on Monday, October 24, 2005. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: vapreotide acetate
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re H3 Pharma, Inc. Request for Patent Term Extension U.S. Patent No. 4,650,787	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On April 7, 2005, H3 Pharma, Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, the patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the human drug product Sanvar®, and a method of use of said product. The application indicates that a New Drug Application for Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since the regulatory review period extended beyond the expiration date of the patent April 25, 2005, interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the expiration date of the patent, i.e., until April 25, 2006.

10/17/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. 2005-P-071]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,650,787; vapreotide acetate

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,650,787.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (571) 272-7744; by mail marked to her attention and addressed to Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7744, or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has

been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On April 7, 2005, H3 Pharma, Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, the patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the human drug product Sanvar®, and a method of use of said product. The application indicates that a New Drug Application for Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since the regulatory review period extended beyond the expiration date of the patent April 25, 2005, interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the expiration date of the patent, i.e., until April 25, 2006.

10/17/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Anita Meiklejohn
Fish & Richardson
225 Franklin St.
Boston MA 02110

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

MAILED

JAN 22 2007

CENTRAL REEXAMINATION UNIT

Dear Ms. Meiklejohn

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2007. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: vapreotide acetate
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc. Request for Patent Term Extension U.S. Patent No. 4,650,787	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On March 23, 2006, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a second subsequent interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B). Since it is apparent that the regulatory review period has continued beyond the extended expiration date of the patent (April 25, 2006), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2007.

1/17/07
Date

Jon W. Dudas
Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 17 2007

Anita Meiklejohn
Fish & Richardson
225 Franklin St.
Boston MA 02110

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

Dear Ms. Meiklejohn

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2008. A copy of the Federal Register notice, published on April 10, 2007, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: vapreotide acetate
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc. Request for Patent Term Extension U.S. Patent No. 4,650,787	: : :	**ORDER GRANTING** **INTERIM EXTENSION**

On March 23, 2007, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a third subsequent interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2007), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2008.

April 3, 2007
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Anita Meiklejohn
Fish & Richardson
225 Franklin St.
Boston MA 02110

APR 23 2008

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

Dear Ms. Meiklejohn

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2009. A copy of the Federal Register notice, published on April 15, 2008 at 73 Fed. Reg. 20256, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Building 51, Rom 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: SANVAR® (vapreotide acetate)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc. Request for Patent Term Extension U.S. Patent No. 4,650,787	: : :	 **ORDER GRANTING** **INTERIM EXTENSION**

On March 24, 2008, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2008), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2009.

4/09/08
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APR 30 2009

Anita Meiklejohn
Fish & Richardson
225 Franklin St.
Boston MA 02110

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

Dear Ms. Meiklejohn

A final interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2010. A copy of the Federal Register notice, published on April 22, 2009 at 74 Fed. Reg. 18352, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Building 51, Rom 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: SANVAR® (vapreotide acetate)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc. Request for Patent Term Extension U.S. Patent No. 4,650,787	: : :	**ORDER GRANTING** **INTERIM EXTENSION**

On March 19, 2009, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a fifth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B) and 35 U.S.C. § 156(d)(5)(C). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2010.

04/15/09
Date

John Doll
John J. Doll
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

candidate may not be a registered foreign agent under the Foreign Agents Registration Act of 1938, as amended.

Evaluation of applications for membership in the U.S. Section by eligible individuals will be based on the following criteria:

—A demonstrated commitment by the individual's company to the Brazilian market either through exports or investment.

—A demonstrated strong interest in Brazil and its economic development.

—The ability to offer a broad perspective and business experience to the discussions.

—The ability to address cross-cutting issues that affect the entire business community.

—The ability to initiate and be responsible for activities in which the Forum will be active.

Members will be selected on the basis of who will best carry out the objectives of the Forum as stated in the Terms of Reference establishing the U.S.-Brazil CEO Forum. The U.S. Section of the Forum should also include members that represent a diversity of business sectors and geographic locations. To the extent possible, Section members also should represent a cross-section of small, medium, and large firms.

U.S. members will receive no compensation for their participation in Forum related activities. Individual members will be responsible for all travel and related expenses associated with their participation in the Forum, including attendance at Committee and Section meetings. Only appointed members may participate in official Forum meetings; substitutes and alternates will not be designated. U.S. members will normally serve for two-year terms, but may be reappointed.

To be considered for membership, please submit the following information as instructed in the **ADDRESSES** and **DATES** captions above: Name(s) and title(s) of the individual(s) requesting consideration; name and address of company's headquarters; location for incorporation; size of the company; size of company's export trade, investment, and nature of operations or interest in Brazil; and a brief statement of why the candidate should be considered, including information about the candidate's ability to initiate and be responsible for activities in which the Forum will be active. Applications will be considered as they are received. All candidates will be notified of whether they have been selected.

Dated: April 15, 2009.

Anne Driscoll,

Director for the Office of South America.

[FR Doc. E9–9292 Filed 4–21–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2009–0016]

Grant of Interim Extension of the Term of U.S. Patent No. 4,650,787; Sanvar®

AGENCY: United States Patent and Trademark Office.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a fifth one-year interim extension of the term of U.S. Patent No. 4,650,787.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755, or by e-mail to *Mary.Till@uspto.gov.*

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On March 19, 2009, Debiovision Inc., the exclusive agent of Debiopharm S.A. and Debio Recherche Pharmaceutique S.A., who is the exclusive licensee of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, the patent owner, timely filed an application under 35 U.S.C. 156(d)(5) for a fifth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the human drug product Sanvar® (vapreotide acetate). The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. 156(d)(5)(B) and 35 U.S.C. 156(d)(5)(C). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2009), a fifth interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fifth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2010.

April 15, 2009.

John J. Doll,

Acting Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E9–9145 Filed 4–21–09; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XO70

Incidental Taking of Marine Mammals; Taking of Marine Mammals Incidental to the Explosive Removal of Offshore Structures in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of letters of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) and implementing regulations, notification is hereby given that NMFS has issued one-year Letters of Authorization (LOA) to take marine mammals incidental to the explosive removal of offshore oil and gas structures (EROS) in the Gulf of Mexico.

DATES: These authorizations are effective from May 15, 2009 through May 14, 2010.

ADDRESSES: The application and LOAs are available for review by writing to P. Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3235 or by telephoning the

Ex R

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL 29 2004

Audley A. Ciamporcero
One Johnson & Johnson Plaza
NEW BRUNSWICK NJ 08933-7003

Re: Patent Term Extension
Application for
U.S. Patent No. 4,631,278

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,631,278 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: CLINACOX®
FDA Docket No.: 99E-5113

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Janssen Pharmaceutica N.V.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,631,278	:	**INTERIM EXTENSION**

On June 17, 1999, Janssen Pharmaceutica N.V., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,631,278, filed an application under 35 U.S.C. § 156, requesting an extension of three years. The original expiration date of the patent is August 1, 2004. The patent claims the active ingredient diclazuril of the animal drug product "CLINACOX®," and the method of use of said product. The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,631,278 is granted for a period of one year from the original expiration date of the patent, until August 1, 2005.

7/28/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL 25 2006

Audley A. Ciamporcero
One Johnson & Johnson Plaza
NEW BRUNSWICK NJ 08933-7003

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,631,278

Dear Mr. Ciamporcero :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,631,278 for a period of one additional year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: CLINACOX®
FDA Docket No.: 99E-5113

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Janssen Pharmaceutica N.V. Request for Patent Term Extension U.S. Patent No. 4,631,278	: : :	**ORDER GRANTING** **INTERIM EXTENSION**

On June 17, 1999, Janssen Pharmaceutica N.V., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,631,278, filed an application under 35 U.S.C. § 156, requesting an extension of three years. The patent was previously extended for a second period of one year, until August 1, 2006. The patent claims the active ingredient diclazuril of the animal drug product "CLINACOX®," and the method of use of said product. The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, as previously extended, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,631,278 is granted for a period of one year from the extended expiration date of the patent, until August 1, 2007.

July 21, 2006
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APR 12 2007

Thomas S. Szatkowski
Wyeth
5 Giralda Farms
Patent Law Group
Madison, NJ 07940

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,704,275

Dear Mr. Szatkowski :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,704,275 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: Rotashield®
FDA Docket No.: 99E-0116

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re American Home Products Corporation	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,704,275	:	INTERIM EXTENSION

American Home Products Corporation, a licensee of the United States of America as represented by the Department of Health and Human Services, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,704,275, timely filed an application for patent term extension under 35 U.S.C. § 156 on October 29, 1998. The original term of the patent expired on August 26, 2005. The patent claims a live tetravalent rotavirus vaccine which contains as active ingredients, four live viruses, a rhesus rotavirus (serotype 3) and three rhesus-human reassortant rotaviruses (serotypes 1, 2 and 4) in the human biologic product Rotashield® which was approved by the Food and Drug Administration for commercial marketing or use on August 21, 1998. An extension of five years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent has expired before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

A first interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,704,275 is granted for a period of one year from the original expiration date of the patent, from August 26, 2005, to August 26, 2006, and for a second interim extension from August 26, 2006, to August 26, 2007.

April 3, 2007
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Timothy J. Douros
Cubist Pharmaceuticals, Inc.
65 Hayden Avenue
Lexington, MA 02421

In re: Patent Term Extension
Application for
U.S. Patent No. 4,885,243

MAILED

DEC 04 2006

CENTRAL REEXAMINATION UNIT

Dear Mr. Douros:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,885,243 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7754, or by e-mail at kathleen.fonda@uspto.gov.

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: CUBICIN® (daptomycin)
FDA Docket No.: 2006E-0042

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cubist Pharmaceuticals, Inc. Request for Patent Term Extension U.S. Patent No. 4,885,243	: : :	ORDER GRANTING INTERIM EXTENSION

Cubist Pharmaceuticals, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,885,243, filed an application for patent term extension under 35 U.S.C. § 156 on November 10, 2003. The original term of the patent is due to expire on December 5, 2006. The patent claims the active ingredient daptomycin in the human drug product CUBICIN® which was approved by the Food and Drug Administration for commercial marketing or use on September 12, 2003. An extension of 1,347 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,885,243 is granted for a period of one year from the original expiration date of the patent.

11/20/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Paper No.

OSTRAGER CHONG FLAHERTY &
BROITMAN PC
250 PARK AVENUE, SUITE 825
NEW YORK NY 10177

COPY MAILED

OCT 31 2006

OFFICE OF PETITIONS

In re Patent No. 4,706,275	:	
Zvi Kamil	:	DECISION ON
Application No. 06/797,658	:	PETITION
Issued: November 10, 1987	:	
Title: TELEPHONE SYSTEM	:	

This is a decision on the PETITION UNDER RULE 1.182 FOR OBTAINING REPLACEMENT OF LETTERS PATENT AND PETITION TO EXPEDITE filed October 26, 2006, requesting a duplicate because applicant lost the original Letters Patent. The petition has been made by an appropriate party in interest, i.e., an attorney of record and includes the petition fee of $400.

The petition to expedite is **GRANTED**.

Accordingly, the petition under 1.182 for duplicate letters patent is **GRANTED**.

The Publishing Division is directed to issue a Duplicate Letters Patent to patentee at:

Joseph S. Broitman
Ostrager Chong Flaherty & Broitman P.C.
250 Park Avenue
Suite 825
New York, NY 10177-0899

Any questions concerning this matter may be directed to the undersigned at (571) 272 - 3219. Any questions concerning issuance of the duplicate Letters Patent should be directed to Krystal Paige at (703) 308-9250 x 139.

A copy of this decision is being forwarded to Publishing Division for issuance of a duplicate Letters Patent.

Nancy Johnson
Senior Petitions Attorney
Office of Petitions

cc: Krystal Paige, P/OPPD, South Tower, 8th Floor, Room C-32

UNITED STATES PATENT AND TRADEMARK OFFICE

#15

In re Schering Corporation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,659,716	:	**INTERIM EXTENSION**

On February 15, 2002, Schering Corporation, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,659,716, filed an application under 35 U.S.C. § 156, requesting an extension of 1,074 days. The original expiration date of the patent is April 21, 2004. The patent claims the active ingredient desloratadine of the human drug product "CLARINEX®," and the method of use of said product. The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension was not completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,659,716 is granted for a period of one year from the original expiration date of the patent, until April 21, 2005.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DEC 20 2005

Thomas D. Hoffman
Schering-Plough Corporation, Patent Department
K-6-1 1900
2000 Galloping Hill Road
Kenilworth NJ 07033-0530

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,659,716

Dear Mr. Hoffman:

A certificate under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,659,716 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the PSC Forms Download Website: http://forms.psc.gov/forms/FDA/fda.html (http://forms.psc.gov/forms/FDA/Fda-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned at (571)272-7744.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: Clarinex® (desloratadine)
FDA Docket No.: 02E-0097

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Schering Corporation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,659,716	:	**INTERIM EXTENSION**

On February 15, 2002, Schering Corporation, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,659,716, filed an application under 35 U.S.C. § 156, requesting an extension of 1,074 days. The patent was previously extended under 35 U.S.C. 156(e)(2) for a period of one year, until April 21, 2005. The patent claims the active ingredient desloratadine of the human drug product "CLARINEX®," and the method of use of said product. The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of extended expiration of the patent, a second interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,659,716 is granted for a period of one year from the expiration date of the patent, as previously extended, until April 21, 2006.

4/19/05
Date

Jon W. Dudas
Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL - 6 2004

#14

Thomas D. Hoffman
Schering-Plough Corporation, Patent Department
K-6-1 1900
2000 Galloping Hill Road
Kenilworth NJ 07033-0530

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,659,716

Dear Mr. Hoffman:

A certificate under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,659,716 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the PSC Forms Download Website: http://forms.psc.gov/forms/FDA/fda.html (http://forms.psc.gov/forms/FDA/Fda-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: Clarinex® (desloratadine)
FDA Docket No.: 02E-0097

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Schering Corporation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,659,716	:	**INTERIM EXTENSION**

On February 15, 2002, Schering Corporation, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,659,716, filed an application under 35 U.S.C. § 156, requesting an extension of 1,074 days. The original expiration date of the patent is April 21, 2004. The patent claims the active ingredient desloratadine of the human drug product "CLARINEX®," and the method of use of said product. The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension was not completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,659,716 is granted for a period of one year from the original expiration date of the patent, until April 21, 2005.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5167229	1992-12-01	06843159	1986-03-24	CASEP0413US

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☒ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity			Small Entity		
	Fee	Code		Fee	Code
○	3 ½ year	(1551)	○	3 ½ year	(2551)
○	7 ½ year	(1552)	○	7 ½ year	(2552)
○	11 ½ year	(1553)	◉	11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/Christopher B. Jacobs.../	Date (YYYY-MM-DD)	2006-11-15
Name	Christopher B. Jacobs	Registration Number	37853

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5167229
Issue Date: December 1,1992
Application No. 06843159
Filed: March 24,1986
Attorney Docket No. CWR 2 044

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed November 15,2006 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of November 15,2006. This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APR - 5 2006

Leslie Morioka
Patent Department, White & Case
1155 Avenue of the Americas
New York, NY 10036-2787

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,738,974

Dear Ms. Morioka:

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,738,974 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at mary.till@uspto.gov by e-mail.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: NEXIUM™ (esomeprazole)
FDA Docket No.: 01E-0365

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Aktiebologet Hassle	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,738,974	:	INTERIM EXTENSION

Aktiebologet Hässle, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,738,974, filed an application for patent term extension under 35 U.S.C. § 156 on April 19, 2001. The extended term of the patent is due to expire on April 19, 2006. The patent claims the active ingredient esomeprazole in the human drug product "NEXIUM®," and a method of use of said product. "NEXIUM®" (esomeprazole) was approved by the Food and Drug Administration for commercial marketing or use on February 20, 2001. An extension of 865 days is requested.

The initial review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by the Food and Drug Administration. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,738,974 is granted for a period of one year from the extended expiration date of the patent, until April 19, 2007.

4/5/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Leslie Morioka
Patent Department, White & Case
1155 Avenue of the Americas
New York, NY 10036-2787

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,738,974

MAILED

MAR 31 2005

REEXAM UNIT

Dear Ms. Morioka:

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,738,974 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Terry J Dey for

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: NEXIUM™ (esomeprazole)
FDA Docket No.: docket no

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Aktiebolaget Hassle	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,738,974	:	INTERIM EXTENSION

Aktiebolaget Hässle, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,738,974, filed an application for patent term extension under 35 U.S.C. § 156 on April 19, 2001. The original term of the patent is due to expire on April 19, 2005. The patent claims the active ingredient esomeprazole in the human drug product "NEXIUM®," and a method of use of said product. "NEXIUM®" (esomeprazole) was approved by the Food and Drug Administration for commercial marketing or use on February 20, 2001. An extension of 865 days is requested.

The initial review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by the Food and Drug Administration. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,738,974 is granted for a period of one year from the original expiration date of the patent, until April 19, 2006.

March 29, 2005
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BAKER BOTTS LLP
2001 ROSS AVENUE, SUITE 600
DALLAS, TX 75201-2980

COPY MAILED

JAN 19 2006

OFFICE OF PETITIONS

In re Patent No. 4,793,353 :
Issue Date: December 27, 1988 :
Application No. 06/860,429 : ON PETITION
Filed: May 7, 1986 :
Attorney Docket No. 065274.0144 :

This is a decision on the petition under 37 CFR 1.182, received January 19, 2006, requesting issuance of a duplicate Letters Patent for the above-identified application. This is also a decision on the petition under 37 CFR 1.182 requesting expedited consideration of the petition for a duplicate Letters Patent.

The petitions are **granted**.

The Publishing Division is directed to issue a duplicate Letters Patent.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3218. Any questions concerning issuance of the duplicate Letters Patent should be directed to Kimberly Terrell at (703) 308-9250, Ext. 147.

A copy of this decision is being forwarded to Publishing Division for issuance of a duplicate Letters Patent.

Frances Hicks
Petitions Examiner
Office of Petitions

cc: Kimberly Terrell, P/OPPD, South Tower 08C32 (FAX 571-273-9740)

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

FEB - 6 2006

Michael D. Alexander
Sanofi-Aventis
9 Great Valley Parkway
Malvern PA 19355

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,661,491

Dear Mr. Alexander:

An order granting Interim Extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,661,491 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries

Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: Uroxatral® (Alfuzosin hydrochloride)
FDA Docket No.: 04E-0393

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Sanofi-Aventis	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,661,491	:	**INTERIM EXTENSION**

Sanofi-Aventis, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,661,491, filed an application under 35 U.S.C. § 156(d)(1), requesting an extension of 1,481 days. The original expiration date of the patent is May 27, 2006. The patent claims a method of use of the approved drug product, alfuzosin hydrochloride (Uroxatral®). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505(i) and 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, an interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,661,491 is granted for a period of one year from the original expiration date of the patent, i.e., until May 27, 2007.

2/6/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: _____

DATE : 4-26-05

TO SPE OF : ART UNIT 2182

SUBJECT : Request for Certificate of Correction on Patent No.: 6874046

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within **7** days to:
Certificates of Correction Branch - PK 3-915
Palm location **7580** - Tel. No. 305-8309

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please check Fig.

Thank You For Your Assistance

Certificates of Correction Branch

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

- ☒ **Approved** — **All** changes apply.
- ☐ **Approved in Part** — Specify below which changes **do not** apply.
- ☐ **Denied** — State the reasons for denial below.

Comments:

The changes do not affect the scope of the claims

5/4/04

SPE

2182
Art Unit

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

.. 10 2006

JUN 16 2006

Steven J. Sarussi
McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,826,811

Dear Mr. Sarussi:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,826,811 for a period of one year. Because PolyHeme® has not received permission from the Food and Drug Administration for commercial market or use, the interim extension will be published in the Federal Register pursuant to 35 USC 156(d)(5).

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: PolyHeme®
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Northfield Laboratories, Inc.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,826,811	:	**INTERIM EXTENSION**

On May 31, 2006, patent owner, Northfield Laboratories, Inc., timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,826,811. The patent claims the human biological product PolyHeme® (acellular red blood cell substitute), a method of use of the biological product and a method of producing the biological product. The application indicates, and the Food and Drug Administration has confirmed, that an investigational new drug application for the human biological product PolyHeme® has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (June 20, 2006), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for one year, i.e., until June 20, 2007.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,826,811 is granted for a period of one year from the original expiration date of the patent, i.e., until June 20, 2007.

6/15/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED

JAN 23 2007

CENTRAL REEXAMINATION UNIT

B. Timothy Creagan
Pfizer Inc.
Eastern Point Road, MS 8260-1611
Groton CT 06340

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,861,779

Dear Mr. Creagan :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,861,779 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates as required. set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: A180® (danofloxacin mesylate)
FDA Docket No.: 03E-0252

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Pfizer, Inc.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,861,779	:	INTERIM EXTENSION

Pfizer, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,861,779, filed an application for patent term extension under 35 U.S.C. § 156 on November 19, 2002. The original term of the patent expired on August 29, 2006. The patent claims the active ingredient danofloxacin mesylate in the animal drug product A180® which was approved by the Food and Drug Administration for commercial marketing or use on September 20, 2002. An extension of 5 years has been requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,861,779 is granted for a period of one year from the original expiration date of the patent.

1-18-07
Date

STEPHEN M. PINKOS
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 2 5 2005

Thomas Hoxie
Vice President, Head of Intellectual Property
Corporate Intellectual Property
One Health Plaza
East Hanover, NJ 07936-1080

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,745,177

Dear Mr. Hoxie:

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,745,177 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: Iprivask™ (desirudin)
FDA Docket No.: 03E-0419

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Novartis Corporation and	:	
UCP Gen-Pharma AG	:	ORDER GRANTING
Request for Patent Term Extension	:	INTERIM EXTENSION
U.S. Patent No. 4,745,177	:	

Novartis Corporation and UCP Gen-Pharma AG, the owners of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,745,177, filed an application for patent term extension under 35 U.S.C. § 156 on May 2, 2003. The original term of the patent is due to expire on May 17, 2005. The patent claims the active ingredient desirudin in the human drug product "Iprivask™" which was approved by the Food and Drug Administration for commercial marketing or use on April 4, 2003. An extension of five years is requested. In accordance with the limitation of 35 U.S.C. § 156(g)(6)(A), applicant is entitled to an extension of five years.

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,745,177 is granted for a period of one year from the original expiration date of the patent, until May 17, 2006.

May 19, 2005
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Dated: May 18, 2007.

Susan K. Fawcett,

Records Officer, U.S. Patent and Trademark Office, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E7–10042 Filed 5–23–07; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2007–0021]

Grant of Interim Extension of the Term of U.S. Patent No. 4,927,855; NUVIGIL(TM) (armodafinil)

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,927,855.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE., P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755, or by e-mail to *Mary.Till@uspto.gov.*

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On May 7, 2007, Cephalon, Inc., an agent of Laboratoire L. Lafon, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,927,855. The patent claims the human drug product NUVIGIL(TM) (armodafinil) and a method of said product. The application indicates, and the Food and Drug Administration has confirmed, that a new drug application (NDA 21–875) for the human drug product NUVIGIL(TM) (armodafinil) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (May 22, 2007), interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,927,855 is granted for a period of one year from the expiration date of the patent, i.e., until May 22, 2008.

Dated: May 18, 2007.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E7–10084 Filed 5–23–07; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Sub Committee Meeting of the President's Commission on Care for America's Returning Wounded Warriors

AGENCY: Department of Defense.

ACTION: Federal Advisory Committee Sub Committee Meeting Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended) and 41 Code of Federal Regulations (CFR) 102–3.140 thorough 160, the Department of Defense announces the forthcoming sub committee meeting:

Subcommittees of the Commission will conduct preparatory work meetings at Ft. Bragg and Camp Lejeune, North Caroline June 19th to gather information, conduct research and analyze relevant issues and facts in preparation for a meeting of the Commission. Pursuant to section 102–3.160(a) of 41 Code of Federal Regulations (CFR), these subcommittee meetings are not open to the public, and the subcommittees are required to report their findings to the Commission for further deliberation.

Dated: May 18, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–2596 Filed 5–22–07; 10:59 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Sub Committee Meeting of the President's Commission on Care for America's Returning Wounded Warriors

AGENCY: Department of Defense.

ACTION: Federal Advisory Committee Sub Committee Meeting Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended) and 41 Code of Federal Regulations (CFR) 102–3.140 through 160, the Department of Defense announces the forthcoming sub committee meeting:

Subcommittees of the Commission will conduct preparatory work meetings in the New Jersey area June 15th to gather information, conduct research and analyze relevant issues and facts in preparation for a meeting of the Commission. Pursuant to section 102–3.160(a) of 41 Code of Federal Regulations (CFR), these subcommittee meetings are not open to the public, and the subcommittees are required to report their findings to the Commission for further deliberation. Locations include the East Orange VA Health Center. Additionally, the Sub Committees may visit public and private hospitals in the area for investigation of Centers of Excellence that apply to the Commission's Charter.

Dated: May 18, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–2597 Filed 5–22–07; 8:45 am]

BILLING CODE 5001–06–M

ELECTION ASSISTANCE COMMISSION

Sunshine Act Notice

AGENCY: United States Election Assistance Commission.

ACTION: Notice of Public Teleconference Meetings for the Working Subcommittees of the Technical Guidelines Development Committee.

DATES AND TIMES:

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN - 5 2007

Robert T. Hrubiec, Ph.D, J.D.
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19300

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,927,855

Dear Dr. Hrubiec :

An order granting interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 1 year. Pursuant to 35 U.S.C. § 156(d)(5)(B), a notice regarding the grant of an interim extension under 35 U.S.C. § 156(d)(5) was published in the Federal Register of May 24, 2007 (72 Fed. Reg. 29137), a copy of which is enclosed for your records.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NUVIGIL™ (armodafinil)
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cephalon Inc.	:	
Request for Interim Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,927,855	:	**INTERIM EXTENSION**

On May 7, 2007, Cephalon, Inc., an agent of Laboratoire L. Lafon, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of U.S. Patent No. 4,927,855. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL™ and a method of use of said product. The application indicates that a New Drug Application for the human drug product NUVIGIL™ (armodafinil) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (May 22, 2007), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,927,855, is granted for a period of one year from the original expiration date of the patent, i.e., until May 22, 2008.

May 18, 2007
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

SEP 18 2007

Robert T. Hrubiec, Ph.D, J.D.
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19300

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,927,855

Dear Mr. Hrubiec :

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NUVIGIL™ (armodafinil)
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cephalon Inc.	:	
Request for Interim Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,927,855	:	**INTERIM EXTENSION**

Cephalon, Inc., an agent of Laboratoire L. Lafon, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed an application under 35 U.S.C. § 156 for extension of U.S. Patent No. 4,927,855 on July 26, 2007. The extended term of the patent is due to terminate on August 13, 2007, in accordance with 37 C.F.R. § 1.791. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL™ and a method of use of said product which was approved by the Food and Drug Administration for commercial marketing or use on June 15, 2007. An extension of 700 days is requested.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the extended term of the patent will terminate on August 13, 2007, as per 37 C.F.R. § 1.791, before a certificate of extension can be issued, interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,855, is granted for a period of one year from the original expiration date of the patent, i.e., until August 13, 2008.

13 AUG 2007
Date

M. J. A. Peterlin
Margaret J. A. Peterlin
Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

AUG - 1 2008

Robert T. Hrubiec, Ph.D, J.D.
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19300

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,927,855

Dear Dr. Hrubiec :

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 282 days. This second interim extension under 35 U.S.C. § 156(e)(2) is for less than one year so that any subsequent interim extensions under 35 U.S.C. § 156(e)(2) will extend the term of the patent from the original expiration date of the patent, May 22, 2007.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NUVIGIL™ (armodafinil)
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cephalon Inc.	:	
Request for Interim Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,927,855	:	**INTERIM EXTENSION**

Cephalon, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed a second application under 35 U.S.C. § 156(e)(2) for interim extension of U.S. Patent No. 4,927,855 on July 1, 2008. The previously extended term of the patent is due to expire on August 13, 2008. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL™ and a method of use of said product which was approved by the Food and Drug Administration for commercial marketing or use on June 15, 2007. An extension of 1,066 days from the original expiration date was requested in an application for patent term extension under 35 U.S.C. § 156 filed on July 27, 2007.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the extended term of the patent will expire on August 13, 2008, before a certificate of extension can be issued, further interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,855, is granted for an additional period of 282 days to further extend the patent from the extended expiration date of August 13, 2008, until the new extended expiration date, May 22, 2009.

July 28, 2008
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APR 29 2009

Robert T. Hrubiec, Ph.D, J.D.
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19300

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,927,855

Dear Dr. Hrubiec :

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 335 days. This third interim extension under 35 U.S.C. § 156(e)(2) is for less than one year since Applicant, in accordance with their application for patent term extension under 35 U.S.C. § 156(d)(1), is entitled to no more than 1,066 days extension from the original expiration date of U.S. Patent No. 4,927,855.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: NUVIGIL™ (armodafinil)
Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cephalon Inc.	:	
Request for Interim Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,927,855	:	**INTERIM EXTENSION**

Cephalon, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed a third application under 35 U.S.C. § 156(e)(2) for interim extension of U.S. Patent No. 4,927,855 on April 3, 2009. The previously extended term of the patent is due to expire on May 22, 2009. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL® and a method of use of said product which was approved by the Food and Drug Administration for commercial marketing or use on June 15, 2007. An extension of 1,066 days from the original expiration date was requested in an application for patent term extension under 35 U.S.C. § 156 filed on July 27, 2007.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the extended term of the patent will expire on May 22, 2009, before a certificate of extension can be issued, further interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,855, is granted for an additional period of 335 days to further extend the patent from the extended expiration date of May 22, 2009, until the extended expiration date, April 22, 2010.

04/15/09
Date

John J. Doll
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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www.uspto.gov

JOSEPH H. PAQUIN, JR.
MCDERMOTT, WILL & EMERY
227 WEST MONROE STREET
CHICAGO IL 60606

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DEC 10 2008

In re Patent Number: 4972181	:	
Issue Date: 11/20/1990	:	
Application No. 07/011024	:	NOTICE
Filed: 02/05/1987	:	
Attorney Docket No. 32202-022	:	

This is a notice regarding your request for acceptance of a fee deficiency submission under 37 CFR 1.28, filed on October 2, 2008.

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

This application is no longer entitled to small entity status. Accordingly, all future fees paid in this application must be paid at the large entity rate.

The address in the petition is different than the correspondence address. A courtesy copy of this decision is being mailed to the address in the petition. All future correspondence will be mailed solely to the address of record. A change of correspondence address should be filed if the correspondence address needs to be updated.

Inquiries related to this communication should be directed to the undersigned at (571) 272-3231.

D Wood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc: ROBERT E. BROWNE, ESQ.
NEAL, GERBER & EISENBERG, LLP
2 NORTH LA SALLE ST, STE. 2200
CHICAGO IL 60602

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WALTER G. SUTCLIFF
NORTHROP GRUMMAN CORPORATION
P. O. BOX 17319, MAIL STOP A440
BALTIMORE, MD 21203-3197

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FEB 09 2006

OFFICE OF PETITIONS

In re Application of :
Charles F. Chubb, et al. :
Application No. 07/012,598 : ON PETITION
Filed: January 27, 1987 :
Attorney Docket No. N-1034A :

This is a decision on the petition under 37 CFR 1.137(b), filed November 22, 2005, to revive the above-identified application.

The petition is **GRANTED.**

The above-identified application became abandoned for failure to submit the issue fee in a timely manner in reply to the Notice of Allowance mailed August 9, 2005, which set a statutory period for reply of three (3) months. Accordingly, the above-identified application became abandoned on November 10, 2005.

It is not apparent whether the person signing the statement of unintentional delay was in a position to have firsthand or direct knowledge of the facts and circumstances of the delay at issue. Nevertheless, such statement is being treated as having been made as the result of a reasonable inquiry into the facts and circumstances of such delay. See 37 CFR 10.18(b) and Changes to Patent Practice and Procedure; Final Rule Notice, 62 Fed. Reg. 53131, 53178 (October 10, 1997), 1203 Off. Gaz. Pat. Office 63, 103 (October 21, 1997). In the event that such an inquiry has not been made, petitioner must make such an inquiry. If such inquiry results in the discovery that it is not correct that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional, petitioner must notify the Office.

There is no indication that the person signing the instant petition was ever given a power of attorney or authorization of agent to prosecute the above-identified application. If the person signing the instant petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. While a courtesy copy of this decision is being mailed to the person signing the instant petition, all future correspondence will be directed to the address currently of record until such time as appropriate instructions are received to the contrary.

The petition satisfies the conditions for revival pursuant to the provisions of 37 CFR 1.137(b) in that (1) the reply in the form of payment of the issue fee; (2) the petition fee; and (3) the required statement of unintentional delay have been received. Accordingly, the issue fee is accepted as having been unintentionally delayed.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3229.

This application matter is being referred to the Publishing Division for further processing.

Retta Williams

Retta Williams
Petitions Examiner
Office of Petitions

cc: William L. Gates
Birch, Stewart, Kolasch & Birch, LLP
8110 Gatehouse Road
Suite 100 East, P. O. Box 747
Falls Church, VA 22040-0747

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OLE K. NILSSEN
200 N. HARRISON STREET, SUITE 103
ALGONQUIN, IL 60102

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OFFICE OF PETITIONS

In re Patent No. 4,857,806
Issue Date: August 15, 1989
Application No. 07/020,478
Filed: March 2, 1987
Title of Invention: SELF-BALLASTED SCREW-IN FLUORESCENT LAMP

ON PETITION

This is a decision regarding your request for acceptance of a fee deficiency submission under 37 CFR 1.28 filed December 5, 2005.

On September 1, 1998, the Court of Appeals for the Federal Circuit held that 37 CFR 1.28(c) is the sole provision governing the time for correction of the erroneous payment of the issue fee as a small entity. See DH Technology v. Synergystex International, Inc.. 154 F.33d 1333, 47 USPQ2d 1865 (Fed. Cir. Sept. 1, 1998).

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. 1098 Off. Gaz. Pat. Office 502 (January 3, 1989). Therefore nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby accepted and the petition is **GRANTED**.

Inquiries related to this communication should be directed to the Office of Petitions Staff at (571) 272-3282.

This file is being forwarded to the Files Repository.

Patricia Faison-Ball

Patricia Faison-Ball
Senior Petitions Attorney
Office of Petitions

NOTICE RE: CERTIFICATES OF CORRECTION

DATE : 05,17,02 **Paper No.:** 50

TO : **Supervisor, Art Unit** 3700

SUBJECT : Certificate of Correction Request in Patent No.: 6,352,559

A response to the following question is requested with respect to the accompanying request for a certificate of correction.

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

PLEASE COMPLETE THIS FORM AND RETURN WITH FILE, WITHIN 7 DAYS, TO CERTIFICATES OF CORRECTION BRANCH - PK 3-915/922 PALM LOCATION 7580 - TEL. N0. 305-8309

THANK YOU FOR YOUR ASSISTANCE!

Note your decision, regarding the changes requested in the Request for Certificate of Correction, by placing a check mark (+) in the box that reflects your decision, which corresponds to the question checked above.

☒ **YES** ☐ **NO** ☐ **Comments below**

☒ **Comments:** The changes correct errors of the application and the changes don't affect the scope and/or meaning of the claims

David J. Isabella
Primary Examiner

[signature] 3738

Supervisor **Art Unit**

PTOL-306 (REV. 2/02) U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,352,559 B1
DATED : March 5, 2002
INVENTOR(S) : Church

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1,
Line 33, delete "of,the" and replace it with -- of the --

Column 3,
Lines 56-57, delete the extra spaces between "with" and "increase"

Column 4,
Line 18, delete "numberal" and replace it with -- numeral --

Column 6,
Line 17, delete "said" (both occurrences)
Line 63, delete "a femoral" and replace it with -- the femoral --

Column 7,
Line 22, delete "said" (both occurrences)
Line 53, delete "aperture" and replace it with -- apertured --

Column 8,
Line 8, after "patient;" insert -- and --
Line 31, delete "said" (both occurrences)

Column 10,
Line 3, delete "said" (both occurrences)

Signed and Sealed this

Twenty-fifth Day of June, 2002

Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. 6,352,559 B1

ISSUE DATE: March 5, 2002

INVENTOR: Church

It is hereby certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

~~In the specification,~~ col. 1, line 33, delete "of,the" and replace it with -- of the --

~~In the specification,~~ col. 3, lines 56-57, delete the extra spaces between "with" and "increase"

~~In the specification,~~ col. 4, line 18, delete "numberal" and replace it with -- numeral --

~~Claim 6,~~ col. 6, line 17, delete "said" (both occurrences)

~~Claim 17~~, col. 6, line 63, delete "a femoral" and replace it with -- the femoral --

~~Claim 22~~, col. 7, line 22, delete "said " (both occurrences)

~~Claim 30,~~ col. 7, line 53, delete "aperture" and replace it with -- apertured --

~~Claim 33,~~ col. 8, line 8, after "patient;" insert -- and --

~~Claim 38,~~ col. 8, line 31, delete "said" (both occurrences)

~~Claim 54,~~ col. 10, line 3, delete "said" (both occurrences)

MAILING ADDRESS OF SENDER

Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315

Patent No. 6,352,559 B1

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. 6,352,559 B1

ISSUE DATE: March 5, 2002

INVENTOR: Church

It is hereby certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the specification, col. 1, line 33, delete "of,the" and replace it with -- of the --

In the specification, col. 3, lines 56-57, delete the extra spaces between "with" and "increase"

In the specification, col. 4, line 18, delete "numberal" and replace it with -- numeral --

Claim 6, col. 6, line 17, delete "said" (both occurrences)

Claim 17 , col. 6, line 63, delete "a femoral" and replace it with -- the femoral --

Claim 22, col. 7, line 22, delete "said " (both occurrences)

Claim 30, col. 7, line 53, delete "aperture" and replace it with -- apertured --

Claim 33, col. 8, line 8, after "patient;" insert -- and --

Claim 38, col. 8, line 31, delete "said" (both occurrences)

Claim 54, col. 10, line 3, delete "said" (both occurrences)

MAILING ADDRESS OF SENDER

Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315

Patent No. 6,352,559 B1

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MAR 0 1 2006

OFFICE OF PETITIONS

In re Application of	:	
Ching-Wu CHU	:	
Application No. 07/032,041	:	DECISION ON PETITION
Filed: March 26, 1987	:	
Attorney Docket No. CIP - 81297	:	

This is a decision on the petition under 37 CFR 1.183, filed February 21, 2006, which is being treated as a petition under 37 CFR 1.314 to defer issuance of the patent.

The petition is **GRANTED**.

Issuance will be deferred for a period of one month from the date of this decision. At the end of this period, the application will be referred to Publishing Division to be processed into a patent.

If an additional deferral period is required, another petition and fee should be promptly submitted. The petition must include a showing of extraordinary circumstances. See MPEP 1306.01.

Petitioner submitted the $400 petition fee due under 37 CFR 1.17(f) for a petition under 37 CFR 1.183. The petition fee due under 37 CFR 1.17(h) for a petition under 37 CFR 1.314 is $130. Accordingly, $270 will be refunded to petitioner's Deposit Account No. 16-2435.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop PETITION
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Service Window
Mail Stop Petitions
Randolph Building
401 Dulany Street
Alexandria, VA 22314

By Fax: (571) 273-8300
ATTN: Office of Petitions

Telephone inquiries should be directed to David Bucci at (571) 272-7099.

Frances Hicks

Frances Hicks
Lead Paralegal
Office of Petitions

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OFFICE OF PETITIONS

In re Application of	:	
Ching-Wu CHU	:	
Application No. 07/032,041	:	*SUA SPONTE* LETTER
Filed: March 26, 1987	:	
Attorney Docket No. CIP - 81297	:	

A decision on the petition filed February 21, 2006, which petition was treated as a petition under 37 CFR 1.314 to defer issuance of the patent, was mailed March 1, 2006.

The decision deferred issuance for a period of one month from the date of the decision and further stated: (1) at the end of this period, the application will be referred to Publishing Division to be processed into a patent; and (2) if an additional deferral period is required, another petition and fee should be promptly submitted.

The period of one month given in the March 1, 2006 decision has expired. No further request for an additional deferral period has been requested. Accordingly, the above-identified application is being referred to the Office of Patent Publication for issuance as a patent in due course.

Telephone inquiries should be directed to David Bucci at (571) 272-7099.

Brian Hearn
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

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OFFICE OF PETITIONS

In re Application of	:	
Chu	:	
U.S. Patent No. 7,056,866	:	
Issue Date: June 6, 2006	:	Letter For
Application No. 07/032,041	:	Certificate of Correction
Filed: June 6, 1995	:	
For: SUPERCONDUCTIVITY IN SQUARE-	:	
PLANAR COMPOUND SYSTEMS	:	

The above-identified application has been forwarded to the undersigned for correction of the patent term extension information printed on the front page of the patent. In a telephone call with Lester Hewitt on August 17, 2006, it was confirmed that the Office would request a certificate of correction to correct the patent term extension information printed on the face of the patent. See 35 U.S.C. § 154(b)[1] and 37 C.F.R. § 1.701.

The Notice of Allowance and Issue Fee Due mailed on October 17, 2005, correctly indicated that the patent to issue from Application No. 07/056,866 was not eligible for a patent term extension, as the application was filed before June 8, 1995. The front page of the patent incorrectly indicates that the term of the patent is extended for 785 days. Since the filing date was before June 8, 1995, the patent to issue from the application is eligible only for a 17-year term, which does not permit a patent term extension.

After mailing of this letter, the Office will issue a certificate of correction in order to rectify the error regarding the patent term extension information. See 35 U.S.C. 254 and 37 CFR 1.322. The Office will issue a certificate of correction deleting the patent term extension information.

Telephone inquiries with regard to this communication should be directed to the undersigned at (571) 272-7709.

Mark Polutta
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

[1] 35 U.S.C. § 154 was amended by the "American Inventors Protection Act of 1999," which was enacted on November 29, 1999 as part of Public Law 106-113 (Consolidated Appropriations Act for Fiscal Year 2000). Since this amendment is effective May 29, 2000 and applies to applications filed on or after that date, the existing patent term adjustment provisions of 35 U.S.C. § 154 continue to apply to the above-identified application.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 7,056,866

DATED : June 6, 2006

INVENTOR(S) : Chu

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page,
[*] delete "Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 785 days."

UNITED STATES PATENT AND TRADEMARK OFFICE

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MAY 18 2006

Philip S. Johnson, Esq.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NEW JERSEY 08933-7003

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,826,868

Dear Mr. Johnson :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,826,868 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: ZUBRIN®
FDA Docket No.: 2003E-410

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Ortho Pharmaceutical, Inc.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,826,868	:	INTERIM EXTENSION

Ortho Pharmaceutical, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,826,868, filed an application for interim patent term extension under 35 U.S.C. § 156 on March 24, 2006. The original term of the patent is due to expire on May 29, 2006. The patent claims the active ingredient, tepoxalin, in the animal drug product ZUBRIN®, which was approved by the Food and Drug Administration for commercial marketing or use on March 31, 2003. An interim extension of one year is requested under 35 USC § 156(e)(2).

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,826,868 is granted for a period of one year from the original expiration date of the patent.

5/17/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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Paper No. 20

NICHOLAS C. GEORGALIS
6981 IVANDALE
INDEPENDENCE OH 44131

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OFFICE OF PETITIONS

In re Application of	:	
NICHOLAS C. GEORGALIS	:	
Application No. 07/043,863	:	DECISION ON PETITION UNDER
Patent No. 4,740,967	:	37 C.F.R. §1.378(B)
Filed: January 7, 1987	:	
Issue Date: April 26, 1988	:	
Title: DISPERSED SWITCHING	:	
TELECOMMUNICATION SYSTEM	:	

This is a decision on the petition filed October 1, 2004, pursuant to 37 C.F.R. §1.378(b)[1], to revive the above-identified application. On October 18, 2004, Petitioner filed a petition to expedite.

The patent issued April 26, 1988. The grace period for paying the 3½ year maintenance fee provided in 37 CFR 1.362(e) expired at midnight on April 26, 1992, with no payment received. Accordingly, the patent expired on April 26, 1992.

With the instant petition, Petitioner submitted payment in the amount of $455, $1045, and $1610 for the delayed payment of the required 3½ year , 7½ year, and 11½ year maintenance fees, respectively, as well as the surcharge associated with the filing of this petition. To establish

[1] Any petition to accept an unavoidably delayed payment of a maintenance fee filed under 37 C.F.R. §1.378(b) must include:

(1) The required maintenance fee set forth in 37 C.F.R. §1.20 (e) through (g);
(2) The surcharge set forth in 37 C.F.R. §1.20(i)(1), and;
(3) A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

unavoidable delay, petitioner has submitted a statement of facts where petitioner asserts financial hardship.

Petitioner has failed to meet requirements (1) and (3) above.

Regarding the first requirement above, Petitioner has failed to submit the maintenance fees in full. On October 1, 2004, the day this petition was filed, the maintenance fees increased to $470, $1075, and $1660, respectively.

The third requirement will be discussed below.

The standard

35 U.S.C. §41(c)(1) states:

The Director may accept the payment of any maintenance fee... after the six-month grace period if the delay[2] is shown to the satisfaction of the Director to have been unavoidable.

§1.378(b)(3) is at issue in this case. Acceptance of a late maintenance fee under the unavoidable delay standard is considered under a very stringent standard. Decisions on reviving abandoned applications on the basis of "unavoidable" delay have adopted the reasonably prudent person standard in determining if the delay was unavoidable:

The word 'unavoidable' ... is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business[3].

In addition, decisions are made on a "case-by-case basis, taking all the facts and circumstances into account."[4] Nonetheless, a petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable."[5]

An adequate showing that the delay in payment of the maintenance fee at issue was "unavoidable" within the meaning of 35 U.S.C. 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent. Where the record fails to disclose that the patentee took reasonable steps, or discloses that the

---

2 This delay includes the entire period between the due date for the fee and the filing of a grantable petition pursuant to 37 C.F.R. §1.378(b).

3 In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(*quoting* Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 U.S.P.Q. 666, 167-68 (D.D.C. 1963), aff'd, 143 U.S.P.Q. 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

4 Smith v. Mossinghoff, 671 F.2d at 538, 213 U.S.P.Q. at 982.

5 Haines, 673 F. Supp. at 316-17, 5 U.S.P.Q.2d at 1131-32.

patentee took no steps, to ensure timely payment of the maintenance fee, 35 U.S.C. 41(c) and 37 C.F.R. §1.378(b)(3) preclude acceptance of the delayed payment of the maintenance fee under 37 CFR 1.378(b).

A delay caused by an applicant's lack of knowledge or improper application of the patent statute, rules of practice, or the MPEP is not rendered "unavoidable" due to either the applicant's reliance upon oral advice from USPTO employees or the USPTO's failure to advise the applicant to take corrective action[6].

The portions of the MPEP relevant to the facts as presented

2504 Patents Subject to Maintenance Fees

37 CFR 1.362. Time for payment of maintenance fees.

(a) Maintenance fees as set forth in § § 1.20(e) through (g) are required to be paid in all patents based on applications filed on or after December 12, 1980, except as noted in paragraph (b) of this section, to maintain a patent in force beyond 4, 8 and 12 years after the date of grant.

(b) Maintenance fees are not required for any plant patents or for any design patents. Maintenance fees are not required for a reissue patent if the patent being reissued did not require maintenance fees.

(c) The application filing dates for purposes of payment of maintenance fees are as follows:
  (1) For an application not claiming benefit of an earlier application, the actual United States filing date of the application.
  (2) For an application claiming benefit of an earlier foreign application under 35 U.S.C. 119, the United States filing date of the application.
  (3) For a continuing (continuation, division, continuation-in-part) application claiming the benefit of a prior patent application under 35 U.S.C. 120, the actual United States filing date of the continuing application.
  (4) For a reissue application, including a continuing reissue application claiming the benefit of a reissue application under 35 U.S.C. 120, the United States filing date of the original non-reissue application on which the patent reissued is based.
  (5) For an international application which has entered the United States as a Designated Office under 35 U.S.C. 371, the international filing date granted under Article 11(1) of the Patent Cooperation Treaty which is considered to be the United States filing date under 35 U.S.C. 363.

(d) Maintenance fees may be paid in patents without surcharge during the periods extending respectively from:
  (1) 3 years through 3 years and 6 months after grant for the first maintenance fee,
  (2) 7 years through 7 years and 6 months after grant for the second maintenance fee, and
  (3) 11 years through 11 years and 6 months after grant for the third maintenance fee.

(e) Maintenance fees may be paid with the surcharge set forth in § 1.20(h) during the respective grace periods after:
  (1) 3 years and 6 months and through the day of the 4th anniversary of the grant for the first maintenance fee.
  (2) 7 years and 6 months and through the day of the 8th anniversary of the grant for the second maintenance fee, and
  (3) 11 years and 6 months and through the day of the 12th anniversary of the grant for the third maintenance fee.

(f) If the last day for paying a maintenance fee without surcharge set forth in paragraph (d) of this section, or the last day for paying a maintenance fee with surcharge set forth in paragraph (e) of this section, falls on a Saturday, Sunday, or a federal holiday within the District of Columbia, the maintenance fee and any necessary surcharge may be paid under paragraph (d) or paragraph (e) respectively on the next succeeding day which is not a Saturday, Sunday, or Federal holiday.

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6 See In re Sivertz, 227 USPQ 255, 256 (Comm'r Pat. 1985).

(g) Unless the maintenance fee and any applicable surcharge is paid within the time periods set forth in paragraphs (d), (e) or (f) of this section, the patent will expire as of the end of the grace period set forth in paragraph (e) of this section. A patent which expires for the failure to pay the maintenance fee will expire at the end of the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant.

(h) The periods specified in § § 1.362 (d) and (e) with respect to a reissue application, including a continuing reissue application thereof, are counted from the date of grant of the original non-reissue application on which the reissued patent is based.

Maintenance fees are required to be paid on all patents based on applications filed on or after December 12, 1980, except for plant patents and design patents. Furthermore, maintenance fees are not required for a reissue patent if the patent being reissued did not require maintenance fees. Application filing dates for purposes of determining whether a patent is subject to payment of maintenance fees are as follows:

(A) For an application not claiming benefit of an earlier application, the actual United States filing date of the application.

(B) For an application claiming benefit of an earlier foreign application under 35 U.S.C. 119(a)-(d), the actual United States filing date of the application.

(C) For a continuing (continuation, division, continuation-in-part) application claiming the benefit of a prior patent application under 35 U.S.C. 120, the actual United States filing date of the continuing application.

(D) For a reissue application, including a continuing reissue application claiming the benefit of a reissue application under 35 U.S.C. 120, the United States filing date of the original nonreissue application on which the patent reissued is based.

(E) For an international application that has entered the United States as a Designated Office under 35 U.S.C. 371, the international filing date granted under Article 11(1) of the Patent Cooperation Treaty which is considered to be the United States filing date under 35 U.S.C. 363.

2506 Times for Submitting Maintenance Fee Payments

37 CFR 1.362(d) sets forth the time periods when the maintenance fees for a utility patent can be paid without surcharge. Those periods, referred to generally as the "window period," are the 6-month periods preceding each due date. The "due dates" are defined in 35 U.S.C. 41(b). The window periods are (1) 3 years to 3 1/2 years after the date of issue for the first maintenance fee payment, (2) 7 years to 7 1/2 years after the date of issue for the second maintenance fee payment, and (3) 11 years to 11 1/2 years after the date of issue for the third and final maintenance fee payment. A maintenance fee paid on the last day of a window period can be paid without surcharge. The last day of a window period is the same day of the month the patent was granted 3 years and 6 months, 7 years and 6 months, or 11 years and 6 months after grant of the patent. 37 CFR 1.362(e) sets forth the time periods when the maintenance fees for a utility patent can be paid with surcharge. Those periods, referred to generally as the "grace period," are the 6-month periods immediately following each due date. The grace periods are (1) 3 1/2 years and through the day of the 4th anniversary of the grant of the patent, (2) 7 1/2 years and through the day of the 8th anniversary of the grant of the patent and, (3) 11 1/2 years and through the day of the 12th anniversary of the grant of the patent. A maintenance fee may be paid with the surcharge on the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant to prevent the patent from expiring. Maintenance fees for a reissue patent are due based upon the schedule established for the original utility patent. The filing of a request for ex parte or inter partes reexamination and/or the publication of a reexamination certificate does not alter the schedule of maintenance fee payments of the original patent. If the day for paying a maintenance fee falls on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee may be paid on the next succeeding day that is not a Saturday, Sunday, or Federal holiday. For example, if the window period for paying a maintenance fee without a surcharge ended on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee can be paid without surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia. Likewise, if the grace period for paying a maintenance fee with a surcharge ended on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee can be paid with surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia. In the latter situation, the failure to pay the maintenance fee and surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia will result in the patent expiring on a date (4, 8, or 12 years after the date of grant) earlier than the last date on which the maintenance fee and surcharge could be paid. This situation results

from the provisions of 35 U.S.C. 21, but those provisions do not extend the expiration date of the patent if the maintenance fee and any required surcharge are not paid when required. For example, if the grace period for paying a maintenance fee with a surcharge ended on a Saturday, the maintenance fee and surcharge could be paid on the next succeeding business day, e.g., Monday, but the patent will have expired at midnight on Saturday if the maintenance fee and surcharge were not paid on the following Monday. Therefore, if the maintenance fee and any applicable surcharge are not paid, the patent will expire as of the end of the grace period as listed above. A patent that expires for failure of payment will expire on the anniversary date the patent was granted in the 4th, 8th, or 12th year after the grant.

Application of the standard to the current facts and circumstances

Petitioner should be made aware that the standard associated with the filing of a petition under 37 C.F.R. §1.378(b) is extremely difficult to meet.

Petitioner's explanation of the delay has been considered, and it has been determined that it fails to meet the standard for acceptance of a late payment of the maintenance fee and surcharge. Petitioner has not made an adequate showing that the failure to pay the maintenance fee was unavoidable, given the exercise of due care. The period for paying the 3½ year maintenance fee without the surcharge extended from April 26, 1991 to October 26, 1991, and for paying with the surcharge from October 27, 1991 to April 26, 1992. Thus, the delay in paying the 11 ½ year maintenance fee extended from April 26, 1992 to the filing of the instant petition on October 1, 2004.

Petitioner has set forth that although he was aware that these maintenance fees were due, only recently could he afford to submit them.

In essence, Petitioner has asserted financial difficulty in that he lacked the funds necessary to submit each of the three required maintenance fees. A showing of "unavoidable" delay based upon financial difficulty is very stringent, in that in order for a petitioner to demonstrate that he lacked the financial resources to pay the required fee, substantial documentation must be provided. Such a showing must be supported by a **complete and thorough** showing of his financial condition during the entire period between April 26, 1992 and the date on which the petition was submitted, including income, expenses, tax return statements, bank records, assets, credit and obligations, which made the submission of the maintenance fee unavoidable. Petitioner should provide copies of all documents or records pertaining to each of these so as to confirm the financial difficulty.

For these reasons, acceptance of the delayed payment of the maintenance fee is precluded.

CONCLUSION

In view thereof, the petition is **DISMISSED**.

Any response to this decision must be filed within **TWO MONTHS** of the mailing date of this decision. Any such reply must be accompanied by the $130 petition fee set forth in §1.17(h). **After decision on the petition for reconsideration, no further reconsideration or review of**

the matter will be undertaken by the Commissioner. Accordingly, it is extremely important that petitioner supply **any** and **all** relevant information and documentation in order to meet his burden of showing unavoidable delay. This includes statements by all persons with direct knowledge of the cause of the delay, setting forth the facts as they know them.

If on renewed petition, the delayed payment of the maintenance fee is not accepted, then the maintenance fee is subject to refund following the decision on the petition for reconsideration, or after the expiration of the time for filing such a petition for reconsideration, if none is filed. (Petitioner may request a refund of the maintenance fee and surcharge by writing to the Office of Finance, Refund Section, Commissioner for Patents, Washington DC 20231. A copy of the last decision rendered should accompany the request for refund).

On renewed petition, Petitioner may wish to further develop his assertion that he encountered financial hardship. A showing of "unavoidable" delay based upon financial difficulty is very stringent, in that in order for a petitioner to demonstrate that he lacked the financial resources to pay the fee(s) associated with patent prosecution, substantial documentation must be provided. Such a showing must be supported by a **complete and thorough** showing of his financial condition during the entire period between April 26, 1992 until the filing of the renewed petition, including **income, expenses, tax return statements, bank records, assets, credit and obligations**, which made the delay in payment of the maintenance fee and surcharge unavoidable. Petitioner should provide copies of all documents or records pertaining to each of these so as to confirm the financial difficulty.

Again, Petitioner is reminded that the period of delay with which he must be concerned is the *entire* period of delay in filing the required reply, from the due date for the maintenance fee up until the filing of a grantable petition. Financial hardship must be shown for this entire period.

The renewed petition should display "Please deliver to Paul Shanoski, c/o Office of Petitions" in a prominent manner.

To help assure prompt and proper attention to your response, please see the enclosed copy of Request for Alert Concerning Submitted Petitions, 1282 Official Gazette (May 18, 2004) for further information on how to assist the Office in delivering your submission to the correct location. The Petitioner may wish to consider telephoning the undersigned one month after the submission is made to confirm that the documents were properly delivered.

Any renewed petition may be submitted by mail[7], hand-delivery[8], or facsimile[9].

The application file will be retained in the Office of Petitions for two (2) months.

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7 Mail Stop Petition, Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

8 Customer Window, Mail Stop Petition, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202.

9 (703) 872-9306 - please note this is a central facsimile number, and as such, there will be a delay in the delivery of the facsimile to the undersigned.

The general phone number for the Office of Petitions which should be used for status requests is (571) 272-3282. Telephone inquiries regarding *this decision* should be directed to the undersigned at (571) 272-3225.

Paul Shanoski
Senior Attorney
Office of Petitions
United States Patent and Trademark Office

Encl. Request for Alert Concerning Submitted Petitions, 1282 Official Gazette (May 18, 2004)

UNITED STATES PATENT AND TRADEMARK OFFICE

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Paper No. 22

NICHOLAS C. GEORGALIS
6981 IVANDALE
INDEPENDENCE OH 44131

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MAY 1 2 2005

OFFICE OF PETITIONS

In re Application of	:	
NICHOLAS C. GEORGALIS	:	
Application No. 07/043,863	:	DECISION ON RENEWED PETITION
Patent No. 4,740,967	:	UNDER 37 C.F.R. §1.378(E)
Filed: January 7, 1987	:	
Issue Date: April 26, 1988	:	
Title: DISPERSED SWITCHING	:	
TELECOMMUNICATION SYSTEM	:	

This is a decision on the renewed petition filed November 16, 2004, under 37 C.F.R. §1.378(e), requesting reconsideration of a prior decision pursuant to 37 C.F.R. §1.378(b)[1], which refused to accept the delayed payment of two maintenance fees for the above-referenced patent. On December 14, 2004, Petitioner submitted supplemental material.

The request to accept the delayed payment of the maintenance fee is **DENIED**[2].

The patent issued April 26, 1988. The grace period for paying the 7½ year maintenance fee[3] provided in 37 CFR 1.362(e) expired at midnight on April 26, 1996, with no payment received. Accordingly, the patent expired at midnight on April 26, 1996.

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[1] Any petition to accept an unavoidably delayed payment of a maintenance fee filed under 37 C.F.R. §1.378(b) must include:

(1) The required maintenance fee set forth in 37 C.F.R. §1.20 (e) through (g);
(2) The surcharge set forth in 37 C.F.R. §1.20(i)(1), and;
(3) A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

2 This decision may be regarded as a final agency action within the meaning of 5 U.S.C. §704 for the purposes of seeking judicial review. See MPEP 1002.02.

3 The PTO's Patent Location and Monitoring System software does not show that the 3½ year maintenance fee was received. However, Petitioner has submitted evidence on renewed petition by way of a Maintenance Fee Statement, mailed by the Office on November 14, 1991, which establishes that this maintenance fee was paid.

With the original petition submitted on October 1, 2004 under 37 C.F.R. §1.378(b), Petitioner submitted payment in the amount of $455, $1045, and $1610 for the delayed payment of the required 3½ year , 7½ year, and 11½ year maintenance fees, respectively, as well as the surcharge associated with the filing of this petition.

The application issued on April 26, 1988. Petitioner asserted that due to financial hardship, he was unable to submit the required maintenance fees until the present time.

To establish unavoidable delay, Petitioner submitted a statement of facts where Petitioner asserted financial hardship. A decision was mailed on November 15, 2004 which dismissed the petition for failing to establish that the delay was unavoidable in that Petitioner failed to submit a complete and thorough showing of his financial condition during the entire period between April 26, 1996 and the date on which the petition was submitted.

With the instant petition pursuant to 37 C.F.R. §1.378(e), Petitioner has again failed to meet the requirement under 37 C.F.R. §1.378(b)(3) of an adequate showing that the delay was unavoidable. A discussion follows.

The standard

35 U.S.C. §41(c)(1) states:

The Director may accept the payment of any maintenance fee... after the six-month grace period if the delay[4] is shown to the satisfaction of the Director to have been unavoidable.

§1.378(b)(3) is at issue in this case. Acceptance of a late maintenance fee under the unavoidable delay standard is considered under a very stringent standard. Decisions on reviving abandoned applications on the basis of "unavoidable" delay have adopted the reasonably prudent person standard in determining if the delay was unavoidable:

The word 'unavoidable' ... is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business[5].

In addition, decisions are made on a "case-by-case basis, taking all the facts and circumstances into account."[6] Nonetheless, a petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable."[7]

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4 This delay includes the entire period between the due date for the fee and the filing of a grantable petition pursuant to 37 C.F.R. §1.378(b).

5 In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(*quoting* Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 U.S.P.Q. 666, 167-68 (D.D.C. 1963), aff'd, 143 U.S.P.Q. 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

6 Smith v. Mossinghoff, 671 F.2d at 538, 213 U.S.P.Q. at 982.

An adequate showing that the delay in payment of the maintenance fee at issue was "unavoidable" within the meaning of 35 U.S.C. 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent. Where the record fails to disclose that the patentee took reasonable steps, or discloses that the patentee took no steps, to ensure timely payment of the maintenance fee, 35 U.S.C. 41(c) and 37 C.F.R. §1.378(b)(3) preclude acceptance of the delayed payment of the maintenance fee under 37 CFR 1.378(b).

A delay caused by an applicant's lack of knowledge or improper application of the patent statute, rules of practice, or the MPEP is not rendered "unavoidable" due to either the applicant's reliance upon oral advice from USPTO employees or the USPTO's failure to advise the applicant to take corrective action[8].

Presuming for the purposes of discussion that it was an act/omission of Counsel that contributed to any of the delay herein, the act(s) or omissions of the attorney/agent are imputed wholly to the applicant/client[9] in the absence of evidence that the attorney/agent has acted to deceive the client.[10]

The portions of the MPEP relevant to the facts as presented

2504 Patents Subject to Maintenance Fees

37 CFR 1.362. Time for payment of maintenance fees.

(a) Maintenance fees as set forth in § § 1.20(e) through (g) are required to be paid in all patents based on applications filed on or after December 12, 1980, except as noted in paragraph (b) of this section, to maintain a patent in force beyond 4, 8 and 12 years after the date of grant.

(b) Maintenance fees are not required for any plant patents or for any design patents. Maintenance fees are not required for a reissue patent if the patent being reissued did not require maintenance fees.

(c) The application filing dates for purposes of payment of maintenance fees are as follows:

  (1) For an application not claiming benefit of an earlier application, the actual United States filing date of the application.

  (2) For an application claiming benefit of an earlier foreign application under 35 U.S.C. 119, the United States filing date of the application.

  (3) For a continuing (continuation, division, continuation-in-part) application claiming the benefit of a prior patent application under 35 U.S.C. 120, the actual United States filing date of the continuing

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7 Haines, 673 F. Supp. at 316-17, 5 U.S.P.Q.2d at 1131-32.

8 See In re Sivertz, 227 USPQ 255, 256 (Comm'r Pat. 1985).

9 The actions or inactions of the attorney/agent must be imputed to the petitioners, who hired the attorney/agent to represent them. Link v. Wabash Railroad Co., 370 U.S. 626, 633-634, 82 S.Ct. 1386, 1390-91 (1962). The failure of a party's attorney to take a required action or to notify the party of its rights does not create an extraordinary situation. Moreover, the neglect of a party's attorney is imputed to that party and the party is bound by the consequences. See Huston v. Ladner, 973 F.2d 1564, 23 USPQ2d 1910 (Fed Cir. 1992); Herman Rosenberg and Parker_Kalon Corp. v. Carr Fastener Co., 10 USPQ 106 (2d Cir. 1931).

10 When an attorney intentionally conceals a mistake he has made, thus depriving the client of a viable opportunity to cure the consequences of the attorney's error, the situation is not governed by the stated rule in Link for charging the attorney's mistake to his client. In re Lonardo, 17 USPQ2d 1455 (Comm'r. Pat. 1990).

application.

(4) For a reissue application, including a continuing reissue application claiming the benefit of a reissue application under 35 U.S.C. 120, the United States filing date of the original non-reissue application on which the patent reissued is based.

(5) For an international application which has entered the United States as a Designated Office under 35 U.S.C. 371, the international filing date granted under Article 11(1) of the Patent Cooperation Treaty which is considered to be the United States filing date under 35 U.S.C. 363.

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(1) 3 years through 3 years and 6 months after grant for the first maintenance fee,
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(3) 11 years through 11 years and 6 months after grant for the third maintenance fee.

(e) Maintenance fees may be paid with the surcharge set forth in § 1.20(h) during the respective grace periods after:
(1) 3 years and 6 months and through the day of the 4th anniversary of the grant for the first maintenance fee.
(2) 7 years and 6 months and through the day of the 8th anniversary of the grant for the second maintenance fee, and
(3) 11 years and 6 months and through the day of the 12th anniversary of the grant for the third maintenance fee.

(f) If the last day for paying a maintenance fee without surcharge set forth in paragraph (d) of this section, or the last day for paying a maintenance fee with surcharge set forth in paragraph (e) of this section, falls on a Saturday, Sunday, or a federal holiday within the District of Columbia, the maintenance fee and any necessary surcharge may be paid under paragraph (d) or paragraph (e) respectively on the next succeeding day which is not a Saturday, Sunday, or Federal holiday.

(g) Unless the maintenance fee and any applicable surcharge is paid within the time periods set forth in paragraphs (d), (e) or (f) of this section, the patent will expire as of the end of the grace period set forth in paragraph (e) of this section. A patent which expires for the failure to pay the maintenance fee will expire at the end of the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant.

(h) The periods specified in § § 1.362 (d) and (e) with respect to a reissue application, including a continuing reissue application thereof, are counted from the date of grant of the original non-reissue application on which the reissued patent is based.

Maintenance fees are required to be paid on all patents based on applications filed on or after December 12, 1980, except for plant patents and design patents. Furthermore, maintenance fees are not required for a reissue patent if the patent being reissued did not require maintenance fees. Application filing dates for purposes of determining whether a patent is subject to payment of maintenance fees are as follows:

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(B) For an application claiming benefit of an earlier foreign application under 35 U.S.C. 119(a)-(d), the actual United States filing date of the application.

(C) For a continuing (continuation, division, continuation-in-part) application claiming the benefit of a prior patent application under 35 U.S.C. 120, the actual United States filing date of the continuing application.

(D) For a reissue application, including a continuing reissue application claiming the benefit of a reissue application under 35 U.S.C. 120, the United States filing date of the original nonreissue application on which the patent reissued is based.

(E) For an international application that has entered the United States as a Designated Office under 35 U.S.C. 371, the international filing date granted under Article 11(1) of the Patent Cooperation Treaty which is considered to be the United States filing date under 35 U.S.C. 363.

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37 CFR 1.362(d) sets forth the time periods when the maintenance fees for a utility patent can be paid without surcharge. Those periods, referred to generally as the "window period," are the 6-month periods preceding each due date. The "due dates" are defined in 35 U.S.C. 41(b). The window periods are (1) 3 years to 3 1/2 years after the

date of issue for the first maintenance fee payment, (2) 7 years to 7 1/2 years after the date of issue for the second maintenance fee payment, and (3) 11 years to 11 1/2 years after the date of issue for the third and final maintenance fee payment. A maintenance fee paid on the last day of a window period can be paid without surcharge. The last day of a window period is the same day of the month the patent was granted 3 years and 6 months, 7 years and 6 months, or 11 years and 6 months after grant of the patent. 37 CFR 1.362(e) sets forth the time periods when the maintenance fees for a utility patent can be paid with surcharge. Those periods, referred to generally as the "grace period," are the 6-month periods immediately following each due date. The grace periods are (1) 3 1/2 years and through the day of the 4th anniversary of the grant of the patent, (2) 7 1/2 years and through the day of the 8th anniversary of the grant of the patent and, (3) 11 1/2 years and through the day of the 12th anniversary of the grant of the patent. A maintenance fee may be paid with the surcharge on the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant to prevent the patent from expiring. Maintenance fees for a reissue patent are due based upon the schedule established for the original utility patent. The filing of a request for ex parte or inter partes reexamination and/or the publication of a reexamination certificate does not alter the schedule of maintenance fee payments of the original patent. If the day for paying a maintenance fee falls on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee may be paid on the next succeeding day that is not a Saturday, Sunday, or Federal holiday. For example, if the window period for paying a maintenance fee without a surcharge ended on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee can be paid without surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia. Likewise, if the grace period for paying a maintenance fee with a surcharge ended on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee can be paid with surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia. In the latter situation, the failure to pay the maintenance fee and surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia will result in the patent expiring on a date (4, 8, or 12 years after the date of grant) earlier than the last date on which the maintenance fee and surcharge could be paid. This situation results from the provisions of 35 U.S.C. 21, but those provisions do not extend the expiration date of the patent if the maintenance fee and any required surcharge are not paid when required. For example, if the grace period for paying a maintenance fee with a surcharge ended on a Saturday, the maintenance fee and surcharge could be paid on the next succeeding business day, e.g., Monday, but the patent will have expired at midnight on Saturday if the maintenance fee and surcharge were not paid on the following Monday. Therefore, if the maintenance fee and any applicable surcharge are not paid, the patent will expire as of the end of the grace period as listed above. A patent that expires for failure of payment will expire on the anniversary date the patent was granted in the 4th, 8th, or 12th year after the grant.

Application of the standard to the current facts and circumstances

Petitioner's explanation of the delay has been considered, and it has been determined that it fails to meet the standard for acceptance of a late payment of the maintenance fee and surcharge based on unavoidable delay.

In the original petition under 37 C.F.R.§1.378(b), submitted October 1, 2004, Petitioner set forth that he was not able to pay the maintenance fees at the time which they were due. In the decision mailed November 15, 2004, Petitioner was instructed to submit a complete and thorough showing of his financial condition during the entire period of delay.

With the renewed petition, Petitioner has supplied a rather voluminous packet of information containing, among other things, a statement of facts, charts showing cash flows from 1991 - 1995, a Net Worth Table spanning from 1987 – 2003, a receipt which confirms submission of the 3½ year maintenance fee, tax returns for 1991 – 1995, end of year bank statements for this same time period, a listing of home mortgage payments from 1991 – 2004, end of year credit card

summaries for 1991 – 1995 and 2002, utility payments for 2004, a summary of Petitioner's severance pay and pension buyout, and a personal statement of benefits from Petitioner's former employer.

As set forth in the previous decision, Petitioner should be made aware that the standard associated with the filing of a petition under the unavoidable standard is extremely difficult to meet.

Petitioner's explanation of the delay has been considered, and it has been determined that it fails to meet the standard for acceptance of a late payment of the maintenance fees and surcharge, for the reasons which follow[11].

Petitioner has not made an adequate showing that the failure to pay the maintenance fee was unavoidable, given the exercise of due care. The period for paying the 7½ year maintenance fee without the surcharge extended from April 26, 1995 to October 26, 1995, and for paying with the surcharge from October 27, 1995 to April 26, 1996. Thus, the delay in paying the 7½ year maintenance fee extended from April 27, 1996 to the filing of the petition on October 1, 2004.

The entire period of delay is the relevant period:

Petitioner states that he does not agree that the entire period of the delay should be considered, but rather the only time that is relevant is the time when the maintenance fee was due. Petitioner states that if the Office were to consider only the period following the date the maintenance fee was due would be to provide "no rational basis for explaining why the maintenance fee was not paid at the time that it was due thereby making the delay in payment unavoidable in the first instance[12]." Petitioner is reminded that the statue, 35 U.S.C. 41(c)(1) cited above, requires that the delay in submitting the maintenance fee was unavoidable. By definition, the delay inherently includes the period following the date the maintenance fee was due. Petitioner's argument is inconsistent with the statute. See also MPEP 711.03(c) and 37 C.F.R. §1.378(b)(3), which requires

> A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly. (Emphasis added).

Since the petition which Petitioner has filed requires a showing that the delay was unavoidable, Petitioner is required to establish that he could not submit the maintenance fees from the time

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[11] See: In re Application of S, 8 USPQ2d 1630, 1632 (Comm'r Pats. 1988). Where there is a question whether the delay was unintentional, the petitioner must meet a burden of establishing that the delay was unintentional within the meaning of 35 U.S.C. § 41(a)(7) and 37 C.F.R. §1.137(b). See: In re Application of G, 11 USPQ2d 1378, 1380 (Comm'r Pats. 1989).

12 Supplement to renewed petition, page 2.

that they were due until the time that they were eventually submitted to the Office. Put another way, Petitioner is required to establish that the entire period of delay was unavoidable.

Petitioner argues, inter alia, "that it is unreasonable to expect that [a "financial hardship"] standard can be met for the entire period [from 1995 to 2004];" that "the standard will always lead to a denial of the petition, hence thwart the intent of the law," and that the "effect of high standards relating to unavoidable delay of maintenance fees required by the Patent Office is to deny permanently the property rights of an inventor granted under the Patent Law and the United States." Petitioner asserts that the standard applied by the Office is arbitrary and capricious.[13] Unfortunately for Petitioner, the heavy burden necessary to establish that a delay was unavoidable is precisely what Congress required when 35 U.S.C. §41(c) was enacted. See 49 FR34716: "The legislative history of Pub. L. 97-247, House Report. 47-542 (Committee of the Judiciary) which indicates that "[a]fter the expiration of a reasonable period of time, the patentee would bear a heavy burden of proof that the delay was unavoidable." It was because of the difficulty in satisfying the standard that prompted Congress, in 1992, to amend 35 U.S.C. §41(c) to include the lesser standard of "unintentional" delay, subject to the 24 month time period. See House Report 102-993 ("The 'unavoidable' standard has proved to be too stringent in many cases. Many patentees have been deprived of their patent rights in failure to [pay the maintenance fees for reasons that may have been unintentional yet not avoidable.")

Petitioner has failed to address the entire period of the delay, and it is not clear why Petitioner waited until recently to submit his maintenance fees. The 7½ year and 11½ year maintenance fees, at the time which they were due, were $995 and $1455, respectively. As will be shown below, Petitioner was clearly financially capable of making these payments.

The issue of affordability/financial hardship:

Petitioner has alleged that he was unable to submit the maintenance fees for the above-identified patent. Petitioner has a wife and four children, and was employed by the local phone company as an engineer and manager until he was laid off in September of 1994. At the time of his layoff, Petitioner received $50,000 after taxes.

In 1995, Petitioner's daughter transferred to Cleveland State University after spending a year at Ohio State University, and Petitioner assisted her in her expenses[14].

In 1997, Petitioner paid for his oldest son to attend Case Western Reserve University, the cost of which Petitioner estimated at $20,000 per year. It is assumed that his son attended the school for four years[15]. This same year, Petitioner purchased a new car for $23,000[16]. Petitioner also makes mention of expenses for a "long planned vacation to Greece[17]." Petitioner's "End of Year Credit Card Summary for 2002" shows, inter alia, credit card charges to restaurants totaling over

13 Id.
14 Renewed petition, page 4.
15 Id.
16 Id. at page 8.
17 Id.

$5000, retail charges of over $11,000, lodging and airfare charges over $3000, miscellaneous charges over $6,000, etc.

Petitioner explains:

these expenses along with my diminished prospects about my future retirement as well as the expectation of at least 13 more years of college payments[18] played a pivotal role in my decision regarding the payment of maintenance fees in 1995.

Renewed petition, page 5.

Clearly, Petitioner had the means to submit the maintenance fee, but allocated these funds to other sources. Petitioner has reported his net worth for the years 1996 and 1997 as $311,634 and $333,973, respectively. A net worth amount of $201,915 appears to be indicated for year 2002, though the data in this column appears incomplete. It is noted that Petitioner has not reported his present net worth, or the net worth for years 1998-2001 or 2003.

In the supplement to the petition, received on December 14, 2004, Petitioner states that he is not asserting financial hardship, which Petitioner understands as implying that he must show that he was in bankruptcy in the entire period, but rather that when he was laid off, his perception of his future net worth diminished[19]. As such, Petitioner asserts that the standard should not be financial hardship, but rather affordability, and as such, "the projected loss of net worth can be used to make a reasonable judgment regarding the ability to pay the maintenance fee at the time that it was due and thereafter as well[20]." In other words, Petitioner realized that he would not have as much money in the future as he once though that he might, and as such, present spending had to be curtailed so as to prepare for the diminishment in his perceived future new worth. Petitioner adds that his case is unique in that his business interests and his family interests are bound together. Every person with a family has business interests which cannot be separated from his family interests.

Petitioner has asserted that he simply could not afford to pay the $995 maintenance fee in 1996 and the $1455 maintenance fee in 2000. However, Petitioner has made it clear that he was able to afford to send his son to a rather expensive university, he was able to afford the purchase of a brand new car, he was able to afford a trip to Europe, he was able to eat out at restaraunts and stay at hotels, etc. This, coupled with the fact that his net worth was hundreds of thousands of dollars, suggests that Petitioner had the $995 in 1996 and the $1455 in 2000, had he chose to spend it. It is clear that Petitioner could have submitted the payments, but chose not to, since he had other priorities which were placed above the maintenance of this patent.

On page 4 of the supplement to the renewed petition under 37 C.F.R. §1.378(e), Petitioner correctly sets forth that the standard adopted by the courts is that of a reasonably prudent person acting in relation to their <u>most important business</u>. Petitioner then immediately writes that the

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18 There were still two younger children who would eventually be attending college.
19 Supplement, page 2.
20 <u>Id</u>.

payment of the maintenance fee was not his most important business[21]. As such, Petitioner has set forth that he cannot meet the standard required under this rule, in that he has set forth that paying his current debts, paying his mortgage, food, clothing, fuel, utilities, taxes, insurance, home and car maintenance, entertainment, saving for college tuition, saving for his retirement, contributing to his church, and contributing to charities are each more important to him than his patent. As such, Petitioner has not treated this patent as his most important business, because he has other obligations which are more important to him. As stated above, the failure of a patentee to treat his patent as his most important business precludes the granting of a petition under 37 C.F.R. §1.378(e).

Furthermore, Petitioner has set forth that if this petition is denied, that would have the effect of the PTO reordering his personal priorities through beauracratic fiat[22]. Such is not the case. The reasonably prudent person standard recited above comes not from beauracratic fiat, but rather from judicial decree interpreting the statutory requirements that the delay be "unavoidable[23]."

Finally, as stated above, Petitioner had the means to pay the maintenance fee, but chose to allocate his financial resources to other matters. Petitioner has set forth that he believed that failure to submit the maintenance fee in a timely fashion would result in the patent becoming dormant, but not expired[24]. As such, Petitioner was clearly misinformed, and this belief indicates a lack of understanding of the consequences which befall patentees when maintenance fees are not timely paid. The lack of knowledge pertaining to failure to submit maintenance fees will not shift the burden of monitoring the time for paying a maintenance fee from the patentee to the Office, and as such, a lack of understanding cannot be used to support a finding that the delay was "unavoidable[25]."

CONCLUSION

The prior decision which refused to accept, under 37 C.F.R §1.378(b), the delayed payment of a maintenance fee for the above-identified patent, has been reconsidered. For the above stated reasons, the delay in this case cannot be regarded as unavoidable within the meaning of 35 U.S.C. §41(c)(1) and 37 C.F.R. §1.378(b).

Since this patent will not be reinstated, Petitioner is entitled to a refund of the surcharge and the three maintenance fees he submitted with the original petition. The $130 fee associated with the filing of a renewed petition under 37 C.F.R. §1.378(e) will not be refunded. A treasury check will be issued in due course.

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21 Id. at 5.
22 Id.
23 In re Mattullath, supra.
24 Supplemental petition, page 5.
25 See In re Sivertz, supra.

Telephone inquiries should be directed to Senior Attorney Paul Shanoski at (571) 272-3225.

Charles Pearson
Director
Office of Petitions
United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

David E. Wildman
Hoffman-La Roche Inc.
Patent Law Department
340 Kingsland Street
Nutley NJ 07110

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,927,814

MAR 20 2007

Dear Mr. Wildman :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,814 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: BONIVA® (ibandronate)
FDA Docket No.: 2004E-0444

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Diagnostics GmbH	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,927,814	:	INTERIM EXTENSION

Roche Diagnostics GmbH, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,927,814, acting through their agent Hoffman-LaRoche, filed an application for patent term extension under 35 U.S.C. § 156 on July 14, 2003. The original term of the patent is due to expire on July 9, 2007. The patent claims the active ingredient ibandronate in the human drug product BONIVA® which was approved by the Food and Drug Administration for commercial marketing or use on May 16, 2003. An extension of 1,713 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,814 is granted for a period of one year from the original expiration date of the patent.

3/15/07
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR - 9 2007

John W. Hogan, Jr.
American Home Products Corporation
Patent Section
Five Giralda Farms
Madison, NJ 07940-0874

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,916,154

Dear Mr. Hogan:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,916,154 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Cydectin® (moxidectin)
FDA Docket No.: 2004E-0040

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Wyeth Holdings Corporation	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,916,154	:	INTERIM EXTENSION

Wyeth Holdings Corporation, through the previous owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,916,154, American Cynamid Company, filed an application for patent term extension under 35 U.S.C. § 156 on March 27, 1998. The original term of the patent is due to expire on April 10, 2007. The patent claims the active ingredient moxidectin in the animal drug product Cydectin® which was approved by the Food and Drug Administration for commercial marketing or use on January 28, 1998. An extension of 1,754 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,916,154 is granted for a period of one year from the original expiration date of the patent.

3/07/07
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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JAN 29 2008

John W. Hogan
Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940-0874

In re Patent Term Extension Application of	:
U.S. Patent No. 4,916,154	:
Issue Date: April 10, 1990	: Decision on Petition to
U.S. Application No. : 07/088,953	: Stay Grant of Certificate in Patent
PTE Filing Date: March 27, 1998	: Term Extension Application
For: 23-Imino Derivatives of LL-F28249	:
Compounds	

The above-identified application has been forwarded to the Office of Patent Legal Administration in the United States Patent and Trademark Office (the "USPTO") for consideration of a petition titled "Petition under 37 C.F.R. § 1.182 for Stay of Grant of Patent Term Extension Certificate," in U.S. Patent No. 4,916,154, which was filed on January 9, 2008.

The petition is granted for a period of 6 months from the mailing date of this decision.

Background and Analysis

On November 20, 2006, Petitioner requested revision of the regulatory review period that the Food and Drug Administration ("FDA") determined and published in the Federal Register on September 20, 2006 at page 54993 of volume 71.

On May 8, 2007, the FDA sent a final determination of the regulatory review period to the USPTO stating, "FDA considers the regulatory review period determination to be final."

On June 13, 2007, the USPTO sent a notice of final determination to Petitioner indicating that the USPTO had relied upon the dates of the regulatory review period as published by FDA in the Federal Register of September 20, 2006, found at page 54993 in volume 71 and determined the term extension to be 1,434 days. The USPTO's letter set forth a time period of one month, from the date of the letter, for requesting reconsideration of the amount of term calculated therein.

On July 10, 2007, in accordance with 37 C.F.R. § 1.10, Petitioner submitted a request for reconsideration of the term calculated by the USPTO, indicating that on November 20, 2006, Petitioner submitted, through outside counsel, a request for revision of the regulatory review period to FDA. Petitioner indicated that the May 8, 2007, letter from FDA did not include a reference to Petitioner's November 20, 2006, request for revision of the determination of the regulatory review period.

On January 9, 2008, Petitioner filed the present petition where Petitioner now petitions for a stay of the issuance of the certificate of extension so that FDA can consider and act on the November 20, 2006, submission relating to Petitioner's request for revision of the determination of the regulatory review period.

The Office treats the present petition as falling under 37 C.F.R. § 1.182, which addresses all situations not specifically provided for in other regulations. Further, the Office analogizes the request made by Petitioner to requests for staying action in patent applications and for deferring issuance of a patent filed under 37 C.F.R. § 1.103 and 37 C.F.R. § 1.314, respectively. The standard for granting requests under both 37 C.F.R. § 1.103 and 37 C.F.R. § 1.314 is good and sufficient cause. Accordingly, the Office shall apply that same good and sufficient cause standard to the present petition under 37 C.F.R. § 1.182.

Because a stay in the proceedings of the patent term extension application for providing an opportunity for FDA to consider and act on Petitioner's timely submission requesting revision of the determination of the regulatory review period appears to constitute good and sufficient cause, a stay is **granted** for a time period of 6 months from the mailing date of this decision.

Conclusion

The petition under 37 C.F.R. § 1.182 is granted for a period of 6 months from the mailing date of this decision.

The rules and statutory provisions governing the operations of the U.S. Patent and Trademark Office require payment of a fee on filing a petition. *See* 37 C.F.R. § 1.17(f). The required petition fees have been received for the present petition.

Telephone inquiries with regard to this communication should be directed to Mary C. Till at (571) 272-7755.

Mary C. Till

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Cydectin® (moxidectin)
FDA Docket No.: 2004E-0040

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313-1450
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MAR 2 1 2008

John W. Hogan, Jr.
Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940-0874

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,916,154

Dear Mr. Hogan:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,916,154 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: CYDECTIN® (moxidectin)
FDA Docket No.: 2004E-0040

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Wyeth Holdings Corporation	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,916,154	:	INTERIM EXTENSION

Wyeth Holdings Corporation, through the previous owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,916,154, American Cyanamid Company, filed an application for patent term extension under 35 U.S.C. § 156 on March 27, 1998. The extended term of the patent is due to expire on April 10, 2008. The patent claims the active ingredient moxidectin in the animal drug product CYDECTIN® which was approved by the Food and Drug Administration for commercial marketing or use on January 28, 1998. An extension of 1,754 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,916,154 is granted for a period of one year from the extended expiration date of the patent.

3/14/08
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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P.O. Box 1450
Alexandria, VA 22313-1450
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Date: 04/24/08

Patent No. : 4779635 C1
Ser. No. : 07/089,441
Inventor(s) : LYNCH, JAMES P.
Issued : 03/20/07
Title : **COLLAPSIBLE CANOPY WITH TELESCOPING ROOF SUPPORT STRUCTURE**
Docket No. : **1228**

Re: Request for Certificate of Correction

Consideration has been given your request for the issuance of a certificate of correction for the above-identified patent under the provisions of Rule(s) 1.322 and/or 1.323.

Assignees' names and addresses (assignment data) printed in a patent, are based *solely* on information supplied in the appropriate space for identifying the assignment data, i.e., item 3 of the Issue Fee Transmittal Form PTOL-85B. Granting of a request under 37 CFR 3.81(b) is required to correct applicant's error providing ***incorrect or erroneous*** assignment data, *before* issuance of a Certificate of Correction, under 37 CFR 1.323 *(see Manual of Patent Examining Procedures (M.P.E.P) Chp.1400, sect. 1481).* This procedure is required *at any time after the issue fee is paid*, including after issuance of the patent.

In view of the foregoing, your request, in this mater, is hereby denied.

A request to correct the Assignee under 37 CFR 3.81(b) should include:

A. **the processing fee set forth in 37 CFR 1.117(h) (currently $130);**
B. a statement that the failure to include the correct assignee name on the PTOL-85B was inadvertent; and
C. a copy of the Notice of Recordation of Assignment Document, reflecting the reel and frame number where the assignment(s) is recorded and/or reflecting proof of *the date* the assignment was submitted for recordation.

In the Request, Applicant(s) may request that the file be forwarded to Certificates of Correction Branch, for issuance of a Certificate of Correction, if the Request is granted.

Any request under 37 CFR 3.81(b) should be directed to the following address or facsimile number:

By mail: Mail Stop PETITIONS

Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Service Window
Mail Stop Petitions
Randolph Building
401 Dulany Street
Alexandria, VA 22314

By fax: (703) 872-9306
ATTN: Office of Petitions

If a fee (currently $100) was previously submitted for consideration of a Request for Certificate of Correction, under CFR 1.323, to correct assignment data, no additional fee is required.

Lamonte M. Newsome
For Mary Diggs, Supervisor
Decisions & Certificates
Of Correction Branch
(703)-305-5358 or (703) 308-9390 #112

TIMOTHY J. MARTIN
9250 W. 5TH AVENUE, SUITE 200
LAKEWOOD CO 80226

LMN

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

Mailed: January 15, 2003

#51

Paul E. Dupont
Sanofi-Synthelabo Inc.
9 Great Valley Parkway
Malvern PA 19355

Re: Patent Term Extension
Application for
U.S. Patent No. 4,818,816

ACKNOWLEDGMENT OF WITHDRAWAL OF APPLICATION FOR PATENT TERM EXTENSION

This is in response to the "Express Withdrawal of Application for Extension of Patent Term," filed January 2, 2003 (duplicate copy received by facsimile on January 14, 2003).

The withdrawal of the application is hereby acknowledged and the application is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Karin Ferriter

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter

Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: Arixtra® (fondaparinux sodium)
FDA Docket No.: 02E-0098

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

NOV - 6 2007

Jay S. Cinamon
Abelman, Frayne & Schwab
666 Third Avenue, 10th Fl.
New York, NY 10017

Re: Patent Term Extension
Application for
U.S. Patent No. 4,948,805

ACKNOWLEDGMENT OF WITHDRAWAL OF APPLICATION FOR PATENT TERM EXTENSION

This is in response to the "Withdrawal of Application for Extension of Patent Term," filed October 24, 2007, of the application for patent term extension for U.S. Patent No. 4,948,805, (FLECTOR® PATCH (diclofenac epolamine topical patch)).

The withdrawal of the application is hereby acknowledged and the application is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-0100

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755. E-mail inquiries should be directed to mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: FLECTOR® PATCH
(diclofenac epolamine topical patch)
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
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THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP
100 GALLERIA PARKWAY, NW
STE 1750
ATLANTA GA 30339-5948

COPY MAILED

MAR 1 4 2005

OFFICE OF PETITIONS

In re Application of	:	
Wall, W. Henry	:	
Application No. 07/129,834	:	ON PETITION
Filed: December 8, 1987	:	
Attorney Docket No. 12310-1010	:	

This is a decision on the petition under 37 C.F.R. § 1.137(b), filed February 14, 2005, to revive the above-identified application.

The petition is **GRANTED.**

Petitioner has met the requirements to revive the above-identified application pursuant to 37 CFR 1.137(b).

This matter is being referred to Technology Center 3700 for further examination on the merits.

Telephone inquiries regarding this decision should be directed to the undersigned at (571) 272-3282.

Liana Chase
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP
100 GALLERIA PARKWAY, NW
STE 1750
ATLANTA GA 30339-5948

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DEC 2 2 2005

OFFICE OF PETITIONS

In re Application of	:	
Wall	:	
U.S. Patent No. 6,974,475	:	
Issue Date: December 13, 2005	:	Letter For
Application No. 07/129,834	:	Certificate of Correction
Filed: December 8, 1997	:	
For: ANGIOPLASTY STENT	:	

In response to a telephone call with George Thomas on December 21, 2005, the above-identified application has been forwarded to the undersigned for review of the extension information printed on the face of the patent. See 35 U.S.C. § 154(b)[1] and 37 C.F.R. § 1.701.

The Notice of Allowance and Issue Fee Due mailed on June 22, 2005, correctly indicated that the patent to issue from Application No. 07/129,834 was not eligible for a patent term extension, as the application was filed before June 8, 1995. The front page of the patent incorrectly indicates that the term of the patent is extended for 903 days. Since the filing date was before June 8, 1995, the patent to issue from the application is eligible only for a 17-year term, which does not permit a patent term extension.

After mailing of this letter, the Office will issue a certificate of correction in order to rectify the error regarding the patent term extension information. See 35 U.S.C. 254 and 37 CFR 1.322. The Office will issue a certificate of correction deleting the patent term extension information.

Telephone inquiries with regard to this communication should be directed to the undersigned at (571) 272-7709.

Mark Polutta
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

[1]35 U.S.C. § 154 was amended by the "American Inventors Protection Act of 1999," which was enacted on November 29, 1999 as part of Public Law 106-113 (Consolidated Appropriations Act for Fiscal Year 2000). Since this amendment is effective May 29, 2000 and applies to applications filed on or after that date, the existing patent term adjustment provisions of 35 U.S.C. § 154 continue to apply to the above-identified application.

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NOV 28 2007

David M. Gryte
Intervet Inc.
29160 Intervet Lane
Millsboro, DE 19966

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,900,735

Dear Mr. Gryte:

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,900,735 for a period of one (1) year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: ZILMAX® (zilpaterol hydrochloride)
FDA Docket No.: 2007E-0046

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Intervet International B.V.	:	
Request for Interim Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,900,735	:	**INTERIM EXTENSION**

Intervet International B.V., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,900,735, filed an application for patent term extension under 35 U.S.C. § 156 on October 6, 2006. The original term of the patent is due to expire on December 11, 2007. The patent claims the active ingredient zilpaterol hydrochloride in the animal drug product ZILMAX® which was approved by the Food and Drug Administration for commercial marketing or use on August 10, 2006. An extension of five (5) years is requested.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the original term of the patent will expire on December 11, 2007, before a certificate of patent term extension can be issued, an interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,900,735 is granted for a period of one year from the original expiration date of the patent, i.e., until December 11, 2008.

11/16/07
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
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#32

Mailed June 20, 2003

John S. Pratt
KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta GA 30309-4530

Re: Patent Term Extension
Application for
U.S. Patent No. 5,009,889

ACKNOWLEDGMENT OF WITHDRAWAL OF APPLICATION FOR PATENT TERM EXTENSION

This is in response to the "Express Withdrawal of Application for Extension of Patent Term," filed May 27, 2003, of the application for patent term extension for U.S. Patent No. 5,009,889, (XIGRIS™ (drotrecogin alpha)).

The withdrawal of the application is hereby acknowledged and the application is dismissed.

The petition fee ($130.00) will be refunded, since no petition fee was required for the withdrawal.

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter

Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: XIGRIS™ (drotrecogin alpha)
FDA Docket No.: 02E-

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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JUN 13 2006

Bruce A. Johnson
Fredrikson & Byron, P.A.
200 South Sixth Street
Suite 4000
Minneapolis, MN 55402

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,850,962

Dear Mr. Johnson:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,850,962 for a period of one year.

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: Esteem™
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Envoy Medical Corporation	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,850,962	:	**INTERIM EXTENSION**

On March 31, 2006, patent owner, Envoy Medical Corporation, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,850,962. The patent claims the medical device Esteem™ (a totally implantable hearing system). The application indicates that an Investigational Device Exemption for the medical device Esteem™ has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (July 25, 2006), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for one year, i.e., until July 25, 2007.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,850,962 is granted for a period of one year from the original expiration date of the patent, i.e., until July 25, 2007.

6/12/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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P.O. Box 1450
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Blank Rome LLP
600 New Hampshire Avenue, N.W.
Washington, DC 20037

MAILED
FROM DIRECTORS OFFICE

MAY 24 2007

TECHNOLOGY CENTER 3600

In re patent of :
Tateki Jozaki et al. :
Patent No. 7,169,070 :
Issued: January 30, 2007 :
For: TRANSMISSION CONTROLLER OF A V-BELT TYPE CONTINUOUSLY VARIABLE AUTOMATIC TRANSMISSION :

NOTIFICATION OF IMPROPER PRIOR ART CITATION UNDER 37 CFR 1.501

The prior art citation filed by the patent owner under 37 CFR 1.501 on March 9, 2007 is hereby acknowledged to have been received and reviewed by the Patent and Trademark Office. The requirements for a proper prior art citation under 37 CFR 1.501 are as follows:

A) prior art submitted must be limited to "written prior art consisting of patents and publications". Any submission that contains any issue not directed to patents and publications will not be entered into the file and will be returned unconsidered, despite the fact that it may also contain "properly considerable" prior art. MPEP 2205.

B) an explanation of how the person submitting the prior art considers it to be pertinent and applicable to the patent. MPEP 2205.

C) if filed by a party other than the patent owner, an explanation of why it is believed that the prior art has a bearing on the patentability of any claim of the patent. MPEP 2205.

D) if filed by a party other than the patent owner, an indication must be present that a copy of the submission has been served on the patent owner, or includes a duplicate copy if service on the patent owner was not possible.

The prior art submission of March 9, 2007 lack item A) above. It is not clear that the submitted Office action from the Japanese Patent Office is a published document. Accordingly, the submission is hereby returned to the patent owner as an attachment to this Notification as per the procedure outlined in MPEP 2206.

Telephone inquiries relative to this letter should be directed to Quality Assurance Specialist Steven N. Meyers at (571) 272-6611.

Katherine Matecki, ACTING

Katherine Matecki, Director
Patent Technology Center 3600
(571) 272-5250

SM: 5/24/07
SM

Attachment: Submission under 37 CFR 1.501 filed March 9, 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON TX 77056

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NOV 0 6 2008

OFFICE OF PETITIONS

In re Application of:	:	
Ivan G. Rice	:	
Pat. Num.: 4835958	:	
Issue Date: 03/16/1988	:	
Application No. 07/170647	:	ON PETITION
Filing or 371(c) Date: 03/16/1988	:	
Title of Invention: PROCESS FOR	:	
DIRECTING A COMBUSTION GAS	:	
STREAM ONTO ROTATABLE BLADES	:	
OF A GAS TURBINE	:	

This is a decision on the Petition for Replacement Letters Patent Under 37 C.F.R. § 1.182, filed September 4, 2008.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

Questions concerning this decision may be directed to the undersigned at 571-232-3232. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Niomi Farmer, in the Office of Data Management at (703) 308-9250, Ext. 129.

A copy of this decision is being faxed to the Office of Data Management for issuance of a duplicate Letters Patent.

/Derek L. Woods/
Derek L. Woods
Attorney
Office of Petitions

CC: Niomi Farmer
South Tower 8th floor, Room C-32 (FAX 571-270-9937)

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 237

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

DOUGLAS G. NOILES,
Junior Party,[1]

v.

John C.T. Church,
Senior Party.[2]

MAILED
MAR - 3 1997
PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Interference No. 102,732

CORRECTED JUDGMENT

[1] Application 07/485,944, filed February 27, 1990. Accorded the benefit of Application 07/342,722, filed April 24, 1989, now U.S. Patent No. 4,960,427, issued October 2, 1990; Serial No. 07/069,821, filed July 6, 1987; Serial No. 06/553,520, filed November 21, 1983, now U.S. Patent No. 4,678,472, issued July 7, 1987.

[2] Application 07/021,609, filed March 2, 1987. Accorded the benefit of Application 06/482,708, filed April 6, 1983 and United Kingdom Application 8210272, filed April 7, 1982.

Interference No. 102,732

Before METZ, PATE, and MARTIN, Administrative Patent Judges.

PATE, Administrative Patent Judge.

Judgment in Interference No. 102,732 is entered in favor of Douglas G. Noiles, the junior party. Douglas G. Noiles is entitled to his U.S. Patent No. 4,678,472 containing claims 1, 4, 5, and 8, which claims correspond to count 1 in interference. Douglas G. Noiles is also entitled to a patent with respect to his application Serial No. 07/485,944 containing claims 1 and 2, which claims correspond to count 1 in interference. Douglas G. Noiles is also entitled to a patent with respect to his application Serial No. 07/191,225 containing claims 1, 4, 5, 8, 11, and 14, which claims correspond to count 1 in interference.

Judgment is entered against John C. T. Church, the senior party. John C. T. Church is not entitled to a patent containing claims 34 through 43, 53, 54, 60, 61, and 70 though 72, which claims correspond to count 1 in interference.

Andrew H. Metz)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
) APPEALS
William F. Pate, III)
Administrative Patent Judge) AND
) INTERFERENCES
)
)
John C. Martin)
Administrative Patent Judge)

dem

Interference No. 102,732

Maurice M. Klee
Fish & Neave
1251 Avenue of the Americas
New York, NY 10020

Paul N. Kokulis
Cushman, Darby & Cushman
Ninth Floor
1100 New York Avenue, NW
Washington, DC 20005-3918

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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Paper No. 29

WENDY M. LEE
GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080-4990

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MAY 07 2002

OFFICE OF PETITIONS

In re Patent No. 6,331,415 :
Issue Date: December 18, 2001 :
Application No. 07/205,419 : ON PETITION
Filed: June 10, 1988 :
Attorney Docket No. 010057-051 :

This is a decision on the petition filed February 7, 2002, to waive the rules and accept the correction of the assignee on the front page of the above-identified patent.

The petition is granted.

There is no indication that the person signing the instant petition was ever given a power of attorney or authorization of agent to prosecute the above-identified application. If the person signing the instant petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. While a courtesy copy of this decision is being mailed to the person signing the instant petition, all future correspondence will be directed to the address currently of record until such time as appropriate instructions are received to the contrary.

The file is being forwarded to the Certificates of Correction Branch for issuance of the requested Certificate of Correction.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 305-8859.

Karen Creasy

Karen Creasy
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

Certificate

MAY 22 2002

of Correction

cc:
SHARON E. CRANE
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P. O. BOX 1404
ALEXANDRIA, VA 22313-1404

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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KEVIN MCMAHON
69 PROSPECT AVENUE
LARCHMONT NY 10538

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MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 6,107,023 :
Issue Date: 22 August, 2000 :
Application No. 07/208,512 : ON PETITION
Filed: 17 June, 1988 :
Attorney Docket No. 4600-0062 :

This is a decision on the petition under 37 C.F.R. §1.378(c), filed on 29 August, 2008, to accept the unintentionally delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED**.

This patent expired after midnight 22 August, 2008, for failure to pay the first maintenance fee.

Because the instant petition was submitted within twenty-four months after the six-month grace period provided in 37 C.F.R. §1.362(e), the petition was timely filed under the provisions of 37 C.F.R. §1.378(c).

The maintenance fee is hereby accepted and the above-identified patent is reinstated as of the mail date of this decision.

The patent file is being released to IFW Files Repository.

Patent No. 6,107,023
Application No. 07/208,512

Telephone inquiries regarding this decision may be directed to the undersigned at (571) 272-3214—it is noted, however, that all practice before the Office is in writing (see: 37 C.F.R. §1.2[1]) and the proper authority for action on any matter in this regard are the statutes (35 U.S.C.), regulations (37 C.F.R.) and the commentary on policy (MPEP). Therefore, no telephone discussion may be controlling or considered authority for Petitioner's action(s).

/John J. Gillon, Jr./
John J. Gillon, Jr.
Senior Attorney
Office of Petitions

[1] The regulations at 37 C.F.R. §1.2 provide:

§1.2 Business to be transacted in writing.

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,918,515	:	
Issue Date: April 17, 1990	:	
Application No. 07/209,192	:	DECISION ON PETITION
Filed: June 20, 1988	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '515 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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Paper No. 25

Dr. Kenneth R. Fox
White Star Holdings, Ltd.
C/O The Service Group
Dowdeswell St.
Nassau 00000 BS Bahamas

COPY MAILED

MAY 0 3 2002

OFFICE OF PETITIONS

ON PETITION

In re Patent of:
Fox, *et al.*
Application No. 07/227,000
U. S. Patent No. 4848336
Issued: July 18, 1989

This is a decision on the January 24, 2002 petition under 37 C.F.R. §1.378(c) to accept the unintentionally delayed payment of the maintenance fee on an expired patent.

The petition is **GRANTED**.

The USPTO issued this patent on July 18, 1989. Therefore, the final maintenance fee became payable 11 years later on July 18, 2000 and remained payable through July 18, 2001. However, as of the deadline, no payment was received. Therefore, the patent expired as of July 19, 2001.[1]

All requirements have been met for the filing of a petition under 37 C.F.R. §1.378(c) and, pursuant to 37 C.F.R. §1.378(a), the patent shall be treated as not having been expired.

There is no indication that Petitioner herein was ever empowered to prosecute the instant application. Therefore, there is insufficient information to make determinable whether the statement of unintentional delay was signed by a person who would have been in a position of knowing that the delay in paying the maintenance fee was unintentional. Nevertheless, in accordance with 37 C.F.R. §10.18, the statement is accepted as constituting a certification of unintentional delay. However, in the event that Petitioner has no knowledge that the delay was in fact unintentional, Petitioner should make a reasonable inquiry to ascertain that, in fact, the delay was unintentional. If Petitioner discovers that the delay was intentional, Petitioner must so notify the Office. If Petitioner desires to receive future correspondence regarding this application, the appropriate power of attorney documentation must be submitted. A courtesy copy of this decision will be mailed to Petitioner. However, all future correspondence will be directed to the address of record until such time as appropriate instructions are received to the contrary.

This file will be forwarded to Files Repository.

---

[1] See 35 U.S.C. §21, 35 U.S.C. §41(b), 37 C.F.R. §1.362(d) & (e), M.P.E.P. 2506.

Telephone inquiries concerning this matter may be directed to the undersigned in the Office of Petitions at (703) 306-5593.

Scott M. Ledford
Attorney
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Jay S. Cinnamon
Abelman, Frayne, & Schwab
150 East 42nd Street
New York, NY 10017-5612

#23

UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 21 2006

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www.uspto.gov

OBLON, FISHER, SPIVAK,
MC CLELLAND & MAIER
CRYSTAL SQUARE FIVE - SUITE 400
1755 SOUTH JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

In re Patent No. 4, 935, 507 TAKAYA ET AL. Issue Date: June 19, 1990 Appl No.: 07/229,489 Filed: August 08, 1988 For: Correction of Inventorship	**DECISION GRANTING PETITION** *37 CFR 1.324*

This is a decision on the petition filed August 4, 2006, to correct inventorship under 37 CFR 1.324.

The petition is granted.

The patented file is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

William R. Dixon, Jr
Special Program Examiner
Technology Center 1600

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Certificate
NOV 03 2006
of Correction

DATE: October 31, 2006
TO: Certificates of Correction Branch
FROM: William R. Dixon, Jr.
Technology Center 1600
SUBJECT: REQUEST FOR CERTIFICATE OF CORRECTION

Please issue a Certificate of Correction in U. S. Letters Patent No. 4,935,507 as specified on the attached Certificate.

William R. Dixon, Jr.
Technology Center 1600

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
WWW.USPTO.GOV

Paper No. 7

BRIAN D. OGONOWSKY
PATENT LAW GROUP
2635 N. FIRST ST.
SUITE 223
SAN JOSE, CA 95134

COPY MAILED

MAY 23 2003

OFFICE OF PETITIONS

In re Patent No. 4,832,342	:	
Issue Date: May 23, 1989	:	
Application No. 07/230,705	:	ON PETITION
Filed: August 5, 1988	:	
Patentee(s) Jerome B. Plevyak et al	:	

This is a decision on the petition under 37 CFR 1.378(c), filed May 16, 2003, to accept the delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED**.

The maintenance fee is hereby accepted and the above-identified patent is reinstated as of the mail date of this decision.

Pursuant to petitioner's authorization, Deposit Account No. 50-2226 was charged a total of $4,790.00 -- $1,640.00 for the surcharge and $3,150.00 for the 11½ years maintenance fee.

Telephone inquiries concerning this decision should be directed to Wan Laymon at (703) 305-9282.

The patent file is being forwarded to Files Repository.

Wan Laymon
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,943,849	:	
Issue Date: July 24, 1990	:	
Application No. 07/239,298	:	DECISION ON PETITION
Filed: September 1, 1988	:	
Inventor: Yves C. Faroudja et al	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED**.

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '849 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

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DEC 29 2008

David B. Quick
ICE MILLER LLP
One American Square
Suite 2900
Indianapolis, IN 46282-0200

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,919,140

Dear Mr. Quick :

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,919,140 for a period of 1 year. A copy of the Federal Register notice published in accordance with 35 U.S.C. 156(d)(5)(B) on October 20, 2008 at 73 Fed. Reg. 62260 is enclosed herewith. While a courtesy copy of this letter and the application for interim extension is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Andara™ OFS™ System
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Purdue Research Foundation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,919,140	:	**INTERIM EXTENSION**

On September 29, 2008, the patent owner, Purdue Research Foundation, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,919,140. The patent claims the medical device known as Andara™ OFS™ System and a method of using the Andara™ OFS™ System. The application indicates that a Humanitarian Device Exemption, HDE 070002, for the medical device Andara™ OFS™ System has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the expiration date of the patent (October 14, 2008), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,919,140 is granted for a period of one year from the expiration date of the patent, i.e., until October 14, 2009.

October 14, 2008
Date

Jon W. Dudas
JON W. DUDAS
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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OCT 20 2009

David B. Quick
ICE MILLER LLP
One American Square
Suite 2900
Indianapolis, IN 46282-0200

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,919,140

Dear Mr. Quick :

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,919,140 for a period of 1 year. A copy of the Federal Register notice published in accordance with 35 U.S.C. 156(d)(5)(B) on October 16, 2009 at 74 Fed. Reg. 53217 is enclosed herewith. While a courtesy copy of this letter and the interim extension is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail to mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Andara™ OFS™ System
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Purdue Research Foundation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,919,140	:	**INTERIM EXTENSION**

On September 11, 2009, the patent owner, Purdue Research Foundation, timely filed a second application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,919,140. The patent claims the medical device known as Andara™ OFS™ System and a method of using the Andara™ OFS™ System. The application indicates that a Humanitarian Device Exemption, HDE 070002, for the medical device Andara™ OFS™ System has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (October 14, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

A second interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,919,140 is granted for a period of one year from the expiration date of the patent, i.e., until October 14, 2010.

10/09/09
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

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MAR 3 0 2009

OFFICE OF PETITIONS

In re Patent No. 4,876,596	:	
Issue Date: October 24, 1989	:	
Application No. 07/262,321	:	DECISION ON PETITION
Filed: October 25, 1988	:	
Inventor: Yves C. Faroudja	:	

This is a decision on the petitions, filed August 15, 2008, and October 7, 2008, pursuant to 37 CFR §§ 1.59(b), and 1.183. The petition is being treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent.

The petition under 37 CFR § 1.183 is **dismissed as premature**.

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '385 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

A review of the complete file history in this case indicates that there is no petition decision mailed September 19, 2008, as alleged in petitioner's Request for Reconsideration under 37 CFR § 1.183. Hence the petition under 37 CFR § 1.183 petition is dismissed as being premature.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and

(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The

assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

In addition, the petition fee paid is not sufficient. A petition under 37 CFR § 1.182 requires the payment of $400.00. However, only $200.00 has been paid due to the erroneous assumption that the petition was properly filed under 37 CFR § 1.59. A petition under 37 CFR § 1.59 applies to application files, not assignment records. The $200.00 payment has been credited to petitioner's Deposit Account 50-4481. A petition to expunge assignment documents is properly addressed under 37 CFR § 1.182 and a fee of $400.00 is required. As authorized, the required fee of $400.00 has been charged to petitioner's Deposit Account 50-4481.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

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MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,951,149	:	
Issue Date: August 21, 1990	:	
Application No. 07/263,534	:	DECISION ON PETITION
Filed: October 27, 1988	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '149 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

NOTICE RE: CERTIFICATES OF CORRECTION

27

DATE : 5-12-00

TO : Supervisor, Art Unit 1202

SUBJECT: Certificate of Correction Request in Patent No. 5004758

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

- [x] 1. Would the change(s) requested under 37 CFR 1.323 constitute new matter or require reexamination of the application'
- [x] 2. Would the change(s) requested under 37 CFR 1.323 Materially affect the scope or meaning of the claims allowed by the examiner in the patent?
- [ ] 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Should the change request be granted?
- [ ] 4. With respect to the change(s) requested, correcting Office errors, should the patent read as shown in the certificate of correction?
- [ ] 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO ROOM 918, PK III

Eva James E. James

Legal Insturment Examiner

TO: CERTIFICATE OF CORRECTION BRANCH | DATE:

The decision regarding the change(s) requested in the certificate of correction is shown below.

[x] 1.YES (in part)	[ ] NO	[x] Comments below
[ ] 2.YES	[x] NO	[ ] Comments below
[ ] 3.YES	[ ] NO	[ ] Comments below
[ ] 4.YES	[ ] NO	[ ] Comments below
[ ] 5.YES	[ ] NO	[ ] Comments below

[x] Comments The changes requested to column 40 (both instances) do not appear to be the equivalent of 10 lbs/in^2. The conversion factor is of the order of 0.31 so 704.6 g/cm^2 appears incorrect. Also the requested change is not consistently made, See col. 41, line 59.

Mukund J. Shah — Supervisor

1624 — Art Unit

EB

PTOL-306 (REV. 10/87)

U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

NOTICE RE: CERTIFICATES OF CORRECTION

DATE : 7-11-00

TO : Supervisor, Art Unit 1803

SUBJECT: Certificate of Correction Request in Patent No. ~~5405939~~ 5004758

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

☐ 1. Would the change(s) requested under 37 CFR 1.323 constitute new matter or require reexamination of the appl

☐ 2. Would the change(s) requested under 37 CFR 1.323 Materially affect the scope or meaning of the claims allow by the examiner in the patent?

☐ 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Sho the change request be granted?

☒ 4. With respect to the change(s) requested, correcting Office errors, should the patent read as shown in the certifi of correction? Reconsideration (See attached Sheet, faxed by Applicant

☐ 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO ROOM 918, PK III

Eva James E. James

Legal Insturment Examiner

Please do not send to warehouse

TO: CERTIFICATE OF CORRECTION BRANCH | DATE:

The decision regarding the change(s) requested in the certificate of correction is shown below.

☐ 1.YES	☐ NO	☐ Comments below
☐ 2.YES	☐ NO	☐ Comments below
☐ 3.YES	☐ NO	☐ Comments below
☒ 4.YES	☐ NO	☐ Comments below
☐ 5.YES	☐ NO	☐ Comments below

☐ Comments _____

R Ruggiero 1620

Supervisor

1620

Art Unit

PTOL-306 (REV. 10/87)

U.S. DEPARTMENT OF COMMERCE Patent and Trademark

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,004,758
DATED : April 2, 1991
INVENTOR(S) : Boehm, et. al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 31, line 34, before "Unless", insert -- NMR spectra are given in δ units --;

In column 33, line 61, after "Hz,", insert -- ,C19--;

In column 35, line 4, delete "CH_3H_2O", and insert therefor -- CH_3SO_3H --;

In column 36, line 68, delete "1.B5", and substitute therefor -- 1.05 --;

In column 37, line 55, delete "9-Dimethylaminoethyl-10-hydroxycamptothecin" and substitute therefor -- 9-Dimethylaminomethyl-10-hydroxycamptothecin --;

In column 38, line 7, delete "9-Dimethylaminoethyl-10-hydroxycamptothecin" and substitute therefor -- 9-Dimethylaminomethyl-10-hydroxycamptothecin --;

In column 38, line 25, delete "9-Dimethylaminoethyl-10-hydroxycamptothecin" and substitute therefor -- 9-Dimethylaminomethyl-10-hydroxycamptothecin --;

In column 39, line 47, delete "(MH^{30})", and substitute therefor -- (MH^+) --;

In column 40, line 38, delete "(1785.8 grams/cm)", and substitute therefor --

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,004,758

DATED : April 2, 1991

INVENTOR(S) : Boehm, et. al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

--703.1 g/cm^2)--; and

In column 40, line 59, delete "(1785.8 grams/cm)", and substitute therefor -- --703.1 g/cm^2)--.

In column 41, line 28, delete "(3,2)", and substitute therefor -- (s,2) --;

In column 42, line 1, delete "$C_{24}H_{25}N_3O_u \cdot 10\ H_2O$)", and substitute therefor -- $C_{24}H_{25}N_3O_7 \cdot 10\ H_2O$)--; and

In column 42, line 5, delete "5.0(3,2)", and substitute therefor -- 5.0(s,2)--.

Signed and Sealed this

Twenty-fourth Day of October, 2000

Attest:

Attesting Officer

Q. TODD DICKINSON

Director of Patents and Trademarks

28

NOTICE RE: CERTIFICATES OF CORRECTION

DATE : 8-1-00

TO : Supervisor, Art Unit 1202

SUBJECT: Certificate of Correction Request in Patent No. 5004758

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

- [x] 1. Would the change(s) requested under 37 CFR 1.323 constitute new matter or require reexamination of the appl
- [x] 2. Would the change(s) requested under 37 CFR 1.323 Materially affect the scope or meaning of the claims allow by the examiner in the patent?
- [ ] 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Sho the change request be granted?
- [x] 4. With respect to the change(s) requested, correcting office errors, should the patent read as shown in the certifi of correction?
- [ ] 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO ROOM 918, PK III

Eva James

Legal Instrument Examiner

Please do not send to Warehouse Thanks.

TO: CERTIFICATE OF CORRECTION BRANCH | DATE:

The decision regarding the change(s) requested in the certificate of correction is shown below.

[ ] 1.YES	[x] NO	[ ] Comments below
[ ] 2.YES	[x] NO	[ ] Comments below
[ ] 3.YES	[ ] NO	[ ] Comments below
[x] 4.YES	[ ] NO	[ ] Comments below
[ ] 5.YES	[ ] NO	[ ] Comments below

[ ] Comments _____

R Rupnick — Supervisor

1624 — Art Unit

PTOL-306 (REV. 10/87)

U.S. DEPARTMENT OF COMMERCE Patent and Tradema

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: _____

DATE : 4/1/2008

TO SPE OF : ART UNIT **2800 (2889)**

SUBJECT : Request for Certificate of Correction on Patent No.:**7,276,846**

Attn: Ashok Patel

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and forward within **7** days to: **Scanning customer Support**

Send copy also via PTO mail to:
Certificates of Correction Branch – 2900 South Tower 9A39A
Palm location **7580** - Tel. No. 308-8309

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

***ok to enter changes to claim dependencies as req. in COCIN? eDan.**

Ernest C. White, LIE - 308-9390x122
Certificates of Correction Branch

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

_X_ **Approved**	**All** changes apply.
___ **Approved in Part**	Specify below which changes **do not** apply.
___ **Denied**	State the reasons for denial below.

Comments:
Col. 14, line 32 (claim 4): Ok to enter a change of dependency from "claim 3" to --claim 5--.

/Ashok Patel/
Ashok Patel 2889
For SPE (Minh-Toan Ton) AU 2889 **Art Unit**

UNITED STATES PATENT AND TRADEMARK OFFICE

Technology Center 1700

JAN 11 2004 rvk

Mailed:_____ Paper Number: ____

In re application of :
Hiroshi Maeda et al : DECISION ON
Serial No. 07/293,465 : PETITION
Filed: January 04, 1989 :
For: HIGH-TEMPERATURE OXIDE SUPERCONDUCTOR:

This is a response to the PETITION TO WITHDRAWAL OF ABANDONMENT FOR FAILURE TO RECEIVE OFFICIAL ACTION DATED APRIL 10, 2003, filed May 12, 2004. The petition requests that the abandonment, as set forth in the Notice of Abandonment of October 22, 2003, for failure to timely file a proper response to the Office letter dated April 10, 2003 be withdrawn. The petitioner asserts that the Office letter of April 10, 2003 was not received by applicants.

DECISION

The instant request is accepted as a petition under 37 C.F.R. 1.181 (no fee), and is evaluated under the procedures regarding an acceptable showing of non-receipt of an office action. See MPEP 711.03(c)(II).

The evidence presented is sufficient to establish that the Office letter of April 10, 2003 was not received by petitioner. The evidence provided includes a statement by the petitioner that the Office letter of April 10, 2003 was not received, a statement that a search of the file and docket records was made, and a statement that the search revealed the Office letter of April 10, 2003 was not received. A review of the instant application file indicates that the applicants filed an addresss change on February 03, 1998 to change the correspondence address to :

UNITED STATES PATENT AND TRADEMARK OFFICE

Technology Center 1700

WENDEROTH, LIND & PONACK, LLP
2033 K STREET, N.W.
SUITE 800
WASHINGTON, D.C. 20006

The Decision of the Board of Patent Appeal and Interferences dated September 25, 2001 was mailed to the changed address. However, both the Office letter dated April 10, 2003 and the Office letter dated October 22, 2003 were mailed to the old correspondence address.

Therefore, the abandonment is hereby withdrawn, and the application is returned to pending status. The application shall be forwarded to the examiner for prompt remailing of the Office letter of April 10, 2003 to the correct correspondence address and restarting of the statutory period of response from the remail date thereof.

The Petition is **GRANTED**.

Jacqueline Stone, Director
Technology Center 1700
Chemical and Materials Engineering

WENDEROTH, LIND & PONACK, LLP
2033 K Street N.W.
SUITE 800
WASHINGTON, D.C. 20006

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

AKIN GUMP STRAUSS HAUER & FELD LLP
1111 Louisiana Street
44th Floor
Houston, Texas 77002

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JUL 11 2007

OFFICE OF PETITIONS

In re Application of

CHING-WU CHU
Application No. 07/300,063
Filed: January 23, 1989
Attorney Docket No. NONE

DECISION ON PETITION
TO MAKE SPECIAL UNDER
37 C.F.R. § 1.102(c)

This is a decision on the petition under 37 CFR 1.102(c), filed on March 14, 2006, to make the above-identified application special based on superconductivity technologies as set forth in M.P.E.P. § 708.02, Section IX.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c) and MPEP § 708.02, Section IX: Special Status for Patent Applications Relating to Superconductivity, must be accompanied by a statement that the invention involves superconductive materials. Examples of such inventions would include those directed to superconductive materials themselves as well as to their manufacture and application. No fee is required.

The instant petition includes high temperature superconducting compositions and methods of using them to conduct electrical current. Characteristic of the claimed compositions' property is the near total loss of electrical resistance by the material when at or below the superconducting transition temperature. Accordingly, the above-identified application has been accorded "special" status.

Telephone inquiries concerning this decision should be directed to Thurman K. Page at 571-272-0602.

All other inquiries concerning either the examination or status of the application should be directed to the Technology Center.

The application is being forwarded to the Technology Center Art Unit 1751 for action on the merits commensurate with this decision.

David Bucci
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

F. Dominic Cerrito, Esq.
JONES DAY
222 East 41st Street
New York, New York 10017

FEB 19 2008

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,994,078

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156(d)(5) FOR U.S. PATENT NO. 4,994,078

This is in response to the application for interim extension of the term of U.S. Patent No. 4,994,078 ("the '078 patent") filed under 35 U.S.C. § 156(d)(5) in the United States Patent and Trademark Office ("USPTO") on February 1, 2008 ("the PTE Application"). The PTE Application was filed by Jarvik Heart Inc. ("Applicant"). Interim extension is sought based upon the continuing premarket review of the Jarvik 2000 Heart under section 515 of the Federal Food Drug and Cosmetic Act ("FFDCA"). Because the USPTO has determined that no application under section 515 of the FFDCA was submitted for the Jarvik 2000 Heart, Applicant's request for interim extension of the patent term of the '078 patent under 35 U.S.C. § 156(d)(5) is **DENIED.**

A. Factual Background

A pre-Investigational Device Exemption ("IDE") application was submitted to the FDA on November 16, 1998.

An IDE application was submitted to the FDA on March 2, 2000, and received by the FDA on March 3, 2000.

The IDE application was approved on March 31, 2000, and was assigned IDE No. G000058.

A Pre-Market Approval ("PMA") Shell was submitted to the FDA on November 20, 2007.

The PMA Shell was accepted on January 14, 2008, by FDA and assigned PMA Shell No. M070017.

On February 1, 2008, an application for interim patent term extension under 35 U.S.C. § 156(d)(5) was filed. The application for patent term extension seeks to extend U.S. Patent No. 4,994,078 under the statutory provisions of 35 U.S.C. § 156(d)(5) which govern interim extensions where a product claimed in a patent has not yet received approval for commercial marketing or use from the regulating agency.

On February 15, 2008, pursuant to 37 C.F.R. § 1.740(a)(13), Applicant filed a

Submission ("Submission") with the USPTO copies of correspondence to FDA in relation to the submission of PMA Module 1.

B. Decision

For a medical device, 35 U.S.C. § 156(d)(5) requires a regulatory review period under 35 U.S.C. § 156(g)(3)(B)(ii) to have begun

According to 35 U.S.C. § 156(g), the term "regulatory review period" includes a testing phase and an approval phase, see 21 C.F.R. § 60.22. Depending upon the type of product subject to regulatory review, the "testing phase" is defined in (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156. Similarly, depending upon the type of product subject to regulatory review, the "approval phase" is defined in (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) of subsection (g) of 35 U.S.C. § 156.

One of the requirements for an interim extension under 35 U.S.C. § 156(d)(5) is that the owner of record or his agent reasonably expects that the "approval phase" (recited in 156(d)(5)(A) as "the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii) and (5)(B)(ii) of subsection (g) of 35 U.S.C. § 156"), which must have **begun** for a product would continue beyond the original expiration of the patent term. In other words, in order to be eligible for an interim extension under 35 U.S.C. § 156(d)(5) for the subject medical device, a Pre-Market Approval application (PMA) must have been filed under section 515 of the FFDCA for Jarvik 2000 Heart. Specifically, section 156(d)(5)(A) provides (in part):

> If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration date of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire.

35 U.S.C. § 156(d)(5)(A).

Although page 2 of the initial application materials states that "[t]he product is subject to regulatory review under section 515 of the [FFDCA]," no PMA application under section 515 of the FFDCA for Jarvik 2000 Heart has been filed. In this regard, page 11 of the initial application materials states that a PMA Shell (M070017) was submitted on November 20, 2007. Further, page 1 of the Submission states that a Module 1: System Engineering for PMA Shell M070017 was submitted on January 30, 2008. However, neither the PMA Shell nor the PMA Module 1 constitutes "an application . . . initially submitted with respect to the device under section 515." Therefore, the applicable regulatory review period described in paragraph (3)(B)(ii) of subsection (g) of 35 U.S.C. § 156 has not begun.

In particular, the FDA does not consider the submission of a PMA shell or a first PMA module to trigger the beginning of the period described in paragraph (3)(B)(ii) of subsection (g). For example, with respect to the medical device Genesis Neurostimulation System, for which patent term extension was sought for U.S. Patent No. 4,793,353, the Applicant for extension proffered that the submission of a PMA Module 1 on April 3, 2001, started the regulatory review period of 156(g)(3)(B)(ii). FDA concluded that April 3, 2001 was not the date the premarket approval application for Genesis Neurostimulation System (PMA P010032) was initially submitted. Rather, FDA concluded that the date the application was initially submitted was the date that the PMA application was completed, i.e., May 29, 2001 (copies of FDA's letter of February 24, 2003, in relation to the patent term extension of U.S. Patent No. 4,793,353, and the Applicant's Exhibit E indicating submission of Modules 1 and 2 are attached hereto).

Since 35 U.S.C. § 156(d)(5) requires that, in the case of medical devices, a regulatory review under 35 U.S.C. § 156 (g)(3)(B)(ii) have begun, and a PMA under section 515 of the FFDCA triggering the regulatory review period under 156(g)(3)(B)(ii) has not been filed, the USPTO must deny Applicant's application for an interim extension under 35 U.S.C. § 156(d)(5) for U.S. Patent No. 4,994,078.

C. Conclusion

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,994,078 is not eligible for interim extension of the patent term under 35 U.S.C. § 156. A regulatory review period under 35 U.S.C. § 156(g)(3)(B)(ii) has not begun for the Jarvik 2000 Heart. Accordingly, the application for extension of the patent term is **DENIED**.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7728

Telephone inquiries related to this determination should be directed to the Raul Tamayo at (571) 272-7728.

Robert A. Clarke

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Building 51, Room 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: Jarvik 2000 Heart
FDA Docket No.:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Genesis Neurostimulation System
Docket No.: 02E-0149

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

FEB 24 2003

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,793,353, filed by Advanced Neuromodulation Systems, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Genesis Neurostimulation System, the medical device claimed by the patent.

The total length of the regulatory review period for Genesis Neurostimulation System is 469 days. Of this time, 292 days occurred during the testing phase and 177 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: August 11, 2000.

   The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on June 16, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 11, 2000, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: May 29, 2001.

   The applicant claims April 3, 2001, as the date the premarket approval application (PMA) for Genesis Neurostimulation System (PMA P010032) was initially submitted. However, FDA records indicate that PMA P010032 was submitted on May 29, 2001.

3. The date the application was approved: November 21, 2001.

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OFFICE OF PETITIONS

FDA has verified the applicant's claim that PMA P010032 was approved on November 21, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Peter Lando
Hughes & Luce, L.L.P.
Patent Docketing
1717 Main Street, Suite 2800
Dallas, TX 75201

EXHIBIT E

STATEMENT OF RELEVANT DATES AND INFORMATION PURUSANT TO 35 U.S.C. 156(g) AS SET FORTH IN 37 CFR § 1.740(a)(10)

1. The § 515(a)(2) Review was submitted on June 16, 1999. The § 515(a)(2) Review was determined on February 23, 2001. The FDA administrative record for the § 515(a)(2) Review is referenced and documented at the FDA under Docket # 00P-0788.

2. The Class III Review was submitted on April 3, 2001. The first section of the application concerned Module 1, whereby the manufacturing facility and design control information was reviewed. The application for Module 2 of the Class III Review was submitted on May 25, 2001 and approved on November 21, 2001. The PMA filing number for the Class III Review is P010032.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
WWW.USPTO.GOV

Paper No. 26

CORPORATE PATS. & TRADEMARKS,
THE UPJOHN COMPANY
KALAMAZOO MI 49001

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OFFICE OF PETITIONS

In re Application of :
Mahendra I. Amin et al. :
Application No. 07/312,401 :
Patent No. 4,902,683 :
Filed: February 17, 1989 :
Issue Date: February 20, 1990 :
Attorney Docket No.: 4121FW1 :
Title: CRYSTALLINE CEPHALOSPORIN :
HYDROHALIDE SALTS :

DECISION ON PETITION UNDER
37 C.F.R. §1.378(b)

This is a decision on the petition filed April 9, 2004, pursuant to 37 C.F.R. §1.378(b)[1] to revive the above-identified patent which has expired for failure to submit the 11½ year maintenance fee.

The patent issued February 20, 1990. The grace period for paying the 11½ year maintenance fee provided in 37 CFR 1.362(e) expired at midnight on February 20, 2002, with no payment received. Accordingly, the patent expired on February 20, 2002.

It is noted that a 460 day extension of the patent term from February 20, 2007, pursuant to 35 U.S.C. §156, was granted on July 15, 1998.

With the instant petition, Petitioner has submitted the required 11½ year maintenance fee, as well as the surcharge associated with the unavoidably late submission of a maintenance fee after

[1] Any petition to accept an unavoidably delayed payment of a maintenance fee filed under 37 C.F.R. §1.378(b) must include:
(1) The required maintenance fee set forth in 37 C.F.R. §1.20 (e) through (g);
(2) The surcharge set forth in 37 C.F.R. §1.20(i)(1), and;
(3) A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

expiration.

As such, Petitioner has met requirements (1) and (2) above. Regarding the third requirement, see the discussion below.

The standard

35 U.S.C. §41(c)(1) states:

The Director may accept the payment of any maintenance fee... after the six-month grace period if the delay[2] is shown to the satisfaction of the Director to have been unavoidable.

§1.378(b)(3) is at issue in this case. Acceptance of a late maintenance fee under the unavoidable delay standard is considered under the same standard for reviving an abandoned application under 37 C.F.R. §1.137(a). This is a very stringent standard. Decisions on reviving abandoned applications on the basis of "unavoidable" delay have adopted the reasonably prudent person standard in determining if the delay was unavoidable:

The word 'unavoidable' ... is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business[3].

In addition, decisions are made on a "case-by-case basis, taking all the facts and circumstances into account."[4] Nonetheless, a petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable."[5]

An adequate showing that the delay in payment of the maintenance fee at issue was "unavoidable" within the meaning of 35 U.S.C. 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent. Where the record fails to disclose that the patentee took reasonable steps, or discloses that the patentee took no steps, to ensure timely payment of the maintenance fee, 35 U.S.C. 41(c) and 37 C.F.R. §1.378(b)(3) preclude acceptance of the delayed payment of the maintenance fee under 37 CFR 1.378(b).

The general question asked by the Office is: "Did petitioner act as a reasonable and prudent person in relation to his most important business[6]?"

---

2 This delay includes the entire period between the due date for the fee and the filing of a grantable petition pursuant to 37 C.F.R. §1.378(b).

3 In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(*quoting* Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 U.S.P.Q. 666, 167-68 (D.D.C. 1963), aff'd, 143 U.S.P.Q. 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

4 Smith v. Mossinghoff, 671 F.2d at 538, 213 U.S.P.Q. at 982.

5 Haines, 673 F. Supp. at 316-17, 5 U.S.P.Q.2d at 1131-32.

Nonawareness of a PTO rule will not constitute unavoidable delay[7]

The burden of showing the cause of the delay is on the person seeking to revive the application[8].

A delay resulting from an error (e.g., a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay.

Such a showing should identify the specific error[9], the individual who made the error, and the business routine in place for performing the action which resulted in the error. The showing must establish that the individual who erred was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care. The showing should include information regarding the training provided to the personnel responsible for the docketing error, degree of supervision of their work, examples of other work functions carried out, and checks on the described work which were used to assure proper execution of assigned tasks.

A delay resulting from an error (e.g., a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown that:

(1) the error was the cause of the delay at issue[10],
(2) a business routine was in place for performing the clerical function that could reasonably be relied upon to avoid errors in its performance, and;
(3) the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care.

See MPEP 711.03(c)(III)(C)(2).

---

6 See In re Mattulah, 38 App. D.C. 497 (D.C. Cir. 1912).

7 See Smith v. Mossinghoff, 671 F.2d 533, 538, 213 U.S.P.Q. (BNA) 977 (Fed. Cir. 1982) (citing Potter v. Dann, 201 U.S.P.Q. (BNA) 574 (D.D.C. 1978) for the proposition that counsel's nonawareness of PTO rules does not constitute "unavoidable" delay)). Although court decisions have only addressed the issue of lack of knowledge of an attorney, there is no reason to expect a different result due to lack of knowledge on the part of a pro se (one who prosecutes on his own) applicant. It would be inequitable for a court to determine that a client who spends his hard earned money on an attorney who happens not to know a specific rule should be held to a higher standard than a pro se applicant who makes (or is forced to make) the decision to file the application without the assistance of counsel.

8 Id.

9 Petitioner must identify the error which caused the delay. If the specific error cannot be identified, the petitioner must identify any and all possible causes and prove that any of them, if they were the true cause, constitute unavoidable delay. A full and complete discussion for each possible error must be presented. A full and complete discussion of each possible error must be presented. Petitioner is reminded that petitioner has the burden of proof.

10 Petitioner must identify the error which caused the delay. If the specific error cannot be identified, the petitioner must identify any and all possible causes and prove that any of them, if they were the true cause, constitute unavoidable delay. A full and complete discussion for each possible error must be presented. A full and complete discussion of each possible error must be presented. Petitioner is reminded that petitioner has the burden of proof.

An adequate showing should include (when relevant):

(1) statements by all persons with direct knowledge of the circumstances surrounding the delay, setting forth the facts as they know them;
(2) a thorough explanation of the docketing and call-up system in use;
(3) identification of the type of records kept;
(4) identification of the persons responsible for the maintenance of the system;
(5) copies of mail ledger, docket sheets, filewrappers and such other records as may exist which would substantiate an error in docketing;
(6) include an indication as to why the system failed in this instance, and;
(7) information regarding the training provided to the personnel responsible for the docketing error, degree of supervision of their work, examples of other work functions carried out, and checks on the described work which were used to assure proper execution of assigned tasks.

A petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable[11]."

The portions of the MPEP relevant to the facts as presented

1415.01 Maintenance Fees on the Original Patent

The filing of a reissue application does not alter the schedule of payments of maintenance fees on the original patent. If maintenance fees have not been paid on the original patent as required by 35 U.S.C. 41(b) and 37 CFR 1.20, and the patent has expired, no reissue patent can be granted. 35 U.S.C. 251, first paragraph, only authorizes the granting of a reissue patent for the unexpired term of the original patent. Once a patent has expired, the Commissioner no longer has the authority under 35 U.S.C. 251 to reissue the patent. See In re Morgan, 990 F.2d 1230, 26 USPQ2d 1392 (Fed. Cir. 1993).

2504 Patents Subject to Maintenance Fees

37 CFR 1.362. Time for payment of maintenance fees.

(a) Maintenance fees as set forth in § § 1.20(e) through (g) are required to be paid in all patents based on applications filed on or after December 12, 1980, except as noted in paragraph (b) of this section, to maintain a patent in force beyond 4, 8 and 12 years after the date of grant.
(b) Maintenance fees are not required for any plant patents or for any design patents. Maintenance fees are not required for a reissue patent if the patent being reissued did not require maintenance fees.
(c) The application filing dates for purposes of payment of maintenance fees are as follows:
  (1) For an application not claiming benefit of an earlier application, the actual United States filing date of the application.
  (2) For an application claiming benefit of an earlier foreign application under 35 U.S.C. 119, the United States filing date of the application.
  (3) For a continuing (continuation, division, continuation-in-part) application claiming the benefit of a prior patent application under 35 U.S.C. 120, the actual United States filing date of the continuing application.
  (4) For a reissue application, including a continuing reissue application claiming the benefit of a reissue application under 35 U.S.C. 120, the United States filing date of the original non-reissue application on

11 Haines, 673 F. Supp. at 314, 316-17; 5 USPQ2d at 1131-32.

which the patent reissued is based.

(5) For an international application which has entered the United States as a Designated Office under 35 U.S.C. 371, the international filing date granted under Article 11(1) of the Patent Cooperation Treaty which is considered to be the United States filing date under 35 U.S.C. 363.

(d) Maintenance fees may be paid in patents without surcharge during the periods extending respectively from:
(1) 3 years through 3 years and 6 months after grant for the first maintenance fee,
(2) 7 years through 7 years and 6 months after grant for the second maintenance fee, and
(3) 11 years through 11 years and 6 months after grant for the third maintenance fee.

(e) Maintenance fees may be paid with the surcharge set forth in § 1.20(h) during the respective grace periods after:
(1) 3 years and 6 months and through the day of the 4th anniversary of the grant for the first maintenance fee.
(2) 7 years and 6 months and through the day of the 8th anniversary of the grant for the second maintenance fee, and
(3) 11 years and 6 months and through the day of the 12th anniversary of the grant for the third maintenance fee.

(f) If the last day for paying a maintenance fee without surcharge set forth in paragraph (d) of this section, or the last day for paying a maintenance fee with surcharge set forth in paragraph (e) of this section, falls on a Saturday, Sunday, or a federal holiday within the District of Columbia, the maintenance fee and any necessary surcharge may be paid under paragraph (d) or paragraph (e) respectively on the next succeeding day which is not a Saturday, Sunday, or Federal holiday.

(g) Unless the maintenance fee and any applicable surcharge is paid within the time periods set forth in paragraphs (d), (e) or (f) of this section, the patent will expire as of the end of the grace period set forth in paragraph (e) of this section. A patent which expires for the failure to pay the maintenance fee will expire at the end of the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant.

(h) The periods specified in § § 1.362 (d) and (e) with respect to a reissue application, including a continuing reissue application thereof, are counted from the date of grant of the original non-reissue application on which the reissued patent is based.

Maintenance fees are required to be paid on all patents based on applications filed on or after December 12, 1980, except for plant patents and design patents. Furthermore, maintenance fees are not required for a reissue patent if the patent being reissued did not require maintenance fees. Application filing dates for purposes of determining whether a patent is subject to payment of maintenance fees are as follows:

(A) For an application not claiming benefit of an earlier application, the actual United States filing date of the application.

(B) For an application claiming benefit of an earlier foreign application under 35 U.S.C. 119(a)-(d), the actual United States filing date of the application.

(C) For a continuing (continuation, division, continuation-in-part) application claiming the benefit of a prior patent application under 35 U.S.C. 120, the actual United States filing date of the continuing application.

(D) For a reissue application, including a continuing reissue application claiming the benefit of a reissue application under 35 U.S.C. 120, the United States filing date of the original nonreissue application on which the patent reissued is based.

(E) For an international application that has entered the United States as a Designated Office under 35 U.S.C. 371, the international filing date granted under Article 11(1) of the Patent Cooperation Treaty which is considered to be the United States filing date under 35 U.S.C. 363.

2506 Times for Submitting Maintenance Fee Payments

37 CFR 1.362(d) sets forth the time periods when the maintenance fees for a utility patent can be paid without surcharge. Those periods, referred to generally as the "window period," are the 6-month periods preceding each due date. The "due dates" are defined in 35 U.S.C. 41(b). The window periods are (1) 3 years to 3 1/2 years after the date of issue for the first maintenance fee payment, (2) 7 years to 7 1/2 years after the date of issue for the second maintenance fee payment, and (3) 11 years to 11 1/2 years after the date of issue for the third and final maintenance fee payment. A maintenance fee paid on the last day of a window period can be paid without surcharge. The last day of a window period is the same day of the month the patent was granted 3 years and 6 months, 7 years and 6 months,

or 11 years and 6 months after grant of the patent. 37 CFR 1.362(e) sets forth the time periods when the maintenance fees for a utility patent can be paid with surcharge. Those periods, referred to generally as the "grace period," are the 6-month periods immediately following each due date. The grace periods are (1) 3 1/2 years and through the day of the 4th anniversary of the grant of the patent, (2) 7 1/2 years and through the day of the 8th anniversary of the grant of the patent and, (3) 11 1/2 years and through the day of the 12th anniversary of the grant of the patent. A maintenance fee may be paid with the surcharge on the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant to prevent the patent from expiring. Maintenance fees for a reissue patent are due based upon the schedule established for the original utility patent. The filing of a request for ex parte or inter partes reexamination and/or the publication of a reexamination certificate does not alter the schedule of maintenance fee payments of the original patent. If the day for paying a maintenance fee falls on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee may be paid on the next succeeding day that is not a Saturday, Sunday, or Federal holiday. For example, if the window period for paying a maintenance fee without a surcharge ended on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee can be paid without surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia. Likewise, if the grace period for paying a maintenance fee with a surcharge ended on a Saturday, Sunday, or a Federal holiday within the District of Columbia, the maintenance fee can be paid with surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia. In the latter situation, the failure to pay the maintenance fee and surcharge on the next succeeding day that is not a Saturday, Sunday, or a Federal holiday within the District of Columbia will result in the patent expiring on a date (4, 8, or 12 years after the date of grant) earlier than the last date on which the maintenance fee and surcharge could be paid. This situation results from the provisions of 35 U.S.C. 21, but those provisions do not extend the expiration date of the patent if the maintenance fee and any required surcharge are not paid when required. For example, if the grace period for paying a maintenance fee with a surcharge ended on a Saturday, the maintenance fee and surcharge could be paid on the next succeeding business day, e.g., Monday, but the patent will have expired at midnight on Saturday if the maintenance fee and surcharge were not paid on the following Monday. Therefore, if the maintenance fee and any applicable surcharge are not paid, the patent will expire as of the end of the grace period as listed above. A patent that expires for failure of payment will expire on the anniversary date the patent was granted in the 4th, 8th, or 12th year after the grant.

2575 Notices

Under the statutes and the regulations, the Office has no duty to notify patentees when their maintenance fees are due. It is the responsibility of the patentee to ensure that the maintenance fees are paid to prevent expiration of the patent. The Office will, however, provide some notices as reminders that maintenance fees are due, but the notices, errors in the notices or in their delivery, or the lack or tardiness of notices will in no way relieve a patentee from the responsibility to make timely payment of each maintenance fee to prevent the patent from expiring by operation of law. The notices provided by the Office are courtesies in nature and intended to aid patentees. The Office's provision of notices in no way shifts the burden of monitoring the time for paying maintenance fees on patents from the patentee to the Office.

Application of the standard to the current facts and circumstances

Petitioner's explanation of the delay has been considered, and it has been determined that it fails to meet the standard for acceptance of a late payment of the maintenance fee and surcharge.

Petitioner has not made an adequate showing that the failure to pay the maintenance fee was unavoidable, given the exercise of due care. The period for paying the 11½ year maintenance fee without the surcharge extended from February 20, 2001 to August 20, 2001, and for paying with the surcharge from August 21, 2001 to February 20, 2002. Thus, the delay in paying the 11½ year maintenance fee extended from February 20, 2002 to the filing of the instant petition on April 9, 2004.

Petitioner has set forth that the purported assignee (there is no showing in the Patent Office records that the instant patent was assigned to the Upjohn Company) employed the services of an outside company to provide reminders as to when maintenance fees were due (PC Master), and that there was a misunderstanding as to how to deal with the fact that a patent term extension was received. This misunderstanding resulted in an incorrect entry into a database, which resulted in PC Master's failure to submit the 11½ year maintenance fee.

Petitioner has submitted an affidavit from Ms. Julie Lyons, who is a paralegal who is employed by the purported assignee. Ms. Lyons has set forth that she was told by PC Master that if a patent term extension had been received, it was appropriate to enter a "j" in the "case type" field of the PC Master-supplied software. After the patent went abounded for failure to submit the 11½ year maintenance fee, the affiant was told by her supervisor at Upjohn that the proper course of action was to have created a new record, place a "j" in the appropriate field, and leave the original record unmodified. As such, Ms. Lyons asserts that she was given incorrect information from PC Master, and this misinformation resulted in the abandonment of the patent.

Petitioner's submission has been considered, and has been deemed to be unpersuasive, for the reasons which follow.

First, Petitioner has not revealed that the error was the cause of the delay at issue. Ms Lyon sets forth that the software company told her one thing, and her supervisor told her something completely different. Nowhere is it set forth that she followed up with the company to ensure that her supervisor's opinion on how to run the computer program was correct. Furthermore, no statement from a PC Master representative has been provided. A statement to the effect that the method utilized by Miss Lyons would fail to apprise PC Master that a maintenance fee was due would be beneficial to Petitioner's cause.

Secondly, Ms. Lyon's training with this system has not been revealed, and as such, there is no way for the Patent Office to determine whether she was sufficiently trained and experienced with regard to the function and routine for its performance, such that reliance upon Ms. Lyon represented the exercise of due care. Surely the method of dealing with a patent term extension should have been covered in her training. If not, and the paralegal was forced to call the software provider and seek advice from unnamed parties, perhaps her training was insufficient? It follows that if her training was insufficient, reliance on her was not reasonable.

Third, a statement from Ms. Lyon's supervisor, Ms. Tucker, has been provided, yet the statement of Ms. Tucker does not address the conflicting treatment of the "j" entry. This seems odd, since the incorrect entry of the "j" designation is asserted to be the sole reason why this patent went abandoned. As such, although a statement from Ms. Tucker has been provided, it does not appear to be complete.

Fourth, it is not clear if any other Upjohn employees had access to this PC Master program, or if Ms. Lyon was the only employee charged with the duty of ensuring that all appropriate entries were made into the system.

Fifth, no copy of the system (i.e. a print-out of the screen which shows the requisite "j" in the improper column) has been provided.

Finally, no statement has been proffered as to the degree of supervision of Ms. Lyon's work, examples of other work functions carried out by her, and checks on her described work which were used to assure proper execution of assigned tasks. Regarding this final point, if Ms. Lyon's supervisor was aware that the proper way to deal with an extension was to make a new record, it is not clear why Ms. Lyon was allowed to make the "j" entry if her work was being supervised by Ms. Tucker.

CONCLUSION

In view thereof, the petition is **DISMISSED**.

Any response must be filed within **TWO MONTHS** of the mailing date of this decision, and entitled "Renewed Petition under 37 C.F.R. §1.378(e)." Any such petition for reconsideration must be accompanied by the $130 petition fee set forth in §1.17(h). After decision on the petition for reconsideration, no further reconsideration or review of the matter will be undertaken by the Commissioner. Accordingly, on request for reconsideration, it is **extremely important** that petitioner supply **any** and **all** relevant information and documentation in order to meet his burden of showing unavoidable delay. This includes statements by all persons with direct knowledge of the cause of the delay, setting forth the facts as they know them. Petitioner will note that the standard associated with the filing of a petition under the "unavoidable" standard is very high, and as such, he must submit a convincing argument with all documentation attached.

If on renewed petition, the delayed payment of the maintenance fee is not accepted, then the maintenance fee is subject to refund following the decision on the petition for reconsideration, or after the expiration of the time for filing such a petition for reconsideration, if none is filed. (Petitioner may request a refund of the maintenance fee and surcharge by writing to the Office of Finance, Refund Section, Commissioner for Patents, Washington DC 20231. A copy of the last decision rendered should accompany the request for refund).

The reply to this letter may be submitted by mail[12], hand-delivery[13], or facsimile[14].

The reply should display "Please deliver to Paul Shanoski, c/o Office of Petitions" in a prominent manner. The Petitioner may wish to consider telephoning the undersigned at the number provided below to confirm that the documents were delivered to the undersigned. Please note that the delivery process within the PTO can take as much as three weeks.

It is noted that the address listed on the petition differs from the Fee Address of record. The application file does not indicate a change of correspondence address has been filed in this case,

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12 Mail Stop Petition, Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

13 Customer Window, Mail Stop Petition, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202.

14 (703) 872-9306 - please note this is a central facsimile number, and as such, there will be a delay in the delivery of the facsimile to the undersigned.

although the address given on the petition differs from the address of record. If petitioner desires to receive future correspondence regarding this application, the change of correspondence address must be submitted. A courtesy copy of this decision will be mailed to petitioner. However, all future correspondence will be directed to the address of record until such time as appropriate instructions are received to the contrary. Petitioner will not receive future correspondence related to maintenance fees unless a Fee Address Indication Form (PTO/SB/47) is submitted for the above-identified application. For petitioner's convenience, a blank Fee Address Indication Form (PTO/SB/47) may be found at http://www.uspto.gov/web/forms/sb0047.pdf[15].

It is not apparent whether the person signing the statement of unintentional delay was in a position to have firsthand or direct knowledge of the facts and circumstances of the delay at issue. Nevertheless, such statement is being treated as having been made as the result of a reasonable inquiry into the facts and circumstances of such delay[16]. In the event that such an inquiry has not been made, petitioner must make such an inquiry. If such inquiry results in the discovery that the delay in paying the maintenance fee under 37 CFR 1.378(c) was intentional, petitioner must notify the Office.

The application file will be retained in the Office of Petitions for two (2) months.

Telephone inquiries regarding this decision should be directed to the undersigned at (703) 305-0011.

Paul Shanoski
Senior Attorney
Office of Petitions
United States Patent and Trademark Office

cc: Donald Zuhn
McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, IL 60606

15 In order to effectuate a change in the fee address, a customer number may be required. If petitioner needs to obtain a customer number, one may be obtained by the submission of PTO form PTO/SB/125A, which may be located at http://www.uspto.gov/web/forms/sb0125.pdf.

16 See 37 CFR 10.18(b); cf. Changes to Patent Practice and Procedure; Final Rule Notice, 62 Fed. Reg. 53131, 53178 (October 10, 1997), 1203 Off. Gaz. Pat. Office 63, 103 (October 21, 1997).

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
WWW.USPTO.GOV

Paper No. 28

CORPORATE PATS. & TRADEMARKS,
THE UPJOHN COMPANY
KALAMAZOO MI 49001

COPY MAILED

SEP 01 2004

OFFICE OF PETITIONS

In re Application of
Mahendra I. Amin et al.
Application No. 07/312,401
Patent No. 4,902,683
Filed: February 17, 1989
Issue Date: February 20, 1990
Attorney Docket No.: 4121FW1
Title: CRYSTALLINE CEPHALOSPORIN HYDROHALIDE SALTS

DECISION ON RENEWED PETITION UNDER 37 C.F.R. §1.378(E)

This is a decision on the renewed petition filed July 12, 2004, pursuant to 37 C.F.R. §1.378(e) to revive the above-identified patent which has expired for failure to submit the 11½ year maintenance fee.

The patent issued February 20, 1990. The grace period for paying the 11½ year maintenance fee provided in 37 CFR 1.362(e) expired at midnight on February 20, 2002, with no payment received. Accordingly, the patent expired on February 20, 2002.

On April 9, 2004, Petitioner submitted a petition under 37 C.F.R. §1.378(b)[1] to revive the above-identified patent which has expired for failure to submit the 11½ year maintenance fee. This petition was dismissed via the mailing of a decision on May 12, 2004.

[1] Any petition to accept an unavoidably delayed payment of a maintenance fee filed under 37 C.F.R. §1.378(b) must include:

(1) The required maintenance fee set forth in 37 C.F.R. §1.20 (e) through (g);
(2) The surcharge set forth in 37 C.F.R. §1.20(i)(1), and;
(3) A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

With this renewed petition, Petitioner has submitted the required surcharge, as well as a statement of facts.

The renewed petition under 37 C.F.R. §1.378(e) is hereby **GRANTED**. The above-identified patent is hereby reinstated as of the mail date of this decision.

This file is being sent to Files Repository.

Telephone inquiries regarding this decision should be directed to the undersigned at (703) 305-0011. Please note that on approximately September 28, 2004, the Office of Petitions will relocate to the new PTO location in Alexandria. Although the mailing address will remain the same, the general phone number for the Office of Petitions which should be used for status requests will change to 571-272-3282, and the telephone number for the undersigned will change to 571-272-3225.

Paul Shanoski
Senior Attorney
Office of Petitions
United States Patent and Trademark Office

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.:20080407

DATE : April 07, 2008

TO SPE OF : ART UNIT 1634

SUBJECT : Request for Certificate of Correction on Patent No.: 7316899

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within **7** days to:
Certificates of Correction Branch - ST (South Tower) 9A22
Palm location **7590** - Tel. No. (703) 305-8309

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Thank You For Your Assistance **Certificates of Correction Branch**

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriated box.

☐ **Approved** All changes apply.

☐ **Approved in Part** Specify below which changes **do not** apply.

☒ **Denied** State the reasons for denial below.

Comments:

The US Patent and WO references were not listed on an IDS/1449 or 892. The international search reports do not have publication date. It is noted that search reports for pct/us99/16162; pct/us00/19302; pct/us00/19351; pct/us00/19350; pct/us01/03240 and pct/us03/23131 were listed on the 1449 and were review. However, the reports do not have publication dates.

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

SPE: Ram Shukla Art Unit 1634

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Paper No. 43

MERCHANT & GOULD PC
PO BOX 2903
MINNEAPOLIS MN 55402-0903

COPY MAILED

SEP 0 8 2003

OFFICE OF PETITIONS

In re Application of Yoshimura, et al. Application No. 07/330,446 Filed: March 30, 1989 Attorney Docket No. 1173145P	: : : : :	DECISION ON PETITION

This is a decision on paper titled "Request for Remailing of Office Action", filed March 22, 2002, which is being treated as a petition under 37 CFR 1.181 to withdraw the holding of abandonment in the above-identified application.

The petition is **GRANTED.**

The above-identified application became abandoned for failure to timely file a proper response to the final Office action, mailed September 28, 2000, which set a shortened statutory period for reply of three (3) months. No extensions of time under the provisions of 37 CFR 1.136(a) were obtained. Accordingly, the above-identified application became abandoned on December 29, 2000. A Notice of Abandonment was mailed on May 8, 2001.

Petitioner argues that the September 28, 2000 Office action was mailed to the incorrect address. The application file reveals that a Revocation and Power of Attorney was filed with a Certificate of Mailing on June 19, 1997. In addition, a Change of Correspondence Address was filed on August 28, 2000, directing the Office to forward correspondence to Merchant & Gould at P.O. Box 2903, Minneapolis, MN 55402-2903. However, the Change of Correspondence Address was not entered and the September 28, 2000 Office action was mailed to a prior address of record.

In view thereof, **the holding of abandonment is withdrawn.**

The application file is being forwarded to Technology Center 1600 for remailing of the September 28, 2000 Office action, setting a new period for reply.

Telephone inquiries regarding this decision should be directed to the undersigned at (703) 305-0272.

Cliff Congo

Cliff Congo
Petitions Attorney
Office of Petitions

NOTICE RE: CERTIFICATES OF CORRECTION

DATE : 3/17/06 **Paper No.:** __

TO : **Supervisor, Art Unit** _____

SUBJECT : Certificate of Correction Request in Patent No.: 6,869,924

A response to the following question is requested with respect to the accompanying request for a certificate of correction.

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

PLEASE COMPLETE THIS FORM AND RETURN WITH FILE, WITHIN 7 DAYS, TO CERTIFICATES OF CORRECTION BRANCH - PK 3-915/922 PALM LOCATION 7580 - TEL. N0. 305-8309

THANK YOU FOR YOUR ASSISTANCE!

Note your decision by placing a check mark in the appropriate box below, indicating whether all changes requested in the Request for Certificate of Correction should be applied. Please specify which changes should not be applied and indicate the reason(s) for denial, in the "Comments" section below.

[X] **YES** [ ] **NO**

[X] **Comments:**

With respect to the patent term adjustment and extension information on the front page, please correct. Application needs to be sent to the examiner with respect to the other errors.

Mark Polutta OPLA 571-272-7709

Supervisor **Art Unit**

UNITED STATES PATENT AND TRADEMARK OFFICE

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P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
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Paper No. 40

AKIN GUMP STRAUSS HAUER & FELD
ONE COMMERCE SQUARE, SUITE 2200
2005 MARKET STREET
PHILADELPHIA, PA 19103

COPY MAILED
OCT 28 2003
OFFICE OF PETITIONS

In re Patent No. 4,964,736 :
Issue Date: October 23, 1990 :
Application No. 07/331,091 :
Filed: March 27, 1989 :
Patentee(s) Omer Cure et al :

ON PETITION

This is a decision on the petition under 37 CFR 1.378(c), filed August 27, 2003, to accept the delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED**.

The maintenance fee is hereby accepted and the above-identified patent is reinstated as of the mail date of this decision.

Telephone inquiries concerning this decision should be directed to Wan Laymon at (703) 305-9282.

The patent file is being forwarded to Files Repository.

Wan Laymon
Wan Laymon
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
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www.uspto.gov

BEYER, WEAVER & THOMAS, LLP
ATTN: Michael Ferrazano
590 W. El Camino Real
Mountain View, CA. 94040

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,989,090	:	
Issue Date: January 29, 1991	:	
Application No. 07/334,004	:	DECISION ON PETITION
Filed: April 5, 1989	:	
Inventor: Jack J. Campbell et al	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '090 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation

may have been proper. Petitioner should note that recordation is available for numerous documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

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IBM CORP (YA)
C/O YEE & ASSOCIATES PC
P.O. BOX 802333
DALLAS, TX 75380

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SEP 14 2007

OFFICE OF PETITIONS

In re Application of
Robert A. Fabbio
Application No. 07/352,530
Filed: May 15, 1989
Attorney Docket No. AT9-89-039

ON PETITION

This is a decision in response to the petition, filed April 27, 2007, to revive the above-identified application under the provisions of 37 CFR 1.137(b).

The petition is **GRANTED**.

The application became abandoned for a failure to reply in a timely manner to a non-final Office action mailed May 5, 2006. A Notice of Abandonment was mailed on February 27, 2007. In response, on April 27, 2007, the present petition was filed.

The petition satisfies the conditions for revival pursuant to the provisions of 37 CFR 1.137(b) in that petitioner has supplied (1) the reply in the form of an amendment; (2) the petition fee of $1,500; (3) an adequate statement of unintentional delay; and (4) a terminal disclaimer and fee as required by 37 CFR 1.137(d).

The terminal disclaimer is accepted and has been made of record. Any continuing application filed from this application must contain a copy of the terminal disclaimer. The copy of the terminal disclaimer must be filed with a cover letter requesting the terminal disclaimer be recorded on the continuing application. A copy of this decision should be attached to the cover letter.

The application is being referred to Technology Center AU 2628 for consideration of the amendment filed April 27, 2007.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3204. Inquiries relating to further prosecution should be directed to the Technology Center.

Sherry D. Brinkley
Petitions Examiner
Office of Petitions

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COMMISSIONER FOR PATENTS
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P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
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THOMAS A. O'ROURKE
WYATT, GERBER, BURKE & BADIE
645 MADISON AVENUE
NEW YORK, NY 10022

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FEB 18 2005

OFFICE OF PETITIONS

In re Application of	:
Tse, et al.	: DECISION ON PETITION
Application No. 07/370,003	:
Filed: June 22, 1989	:
Docket No.: 14377A1	:

This is a decision on the petition under 37 C.F.R. § 1.137(b), filed December 13, 2004, to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned February 7, 2004 for failure to timely reply to the non-final Office action mailed November 6, 2003. The non-final Office action set a three (3) month shortened statutory period of time for reply. No extensions of time in accordance with 37 C.F.R. § 1.136 were timely requested. Notice of Abandonment was mailed June 24, 2004.

A grantable petition pursuant to 37 C.F.R. § 1.137(b) must be accompanied by: (1) the required reply to the outstanding Office action or notice, unless previously filed; (2) the petition fee as set forth in 37 C.F.R. § 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional; and (4) any terminal disclaimer (and fee set forth in 37 C.F.R. § 1.20(d)) required pursuant to 37 C.F.R. § 1.137(c).

The instant petition has been reviewed and found in compliance with the provisions of 37 C.F.R. § 1.137(b). Accordingly, the failure to timely submit a proper reply to the non-final Office action is accepted as having been unintentionally delayed.

The power of attorney submitted herewith has not been entered into the record as there is insufficient documentation to determine that the individual who executed the power of attorney has been empowered by the assignee to do so. Furthermore, the

record of proceedings lacks a statement in accordance with 37 CFR 3.73(b). Accordingly, there is no indication that petitioner herein was ever empowered to prosecute the instant application. If petitioner desires to receive future correspondence regarding this application, the appropriate power of attorney documentation must be submitted. A courtesy copy of this decision will be mailed to petitioner. However, all future correspondence will be directed to the address of record until such time as appropriate instructions are received to the contrary.

It is not apparent whether the person signing the statement of unintentional delay was in a position to have firsthand or direct knowledge of the facts and circumstances of the delay at issue. Nevertheless, such statement is being treated as having been made as the result of a reasonable inquiry into the facts and circumstances of such delay. See 37 CFR 10.18(b) and Changes to Patent Practice and Procedure; Final Rule Notice, 62 Fed. Reg. 53131, 53178 (October 10, 1997), 1203 Off. Gaz. Pat. Office 63, 103 (October 21, 1997). In the event that such an inquiry has not been made, petitioner must make such an inquiry. If such inquiry results in the discovery that it is not correct that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional, petitioner must notify the Office.

This application will be forwarded to Technology Center 1700 for further processing.

Telephone inquiries concerning this matter may be directed to the undersigned at (571) 272-3205.

Alesia M. Brown
Petitions Attorney
Office of Petitions

CC: STEPHEN T. SCHERRER
MCDERMOTT WILL & EMERY LLP
227 W. MONROE STREET
CHICAGO, IL 60606-5096

UNITED STATES PATENT AND TRADEMARK OFFICE

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660 WHITE PLAINS ROAD, 4TH FLR.
TARRYTOWN NY 10591-5144

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SEP 21 2005

OFFICE OF PETITIONS

In re Patent No. 4,990,517 Petersen et al. Issue Date: February 5. 1991 Application No. 07/375,434 For: 7-(1-PYRROLIDINYL)-3-QUINOLONE- AND -NAPHTHYRIDONE-CARBOXYLIC ACID DERIVATIVES AS ANTIBACTERIAL AGENTS AND FEED ADDITIVES	: : : : :	DECISION ON REQUEST FOR EXPEDITED ISSUANCE OF CERTIFICATE OF CORRECTION

This is a decision on the "Request for Expedited Issuance of Certificate of Correction under 37 CFR 1.322," filed July 7, 2005.

The request is granted.

Certificate of Corrections Branch is instructed to issue the requested Certificate of Correction. As explained in the request, the Certificate of Extension contained a typographical error in the name of the drug product in two places.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-7744.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of Deputy Commissioner
for Patent Examination Policy

cc: Banner & Witcoff, Ltd.
1001 G Street, NW
Washington, DC 20001-4597

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Oblon, Spivak, McClelland, Maier & Neustadt, P.C.
1940 Duke Street
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,977,138

JUL - 9 2009

Dear Sir:

An interim extension certificate under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,977,138 for a period of 1 year, i.e., until July 6, 2010. A copy of the Federal Register notice, published on July 7, 2009, at 74 Fed. Reg. 32116, regarding issuance of this interim extension under 35 U.S.C. 156(d)(5), is also enclosed. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates pertinent to any filings before the FDA

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: ISTODAX™
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Gloucester Pharmaceuticals, Inc. Request for Patent Term Extension U.S. Patent No. 4,977,138	: : :	**ORDER GRANTING** **INTERIM EXTENSION**

On June 12, 2009, Gloucester Pharmaceuticals, Inc., a licensee of Astellas Pharma Inc., the patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,977,138. The patent claims the human drug product ISTODAX™ (romidepsin). The application indicates that a New Drug Application (NDA No. 22-393) for the human drug product ISTODAX™ (romidepsin) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for a year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (July 6, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,977,138 is granted for a period of one year from the original expiration date of the patent, i.e., until July 6, 2010.

06/30/09
Date

John Doll
John J. Doll
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 31 2010

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Oblon, Spivak, McCleeand, Maier & Neustadt, P.C.
1940 Duke Street
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,977,138

Dear Mr. Baxter :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,977,138 for a period of 184 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: ISTODAX™
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Gloucester Pharmaceuticals, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,977,138	:	**INTERIM EXTENSION**

Astellas Pharma Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,977,138, through their licensee, Gloucester Pharmaceuticals, Inc., filed an application for patent term extension under 35 U.S.C. § 156 on December 22, 2009. The original term of the patent expired on July 6, 2009, but was extended until July 6, 2010, via the provisions of 35 U.S.C. § 156(d)(5). The patent claims the active ingredient, romidepsin, in the human drug product ISTODAX® which was approved by the Food and Drug Administration for commercial marketing or use on November 5, 2009. An extension of 1,523 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,977,138 is granted for a period of 184 days from January 4, 2010, the date that the patent lapses under 35 U.S.C. 156(d)(5)(E), until July 6, 2010.

12/29/09
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

JUL 23 2010

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United States Patent and Trademark Office
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Oblon, Spivak, McCleeand, Maier & Neustadt, P.C.
1940 Duke Street
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,977,138

Dear Mr. Baxter :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,977,138 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: ISTODAX®
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Celgene Corporation	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,977,138	:	**INTERIM EXTENSION**

Astellas Pharma Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,977,138, through their licensee, now Celgene Corporation, filed an application for interim patent term extension under 35 U.S.C. § 156 on April 05, 2010. The extended term of the patent expired on July 6, 2010. The patent claims the active ingredient, romidepsin, in the human drug product ISTODAX® which was approved by the Food and Drug Administration for commercial marketing or use on November 5, 2009. An extension of 1,523 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,977,138 has been granted for a period of one year from July 6, 2010, until July 6, 2011.

David J. Kappos

July 23, 2010
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/377,168	07/10/1989	JOSEPH T. EVANS JR.	2668-0004	8512

82652 7590 10/13/2009
Davidson Berquist Jackson & Gowdey LLP
(Ramtron Cases)
4300 Wilson Blvd
Suite 700
Arlington, VA 22203

EXAMINER
BRAGDON, REGINALD GLENWOOD

ART UNIT	PAPER NUMBER
2189	

MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

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Davidson Berquist Jackson & Gowdey LLP
(Ramtron Cases)
4300 Wilson Blvd, Suite 700
Arlington VA 22203

In re Application of: EVANS et al.
Application No. 07/377,168
Filed: July 10, 1989
For: METHOD FOR READING NON-VOLATLILE FERROELECTRIC CAPACITOR MEMORY CELL

DECISION ON PETITION

This is a decision on the petition filed on February 29, 2008, under 37 CFR 1.181(a) to invoke Supervisory Authority requesting that a new office action be mailed in the instant application.

A review of the file wrapper record shows that an Allowance was mailed by examiner in the instant application on August 27, 2009.

Accordingly, the instant petition, filed under 37 CFR §1.181 in this application, is rendered moot.

Accordingly, the Petition is **DISMISSED as moot**.

Any inquiry concerning this decision should be directed to the undersigned whose telephone number is (571) 272-4210.

Mano Padmanabhan

Mano Padmanabhan, WQAS
Technology Center 2100
Computer Architecture, Software, and Information Security

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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,982,280	:	
Issue Date: January 1, 1991	:	
Application No. 07/381,497	:	DECISION ON PETITION
Filed: July 18, 1989	:	
Inventor: Thomas C. Lyon et al	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '280 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

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GRAHAM & JAMES, LLP
600 Hansen Way
Palo Alto, CA. 94304-1043

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OFFICE OF PETITIONS

In re Patent No. 4,939,576 :
Issue Date: July 3, 1990 :
Application No. 07/384,325 : DECISION ON PETITION
Filed: July 24, 1989 :
Inventor: Jack Campbell :

This is a decision on the petitions, filed August 15, 2008, and October 7, 2008, pursuant to 37 CFR §§ 1.59(b), and 1.183. The petition is being treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent.

The petition under 37 CFR § 1.183 is **dismissed as premature**.

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '385 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

A review of the complete file history in this case indicates that there is no petition decision mailed September 19, 2008, as alleged in petitioner's Request for Reconsideration under 37 CFR § 1.183. Hence the petition under 37 CFR § 1.183 petition is dismissed as being premature.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc.

has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

In addition, the petition fee paid is not sufficient. A petition under 37 CFR § 1.182 requires the payment of $400.00. However, only $200.00 has been paid due to the erroneous assumption that the petition was properly filed under 37 CFR § 1.59. A petition under 37 CFR § 1.59 applies to application files, not assignment records. The $200.00 payment has been credited to petitioner's Deposit Account 50-4481. A petition to expunge assignment documents is properly addressed under 37 CFR § 1.182 and a fee of $400.00 is required. As authorized, the required fee of $400.00 has been charged to petitioner's Deposit Account 50-4481.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

APR - 4 2000

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,079,262 was filed on January 31, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, LEVULAN® KERASTICK™ (aminolevulinic acid HCl), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Beth A. Barrous
FOLEY & LARDNER
WASHINGTON HARBOUR, SUITE 500
3000 K Street NW
Washington DC 20007-5109

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OCT 25 2005

BETH A. BURRUS
FOLEY & LARDNER, LLP
3000 K STREET, NW, SUITE 500
WASHINGTON, DC 20007

In re Application of	:
James C. Kennedy et al	:
Patent No.: 5,079,262	: PETITION DECISION
issued: January 7, 1992	:
Attorney Docket No.: 067286-0103	:

This is a decision on the petition under 37 CFR 1.324, filed September 29, 2004, requesting correction of inventorship in the above identified issued patent. The delay in acting on this petition is regretted.

Patent Owner's petition under 37 CFR 1.324 requests addition of omitted inventor Robert L. Reid. A review of the patent file shows that a petition to **delete** Robert L. Reid as an inventor was filed on October 9, 1991, concurrently with the payment of the Issue Fee, stating that Robert L. Reid is no longer a joint inventor of the remaining allowed claims of the application and indicating his invention relates to claim 5 which was withdrawn from consideration pursuant to a restriction requirement and subsequently canceled. The petition was granted on June 12, 1992, subsequent to the issuance of the patent on January 7, 1992, and a Certificate of Correction indicating the correction was issued. Patent Owner now seeks to **add** Robert L. Reid as an inventor more than 12 years after requesting his deletion as an inventor. Other than the required statements under 37 CFR 1.324 no reasoning has been given to justify such action in view of the earlier deletion of Robert L. Reid as an inventor.

The petition is **DENIED**. It is suggested that Patent Owner provide an explanation as to why Robert L. Reid is now being added as a joint inventor when the file record clearly states that Robert L. Reid is not a joint inventor of the issued claims.

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at 571-272-0519 or by facsimile transmission at 571-272-8300.

Bruce M. Kisliuk
Director, Technology Center 1600

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BETH BURRUS
FOLEY & LARDNER, LLP
3000 K STREET, NW, SUITE 500
WASHINGTON, DC 2007

In re Patent No. 5,079,262 KENNEDY ET AL	
Issue Date: January 07, 1992	**DECISION GRANTING**
Appl No.: 07/386414	**PETITION**
Filed: December 27, 2005	*37 CFR 1.324*
For: Correction of Inventorship	

This is a decision on the renewed petition filed December 27, 2005, to correct inventorship under 37 CFR 1.324. The renewed petition has complied with all the requirements under 37 CFR 1.324.

The petition is **GRANTED**.

The patented file is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

Jean F Vollano

Jean F. Vollano
Quality Assurance Specialist
Technology Center 1600

UNITED STATES PATENT AND TRADEMARK OFFICE

JAN 29 2008

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DATE: January 29, 2008
TO: Certificates of Correction Branch
FROM: Jean F. Vollano
Technology Center 1600
SUBJECT: REQUEST FOR CERTIFICATE OF CORRECTION

Please issue a Certificate of Correction in U. S. Letters Patent No. US 5,079,262 as specified on the attached Certificate.

Jean F. Vollano

Jean F. Vollano
Technology Center 1600

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE

Patent No. US 5,079,262
Patented: January 02, 1992

On petition requesting issuance of a certificate for correction of inventorship pursuant to 35 U.S.C. 256, it has been found that the above identified patent, through error and without deceptive intent, improperly sets forth the inventorship. Accordingly, it is hereby certified that the correct inventorship of this patent is:

James C. Kennedy
Roy H. Pottier
Robert L. Reid

Jean F. Vollano

Jean F. Vollano
Quality Assurance Specialist
Technology Center 1600

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Paper No. 19

GREGORY BENDER
P.O. BOX 361777
MILPITAS CA 95036

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OFFICE OF PETITIONS

In re Patent No. 5,103,188	:	
Issued: 7 April, 1992	:	
Application No. 07/389,735	:	DECISION ON PETITION
Filed: 4 August, 1995	:	
For: BUFFERED TRANSCONDUCTANCE	:	
AMPLIFIER	:	

This is a decision on the petition filed on 24 April, 2006, under 37 CFR § 1.378(b) to accept the delayed payment of a maintenance fee for the above-identified patent.

The petition is **dismissed**.

If reconsideration of this decision is desired, a petition for reconsideration under 37 CFR 1.378(e) must be filed within TWO (2) MONTHS from the mail date of this decision. No extension of this 2-month time limit can be granted under 37 CFR 1.136(a) or (b). Any such petition for reconsideration must be accompanied by the petition fee of $400.00 as set forth in 37 CFR 1.17(f). The petition for reconsideration should include an exhaustive attempt to provide the lacking item(s) noted below, since, after a decision on the petition for reconsideration, no further reconsideration or review of the matter will be undertaken by the Commissioner.

The patent issued 7 April, 1992. The first and second maintenance fees were timely paid. The third maintenance fee could have been paid from 7 April through 7 October, 2003, or,

with a surcharge during the period from 8 October, 2003, through 7 April, 2004. Accordingly, the patent expired at midnight 7 April, 2004, for failure to timely submit the maintenance fee. Petitioner states, in pertinent part,

3. I took steps to ensure that business procedures were in place to provide timely reminders for the due dates of the maintenance fee. I annotated the maintenance fee deadlines in my business records used for calendaring deadlines and dates related to my business. I also kept the written reminders on the patent and placed other reminders in my computer files relating to this patent.
4. I have recorded important deadlines and appointments using written notices and a computer scheduling system which has been updated from time-to-time since issue of the patent in 1992. Normally, I have relied upon these two calendaring scheduling systems to provide notice of important dates, meetings and appointments, and I have used copies of written documents as a backup reminder within my business. These reminder methods have provided me with adequate notice of the relevant deadlines for my business, and I have used these reminders to inform me about the first and second maintenance fee payment deadlines as well as other important dates.

Petitioner further states that the delay was unavoidable because:

8. My original written patent records with the dates of record on the inside cover had not been readily available to me since about July 1999, which was several years ago. I had to move and put my all business records, tools, and equipment into storage. Based upon my reminder method, I was under the impression that my third maintenance fee was due at some point in the future.
9. My business reminder method had worked sufficiently well to allow me to make the first two required maintenance fee payments, and I continued to rely upon this method for providing notice for the due date on the third maintenance fee. With my written records in storage, I relied on the computer reminder method which used a calendaring system, and I have found it reliable in the past to provide reminders of important dates within my business, and it provided me with timely reminders to pay the first two maintenance fees.

10. My original computer system used in my business suffered from failures stemming from Y2K related calendar software throughout the 2000 timeframe, requiring manual update of most of the missing date and in many cases installing completely new software upgrades. This Y2K failure caused a loss of data throughout my system and a severe discontinuity in the data concerning most aspects of my business, apparently including the timing issues surround the patent maintenance fee payment. At the time and up to April 13, 2006, I believed all important dates had been updated into the new data files.
11. Since the Y2K related upgrades, a computer virus error caused a several technical failure of the new computer system and software, and during the following update, corrupted backup data disks were also discovered. I believed the various data files had been purged of the virus and relevant important dates and the reminder for the maintenance fee remained intact. However, it is evidence that my computer calendaring system for reminding me of important dates failed to indicate when the last maintenance fee paying was due or when the patent lapse date occurred.

A petition to accept the delayed maintenance fee under 35 U.S.C. § 41(c) and 37 CFR 1.378(b) must be accompanied by (1) an adequate, verified showing that the delay was unavoidable, since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent, (2) payment of the appropriate maintenance fee, unless previously submitted, and (3) payment of the surcharge set forth in 37 CFR 1.20(i)(1).

This petition lacks requirement (1).

The Commissioner may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable".[1]

The showing of record is inadequate to establish unavoidable delay within the meaning of 37 CFR 1.378(b)(3).

A late maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 U.S.C. § 133 because 35 U.S.C. § 41(c)(1) uses identical language (i.e.

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[1] 35 U.S.C. § 41(c)(1).

"unavoidable delay").[2] Decisions reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable.[3] In this regard:

> The word 'unavoidable' . . . is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business. It permits them in the exercise of this care to rely upon the ordinary and trustworthy agencies of mail and telegraph, worthy and reliable employees, and such other means and instrumentalities as are usually employed in such important business. If unexpectedly, or through the unforeseen fault or imperfection of these agencies and instrumentalities, there occurs a failure, it may properly be said to be unavoidable, all other conditions of promptness in its rectification being present.[4]

The Commissioner may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable".[5] A patent owner's failure to pay a maintenance fee may be considered to have been "unavoidable" if the patent owner "exercised the due care of a reasonably prudent person."[6] This determination is to be made on a "case-by-case basis, taking all the facts and circumstances into account."[7] Unavoidable delay under 35 U.S.C. § 41(b) is measured by the same standard as that for reviving an abandoned application under 35 U.S.C. § 133.[8] Under 35 U.S.C. § 133, the Commissioner may revive

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[2] Ray v. Lehman, 55 F.3d 606, 608-09, 34 USPQ2d 1786, 1787 (Fed.Cir. 1995) (quoting In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (Comm'r Pat. 1989)).

[3] Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used by prudent and careful men in relation to their most important business").

[4] In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(quoting Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 USPQ 666, 167-68 (D.D.C. 1963), aff'd, 143 USPQ 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913). In addition, decisions on revival are made on a "case-by-case basis, taking all the facts and circumstances into account." Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982). Finally, a petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable." Haines v. Quigg, 673 F. Supp. 314, 316-17, 5 USPQ2d 1130, 1131-32 (N.D. Ind. 1987).

[5] 35 U.S.C. § 41(c)(1).

[6] Ray v. Lehman, 55 F.3d 606, 608-09 (Fed.Cir.), cert. denied, -- U.S. ---, 116 S.Ct. 304, L.Ed.2d 209 (1995).

[7] Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982).

[8] In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (PTO Comm'r 1988).

an abandoned application if the delay in responding to the relevant outstanding Office requirement is shown to the satisfaction of the Commissioner to have been "unavoidable". Decisions on reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable.[9] However, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay.[10] In view of In re Patent No. 4,409,763, this same standard will be applied to determine whether "unavoidable" delay within the meaning of 37 CFR 1.378(b) occurred.

This petition does not satisfy the requirement of 37 CFR 1.378(b)(3). The statements presented in the petition fail to satisfy the showing required to establish unavoidable delay within the meaning of 37 CFR 1.378(b).

As 35 U.S.C. § 41(c) requires the payment of fees at specified intervals to maintain a patent in force, rather than some response to a specific action by the Office under 35 U.S.C. § 133, a reasonably prudent person in the exercise of due care and diligence would have taken steps to ensure the timely payment of such maintenance fees.[11] That is, an adequate showing that the delay was "unavoidable" within the meaning of 35 U.S.C. § 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent.[12]

With regard to period (1), above, a delay resulting from an error (*e.g.*, a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown that:

(1) the error was the cause of the delay at issue;

(2) there was in place a business routine for performing the clerical function that could reasonably be relied upon to avoid errors in its performance;

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[9] Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-15 (D.C. Cir. 1912); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (Comm'r Pat. 1913).

[10] Haines v. Quigg, 673 F. Supp. 314, 5 USPQ2d 1130 (N.D. Ind. 1987).

[11] Ray, 55 F.3d at 609, 34 USPQ2d at 1788.

[12] Id.

(3) and the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care.[13]

An adequate showing requires:

(A) Statements by all persons with direct knowledge of the circumstances surrounding the delay, setting forth the facts as they know them.

(B) Petitioner must supply a thorough explanation of the docketing and call-up system in use and must identify the type of records kept and the person responsible for the maintenance of the system. This showing must include copies of mail ledgers, docket sheets, filewrappers and such other records as may exist which would substantiate an error in docketing, and include an indication as to why the system failed to provide adequate notice that a reply was due.

(C) Petitioner must supply information regarding the training provided to the personnel responsible for the docketing error, degree of supervision of their work, examples of other work functions carried out, and checks on the described work which were used to assure proper execution of assigned tasks.

At the outset, it is noted that although petitioner tracked the maintenance fees *pro se*, petitioner has not provided copies of any docket sheets, computer tracking reports, or other evidence showing why the system failed to provide adequate and timely notice that the maintenance fee was due.

More importantly, petitioner states that his original written records have not been available since 1999. While petitioner may have believed that the third maintenance fee was due "some time in the future" that belief, alone, does not constitute a proper docketing system. As such, with all records in storage and unavailable, petitioner could not reasonably rely on the written records as a system to track the third maintenance fee for this patent.

Turning to the computer docketing system, petitioner states that the system suffered failures "thoughout the 2000 timeframe" and that a loss of data occurred, including data related to the

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[13] See MPEP 711.03(c)(III)(C)(2).

patent maintenance fee payment. Petitioner apparently switched to a new computer system, but again suffered a "severe technical failure" due to a computer virus.

While petitioner's predicament is unfortunate, rather than unavoidable delay, the showing of record is that petitioner lacked a reliable system for tracking and paying the third maintenance fee. The showing of record is that petitioner relied solely on a computer system of very questionable reliability. If a computer docketing system suffered the known failures described by petitioner, it is a fair question to ask how a reasonable and prudent individual could rely on it in the pursuit of his most important business.

In this regard it is noted that petitioner asserts that since his business routine "worked in the past to provide notice of the two previous maintenance fee payments as well as other important dates" petitioner was entitled to rely on that routine for the present maintenance. The showing of record, however, is that petitioner's business practice had been altered to a point where it was no longer reliable at the time the third maintenance fee was due: Petitioner's written records had been inaccessible for at least several years, and his computer system had suffered a loss of data and other problems, on apparently an ongoing basis, since 2000.

Lastly, with regard to petitioner's statement that he also relied on reminders from the USPTO to pay the maintenance fee, petitioner's contention that he did not receive notification from the USPTO that the maintenance fee was due is not well taken. A patentee's lack of knowledge of the need to pay the maintenance fee and the failure to receive the Maintenance Fee Reminder do not constitute unavoidable delay.[14] Under the statute and regulations, the Office has no duty to notify patentees of the requirement to pay maintenance fees or to notify patentees when the maintenance fees are due. The Office mailing of Maintenance Fee Reminders is carried out strictly as a courtesy. Accordingly, it is solely the responsibility of the patentee to assure that the maintenance fee is timely paid to prevent expiration of the patent. The lack of knowledge of the requirement to pay a maintenance fee and/or the failure to receive the Maintenance Fee Reminder will not shift the burden of

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[14] *See* Patent No. 4,409,763, *supra*; *see also* "Final Rules for Patent Maintenance Fees" 49 Fed. Reg. 34716, 34722-34723 (August 31, 1984), *reprinted in* 1046 Off. Gaz. Pat. Office 28, 34 (September 25, 1984).

monitoring the time for paying a maintenance fee from the patentee to the Office.[15]

In summary, the showing of record is inadequate to establish unavoidable delay. Petitioner has provided no evidence to substantiate a claim of docketing error. Rather, the showing of record is that petitioner failed to docket the third maintenance fee in a reliable tracking system. As such, it appears that petitioner was preoccupied with other matters. Petitioner's preoccupation with other matters which took precedence over payment of the maintenance fees for the above-identified patent constitutes a lack of diligence, not unavoidable delay.[16] As petitioner has not shown that it exercised the standard of care observed by a reasonable person in the conduct of his or her most important business, the petition will be dismissed.[17]

Petitioner should note that if this petition is not renewed, or if renewed and not granted, then the maintenance fee and post-expiration surcharge are refundable. The $400.00 petition fee for seeking reconsideration is not refundable. Any request for refund should be in writing to the address noted below.

The address on counsel's cover letter is different than the address in the petition. A courtesy copy of the decision is being forwarded to the address of petitioner's counsel.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-8300
Attn: Office of Petitions

By hand: Customer Service Window
Mail Stop Petition
Randolph Building
401 Dulany Street
Alexandria, VA 22314

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15 Rydeen v. Quigg, 748 F. supp. at 900.

16 See Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982).

17 See note 4, supra.

Telephone inquiries should be directed to the undersigned at 571-272-3231.

D Wood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

cc: Hemingway & Hansen
Preston Commons West Suite 460
8117 Preston Road
Dallas TX 75225

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Paper No. 21

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OFFICE OF PETITIONS

In re Patent No. 5,103,188	:	
Issued: 7 April, 1992	:	
Application No. 07/389,735	:	REQUEST FOR INFORMATION
Filed: 4 August, 1989	:	
For: BUFFERED TRANSCONDUCTANCE	:	
AMPLIFIER	:	

This is a decision on the petition under 37 CFR 1.378(e),[1] filed on 25 September, 2006 (certificate of mailing date 19 September, 2006), requesting reconsideration of a prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-referenced patent.

The petition is **dismissed**.

If reconsideration of this decision is desired, a petition for reconsideration under 37 CFR 1.378(e) must be filed within TWO (2) MONTHS from the mail date of this decision. No extension of

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[1] A grantable petition to accept a delayed maintenance fee payment under 37 CFR 1.378(b) must be include

(1) the required maintenance fee set forth in § 1.20(e) through (g);
(2) the surcharge set forth in §1.20(i)(1); and
(3) a showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

this 2-month time limit can be granted under 37 CFR 1.136(a) or (b). No further fee is due for seeking reconsideration.

The patent issued on 7 April, 1992. The first and second maintenance fees were timely paid. The third maintenance fee could have been paid The first maintenance fee could have been paid during the period from 7 April through 7 October, 2003, or, with a surcharge, during the period from 8 October, 2003, through 7 April, 2004. Accordingly, this patent expired at midnight on 7 April, 2004, for failure to timely remit the maintenance fee. The petition under 37 CFR 1.378(b) filed on 24 April, 2006, was dismissed on 20 July, 2006. This request for reconsideration, accompanied by a check for $400.00, was filed on 25 September, 2006 (certificate of mailing date 19 September, 2006).

The Director may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Director to have been "unavoidable".[2] A patent owner's failure to pay a maintenance fee may be considered to have been "unavoidable" if the patent owner "exercised the due care of a reasonably prudent person."[3] This determination is to be made on a "case-by-case basis, taking all the facts and circumstances into account."[4] Unavoidable delay under 35 U.S.C. § 41(b) is measured by the same standard as that for reviving an abandoned application under 35 U.S.C. § 133.[5] Under 35 U.S.C. § 133, the Director may revive an abandoned application if the delay in responding to the relevant outstanding Office requirement is shown to the satisfaction of the Director to have been "unavoidable". Decisions on reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable.[6] However, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay.[7] In view of In re Patent No. 4,409,763,[8] this same standard will

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[2] 35 U.S.C. § 41(c)(1).

[3] Ray v. Lehman, 55 F.3d 606, 608-09 (Fed.Cir.), cert. denied, -- U.S. ---, 116 S.Ct. 304, L.Ed.2d 209 (1995).

[4] Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982).

[5] In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (PTO Comm'r 1988).

[6] Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-15 (D.C. Cir. 1912); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (Comm'r Pat. 1913).

[7] Haines v. Quigg, 673 F. Supp. 314, 5 USPQ2d 1130 (N.D. Ind. 1987).

[8] 7 USPQ2d 1798, 1800 (Comm'r Pat. 1988), aff'd sub nom. Rydeen v. Quigg, 748 937 F.2d 623 (Fed. Cir. 1991) (table), cert. denied, 502 U.S. 1075 (1992).

be applied to determine whether "unavoidable" delay within the meaning of 37 CFR 1.378(b) occurred.

This petition does not satisfy the requirement of 37 CFR 1.378(b)(3). The statements presented in the petition fail to satisfy the showing required to establish unavoidable delay within the meaning of 37 CFR 1.378(b).

In the present request for reconsideration, petitioner asserts, in pertinent part, that he recorded maintenance fee due dates utilizing two separate computer scheduling system.

Specifically, petitioner, in the renewed petition, asserts that he used two computer systems: (1) a 1996 computer system which petitioner alleges suffered from Y2K problems. "In 1996, MS Win95 had a Y2k issue, which affected the system's ability to log in dates higher than year 2000." Petitioner continues that he was not able to "log PTO maintenance due dates in my computer system for years 2004 and 2012 with the calendaring system on this computer," and (2) a 2000 computer system, which did not suffer from Y2K issues, but did suffer from "normal errors and systems bugs" and, in early 2003, was "hit with a serious and rather unique virus attack, not once, but twice."

A petition to accept the delayed maintenance fee under 35 U.S.C. § 41(c) and 37 CFR 1.378(b) must be accompanied by (1) an adequate, verified showing that the delay was unavoidable, since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent, (2) payment of the appropriate maintenance fee, unless previously submitted, and (3) payment of the surcharge set forth in 37 CFR 1.20(i)(1). This petition lacks requirement (1).

There are three periods to be considered during the evaluation of a petition under 37 CFR 1.378(b):

(1) The delay in reply that originally resulted in expiration;
(2) The delay in filing an initial petition pursuant to § 1.378(b) to revive the application; and
(3) The delay in filing a *grantable* petition pursuant to § 1.378(b) to revive the application.[9]

---

[9] See Changes to Patent Practice and Procedure; Final Rule Notice, 62 Fed. Reg. 53131 at 53158 (October 10, 1997).

This petition lacks the showing required by periods (1) and (2).

With regard to period (1), petitioners' evidence has been considered, but is not persuasive.

This petition does not satisfy the requirement of 37 CFR 1.378(b)(3). The statements presented in the petition fail to satisfy the showing required to establish unavoidable delay within the meaning of 37 CFR 1.378(b).

As 35 U.S.C. § 41(c) requires the payment of fees at specified intervals to maintain a patent in force, rather than some response to a specific action by the Office under 35 U.S.C. § 133, a reasonably prudent person in the exercise of due care and diligence would have taken steps to ensure the timely payment of such maintenance fees.[10] That is, an adequate showing that the delay was "unavoidable" within the meaning of 35 U.S.C. § 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent.[11]

With regard to period (1), above, a delay resulting from an error (*e.g.*, a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown that:

(1) the error was the cause of the delay at issue;

(2) there was in place a business routine for performing the clerical function that could reasonably be relied upon to avoid errors in its performance;

(3) and the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care.[12]

An adequate showing requires:

(A) Statements by all persons with direct knowledge of the circumstances surrounding the delay, setting forth the facts as they know them.

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[10] Ray, 55 F.3d at 609, 34 USPQ2d at 1788.
[11] Id.
[12] See MPEP 711.03(c)(III)(C)(2).

(B) Petitioner must supply a thorough explanation of the docketing and call-up system in use and must identify the type of records kept and the person responsible for the maintenance of the system. This showing must include copies of mail ledgers, docket sheets, filewrappers and such other records as may exist which would substantiate an error in docketing, and include an indication as to why the system failed to provide adequate notice that a reply was due.

(C) Petitioner must supply information regarding the training provided to the personnel responsible for the docketing error, degree of supervision of their work, examples of other work functions carried out, and checks on the described work which were used to assure proper execution of assigned tasks.

At the outset, an adequate determination of whether the delay was unavoidable required a documented showing of the steps taken to docket and track the maintenance fee.

With regard to petitioner's computer systems, the showing of record is that the 1996 system was not reliable, as petitioner knew that it would not track dates beyond 31 December, 1999, and petitioner could not reasonably rely upon it to docket a maintenance fee due in 2004.

With regard to the 2000 computer system, if that computer system was the one upon which petitioner relied for tracking the maintenance fee in the subject patent, petitioner **must** provide a documented showing of the operation of that computer docketing system. Specifically, petitioner must provide a through explanation of how the 2000 system was set up, how the maintenance fee information was entered, and the operation of the system. Specifically, petitioner must provide copies of any docket sheets, computer tracking reports, or other evidence showing why the system failed to provide adequate and timely notice that the maintenance fee was due.

Further, with regards to the computer virus which petitioner's system allegedly fell victim to, petitioner must provide details regarding the failure caused by the virus, including the dates that the system was affected, when petitioner learned that his system had failed because of the virus, and what steps were taken to eliminate the virus and restore any lost data once petitioner learned of the problem. Petitioner must provide all documentation available regarding the failure caused by the virus and the steps taken to recover the docketing system. Further,

petitioner makes reference to corrupted backup disks. Petitioner must explain in detail the circumstances surrounding any backup disks and provide documentation in support of that showing.

It is imperative that petitioner provide a complete, thorough, and detailed showing that possible that the entire delay, from the date the maintenance fee was due until the date a grantable petition was filed, was unavoidable. Any available documentation, printouts, or correspondence which would support petitioner's assertions must be submitted. If petitioner is unable to provide such a showing, the petition will not be granted.

Petitioner is cautioned to avoid submitting personal information in a patent application that may contribute to identity theft. If personal information such as social security numbers, bank account numbers, or credit card numbers are included in documents submitted to the USPTO (other than a check or credit card authorization form PTO-2038 submitted for payment purposes), petitioners should consider redacting such personal information from the documents before submitting them to the USPTO. This type of personal information is never required by the USPTO to support a petition or an application. Petitioner is advised that any information submitted in an application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, information from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Petitioner should note that if this petition is not renewed, or if renewed and not granted, then the maintenance fee and post-expiration surcharge are refundable.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-8300
Attn: Office of Petitions

By hand: Customer Service Window
Mail Stop Petition
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Telephone inquiries should be directed to the undersigned at 571-272-3231.

D Wood

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Senior Petitions Attorney
Office of Petitions

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UNITED STATES PATENT AND TRADEMARK OFFICE

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DIW Jun-07

Paper No. 23

GREGORY BENDER
P. O. BOX
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COPY MAILED

JUN 2 2 2007

OFFICE OF PETITIONS

In re Patent No. 5,103,188	:	
Issued: 7 April, 1992	:	SECOND
Application No. 07/389,735	:	REQUEST FOR INFORMATION
Filed: 4 August, 1989	:	
For: BUFFERED TRANSCONDUCTANCE	:	
AMPLIFIER	:	

This is a decision on the petition under 37 CFR 1.378(e),[1] filed on 3 April, 2007, requesting reconsideration of a prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-referenced patent.

The petition is **dismissed**.

If reconsideration of this decision is desired, a petition for reconsideration under 37 CFR 1.378(e) must be filed within TWO (2) MONTHS from the mail date of this decision. No extension of this 2-month time limit can be granted under 37 CFR 1.136(a) or (b). No further fee is due for seeking reconsideration.

The patent issued on 7 April, 1992. The first and second maintenance fees were timely paid. The third maintenance fee

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[1] A grantable petition to accept a delayed maintenance fee payment under 37 CFR 1.378(b) must be include

(1) the required maintenance fee set forth in § 1.20(e) through (g);
(2) the surcharge set forth in §1.20(i)(1); and
(3) a showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

could have been paid during the period from 7 April through 7 October, 2003, or, with a surcharge, during the period from 8 October, 2003, through 7 April, 2004. Accordingly, this patent expired at midnight on 7 April, 2004, for failure to timely remit the maintenance fee. The petition under 37 CFR 1.378(b) filed on 24 April, 2006, was dismissed on 20 July, 2006. A request for reconsideration, accompanied by a check for $400.00, was filed on 25 September, 2006 (certificate of mailing date 19 September, 2006). The request was dismissed on 5 February, 2007. This request for reconsideration followed on 3 April, 2007.

The Director may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Director to have been "unavoidable".[2] A patent owner's failure to pay a maintenance fee may be considered to have been "unavoidable" if the patent owner "exercised the due care of a reasonably prudent person."[3] This determination is to be made on a "case-by-case basis, taking all the facts and circumstances into account."[4] Unavoidable delay under 35 U.S.C. § 41(b) is measured by the same standard as that for reviving an abandoned application under 35 U.S.C. § 133.[5] Under 35 U.S.C. § 133, the Director may revive an abandoned application if the delay in responding to the relevant outstanding Office requirement is shown to the satisfaction of the Director to have been "unavoidable". Decisions on reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable.[6] However, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay.[7] In view of In re Patent No. 4,409,763,[8] this same standard will be applied to determine whether "unavoidable" delay within the meaning of 37 CFR 1.378(b) occurred.

This petition does not satisfy the requirement of 37 CFR 1.378(b)(3). The statements presented in the petition fail to

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[2] 35 U.S.C. § 41(c)(1).

[3] Ray v. Lehman, 55 F.3d 606, 608-09 (Fed.Cir.), cert. denied, -- U.S. ---, 116 S.Ct. 304, L.Ed.2d 209 (1995).

[4] Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982).

[5] In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (PTO Comm'r 1988).

[6] Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-15 (D.C. Cir. 1912); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (Comm'r Pat. 1913).

[7] Haines v. Quigg, 673 F. Supp. 314, 5 USPQ2d 1130 (N.D. Ind. 1987).

[8] 7 USPQ2d 1798, 1800 (Comm'r Pat. 1988), aff'd sub nom. Rydeen v. Quigg, 748 937 F.2d 623 (Fed. Cir. 1991) (table), cert. denied, 502 U.S. 1075 (1992).

satisfy the showing required to establish unavoidable delay within the meaning of 37 CFR 1.378(b).

In the present request for reconsideration, petitioner again asserts, in pertinent part, that he recorded maintenance fee due dates utilizing two separate computer scheduling system.

Specifically, petitioner, in the renewed petition, asserts that he used two computer systems: (1) a 1996 computer system which petitioner alleges suffered from Y2K problems. "In 1996, MS Win95 had a Y2k issue, which affected the system's ability to log in dates higher than year 2000." Petitioner continues that he was not able to "log PTO maintenance due dates in my computer system for years 2004 and 2012 with the calendaring system on this computer," and (2) a 2000 computer system, which did not suffer from Y2K issues, but did suffer from "normal errors and systems bugs" and, in early 2003, was "hit with a serious and rather unique virus attack, not once, but twice." Petitioner states that he created a back-up disk with the calendar files on it, but that back-up disk, presumably made after the virus attack, was corrupted by the virus and did not contain the maintenance fee reminders.

A petition to accept the delayed maintenance fee under 35 U.S.C. § 41(c) and 37 CFR 1.378(b) must be accompanied by (1) an adequate, verified showing that the delay was unavoidable, since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent, (2) payment of the appropriate maintenance fee, unless previously submitted, and (3) payment of the surcharge set forth in 37 CFR 1.20(i)(1). This petition lacks requirement (1).

There are three periods to be considered during the evaluation of a petition under 37 CFR 1.378(b):

(1) The delay in reply that originally resulted in expiration;
(2) The delay in filing an initial petition pursuant to § 1.378(b) to revive the application; and
(3) The delay in filing a *grantable* petition pursuant to § 1.378(b) to revive the application.[9]

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[9] See Changes to Patent Practice and Procedure; Final Rule Notice, 62 Fed. Reg. 53131 at 53158 (October 10, 1997).

This petition lacks the showing required by periods (1) and (2).

With regard to period (1), petitioners' evidence has been considered, but is not persuasive.

This petition does not satisfy the requirement of 37 CFR 1.378(b)(3). The statements presented in the petition fail to satisfy the showing required to establish unavoidable delay within the meaning of 37 CFR 1.378(b).

As 35 U.S.C. § 41(c) requires the payment of fees at specified intervals to maintain a patent in force, rather than some response to a specific action by the Office under 35 U.S.C. § 133, a reasonably prudent person in the exercise of due care and diligence would have taken steps to ensure the timely payment of such maintenance fees.[10] That is, an adequate showing that the delay was "unavoidable" within the meaning of 35 U.S.C. § 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent.[11]

With regard to period (1), above, a delay resulting from an error (*e.g.*, a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown that:

(1) the error was the cause of the delay at issue;

(2) there was in place a business routine for performing the clerical function that could reasonably be relied upon to avoid errors in its performance;

(3) and the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care.[12]

An adequate showing requires:

(A) Statements by all persons with direct knowledge of the circumstances surrounding the delay, setting forth the facts as they know them.

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[10] Ray, 55 F.3d at 609, 34 USPQ2d at 1788.
[11] Id.
[12] See MPEP 711.03(c)(III)(C)(2).

(B) Petitioner must supply a thorough explanation of the docketing and call-up system in use and must identify the type of records kept and the person responsible for the maintenance of the system. This showing must include copies of mail ledgers, docket sheets, filewrappers and such other records as may exist which would substantiate an error in docketing, and include an indication as to why the system failed to provide adequate notice that a reply was due.

(C) Petitioner must supply information regarding the training provided to the personnel responsible for the docketing error, degree of supervision of their work, examples of other work functions carried out, and checks on the described work which were used to assure proper execution of assigned tasks.

At the outset, an adequate determination of whether the delay was unavoidable required a documented showing of the steps taken to docket and track the maintenance fee.

With regard to the 2000 computer system, the Office is requesting more information concerning the virus attack and what information was docketed in the system. Specifically, petitioner should provide further information directed to the following:

1. Petitioner states that the two virus attacks occurred on the 2000 computer system "in early 2003." Specifically, the Office would like to know, as accurately as possible, the specific dates of the two virus attacks. In particular, as petitioner states that the computer system would have first provided a warning on 7 February, 2003, that the maintenance fee was due, petitioner must explain whether the virus attacks occurred before any of the maintenance fee reminders had been provided by petitioners system. Petitioner should state whether any maintenance fee reminders were provided prior to the virus attack, and, if so, whether petitioner took any steps to pay the maintenance fee in response to the reminder.

2. Petitioner states that after each virus attack, petitioner reviewed the scheduled dates in the XL Calendar and that they appeared intact. Petitioner should explain whether he verified that the maintenance fee reminder for **this** patent remained in the system and was intact.

3. Petitioner states that the computer calendaring system was relied upon to provide notice of important dates, meetings, and appointments. Petitioner must explain whether other dates docketed in this computer calendaring system were missed because

of the virus attack. It is requested that petitioner state what other information was docketed in this computer system, and whether other deadlines were missed as a result of the software problems. Furthermore, once petitioner realized that dates were being missed as a result of problems with the software, did petitioner take steps to determine what due dates were approaching and docket those dates in an alternate system?

4. Petitioner should explain whether any anti-virus software was utilized, and, if so, at what date was the anti-virus software installed and activated.

5. The Office would like to know specifically how petitioner, and petitioner's counsel, learned of the expiration of this patent. Petitioner has not adequately explained the extended period of delay which elapsed from the date the patent expired until the date petitioner learned of the expiration. Did petitioner receive a Maintenance Fee Reminder from the USPTO regarding the expiration of this patent, and, if so, when was the Reminder received? Additionally, petitioner should explain how and when counsel learned of the expiration of the patent and what steps were taken to timely file a petition to reinstate the patent. Petitioner should provide a copy of any correspondence between counsel and petitioner regarding notification of the expiration of the patent.

The showing of record is that petitioner has failed to substantiate his assertions with documentary evidence. While petitioner has "reconstructed" the calendar entries for the maintenance fee for this patent, no evidence has been provided, save petitioner's bald assertion, that the maintenance fee was ever in fact docketed. Further, petitioner has not demonstrated the level of care and diligence that a reasonably prudent person would exercise in relation to his most important business in that petitioner did not learn of the patent's expiration until over two years after it expired. The showing of record suggests that if petitioner's counsel had not informed him that the patent had expired, petitioner may well have never become aware that the patent had expired.

Additionally, had petitioner acted with the due care of a reasonable and prudent person in relation to his or her most important business, he would have sought assistance from computer professionals to recover data from his computer or back-up disc, and not relied solely upon his memory to verify that no information had been lost. Petitioner would have sought to

verify that the maintenance fee reminders were, in fact, still in the calendaring system after the virus attack.

It is imperative that petitioner provide a complete, thorough, and detailed showing that possible that the entire delay, from the date the maintenance fee was due until the date a grantable petition was filed, was unavoidable. Any available documentation, printouts, or correspondence which would support petitioner's assertions must be submitted. If petitioner is unable to provide such a showing, the petition will not be granted.

Petitioner is cautioned to avoid submitting personal information in a patent application that may contribute to identity theft. If personal information such as social security numbers, bank account numbers, or credit card numbers are included in documents submitted to the USPTO (other than a check or credit card authorization form PTO-2038 submitted for payment purposes), petitioners should consider redacting such personal information from the documents before submitting them to the USPTO. This type of personal information is never required by the USPTO to support a petition or an application. Petitioner is advised that any information submitted in an application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, information from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Petitioner should note that if this petition is not renewed, or if renewed and not granted, then the maintenance fee and post-expiration surcharge are refundable.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-8300
Attn: Office of Petitions

By hand: Customer Service Window
Mail Stop Petition
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Telephone inquiries should be directed to the undersigned at 571-272-3231.

DIWood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc: HEMINGWAY & HANSEN
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DALLAS TX 75201

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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ALEXANDRIA, VA 22313-1450
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Paper No. 25

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OFFICE OF PETITIONS

ON PETITION

GREGORY BENDER
P.O. BOX 2400
SARATOGA CA 95070

In re Patent No. 5,103,188 :
Issued: 7 April, 1992 :
Application No. 07/389,735 :
Filed: 4 August, 1989 :
For: BUFFERED TRANSCONDUCTANCE :
AMPLIFIER :

This is a decision on the petition under 37 CFR 1.378(e),[1] filed on August 24, 2007, requesting reconsideration of a prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-referenced patent.

The petition is **granted**.

In light of the showing of record, it is concluded that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be timely paid.

Accordingly, the maintenance fee in this case is hereby accepted and the above-identified patent is hereby reinstated as of the mail date of this decision.

This patent file is being returned to the Files Repository.

Telephone inquiries should be directed to the undersigned at 571-272-3231.

D Wood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc: HEMINGWAY & HANSEN
BANK ONE CENTER
SUITE 2500
1717 MAIN STREET
DALLAS TX 75201

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[1] A grantable petition to accept a delayed maintenance fee payment under 37 CFR 1.378(b) must be include

(1) the required maintenance fee set forth in § 1.20(e) through (g);
(2) the surcharge set forth in §1.20(i)(1); and
(3) a showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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OCT 23 2007

Dennis A. Bennett
Global Patent Group, LLC
10411 Clayton Rd., Ste 304
St. Louis, Missouri 63131

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,971,802

Dear Mr. Bennett:

An order granting interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,971,802 for a period of one (1) year. Pursuant to 35 U.S.C. § 156(d)(5)(B), a notice regarding the grant of an interim extension under 35 U.S.C. § 156(d)(5) was published in the Federal Register of October 16, 2007, 72 Fed. Reg. 58649, a copy of which is enclosed for your records.

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-7728; or by e-mail to Raul.Tamayo@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: Mifamurtide
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re IDM Pharma	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,971,802	:	**INTERIM EXTENSION**

On August 8, 2007, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover the product Mifamurtide having the active ingredient muramyl tripeptide phosphatidyl ethanolamine. The application indicates that a New Drug Application (NDA No. 22-092) for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the expiration date of the patent (November 20, 2007), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,971,802 is granted for a period of one year from the expiration date of the patent, i.e., until November 20, 2008.

10/4/07
Date

Jon W. Dudas
JON W. DUDAS
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. PTO-P-2007-0037]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,971,802; MIFAMURTIDE

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,971,802.

FOR FURTHER INFORMATION CONTACT: Raul Tamayo by telephone at (571) 272-7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-7728, or by e-mail to Raul.Tamayo@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has

been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On August 8, 2007, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover the product Mifamurtide having the active ingredient muramyl tripeptide phosphatidyl ethanolamine. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the expiration date of the patent (November 20, 2007), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,971,802 is granted for a period of one year from the expiration date of the patent, i.e., until November 20, 2008.

10/4/07
Date

JON W. DUDAS
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DEC 29 2008

Dennis A. Bennett
Global Patent Group, LLC
10411 Clayton Rd., Ste 304
St. Louis, Missouri 63131

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,971,802

Dear Mr. Bennett:

An order granting a second interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,971,802 for a period of one (1) year. Pursuant to 35 U.S.C. § 156(d)(5)(B), a notice regarding the grant of an interim extension under 35 U.S.C. § 156(d)(5) was published in the Federal Register of December 29, 2008, 73 Fed. Reg. 79451, a copy of which is enclosed for your records.

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-7728; or by e-mail to Raul.Tamayo@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Mifamurtide (muramyl tripeptide phosphatidyl ethanolamine)
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re IDM Pharma Request for Patent Term Extension U.S. Patent No. 4,971,802	: : :	**ORDER GRANTING** **INTERIM EXTENSION**

On October 10, 2008, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover the product Mifamurtide having the active ingredient muramyl tripeptide phosphatidyl ethanolamine. The application indicates that a New Drug Application (NDA No. 22-092) for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (November 20, 2008), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,971,802 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until November 20, 2009.

12/18/8
Date

JOHN J. DOLL
Acting Deputy Under Secretary of Commerce for
Intellectual Property and Acting Deputy Director
of the United States Patent and Trademark Office

not oblige NOAA to award any specific project or to obligate any available funds.

National Environmental Policy Act (NEPA): NOAA must analyze the potential environmental impacts, as required by the National Environmental Policy Act (NEPA), for applicant projects or proposals which are seeking NOAA federal funding opportunities. Detailed information on NOAA compliance with NEPA can be found at the following NOAA NEPA Web site: *http://www.nepa.noaa.gov/*, including our NOAA Administrative Order 216–6 for NEPA, *http://www.nepa.noaa.gov/NAO216_6_TOC.pdf*, and the Council on Environmental Quality implementation regulations, *http://ceq.eh.doe.gov/nepa/regs/ceq/toc_ceq.htm*. Consequently, as part of an applicant's package, and under their description of their program activities, applicants are required to provide detailed information on the activities to be conducted, locations, sites, species and habitat to be affected, possible construction activities, and any environmental concerns that may exist (*e.g.*, the use and disposal of hazardous or toxic chemicals, introduction of non-indigenous species, impacts to endangered and threatened species, aquaculture projects, and impacts to coral reef systems). In addition to providing specific information that will serve as the basis for any required impact analyses, applicants may also be requested to assist NOAA in drafting of an environmental assessment, if NOAA determines an assessment is required. Applicants will also be required to cooperate with NOAA in identifying feasible measures to reduce or avoid any identified adverse environmental impacts of their proposal. The failure to do so shall be grounds for not selecting an application. In some cases if additional information is required after an application is selected, funds can be withheld by the Grants Officer under a special award condition requiring the recipient to submit additional environmental compliance information sufficient to enable NOAA to make an assessment on any impacts that a project may have on the environment.

The Department Of Commerce Pre-Award Notification Requirements For Grants And Cooperative Agreements: The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of February 11, 2008 (73 FR 7696), are applicable to this solicitation.

Paperwork Reduction Act: This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, and SF–LLL and CD–346 has been approved by the Office of Management and Budget (OMB) under the respective control numbers 0348–0043, 0348–0044, 0348–0040, 0348–0046, and 0605–0001.

Notwithstanding any other provision of law, no person is required to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

Executive Order 12866: This notice has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 13132 (Federalism): It has been determined that this notice does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

Administrative Procedure Act/Regulatory Flexibility Act: Prior notice and an opportunity for public comment are not required by the Administrative Procedure Act or any other law for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements for the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Charles S. Baker,

Deputy Assistant Administrator for Satellite and Information Services.

[FR Doc. E8–30770 Filed 12–24–08; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2008–0060]

Grant of Interim Extension of the Term of U.S. Patent No. 4,971,802; Mifamurtide

AGENCY: United States Patent and Trademark Office.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. 156(d)(5) for a second one-year interim extension of the term of U.S. Patent No. 4,971,802.

FOR FURTHER INFORMATION CONTACT: Raul Tamayo by telephone at (571) 272–7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to his attention at (571) 273–7728, or by e-mail to *Raul.Tamayo@uspto.gov*.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On October 10, 2008, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover the product Mifamurtide having the active ingredient muramyl tripeptide phosphatidyl ethanolamine. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (November 20, 2008), interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A second interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,971,802 is granted for a period of one year from the extended expiration date of the patent, i.e., until November 20, 2009.

Dated: December 18, 2008.

John J. Doll,

Acting Deputy Under Secretary of Commerce for Intellectual Property and Acting Deputy Director of the United States Patent and Trademark Office.

[FR Doc. E8–30781 Filed 12–24–08; 8:45 am]

BILLING CODE 3510–16–P

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

NOV 17 2009

Dennis A. Bennett
Global Patent Group, LLC
10411 Clayton Rd., Ste 304
St. Louis, Missouri 63131

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,971,802

Dear Mr. Bennett:

An order granting a third interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,971,802 for a period of one (1) year. Pursuant to 35 U.S.C. § 156(d)(5)(B), a notice regarding the grant of an interim extension under 35 U.S.C. § 156(d)(5) was published in the Federal Register of November 10, 2009, at 74 Fed. Reg. 58003; a copy of the notice is enclosed for your records.

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-7728; or by e-mail to Raul.Tamayo@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Mifamurtide (muramyl tripeptide phosphatidyl ethanolamine)
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re IDM Pharma	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,971,802	:	**INTERIM EXTENSION**

On September 30, 2009, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover muramyl tripeptide phosphatidyl ethanolamine, which is labeled as the active ingredient in the human drug product Mifamurtide. The application indicates that a New Drug Application (NDA No. 22-092) for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (November 20, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,971,802 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until November 20, 2010.

10/30/09
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 11 2008

Michael J. Jaro, Esq.
Chief Patent Counsel
Medtronic Vascular
3576 Unocol Place
Santa Rosa CA 95403

Re: Patent Term Extension
Application for
U.S. Patent No. 5,292,331

ACKNOWLEDGMENT OF WITHDRAWAL OF APPLICATION FOR PATENT TERM EXTENSION

This is in response to the "Withdrawal of Application for Extension of Patent Term," filed February, 11, 2008, of the application for patent term extension for U.S. Patent No. 5,292,331, (S8 Over-the-Wire System).

The withdrawal of the application is hereby acknowledged and the application is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-0100

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755. E-mail inquiries should be directed to mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: S8 Over-the-Wire System
FDA Docket No.: 2004E-0304

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,014,119	:	
Issue Date: May 7, 1991	:	
Application No. 07/398,786	:	DECISION ON PETITION
Filed: August 25, 1989	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '119 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

SPE J. Wilson

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: _____

DATE : 6/6/06

TO SPE OF : ART UNIT 1624

SUBJECT : Request for Certificate of Correction for Appl. No.: 07/414,201 Patent No.: 5095030

Please respond to this request for a certificate of correction within 7 days.

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

Lamonte M. Newsome
Certificates of Correction Branch
703-308-9390 ext. 112

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriate box.

- [x] **Approved** — **All** changes apply.
- [ ] **Approved in Part** — Specify below which changes **do not** apply.
- [ ] **Denied** — State the reasons for denial below.

Comments: _____

SPE

1624
Art Unit

PTOL-306 (REV. 7/03)

U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

SPE J. Wilson

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: _____

DATE : 6/6/06

TO SPE OF : ART UNIT 1624

SUBJECT : Request for Certificate of Correction for Appl. No.: 07/414,201 Patent No.: 5095030

Please respond to this request for a certificate of correction within 7 days.

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

Lamonte M. Newsome
Certificates of Correction Branch
703-308-9390 ext. 112

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriate box.

- [x] **Approved** — **All** changes apply.
- [ ] **Approved in Part** — Specify below which changes **do not** apply.
- [ ] **Denied** — State the reasons for denial below.

Comments: All of the changes, which included typographical errors & errors in the figures apply. No new matter was added & changes did not affect patentability.

James D. McCue — 1624

SPE — **Art Unit**

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: _____

DATE : October 3, 2006

TO SPE OF : ART UNIT 1203

SUBJECT : Request for Certificate of Correction for Appl. No.: 07/424719 patent No.: 5,006,528

Please respond to this request for a certificate of correction within 7 days.

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

Magdalene Talley

Certificates of Correction Branch

703-308-9390 ext. 116

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriate box.

- ☒ **Approved** — All changes apply.
- ☐ **Approved in Part** — Specify below which changes **do not** apply.
- ☐ **Denied** — State the reasons for denial below.

Comments: _____

SPE

1625

Art Unit

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5,198,624	1993-03-30	07/436,914	1989-11-14	

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☒ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity			Small Entity		
	Fee	Code		Fee	Code
○	3 ½ year	(1551)	○	3 ½ year	(2551)
○	7 ½ year	(1552)	○	7 ½ year	(2552)
○	11 ½ year	(1553)	◉	11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/Roy Kim/	Date (YYYY-MM-DD)	2007-02-06
Name	Roy Kim	Registration Number	51883

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5198624
Issue Date: March 30,1993
Application No. 07436914
Filed: November 14,1989
Attorney Docket No. 32693

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed February 7,2007 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of February 7,2007 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 18

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JUN 01 2000

SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS

YOUNG & THOMPSON
745 South 23rd Street
Arlington, VA 22202

In re Patent No. 5,084,004
Issue Date: January 28, 1992
Application No. 07/449,942
Filed: December 29, 1989
Inventor: Claud Ranoux

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.378(b), filed February 18, 2000, to accept the delayed payment of a maintenance fee for the above-identified patent.

The petition is DISMISSED.

If reconsideration of this decision is desired, a petition for reconsideration under 37 CFR 1.378(e) must be filed within TWO (2) MONTHS from the mail date of this decision. No extension of this 2-month time limit can be granted under 37 CFR 1.136(a) or (b). Any such petition for reconsideration must be accompanied by the petition fee of $130 as set forth in 37 CFR 1.17(h). The petition for reconsideration should include an exhaustive attempt to provide the lacking item(s) noted below, since, after a decision on the petition for reconsideration, no further reconsideration or review of the matter will be undertaken by the Commissioner.

The patent issued January 28, 1992. The first maintenance fee due could have been paid during the period January 28, 1995 through July 28, 1995, or with a surcharge during the period from July 28, 1996 through January 28, 1996. Accordingly, the patent expired January 28, 1996 for failure to timely submit the first maintenance fee.

The Commissioner may accept late payment of the maintenance fee under 35 U.S.C. § 41(c) and 37 CFR 1.378(b) if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable." 35 U.S.C. § 41(c)(1).

A late maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 U.S.C. § 133

because 35 U.S.C. § 41(c)(1) uses the identical language, *i.e.*, "unavoidable" delay. Ray v. Lehman, 55 F.3d 606, 608-09, 34 USPQ2d 1786, 1787 (Fed. Cir. 1995)(quoting In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (Comm'r Pat. 1988)). Decisions on reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable. Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-15 (D.C. Cir. 1912); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (Comm'r Pat. 1913). In addition, decisions on revival are made on a "case-by-case basis, taking all the facts and circumstances into account." Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982). Finally, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay. Haines v. Quigg, 673 F. Supp. 314, 5 USPQ2d 1130 (N.D. Ind. 1987).

Petitioner has not carried the burden of proof to establish to the satisfaction of the Commissioner that the delay was unavoidable.

In determining whether a delay in paying a maintenance fee was unavoidable, one looks to whether the party responsible for scheduling payment of the maintenance fee exercised the due care of a reasonably prudent person. Ray, 55 F.3d at 608-609, 34 USPQ2d at 1787. While Cushman and Toshiba both assert the belief that the other was the responsible party, such will not be permitted to excuse both Cushman and Toshiba from the obligation of each to exercise the due care of a reasonably prudent person. Assuming, *arguendo*, that Cushman may have erred in assuming that Toshiba would pay the maintenance fee, such error(s) is, nevertheless, chargeable to Toshiba. The Patent and Trademark Office must rely on the actions or inactions of duly authorized and voluntarily chosen representatives of the patent holder, and petitioner is bound by the consequences of those actions or inactions. Link v. Wabash, 370 U.S. 626, 633-34 (1962). Specifically, petitioners' delay caused by mistakes or negligence of a voluntarily chosen representative does not constitute unavoidable delay. Haines v. Quigg, id; Smith v. Diamond, id; Potter v. Dann, 201 USPQ 574 (D.D.C. 1978); Ex parte Murray, id; Douglas v. Manbeck, Id.. Consequently, the delay caused by the failure of Cushman to timely remit the maintenance fee, by Toshiba's asserted understanding (and Cushman's asserted misunderstanding) of the supposed agreement, does not constitute

unavoidable delay. Ray, Id. Moreover, as noted *supra*, that delay is chargeable to Toshiba. Assuming, *arguendo*, that Cushman was correct in assuming that Toshiba bore the responsibility for paying the maintenance fee, the record shows that Toshiba failed to exercise due diligence, after becoming aware of the impending issuance of this patent, to determine its issue date, and thus, in time, the date to submit the maintenance fee, or to allocate that responsibility. Moreover, the showing of record is that neither Toshiba or Cushman had timely reached an adequate understanding in this matter, which is not grounds for a finding of unavoidable delay in submission of the maintenance fee, within the meaning of 35 USC 41(c) and 37 CFR 1.378(b).

Petitioner asserts that the delay in payment of the maintenance fee came about as a result of unusual circumstances occurring upon the transfer of responsibility for payment of the maintenance fee from petitioner Young & Thompson to the French law firm of Cabinet Bonnet-Thirion (hereinafter "CBT"). Petitioner asserts that both Young & Thompson and CBT had reliable computerized docketing and tracking systems to ensure timely payment of the maintenance fee, but that due to the filing of a reissue application shortly after the patent issued, data pertaining to this patent was not entered into CBT's system upon their assumption of responsibility to ensure payment of the fees. Petitioner additionally asserts that error on the part of the examiner by not determining that the patent had expired during examination of the reissue application and the long delay in examination of the reissue application both contributed to the delay in payment of the maintenance fee, preventing delayed payment under the unintentional standard within the two year period specified in 37 CFR § 1.378(c).

Petitioner Young & Thompson is additionally patentee's counsel of record with respect to this patent. As petitioner's representative, Young & Thompson, upon receipt of the letters patent, was aware of the need to diligently schedule and pay the maintenance fee. Petitioner asserts that the computerized docketing and tracking system utilized by Young & Thompson was a reasonably prudent and reliable system. However, the petition does not present any details of the system upon which an evaluation of this assertion can be based. Any renewal of this petition must provide a factual showing of the adequacy and reliability of this system, such as by way of affidavit from one knowledgeable of the system.

Assuming, *arguendo*, that the system of Young & Thompson was a reliably prudent means to ensure payment of maintenance fees, the existence of such a system does not, *per se*, establish unavoidable delay with respect to this patent. No showing has

been submitted to establish that the instant patent was actually entered into this system. In fact, the petition does not even make a specific assertion as to this matter. Petitioner simply states that a reliable system was in place.

Petitioner asserts that their responsibility to ensure payment of the maintenance fee for this patent terminated on February 5, 1994, being assumed at that time by CBT. However, no evidence has been submitted to substantiate assumption of responsibility by CBT with respect to this patent. Exhibit C does not identify this patent by number or identifier.

Exhibit C additionally includes the following statement:

> "Paris February 5, 1984
> We confirm you are to discontinue docketing your cases. The fee address indication form is to be made out under the name of Accumas Computer Packages Annuity Services, payee number....."

The source of this statement is not identified in Exhibit C. It is merely a cut-and-paste from some unidentified source. Additionally, this statement speaks to discontinuing docketing of cases, and does not speak to the tracking of cases already docketed. Any renewed petition with regard to this matter must submit a documentary showing if reliance is to be placed on CBT as the responsible party for payment of maintenance fees with respect to this patent. Also, the record is not clear how both Young & Thompson and CBT separately and together ensured that all patents that were under Young & Thompson's control were satisfactorily transferred to the control of Accumas Computer Packages Annuity Services, and why that control system failed to indicate this patent was not transferred to Accumas. Further, the record is not clear why CBT assumed that Accumas was tracking this patent.

Assuming, *arguendo*, that CBT had been properly appointed to conduct petitioner's patent matters subsequent to February 5, 1994, including matters pertaining to the payment of the maintenance fee, then any showing of unavoidable delay must establish the reasonable and prudent means employed by CBT to ensure payment of the fee. Petitioner merely presents a statement that CBT had such a system in place. Petitioner also asserts that CBT only enters patents into its system when they receive the letters patent grant. Assuming this to be the case, it would not seem prudent with respect to this patent, which CBT was fully aware was sent to petitioner and not CBT, for CBT to rely upon entry of this patent into its system based solely upon receipt of the original letters patent grant. Any renewed petition must present a documentary showing both of the system

used by CBT and their steps to ensure entry of this patent into their system.

Petitioner further states that, after transfer of responsibility for payment of the maintenance fee to CBT, Young & Thompson deleted records with respect to this patent from their system. No explanation is offered as to what steps, if any, were taken by Young & Thompson to ensure transfer of records with regard to this patent to CBT that would warrant deletion of this patent from their system.

Petitioner also contends that "(c)ontributing to the failure to pay maintenance fee with respect to this patent is the silence on this subject from the Examiner in charge of the reissue application." This assertion is not understood. The examiner had no way of knowing that maintenance fees had not been paid for the patent until after it expired. Thus, had the examiner determined at an earlier date that the patent had, in fact, expired, such a determination would have had no effect on failure of petitioner to pay the fee.

It is also asserted that earlier notice from the examiner may have enabled petitioner to file a petition within the two year period prescribed in 37 CFR § 1.378(c). While this may or may not be true, it has no bearing on the issue in this petition, which is unavoidable delay under section 1.378(b). However, it is noted that petitioner received a Reminder Notice from the PTO mailed September 5, 1995 (prior to expiration of the patent on January 28, 1996) and Notice of Expiration mailed 1/28/96. As patentee's designated counsel, it was the responsibility of counsel to pursue timely petition to accept delayed payment of the maintenance fee. That counsel did not pursue this matter within the two year period prescribed in section 1.378(c) is responsibility of counsel, not the PTO.

It is the responsibility of patentee or his designee to pay maintenance fees. Under the statute and rules, the Office has no duty to notify patentee of the need to pay maintenance fees or to notify patentee that maintenance fees are due. While the Office mails maintenance fee reminders strictly as a courtesy, it is solely the responsibility of the patentee to ensure that the maintenance fee is timely paid. Failure to receive the Reminder does not relieve the patentee of the obligation to timely pay the maintenance fee, nor will it constitute unavoidable delay if the patentee seeks reinstatement under the regulation. The lack of knowledge of the patentee to pay maintenance fees does not constitute unavoidable delay. See In re Patent No. 4,409,763, 7 USPQ2d 1798 (Comm'r Pat. 1988), aff'd, Rydeen v. Quigg, 748 F.Supp. 900, 16 USPQ2d 1876 (D.D.C. 1990), aff'd 937 F.2d 623

(Fed. Cir. 1991).

For the above stated reasons, the delay in payment of the maintenance fee in this case cannot be regarded as unavoidable within the meaning of 35 U.S.C. § 41 and 37 CFR 1.378(b).

Petitioner is advised that if the petition is not renewed, or if renewed and not granted, the fees paid to date are refundable. A copy of this decision and a written request for refund should be addressed to the Office of Finance, Refunds, at the PTO address.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box DAC
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Office of Petitions

By hand: Crystal Plaza Four, Suite 3C23
2201 S. Clark Place
Arlington, VA

Telephone inquiries related to this decision should be directed to Robert Garrett at (703) 308-0763, or in his absence, the undersigned at (703) 305-1820.

Brian Hearn

Brian Hearn
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 20

YOUNG & THOMPSON
745 South 23rd Street
Arlington, VA 22202

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OFFICE OF PETITIONS
A/C PATENTS

In re Patent No. 5,084,004
Issue Date: January 28, 1992
Application No. 07/449,942
Filed: December 29, 1999
Inventor: Claude Ranoux

DECISION ON PETITION

This is a decision on the renewed petition filed August 1, 2000 under 37 CFR 1.378(e) to accept the unavoidably delayed payment of the first and second maintenance fees for the above-identified patent.

The petition is **granted**.

In light of the showing of record, it is concluded that the delay was unavoidable in that reasonable care was taken to ensure that the maintenance fees would be timely paid. Accordingly, first and second maintenance fees are hereby accepted and the patent is reinstated.

With regard to payment of the first maintenance fee, petitioner provided a check in the amount of $1,170.00 with the first petition filed February 18, 2000. While no maintenance fee breakdown was provided by petitioner, the following fees were due for the first maintenance fee: $415.00 for the maintenance fee and $700.00 for the surcharge under 37 CFR § 1.20(i)(1), for a total of $1,115.00. Petitioner's check in the amount of $1,170.00 thus exceeded the amount due by $65.00. Petitioner apparently included the additional $65.00 as payment for the surcharge under 37 CFR § 1.20(h) for delayed payment within 6 months. Petitioner is advised that payment of the surcharge under § 1.20(h) is not necessary when the surcharge under § 1.20(i)(1) has been paid.

The petition filed February 18, 2000 additionally included authorization to charge the second maintenance fee for this patent to his deposit account, which would have been due July 28, 1999 if the first maintenance fee had been paid. Accordingly, petitioner's deposit account no. 25-0120 has been charged $950.00 for payment of the second maintenance fee, and has been credited the $65.00 overpayment discussed in the preceding paragraph, for a net charge to the deposit account of $885.00.

This file is being forwarded to the files repository.

Telephone inquiries concerning this decision may be directed to Robert Garrett at (703) 308-0763.

Brian Hearn
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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OFFICE OF PETITIONS

HOVEY WILLIAMS LLP
2405 GRAND BLVD., SUITE 400
KANSAS CITY MO 64108

In re Patent No. 5,110,614
Issue Date: May 5, 1992
Application No. 07/451,115
Filed: December 14, 1989
Attorney Docket No. 88411US01

ON PETITION

This is a decision on the petition under 37 CFR 1.378(c), filed May 5, 2006 to accept the unintentionally delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED**.

This patent expired on May 5, 2004 for failure to pay the 11.5 year maintenance fee. Since this petition was submitted within twenty-four months after the six-month grace period provided in 37 CFR 1.362(e), the petition was timely filed under the provisions of 37 CFR 1.378(c).

The petition states that the "abandonment of this application was unintentional." 37 CFR 1.378(c) requires a statement that "the delay in payment of the maintenance fee was unintentional." Since the statement appearing in the petition varies from the language required by 37 CFR 1.378(c)(3), the statement will be construed as the statement required by 37 CFR 1.378(c)(3). If this is an incorrect reading of the statement appearing in the petition, petitioner must promptly notify the Office.

It is not apparent whether the person signing the statement of unintentional delay was in a position to have firsthand or direct knowledge of the facts and circumstances of the delay at issue. Nevertheless, such statement is being treated as having been made as a result of a reasonable inquiry into the facts and circumstances of such delay. In the event that such an inquiry has not been made, petitioner must make such an inquiry. If such an inquiry results in the discovery that the delay in paying the maintenance fee under 37 CFR 1.378(c) was intentional, petitioner must notify the Office. There is no indication that Petitioner herein was ever empowered to prosecute the application.

The maintenance fee is hereby accepted and the above-identified patent is reinstated as of the mail date of this decision.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3215.

The patent file is being forwarded to Files Repository.

Charlema R. Grant

Charlema R. Grant
Petitions Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
07/451,115	12/14/1989	DENNIS CORBIN	88411US01

CONFIRMATION NO. 5437

OC000000025692731

OC000000025692731

23589
HOVEY WILLIAMS LLP
2405 GRAND BLVD., SUITE 400
KANSAS CITY, MO 64108

Date Mailed: 09/06/2007

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/05/2006.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

C. Grant (OP)

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199

ATTORNEY/APPLICANT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
07/451,115	12/14/1989	DENNIS CORBIN	88411US01

CONFIRMATION NO. 5437

OC000000025692668

OC000000025692668

NORMAN P.FRIEDERICHS
FRIEDERICHS LAW FIRM, PLC.
425 PILLSBURY CENTER
200 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

Date Mailed: 09/06/2007

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/05/2006.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

C. Grant (OP)

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199

NEW ATTORNEY/AGENT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
07/451,115	12/14/1989	DENNIS CORBIN	88411US01

CONFIRMATION NO. 5437

OC000000025692668

OC000000025692668

NORMAN P.FRIEDERICHS
FRIEDERICHS LAW FIRM, PLC.
425 PILLSBURY CENTER
200 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

Date Mailed: 09/06/2007

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/05/2006.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

C. Hunt (OP)

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199

FORMER ATTORNEY/AGENT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,959,717	:	
Issue Date: September 25, 1990	:	
Application No. 07/454,369	:	DECISION ON PETITION
Filed: December 21, 1989	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '717 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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McDERMOTT WILL & EMERY
227 WEST MONROE STREET
CHICAGO, IL 60606-5096

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FEB 1 1 2005

OFFICE OF PETITIONS

In re Application of :
Samuel W. Tse et al :
Application No. 07/456,616 : ON PETITION
Filed: December 22, 1989 :
Attorney Docket No. 24180-088 :

This is a decision on the petition under 37 CFR 1.137(b), filed December 13, 2004, to revive the above-identified application.

The petition is **DISMISSED**.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition under 37 CFR 1.137(b)." No additional fee is required with any renewed petition. Petitioner is advised that this is **not** a final agency action decision.

The above-identified application became abandoned for failure to reply in a timely manner to the non-final Office action mailed November 3, 2003, which set a shortened statutory period for reply of three (3) months. No extensions of time under the provisions of 37 CFR 1.136(a) were obtained. Accordingly, the above-identified application became abandoned on February 4, 2004.

A grantable petition to revive an abandoned application under 37 CFR 1.137(b) must be accompanied by: (1) the required reply (unless previously filed), which may met by the filing of a continuing application in a nonprovisional application abandoned for failure to prosecute, but must be the payment of the issue fee or any outstanding balance thereof in an application or patent, abandoned or lapsed for failure to pay the issue fee or any portion thereof; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) any terminal disclaimer required pursuant to 37 CFR 1.137(d). This petition lacks item (4) above.

The terminal disclaimer filed December 13, 2004 under 37 CFR 1.137(d) has **not** been entered. Effective September 8, 2000, 37 CFR 1.137(d)(1) has been added to state that a terminal disclaimer filed pursuant to this rule must dedicate to the public a terminal part of the term of any patent granted thereon equivalent to the lesser of: 1) the period of abandonment of the

application; or 2) the period extending beyond twenty years from the date on which the application for the patent was filed in the United States, or, if the application contains a specific reference to an earlier filed application(s) under 35 U.S.C. 120, 121 or 365(c), from the date on which the earliest such application was filed. 65 Fed. Reg. 54,674 (2000).

Since the terminal disclaimer fails to dedicate to the public the lesser of period (1) or (2), as noted above, the petition must be dismissed. A blank form for filing a terminal disclaimer is attached.

The Terminal Disclaimer For Untimely Petition to Withdraw Holding of Abandonment filed concurrently is unnecessary and the fee ($130) is being credited to petitioner's deposit account as authorized.

The Revocation of Power of Attorney and Grant of New Power of Attorney filed on December 13, 2004 is not acceptable since the person signing for the assignee has omitted his/her empowerment to sign on behalf of the assignee.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop PETITIONS
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

By fax: (703) 872-9306
ATTN: Office of Petitions

Telephone inquiries concerning this decision should be directed to Wan Laymon at (571) 272-3220.

Wan Laymon

Wan Laymon
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

Attachment: PTO/SB/63

UNITED STATES PATENT AND TRADEMARK OFFICE

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STEPHEN T. SCHERRER
MCDERMOTT WILL & EMERY
227 W. MONROE STREET
CHICAGO, IL 60606-5096

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JUN 07 2005

OFFICE OF PETITIONS

In re Application of	:	
Samuel W. Tse et al	:	
Application No. 07/456,616	:	ON PETITION
Filed: December 22, 1989	:	
Attorney Docket No. 24180-088	:	

This is a decision on the renewed petition under 37 CFR 1.173(b), filed February 23, 2005, to revive the above-identified application.

The petition is **GRANTED.**

The terminal disclaimed filed February 23, 2005 under 37 CFR 1.137(d) has been entered and made of record. Effective September 8, 2000, 37 CFR 1.137(d)(1) has been added to state that a terminal disclaimer filed pursuant to this rule must dedicate to the public a terminal part of the term of any patent granted thereon equivalent to the lesser of: 1) the period of abandonment of the application; or 2) the period extending beyond twenty years from the date on which the application for the patent was filed in the United States, or, if the application contains a specific reference to an earlier filed application(s) under 35 U.S.C. 120, 121 or 365(c), from the date on which the earliest such application was filed. 65 Fed. Reg. 54,674 (2000). Accordingly, the period of the terminal disclaimer filed February 23, 2005 will be equivalent to the lesser of period (1) or (2), as noted above, for this application.

The Revocation of Power of Attorney ... filed on February 23, 2005 is entered and made of record (copies attached).
Telephone inquiries concerning this decision should be directed to Wan Laymon at (571) 272-3220.

This matter is being referred Technology Center AU 1772.

Wan Laymon
Wan Laymon
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

Attachments: Notice Regarding Change of Power of Attorney
Notice of Acceptance of Power of Attorney

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OLE K. NILSSEN
200 N HARRISON STREET
SUITE 103
ALGONQUIN, IL 60102

COPY MAILED
AUG 16 2006
OFFICE OF PETITIONS

In re Patent No. 5,036,253 :
Issue Date: July 30, 1991 :
Application No. 07/461,653 : NOTICE
Filed: January 8, 1990 :
Attorney Docket No.

This is a notice regarding your request for acceptance of a fee deficiency submission under 37 CFR 1.28. On September 1, 1998, the Court of Appeals for the Federal Circuit held that 37 CFR 1.28(c) is the sole provision governing the time for correction of the erroneous payment of the issue fee as a small entity. **See DH Technology v. Synergystex International, Inc. 154 F.3d 1333, 47 USPQ2d 1865 (Fed. Cir. Sept. 1, 1998).**

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

Inquiries related to this communication should be directed to Irvin Dingle at (571) 272-3210.

Irvin Dingle
Petitions Examiner
Office of Petitions

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Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
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MICHAEL FERRAZANO
590 W. El Camino Real
Mountain View, CA. 94040

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 4,967,271 :
Issue Date: October 30, 1990 :
Application No. 07/464,009 : DECISION ON PETITION
Filed: February 5, 1990 :
Inventor: Jack J. Campbell et al :

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '271 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous documents related to a patent, not just the assignment of the entire right, title and interest in the

patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K Page

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,132,795	:	
Issue Date: July 21, 1992	:	
Application No. 07/466,469	:	DECISION ON PETITION
Filed: January 17, 1990	:	
Inventor: Jack J. Campbell	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '795 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

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Paper 14

HERSHKOVITZ & ASSOCIATES
2845 DUKE STREET
ALEXANDRIA VA 22314

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AUG 1 0 2007

OFFICE OF PETITIONS

In re Patent No. 5,060,401
Issue Date: October 29, 1991
Application No. 07/478,369
Filed: February 12, 1990
Attorney Docket Number: P67339

ON PETITION

This is a decision on the petition, filed June 11, 2007, under 37 CFR 1.182, requesting the issuance of a duplicate Letters Patent for the above-identified application.

The petition is **GRANTED**.

Since it is U.S. Patent and Trademark Office practice to assure mailing of all papers on the date indicated, there is a strong presumption that papers duly addressed and indicated as mailed, such as the Letters Patent in this application, are timely delivered to the addressee. To overcome this presumption, a verified statement with supporting evidence, such as any records which would disclose the receipt of other correspondence mailed from the U.S. Patent and Trademark Office on or about October 29, 1991, but fail to disclose receipt of the Letters Patent mailed on that date, should be promptly submitted. Further, copies of records on which receipt of the Letters Patent would have been entered had it been received are required.

However, if the loss of the Letters Patent was not the fault of the U.S. Patent and Trademark Office or if petitioner simply wishes to avoid overcoming the above-noted presumption, a petition may be filed under 37 CFR 1.182 accompanied by a petition fee of $400.00 requesting a duplicate Letters Patent. Upon receipt of the petition and petition fee, the request for a duplicate Letters Patent will be granted.

Petitioners state that the Letters Patent was received from the USPTO and was subsequently lost. The petition fee in the amount of $400.00 has been applied.

A copy of this decision is being forwarded to Publishing Division for issuance of a duplicate Letters Patent.

The Publishing Division is directed to issue a duplicate Letters Patent.

Telephone inquiries concerning this decision may be directed to the undersigned Senior Petitions Attorney at (571) 272-3212. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to the Publishing Division at (703) 308-9250.

Patricia Faison-Ball

Patricia Faison-Ball
Senior Petitions Attorney
Office of Petitions

cc: Krystal Paige, South Tower, 8th Floor (Fax – (571) 270-9937)

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Washington, D.C. 20231
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4/2/02

Paper No. 37

D ARLON GROVES PC
ONE RIVERWAY SUITE 1000
HOUSTON TX 77056

In re Application of Roy Weinstein Application No. 07/481,576 Filed: February 20, 20, 1990 For: MAGNETIC FIELD REPLICATOR AND METHOD	: : : : :	ON PETITION

This is a decision on the petition under 37 CFR 1.183 filed November 26, 2001, which is being treated as a petition under 37 CFR 1.181(a) (no fee) requesting the Director, Technology Center 2800, exercise his supervisory authority and review the decision of the Special Programs Examiner of April 29, 1999, which refused to withdraw the holding of abandonment.

The petition is **granted**.

Background

After reopening of prosecution under the practice of 37 CFR 1.129(a), a final Office action was mailed February 10, 1998, which set a shortened statutory period for reply of three months. Since May 10, 1998, was a Sunday, any reply filed on or before May 11, 1998, would be timely.

An interview was held April 27, 1998. While the interview summary cover sheet remains in the file and indicates that a copy of the interview summary would be mailed to applicant, inspection of the record fails to reveal any fuller description of the substance of the interview by the examiner.

On May 11, 1998, applicant filed, *inter alia*, a reply to the outstanding Office action, and a communication styled as an "Acknowledgment of Interview" (Acknowledgment) which memorialized the April 27, 1998 interview. Applicant's memorialization sets forth in relevant part that "the Examiner acknowledged that the "final rejection of the Action dated 10 February 1998 was not a proper final rejection and stated that it would be withdrawn and another office action would be forthcoming shortly."

On August 11, 1998, an Advisory Action was mailed which indicated that the reply of May 11, 1998, had been treated as an amendment submitted under the provisions of 37 CFR 1.116(b), which is applicable for replies submitted in response to a final Office action. The Advisory Action indicated that the reply did not *prima facie* place the case in condition for allowance.

A Notice of Abandonment was mailed September 14, 1998, which indicated that a proper reply had not been received to the Office action of February 10, 1998. For a finally rejected application, the proper reply is either an amendment *that prima facie* places the application in condition for allowance, or a Notice of Appeal of the finally rejected claims.

On November 16, 1998, applicant filed a petition under 37 CFR 1.181 seeking review and withdrawal of the holding of abandonment, and also, in essence, that the examiner treat the reply of May 11, 1998 under the provisions of 37 CFR 1.111, which applies to any reply by applicant in an application which has not been subjected to a final rejection. The petition also recounted in considerable detail the substance of the interview, which was consistent with the contemporaneous Acknowledgment noted above.

The petition was denied in the decision of the Special Programs Examiner mailed April 29, 1999. The decision maker recounted a then recent interview with the examiner by USPTO personnel, which again indicated that the examiner considered the propriety of the finality of the outstanding Office to have been improper.

The instant petition was filed November 26, 2001.

OPINION

The rules of practice require that the USPTO base its actions exclusively on the written record. See 37 CFR 1.2. The rules further set forth that where an interview is requested by applicant, an applicant may, as here, make a complete written statement of the interview. See 37 CFR 1.133(b). There is nothing in the record of this application written by the examiner that is inconsistent with the applicant's indications that the examiner then considered--and represented to applicant-- the finality of the outstanding Office action to have been in error.

Rather, in this case, the written record supports the conclusion that the examiner considered the finality of the Office action of February 10, 1998, to have been improper, and that such consideration was made prior to the expiration of the period for reply. As shown in MPEP 706.07(e), the examiner may simply withdraw the finality of an Office action, and does not have to also mail out a new office action at that time.

Thus, it is immaterial to the question of abandonment in this application that the supposedly forthcoming office action was not mailed during the pendency of this application.

Under the circumstances of this case, the written record shows that the finality of the Office action of February 10, 1998 was considered to have been withdrawn by the examiner as of April 27, 1998. Thus, the timely reply of May 11, 1998, did not have to comply with the more stringent provisions of 37 CFR 1.113, which only apply to a finally rejected application. It follows that the reply of May 11, 1998, was acceptable to have tolled the period for reply to the Office action of February 10, 1998, under the less stringent provisions of 37 CFR 1.111, which apply to the reply for any application not under a final rejection. As further explained in MPEP 706.07(e), when the finality of an Office action is withdrawn, all amendments filed after the [formerly] final Office action are entered.

DECISION

As requested by applicant, the decision of the Special Programs Examiner of April 29, 1999, has been reconsidered. Upon reconsideration, that decision cannot be permitted to stand, and is vacated. The petition is granted. The holding of abandonment is withdrawn. This decision is also a recognition that this application was never abandoned in fact. Any inconvenience to applicant is sincerely regretted.

The finality of the Office action of February 10, 1998 is formally recognized as withdrawn. Likewise, the Advisory Action of September 14, 1998 is withdrawn as an Office communication not appropriate to an application not then under a final Office action. This application is being forwarded to the examiner for consideration and treatment of the reply of May 11, 1998, as filed in an application not under final rejection, and his formulation of an appropriate Office action.

The $130 petition fee is not necessary and will be refunded by Treasury Check in due course.

It is noted that according to USPTO records, while applicant's registered representative is no longer in an active representational status before the USPTO, applicant has not formally revoked the power of attorney, appointed a currently registered practitioner, or properly notified the USPTO of a change in correspondence address. While the USPTO will not undertake dual correspondence, on a one-time basis applicant is being mailed a courtesy copy of this decision at the address given in the petition.

Enclosed for applicant's convenience is a form for revoking a previous power of attorney, which also would change the correspondence address. Applicant may also

wish to obtain the services of a representative currently registered to practice before the USPTO, to conduct the further prosecution in this application

Howard N. Goldberg
Director, Technology Center 2800

cc:

Roy Weinstein
Institute of Particle Beam Dynamics
IBPD Room 632 SR1
University of Houston
Houston Texas 77204-5506

Enclosure for cc: Revocation of Power of Attorney (Form PTO/SB/82)

Please type a plus sign (+) inside this box → ☐

PTO/SB/82 (10-00)
Approved for use through 10/31/2002. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REVOCATION OF POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	
Filing Date	
First Named Inventor	
Group Art Unit	
Examiner Name	
Attorney Docket Number	

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application:

☐ A Power of Attorney or Authorization of Agent is submitted herewith.

OR

☐ Please change the correspondence address for the above-identified application to:

☐ Customer Number ☐ → *Place Customer Number Bar Code Label here*

OR

☐ Firm *or* Individual Name					
Address					
Address					
City					
Country		State		ZIP	
Telephone		Fax			

I am the:

☐ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Name	
Signature	
Date	

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Paper No.

BERGER HOLDINGS LTD.
N. ARNE BERGER
P.O. BOX 822
NANTON, ALBERTA
T0L 1R0 **AIRMAIL**

COPY MAILED
AUG 1 1 2004
OFFICE OF PETITIONS

In re Patent No. 5,038,969 :
Issue Date: August 13, 1991 :
Application No. 07/484,872 : LETTER
Filed: February 26, 1990 :

This is in response to your letter of July 28, 2004, which is being treated as a request regarding the procedures to reinstate an expired patent.

37 CFR 1.378(a) provides that the Commissioner may accept the payment of any maintenance fee due on a patent based on an expiration of the patent if, upon petition, the delay in payment of the maintenance fee is shown to the satisfaction of the Commissioner to have been unavoidable or unintentional. The appropriate surcharge set forth in § 1.20(i) must be paid as a condition of accepting payment of the maintenance fee. The surcharges set at 37 CFR 1.20(i) are established pursuant to 35 U.S.C. 41(c) and, therefore, are not subject to small entity provisions of 35 U.S.C. 41(h). No separate petition fee is required for this petition. If the Commissioner accepts payment of the maintenance fee upon petition, the patent shall be considered as not having expired but will be subject to the intervening rights and provisions of 35 U.S.C. 41(c)(2). A copy of this section is forwarded herewith for your information, which includes the forms for revival under the unavoidable and unintentional standards of 37 CFR 1.137.

The above-identified patent issued on August 13, 1991. Therefore, the 7½ year maintenance fee payment window opened August 13, 1998 and closed on August 13, 1999. Since patentee failed to pay the second maintenance, the patent expired midnight on August 13, 1999.

Unavoidable Delay

37 CFR 1.378(b) provides that a patent may be reinstated at any time following expiration of the patent for failure to timely pay a maintenance fee. A petition to accept late payment of a maintenance fee, where the delay was unavoidable, must include:

(A) the required maintenance fee set forth in 37 CFR 1.20(e)-(g);
(B) the surcharge set forth in 37 CFR 1.20(i)(1); and
(c) a showing that the delay was unavoidable since reasonable care was

taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly the patentee was notified of, or otherwise became aware of, the expiration of the patent.

The required showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly. Furthermore, an adequate showing requires a statement by all persons with direct knowledge of the cause of the delay, setting forth the facts as they know them. Copies of all documentary evidence referred to in a statement should be furnished as exhibits to the statement.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop PETITION
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Window located at:

U.S. Patent and Trademark Office
220 20th street S
Customer Window, Mail Stop Petitions
Crystal Plaza Two Lobby, Room 1B03
Arlington, VA 22202

By fax: (703) 872-9306
Attn: Office of Petitions

Telephone inquiries concerning this decision should be directed to the Office of Petitions Staff at (703) 305-9282.

Wan Laymon
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

ATTACHMENTS: MPEP Section 2590
PTO/SB/65
Fee Schedule

OIPE IAP22
JAN 30 2009
PATENT & TRADEMARK OFFICE

7484872UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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COMPLETED

Paper No. 7

BERGER HOLDINGS LTD
N. ARNE BERGER
P.O. BOX 822
NANTON 1RO CA CANAD

COPY MAILED
DEC 16 2008

In re Application of	:	
Nelson A. Berger	:	
Application No. 07/484,872	:	
Patent No. 5,038,969	:	REQUEST FOR MORE INFORMATION
Filed: February 26, 1990	:	
Issue Date: August 13, 1991	:	
Title: LID DISPENSER	:	

This is a decision on the second renewed petition pursuant to 37 C.F.R. § 1.378(e), filed on January 28, 2005, requesting reconsideration of a prior decision pursuant to 37 C.F.R. § 1.378(b), which refused to accept the delayed payment of maintenance fees for the above-referenced patent.

The patent issued on August 13, 1991. The grace period for paying the 7½-year maintenance fee provided in 37 C.F.R. § 1.362(e) expired at midnight on August 13, 1999, with no payment received. Accordingly, the patent expired on August 13, 1999.

Office records show that an original petition pursuant to 37 C.F.R. § 1.378(b) was filed on September 17, 2004, which was dismissed via the mailing of a decision on December 2, 2004.

A renewed petition pursuant to 37 C.F.R. § 1.378(e) was filed on March 23, 2005, which was dismissed via the mailing of a decision on December 7, 2005.

The paper file contains a copy of the decision on the original petition, mailed on December 2, 2004 and a copy of a letter entitled "renewed petition under 37 CFR 1.378(b)" that was received on August 31, 2006.

The paper file does not contain the following four documents:

1. A copy of the original petition pursuant to 37 C.F.R. § 1.378(b) was filed on September 17, 2004.

2. A copy of the renewed petition pursuant to 37 C.F.R. § 1.378(e) was filed on March 23, 2005.

3. A copy of the decision on the renewed petition pursuant to 37 C.F.R. § 1.378(e), mailed on December 7, 2005.

4. A copy of the second renewed petition pursuant to 37 C.F.R. § 1.378(e), filed on January 28, 2005.

The Office cannot issue a decision on Petitioner's request while the paper file is incomplete. As such, the **Office will require Petitioner to provide a copy of the above four communications.**

Any response to this inquiry must be filed within **ONE MONTH** of the mailing date of this communication. **This time period is not extendable.** After decision on the petition for reconsideration and the response to this inquiry, no further reconsideration or review of the matter will be undertaken by the Commissioner. Accordingly, on request for reconsideration, it is extremely important that petitioner supply **any** and **all** relevant information and documentation in order to meet his burden of showing unavoidable delay.

If on response to this inquiry, the delayed payment of the maintenance fee is not accepted, then the maintenance fees are subject to refund following the decision on the petition for reconsideration, or after the expiration of the time for responding to this inquiry, if none is filed.

As such, Petitioner has one month to respond to this communication. After one month, if no response is received, the Office will deny this petition and refund the $700 surcharge, the $1610 maintenance fee payment, and the $1045 maintenance fee payment submitted on September 7, 2004.

Alternatively, if Petitioner would prefer to have these payments refunded to him before the expiration of this two-month time period, Petitioner should place this request in writing and indicate that he seeks to have this petition denied.

Petitioner will note that once a petition is denied, revival of this patent is no longer possible.

Any response to this inquiry should indicate in a prominent manner that the attorney handling this matter is Paul Shanoski, and may be submitted by mail,[1] hand-delivery,[2] or facsimile.[3] Registered users of EFS-Web may alternatively submit a response to this decision via EFS-Web.[4]

If responding by mail, Petitioner is advised not to place the undersigned's name on the envelope. Only the information that appears in the footnote should be included - adding anything else to the address will delay the delivery of the response to the undersigned.

Telephone inquiries regarding this decision should be directed to the undersigned at (571) 272-3225.[5]

/Paul Shanoski/
Paul Shanoski
Senior Attorney
Office of Petitions

---

1 Mail Stop Petition, Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.
2 Customer Window, Randolph Building, 401 Dulaney Street, Alexandria, VA, 22314.
3 (571) 273-8300- please note this is a central facsimile number.
4 https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html
5 Petitioner will note that all practice before the Office should be in writing, and the action of the Office will be based exclusively on the written record in the Office. See 37 C.F.R. § 1.2. As such, Petitioner is reminded that no telephone discussion may be controlling or considered authority for Petitioner's further action(s).

Expedite

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

DATE : ~~8-17-07~~ ~~2/20/08~~ 4-1-08 Paper No.: _____

TO SPE OF : ART UNIT 3700

SUBJECT : Request for Certificate of Correction for Appl. No.: 07499724 Patent No.: 5022278

Please respond to this request for a certificate of correction within 7 days.

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image.. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code COCX.

Valerie Jackson

Certificates of Correction Branch

703-308-9390 ext. 114

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriate box.

☐ **Approved**	All changes apply.
☐ **Approved in Part**	Specify below which changes **do not** apply.
☒ **Denied**	State the reasons for denial below.

Comments: (1) THE CLASSIFICATION CORRECTLY READS 279/50 — THERE IS NO PERIOD FOLLOWING "50".

(2) AMENDMENTS TO CLAIMS ATTEMPT TO REINTRODUCE LANGUAGE CANCELLED IN AMENDMENT OF 8/3/90 IN RESPONSE TO 35USC§112-2 REJECTION.

RICHARD RIDLEY
SUPERVISORY PATENT EXAMINER

DAVID FENSTERMACHER
PRIMARY EXAMINER

SPE

3656
Art Unit

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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The Honorable Judges of the
35th, 37th, 38th, and 39th Federal Trial Courts
in the City of Rio de Janeiro
Foro Desembargadora Federal Marilena Franco
Av. Venezuela, 134 - Saude
Rio de Janeiro RJ 20081-312
Brazil

COPY MAILED
JUL 13 2006
OFFICE OF PETITIONS

In re Patent No. 5,023,269 :
issue Date: June 11, 1991 :
Application No. 07/499,940 : LETTER
Filed: March 27, 1990 :
Inventor: Robertson et al. :
For: 3-ARYLOXY-3-SUBSTITUTED
PROPANAMINES

As requested by the patent holder:

> To all of whom these presents shall come, I certify that according to the records on file with the United States Patent and Trademark Office, the expiration date of the above-identified U.S. Patent No. 5,023,269 is June 11, 2008.

A copy of the request dated June 5, 2006, and this communication is also being placed in the official file record for this patent.

Any inquiries concerning this communication may be directed to the undersigned at (571) 272-3217.

Brian Hearn July 12, 2007
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Arvie J. Anderson
Patent Counsel, Legal
Eli Lilly and Company
Drop Code 1104
Lilly Corporate Center
Indianapolis IN 46285

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,025,312	:	
Issue Date: June 18, 1991	:	
Application No. 07/503,313	:	DECISION ON PETITION
Filed: March 30, 1990	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '312 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEYER, WEAVER & THOMAS, LLP
ATTN: Michael Ferrazano
590 W. El Camino Real
Mountain View, CA. 94040

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,081,521	:	
Issue Date: January 14, 1992	:	
Application No. 07/509,314	:	DECISION ON PETITION
Filed: April 13, 1990	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed.**

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '521 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation

may have been proper. Petitioner should note that recordation is available for numerous documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,063,438	:	
Issue Date: November 5, 1991	:	
Application No. 07/511,644	:	DECISION ON PETITION
Filed: April 20, 1990	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed.**

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '438 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

PTO/SB/66 (03-09)
Approved for use through 03/31/2012. OMB 0651-0016
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5470571	1995-11-28	07513668	1990-04-24	000486.27601

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY

☐ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS

☒ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity		Small Entity	
Fee	Code	Fee	Code
○ 3 ½ year	(1551)	○ 3 ½ year	(2551)
○ 7 ½ year	(1552)	○ 7 ½ year	(2552)
◉ 11 ½ year	(1553)	○ 11 ½ year	(2553)

SURCHARGE

The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))

The appropriate maintenance fee must be submitted with this petition.

STATEMENT

THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/Sarah A. Kagan/	Date (YYYY-MM-DD)	2009-07-14
Name	Sarah A. Kagan	Registration Number	32141

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5470571
Issue Date: November 28,1995
Application No. 07513668
Filed: April 24,1990
Attorney Docket No. 0486027601

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed July 14,2009 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is **GRANTED**.

The maintenance fee is accepted, and the above-identified patent reinstated as of July 14,2009 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in the Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy.

Telephone inquiries related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEYER, WEAVER & THOMAS, LLP
ATTN: Michael Ferrazano
590 W. El Camino Real
Mountain View, CA. 94040

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,097,332	:	
Issue Date: March 17, 1992	:	
Application No. 07/517,616	:	DECISION ON PETITION
Filed: May 2, 1990	:	
Inventor: Yves C. Faroudja	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED**.

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '332 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation

may have been proper. Petitioner should note that recordation is available for numerous documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

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DIW Aug-06

EXXONMOBIL CHEMICAL COMPANY
5200 BAYWAY DRIVE
P.O. BOX 2149
BAYTOWN TX 77522-2149

COPY MAILED
AUG 16 2006
OFFICE OF PETITIONS

In re Application of :
Canich et al. :
Application No. 07/542,236 : ON PETITION
Filed: 22 June, 1990 :
Atty Docket No. J3500.2 :

This is a decision on the renewed petition filed on 21 July, 2006, which requests under 37 C.F.R. §1.182 that a previously filed terminal disclaimer be withdrawn. The petition fee has been received.

The petition is granted.

Petitioners state that the Terminal Disclaimer filed on 11 April, 1991, is no longer necessary, and should be withdrawn, because it does not apply to any claims currently of record.

As the examiner has concurred, the request can be favorably considered.

The address in the petition is different than the correspondence address. A copy of this decision is being forwarded to the address listed in the petition. All future correspondence will be mailed solely to the address of record.

This application is being referred to Technology Center Art Unit 1755 for further processing consistent with this decision.

Telephone inquiries relative to this decision should be directed to the undersigned at (571) 272-3231.

DIWood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

cc: Hershkovitz & Associates
2845 Duke Street
Alexandria VA 22314

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
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OLE K. NILSSEN
200 N. Harrison St .Suite 103
Algonquin, IL 60102

COPY MAILED
JUL 17 2006
OFFICE OF PETITIONS

In re Application of
Ole K. Nilssen :
Application No. 07/548,197 :
Filed: July 5, 1990 : NOTICE
Title of Invention: INVERTER WITH :
ELECTRICALLY CONTROLLABLE OUTPUT :

This is a notice regarding your request to change your entity status to large.

In accordance with 37 CFR 1.28, said notice is hereby accepted. Office records have been corrected to indicate loss of small entity status in the above-identified application.

Telephone inquiries concerning this matter should be directed to the undersigned at (571) 272-3232.

Derek L. Woods
Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Hollie L. Baker
Wilmer Cutler Pickering Hale & Dorr LLP
60 State Street
Boston MA 02109

FEB 12 2007

In re Patent Term Extension Application of	:
U.S. Patent No. 5,196,404	:
Issue Date: March 23, 1993	: Decision on Petition to
Application No. 07/549,388	: Stay Final Action on Patent
Filing Date: July 6, 1990	: Term Extension Application
For: Inhibitors of Thrombin	:

The above-identified application has been forwarded to the Office of the Deputy Commissioner for Patent Examination Policy in the United States Patent and Trademark Office (the "Office") for consideration of a petition titled "Petition under 37 C.F.R. §§ 1.182 and 1.183 to Stay Action on Application for Patent Term Extension," which was received on January 26, 2007.

The petition is denied-in-part and granted-in-part for 30 days from the mailing date of this decision.

Background and Analysis

On March 4, 2002, the Office dismissed Petitioner's application for patent term extension of U.S. Patent No. 5,196,404 (PTE application) covering Petitioner's NDA-approved drug product Angiomax® as untimely filed. In response to the dismissal, Petitioner filed a Request for Reconsideration on October 7, 2002. That request is presently pending in the Office. Petitioner now petitions for a stay of the processing of its PTE application, specifically, a stay of a decision on the Request for Reconsideration. Petitioner sets forth three arguments for why a stay is needed:

(1) Legislation was introduced in the 109th Congress, second session, to amend 35 U.S.C. § 156 to permit a 5-day grace period for filing a PTE application. That legislation passed in the House, but the 109th Congress adjourned before the legislation was introduced in the Senate. According to Petitioner, a stay of 6 months gives time for similar legislation to be introduced in the 110th Congress. If passed and enacted, the provisions of such legislation would permit the Office to take action on the merits of Petitioner's PTE application, if such application was filed within 5 days of the current statutory 60-day deadline. See 35 U.S.C. § 156(d)(1).

(2) As part of the legislative process, Petitioner allegedly performed extensive research on the more than 650 PTE applications processed by the Office since 1984 and uncovered information the Petitioner believes necessitates an amendment and supplement of its PTE application. Additionally, based on (1) conflicts in approval dates of Angiomax® as posted by the Food and Drug Administration (FDA) on its website, and (2) inconsistent standards used to determine the date on which filings are made with or by FDA, Petitioner wishes to supplement its PTE application so that the Director may

exercise his authority to determine the appropriate date to be considered the approval date of Angiomax®.

(3) Based on Petitioner's position regarding the approval date of Angiomax®, Petitioner wishes to supplement and amend its underlying PTE application to accurately reflect the correct approval date of Angiomax®.

Under 37 C.F.R. § 1.183, Petitioner requests the Director to suspend or waive the provisions of 37 C.F.R. § 1.750 since 37 C.F.R. § 1.750 does not explicitly recite a timeframe for acting on a request for reconsideration. There is no provision in the Code of Federal Regulations governing practice in applications for PTE with respect to staying final action by the Office. Hence, the petition under 37 C.F.R. § 1.183 is moot. The Office treats the present petition as falling under 37 C.F.R. § 1.182, which addresses all situations not specifically provided for in other regulations. Further, the Office analogizes the request made by Petitioner to requests for staying action in patent applications and for deferring issuance of a patent filed under 37 C.F.R. § 1.103 and 37 C.F.R. § 1.314 respectively. The standard for granting requests under both 37 C.F.R. § 1.103 and 37 C.F.R. § 1.314 is good and sufficient cause. Accordingly, the Office shall apply that same good and sufficient cause standard to the present petition under 37 C.F.R. § 1.182.

Here, Petitioner seeks a 6-month stay in part to permit legislation to be re-introduced into the 110th Congress which, if introduced, passed and enacted, would amend 35 U.S.C. § 156 to provide for a 5-day grace period for submitting applications for PTE. The legislation, which may or may not be introduced, was proposed and pending before the 109th Congress. The mere possibility that same legislation will be re-introduced before the 110th Congress, passed, and enacted is entirely speculative at this point. Such speculation does not constitute a showing of good and sufficient cause.

Petitioner also seeks a 6-month stay, in part, to amend and supplement its PTE application in several ways. This reason appears to constitute a showing of good and sufficient reason. For that purpose, Petitioner's petition under 37 C.F.R. § 1.182 is granted-in-part for a period of 30 days, from the mailing date of this decision. During this 30-day period, the Office will stay consideration of Petitioner's PTE application.

Conclusion

The petition under 37 C.F.R. § 1.182 is granted-in-part and denied-in-part.

The rules and statutory provisions governing the operations of the U.S. Patent and Trademark Office require payment of a fee on filing each petition. *See* 37 C.F.R. § 1.17(f). The required petition fees have been received for the present petition.

Telephone inquiries with regard to this communication should be directed to Mary C. Till at (571) 272-7755.

John J. Love
Deputy Commissioner for Patent Examination Policy
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

APR 26 2007

Commissioner for Patents
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Hollie L. Baker
Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

DECISION DENYING APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5,196,404

This is in response to the application for extension of the patent term of U.S. Patent No. 5,196,404 (the '404 patent) under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on February 14, 2001; the first request for reconsideration, filed October 2, 2002; and the amended request for reconsideration, filed on March 13, 2007. The application was filed by The Medicines Company (Applicant). Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of the human drug product known by the tradename ANGIOMAX®, having the active ingredient bivalirudin. Because the Food and Drug Administration (FDA) confirmed (more than once) that the approval date of NDA 20-873 for ANGIOMAX® (bivalirudin) is December 15, 2000, and because Applicant failed to timely file its patent term extension application within sixty days of that date as required by § 156(d)(1) and 37 C.F.R. § 1.720(f), Applicant's request for extension of the patent term of the '404 patent is **DENIED**.

A. Factual Background

On December 15, 2000, the FDA transmitted a letter via facsimile to Applicant explaining that Applicant's NDA 20-873, seeking approval for ANGIOMAX® (bivalirudin), had been approved. That letter stated: "[T]he application is approved effective on the date of this letter." The letter was dated December 15, 2000, in three places: (1) to the right of the address block by what appears to be a date stamp; (2) adjacent the signature on final page in handwriting; and (3) at the top of each of the three pages by what appears to be a facsimile machine imprint that also indicates the time of transmission as "18:17," i.e., 6:17 pm. Applicant does not deny either that the FDA transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 pm by facsimile.[1]

[1] Notably, Applicant claims that it received the FDA approval letter on December 15, 2000, by facsimile but that the letter did not include an electronic signature page. Applicant claims that it received a second copy of the FDA approval by regular mail the following week. According to Applicant, that second copy did not contain a date stamp, but instead included an electronic signature page with a 5:18 pm time stamp and a December 15, 2000, date stamp. Taking Applicant's claims as true, the bottom line is that the both copies of the approval letter contained a December 15, 2000, date stamp.

On February 14, 2001, Applicant filed its application for patent term extension (PTE) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO. Applicant does not claim any earlier date for its application. In the application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000. In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), Applicant identified significant activities undertaken as part of the regulatory review in a table. Applicant listed a communication from Julie DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Additionally, Applicant's counsel struck through paragraph (5), which set forth the last day for filing the PTE application, and initialed and dated the change. Specifically, Applicant's counsel struck through the following: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last date upon which this application could be submitted is 15 February 2001."

On March 2, 2001, after receiving Applicant's PTE application, the USPTO wrote a letter to the FDA, indicating that the USPTO believed the PTE application to be untimely and requested the FDA's assistance in confirming that (1) ANGIOMAX® (bivalirudin) was subject to regulatory review within the meaning of § 156(g) before its first permitted commercial marketing or use and (2) the PTE application was not filed within sixty days after the product received FDA approval as required by § 156(g)(1).

On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) based upon its "uncertainty as to what the approval date really was." Applicant then explained that it researched the approval date on the FDA web site and identified a document listing the approval date as December 19, 2000. Based upon that later approval date, Applicant restated paragraph (5) as follows: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. 1.720(f). The last date upon which this application could be submitted is 17 February 2001."

On September 6, 2001, the FDA confirmed by letter to the USPTO that ANGIOMAX® (bivalirudin) was subject to a regulatory review period before its first commercial marketing or use and that ANGIOMAX® (bivalirudin) had been approved on December 15, 2000, making Applicant's PTE application untimely within the meaning of § 156(d)(1).

On March 4, 2002, the USPTO mailed a notice of final determination to Applicant stating that its PTE application was not timely filed as required by statute and regulation, and that the application consequently was dismissed.

On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for ANGIOMAX® (bivalirudin) should be effective on December 18, 2000.

On March 23, 2003, the USPTO forwarded the request for reconsideration to the FDA, requesting the FDA's assistance in verifying the approval date of ANGIOMAX® (bivalirudin) as December 15, 2000.

On November 2, 2006, the FDA replied, again indicating that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000, and not December 18, 2000.

On January 26, 2007, Applicant filed a petition under 37 C.F.R. §§ 1.182 and 1.183, requesting a stay of final action on its PTE application.

On February 12, 2007, the PTO granted-in-part and denied-in-part, the petition under 37 C.F.R. §§ 1.182 and 1.183. The PTO granted a limited stay of 30 days to permit Applicant to amend and supplement its request for reconsideration and PTE application.

On March 13, 2007, Applicant filed an amended request for reconsideration and an amended PTE application.

B. Applicable Statutes and Regulation

The following statute and regulation are relevant to the timeliness issue presented in Applicant's PTE application:

35 U.S.C. § 156 Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if -. . . .

(d)
(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain - . . . .

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of--

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section . . . .

37 C.F.R. § 1.720 Conditions for extension of patent term

The term of a patent may be extended if:
(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;
(b) The term of the patent has never been previously extended, except for extensions issued pursuant to §§ 1.701, 1.760, or 1.790;
(c) An application for extension is submitted in compliance with § 1.740;
(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;
(e) The product has received permission for commercial marketing or use and -

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent, including any interim extension issued pursuant to § 1.790, has not expired before the submission of an application in compliance with § 1.741; and
(h) No other patent term has been extended for the same regulatory review period for the product.

C. Decision

This decision addresses arguments raised by Applicant in its first request for reconsideration filed on October 7, 2006, and in its amended request for reconsideration filed on March 13, 2007.

1. First Request for Reconsideration

Despite the unambiguous language of the FDA's December 15, 2000, approval letter stating that the date of that letter was the date of approval of ANGIOMAX® (bivalirudin), and despite the FDA's two subsequent confirmations of December 15, 2000, as the approval date, Applicant makes three arguments why December 18, 2000, or alternatively, December 19, 2000, should be treated as the effective approval date for ANGIOMAX® (bivalirudin): (1) it received the FDA approval letter late in the day on December 15, 2000, after normal business hours; (2) the FDA itself was confused as to the approval date, publishing two different approval dates on its website; and (3) fairness weighs in favor of granting the PTE application since ANGIOMAX® (bivalirudin) is Applicant's first commercial product and a denial of patent term extension is a disproportionately harsh penalty, counter to public policy, and counter to the intent of the Hatch-Waxman Act. The USPTO will address each argument in turn.

a) The FDA Approval Letter Plainly Sets Forth the Approval Date of ANGIOMAX® (bivalirudin)

Applicant asserts that because the approval of ANGIOMAX® (bivalirudin) was transmitted by facsimile after 4:30 pm on Friday, December 15, 2000, the approval should be considered to have occurred on the next business day, namely, Monday, December 18, 2000. Applicant's argument is misplaced. The FDA has made clear three times that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000. First, the original approval letter from FDA explicitly states: "Accordingly, the application is approved effective on the date of this letter." The approval letter is clearly date-stamped December 15, 2000, which Applicant does not dispute. Second, the FDA indicated in its first confirmation letter of September 6, 2001, that "[t]he NDA was approved on December 15, 2000, ..." Third, in its second confirmation letter of November 2, 2006, the FDA reiterated that NDA 20-873 for ANGIOMAX® (bivalirudin) was approved on December 15, 2000.

Applicant would have the USPTO, which is responsible for determining eligibility of a patent for PTE, consider December 18, 2000 or December 19, 2000, as the approval date, but the USPTO cannot do so. The USPTO is not involved in the regulatory review process of new drugs and does not issue drug approvals. Although the USPTO can comprehend Applicant's arguments, the fact of approval date of a new drug product is solely within the written records of FDA. Furthermore, as the Federal Circuit has pointed out, the determination of the length of the regulatory review period is the responsibility of the regulatory agency, here, the FDA.

Aktiebolaget Astra v. Lehman, 71 F.3d 1578, 1580-81 (Fed. Cir. 1995). Because approval for a drug product occurs at the end of such period, it follows that the determination of the date of approval is within the exclusive purview of the FDA. Accordingly, the USPTO cannot entertain Applicant's arguments regarding what date should be considered to be the effective approval date of ANGIOMAX® (bivalirudin).

It is well settled that the approval date is the date appearing on the FDA approval letter. *Norwich Eaton Pharms., Inc. v. Bowen*, 808 F.2d 486, 491 (6th Cir. 1987); *Mead Johnson Pharm. v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988); *Unimed, Inc. v Quigg*, 888 F.2d 826 (Fed. Cir. 1989). In *Norwich*, the Sixth Circuit observed that the FDA adopted a regulation expressly providing that "[t]he date of the agency's approval letter is the date of the approval of the application." 808 F.2d at 491 (quoting 21 C.F.R. § 314.105(a)). The Sixth Circuit concluded that the FDA's regulation was reasonable and in line with its statutory mandate to review NDA applications and approve or disapprove them. *Id.* Accordingly, the Sixth Circuit concluded that FDA approval occurs when the FDA issues its approval letter and not when the FDA approves an applicant's labeling instructions or when the applicant receives the FDA approval letter. In *Mead*, the D.C. Circuit reached the same conclusion, also relying on the FDA regulation set forth in § 314.105(a) as well as the Sixth Circuit's decision in *Norwich*.

In *Unimed*, the Federal Circuit squarely addressed the issue in dispute here, *i.e.*, the timeliness of a PTE application which was filed nearly one year late due the applicant's belief that the sixty-day period set forth in § 156(d)(1) commenced after the Drug Enforcement Agency (DEA) rescheduled its narcotic drug to allow for commercial marketing. The Court reasoned that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date" and not the date of rescheduling by the DEA. *Unimed*, 888 F.2d at 828. Turning to consider what date qualifies as the approval date, the Federal Circuit then observed that "[a]ccording to the FDA, the date of marketing approval for all new drugs is the date appearing on its approval letters." *Id.* It also observed that both the Sixth Circuit in *Norwich* and the D.C. Circuit in *Mead* confirmed that the approval date for a new drug is the date of the FDA approval letter.

Given *Norwich*, *Mead*, and *Unimed*, there can be no doubt that the FDA approval date for ANGIOMAX® (bivalirudin) occurred on December 15, 2000, the date appearing on the FDA's approval letter for NDA 20-873 and subsequently confirmed twice by the FDA.

Turning to the time period triggered by FDA approval, § 156(d)(1) requires that an application for patent term extension of a patent which claims a product,[2] a method of using such product, or a method of manufacturing such product, wherein the product was subject to premarket regulatory review by a regulating agency, must be submitted, "<u>within</u> the sixty-day period <u>beginning on</u> the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." 35 U.S.C. § 156(d)(1) (emphases added). Additionally, the implementing regulations mirror the language of §156 (d)(1): "[t]he application is submitted <u>within</u> the sixty-day period <u>beginning on</u> the date the product first received permission for commercial marketing or use under the

[2] The term "product" is as defined in 35 U.S.C. § 156(f).

provision of law under which the applicable regulatory review period occurred . . . ." 37 CFR § 1.720(f) (emphases added). The phrases used in § 156 (d)(1) to define the time period, i.e., "within" and "beginning on," are clear. *See Unimed*, 888 F.2d at 828 (characterizing the language used in § 156(d)(1) as "crystal clear"); *see also United States v. Inn Foods, Inc.*, 383 F.3d 1319, 1322 (Fed. Cir. 2004) (explaining, in the context of a statute of limitation, that terms such as "within [a particular time period]" and "beginning on" clearly specify a time period and need no further analysis). Thus, under both § 156(d)(1) and § 1.720(f), a PTE applicant has sixty days to submit a PTE application where the first day of that sixty-day period begins on the approval date.

In the present case, the FDA approved NDA 20-873 for ANGIOMAX® (bivalirudin) on December 15, 2000. The absolute deadline for filing the application for patent term extension was sixty days from December 15, 2000, starting the count of that sixty-day period on December 15, 2000. The sixtieth day of that time period was February 12, 2001. Applicant failed to meet that statutory deadline because it filed its patent term extension application on February 14, 2001, two days late.[3] Consequently, Applicant's PTE application was untimely filed under § 156(d)(1) and § 1.720(f), and the USPTO has no choice but to deny it.

b) The FDA Has Repeatedly Confirmed the Approval Date of ANGIOMAX® (bivalirudin) as December 15, 2000

Applicant argues that December 18, 2000, or alternatively, December 19, 2000, should be treated as the effective approval date for ANGIOMAX® (bivalirudin) because the FDA itself was confused as to the approval date, publishing two different approval dates on its website. Specifically, on its "NMEs Approved In Calendar Year 2000" webpage, the FDA listed the approval date for ANGIOMAX® (bivalirudin) as December 15, 2000. However, on its "NDA Approvals for Calendar Year 2000" webpage, it listed the approval date as December 19, 2000, as recently as March 23, 2002. Applicant's argument is unavailing as the case law is quite clear. The FDA has consistently treated the date appearing on the FDA approval letter as the approval date. In fact, the FDA even promulgated a regulation, namely 21 C.F.R. § 314.105(a), to that effect. Thus, whether the FDA may have erroneously published the approval date as December 19, 2000, on its "NDA Approvals for Calendar Year 2000" webpage cannot alter the actual December 15, 2000, approval date found in the FDA approval letter. Additionally, the FDA has repeatedly informed the USPTO upon inquiry that the approval date for ANGIOMAX® (bivalirudin) is December 15, 2000.

Moreover, in Applicant's original PTE application, Applicant indicated that the FDA approval date was December 15, 2000, in more than one location, as required by 37 C.F.R. § 1.740(a)(3), (10) and (11). In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant again stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), the chronology of regulatory events listed a communication from Julie

[3] In the USPTO's notice of final determination, it indicated that Applicant filed its PTE application for ANGIOMAX® (bivalirudin) on the sixty-first day after FDA approval. Upon reconsideration of the dates involved in this application, the USPTO notes that Applicant actually filed its PTE application on the sixty-second day after FDA approval. In other words, the USPTO observes that Applicant's PTE application was not one day late, but instead two days late.

DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Hence, even if the FDA was confused as to the approval date for ANGIOMAX® (bivalirudin), which it plainly was not given its two letters confirming an approval date of December 15, 2000, Applicant gave no indication that it was confused as to, or even questioned, the ANGIOMAX® (bivalirudin) approval date when it filed its PTE application on February 14, 2001.

Furthermore, that Applicant filed a supplemental application asserting that it was uncertain as to the approval date seven days after the USPTO sent a letter to the FDA requesting confirmation that the application was untimely filed does not change the fact that Applicant affirmatively listed the approval date as December 15, 2000, in its original PTE application. Thus, Applicant's "uncertainty" as to the approval date was first raised only after the USPTO revealed that it considered Applicant's PTE application to be untimely.

c) Fairness Considerations Cannot Alter the Statutory Language of § 156 as to the Deadline for Filing a PTE Application

Applicant argues that fairness weighs in favor of treating the effective approval date for ANGIOMAX® (bivalirudin) as December 18, 2000, since the drug is Applicant's first commercial product and since a denial is a disproportionately harsh penalty, counter to public policy, and counter to the intent of the Hatch-Waxman Act. While the USPTO appreciates the importance of ANGIOMAX® (bivalirudin) to Applicant and is aware of the impact a PTE denial may have on Applicant, the sixty-day statutory deadline is non-discretionary. That is, § 156(d)(1) neither provides for a grace period, nor gives the USPTO discretion to waive the sixty-day window. As such, the PTO is bound by statute to implement the provisions of § 156(d)(1), including the sixty-day deadline. What is more, fairness is not a factor in a statutory interpretation case such as this one. *See Unimed*, 888 F.2d at 829 ("[T]his is purely a case of statutory interpretation, so the equitable considerations raised by Unimed are inappropriate.").

2. Amended Request for Reconsideration

In its amended request for reconsideration, Applicant supplements the arguments it made in its first request for reconsideration, urging the USPTO to use its own judgment to determine the effective FDA approval date of NDA 20-873 for ANGIOMAX® (bivalirudin) instead of relying on the FDA for the approval date. More specifically, Applicant provides three arguments why the USPTO should not defer to the FDA's conclusion that the approval date is December 15, 2000. The USPTO will address these arguments in the order presented by Applicant.

a) The USPTO Independently Assessed the Timeliness of Applicant's PTE Application for the '404 Patent

Applicant asserts that the USPTO deferred to the FDA on the issue of whether the PTE application was timely submitted without question and that such deference runs afoul of basic principles of administrative law and statutory construction. Applicant also asserts that FDA's determination of the timeliness question is itself arbitrary, capricious, and contrary to law because the FDA failed to give a coherent reading to the statutory terms used in § 156(g)(1). Upon making an independent assessment of timeliness, Applicant asserts that the

USPTO should conclude that the effective approval date of ANGIOMAX®(bivalirudin) was December 18, 2000, or alternatively, December 19, 2000.

Applicant is correct that § 156 delineates the duties in the patent term extension process between the Director of the USPTO and the Secretary of Health and Human Services acting through the FDA. Additionally, Applicant is correct that FDA is charged with calculating the "regulatory review period," and that the USPTO is charged with determining whether an application meets the statutory requirements for extension. That is, the USPTO must determine whether an application is in compliance with § 156(a)(1)-(5) and § 156(d). To determine compliance with § 156(d)(1), which requires a PTE application to "be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use," the USPTO must ascertain the approval date of ANGIOMAX® (bivalirudin). Only then can the USPTO determine whether Applicant's PTE application is timely filed within the meaning of § 156(d)(1). The USPTO, however, is not involved in the drug approval process; rather, the FDA approves new drugs via the IND and NDA processes. *See* Federal Food Drug & Cosmetic Act §§ 505(i) and 505(b), as codified in 21 U.S.C. § 355. And, while a PTE applicant includes the approval date in its PTE application, the USPTO has no way to verify that the date is accurate. Consequently, the USPTO must rely on the written records for drug approvals maintained by the FDA.

Here, the USPTO followed the above-described process in determining whether Applicant timely filed its PTE application for ANGIOMAX® (bivalirudin). In arguing that the USPTO failed to make an independent timeliness assessment, Applicant misapprehends the nature of the USPTO's communications with the FDA. After reviewing Applicant's original PTE application, the USPTO made an initial determination that the application was not timely filed based upon the December 15, 2000, approval date for ANGIOMAX® (bivalirudin) provided in paragraphs (3), (10), and (11) of Applicant's PTE application. The USPTO communicated that independent initial determination to FDA via a letter on March 2, 2001, and requested the FDA's assistance. Specifically, the USPTO stated in the letter:

> The **assistance** of your Office is requested in confirming that the product identified in the application, Angiomax(bivalirudin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. In addition, the **assistance** of your Office is requested in confirming that the application for patent term extension was NOT filed within sixty days after the product was approved. . . . **Our review** of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. 156.

(Emphases added). The use of the term "assistance" plainly shows that the USPTO made an independent decision over six years ago that Applicant's PTE application was not timely filed in compliance with § 156(d)(1). It simply sought the FDA's help in confirming that decision because of the FDA's access to drug approval records, information outside the purview of the USPTO.

Then, after Applicant filed its first request for reconsideration on October 7, 2002, the USPTO wrote another letter to the FDA, again requesting the FDA's assistance: "The assistance of your Office is requested in preparing a reply to this request." In particular, the USPTO sought the FDA's help in addressing Applicant's argument that the approval date for ANGIOMAX® (bivalirudin) should be considered to be December 18, 2000, because the FDA gave its approval late in the day. Applicant's argument regarding the business practices of FDA with respect to communications relating to approvals of NDAs is misplaced. The USPTO has no control over any of the FDA's business practices. As such, Applicant is complaining to the wrong agency regarding the late day notice it received in this case.

Because the USPTO is informed of the approval date by a PTE applicant and has no independent knowledge of such date, the USPTO must avail itself of the approval records maintained by the FDA for confirmation of the date. Moreover, for nearly twenty years, it has been the USPTO's standard practice in processing PTE applications to request the FDA to confirm the approval date of an NDA as represented by an applicant in a PTE application. *See* 52 FR 17830, 17831 (May 12, 1987) (providing public notice of Memorandum of Understanding between USPTO and FDA and explaining that FDA is responsible for checking their records to determine whether the PTE application was timely filed). Consequently, Applicant's assertion that "[t]he PTO's approach thus far—its complete reliance on the FDA's view—raises the concern of arbitrary and capricious agency action" is false.

Applicant urges that the USPTO must engage in "reasoned decisionmaking" when it carries out its statutory obligation under § 156 of determining whether a patent is eligible for patent term extension. As pointed out above, the USPTO has engaged in reasoned decisionmaking throughout the patent term extension process for the '404 patent. First, it made an initial independent assessment of the eligibility of the '404 patent for patent term extension based on the regulatory review period for ANGIOMAX® (bivalirudin). After doing so, it confirmed that decision by letter on two occasions with the FDA, the agency having the official written records relating to approval of ANGIOMAX® (bivalirudin). More specifically, the USPTO asked the FDA to confirm Applicant's representation that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000, as represented, at least twice, in Applicant's PTE application. Following that confirmation from the FDA, the USPTO provided a notice of final determination and corrected notice of final determination that the '404 patent was not eligible for extension because the application for PTE was not timely filed. Finally, through the present decision, the USPTO is addressing Applicant's challenge to that determination and further explaining its reasoning for denying the extension. Accordingly, the USPTO has carried out its responsibility in deciding whether to grant Applicant's PTE application; it has not delegated that responsibility to the FDA, and is not merely sitting on the sidelines waiting for FDA's decision.

Next, Applicant argues that the USPTO's policies and rulemaking are designed to encourage and reward innovation, not produce an untimely and unnecessary loss of patent rights. In support, Applicant cites in a footnote to several sections of title 37 of the Code of Federal Regulations which permit late filings. The USPTO is not attempting to deny any patent rights to Applicant. As discussed earlier, the USPTO has no discretion under § 156 to waive the sixty-day time period for filing a PTE application. If an applicant fails to file its PTE application within this timeframe, then the USPTO is bound by statute to reject the application. Applicant's reliance on

late filing regulations sidesteps the fact that the patent term extension process is governed by statute. If an applicant is not satisfied with the provisions of that statute, then the fix lies with Congress.

Finally, Applicant points out that "there is simply no sound rationale for the [US]PTO to accept a contrary rule that would always deprive a patent holder of one or more days to commercially exploit its patent." The USPTO has not prevented Applicant from enforcing its patent rights in any way. Holding a patent does not give a patent owner an affirmative right to conduct commercial activities. Rather, it gives the patent owner the right to exclude another who, without authority, makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent.[4] For the term of the '404 patent, Applicant may exclude another who seeks to make, use, offer to sell, or sell ANGIOMAX® (bivalirudin).

b) The USPTO Accepts the FDA's Determination of the Approval Date of ANGIOMAX® (bivalirudin)

Applicant asserts that the USPTO should not accept the FDA's conclusion with respect to the date of approval of the ANGIOMAX® (bivalirudin) because it is arbitrary, capricious, and contrary to law. Applicant's assertion is based on the statutory language "on the date," as found in § 156(g)(1)(B)(ii). That provision provides that the regulatory review period is to be calculated by reference to, *inter alia*, "the period beginning on the date the application was initially submitted for the approved product . . . and ending on the date the application was approved." Applicant claims that Congress, by using the term twice in the same sentence, intended for the date to be calculated in the same way for submissions and approvals. And, contrary to congressional intent, Applicant points out that the FDA treats submissions via facsimile to FDA, which are received after the close of business as received on the next business day, but considers approvals to occur on the calendar date that is stamped on the approval letter,[5] regardless of the time of day such letter was faxed by FDA to the NDA applicant.

Applicant likewise takes issue with the seemingly inconsistent manner in which the FDA treats facsimile correspondence when FDA is the receiver as opposed to the transmitter. Even if Applicant is correct that the FDA's method of counting days is contrary to congressional intent, that is not for the USPTO to decide. In the context of the patent term extension process, the USPTO must gather the necessary facts and apply the laws and regulations to assess the eligibility of an applicant's PTE application. Even though Applicant takes issue with FDA's business practice regarding communication of NDA approvals to NDA applicants, the USPTO cannot override the clear regulatory language of 21 C.F.R. §§ 314.105(a) and 314.108(a). Those provisions expressly provide that the date of approval is the date appearing on the letter to the NDA applicant. *See* 21 C.F.R. § 314.105(a) (providing in pertinent part that "[a]n approval becomes effective on the date of the issuance of the approval letter, except with regard to an

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4 *See* 35 U.S.C. § 271.

5 Applicant accurately points out that 21 C.F.R. § 314.108 defines "date of approval" to mean the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date.

approval under section 505(b)(2) of the act with a delayed effective date") and 21 C.F.R. § 314.108(a) (providing in pertinent part that "[d]ate of approval means the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date). Here, the uncontested date of the approval letter was December 15, 2000. Accordingly, the USPTO must use that date as the trigger for the sixty day time period within which Applicant had to submit its PTE application.

c) The Correct Date of Approval of ANGIOMAX® (bivalirudin) is December 15, 2000

Applicant challenges the way the FDA communicated approval of NDA 20-873 for ANGIOMAX® (bivalirudin) to Applicant and the date afforded the approval letter. Specifically, in the case of ANGIOMAX® (bivalirudin), Applicant contends that the FDA failed to follow its internal procedures for communicating approval of NDA 20-873, sending two approval letters with different time stamps, though both date-stamped December 15, 2000, and posting conflicting approval dates on its website.

Even if Applicant is correct that the FDA did not employ best practices in communicating approval of NDA 20-873 to Applicants, and that the FDA failed to follow internal procedures in the case of ANGIOMAX® (bivalirudin), the USPTO plays no role in those communications and is not in the position to change the FDA's procedures. As repeatedly explained, the USPTO cannot ignore the plain language of the ANGIOMAX® (bivalirudin) approval letter that the USPTO independently reviewed and that states: "Accordingly, the application is approved effective on the date of this letter." The letter was date-stamped December 15, 2000, which Applicant does not dispute. Thus, consistent with 21 C.F.R. § 314.105(a), there can be no doubt that the FDA approved ANGIOMAX® (bivalirudin) on December 15, 2000, triggering day one of the sixty-day period for filing a PTE application.

d) Equity Considerations With Respect to Approval Date of ANGIOMAX® (bivalirudin)

Applicant largely repeats the equity arguments it made in its first request for reconsideration as reasons why the USPTO should consider the approval date of ANGIOMAX® (bivalirudin) to be December 18, 2000, or December 19, 2000, including that the denial of an extension is contrary to public policy and exacts a disproportionately harsh penalty. As Applicant is quick to point out, the USPTO is charged with the duty of administering patent term extensions under Title II of the Hatch-Waxman Act, codified in § 156. The provisions of that statute do not give the USPTO any discretion to permit late PTE application filings, a point repeated above more than once. Additionally, the facts and figures Applicant sets forth in the amended request for reconsideration regarding the time, money, and work involved in developing ANGIOMAX® (bivalirudin), although informative, are not relevant in the face of the statutory constraints of § 156. Accordingly, since the USPTO regards the approval date as December 15, 2000, based on the date stamped on the FDA approval letter, the USPTO must reject Applicant's PTE application as filed two days after the sixty-day statutory window.

Applicant provides arguments relating to the life-saving potential of ANGIOMAX® (bivalirudin) under the heading, "The Public May Benefit Enormously From Angiomax's Life-Saving Potential." Speculation about possible additional indications for ANGIOMAX® (bivalirudin) is not relevant to whether Applicant complied with section 156(d)(1). Section 156 of the statute does not include any provisions for considering such issues. Therefore, the USPTO must administer the statutory provisions of § 156 without regard to the economics of drug development and regulatory requirements for marketing new drug products.

Moreover, Applicant is not left without any protection for new uses for ANGIOMAX® (bivalirudin) after the expiration of the '404 patent. When new clinical tests are required for approval of an additional indication for a previously marketed drug, the FDA provides data exclusivities for such information subject to the new clinical investigations.[6]

Applicant further adds that extension of the '404 patent will not harm the rights or legitimate interests of third parties. Contrary to this argument, a generic producer seeking to enter the market and sell a generic version of ANGIOMAX® (bivalirudin) would, without litigation, have to wait more than four years beyond the original expiration date of the '404 patent if the USPTO granted a certificate of extension for the amount of term sought by Applicant. Hence, Applicant's contention is unavailing.

e) USPTO Precedent Permits the USPTO to Make an Independent Determination of the Approval Date of the NDA for ANGIOMAX® (bivalirudin)

Applicant conducted research into the USPTO's past administration of § 156 and found that, although rare to deny a PTE because of a late filing, the USPTO has done so in the past on four occasions for the anti-nausea drug related to marijuana (litigated in *Unimed*) and the drug products Vantin®, Saraflox, and Kadian®. Applicant contends that the circumstances in those cases were different from those here. Because of those factual differences, Applicant appears to implicitly suggest that the USPTO should not deny a patent term extension in this case.

Just because the four prior PTE denials on timeliness grounds involved facts distinguishable from those here does not mean that the USTPO should grant Applicant's PTE application. The USPTO must evaluate each PTE application on the facts presented therein and in turn deny those applications that fail to comply with the provisions of § 156. Therefore, it is irrelevant how many times the USPTO has denied other PTE applications for different drug products based on considerations of timeliness under § 156(d)(1).

3. Amended Application for Patent Term Extension

On March 13, 2007, Applicant filed an amended application for patent term extension. This amended application has been entered into the records of the USPTO. In the amended application for PTE, Applicant indicates the approval date for NDA 20-873 for ANGIOMAX ® (bivalirudin) should be considered December 18, 2000, or alternatively, December 19, 2000, in compliance with 37 C.F.R. § 1.740(3) and (10) and provides the calculation of term pursuant to 37 C.F.R. § 1.775 in paragraph (12) using the alternative dates. However, the amended

[6] *See* 21 C.F.R. § 314.108.

application also indicates that on December 15, 2000, Julie DuBeau of FDA communicated to Sonja Loar of The Medicines Company, "Approval of Angiomax" in compliance with 37 C.F.R. § 1.740(11). As repeatedly explained above, the USPTO considers the approval date of the NDA 20-873 for ANGIOMAX® (bivalirudin) to be December 15, 2000.

D. Conclusion

In sum, Applicant has accurately pointed out that the USPTO can and should make its own determination as to the appropriate approval date of ANGOMAX® (bivalirudin) for purposes of § 156(d)(1). As the USPTO explained in its letter of March 2, 2001, it relied on the approval date of December 15, 2000, a date presented in three places in Applicant's PTE application. Based upon that approval date, the USPTO determined that Applicant's PTE application was not timely filed. The USPTO then, consistent with its standard practice as set forth in its Memorandum of Understanding with the FDA, verified that determination by consulting with the FDA as to the approval date for ANGIOMAX (bivalirudin), since the FDA maintains all drug approval records. Moreover, regardless how the FDA communicated its approval of NDA 20-873 to Applicant, the FDA's approval letter clearly stated that the approval is effective on the date of the letter, and the letter was date-stamped December 15, 2000. Such treatment is consistent with § 314.105(a), which provides that the approval date of a drug product is the date of the approval letter, and with Federal Circuit precedent. Accordingly, because Applicant filed its PTE application two days late, the application for patent term extension under § 156 is **denied**. This decision may be viewed as a final agency action.

Further correspondence with respect to this matter should be addressed as follows:

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JAN 08 2010

In re Patent Term Extension Application of	:
Maraganore et al.	: Decision on Petition to
U.S. Patent No. 5,196,404	: Suspend Requirements of
Issue Date: March 23, 1993	: 37 C.F.R. § 1.750 and 37 C.F.R. 1.181(f) &
Application No. 07/549,388	: Request for Reconsideration of Application
Filing Date: July 6, 1990	: for Patent Term Extension
For: Inhibitors of Thrombin	:

The patent term extension application containing a petition under 37 C.F.R. § 1.183 and a request for reconsideration, both filed on December 4, 2009, has been forwarded to the Office of the Associate Commissioner for Patent Examination Policy in the United States Patent and Trademark Office (the "USPTO") for consideration. The petition under 37 C.F.R. § 1.183 is being treated as a request to suspend not only the provisions of 37 C.F.R. § 1.750 regarding a "single" request for reconsideration, but also as a request to suspend the timeliness provisions of 37 C.F.R. § 1.181(f).

The petition under 37 C.F.R. § 1.183 to suspend 37 C.F.R. § 1.750 and suspend the provisions of 37 C.F.R. § 1.181(f) is **GRANTED**. The request for reconsideration of the application for patent term extension is **DENIED**.

Factual Background

1. On March 23, 1993, the USPTO granted U.S. Patent No. 5,196,404 (the '404 patent) to John M. Maraganore et al. who assigned their rights to, what is now, Biogen Idec MA, Inc.
2. On December 15, 2000, the FDA transmitted a letter via facsimile to The Medicines Company ("Applicant") explaining that Applicant's New Drug Application ("NDA") 20-873, seeking approval for ANGIOMAX® (bivalirudin), had been approved. That letter stated: "[T]he application is approved effective on the date of this letter." The letter was dated December 15, 2000, in three places: (1) to the right of the address block by what appears to be a date stamp; (2) adjacent the signature on final page in handwriting; and (3) at the top of each of the three pages by what appears to be a facsimile machine imprint that also indicates the time of transmission as "18:17," i.e., 6:17 pm. Applicant does not deny either that the FDA transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 pm by facsimile.

3. On February 14, 2001, Applicant filed its application for patent term extension (PTE) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO ("PTE Application"). Applicant does not claim any earlier date for its application. In the application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000. In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), Applicant identified significant activities undertaken as part of the regulatory review in a table. Applicant listed a communication from Julie DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Additionally, Applicant's counsel struck through paragraph (5), which set forth the last day for filing the PTE application, and initialed and dated the change. Specifically, Applicant's counsel struck through the following: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last date upon which this application could be submitted is 15 February 2001."

4. On March 2, 2001, after receiving Applicant's PTE application, the USPTO wrote a letter to the FDA, indicating that the USPTO believed the PTE application to be untimely and requested the FDA's assistance in confirming that (1) ANGIOMAX® (bivalirudin) was subject to regulatory review within the meaning of section 156(g) before its first permitted commercial marketing or use; and (2) the PTE application was not filed within the sixty day period beginning on the day the product received FDA approval as required by section 156(g)(1).

5. On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) based upon its "uncertainty as to what the approval date really was." Applicant then explained that it researched the approval date on the FDA web site and identified a document listing the approval date as December 19, 2000. Based upon that later approval date, Applicant restated paragraph (5) as follows: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. 1.720(f). The last date upon which this application could be submitted is 17 February 2001."

6. On September 6, 2001, the FDA confirmed by letter to the USPTO that ANGIOMAX® (bivalirudin) was subject to a regulatory review period before its first commercial marketing or use and that ANGIOMAX® (bivalirudin) had been approved on December 15, 2000, making Applicant's PTE application untimely within the meaning of section 156(d)(1).

7. On March 4, 2002, the USPTO mailed a notice of final determination to Applicant stating that its PTE application was not timely filed as required by statute and regulation, and that the application consequently was dismissed.

8. On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for ANGIOMAX® (bivalirudin) should be effective on December 18, 2000, yet a third possible approval date.

9. On March 23, 2003, the USPTO forwarded the request for reconsideration to the FDA, requesting the FDA's assistance in verifying the approval date of ANGIOMAX® (bivalirudin) as December 15, 2000.

10. On November 2, 2006, the FDA replied, indicating for a second time that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000.
11. On January 26, 2007, Applicant filed a petition under 37 C.F.R. §§ 1.182 and 1.183, requesting a stay of final action on its PTE application.
12. On February 12, 2007, the USPTO granted-in-part and denied-in-part the petition under 37 C.F.R. §§ 1.182 and 1.183. The USPTO granted a limited stay of 30 days to permit Applicant to amend and supplement its request for reconsideration and PTE application.
13. On March 13, 2007, Applicant filed an amended request for reconsideration and an amended PTE application.
14. On April 26, 2007, the USPTO denied Applicant's application for patent term extension ("Denial").
15. On December 4, 2009, Applicant filed a petition under 37 C.F.R. § 1.183 ("Petition").
16. On December 4, 2009, Applicant filed a request for reconsideration of the USPTO's denial of Applicant's application for patent term extension ("Request for Reconsideration").

DECISION

A. Petition under 37 C.F.R. § 1.183 to Suspend 37 C.F.R. § 1.750

Applicant requests, under 37 C.F.R. § 1.183, to suspend the provisions of 37 C.F.R. § 1.750 to the extent that the regulation mandates a single request for reconsideration within a specified time frame. Petition at 3. Applicant argues that section 156 does not set a limit on the number of requests for reconsideration of an application for patent term extension, nor does it set forth a time frame within which such requests for reconsideration must be filed. *Id.* Applicant thus argues that the requirements of Rule 750 are not requirements of the statute. Further, Applicant points out that the USPTO set forth a new methodology for counting the time period of section 156(d)(1) in the denial of its PTE application on April 26, 2007, and as a result, justice supports giving Applicant an opportunity to address that new counting methodology. *Id.* at 4.

The USPTO is persuaded by Applicant's argument for suspension of Rule 750 under the terms of Rule 183. That latter regulation states: "In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed." 37 C.F.R. § 1.183. Since the USPTO has corrected its methodology of counting the time period of 35 U.S.C. § 156(d)(1) to conform with the express language of the statute and first applied its corrected counting methodology in finally denying Applicant's PTE application, the USPTO finds that justice favors giving Applicant the opportunity to address the denial of its PTE application under the USPTO new counting methodology.[1] Accordingly, Applicant's petition

[1] Notably, Applicant does not actually challenge the application of the USPTO's new counting methodology in its Request for Reconsideration, but instead raises arguments focused only on the specific date that the triggered the 60 day window for filing its PTE application, i.e., Applicant disputes whether the correct trigger date is December 15, 2000, as applied by the USPTO, or December 18, 2000, which Applicant asserts is correct.

filed under Rule 183 to suspend Rule 750 is **GRANTED**.

B. Petition under 37 C.F.R. § 1.183 to Suspend 37 C.F.R. § 1.181(f)

Any consideration of the petition filed under 37 C.F.R. § 1.183 is predicated upon a suspension of the timeliness requirement of 37 C.F.R. § 1.181(f). Rule 181(f) provides: "The mere filing of a petition will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings. Any petition under this part not filed within two months of the mailing date of the action or notice from which relief is requested may be dismissed as untimely, except as otherwise provided. This two-month period is not extendable." 37 C.F.R. § 1.181(f). Even though Applicant did not file a petition to suspend the timeliness provision Rule 181(f), the USPTO is nevertheless *sua sponte* considering Applicant's petition under Rule 183 as a request to also suspend the timeliness provisions of Rule 181(f). For the reasons explained above — in short, because justice favors waiver — Applicant's petition filed under Rule 183 to suspend Rule 181(f) is **GRANTED**.

C. Request for Reconsideration of Application for Extension of Patent Term Under 35 U.S.C. § 156

Applicant raises numerous arguments why the USPTO should consider its PTE application for the '404 patent based on the regulatory review period for Angiomax®(bivalirudin) timely filed under section 156(d)(1). Distilling those arguments to their core, Applicant asserts that the 60-day time window of section 156(d)(1) should not commence until an applicant can "be deemed to be on notice" of the FDA approval. Request for Reconsideration at 11. Because the USPTO finds that the section 156(d)(1) expressly sets forth the trigger date for compliance with section 156(d)(1) as the date the applicant may commercially market or use the approved product, which is the date of NDA approval, and does not take an applicant's receipt of such notice into consideration, the USPTO considers Applicant's arguments to be unpersuasive. The present request for reconsideration of the denial of the PTE application for the '404 patent therefore is **DENIED**. Each of Applicant's arguments will be considered in detail in turn.

1. The USPTO Independently Determined Compliance with Section 156(d)(1)

Applicant argues that the USPTO should make its own determination regarding whether the timeliness requirement of § 156(d)(1) is satisfied and should not defer that determination to the FDA. Request for Reconsideration at 6-8. In support of its argument, Applicant points out that section 156 of Title 35 expressly assigns the USPTO Director with responsibility for determining compliance with section 156(d)(1). Request for Reconsideration at 6. Applicant contends that when Congress appoints a particular agency to administer a statute, the appointed agency cannot delegate such duties to a different agency. Request for Reconsideration at 8. As further support, Applicant points out that the USPTO and the FDA entered into a Memorandum of Understanding regarding the administration of section 156 wherein the USPTO acknowledged its responsibility for deciding compliance with section 156(d)(1). Request for Reconsideration at 7-8.

The USPTO agrees with Applicant that the USPTO — and only the USPTO — is assigned responsibility for determining compliance with section 156(d)(1) pursuant to the statute. Indeed, section 156 explicitly provides that "[a] determination that a patent is eligible for

extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension[,]" then the Director shall issue a certificate of extension. 35 U.S.C. § 156(e)(1). The USPTO also agrees with Applicant that the Memorandum of Understanding is evidence of the USPTO's appreciation for its statutory duty. To that end, the Memorandum of Understanding states:

This agreement establishes the procedures whereby the Food and Drug Administration (FDA) assists the Patent and Trademark Office (PTO) in determining a product's eligibility for patent term restoration under 35 U.S.C. 156. It also establishes *procedures for exchanging information between FDA and PTO* regarding regulatory review period determinations, due diligence petitions and informal FDA hearings under the law.

Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration, page 1 (executed September 1986) (emphasis added) (hereinafter "PTO-FDA MOU"). The USPTO disagrees with Applicant, however, that it deferred to the FDA for a determination of timeliness. In making such argument, Applicant misunderstands the process that the USPTO employed in deciding the timeliness of its PTE application.

The Director addressed the timeliness of Applicant's PTE application as early as March 2, 2001. At that time, the USPTO wrote a letter to the FDA, informing the FDA that it determined that Applicant's PTE application was not timely filed. The USPTO made its timeliness finding based solely on Applicant's statements in its PTE application that (i) "[t]he date the product received permission for commercial marketing was 15 December 2000," (ii) "[t]he date on which the NDA was approved was 15 December 2000;" and (iii) a table entry listing December 15, 2000 as the "Approval of Angiomax." *See* PTE Application at 1. This is exactly what the USPTO is obligated to do under section 156(e)(1). The USPTO repeated its independent determination regarding the untimeliness of Applicant's PTE application in its final determination of March 4, 2002 and its Denial on April 26, 2007. Finally, herein, the USPTO explains once more that Applicant's PTE application was not timely filed. *See infra* at page 9.

Focusing more specifically on the USPTO's interaction with the FDA to place the FDA's role in proper perspective, the USPTO wrote to the FDA on two occasions asking for the FDA to <u>confirm</u> that the Applicant correctly represented the date of NDA approval in its PTE application. The USPTO sought information about the NDA approval date from the FDA because the USPTO is not privy to such records; they are solely within the purview of the FDA. Thus, the USPTO often requests the FDA's assistance with PTE applications, particularly since an applicant for a PTE application is not required to submit a copy of the NDA approval letter, enabling the USPTO to see the NDA approval date. But the FDA's assistance is limited exclusively to providing information to the USPTO; it does not mean that the USPTO defers any decisions on PTE eligibility to the FDA. Said differently, seeking assistance from the FDA regarding a factual inquiry, that is, the approval date of an NDA, and then using that fact to conclude that a PTE application was not timely filed in no way constitutes deferral to the FDA on compliance with section 156(d)(1). The USPTO's own regulation provides for the USPTO to make inquiries about the underlying facts when deciding a PTE application. *See* 37 C.F.R. 1.750 ("The Director or other appropriate officials may . . . make independent inquiries as desired before a final determination is made on whether a patent is eligible for extension."). What is more, the Memorandum of Understanding even reflects the nature of the relationship between the agencies in this regard:

While it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied these six conditions, FDA possesses expertise and records regarding the last four and has certain direct responsibilities under 35 U.S.C. 156 for determining the length of the regulatory review period. . . . Under this agreement, FDA, upon receipt of a written request from PTO, will convey to PTO the following information regarding eligibility for extension. . . . (3) whether the patent term extension application was submitted within 60 days after the product was approved . . . .

PTO-FDA MOU at 2 (emphases added). Thus, the FDA did not decide the timeliness of Applicant's PTE application for purposes of Applicant's satisfaction of section 156(g)(1); the USPTO did, exactly as it is required to do by statute.

2. The Date the Product Received Permission for Commercial Marketing or Use is the Date Stamped on the NDA Approval Letter

Applicant argues that the date a drug receives permission for commercial marketing under section 156(d)(1) is not required by statute to be the date the new drug application (NDA) is approved when the FDA transmits the NDA approval after normal business hours. Request for Reconsideration at 9. For support, Applicant points to section 355 of the Federal Food Drug and Cosmetic Act and section 156(g)(1)(B)(ii) of the Hatch-Waxman Act, both of which use different language than section 156(d)(1). *Id.* at 10-12. Applicant contends that "[t]he fact that Congress used two different formulations in the same statutory section reinforces the conclusion that these two dates do not have the same meaning." *Id.* at 10. Applicant misunderstands the Hatch-Waxman scheme.

Section 355(a) of Title 21 governs the approval of new drugs. It provides: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." 35 U.S.C. § 355(a). In other words, the date that an NDA sponsor receives NDA approval is the date that the sponsor may commercially market or use the approved drug. This provision means that NDA approval constitutes the permission for commercial marketing or use of the new drug product, and in turn, that the date of NDA approval is the date a drug receives permission for commercial marketing or use. Accordingly, the date stamped on a NDA approval letter is the appropriate trigger date for section 156(d)(1). To be sure, the FDA defines an "approval letter" as "[a]n official communication from FDA to a new drug application (NDA) sponsor that allows the commercial marketing of the product."[2] The time of day of FDA approval in no way factors into the calculus. And Applicant does not point to any law, regulation, or case law precedent which compels that the NDA approval date is not the same date that a product receives permission for commercial marketing or use when the FDA transmits approval after normal business hours.

Applicant asserts that the Federal Circuit's discussion of the timeliness requirement of section 156(d)(1) in *Unimed, Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989), is "not even *dicta*" because timing was not at issue in that case. Request for Reconsideration at 13-15. Applicant reads that decision to resolve only the very narrow dispute of whether the triggering event for the time period of § 156(d)(1) is FDA approval or the removal of other government obstacles to marketing. *Id.* Applicant's reading is in error.

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[2] *See* Drugs@FDA Glossary of Terms.http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.

Turning to the specific facts, Unimed sought FDA approval of a particular drug product that was a controlled substance. 888 F.2d at 827. The FDA approved Unimed's NDA on May 31, 1985. In its approval letter, the FDA reminded Unimed that the drug could not be legally marketing until the Drug Enforcement Administration ("DEA") rescheduled the drug, which DEA did on May 13, 1986. Unimed then filed a PTE application. The USPTO denied the PTE application as untimely filed under section 156(d)(1). Unimed challenged the USPTO's denial, arguing that the 60-day time period set forth in section 156(d)(1) did not begin until the date of DEA rescheduling because the drug could not legally be marketed until then. The Federal Circuit rejected Unimed's argument.

The Federal Circuit framed the issue as "whether the sixty-day period specified in section 156(d)(1) began, as the Commissioner argues, when the FDA sent its approval letter, on May 31, 1985 or, as Unimed argues, when the DEA rescheduled Marinol nearly a year later." 888 F.2d at 828. To answer the question, the Federal Circuit looked to express language of section 156(d)(1), which it concluded explicitly identified the FDA approval via the language "provision of law under which regulatory review occurred," referring to section 505 of the Federal Food Drug and Cosmetic Act. Applying that statutory construction, the Federal Circuit then explained: "The sixty-day period specified in section 156(d)(1) commenced on May 31, 1985, the date of the FDA's letter to Unimed giving notice of its final approval of Marinol and Unimed's application for extension of the patent term was untimely." *Id.* at 829. The Court's decision here not only addressed the triggering event — FDA approval versus DEA rescheduling, but also addressed the triggering date for section 156(d)(1) and whether the timeliness provision was satisfied based upon an NDA approval date of May 31, 1985, which the Court concluded it was not. Thus, the triggering date was integral to the Court's conclusion, and as a result, *Unimed* is instructive as to how to calculate the 60-day time period of section 156(d)(1).

3. A Product Receives Permission for Commercial Marketing or Use on the Date Stamped on the NDA Approval Letter, Regardless of the Time of Day the Letter is Transmitted

Applicant argues that Congress's intent to give an applicant a full sixty days within which to prepare and submit a PTE application is not followed if an "after hours" NDA approval is considered to trigger compliance with section 156(d)(1). Request for Reconsideration at 16. Applicant thus argues for a "next business day" rule to be applied when the FDA communicates NDA approval outside the FDA business hours of 8:00 AM to 4:30 PM. *Id.* Here, because the FDA transmitted NDA approval to Applicant by facsimile at 6:17 PM on December 15, 2000, Applicant asserts that the 60-day time period should begin on the next business day — December 18, 2000. In other words, Applicant argues that "what matters is when the applicant should be deemed to be on notice of the approval." Request for Reconsideration at 11. Applicant asserts that its "next business day" rule would not have any adverse impact on the FDA or on other determinations by the USPTO, but instead would result in an "objective and straightforward bright-line rule." Request for Reconsideration at 20-21. Applicant's arguments are unpersuasive.

Applicant's "next business day" rule is contrary to statute. Section 156(d)(1) does not consider the time of day that the FDA gives NDA approval, which opens the door for the NDA holder to commercially market the approved drug. Rather, the statute focuses only on "the *date*

the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." 35 U.S.C. 156(d)(1) (emphasis added). A particular "date" spans the course of 24 hours; it does not end with the close of business. Hence, for the USPTO to construe section 156(d)(1) to contain a "next business day" requirement for "after hours" NDA approval simply puts words into the statute that are not there.

Applicant's "next business day" rule is also contrary to regulations. No USPTO regulation regarding patent term extension requires a PTE applicant to state at what time of day the FDA transmitted the approval. Like the language of the statute, the USPTO regulation focuses only on the "date" of NDA approval. *See* 37 C.F.R. 1.740(a)(3) ("A formal application for the extension of a patent term must include: . . . an identification of the *date* on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred.") (emphasis added). The FDA's regulations support the idea that the "date" of FDA approval of a NDA application runs for a 24 hour period. Specifically, 21 C.F.R. § 314.105, which governs the FDA's approval of an NDA application, speaks in terms of the "date" of NDA approval as all day; it makes no mention of the time of day that the letter is transmitted from CDER to the NDA sponsor. That regulation states: "The approval becomes effective on the *date of the issuance* of the agency's approval letter unless the approval letter provides for a delayed effective date." 21 C.F.R. § 314.105(a) & (e) (emphasis added).

Additionally, Applicant's "next business day" rule breaks with the USPTO's historical practice in existence since the inception of the Hatch-Waxman Act of treating the trigger date of section 156(d)(1) as the NDA approval date when the product under regulatory review is a new drug product. The USPTO has never considered the time of day that the NDA was approved. The Manual of Patent Examining Procedure ("MPEP") contains a section entitled: "Deadline for Filing an Application Under 35 U.S.C. – 2700 Patent Terms and Extensions." In that section, the MPEP states:

The sixty-day period *begins on the regulatory agency approval date* which marks the end of the regulatory review period. The statute takes into account only the regulatory review carried out by the Food and Drug Administration or the Department of Agriculture and no other government obstacles to marketing or use. *See Unimed, Inc. v. Quigg*, 888 F2d 826, 828; 12 USPQ2d 1644, 1646 (Fed. Cir. 1989). For drug products *the approval date is the date of a letter by the Food and Drug Administration indicating that the application has been approved*, even if the letter requires further action before the drug can be marketed. *Mead Johnson Pharmaceutical Group v. Bowen*, 838 F2d 1332, 1336; 6 USPQ2d 1565, 1568 (D.C. Cir. 1988).

U.S. Patent & Trademark Office, Manual of Patent Examining Procedure § 2754.01 (emphases added). The MPEP says nothing about the time of day of NDA approval.

Finally, in terms of administration, Applicant's "next business day" rule will not result in an "objective and straightforward bright-line rule."[3] It would instead result in much speculation

[3]Applicant does contend that PTE applicants should be required to submit PTE applications to the USPTO during "normal business hours," perhaps because such submission are permitted up to 11:59PM on the last day of any time period for which a reply is due.

and confusion for PTE applicants as well as the USPTO. Both applicants and the USPTO would be placed in the position of having to track not only the date of NDA approval but also the exact time of day that approval was given. Finally, it is not clear how the regular business hours of the approving agency affect the question of whether an applicant should be on notice of a communication it received from that agency.

4. Applicant Untimely Filed Its PTE Application for Angiomax® (bivalirudin) based on the Regulatory Review Period of NDA 20-873

Applying the statutory language to the facts here, "the date [Angiomax® (bivalirudin)] received permission . . . for commercial marketing or use. . ." was December 15, 2000, as indicated on the face of the FDA's NDA approval letter, as stated by Applicant three separate times in its PTE Application, and as twice confirmed by the FDA upon a request for information from the UPSTO. Under the USPTO's counting methodology of treating the date of approval as day one in conformity with the express language of the statute and case law, *see Unimed*, 888 F.2d at 828, Applicant's PTE application was due by the last day of the 60-day period beginning on December 15, 2000, *i.e.*, February 12, 2001.[4] Applicant filed its PTE application on February 14, 2001, two days late. Notably, even under the USPTO's former counting methodology of treating the day after the date of approval as day one, Applicant still untimely filed its PTE application by one day. Thus, because Applicant filed its application for patent term extension on February 14, 2001, more than 60 days after receiving permission for commercial marketing or use for Angiomax® (bivalirudin), the present application for patent term extension is **DENIED**.

Telephone inquiries with regard to this communication should be directed to Mary C. Till at (571) 272-7755.

Brian E. Hanlon

Brian E. Hanlon
Director
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

[4] As noted earlier, Applicant does not challenge the USPTO's new counting methodology. A full discussion of the USPTO's new counting methodology is set forth in the USPTO denial of Applicant's PTE application on April 26, 2007, which is incorporated herein by reference and attached herewith.

UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

DECISION DENYING APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5,196,404

This is in response to the application for extension of the patent term of U.S. Patent No. 5,196,404 (the '404 patent) under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on February 14, 2001; the first request for reconsideration, filed October 2, 2002; and the amended request for reconsideration, filed on March 13, 2007. The application was filed by The Medicines Company (Applicant). Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of the human drug product known by the tradename ANGIOMAX®, having the active ingredient bivalirudin. Because the Food and Drug Administration (FDA) confirmed (more than once) that the approval date of NDA 20-873 for ANGIOMAX® (bivalirudin) is December 15, 2000, and because Applicant failed to timely file its patent term extension application within sixty days of that date as required by § 156(d)(1) and 37 C.F.R. § 1.720(f), Applicant's request for extension of the patent term of the '404 patent is **DENIED**.

A. Factual Background

On December 15, 2000, the FDA transmitted a letter via facsimile to Applicant explaining that Applicant's NDA 20-873, seeking approval for ANGIOMAX® (bivalirudin), had been approved. That letter stated: "[T]he application is approved effective on the date of this letter." The letter was dated December 15, 2000, in three places: (1) to the right of the address block by what appears to be a date stamp; (2) adjacent the signature on final page in handwriting; and (3) at the top of each of the three pages by what appears to be a facsimile machine imprint that also indicates the time of transmission as "18:17," i.e., 6:17 pm. Applicant does not deny either that the FDA transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 pm by facsimile.[1]

[1] Notably, Applicant claims that it received the FDA approval letter on December 15, 2000, by facsimile but that the letter did not include an electronic signature page. Applicant claims that it received a second copy of the FDA approval by regular mail the following week. According to Applicant, that second copy did not contain a date stamp, but instead included an electronic signature page with a 5:18 pm time stamp and a December 15, 2000, date stamp. Taking Applicant's claims as true, the bottom line is that the both copies of the approval letter contained a December 15, 2000, date stamp.

On February 14, 2001, Applicant filed its application for patent term extension (PTE) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO. Applicant does not claim any earlier date for its application. In the application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000. In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), Applicant identified significant activities undertaken as part of the regulatory review in a table. Applicant listed a communication from Julie DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Additionally, Applicant's counsel struck through paragraph (5), which set forth the last day for filing the PTE application, and initialed and dated the change. Specifically, Applicant's counsel struck through the following: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last date upon which this application could be submitted is 15 February 2001."

On March 2, 2001, after receiving Applicant's PTE application, the USPTO wrote a letter to the FDA, indicating that the USPTO believed the PTE application to be untimely and requested the FDA's assistance in confirming that (1) ANGIOMAX® (bivalirudin) was subject to regulatory review within the meaning of § 156(g) before its first permitted commercial marketing or use and (2) the PTE application was not filed within sixty days after the product received FDA approval as required by § 156(g)(1).

On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) based upon its "uncertainty as to what the approval date really was." Applicant then explained that it researched the approval date on the FDA web site and identified a document listing the approval date as December 19, 2000. Based upon that later approval date, Applicant restated paragraph (5) as follows: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. 1.720(f). The last date upon which this application could be submitted is 17 February 2001."

On September 6, 2001, the FDA confirmed by letter to the USPTO that ANGIOMAX® (bivalirudin) was subject to a regulatory review period before its first commercial marketing or use and that ANGIOMAX® (bivalirudin) had been approved on December 15, 2000, making Applicant's PTE application untimely within the meaning of § 156(d)(1).

On March 4, 2002, the USPTO mailed a notice of final determination to Applicant stating that its PTE application was not timely filed as required by statute and regulation, and that the application consequently was dismissed.

On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for ANGIOMAX® (bivalirudin) should be effective on December 18, 2000.

On March 23, 2003, the USPTO forwarded the request for reconsideration to the FDA, requesting the FDA's assistance in verifying the approval date of ANGIOMAX® (bivalirudin) as December 15, 2000.

On November 2, 2006, the FDA replied, again indicating that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000, and not December 18, 2000.

On January 26, 2007, Applicant filed a petition under 37 C.F.R. §§ 1.182 and 1.183, requesting a stay of final action on its PTE application.

On February 12, 2007, the PTO granted-in-part and denied-in-part, the petition under 37 C.F.R. §§ 1.182 and 1.183. The PTO granted a limited stay of 30 days to permit Applicant to amend and supplement its request for reconsideration and PTE application.

On March 13, 2007, Applicant filed an amended request for reconsideration and an amended PTE application.

B. Applicable Statutes and Regulation

The following statute and regulation are relevant to the timeliness issue presented in Applicant's PTE application:

35 U.S.C. § 156 Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if -. . . .

(d)
(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain - . . . .

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of--

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section . . . .

37 C.F.R. § 1.720 Conditions for extension of patent term

The term of a patent may be extended if:
(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;
(b) The term of the patent has never been previously extended, except for extensions issued pursuant to §§ 1.701, 1.760, or 1.790;
(c) An application for extension is submitted in compliance with § 1.740;
(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;
(e) The product has received permission for commercial marketing or use and -

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent, including any interim extension issued pursuant to § 1.790, has not expired before the submission of an application in compliance with § 1.741; and
(h) No other patent term has been extended for the same regulatory review period for the product.

C. Decision

This decision addresses arguments raised by Applicant in its first request for reconsideration filed on October 7, 2006, and in its amended request for reconsideration filed on March 13, 2007.

1. First Request for Reconsideration

Despite the unambiguous language of the FDA's December 15, 2000, approval letter stating that the date of that letter was the date of approval of ANGIOMAX® (bivalirudin), and despite the FDA's two subsequent confirmations of December 15, 2000, as the approval date, Applicant makes three arguments why December 18, 2000, or alternatively, December 19, 2000, should be treated as the effective approval date for ANGIOMAX® (bivalirudin): (1) it received the FDA approval letter late in the day on December 15, 2000, after normal business hours; (2) the FDA itself was confused as to the approval date, publishing two different approval dates on its website; and (3) fairness weighs in favor of granting the PTE application since ANGIOMAX® (bivalirudin) is Applicant's first commercial product and a denial of patent term extension is a disproportionately harsh penalty, counter to public policy, and counter to the intent of the Hatch-Waxman Act. The USPTO will address each argument in turn.

a) The FDA Approval Letter Plainly Sets Forth the Approval Date of ANGIOMAX® (bivalirudin)

Applicant asserts that because the approval of ANGIOMAX® (bivalirudin) was transmitted by facsimile after 4:30 pm on Friday, December 15, 2000, the approval should be considered to have occurred on the next business day, namely, Monday, December 18, 2000. Applicant's argument is misplaced. The FDA has made clear three times that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000. First, the original approval letter from FDA explicitly states: "Accordingly, the application is approved effective on the date of this letter." The approval letter is clearly date-stamped December 15, 2000, which Applicant does not dispute. Second, the FDA indicated in its first confirmation letter of September 6, 2001, that "[t]he NDA was approved on December 15, 2000, ..." Third, in its second confirmation letter of November 2, 2006, the FDA reiterated that NDA 20-873 for ANGIOMAX® (bivalirudin) was approved on December 15, 2000.

Applicant would have the USPTO, which is responsible for determining eligibility of a patent for PTE, consider December 18, 2000 or December 19, 2000, as the approval date, but the USPTO cannot do so. The USPTO is not involved in the regulatory review process of new drugs and does not issue drug approvals. Although the USPTO can comprehend Applicant's arguments, the fact of approval date of a new drug product is solely within the written records of FDA. Furthermore, as the Federal Circuit has pointed out, the determination of the length of the regulatory review period is the responsibility of the regulatory agency, here, the FDA.

Aktiebolaget Astra v. Lehman, 71 F.3d 1578, 1580-81 (Fed. Cir. 1995). Because approval for a drug product occurs at the end of such period, it follows that the determination of the date of approval is within the exclusive purview of the FDA. Accordingly, the USPTO cannot entertain Applicant's arguments regarding what date should be considered to be the effective approval date of ANGIOMAX® (bivalirudin).

It is well settled that the approval date is the date appearing on the FDA approval letter. *Norwich Eaton Pharms., Inc. v. Bowen*, 808 F.2d 486, 491 (6th Cir. 1987); *Mead Johnson Pharm. v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988); *Unimed, Inc. v Quigg*, 888 F.2d 826 (Fed. Cir. 1989). In *Norwich*, the Sixth Circuit observed that the FDA adopted a regulation expressly providing that "[t]he date of the agency's approval letter is the date of the approval of the application." 808 F.2d at 491 (quoting 21 C.F.R. § 314.105(a)). The Sixth Circuit concluded that the FDA's regulation was reasonable and in line with its statutory mandate to review NDA applications and approve or disapprove them. *Id.* Accordingly, the Sixth Circuit concluded that FDA approval occurs when the FDA issues its approval letter and not when the FDA approves an applicant's labeling instructions or when the applicant receives the FDA approval letter. In *Mead*, the D.C. Circuit reached the same conclusion, also relying on the FDA regulation set forth in § 314.105(a) as well as the Sixth Circuit's decision in *Norwich*.

In *Unimed*, the Federal Circuit squarely addressed the issue in dispute here, *i.e.*, the timeliness of a PTE application which was filed nearly one year late due the applicant's belief that the sixty-day period set forth in § 156(d)(1) commenced after the Drug Enforcement Agency (DEA) rescheduled its narcotic drug to allow for commercial marketing. The Court reasoned that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date" and not the date of rescheduling by the DEA. *Unimed*, 888 F.2d at 828. Turning to consider what date qualifies as the approval date, the Federal Circuit then observed that "[a]ccording to the FDA, the date of marketing approval for all new drugs is the date appearing on its approval letters." *Id.* It also observed that both the Sixth Circuit in *Norwich* and the D.C. Circuit in *Mead* confirmed that the approval date for a new drug is the date of the FDA approval letter.

Given *Norwich*, *Mead*, and *Unimed*, there can be no doubt that the FDA approval date for ANGIOMAX® (bivalirudin) occurred on December 15, 2000, the date appearing on the FDA's approval letter for NDA 20-873 and subsequently confirmed twice by the FDA.

Turning to the time period triggered by FDA approval, § 156(d)(1) requires that an application for patent term extension of a patent which claims a product,[2] a method of using such product, or a method of manufacturing such product, wherein the product was subject to premarket regulatory review by a regulating agency, must be submitted, "<u>within</u> the sixty-day period <u>beginning on</u> the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." 35 U.S.C. § 156(d)(1) (emphases added). Additionally, the implementing regulations mirror the language of §156 (d)(1): "[t]he application is submitted <u>within</u> the sixty-day period <u>beginning on</u> the date the product first received permission for commercial marketing or use under the

[2] The term "product" is as defined in 35 U.S.C. § 156(f).

provision of law under which the applicable regulatory review period occurred . . . ." 37 CFR § 1.720(f) (emphases added). The phrases used in § 156 (d)(1) to define the time period, i.e., "within" and "beginning on," are clear. *See Unimed*, 888 F.2d at 828 (characterizing the language used in § 156(d)(1) as "crystal clear"); *see also United States v. Inn Foods, Inc.*, 383 F.3d 1319, 1322 (Fed. Cir. 2004) (explaining, in the context of a statute of limitation, that terms such as "within [a particular time period]" and "beginning on" clearly specify a time period and need no further analysis). Thus, under both § 156(d)(1) and § 1.720(f), a PTE applicant has sixty days to submit a PTE application where the first day of that sixty-day period begins on the approval date.

In the present case, the FDA approved NDA 20-873 for ANGIOMAX® (bivalirudin) on December 15, 2000. The absolute deadline for filing the application for patent term extension was sixty days from December 15, 2000, starting the count of that sixty-day period on December 15, 2000. The sixtieth day of that time period was February 12, 2001. Applicant failed to meet that statutory deadline because it filed its patent term extension application on February 14, 2001, two days late.[3] Consequently, Applicant's PTE application was untimely filed under § 156(d)(1) and § 1.720(f), and the USPTO has no choice but to deny it.

b) The FDA Has Repeatedly Confirmed the Approval Date of ANGIOMAX® (bivalirudin) as December 15, 2000

Applicant argues that December 18, 2000, or alternatively, December 19, 2000, should be treated as the effective approval date for ANGIOMAX® (bivalirudin) because the FDA itself was confused as to the approval date, publishing two different approval dates on its website. Specifically, on its "NMEs Approved In Calendar Year 2000" webpage, the FDA listed the approval date for ANGIOMAX® (bivalirudin) as December 15, 2000. However, on its "NDA Approvals for Calendar Year 2000" webpage, it listed the approval date as December 19, 2000, as recently as March 23, 2002. Applicant's argument is unavailing as the case law is quite clear. The FDA has consistently treated the date appearing on the FDA approval letter as the approval date. In fact, the FDA even promulgated a regulation, namely 21 C.F.R. § 314.105(a), to that effect. Thus, whether the FDA may have erroneously published the approval date as December 19, 2000, on its "NDA Approvals for Calendar Year 2000" webpage cannot alter the actual December 15, 2000, approval date found in the FDA approval letter. Additionally, the FDA has repeatedly informed the USPTO upon inquiry that the approval date for ANGIOMAX® (bivalirudin) is December 15, 2000.

Moreover, in Applicant's original PTE application, Applicant indicated that the FDA approval date was December 15, 2000, in more than one location, as required by 37 C.F.R. § 1.740(a)(3), (10) and (11). In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant again stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), the chronology of regulatory events listed a communication from Julie

[3] In the USPTO's notice of final determination, it indicated that Applicant filed its PTE application for ANGIOMAX® (bivalirudin) on the sixty-first day after FDA approval. Upon reconsideration of the dates involved in this application, the USPTO notes that Applicant actually filed its PTE application on the sixty-second day after FDA approval. In other words, the USPTO observes that Applicant's PTE application was not one day late, but instead two days late.

DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Hence, even if the FDA was confused as to the approval date for ANGIOMAX® (bivalirudin), which it plainly was not given its two letters confirming an approval date of December 15, 2000, Applicant gave no indication that it was confused as to, or even questioned, the ANGIOMAX® (bivalirudin) approval date when it filed its PTE application on February 14, 2001.

Furthermore, that Applicant filed a supplemental application asserting that it was uncertain as to the approval date seven days after the USPTO sent a letter to the FDA requesting confirmation that the application was untimely filed does not change the fact that Applicant affirmatively listed the approval date as December 15, 2000, in its original PTE application. Thus, Applicant's "uncertainty" as to the approval date was first raised only after the USPTO revealed that it considered Applicant's PTE application to be untimely.

c) Fairness Considerations Cannot Alter the Statutory Language of § 156 as to the Deadline for Filing a PTE Application

Applicant argues that fairness weighs in favor of treating the effective approval date for ANGIOMAX® (bivalirudin) as December 18, 2000, since the drug is Applicant's first commercial product and since a denial is a disproportionately harsh penalty, counter to public policy, and counter to the intent of the Hatch-Waxman Act. While the USPTO appreciates the importance of ANGIOMAX® (bivalirudin) to Applicant and is aware of the impact a PTE denial may have on Applicant, the sixty-day statutory deadline is non-discretionary. That is, § 156(d)(1) neither provides for a grace period, nor gives the USPTO discretion to waive the sixty-day window. As such, the PTO is bound by statute to implement the provisions of § 156(d)(1), including the sixty-day deadline. What is more, fairness is not a factor in a statutory interpretation case such as this one. *See Unimed*, 888 F.2d at 829 ("[T]his is purely a case of statutory interpretation, so the equitable considerations raised by Unimed are inappropriate.").

2. Amended Request for Reconsideration

In its amended request for reconsideration, Applicant supplements the arguments it made in its first request for reconsideration, urging the USPTO to use its own judgment to determine the effective FDA approval date of NDA 20-873 for ANGIOMAX® (bivalirudin) instead of relying on the FDA for the approval date. More specifically, Applicant provides three arguments why the USPTO should not defer to the FDA's conclusion that the approval date is December 15, 2000. The USPTO will address these arguments in the order presented by Applicant.

a) The USPTO Independently Assessed the Timeliness of Applicant's PTE Application for the '404 Patent

Applicant asserts that the USPTO deferred to the FDA on the issue of whether the PTE application was timely submitted without question and that such deference runs afoul of basic principles of administrative law and statutory construction. Applicant also asserts that FDA's determination of the timeliness question is itself arbitrary, capricious, and contrary to law because the FDA failed to give a coherent reading to the statutory terms used in § 156(g)(1). Upon making an independent assessment of timeliness, Applicant asserts that the

USPTO should conclude that the effective approval date of ANGIOMAX®(bivalirudin) was December 18, 2000, or alternatively, December 19, 2000.

Applicant is correct that § 156 delineates the duties in the patent term extension process between the Director of the USPTO and the Secretary of Health and Human Services acting through the FDA. Additionally, Applicant is correct that FDA is charged with calculating the "regulatory review period," and that the USPTO is charged with determining whether an application meets the statutory requirements for extension. That is, the USPTO must determine whether an application is in compliance with § 156(a)(1)-(5) and § 156(d). To determine compliance with § 156(d)(1), which requires a PTE application to "be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use," the USPTO must ascertain the approval date of ANGIOMAX® (bivalirudin). Only then can the USPTO determine whether Applicant's PTE application is timely filed within the meaning of § 156(d)(1). The USPTO, however, is not involved in the drug approval process; rather, the FDA approves new drugs via the IND and NDA processes. *See* Federal Food Drug & Cosmetic Act §§ 505(i) and 505(b), as codified in 21 U.S.C. § 355. And, while a PTE applicant includes the approval date in its PTE application, the USPTO has no way to verify that the date is accurate. Consequently, the USPTO must rely on the written records for drug approvals maintained by the FDA.

Here, the USPTO followed the above-described process in determining whether Applicant timely filed its PTE application for ANGIOMAX® (bivalirudin). In arguing that the USPTO failed to make an independent timeliness assessment, Applicant misapprehends the nature of the USPTO's communications with the FDA. After reviewing Applicant's original PTE application, the USPTO made an initial determination that the application was not timely filed based upon the December 15, 2000, approval date for ANGIOMAX® (bivalirudin) provided in paragraphs (3), (10), and (11) of Applicant's PTE application. The USPTO communicated that independent initial determination to FDA via a letter on March 2, 2001, and requested the FDA's assistance. Specifically, the USPTO stated in the letter:

> The **assistance** of your Office is requested in confirming that the product identified in the application, Angiomax(bivalirudin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. In addition, the **assistance** of your Office is requested in confirming that the application for patent term extension was NOT filed within sixty days after the product was approved. . . . **Our review** of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. 156.

(Emphases added). The use of the term "assistance" plainly shows that the USPTO made an independent decision over six years ago that Applicant's PTE application was not timely filed in compliance with § 156(d)(1). It simply sought the FDA's help in confirming that decision because of the FDA's access to drug approval records, information outside the purview of the USPTO.

Then, after Applicant filed its first request for reconsideration on October 7, 2002, the USPTO wrote another letter to the FDA, again requesting the FDA's assistance: "The assistance of your Office is requested in preparing a reply to this request." In particular, the USPTO sought the FDA's help in addressing Applicant's argument that the approval date for ANGIOMAX® (bivalirudin) should be considered to be December 18, 2000, because the FDA gave its approval late in the day. Applicant's argument regarding the business practices of FDA with respect to communications relating to approvals of NDAs is misplaced. The USPTO has no control over any of the FDA's business practices. As such, Applicant is complaining to the wrong agency regarding the late day notice it received in this case.

Because the USPTO is informed of the approval date by a PTE applicant and has no independent knowledge of such date, the USPTO must avail itself of the approval records maintained by the FDA for confirmation of the date. Moreover, for nearly twenty years, it has been the USPTO's standard practice in processing PTE applications to request the FDA to confirm the approval date of an NDA as represented by an applicant in a PTE application. *See* 52 FR 17830, 17831 (May 12, 1987) (providing public notice of Memorandum of Understanding between USPTO and FDA and explaining that FDA is responsible for checking their records to determine whether the PTE application was timely filed). Consequently, Applicant's assertion that "[t]he PTO's approach thus far—its complete reliance on the FDA's view—raises the concern of arbitrary and capricious agency action" is false.

Applicant urges that the USPTO must engage in "reasoned decisionmaking" when it carries out its statutory obligation under § 156 of determining whether a patent is eligible for patent term extension. As pointed out above, the USPTO has engaged in reasoned decisionmaking throughout the patent term extension process for the '404 patent. First, it made an initial independent assessment of the eligibility of the '404 patent for patent term extension based on the regulatory review period for ANGIOMAX® (bivalirudin). After doing so, it confirmed that decision by letter on two occasions with the FDA, the agency having the official written records relating to approval of ANGIOMAX® (bivalirudin). More specifically, the USPTO asked the FDA to confirm Applicant's representation that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000, as represented, at least twice, in Applicant's PTE application. Following that confirmation from the FDA, the USPTO provided a notice of final determination and corrected notice of final determination that the '404 patent was not eligible for extension because the application for PTE was not timely filed. Finally, through the present decision, the USPTO is addressing Applicant's challenge to that determination and further explaining its reasoning for denying the extension. Accordingly, the USPTO has carried out its responsibility in deciding whether to grant Applicant's PTE application; it has not delegated that responsibility to the FDA, and is not merely sitting on the sidelines waiting for FDA's decision.

Next, Applicant argues that the USPTO's policies and rulemaking are designed to encourage and reward innovation, not produce an untimely and unnecessary loss of patent rights. In support, Applicant cites in a footnote to several sections of title 37 of the Code of Federal Regulations which permit late filings. The USPTO is not attempting to deny any patent rights to Applicant. As discussed earlier, the USPTO has no discretion under § 156 to waive the sixty-day time period for filing a PTE application. If an applicant fails to file its PTE application within this timeframe, then the USPTO is bound by statute to reject the application. Applicant's reliance on

late filing regulations sidesteps the fact that the patent term extension process is governed by statute. If an applicant is not satisfied with the provisions of that statute, then the fix lies with Congress.

Finally, Applicant points out that "there is simply no sound rationale for the [US]PTO to accept a contrary rule that would always deprive a patent holder of one or more days to commercially exploit its patent." The USPTO has not prevented Applicant from enforcing its patent rights in any way. Holding a patent does not give a patent owner an affirmative right to conduct commercial activities. Rather, it gives the patent owner the right to exclude another who, without authority, makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent.[4] For the term of the '404 patent, Applicant may exclude another who seeks to make, use, offer to sell, or sell ANGIOMAX® (bivalirudin).

b) The USPTO Accepts the FDA's Determination of the Approval Date of ANGIOMAX® (bivalirudin)

Applicant asserts that the USPTO should not accept the FDA's conclusion with respect to the date of approval of the ANGIOMAX® (bivalirudin) because it is arbitrary, capricious, and contrary to law. Applicant's assertion is based on the statutory language "on the date," as found in § 156(g)(1)(B)(ii). That provision provides that the regulatory review period is to be calculated by reference to, *inter alia*, "the period beginning on the date the application was initially submitted for the approved product . . . and ending on the date the application was approved." Applicant claims that Congress, by using the term twice in the same sentence, intended for the date to be calculated in the same way for submissions and approvals. And, contrary to congressional intent, Applicant points out that the FDA treats submissions via facsimile to FDA, which are received after the close of business as received on the next business day, but considers approvals to occur on the calendar date that is stamped on the approval letter,[5] regardless of the time of day such letter was faxed by FDA to the NDA applicant.

Applicant likewise takes issue with the seemingly inconsistent manner in which the FDA treats facsimile correspondence when FDA is the receiver as opposed to the transmitter. Even if Applicant is correct that the FDA's method of counting days is contrary to congressional intent, that is not for the USPTO to decide. In the context of the patent term extension process, the USPTO must gather the necessary facts and apply the laws and regulations to assess the eligibility of an applicant's PTE application. Even though Applicant takes issue with FDA's business practice regarding communication of NDA approvals to NDA applicants, the USPTO cannot override the clear regulatory language of 21 C.F.R. §§ 314.105(a) and 314.108(a). Those provisions expressly provide that the date of approval is the date appearing on the letter to the NDA applicant. *See* 21 C.F.R. § 314.105(a) (providing in pertinent part that "[a]n approval becomes effective on the date of the issuance of the approval letter, except with regard to an

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[4] *See* 35 U.S.C. § 271.

[5] Applicant accurately points out that 21 C.F.R. § 314.108 defines "date of approval" to mean the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date.

approval under section 505(b)(2) of the act with a delayed effective date") and 21 C.F.R. § 314.108(a) (providing in pertinent part that "[d]ate of approval means the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date). Here, the uncontested date of the approval letter was December 15, 2000. Accordingly, the USPTO must use that date as the trigger for the sixty day time period within which Applicant had to submit its PTE application.

c) The Correct Date of Approval of ANGIOMAX® (bivalirudin) is December 15, 2000

Applicant challenges the way the FDA communicated approval of NDA 20-873 for ANGIOMAX® (bivalirudin) to Applicant and the date afforded the approval letter. Specifically, in the case of ANGIOMAX® (bivalirudin), Applicant contends that the FDA failed to follow its internal procedures for communicating approval of NDA 20-873, sending two approval letters with different time stamps, though both date-stamped December 15, 2000, and posting conflicting approval dates on its website.

Even if Applicant is correct that the FDA did not employ best practices in communicating approval of NDA 20-873 to Applicants, and that the FDA failed to follow internal procedures in the case of ANGIOMAX® (bivalirudin), the USPTO plays no role in those communications and is not in the position to change the FDA's procedures. As repeatedly explained, the USPTO cannot ignore the plain language of the ANGIOMAX® (bivalirudin) approval letter that the USPTO independently reviewed and that states: "Accordingly, the application is approved effective on the date of this letter." The letter was date-stamped December 15, 2000, which Applicant does not dispute. Thus, consistent with 21 C.F.R. § 314.105(a), there can be no doubt that the FDA approved ANGIOMAX® (bivalirudin) on December 15, 2000, triggering day one of the sixty-day period for filing a PTE application.

d) Equity Considerations With Respect to Approval Date of ANGIOMAX® (bivalirudin)

Applicant largely repeats the equity arguments it made in its first request for reconsideration as reasons why the USPTO should consider the approval date of ANGIOMAX® (bivalirudin) to be December 18, 2000, or December 19, 2000, including that the denial of an extension is contrary to public policy and exacts a disproportionately harsh penalty. As Applicant is quick to point out, the USPTO is charged with the duty of administering patent term extensions under Title II of the Hatch-Waxman Act, codified in § 156. The provisions of that statute do not give the USPTO any discretion to permit late PTE application filings, a point repeated above more than once. Additionally, the facts and figures Applicant sets forth in the amended request for reconsideration regarding the time, money, and work involved in developing ANGIOMAX® (bivalirudin), although informative, are not relevant in the face of the statutory constraints of § 156. Accordingly, since the USPTO regards the approval date as December 15, 2000, based on the date stamped on the FDA approval letter, the USPTO must reject Applicant's PTE application as filed two days after the sixty-day statutory window.

Applicant provides arguments relating to the life-saving potential of ANGIOMAX® (bivalirudin) under the heading, "The Public May Benefit Enormously From Angiomax's Life-Saving Potential." Speculation about possible additional indications for ANGIOMAX® (bivalirudin) is not relevant to whether Applicant complied with section 156(d)(1). Section 156 of the statute does not include any provisions for considering such issues. Therefore, the USPTO must administer the statutory provisions of § 156 without regard to the economics of drug development and regulatory requirements for marketing new drug products.

Moreover, Applicant is not left without any protection for new uses for ANGIOMAX® (bivalirudin) after the expiration of the '404 patent. When new clinical tests are required for approval of an additional indication for a previously marketed drug, the FDA provides data exclusivities for such information subject to the new clinical investigations.[6]

Applicant further adds that extension of the '404 patent will not harm the rights or legitimate interests of third parties. Contrary to this argument, a generic producer seeking to enter the market and sell a generic version of ANGIOMAX® (bivalirudin) would, without litigation, have to wait more than four years beyond the original expiration date of the '404 patent if the USPTO granted a certificate of extension for the amount of term sought by Applicant. Hence, Applicant's contention is unavailing.

e) USPTO Precedent Permits the USPTO to Make an Independent Determination of the Approval Date of the NDA for ANGIOMAX® (bivalirudin)

Applicant conducted research into the USPTO's past administration of § 156 and found that, although rare to deny a PTE because of a late filing, the USPTO has done so in the past on four occasions for the anti-nausea drug related to marijuana (litigated in *Unimed*) and the drug products Vantin®, Saraflox, and Kadian®. Applicant contends that the circumstances in those cases were different from those here. Because of those factual differences, Applicant appears to implicitly suggest that the USPTO should not deny a patent term extension in this case.

Just because the four prior PTE denials on timeliness grounds involved facts distinguishable from those here does not mean that the USTPO should grant Applicant's PTE application. The USPTO must evaluate each PTE application on the facts presented therein and in turn deny those applications that fail to comply with the provisions of § 156. Therefore, it is irrelevant how many times the USPTO has denied other PTE applications for different drug products based on considerations of timeliness under § 156(d)(1).

3. Amended Application for Patent Term Extension

On March 13, 2007, Applicant filed an amended application for patent term extension. This amended application has been entered into the records of the USPTO. In the amended application for PTE, Applicant indicates the approval date for NDA 20-873 for ANGIOMAX ® (bivalirudin) should be considered December 18, 2000, or alternatively, December 19, 2000, in compliance with 37 C.F.R. § 1.740(3) and (10) and provides the calculation of term pursuant to 37 C.F.R. § 1.775 in paragraph (12) using the alternative dates. However, the amended

[6] *See* 21 C.F.R. § 314.108.

application also indicates that on December 15, 2000, Julie DuBeau of FDA communicated to Sonja Loar of The Medicines Company, "Approval of Angiomax" in compliance with 37 C.F.R. § 1.740(11). As repeatedly explained above, the USPTO considers the approval date of the NDA 20-873 for ANGIOMAX® (bivalirudin) to be December 15, 2000.

D. Conclusion

In sum, Applicant has accurately pointed out that the USPTO can and should make its own determination as to the appropriate approval date of ANGOMAX® (bivalirudin) for purposes of § 156(d)(1). As the USPTO explained in its letter of March 2, 2001, it relied on the approval date of December 15, 2000, a date presented in three places in Applicant's PTE application. Based upon that approval date, the USPTO determined that Applicant's PTE application was not timely filed. The USPTO then, consistent with its standard practice as set forth in its Memorandum of Understanding with the FDA, verified that determination by consulting with the FDA as to the approval date for ANGIOMAX (bivalirudin), since the FDA maintains all drug approval records. Moreover, regardless how the FDA communicated its approval of NDA 20-873 to Applicant, the FDA's approval letter clearly stated that the approval is effective on the date of the letter, and the letter was date-stamped December 15, 2000. Such treatment is consistent with § 314.105(a), which provides that the approval date of a drug product is the date of the approval letter, and with Federal Circuit precedent. Accordingly, because Applicant filed its PTE application two days late, the application for patent term extension under § 156 is **denied**. This decision may be viewed as a final agency action.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

Telephone inquiries with regard to this communication should be directed to Mary C. Till at (571) 272-7755.

John J. Love

John J. Love
Deputy Commissioner for Patent Examination Policy
Commissioner for Patents
United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

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Donald R. Steinberg
WIlmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

Dear Mr. Steinberg :

MAR 18 2010

Pursuant to the Order of United States District Court for the Eastern District of Virginia, Alexandria Division, in The Medicines Company v. David Kappos et al., civil action no. 01:10-cv-81, the USPTO is issuing an interim extension under the provision of § 156(e)(2) for a period of 60 days.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Angiomax
FDA Docket No.: 01E-0213

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Biogen Idec MA Inc.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 5,196,404	:	INTERIM EXTENSION

Biogen Idec MA Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,196,404 (the '404 patent), through its authorized agent, The Medicines Company, filed an application for patent term extension under 35 U.S.C. § 156 on February 14, 2001. The original term of the patent is due to expire on March 23, 2010. The patent claims the active ingredient bivalirudin, in the human drug product Angiomax®, which was approved by the Food and Drug Administration for commercial marketing or use on December 15, 2000. An extension of 1,728 days is requested.

Pursuant to the Memorandum Opinion of United States District Court for the Eastern District of Virginia, Alexandria Division, in The Medicines Company v. David Kappos et al., civil action no. 01:10-cv-81, the USPTO is issuing an interim extension under the provision of § 156(e)(2).

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,196,404 is granted for a period of 60 days from the original expiration date of the patent, to and including, May 23, 2010.

3/18/2010
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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MAR 19 2010

Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

DECISION DENYING APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5,196,404

This decision is in response to the memorandum opinion and order of the United States District Court for the Eastern District of Virginia in Civil Action No. 01:10-cv-81, *The Medicines Company v. David Kappos, et al.*, issued on March 16, 2010. The district court vacated the USPTO's denial of the application for extension of the patent term of U.S. Patent No. 5,196,404 (the '404 patent) under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on February 14, 2001, and remanded the case to the USPTO for reconsideration. The USPTO has carefully reconsidered the issues raised in the district court's opinion as well as the arguments present in the Medicines Company's ("MDCO" or "Applicant") request for reconsideration. Because the USPTO again concludes that MDCO's application for patent term extension (PTE application) for the '404 patent was not timely filed as required by 35 U.S.C. § 156(d)(1), its request for a patent term extension of the '404 patent is **DENIED**.[1]

A. Factual Background

1. On March 23, 1993, the USPTO granted the '404 patent.
2. On December 15, 2000, the Food and Drug Administration (FDA) transmitted a letter via facsimile to Applicant explaining that Applicant's New Drug Application No. 20-873, seeking approval for Angiomax, had been approved. That letter stated: "[T]he application is approved effective on the date of this letter." The letter was dated December 15, 2000, in three places: (1) to the right of the address block by what appears to be a date stamp; (2) adjacent the signature on final page in handwriting; and (3) at the top of each of the three pages by what appears to be a facsimile machine imprint that also indicates the time of transmission as "18:17," i.e., 6:17 p.m. Applicant does not deny either that the FDA

[1] This decision incorporates the USPTO's decision dated January 8, 2010, regarding the grant of MDCO's petition under 37 C.F.R. § 1.183 to suspend 37 C.F.R. §§ 1.750 and 1.181(f).

transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 p.m. by facsimile.[2]

3. On February 13, 2001, Applicant, in their Annual Report for 2000, explicitly stated: "On December 15, 2000, the Company received FDA approval for Angiomax." The Medicines Company, Annual Report 2000 at 25-26 (issued Feb. 13, 2001) (Annual Report) (Attachment 1).
4. On February 14, 2001, Applicant filed its PTE application to extend the term of the '404 patent with the USPTO. In its application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of Angiomax was December 15, 2000.
5. In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), Applicant identified significant activities undertaken as part of the regulatory review in a table. Applicant listed a communication from Julie DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Additionally, Applicant's counsel struck through paragraph (5), which set forth the last day for filing the PTE application, and initialed and dated the change. Specifically, Applicant's counsel struck through the following text: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last date upon which this application could be submitted is 15 February 2001."
6. On March 2, 2001, after receiving Applicant's PTE application, the USPTO wrote a letter to the FDA, indicating that the USPTO believed the PTE application to be untimely and requested the FDA's assistance in confirming that (1) Angiomax was subject to regulatory review within the meaning of section 156(g) before its first permitted commercial marketing or use and (2) the PTE application was not filed within sixty days after the product received FDA approval as required by section 156(g)(1).
7. On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) because of its "uncertainty as to what the approval date really was." Applicant then explained that it researched the approval date on the FDA web site and identified a document listing the approval date as December 19, 2000. Based upon that later approval date discovered months after their actual approval and weeks after the February 14, 2001 PTE application filing, Applicant restated paragraph (5) as follows: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. 1.720(f). The last date upon which this application could be submitted is 17 February 2001."

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[2] Notably, Applicant claims that it received the FDA approval letter on December 15, 2000, by facsimile but that the letter did not include an electronic signature page. Applicant claims that it received a second copy of the FDA approval by regular mail the following week. According to Applicant, that second copy did not contain a date stamp, but instead included an electronic signature page with a 5:18 p.m. time stamp and a December 15, 2000, date stamp. Taking Applicant's claims as true, the bottom line is that the both copies of the approval letter contained a December 15, 2000, date stamp.

8. On May 21, 2001, Applicant filed a registration statement with the Security and Exchange Commission wherein it stated: "On December 15, 2000, the Company received FDA approval for Angiomax and any Angiomax bulk drug product to which the Company took title after that date is recorded as inventory." The Medicines Company, Form S-1 Registration Statement Under The Securities Act of 1933 at 84 (filed with Security Exchange Commission May 2001) (SEC Statement) (Attachment 2).

9. On September 6, 2001, the FDA confirmed by letter to the USPTO that Angiomax was subject to a regulatory review period before its first commercial marketing or use and that Angiomax had been approved on December 15, 2000, making Applicant's PTE application untimely within the meaning of section 156(d)(1).

10. On March 4, 2002, the USPTO mailed a notice of final determination to Applicant stating that its PTE application was not timely filed and that the application consequently was dismissed.

11. On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for Angiomax should be effective on December 18, 2000.

12. On March 23, 2003, the USPTO forwarded the request for reconsideration to the FDA, requesting the FDA's assistance in verifying the approval date of Angiomax as December 15, 2000.

13. On September 14, 2006, Applicant's Chairman and Chief Executive Officer, Clive Meanwell, testified before Congress about specific legislation it was lobbying Congress to pass, which would provide a legislative remedy for its untimely PTE application filing. Dr. Meanwell testified as follows:

> The FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000 . . . . But then human error intervened. The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, but one day late for the actual 60-day deadline. Unlike other filing provisions of the patent laws, this provision of Hatch-Waxman does not allow for any discretion to accept late applications, no matter the reason and no matter how close to the actual deadline. So, the Patent and Trademark Office denied the petition as untimely. We filed a motion for reconsideration which is still pending, but the USPTO lacks the authority to grant it.

A Bill to Amend Title 35, U.S. Code, To Conform Certain Filing Provisions Within the Patent and Trademark Office: Hearing on H.R. 5120 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. On the Judiciary, 109th Cong. 11 (2006) (statement of Clive Meanwell, Chairman and CEO of the Medicines Company) (2006 Legislation) (Attachment 3). This was not Applicant's first or only attempt to secure a legislative fix for its untimely PTE application filing. Since September of 2005, Applicant's attempt to secure a legislative fix for its untimely PTE application filing resulted in at least four other bills, each of which provided relief to Applicant by providing a mechanism for the USPTO Director to accept

unintentionally delayed PTE application filings. *See, e.g.*, S. 1785, 109th Cong.; H.R. 1178, 110th Cong.; S. 1145, 110th Cong.; H.R. 6344, 110th Cong.

14. On November 2, 2006, the FDA replied to the USPTO March 2003 letter of inquiry regarding the approval date of Angiomax, again indicating that Angiomax was approved by the FDA on December 15, 2000, and not December 18, 2000.

15. On January 26, 2007, Applicant filed a petition under 37 C.F.R. §§ 1.182 and 1.183, requesting a stay of final action on its PTE application due to its pending legislation which, as explained earlier, would have provided an exception for Applicant's PTE to be considered timely.

16. On February 12, 2007, the USPTO granted-in-part and denied-in-part the petition under 37 C.F.R. §§ 1.182 and 1.183. The USPTO granted a limited stay of 30 days to permit Applicant to amend and supplement its request for reconsideration and PTE application.

17. On March 13, 2007, Applicant filed an amended request for reconsideration and an amended PTE application.

18. On April 26, 2007, the USPTO denied Applicant's application for patent term extension in final agency action.

19. On December 4, 2009, two years and eight months after Applicant could have brought suit to challenge the USPTO's final denial of its patent term extension application, Applicant filed a petition under 37 C.F.R. § 1.183 asking the USPTO to waive the requirements of 37 C.F.R. § 1.183, which limits an applicant to a single request for reconsideration within a specified time.

20. On December 4, 2009, Applicant also filed another request for reconsideration of the USPTO's denial of Applicant's application for patent term extension (Reconsideration Request).

21. On January 8, 2010, USPTO again denied Applicant's application for patent term extension in final agency action.

22. On January 27, 2010, Applicant filed suit against the USPTO, FDA, and Department of Health and Human Services in the United States District Court for the Eastern District of Virginia, Alexandria, Division under the Administrative Procedures Act, challenging the USPTO's denial of its PTE application.

23. On March 16, 2010, the district court issued a memorandum opinion and order vacating the denial of the PTE application and remanding the case to the agency for reconsideration "as to the date of approval under § 156." *The Medicines Co. v. Kappos*, Civ. Act. No. 01:10-cv-81, slip op. at 18 ("District Court Decision"). The district court explained that the USPTO erroneously believed that its construction of the term "date" in section 156(d)(1) to mean "calendar day" was compelled by the statute and that it lacked any discretion to adopt Applicant's proffered "business day" construction. *Id.* at 10. The district court also identified four argument that Applicant made to support its "business day" construction, including: "§ 156(d)(1)'s focus on the date approval was received, the purpose of § 156(d)(1), the need to ensure that all applicants received the 60 days to file extension applications that Congress required[,] and the ways in which its interpretation of date in combination with its new counting rule is inconsistent with that requirement." *Id.* at 11. The

district court faulted the USPTO for not expressly considering these arguments, *id.* at 11, as well as for failing to provide an analysis of its plain meaning definition of "date" as "calendar day," *id.* at 14. Finally, the district court directed the USPTO "to take such actions as necessary to ensure that [Applicant's] patent does not expire pending further resolution of these proceedings." *Id.* at 18.

B. Decision

I. The USPTO Independently Determined that Applicant's PTE was Untimely Filed based on Information Supplied by the FDA

Applicant argues that section 156 expressly assigns the USPTO Director — not the FDA — responsibility for determining whether a PTE application has been timely filed as required by section 156(d)(1). Reconsideration Request at 6. Applicant also argues that just because the FDA has the approval date within their records, the USPTO must not defer to FDA's determination of compliance with section 156(d)(1). *Id.* at 7. Finally, Applicant argues that the Memorandum of Understanding between the USPTO and the FDA assigned certain duties to each agency, and USPTO is not authorized to delegate determination of compliance with the timeliness requirement of section 156(d)(1). *Id.* at 8. The USPTO agrees; it did not delegate a timeliness determination to the FDA here.

The USPTO wrote to the FDA on two occasions asking for the FDA to confirm that Applicant correctly represented the date of FDA approval of Angiomax in its PTE application. The USPTO sought this information from the FDA because the USPTO is not privy to such records; they are solely within the purview of the FDA. Because of this, the USPTO often requests the FDA's assistance with PTE applications, particularly since an applicant for a PTE application is not required to submit a copy of the FDA's approval letter to the USPTO. The USPTO's own regulation provides for the USPTO to make inquiries about the underlying facts when deciding a PTE application. *See* 37 C.F.R. § 1.750 ("The Director or other appropriate officials may . . . make independent inquiries as desired before a final determination is made on whether a patent is eligible for extension."). But the FDA's assistance is limited exclusively to providing information to the USPTO; it does not mean that the USPTO defers to the FDA on any decisions about timeliness or any other eligibility requirement. With information about the date that the FDA approved Angiomax as provided by the FDA in hand, the USPTO independently decided whether Applicant's PTE application satisfied the timeliness requirement of section 156(d)(1).

The USPTO's past practice indicates that it does not defer to the FDA for a determination of timeliness. For example, in considering a PTE application filed for U.S. Patent No. 4,911,920, the USPTO sent an inquiry to the FDA asking for confirmation of the drug approval date (Attachment 4). In response to the USPTO's inquiry, the FDA indicated that the approval date was February 23, 2000, and that the submission of the PTE application on April 26, 2000, was not timely filed under section 156(d)(1) (Attachment 5). In the USPTO's very next communication, the USPTO disagreed with the FDA's timeliness finding and stated: "The application was filed on April 19, 2000 under 35 U.S.C. § 156. The application was received by the undersigned on April 26, 2000, but was mailed by Express Mail on April 19, 2000, and is entitled to a filing date of April 19, 2000. As a result, the application was timely filed." (Attachment 6). Clearly, just as the USPTO did not defer to the FDA's timeliness determination in the PTE application for U.S. Patent No. 4,911,920, the agency did not defer to FDA here.

II. Construing the Term "Date" in Section 156(d)(1) to Mean "Calendar Day" is the Best Interpretation of the Text, Structure, and Purpose of the Statute

In its decision, the district court explained that section 156(d)(1) is not "so inflexible" as to admit of only one meaning, namely "calendar day," and implicitly found that the term "date" could have the "business day" definition that Applicant subscribes to it. District Court Decision at 13. In other words, the district court appears to find that the term "date" in section 156(d)(1) is open to more than one interpretation, freeing the USPTO to exercise its discretion in interpreting it. The USPTO finds that the best definition of "date" in section 156(d)(1) is "calendar day" based upon the text, structure, and purpose of the statute. In making this determination, the USPTO notes that section 156(d) squarely deals with the procedural requirements for obtaining a patent term extension. The USPTO's interpretation here is thus undertaken in the course of governing the conduct of its proceedings.

Beginning with the text and structure of the statute, section 156(d)(1) states:

> [t]o obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on *the date the product received permission* under the provision of law under which the regulatory review period occurred *for commercial marketing or use.*

35 U.S.C. § 156(d)(1) (emphases added). To determine what the term "date" means, the USPTO looks to the words surrounding that term, namely the phrase "the product received permission . . . for commercial marketing or use." A drug product "receive[s] permission . . . for commercial marketing or use" when the FDA approves the drug. Section 355(a) of Title 21 makes this clear. It provides: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." 21 U.S.C. § 355(a). The requirement that all "new drugs" obtain approval from FDA before they may be distributed in interstate commerce is the linchpin of drug regulation under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 331(d).

The FDA approves a drug on the date stamped on the FDA approval letter. Various FDA regulations establish this. *See* 21 C.F.R. § 60.22(f) (explaining that "[a] marketing application . . . is approved on the date FDA sends the applicant a letter informing it of the approval"); 21 C.F.R. § 314.105(a) (stating that "[a]n approval becomes effective on the date of the issuance of the approval letter"); 21 C.F.R. § 314.108(a) (noting that "[d]ate of approval means the date on the letter"). It is likewise the FDA's long-standing practice — both before and after enactment of the Hatch-Waxman Act — to treat a drug as approved on the date of the approval letter. *See Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988) ("[21 C.F.R. § 314.105(a)] thus reflects a well-considered, long-standing policy."). To this end, FDA approval letters explicitly state that the "application is approved effective on the date of th[e] letter." *See, e.g.*, FDA Approval Letter to Applicant at 1 (Attachment 7). Additionally, three appellate courts have recognized the same. *See Mead Johnson*, 838 F.2d at 1336 (determining

that FDA's regulations which note that an approval is the date on the approval letter reflect a "well-considered, long-standing policy"); *Norwich Eaton Pharms, Inc. v. Bowen*, 808 F.2d 486, 491 (6th Cir. 1987) (noting that FDA approval was effective on the date of the approval letter, not the date the drug company received the approval letter), *cert. denied*, 108 S. Ct. 68 (1987); *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989) (concluding that the sixty day period mandated by 35 U.S.C. § 156(d) began on the date of the FDA approval letter). Accordingly, the date of approval is the date of the FDA approval letter.

The date stamped on the FDA approval letter covers a calendar day. Under Federal Food, Drug, and Cosmetic Act, there are no limits on what days (weekdays, weekends, or holidays) or at what times (business and non-business hours) that the FDA may approve a drug. *See* 21 U.S.C. §§ 355(a)-(d). Accordingly, Congress has implicitly authorized the FDA to approve drugs at any time of day. Said differently, Congress has not restricted the FDA to approve drugs before a certain time of day such as 4:30 p.m., the cut-off time that Applicant advocates here. Applicant's position that approval must occur on a business day, prior to 4:30 p.m. east coast time, in order to be deemed effective on that day is consequently not supported by statute. Nor does it make sense for the FDA to limit its approval window to a few hours in a day. Because Applicant essentially argues that FDA must stop official business at 4:30 p.m. east coast time, including halting the review of applications, Applicant's position could also prolong the approval process — to the detriment of industry and the public.

MDCO isolates the word "received" from section 156(d)(1) and contends that it shows that Congress intended for the patentee to have constructive receipt of the FDA approval before triggering the 60-day filing window. *See* Reconsideration Request at 16-17. In Applicant's view, "an after-hours communication should be deemed to have been received on the next business day." *Id.* at 17. The presence of the word "received" in section 156(d)(1), however, must be read in context. The statute speaks in terms of the "product receiv[ing] . . . permission for commercial marketing or use." The statute says nothing about the patentee actually or constructively receiving notice of the FDA approval. Hence, Applicant's argument is not fully consistent with the statutory language of section 156(d)(1). In fact, as explained more fully below, one reason why the term "received" in section 156(d)(1) cannot refer to the actual, or even constructive, receipt of an approval letter is because some permissions within the scope of section 156(d)(1) do not come in the form of approval letters at all. *See, e.g.*, 35 U.S.C. § 156(g)(2)(B)(ii) (specifying that the regulatory review period for a food or color additive ends on the effective date of a regulation).

Moreover, MDCO's argument that the date a human drug "receive[s] permission . . . for commercial marketing or use" is not the same day as the date that the new drug "application [i]s approved" because the language of section 156(d)(1) is distinct from the language of section 156(g)(1)(B)(ii) is unpersuasive. *See* Reconsideration Request at 9-10. Section 156(d) is simply using broader language to refer to the specific permission events that are also referred to in section 156(g). A review of the structure of section 156 reveals that the "receives permission . . . " language used in section 156(d)(1) covers various specific terms used in section 156(g). There are several different categories of products referenced in section 156(g): new drugs, food or color additives, medical devices, new animal drugs, and veterinary biological products. Section 156(d)(1) also explains that the "permission" that the various particular products "receive[]"

occurs pursuant to "the applicable regulatory review period" for that given product. Those applicable regulatory review periods are set forth in section 156(g). The nature of the "permission" that the FDA gives for the commercial marketing or use of a product depends upon what category the product falls under. Some are based on the date an "application was approved," while others are based on some other act by the FDA.

In reviewing the specific provisions of section 156(g), it becomes clear that section 156(d)(1) uses the broader language "permission ..." to encompass the various different acts of permission referred to by section 156(g). Thus, the date a new drug application is "approved" [156(g)(1)(B)(ii)], the date a regulation "became effective" for use of a food or color additive [156(g)(2)(B)(ii)], the date the protocol "was declared completed" for a medical device [156(g)(3)(B)(ii)], the date a new animal drug is "approved" [156(g)(4)(B)(ii)], and the date a license "was issued" for a veterinary biological product [156(g)(5)(B)(ii)], are all types of "permission" for commercial marketing and use contemplated in section 156(d)(1). Because of that, section 156(d)(1) does not use the same "date such application was approved" language that appears in section 156(g)(1)(B)(ii), and instead uses the broader, more generic "product received permission" language. Section 156(d)(1) necessarily uses language broader — and hence different — to encompass the specific approval or permission language particular to the various products referred to in section 156(g).

MDCO's argument that section 156(d)(1) and section (g)(1)(B)(ii) serve distinct purposes, and therefore must be construed to mean different things, is equally unpersuasive. *See* Reconsideration Request at 10-12. The USPTO agrees with MDCO's premise that the two provisions serve distinct purposes. Specifically, section 156(d)(1) serves to inform all patent term extension applicants of the trigger date which starts the sixty-day period for submission of a PTE application for his product, which could a human drug, food or color additive, medical device etc., whereas section 156(g)(1)(B)(ii) informs drug sponsors when a human drug product is approved, i.e., the regulatory review period ends, and commercial marketing may begin. Although these two provisions have different purposes, it does not follow that the specific temporal triggers that they include must be different. Title 21 of the Federal Food, Drug, and Cosmetic Act establish that the words "the date the product received permission . . . for commercial marketing or use" in section 156(d)(1) is synonymous with the language "the date [the drug] application was approved" in section 156(g)(1)(B)(ii). *See* 21 U.S.C. § 355(a). Moreover, as the Federal Circuit has made clear, it could "find no implication that the approval date that commences the 60-day application period under [section 156(d)(1)] should be different from the approval date that marks the end of the regulatory review period under [section 156(g)(1)(B)(ii)]." *Unimed*, 888 F.2d at 829.

Finally, it is critical that the "date" of section 156(d)(1) be certain because the consequence of missing the filing window is drastic. Indeed, the date of FDA approval is "of great concern to the FDA, the NDA applicant, and competing drug manufacturers, even before the Hatch-Waxman Amendments." *Mead Johnson,* 838 F.2d at 1336. Certainty is achieved under the calendar day definition only, which does not take time of day into account. Under a "business day" definition, by contrast, applicants for a patent term extension, the USPTO, the FDA, and the public must track down the precise time of day that the FDA approval is granted. But of the foregoing entities, only the FDA has access to that information. In many

circumstances, it is even possible that applicants for a patent term extension — the entities most in need of the information — do not have it since the FDA transmits the approval letter to the NDA sponsor, who may not be the patentee who will file the patent term extension application. *See, e.g.*, U.S. Patent No. 4,486,425 (decision denying PTE application where patent owner unaware of approval because patent owner and drug sponsor were distinct entities) (Attachment 8). Consequently, adopting a business day definition strains the purpose of section 156(d)(1).

III. The USPTO's Construction of the Term "Date" in Section 156(d)(1) to Mean "Calendar Day" is Consistent with Federal Circuit Precedent

Precedent establishes that the "date" in section 156(d)(1) means the date stamped on the FDA approval letter. In *Unimed*, the Federal Circuit considered whether the sixty-day period to file a patent term extension application for a patent claiming a drug product, which required DEA rescheduling, begins on the date the FDA sent the approval letter or on the date that the DEA rescheduled the drug product, which occurred nearly one year after FDA approval. 888 F.2d at 828. In answering this question, the Federal Circuit analyzed the statutory language of section 156(d)(1) and found that section 156(d)(1) is triggered by the date of the approval letter:

> According to section 156(d)(1), the sixty-day period begins "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." Read in light of the definition of the "regulatory review period" in section 156(g)(1)(B), *this language is crystal clear*. In this case, "the provision of law under which the applicable regulatory review period occurred" is section 505 of the FFDCA, which governs the approval of new drugs by the FDA. There is no mention of DEA rescheduling or of 21 U.S.C. § 811(a), the statute under which rescheduling takes place. Therefore, *section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date.*
>
> *According to the FDA, the date of marketing approval for all new drugs is the date appearing on its approval letters.* Two circuit courts of appeals have confirmed this.

Id. (emphases added).

MDCO attempts to avoid *Unimed* by narrowly characterizing the case on its specific facts. Particularly, MDCO casts *Unimed* as concerning whether the 60-day filing window of section 156(d)(1) started from the date that the DEA rescheduled the drug as opposed to the date the product received permission for commercial marketing or use from the FDA and not whether transmission of the FDA approval letter by courtesy facsimile after 4:30 p.m. triggers the date of section 156(d)(1) — the issue here. *See* Reconsideration Request at 13-15. While *Unimed* did not involve the precise facts here, *Unimed* construed the word "date" in section 156(d)(1). The construction of the word "date" in section 156(d)(1) is central to deciding the issue here, and *Unimed,* thus is applicable precedent. Moreover, even if *Unimed* is factually distinguishable, the

USPTO's independent construction of the term "date," which the agency made exercising its discretion as ordered by the district court to do, is consistent with *Unimed.*

IV. The USPTO's Construction of "Date" as "Calendar Day" is Consistent with the USPTO's Historic Practice

Although the USPTO has not previously addressed a dispute over whether the term date means "calendar day" or "business day," the USPTO has in practice, since the enactment of the Hatch-Waxman Act, applied a "calendar day" definition for all PTE applications where the FDA issued what MDCO would characterize as an "after business hours" drug approval. *See Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 740 (1996) ("To be sure, agency interpretations that are of long standing come before us with a certain credential of reasonableness, since it is rare that error would long persist."). For example, when the FDA provided a courtesy facsimile of the drug approval letter for the drug Betaxon on February 23, 2000, at 4:44 p.m., the USPTO treated February 23, 2000, as the approval date for purposes of determining whether the PTE application was timely under section 156(d)(1). *See* U.S. Patent No. 4,911,920 (February 23, 2000 Approval Letter) (Attachment 9). The USPTO has done the same in connection with other PTE applications with similar facts. *See also, e.g.*, U.S. Patent No. 5,951,974 (January 19, 2001 Approval Letter) and U.S. Patent No. 5,565,447 (May 7, 2001 Approval Letter) (Attachments 10 and 11, respectively).

The patent law includes various time periods (other than the one at issue) that are measured from events or actions that do not take place in the USPTO, for example, the publication of a description of the invention, the public use of an invention, the placement of an invention on sale, the filing of an application in a foreign country. In all instances, the USPTO uses the calendar date for all trigger dates. Regarding the actions that the USPTO itself takes, the agency, like the FDA, is not limited to "business hours." For example, the USPTO grants patents on holidays. *See* Kenneth W. Dobyns, The Patent Office Pony 123 (1997) (". . .beginning in early 1848 and continuing to date, patents have issued at noon every Tuesday, and only on Tuesday, come fire, flood, war, riot or national holiday") (Attachment 12). The trigger date for periods measured from the grant of a patent (*e.g.*, the due dates in 35 U.S.C. § 41(b) for payment of maintenance fees, and the two-year period in 35 U.S.C. § 251 for filing a broadening reissue) is measured from the calendar date on which the patent is granted, and does not carry over to the next business day when a patent is granted on a federal holiday. The only instance when the USPTO considers business versus non-business days is when a time period for taking action before the USPTO ends on a non-business day. *See* 35 U.S.C. § 21(b).

Furthermore, it is the USPTO's practice to accept filings until midnight on the date a filing is due – thus a PTE application submitted to USPTO after "business hours" on the sixtieth day after FDA approval would be deemed timely. *See, e.g.*, Official Gazette Notice (Feb. 1, 2005) (Attachment 13); 37 C.F.R. § 1.10; 37 C.F.R. § 1.8; 37 C.F.R. § 1.6 (permits timely filing by facsimile so long as actual receipt by USPTO is by midnight EST); USPTO Legal Framework for EFS-Web 12, XXIII (Sept. 2008) (Attachment 14).

V. MDCO's Suggested Business-Day Interpretation of Section 156(d) Conflicts With the FDA's Interpretation of the Analogous Provision in Section 156(g)(1)(B)(ii)

MDCO argues that the USPTO should adopt a construction of section 156(d)'s date language—*i.e.*, "the date the product received permission . . . ," that mirrors the FDA's practice of considering new drug applications that are electronically submitted after 4:30 p.m. to have been received on the next business day (the 4:30 rule). Reconsideration Request at 15, n.8; 17-18.

The USPTO acknowledges that the FDA uses the 4:30 rule in the limited context of electronic submissions to determine when a new drug application is *submitted*,[3] but the FDA does not use that same rule when assessing the date that same application is *approved*. Critical to the question of whether the FDA and the USPTO are interpreting the term "date" similarly is the fact that while the word "date" only appears once in the provision interpreted by the USPTO, 35 U.S.C. § 156(d)(1), the word "date" appears *twice* in the provision interpreted by the FDA, 35 U.S.C. § 156(g)(1)(B)(ii):

> (ii) the period *beginning on the date* the application was initially submitted for the approved product under section 351, subsection (b) or section 505, or section 507 and *ending on the date* such application was approved under such section.

(Emphasis added). That provision defines a portion of the regulatory review period in terms of a beginning *date* and an ending *date*. The FDA only applies the 4:30 rule to the beginning date. That beginning date is not relevant to the 60-day filing window provided in section 156(d)(1) because the date an applicant submits a new drug application to the FDA is unrelated to a time period that turns on a subsequent approval of that application. Instead, it is the ending date in section 156(g)(1)(B)(ii) that is relevant to 60-day filing window of section 156(d)(1) because the conclusion of the review period marks the beginning PTE application filing window. By rule, the FDA considers the date of approval — which of course marks the end of the review period — to be the "date of issuance of the approval letter." 21 C.F.R. § 314.105(a). The USPTO cannot speak to whether the FDA's approach to interpreting section 156(g)(1)(B)(ii) is internally inconsistent, as MDCO argues. Reconsideration Request at 15, n.8. In any event, the USPTO should not compound that perceived inconsistency by applying the 4:30 rule to the ending date of the approval period, *i.e.*, to the date that the FDA *does not* apply the 4:30 rule. Thus, the USPTO concludes that the best approach is to interpret section 156(d)'s date language in harmony with the FDA's approach to interpreting the ending date language in section 156(g)(1)(B)(ii).

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[3] It is worth noting that MDCO does not assert that the FDA's 4:30 rule was used to determine the submission date of the ANGIOMAX application or that the ANGIOMAX application was even subject to the 4:30 rule, *i.e.*, MDCO does not assert it filed an electronic application. In other words, although MDCO implicitly makes the equitable argument that an outgoing approval should be treated like an incoming submission, it never asserts that *its* application should be subject to that equitable comity.

VI. MDCO's Suggested Interpretation of 156(g)(1)(B)(ii) Is Unpersuasive For Additional Reasons

Beyond the disharmony it would create with the FDA's interpretation of section 156(g)(1)(B)(ii), there are other problems with MDCO's arguments in favor of the 4:30 rule. First, the FDA's refusal to accept new drug application submissions after 4:30 p.m. bears no logical connection to whether a facsimile transmission sent after that time is received on the same calendar day. MDCO's concern is with notice. Reconsideration Request at 11. But MDCO fails to articulate why its ability to receive notice is linked to the FDA's hours for accepting new drug applications. Instead, MDCO's ability to receive notice logically turns on whether *it* was closed for business when the FDA sent its courtesy facsimile on December 15, 2000. MDCO is careful to steer clear of urging actual notice because it has never asserted that it was not on actual notice of FDA approval on December 15, 2000. MDCO candidly admits that any standard that turns on actual notice would be "difficult to administer" and involve "potentially burdensome fact-finding that the [USPTO] is not equipped to undertake." Reconsideration Request at 20.

Second, the FDA *was* conducting business after 4:30 p.m. on December 15, 2000, and any other time it takes action. The "business" of the FDA is drug approval, and MDCO agrees that the regulatory review period here "ended on December 15, 2000." Reconsideration Request at 21, n.14. Because MDCO also agrees that the FDA's act of approval is what ends the review period, *id.* at 20-21 (acknowledging that the end of the review period under section 156(g)(1)(B)(ii) is the date of FDA's approval), and because that approval occurred after 4:30 p.m., MDCO cannot seriously argue that the FDA was not conducting business when it sent the courtesy facsimile to MDCO. Although it might not have been accepting new drug applications at the time it approved Angiomax and almost immediately informed MDCO of that fact, it was clearly conducting the very business desired by MDCO. In addition, MDCO's permission for commercial market or use of Angiomax began on December 15, 2000, and was not delayed until the next business day (i.e., December 18, 2000) as a consequence of when, during the day on December 15, 2000, the FDA transmitted this courtesy facsimile to MDCO. The USPTO declines to adopt the *non sequitur* rule that a valid FDA approval should not count until the next business day just because the FDA was not accepting new applications at the time it issued its approval of an application that had been filed years earlier.

Third, MDCO fails to consider that a 4:29 p.m. approval would deprive an applicant for a patent term extension of the full 60-day period just as much as a 4:31 p.m. approval. Similarly, a facsimile transmission from the FDA of an approval at 4:35 p.m. east coast time to a drug sponsor in California, would, under MDCO's rationale, be outside the normal business hours of the FDA for purposes of triggering the 60-day filing window of section 156(d)(1) but would have provided many "business hours" for the California sponsor to commercially market or use its new drug.

Finally, MDCO's argument in favor of a 4:30 rule is made possible because the FDA provided a courtesy facsimile to Applicant. Nothing in the Federal Food, Drug, or Cosmetic Act or FDA regulations requires the FDA to facsimile notification of FDA approval to a drug sponsor. Had the FDA notified MDCO of the approval of its drug via postal mail only, MDCO could not allege that the term "date" in section 156(d)(1) means "business day" because there

would be no after business hours transmission of approval from the FDA to quibble over. Thus, this entire litigation was made possible solely because the FDA chose to extend a courtesy to MDCO and provide as prompt notification of FDA approval as possible.

VII. MDCO's Remaining Fairness Arguments Regarding Section 156

Urging that the USPTO should interpret section 156(d)(1) in a way that benefits it, MDCO argues that the USPTO "has historically developed policies to avoid the unnecessary loss of patent rights." Reconsideration Request at 19. MDCO fails to appreciate, however, that those policies are provided by statutory provisions absent here. For example, the USPTO allows filing on the next business day when a time period ends on a weekend or holiday, 37 C.F.R. § 1.7, and allows certain filing dates to be met by timely deposit of the filing with the U.S. Postal Service, 37 C.F.R. § 1.8. Both rules are specifically authorized by statute. *See* 35 U.S.C. § 21. Likewise, the USPTO will, under certain circumstances, allow revival of a patent that expires for failure to pay a fee, or revival of an application that is abandoned for failure to take action, but only because Congress authorized the USPTO to do so. 35 U.S.C. § 41(c) (patent maintenance fees) 35 U.S.C. §§ 41(a)(7) and 133 (application abandonment). Furthermore, the USPTO can even extend the time for appealing its Board decision to the U.S. Court of Appeals for the Federal Circuit, and accept late priority claims to earlier applications, but only because both practices are authorized by statute. 35 U.S.C. §§ 142 (Federal Circuit Appeal), 120 (priority).

The point is that there are indeed many instances where the USPTO prevents loss of rights due to an applicant, appellant, or patentee's failure to meet certain deadlines. But in all of those cases, Congress has provided the avenue for the relief available at the agency, and thus to the applicant or patentee. In light of that, it speaks volumes that Congress provided no avenue to allow the USPTO to accept a late PTE application filed under section 156. Given Congress's unquestionable awareness that lawyers make mistakes, and the various provisions it provided to redress those mistakes, Congress's failure to include a similar provision related to the section 156(d)(1) 60-day filing window compels the conclusion that Congress did not intend the provision to be remedial, or to be interpreted in a way that benefits late-filing PTE applicants.

Finally, although not specifically advanced in the Reconsideration Request, the USPTO notes that in its decision, the district court referred to section 156 as "remedial." While section 156, and more generally the Hatch-Waxman Act, in part, was certainly meant to remedy the loss of effective patent term due to lengthy regulatory delay, it does not follow that every provision within section 156 is "remedial." In section 156(d)(1), Congress provided a 60-day window within which a patentee can file its PTE application. No provision for extension of the time period is included. By creating such a non-extendable period, Congress provided a date-certain by which all players would know their future rights. Lastly, interpreting section 156(d)(1) "is purely a case of statutory interpretation, so the equitable considerations" are inappropriate. *Unimed*, 888 F.2d at 829.

VIII. MDCO's Situation is Not a Result of USPTO's "Calendar Day" Construction

At its core, MDCO's situation appears to turn on its failure to correctly docket the due date for filing the patent term extension application with the USPTO. That is, instead of

correctly docketing the 60-day filing window deadline as February 12, 2001 — 60 days from December 15, 2000, MDCO seemingly docketed the deadline as February 15, 2001 — 2 months from December 15, 2000. Because 60 days is not the same as two months in all instances due to the varying number of days in a month, MDCO's docketing mistake lead to its missed deadline. Dr. Clive Meanwell, Chairman and CEO of MDCO, admitted before Congress that MDCO's situation is the product of "human error" and not the USPTO long's standing "calendar day" definition of "date" in section 156(d)(1):

> The FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000 . . . . But then *human error intervened.* The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. *Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, but one day late for the actual 60-day deadline.*

A Bill to Amend Title 35, U.S. Code, To Conform Certain Filing Provisions Within the Patent and Trademark Office: Hearing on H.R. 5120 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. On the Judiciary, 109th Cong. 11 (2006) (emphases added). Dr. Meanwell made this admission under oath, not in a litigation-induced setting. And who better to know exactly why MDCO filed its PTE application on February 14, 2001, than the head of its company.

Furthermore, MDCO has made numerous attempts to secure legislation to remedy its situation rather than bring timely suit against the USPTO or the FDA. Specifically, the USPTO issued a final agency decision on April 26, 2007. MDCO could have brought suit immediately thereafter. But it did not do so. Instead, it spent at least the past three years lobbying Congress for a legislative fix to its problem. *See, e.g.*, S. 1785, 109th Cong.; H.R. 1178, 110th Cong.; S. 1145, 110th Cong.; H.R. 6344, 110th Cong. Thus, it was MDCO's choice to place itself on the courthouse steps on the eve of its patent expiration. Just as MDCO waited until the very last minute to file its PTE application, and then some, it likewise waited to the very last minute to seek redress of the USPTO's adverse patent term extension decision. MDCO's dire situation is therefore exclusively of its own making.

Finally, a PTE application is a relatively short filing. The statute requires only certain minimal items of information. *See* 35 U.S.C. § 156 (d)(1)(A)-(E). Consequently, it is not as if a patent owner needs a full 60-days to assemble all of the necessary information and/or prepare the application. In fact, all the information that MDCO needed, except for its FDA approval, was available well before December 15, 2000. And on December 15, 2000, MDCO received the missing FDA approval. Thus, MDCO was equipped on December 16, 2000, to file its PTE application. An applicant for PTE gains no advantage, nor does it receive any additional restored term, by waiting to the last minute to file its PTE.

IX. MDCO's Patent Term Extension Application Was Filed Two Days Late

As explained earlier, the trigger date for the 60-day filing window of section 156(d)(1) is the date stamped on the face of the FDA approval letter, here, December 15, 2000. MDCO has repeatedly acknowledged to various governmental bodies as well as the public that the date of FDA approval of its drug was December 15, 2000:

- In its patent term extension application to the USPTO, Applicant stated three times that the FDA approved its drug on December 15, 2000. For example, it stated: "The date on which the NDA was approved was 15 December 2000." PTE Application at 4.

- In testimony before Congress as part of its lobbying efforts for a legislative resolution to its untimely filing PTE application filing, Dr. Clive Meanwell, Chairman and CEO of MDCO, stated that "[t]he FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000." 2006 Legislation.

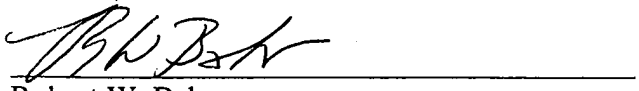
- In its filing to the Security and Exchange Commission, Applicant stated that "[i]n December 2000, the U.S. Food and Drug Administration (FDA) approved Angiomax(R) (bivalirudin), the Company's lead product, for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA)." SEC Statement at 84.

- In its Annual Report for 2000 to its shareholders and the public, Applicant notified stated that "[o]n December 15, 2000, the Company received FDA approval for Angiomax." Annual Report at 25-26.

With December 15, 2000, as the start of the 60-day filing window of section 156(d)(1), Applicant's patent term extension filing on February 14, 2001, was 2 days late. Thus, MDCO does not qualify for a patent term extension under section 156. Therefore, the application for extension of the patent term of U.S. Patent No. 5,196,404 under section 156 is **DENIED**. **THIS IS A FINAL AGENCY DECISION.**

Further correspondence with respect to this matter should be addressed as follows:

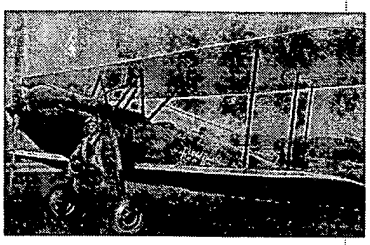
By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

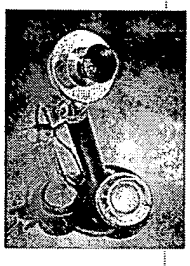


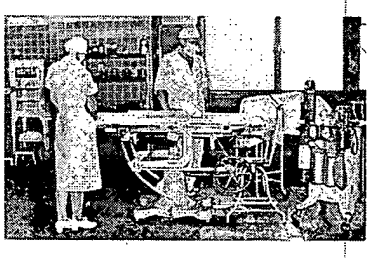
Robert W. Bahr
Acting Associate Commissioner
for Patent Examination Policy

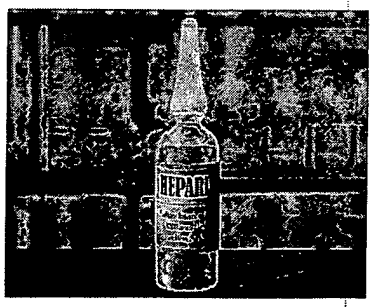
Attachment 1

THE **MEDICINES** COMPANY









ANNUAL REPORT 2000

Best Available Copy

THE **MEDICINES** COMPANY

Company Profile

Our strategy is to build a biopharmaceutical business focused on selected franchises such as acute hospital care where we can deliver differentiated products with economic advantages to hospital decision makers.

We seek to acquire products in late stages of clinical development and invest in further product development and commercialization. We aim to minimize our fixed costs by partnering with highly proficient contract organizations and seek to maximize value creation through strategic brand management led by our experienced in-house project teams.

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6 Economics of Angiomax

8 Developing Additional Angiomax Applications

10 Strategy for Growth

THE MEDICINES COMPANY'S

MILESTONES 2000

August 2000:

We completed our initial public offering (IPO) in which we raised $101.4 million by selling 6.9 million shares of Common Stock, including the underwriters' over-allotment option, at $16.00 per share.

September 2000:

We initiated with NIH a double-blind randomized placebo-controlled Phase 2 trial of our second product, CTV-05, as an adjunct to standard antibiotic treatment of bacterial vaginosis (BV). CTV-05 is a proprietary biotherapeutic agent with a potentially broad range of applications in the treatment of gynecological and reproductive infections.

November 2000:

We initiated the REPLACE trial program—a large randomized Phase 3b trial comparing Angiomax (bivalirudin), our lead product, to heparin in patients undergoing percutaneous coronary intervention including intravenous GP IIb/IIIa inhibitors. We have since completed enrollment of the first part of the trial and will soon begin the second part.

We began a Phase 2 trial of Angiomax in patients undergoing coronary artery bypass graft surgery (CABG) without the use of a bypass pump.

December 2000:

We gained marketing approval from the U.S. Food and Drug Administration, or FDA, for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty.

We signed a commercialization agreement with Innovex Inc. to provide us with a sales force, sales territory management systems and operational support for the launch of Angiomax.

January 2001:

We began selling Angiomax in cardiac catheterization laboratories in the United States targeting approximately 700 hospitals where about 95% of the angioplasty procedures are performed.

Dear Fellow Shareholders:

A Strategic Acquired Product Commercialized

During 2000 we transformed The Medicines Company from a private company focused on product development to a public commercial enterprise. In August, we raised $101.4 million by selling 6.9 million shares of Common Stock, including the underwriters' over-allotment option, at $16.00 per share. In December 2000 we gained marketing approval for Angiomax (bivalirudin), our lead product, for use in patients with unstable angina undergoing coronary angioplasty.

Having achieved these significant milestones, we recruited experienced and dynamic commercial leadership and assembled a quality 65-person field sales organization dedicated solely to selling Angiomax in the United States. With extensive direct hospital selling and national account experience, the marketing and sales team will target both hospital decision-makers and group purchasing organizations.

The features and benefits of Angiomax present our customers with an exciting medical and economic opportunity. We believe that this opportunity will translate into better care for patients and more efficient management of cardiac catheterization laboratory businesses.

The FDA's approval of Angiomax was based on data from a broad group of patients undergoing angioplasty with new onset severe angina, accelerating angina, angina at rest, including both patients with pain within the month prior to study entry and those with recurrent angina developing within two weeks after a heart attack.

Angiomax treatment is associated with fewer ischemic and bleeding complications than heparin providing the basis for better patient care and improved hospital economics. Given the clinical features and benefits of Angiomax and its economic advantages, we believe that it has the potential to replace heparin as the foundation anticoagulant in angioplasty.

To support the commercialization of Angiomax, we have initiated educational programs including symposia at major medical conferences, a far-reaching speaker training program for physicians, nurses and pharmacists and a series of peer-reviewed and sponsored publications designed to highlight the medical and economic value of Angiomax. We are grateful for the support of some of the world's leading academic institutions in helping to implement these programs.

We began the REPLACE clinical trial program as an initiative to enable professionals in the cardiac catheterization laboratory to learn how to integrate Angiomax into their own practices. In addition, this program will generate additional

clinical information for Angiomax used with and without GP IIb/IIIa platelet inhibitors and stents. From its initiation in late 2000, REPLACE has progressed very quickly with enrollment of part one completed in February 2001. We expect to begin part two in the near future.

Beyond angioplasty we are also developing Angiomax for use in the treatment of arterial thrombosis. To date clinical investigators have administered Angiomax to over 16,000 patients with a series of trials underway. The 17,000 patient Phase 3 trial in heart attack patients called HERO-2 is nearing completion. We have a Phase 3 program studying Angiomax in angioplasty patients who experience allergic reactions to heparin. In November 2000 we began a Phase 2 program studying Angiomax in patients undergoing CABG without the use of a bypass pump. We have plans to commence a Phase 3 program to evaluate the use of Angiomax in patients with unstable angina.

Our development objective is to expand the use of Angiomax so that it can become the leading replacement for heparin in acute hospital care—a substantial commercial opportunity. Heparin is used to treat at least five million hospitalized patients per year in the United States. We believe the medical opportunity is compelling; patients who are treated with heparin are at risk for excessive bleeding, thrombosis and allergic reactions. In addition, the dosing and therapeutic response to heparin are difficult to predict. Although heparin was discovered in 1906 and has been on the market for more than 50 years, the manufacturing method of this animal derived substance has changed little during that time and batch-to-batch variability in biological activity is typical. We, and many experts in the field, believe that it is time to move intravenous anti-thrombin treatment into the 21st century.

We plan for Angiomax to become the cornerstone of the hospital care franchise we plan to build. We intend to build this franchise through acquisitions and commercialization of additional hospital products that meet our investment criteria while utilizing our core strengths in hospital selling and product development.

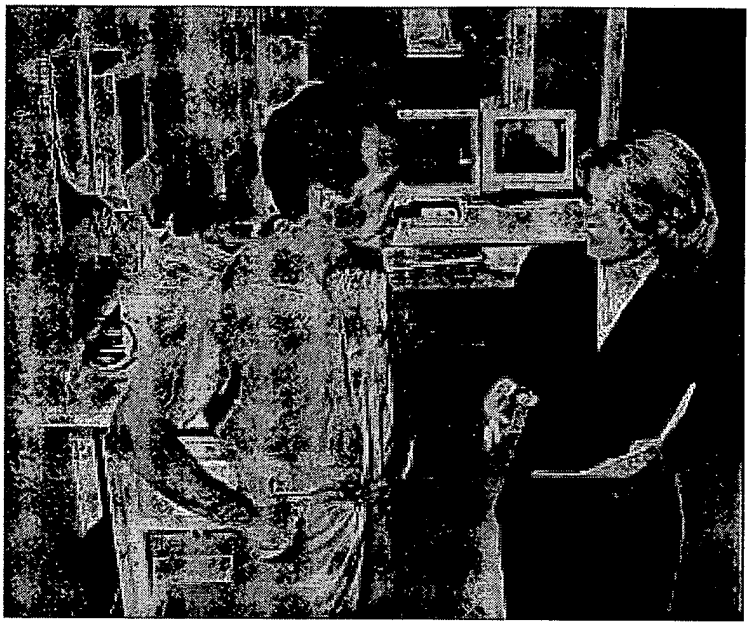
In January 2000 we announced the acquisition of CTV-05 a strain of *lactobacillus* found in humans with a potential range of applications in the areas of urogenital and reproductive health. With the National Institutes of Health, we began a large, randomized clinical trial of CTV-05 as an adjunct to standard antibiotic treatment of bacterial vaginosis (BV).

The Medicines Company enters 2001 as a commercial enterprise providing an exciting new standard of care for patients undergoing angioplasty. We are committed to making Angiomax a market leader in angioplasty, expanding the uses of Angiomax in hospital care and building a valuable pharmaceutical business.

Sincerely,

Clive Meanwell, M.D., Ph.D.
President, Chief Executive Officer and Director

Angiomax
Commercialization



Douglas Losordo, M.D., St. Elizabeth's Hospital and Carrie Beal, R.N., Regional Account Specialist, The Medicines Company

Angioplasty Market

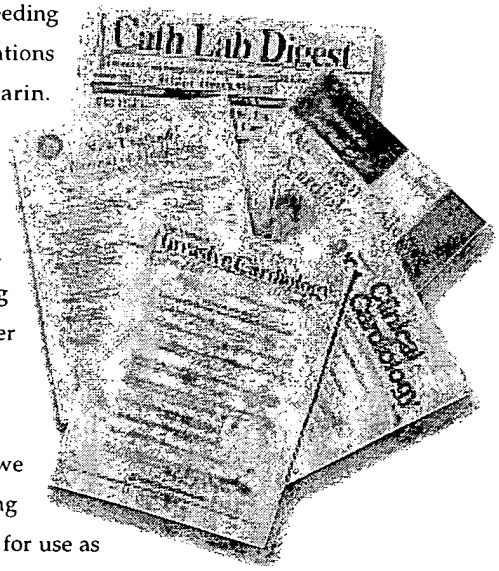
There are approximately 686,000 inpatient coronary angioplasty procedures a year in the United States. Coronary angioplasty is a procedure used to restore normal blood flow in an obstructed artery in the heart. Heparin is used in the vast majority of angioplasty patients in the United States and has long been considered the foundation anticoagulant for coronary angioplasty, although it is associated with significant clinical limitations.

Heparin Clinical Limitations

Because it is an indirect thrombin inhibitor, heparin is ineffective on thrombin when clots have formed. Patients who receive heparin have a high incidence of bleeding. The anticoagulant effect of a given dose of heparin is unpredictable and therefore requires close monitoring. Heparin can cause dangerous immunological reactions and can be problematic in patients with impaired kidney or liver function.

Angiomax Potential Advantages

The Clinical data has demonstrated the effectiveness and safety of Angiomax compared to heparin. Angiomax, as a direct thrombin inhibitor, is equally effective on thrombin in the clot as well as on thrombin circulating in the blood. As a reversible thrombin inhibitor, Angiomax has demonstrated consistent clinically meaningful reductions in bleeding and ischemic complications as compared to heparin. Angiomax is a synthetic peptide that provides predictable levels of anticoagulation in all patients, including those with impaired liver or kidney function.



FDA Approval

In December 2000, we received FDA marketing approval for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. The approval of Angiomax was based primarily on data from double-blinded clinical trials in 4,312 patients undergoing coronary angioplasty for new onset angina, accelerating episodes of angina or angina at rest. In clinical trials in angioplasty compared

"We believe Angiomax will become the leading replacement for heparin in acute cardiovascular care."

Paul Puccioni
Senior Director, Commercial and Clinical Development

"With our years of experience in hospital marketing and sales, we are well positioned to launch Angiomax in the US anticoagulant market."

Thomas Quinn
Vice President, Sales and Marketing

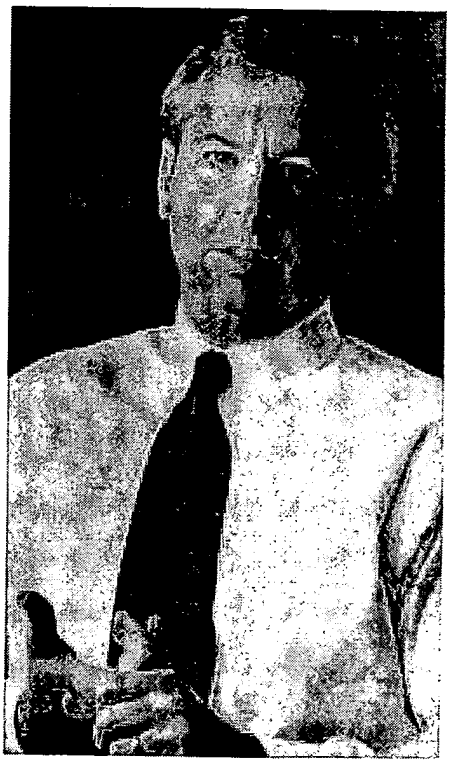
to heparin, Angiomax showed a 22% reduction in the risk of death, heart attack or the need for emergency coronary procedures. In addition, Angiomax reduced the likelihood of major bleeding by 62%. We began selling Angiomax in the United States in January 2001.

Sales Force

We have a 65 person sales effort with years of direct selling and national account experience dedicated solely to selling Angiomax. Our sales force, with an average of four and a half years of selling experience, is targeting approximately 700 hospitals. These targeted hospitals perform the vast majority of angioplasty procedures in the United States. We have signed a commercialization agreement with Innovex Inc. to provide us with 52 members of our sales effort dedicated exclusively to selling Angiomax. The Innovex agreement also provides us with sales territory management systems and operational support in the field. We are working actively with a number of major group purchasing organizations to establish contracts.

REPLACE

To support the launch of Angiomax in angioplasty, we initiated the REPLACE clinical trial program. This two-part trial will examine the use of Angiomax versus heparin with and without a GP IIb/IIIa platelet inhibitor. In February 2001 we completed enrollment in part one of the REPLACE program and expect to begin part two of the trial in the near future.



Medical Education

To support the launch we initiated a medical education program including a series of publications and educational symposia. In addition to the publications to date, there are numerous manuscripts regarding Angiomax either in press or in scientific review. To educate the physicians, nurses and pharmacists, we have an Angiomax speaker training program that will develop more than 600 physician, pharmacist and nurse speakers to facilitate the appropriate cost-effective use of Angiomax.

With our experienced sales and marketing team and the product attributes of Angiomax, we believe that Angiomax will become the foundation anticoagulant replacing heparin in angioplasty patients.

Economics of Angiomax

"We believe Angiomax will enable hospitals to provide better patient care while improving the economics of the hospital."

Stephanie Plent, M.D.
Senior Director, Medical Policy and Economics

Angioplasty Costs

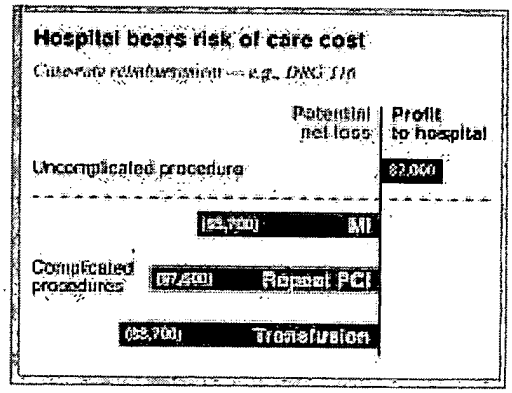
Coronary angioplasty has been performed for approximately twenty years. Over time, the procedure has improved with the introduction of new drugs, including fibrinolytics and platelet inhibitors and new devices, such as stents. As these new items are added to the procedure, the associated cost has increased significantly.

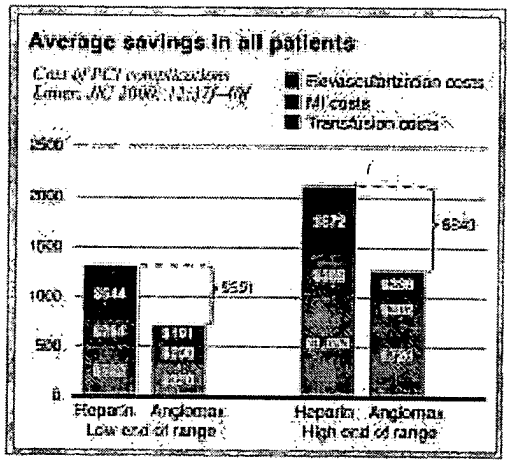
Angioplasty Reimbursement

The majority of hospitals are reimbursed according to contract rates that pay a fixed amount for each coronary angioplasty regardless of the costs incurred by the hospital. This is true for all Medicare cases (the Diagnosis Related Group prospective payment system) and most commercial insurance arrangements. In this payment environment, hospitals are at risk of losing money when clinical complications occur and costs exceed the fixed reimbursement. In 1999 the average hospital reimbursement for an uncomplicated angioplasty procedure with a stent was approximately $11,500. The average cost to a hospital of performing an uncomplicated angioplasty procedure is approximately $9,500. As a result, an uncomplicated angioplasty procedure may result in an average $2,000 per case profit for the hospital.

Cost of Clinical Complications

When complications arise, the hospital could lose money. On average a hospital incurs an additional $7,700 cost to treat a patient who has a heart attack, an additional $9,600 cost for a patient undergoing a repeat coronary angioplasty, an additional $20,800 cost for a patient requiring CABG and an additional $10,700 cost for managing a patient who requires a blood transfusion. While the hospital will receive greater reimbursement for a CABG, there will be no additional reimbursement for a patient who experiences a heart attack, repeat angioplasty or blood transfusion as a complication. Therefore the associated





costs may result in an average net loss for the hospital of $5,700 for a heart attack, $7,600 for a repeat coronary angioplasty procedure and $8,700 for a blood transfusion. Several studies have shown the community transfusion rate for angioplasty cases is approximately 5% making bleeding the most frequent and costly complication of angioplasty.

Economics of Heparin

Even as techniques, drug treatments and devices have improved, heparin has remained the foundation anticoagulant in angioplasty. Heparin, a generic drug with numerous manufacturers, has a low acquisition cost. However, due to its associated adverse events and bleeding complications, using heparin can result in significant hospital costs.

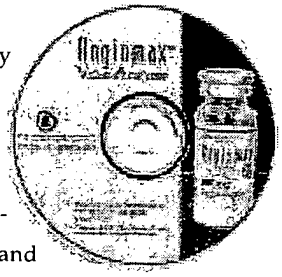
Angiomax Economic Advantage

Angiomax has been shown in clinical trials to decrease both ischemic and bleeding complications. Fewer complications during coronary angioplasty procedures translate into cost avoidance for the hospital and therefore overall cost savings.

If published complications costs were applied to the improvement in complication rates seen with Angiomax in the pivotal trials, Angiomax use would result in reduction of overall hospital costs. The reduction in costs would range from $591 to $843 per patient.

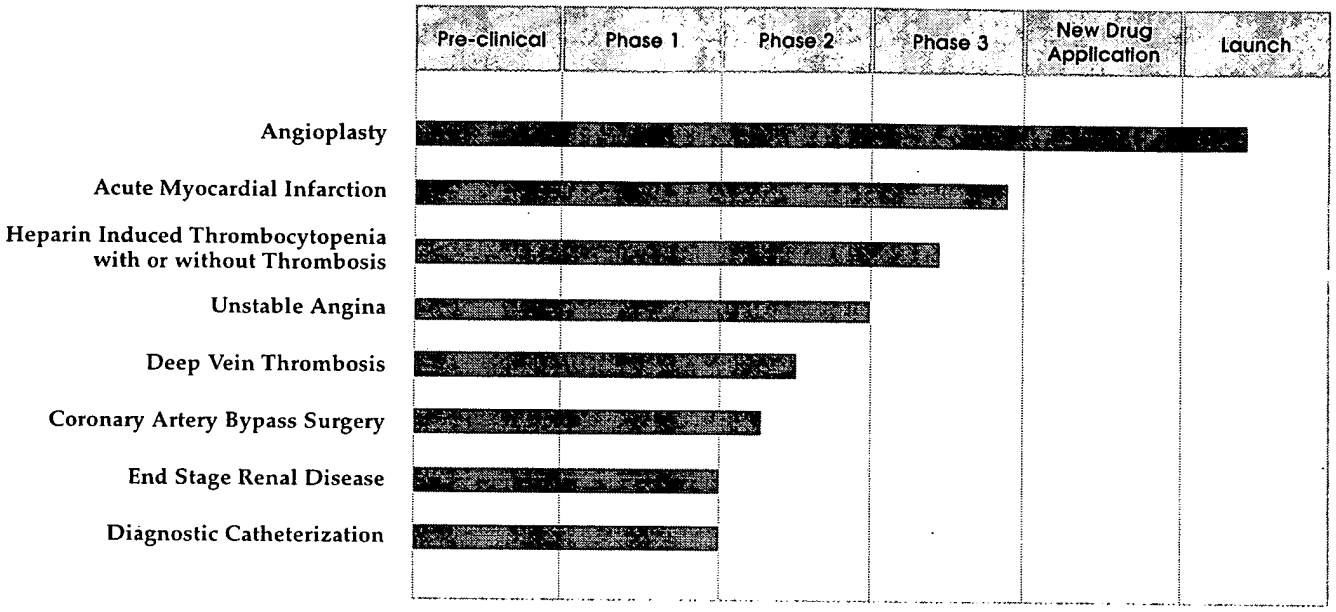
Helping Hospitals Understand Value

To enable hospitals to evaluate the potential economic impact of using Angiomax compared to heparin during angioplasty, we have created the Angiomax Value Analyzer (AVA). The AVA, a software analytical tool, helps hospitals analyze the cost of ischemic and bleeding complications. The AVA allows a hospital to customize the analysis to its particular practice pattern, complication rates and cost experience.



The AVA tool is one of many tools by which our sales and national account team can work with our customers to provide solutions to their clinical and economic problems and help them make valuable improvements in the hospital care of patients.

Developing Additional Applications for Angiomax



Angiomax Vision

We believe that Angiomax will become the leading replacement for heparin in hospital care. In the United States, heparin is the most widely used acute care anticoagulant and is used to treat approximately five million hospitalized patients per year. We have development programs designed to expand the applications of Angiomax for use in the treatment of ischemic heart disease.

Angiomax Development Strategy

Our objectives in developing Angiomax are to establish the basis of clinical and economic value for Angiomax in the marketplace and to obtain regulatory approval in each of three settings in the hospital: in the cardiac catheterization laboratory, in the emergency room and in the operating room. Angiomax has consistently demonstrated reduced ischemia and bleeding when compared to heparin. Given this profile we believe that Angiomax provides a broad clinical and commercial opportunity in the hospital treatment of patients with ischemic heart disease.

Cardiac Catheterization Laboratory

Angiomax development programs to date have provided clinical experience in the use of Angiomax in over 12,000 angioplasty patients. This includes clinical data from the pivotal Phase 3 trials in angioplasty that demonstrated a reduction

Christina Correla
Senior Director, Product Development

Sonia Barton Loar
Pharm. D., Senior Director, Regulatory Affairs

in ischemic complications and bleeding complications for Angiomax patients in comparison to heparin patients. The Phase 2 CACHET trials studying Angiomax plus provisional ReoPro (abciximab) versus heparin with ReoPro in angioplasty patients showed a significant reduction in ischemic and bleeding complications for the Angiomax patients.

In November 2000 we initiated the REPLACE program, a Phase 3b clinical trial program in angioplasty. This two-part trial will examine the use of Angiomax with and without a GP IIb/IIIa platelet inhibitor. In February 2001 we completed enrollment in part one of the REPLACE program and expect to begin the second part of the trial in the near future.

We have an ongoing Phase 3 trial program studying the use of Angiomax for the treatment of patients undergoing angioplasty who have in the past experienced reduced platelet count and clotting due to an allergic reaction to heparin (HIT/HITTS).

Emergency Room

In the United States there are approximately 870,000 heart attack and 950,000 unstable angina patients who were treated in a hospital in 1997.

Angiomax has been studied in three Phase 2 trials in heart attack patients treated with aspirin and fibrinolytics. In these studies the use of Angiomax resulted in normal blood flow in 34% more patients than heparin and resulted in substantially less bleeding. In Phase 2 studies in unstable angina patients, Angiomax showed a reduction in death and heart attack rates in comparison to placebo doses of anticoagulant.

HERO-2, our Phase 3 trial program studying the use of Angiomax for the treatment of patients who have suffered a heart attack, is nearing completion. Heart attack patients in this study are randomized to Angiomax or heparin prior to treatment with a fibrinolytic. At present we have recruited over 16,000 of the planned 17,000 patients into the HERO-2 trial. We are also actively planning for a Phase 3 program in patients with acute coronary syndromes.

Operating Room

Heparin is used extensively in the operating room in cardiac surgery, vascular surgery and orthopedic surgery and a variety of other operations. Angiomax has been studied as an anticoagulant in a Phase 1 program in coronary artery bypass graft surgery and a Phase 2 program in patients undergoing orthopedic surgical procedures.

In November 2000 we initiated a 100 patient Phase 2 trial of Angiomax in patients undergoing coronary artery bypass graft surgery without the use of a bypass pump.

STRATEGY FOR GROWTH

Strategic Objectives

We plan to continue to acquire, develop and commercialize late-stage product candidates or approved products that make a clinical difference in critical care medicine. Our strategy is to acquire late-stage development product candidates with an anticipated time to market of four years or less and existing clinical data which provides reasonable evidence of safety and efficacy. In addition we aim to acquire approved products that can be marketed by our commercial organization.

Andrew Sternlicht, M.D.
Senior Director, Business Development
Board Certified Anesthesiologist and Critical Care Specialist

We believe the changes underway in the pharmaceutical and biotechnology industries will continue to result in the availability of high quality products or product candidates with attractive investment characteristics. We continually assess potential product acquisitions to determine whether they meet the investment requirements we have established.

Hospital Care Franchise

With our team's operational experience in hospital marketing and sales, we plan to build a hospital care franchise in which Angiomax will be the cornerstone product. To expand the applications of Angiomax in the hospital, we have clinical trial programs examining the use of Angiomax in angioplasty patients, in heart attack patients, in patients undergoing angioplasty who experience reduced platelet count and clotting due to an allergic reaction to heparin and in patients undergoing coronary artery bypass graft surgery without the use of a bypass pump. In addition, we are actively considering potential product candidates that can be effectively sold by our hospital field force.

Specialty Anti-Infective Franchise

We are also focused on specialty anti-infectives. We are developing a product, CTV-05, a proprietary biotherapeutic agent with a broad range of potential applications in the treatment of gynecological and reproductive infections. CTV-05 is currently being studied in a double-blind, placebo-controlled Phase 2 trial supported by NIH, examining the safety and effectiveness of the compound as an adjunct to antibiotic therapy in the treatment of bacterial vaginosis.

SELECTED CONSOLIDATED FINANCIAL DATA

In the table below, we provide you with our selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the period July 31, 1996 (date of inception) to December 31, 1996 and for the years ended December 31, 1997, 1998, 1999 and 2000. The pro forma net loss per share data reflects the conversion of our convertible notes, and accrued interest, and the conversion of our outstanding convertible preferred stock, and accrued dividends, into common stock upon the closing of our initial public offering in August 2000. The pro forma net loss per share data does not include the effect of any options or warrants outstanding. For further discussion of earnings per share, please see note 8 to the consolidated financial statements.

	Period from Inception (July 31, 1996) Through December 31, 1996	Year Ended December 31, 1997	1998	1999	2000
	In thousands, except share and per share data				
Statements of Operations Data					
Operating expenses					
Research and development	$ 827	$ 16,044	$ 24,005	$ 30,345	**$ 39,572**
Selling, general and administrative	702	2,421	6,248	5,008	**15,034**
Total operating expenses	1,529	18,465	30,253	35,353	**54,606**
Loss from operations	(1,529)	(18,465)	(30,253)	(35,353)	**(54,606)**
Interest income (expense), net	62	659	1,302	640	**(16,686)**
Net loss	(1,467)	(17,806)	(28,951)	(34,713)	**(71,292)**
Dividends and accretion to redemption value of redeemable convertible preferred stock	(118)	(2,018)	(3,959)	(5,893)	**(30,343)**
Net loss attributable to common stockholders	$ (1,585)	$ (19,824)	$ (32,910)	$ (40,606)	**$ (101,635)**
Net loss attributable to common stockholders per common share, basic and diluted	$ (2.85)	$ (4.06)	$ (6.03)	$ (80.08)	**$ (8.43)**
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	557,178	4,887,230	5,454,653	507,065	**12,059,275**
Unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted				$ (1.94)	**$ (2.10)**
Shares used in computing unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted				17,799,876	**24,719,075**

	As of December 31, 1996	1997	1998	1999	2000
	In thousands				
Balance Sheet Data					
Cash, cash equivalents, marketable securities and accrued interest receivable	$ 3,421	$ 25,416	$ 29,086	$ 7,238	**$ 80,718**
Working capital (deficit)	3,174	18,779	24,570	(4,103)	**68,023**
Total assets	3,473	25,595	29,831	7,991	**84,363**
Convertible notes	—	—	—	5,776	**—**
Redeemable convertible preferred stock	4,793	40,306	79,384	85,277	**—**
Deficit accumulated during the development stage	(1,585)	(21,409)	(54,319)	(94,925)	**(196,560)**
Total stockholders' (deficit) equity	(1,582)	(21,387)	(54,266)	(94,558)	**69,239**

Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We acquire, develop and commercialize biopharmaceutical products that are in late stages of development or have been approved for marketing. In December 2000, we received marketing approval from the FDA for Angiomax, our lead product, for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. Coronary angioplasty is a procedure used to restore normal blood flow in an obstructed artery in the heart. We began selling Angiomax in the United States in January 2001. In August and September 2000, we consummated our initial public offering resulting in $101.4 million in net proceeds.

Since our inception, we have incurred significant losses and, as of December 31, 2000, had a deficit accumulated during the development stage of $196.6 million. Most of our expenditures to date have been for research and development activities, selling, general and administrative expenses and interest expense. Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. We generally outsource our clinical and manufacturing development activities to independent organizations to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with initial product marketing activities. Interest expense consists of costs associated with convertible notes which were issued to fund our business activities.

We expect to continue to incur operating losses for the foreseeable future as a result of research and development activities attributable to new and existing products and costs associated with the commercialization and launch of our products. In 2001, we expect increased cash outlays for research and development costs associated with our ongoing clinical trials and manufacturing development activities. We also expect increased outlays during 2001 for sales, general and administrative costs related to the commercial launch in the United States of Angiomax. We will need to generate significant revenues to achieve and maintain profitability. Through December 31, 2000, we have had no revenues from any product sales, and we have not achieved profitability on a quarterly or annual basis.

In March 1997, we acquired exclusive worldwide commercial rights from Biogen, Inc. to the technology, patents, trademarks, inventories, know-how and all regulatory and clinical information related to Angiomax. Under the Biogen license, we paid $2.0 million upon execution of the license agreement and are obligated to pay up to an additional $8.0 million upon reaching certain Angiomax sales milestones, including the first sale of Angiomax for certain indications. In addition, we will pay royalties on future sales of Angiomax and on any sublicense royalties earned.

In August 1999, we acquired exclusive worldwide rights from GyneLogix, Inc. to the patents and know-how related to the biotherapeutic agent CTV-05. Under the GyneLogix license, we have paid $400,000 and are obligated to pay up to an additional $100,000 upon reaching certain development and regulatory milestones and to fund agreed-upon operational costs of GyneLogix related to the development of CTV-05 on a monthly basis subject to a limitation of $50,000 per month. In addition, we will pay royalties on future sales of CTV-05 and on any sublicense royalties earned.

In July 1998, we acquired from Immunotech S.A., a wholly-owned subsidiary of Beckman Coulter, Inc., exclusive worldwide rights to IS-159, which is under clinical investigation for the treatment of acute migraine headache. Under the Immunotech license, we paid $1.0 million upon execution of the license agreement and are obligated to pay up to an additional $4.5 million upon reaching certain development and regulatory milestones. In addition, we will pay royalties on future sales of IS-159 and on any sublicense royalties earned. We are seeking a collaborator to develop IS-159 and do not intend to initiate further studies of IS-159 until we enter into a collaborative agreement.

During the year ended December 31, 2000, we recorded deferred stock compensation on the grant of stock options of approximately $17.3 million, representing the difference between the exercise price of such options and the fair market value of our common stock at the date of grant of such options. The exercise prices of these options were below the estimated fair market value of our common stock as of the date of grant based on the estimated initial public offering price of our common stock.

We amortize deferred stock compensation over the respective vesting periods of the individual stock options. We recorded amortization expense for deferred compensation of approximately $3.7 million for the year ended December 31, 2000. We expect to record an amortization expense for deferred compensation as follows, reduced, where applicable, for employee terminations: approximately $4.2 million for 2001, approximately $3.9 million for 2002, approximately $3.9 million for 2003 and approximately $1.4 million for 2004.

In May 2000, we sold shares of series IV convertible preferred stock. These shares contained a beneficial conversion feature based on the estimated fair market value as of the date of such sale of the common stock into which such shares were convertible. The total amount of such beneficial conversion

was approximately $25.5 million and has been reflected as a dividend in the period of issuance, the second quarter of 2000. In the year ended December 31, 2000, we also recorded approximately $19.4 million as interest expense, including the discount on our convertible notes issued in October 1999 and March 2000.

Through December 31, 2000, we had not generated taxable income. At December 31, 2000, net operating losses available to offset future taxable income for federal income tax purposes were approximately $122.2 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2011 and ending 2020. We have not recognized the potential tax benefit of our net operating losses in our statements of operations. The future utilization of our net operating loss carryforwards may be limited pursuant to regulations promulgated under the Internal Revenue Code of 1986, as amended.

Results of Operations

Years Ended December 31, 2000 and 1999

Research and Development Expenses. Research and development expenses increased 30% from $30.3 million in 1999 to $39.6 million in 2000. The increase of $9.3 million was primarily due to the increased enrollment rate of our Phase 3 clinical trial in AMI, called HERO-2 during 2000, initiation in 2000 of a Phase 3b trial in angioplasty called REPLACE and by the recognition of $12.2 million of research and development costs in connection with the completion of UCB Bioproduct's manufacture of Angiomax bulk drug substance prior to FDA approval. The increase in costs was partly offset by reduced development expenses reflecting our termination of the semi-log manufacturing development program with Lonza AG in the fourth quarter of 1999 and a reduction in development activity for IS-159 in 2000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased 200% from $5.0 million in 1999 to $15.0 million in 2000. The increase of $10.0 million was primarily due to an increase in marketing and selling expenses and corporate infrastructure costs arising from an increase in activity in preparation for the commercial launch of Angiomax.

Interest Income and Interest Expense. Interest income increased 223% from $838,000 in 1999 to $2.7 million in 2000. The increase of $1.9 million was primarily due to interest income arising from investment of the proceeds of our initial public offering.

Interest expense was $19.4 million in 2000 and was related to interest charges and the amortization of the discount on our convertible notes issued in October 1999 and March 2000. The notes were converted into series IV convertible preferred stock in May 2000, accelerating the remaining unamortized discount.

Years Ended December 31, 1999 and 1998

Research and Development Expenses. Research and development expenses increased 26% from $24.0 million in 1998 to $30.3 million in 1999. The increase of $6.3 million was due to the expansion in 1999 of our clinical development programs, primarily those relating to our Angiomax HERO-2 Phase 3 clinical trial in AMI which commenced in late 1998, our IS-159 development program and our Angiomax trials in angioplasty.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased 20% from $6.2 million in 1998 to $5.0 million in 1999. The decrease of $1.2 million was primarily due to a decrease in Angiomax-related marketing expenses.

Interest Income and Interest Expense. Interest income decreased 36% from $1.3 million in 1998 to $838,000 in 1999 due to a lower level of cash and marketable securities available for investment during 1999 as compared to 1998. Interest expense was $197,000 in 1999 and related to interest expense and amortization of the discount on our convertible notes issued in the aggregate principal amount of $6.0 million in October 1999.

Liquidity and Capital Resources

In August and September 2000, we received $101.4 million in net proceeds from the sale of an aggregate of 6,900,000 shares of common stock in our initial public offering at a price of $16.00 per share. Prior to our initial public offering, we had financed our operations primarily through the private placement of equity, convertible debt securities and warrants. Until our initial public offering, we had received net proceeds of $79.4 million from the private placement of equity securities, primarily redeemable convertible preferred stock, and $19.4 million from the issuance of convertible notes and warrants.

As of December 31, 2000, we had $79.3 million in cash, cash equivalents and marketable securities, as compared to $7.2 million and $28.3 million as of December 31, 1999 and 1998, respectively.

During 2000, we used net cash of $48.1 million in operating activities. This consisted of a net loss for the period of $71.3 million, combined with a decrease in accounts payable of $1.8 million, an increase in inventory of $2.0 million and an increase in accrued interest receivable of $1.3 million, partly offset by an increase in accrued expenses of $5.7 million, non-cash amortization of discount on convertible notes of $19.0

million and deferred compensation of $3.7 million. We spent $42.8 million for investing activities, which consisted principally of purchases of marketable securities with net proceeds from our initial public offering. We received $121.1 million from financing activities, primarily from our initial public offering, which resulted in net proceeds of $101.4 million, and from the issuance of convertible notes and preferred stock, which resulted in proceeds of $19.4 million during 2000.

During 1999, we placed an order with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Manufacture of $14.2 million of this material was completed in 2000, of which $12.2 million was expensed during that period. All costs associated with the manufacture of Angiomax bulk drug product and finished products to which title has transferred to us prior to the date of FDA approval of Angiomax were expensed as research and development. We recorded Angiomax bulk drug product to which we took title after the date of FDA approval of Angiomax as inventory, which will increase our cost of sales in 2001 and possibly the following year. In November 2000, we placed additional orders with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Under the terms of these purchase orders, we are scheduled to take title to material and become obligated to make payments totaling approximately $24.0 million in 2001 and early 2002.

As of December 31, 2000, we had net operating loss carryforwards of approximately $122.2 million to offset future federal taxable income expiring in 2011 through 2020 and approximately $116.0 million to offset future state taxable income expiring in 2001 through 2004. Due to the degree of uncertainty related to the ultimate realization of such net operating losses, no benefit has been recognized in the financial statements as of December 31, 2000. If we achieve profitability, such tax benefits would be recognized when their realization was considered more likely than not. Our ability to utilize these losses in future years, however, may be subject to limitation based upon changes in ownership under the rules of the Internal Revenue Code.

We expect to devote substantial resources to continue our research and development efforts and to expand our sales, marketing and manufacturing programs associated with the commercialization and launch of our products. Our funding requirements will depend on numerous factors, including whether Angiomax is commercially successful, the progress, level and timing of our research and development activities, the cost and outcomes of regulatory reviews, the establishment, continuation or termination of third-party manufacturing or sales and marketing arrangements, the cost and effectiveness of our sales and marketing programs, the status of competitive products, our ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

We anticipate that our existing capital resources will enable us to maintain our current operations for at least the next 12 months. If our existing resources are insufficient to satisfy our liquidity requirements, or if we acquire additional product candidates or approved products, we may be required to seek additional financing prior to that time. The sale of additional equity and debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Factors Which May Affect Future Results

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For this purpose, any statements contained in this Report that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "intends," "may" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by forward-looking statements contained in this Report and presented elsewhere by management from time to time. These factors include the risk factors set forth below.

Risks Related to Our Business

WE HAVE A HISTORY OF NET LOSSES, AND WE EXPECT TO CONTINUE TO INCUR NET LOSSES AND MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY

We are a development stage company with no revenues through December 31, 2000. We have incurred net losses since our inception, including net losses of approximately $71.3 million for the year ended December 31, 2000. As of December 31, 2000, we had an accumulated deficit of approximately $196.6 million. We expect to make substantial expenditures to further develop and commercialize our products and expect that our rate of spending will accelerate as the result of costs and expenses associated with increased clinical trials, regulatory approval and commercialization of products. As a result, we are unsure when we will become profitable, if at all.

OUR BUSINESS WILL BE VERY DEPENDENT ON THE COMMERCIAL SUCCESS OF ANGIOMAX

Other than Angiomax, our products are in clinical phases of development and, even if approved by the FDA, are a number of years away from entering the market. As a result, Angiomax will account for almost all of our revenues for the foreseeable future. The commercial success of Angiomax will depend upon its acceptance by physicians, patients and other key decision-makers as a therapeutic and cost-effective alternative to heparin and other products used in current practice. If Angiomax is not commercially successful, we will have to find additional sources of revenues or curtail or cease operations.

FAILURE TO RAISE ADDITIONAL FUNDS IN THE FUTURE MAY AFFECT THE DEVELOPMENT, MANUFACTURE AND SALE OF OUR PRODUCTS

Our operations to date have generated substantial and increasing needs for cash. Our negative cash flow from operations is expected to continue into the foreseeable future. The clinical development of Angiomax for additional indications, the development of our other product candidates and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors and may be significantly greater than we expect.

We anticipate that our existing capital resources will enable us to maintain our current operations for at least the next 12 months. If our existing resources are insufficient to satisfy our liquidity requirements, or if we acquire any additional product candidates, we may be required to seek additional financing prior to that time. We intend to seek additional funding through collaborative arrangements and private or public financings, including equity financings. Such additional funding may not be available on acceptable terms, if at all. If additional funds are not available to us, we may need to delay or significantly curtail our acquisition, development or commercialization activities.

WE CANNOT EXPAND THE INDICATIONS FOR ANGIOMAX UNLESS WE RECEIVE FDA APPROVAL FOR EACH ADDITIONAL INDICATION. FAILURE TO EXPAND THESE INDICATIONS WILL LIMIT THE SIZE OF THE COMMERCIAL MARKET FOR ANGIOMAX

We received, in December 2000, approval from the FDA of the use of Angiomax as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. One of our key objectives is to expand the indications for which the FDA will approve Angiomax. In order to do this, we will need to conduct additional clinical trials and obtain FDA approval for each proposed indication. If we are unsuccessful in expanding the approved indication for the use of Angiomax, the size of the commercial market for Angiomax will be limited.

FAILURE TO OBTAIN REGULATORY APPROVAL IN FOREIGN JURISDICTIONS WILL PREVENT US FROM MARKETING ANGIOMAX ABROAD

We intend to market our products in international markets, including Europe. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. In February 1998, we submitted a MAA to the EMEA for use in unstable angina patients undergoing angioplasty. Following extended interaction with European regulatory authorities, the CPMP of the EMEA voted in October 1999 not to recommend Angiomax for approval in angioplasty. The United Kingdom and Ireland dissented from this decision. We have withdrawn our application to the EMEA and are in active dialog with European regulators to determine our course of action including seeking approval of Angiomax in Europe on a country-by-country basis. We may not be able to obtain approval from any or all of the jurisdictions in which we seek approval to market Angiomax. Obtaining foreign approvals may require additional trials and additional expense.

THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS MAY BE TERMINATED OR DELAYED, AND THE COSTS OF DEVELOPMENT AND COMMERCIALIZATION MAY INCREASE, IF THIRD PARTIES WHO WE RELY ON TO MANUFACTURE AND SUPPORT THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS DO NOT FULFILL THEIR OBLIGATIONS

Our development and commercialization strategy entails entering into arrangements with corporate and academic collaborators, contract research organizations, contract sales organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage our clinical trials and manufacture, market and sell our products. Although we manage these services, we do not have the expertise or the resources to conduct such activities on our own and, as a result, are particularly dependent on third parties in most areas.

We may not be able to maintain our existing arrangements with respect to the commercialization of Angiomax or establish and maintain arrangements to develop and commercialize any additional products on terms that are acceptable to us. Any current or future arrangements for the development and commercialization of our products may not be successful. If we are not able to establish or maintain our agreements relating to Angiomax or any additional products on terms which we deem favorable, our financial condition would be materially adversely effected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote

to developing, manufacturing and commercializing our products may not be within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive. If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely manner, such breach, termination or failure could:

— delay the development or commercialization of Angiomax, our other product candidates or any additional product candidates that we may acquire or develop;

— require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

— result in the termination of the development or commercialization of our products.

WE ARE CURRENTLY DEPENDENT ON A SINGLE SUPPLIER FOR THE PRODUCTION OF ANGIOMAX BULK DRUG SUBSTANCE AND A DIFFERENT SINGLE SUPPLIER TO CARRY OUT ALL FILL-FINISH ACTIVITIES FOR ANGIOMAX

Currently, we obtain all of our Angiomax bulk drug substance from one manufacturer, UCB Bioproducts, and rely on another manufacturer, Ben Venue Laboratories, to carry out all fill-finish activities for Angiomax, which includes final formulation and transfer of the drug into vials where it is then freeze-dried and sealed. The FDA requires that all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's current Good Manufacturing Practice, or cGMP, regulations and guidelines. There are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing Angiomax. The FDA has inspected Ben Venue Laboratories for cGMP compliance for the manufacture of Angiomax and UCB Bioproducts for cGMP compliance in the manufacture of pharmaceutical ingredients generally. Ben Venue Laboratories and UCB Bioproducts have informed us that they have no material deficiencies in cGMP compliance. We do not currently have alternative sources for production of Angiomax bulk drug substance or to carry out fill-finish activities. In the event that either of our current manufacturers is unable to carry out its respective manufacturing obligations to our satisfaction, we may be unable to obtain alternative manufacturing, or obtain such manufacturing on commercially reasonable terms or on a timely basis.

Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Angiomax on a timely basis and supply product for clinical trials of Angiomax.

IF WE DO NOT SUCCEED IN DEVELOPING A SECOND GENERATION PROCESS FOR THE PRODUCTION OF BULK ANGIOMAX DRUG SUBSTANCE, OUR GROSS MARGINS MAY BE BELOW INDUSTRY AVERAGES

We are currently developing with UCB Bioproducts a second generation process for the production of bulk Angiomax drug substance. This process involves limited changes to the early manufacturing steps of our current process in order to improve our gross margins on the future sales of Angiomax. If we cannot develop the process successfully or regulatory approval of the process is not obtained or is delayed, then our ability to improve our gross margins on future sales of Angiomax may be limited.

CLINICAL TRIALS OF OUR PRODUCT CANDIDATES ARE EXPENSIVE AND TIME CONSUMING, AND THE RESULTS OF THESE TRIALS ARE UNCERTAIN

Before we can obtain regulatory approvals for the commercial sale of any product which we wish to develop, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product. We are currently conducting four clinical trials of Angiomax for use in the treatment of ischemic heart disease. There are numerous factors which could delay our clinical trials or prevent us from completing these trials successfully. We or the FDA may suspend a clinical trial at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient population targeted by some of our clinical trials may be small. Delays in future planned patient enrollment may result in increased costs and program delays.

In addition, clinical trials, if completed, may not show any potential product to be safe or effective. Results obtained in pre-clinical studies or early clinical trials are not always indicative of results that will be obtained in later clinical trials. Moreover, data obtained from pre-clinical studies and clinical trials may be subject to varying interpretations. As a result, the FDA or other applicable regulatory authorities may not approve a product in a timely fashion, or at all.

OUR FAILURE TO ACQUIRE AND DEVELOP ADDITIONAL PRODUCT CANDIDATES OR APPROVED PRODUCTS WILL IMPAIR OUR ABILITY TO GROW

As part of our growth strategy, we intend to acquire and develop additional pharmaceutical product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire pharmaceutical products in late-stage development or that have been approved that meet the criteria we have established. Because we do not have, nor intend to establish, internal scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us.

Identifying suitable product candidates and approved products and proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. In addition, other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

IF WE BREACH ANY OF THE AGREEMENTS UNDER WHICH WE LICENSE COMMERCIALIZATION RIGHTS TO PRODUCTS OR TECHNOLOGY FROM OTHERS, WE COULD LOSE LICENSE RIGHTS THAT ARE IMPORTANT TO OUR BUSINESS

We license commercialization rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we acquired our first three products through exclusive licensing arrangements. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. In addition, upon the termination of the license we may be required to license to the licensor the intellectual property that we developed.

OUR ABILITY TO MANAGE OUR BUSINESS EFFECTIVELY COULD BE HAMPERED IF WE ARE UNABLE TO ATTRACT AND RETAIN KEY PERSONNEL AND CONSULTANTS

The biopharmaceutical industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our chief executive officer, Dr. Clive A. Meanwell, or other key employees or consultants, our business and operating results could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in the biotechnology industry with the breadth of skills and experience required to develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

WE FACE SUBSTANTIAL COMPETITION, WHICH MAY RESULT IN OTHERS DISCOVERING, DEVELOPING OR COMMERCIALIZING COMPETING PRODUCTS BEFORE OR MORE SUCCESSFULLY THAN WE DO

The biopharmaceutical industry is highly competitive. Our success will depend on our ability to develop products and apply technology and our ability to establish and maintain a market for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources than we do. Accordingly, our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that have been competing or are being developed by us or may obtain FDA approval for products more rapidly than we are able. Technological development by others may render our products or product candidates noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

BECAUSE THE MARKET FOR THROMBIN INHIBITORS IS COMPETITIVE, OUR PRODUCT MAY NOT OBTAIN WIDESPREAD USE

We plan to position Angiomax as a replacement to heparin, which is widely-used and inexpensive, for use in patients with ischemic heart disease. Because heparin is inexpensive and has been widely used for many years, medical decision-makers may be hesitant to adopt our alternative treatment. In addition, due to the high incidence and severity of cardiovascular diseases, the market for thrombin inhibitors is large and competition is intense and growing. There are a number of thrombin inhibitors currently on the market, awaiting regulatory approval and in development, including orally administered agents.

THE LIMITED RESOURCES OF THIRD-PARTY PAYORS MAY LIMIT THE USE OF OUR PRODUCTS

In general, anticoagulant drugs may be classified in three groups: drugs that directly or indirectly target and inhibit thrombin, drugs that target and inhibit platelets and drugs that break down fibrin. Because each group of anticoagulants acts on different components of the clotting process, we believe that there will be continued clinical work to determine the best combination of drugs for clinical use. We expect Angiomax to be used with aspirin alone or in conjunction with other therapies. Although we do not plan to position Angiomax as a direct competitor to platelet inhibitors or fibrinolytic drugs, platelet inhibitors and fibrinolytic drugs may compete with Angiomax for the use of hospital financial resources. Many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. Because this amount is not based on the actual expenses the hospital incurs, U.S. hospitals may have to choose among Angiomax, platelet inhibitors and fibrinolytic drugs.

FLUCTUATIONS IN OUR OPERATING RESULTS COULD AFFECT THE PRICE OF OUR COMMON STOCK

Our operating results may vary from period to period based on the amount and timing of sales of Angiomax to customers in the United States, the availability and timely delivery of a sufficient supply of Angiomax, the timing and expenses of clinical trials, the availability and timing of third-party reimbursement and the timing of approval for our product candidates. If our operating results do not match the expectations of securities analysts and investors as a result of these and other factors, the trading price of our common stock may fluctuate.

Risks Related to Our Industry

IF WE DO NOT OBTAIN FDA APPROVALS FOR OUR PRODUCTS OR COMPLY WITH GOVERNMENT REGULATIONS, WE MAY NOT BE ABLE TO MARKET OUR PRODUCTS AND MAY BE SUBJECT TO STRINGENT PENALTIES

Except for Angiomax, which has been approved for sale in the United States and New Zealand, we do not have a product approved for sale in the United States or any foreign market. We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. We must successfully complete our clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell our products. The FDA could require us to repeat clinical trials as part of the regulatory review process. Delays in obtaining or failure to obtain regulatory approvals may:

— delay or prevent the successful commercialization of any of our product candidates;

— diminish our competitive advantage; and

— defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical data, clinical data and supporting information must be submitted to the FDA for each additional indication to obtain such approvals, and we cannot be certain when we will receive these regulatory approvals, if ever.

In addition to initial regulatory approval, our products and product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation. Any approvals, once obtained, may be withdrawn if compliance with regulatory requirements is not maintained or safety problems are identified. Failure to comply with these requirements may also subject us to stringent penalties.

WE MAY NOT BE ABLE TO OBTAIN OR MAINTAIN PATENT PROTECTION FOR OUR PRODUCTS, AND WE MAY INFRINGE THE PATENT RIGHTS OF OTHERS

The patent positions of pharmaceutical and biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

— obtain patents;

— protect trade secrets;

— operate without infringing the proprietary rights of others; and

— prevent others from infringing our proprietary rights.

We may not have any patents issued from any patent applications that we own or license. If patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States are maintained in secrecy until patents issue, others may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications. In all, we exclusively license 10 issued United States patents and a broadly filed portfolio of corresponding foreign patents and patent applications. We have not yet filed any independent patent applications.

We may not hold proprietary rights to some patents related to our product candidates. In some cases, others may own or control these patents. As a result, we may be required to obtain licenses under third-party patents to market some of our product candidates. If licenses are not available to us on acceptable terms, we will not be able to market these products.

We may become a party to patent litigation or other proceedings regarding intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. If any patent litigation or other intellectual property proceeding in which we are involved is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products and services without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms, or at all.

IF WE ARE NOT ABLE TO KEEP OUR TRADE SECRETS CONFIDENTIAL, OUR TECHNOLOGY AND INFORMATION MAY BE USED BY OTHERS TO COMPETE AGAINST US

We rely significantly upon unpatented proprietary technology, information, processes and know how. We seek to protect this information by confidentiality agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements. In addition, our competitors may learn or independently develop our trade secrets.

WE COULD BE EXPOSED TO SIGNIFICANT LIABILITY CLAIMS IF WE ARE UNABLE TO OBTAIN INSURANCE AT ACCEPTABLE COSTS AND ADEQUATE LEVELS OR OTHERWISE PROTECT OURSELVES AGAINST POTENTIAL PRODUCT LIABILITY CLAIMS

Our business exposes us to potential product liability risks which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise possess regulatory approval for commercial sale.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. We are currently covered, with respect to our commercial sales in the United States and New Zealand and our clinical trials, by primary product liability insurance in the amount of $20.0 million per occurrence and $20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover any product liability claims. As we commence commercial sales of our products, we may wish to increase our product liability insurance, and we will need to extend the coverage of our product liability insurance to cover our commercial sales of Angiomax in the United States. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We place our investments in high-quality financial instruments, primarily money market funds and corporate debt securities with maturities or auction dates of less than one year, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. At December 31, 2000, we held $79.3 million in cash, cash equivalents, and marketable securities, all due within one year, which had an average interest rate of approximately 6.5%.

We currently hold a $3.0 million principal investment in Southern California Edison 5⅞% bonds due January 15, 2001, which is accounted for in accordance with Statement of Financial Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." We classify these securities as available-for-sale and carry them at fair market value based on the quoted market price. We have exposure to market risk related to the fluctuation of the Southern California Edison bonds' price, which fluctuation has increased significantly as a result of events which occurred after December 31, 2000, including the non-payment of principal and interest on the bonds at maturity on January 15, 2001. The value of our investments in these Southern California Edison bonds was approximately $2.5 million as of March 28, 2001.

Most of our transactions are conducted in U.S. dollars. We do have certain development and commercialization agreements with vendors located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. If the applicable exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

THE MEDICINES COMPANY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	1999	2000
Assets		
Current assets:		
Cash and cash equivalents	$ 6,643,266	$ 36,802,356
Marketable securities	539,274	42,522,729
Accrued interest receivable	55,225	1,392,928
	7,237,765	80,718,013
Inventory	—	1,963,491
Prepaid expenses and other current assets	154,967	465,650
Total current assets	7,392,732	83,147,154
Fixed assets, net	430,061	965,832
Other assets	168,605	250,144
Total assets	$ 7,991,398	$ 84,363,130
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 7,815,028	$ 5,987,213
Accrued expenses	3,680,293	9,136,934
Total current liabilities	11,495,321	15,124,147
Convertible notes	5,776,319	—
Commitments and contingencies		
Redeemable Convertible Preferred Stock, $1 par value; 31,550,000 and 5,000,000 shares authorized at December 31, 1999 and 2000, respectively; shares issued and outstanding: 22,962,350 and none at December 31, 1999 and 2000, respectively; at redemption value (liquidation value of $86,167,821 and $0 at December 31, 1999 and 2000, respectively)	85,277,413	—
Stockholders' equity/(deficit):		
Common stock, $.001 par value, 36,000,000 and 75,000,000 shares authorized at December 31, 1999 and 2000, respectively; shares issued and outstanding: 833,400 and 30,320,455 at December 31, 1999 and 2000, respectively	834	30,320
Additional paid-in capital	339,144	279,126,337
Deferred stock compensation	—	(13,355,694)
Deficit accumulated during the development stage	(94,925,028)	(196,560,034)
Accumulated other comprehensive income (loss)	27,395	(1,946)
Total stockholders' equity (deficit)	(94,557,655)	69,238,983
Total liabilities and stockholders' equity (deficit)	$ 7,991,398	$ 84,363,130

See accompanying notes.

Consolidated Statements of Operations

	Year Ended December 31,			Period July 31, 1996 (Date of Inception) to December 31, 2000
	1998	1999	2000	
Operating expenses:				
Research and development	$ 24,004,606	$ 30,344,892	**$ 39,572,297**	$ 110,793,397
Selling, general and administrative	6,248,265	5,008,387	**15,033,585**	29,411,917
Total operating expenses	30,252,871	35,353,279	**54,605,882**	140,205,314
Loss from operations	(30,252,871)	(35,353,279)	**(54,605,882)**	(140,205,314)
Other income (expense):				
Interest income	1,302,073	837,839	**2,704,126**	5,593,904
Interest expense	—	(197,455)	**(19,390,414)**	(19,617,104)
Net loss	(28,950,798)	(34,712,895)	**(71,292,170)**	(154,228,514)
Dividends and accretion to redemption value of redeemable preferred stock	(3,958,903)	(5,893,016)	**(30,342,988)**	(42,331,520)
Net loss attributable to common stockholders	$(32,909,701)	$(40,605,911)	**$(101,635,158)**	$(196,560,034)
Basic and diluted net loss attributable to common stockholders per common share	$ (6.03)	$ (80.08)	**$ (8.43)**	
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share	$ —	$ (1.94)	**$ (2.10)**	
Shares used in computing net loss attributable to common stockholders per common share:				
Basic and diluted	5,454,653	507,065	**12,059,275**	
Unaudited pro forma basic and diluted	—	17,799,876	**24,719,075**	

See accompanying notes.

Consolidated Statements of Redeemable Preferred Stock and Stockholders' Equity (Deficit)

	For the Period July 31, 1996 (Date of Inception) to December 31, 2000					
	Redeemable Preferred Stock		Redeemable Convertible Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common stock				$ —	2,042,175	$ 2,042
Issuance of redeemable preferred stock	4,675	$ 4,675,000				
Accretion of preferred stock to redemption value		118,348				
Net loss						
Balance at December 31, 1996	4,675	4,793,348	—	—	2,042,175	2,042
Employee stock purchases					627,070	627
Issuance of common stock					7,186,537	7,187
Issuance of redeemable preferred stock	34,456	33,498,408				
Dividends on preferred stock	1,175	1,056,652				
Accretion of preferred stock to redemption value		957,592				
Net loss						
Currency translation adjustment						
Unrealized gain on marketable securities						
Comprehensive loss						
Balance at December 31, 1997	40,306	40,306,000	—	—	9,855,782	9,856
Employee stock purchases					34,887	35
Repurchase of common stock					(107,979)	(108)
Exchange of redeemable preferred stock for redeemable convertible preferred stock	(41,992)	(41,992,000)	13,071,714	41,992,000	(8,892,912)	(8,893)
Issuance of redeemable convertible preferred stock			8,421,907	35,126,419		
Dividends on preferred stock	1,686	1,686,000				
Accretion of preferred stock to redemption value				2,266,051		
Net loss						
Currency translation adjustment						
Unrealized loss on marketable securities						
Comprehensive loss						
Balance at December 31, 1998	—	—	21,493,621	79,384,470	889,778	890
Repurchase of common stock					(56,378)	(56)
Dividends on preferred stock			1,468,729	5,351,178		
Accretion of preferred stock to redemption value				541,765		
Issuance of warrants associated with convertible notes						
Net loss						
Currency translation adjustment						
Unrealized loss on marketable securities						
Comprehensive loss						
Balance at December 31, 1999	—	—	22,962,350	85,277,413	833,400	834
Repurchase of common stock					(22,205)	(22)
Employee stock purchases					227,525	226
Issuance of redeemable convertible preferred stock			5,946,366	25,688,284		
Accretion and dividend on preferred stock			1,751,241	4,898,537		
Beneficial conversion of redeemable convertible preferred stock						
Issuance of warrants associated with convertible notes						
Issuance of common stock through initial public offering					6,900,000	6,900
Conversion of preferred stock to common stock			(30,659,957)	(115,864,234)	22,381,735	22,382
Deferred compensation expense associated with stock options						
Adjustments to deferred compensation for terminations						
Amortization of deferred compensation						
Net loss						
Currency translation adjustment						
Unrealized loss on marketable securities						
Comprehensive loss						
Balance at December 31, 2000	—	$ —	—	$ —	30,320,455	$30,320

See accompanying notes.

For the Period July 31, 1996 (Date of Inception) to December 31, 2000

Additional Paid-In Capital	Deferred Stock Compensation	Deficit Accumulated During the Development Stage	Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
$ 755	$ —		$ —	$ 2,797
		$ (118,348)		(118,348)
		(1,466,877)		(1,466,877)
755	—	(1,585,225)	—	(1,582,428)
232				859
2,658				9,845
		(1,060,673)		(1,060,673)
		(957,592)		(957,592)
		(17,805,926)		(17,805,926)
			1,806	1,806
			7,274	7,274
				(17,796,846)
3,645	—	(21,409,416)	9,080	(21,386,835)
1,312				1,347
(40)				(148)
8,893				—
		(1,692,852)		(1,692,852)
		(2,266,051)		(2,266,051)
		(28,950,798)		(28,950,798)
			31,562	31,562
			(1,984)	(1,984)
				(28,921,220)
13,810		(54,319,117)	38,658	(54,265,759)
(21)				(77)
		(5,351,251)		(5,351,251)
		(541,765)		(541,765)
325.355				325,355
		(34,712,895)		(34,712,895)
			(3,847)	(3,847)
			(7,416)	(7,416)
				(34,724,158)
339,144	—	(94,925,028)	27,395	(94,557,665)
				(22)
286,068				286,294
				—
		(4,898,537)		(4,898,537)
25,444,299		(25,444,299)		—
18,789,805				18,789,805
101,343,162				101,350,062
115,841,732				115,864,114
17,279,612	(17,279,612)			—
(197,485)	197,485			—
	3,726,433			3,726,433
		(71,292,170)		(71,292,170)
			5,141	5,141
			(34,482)	(34,482)
				(71,321,511)
$279,126,337	**$(13,355,694)**	**$(196,560,034)**	**$ (1,946)**	**$ 69,238,983**

Consolidated Statements of Cash Flows

	Year Ended December 31,			Period July 31, 1996 (Date of Inception)
	1998	1999	2000	to December 31, 2000
Cash flows from operating activities:				
Net loss	$(28,950,798)	$(34,712,895)	**$ (71,292,170)**	$(154,228,514)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	98,413	207,663	**277,307**	618,677
Amortization of discount on convertible notes	—	101,674	**19,013,486**	19,115,160
Amortization of deferred stock compensation	—	—	**3,726,433**	3,726,433
Loss on sales of fixed assets	—	—	**14,631**	14,631
Changes in operating assets and liabilities:				
Accrued interest receivable	(705,515)	690,290	**(1,337,703)**	(1,392,928)
Inventory	—		**(1,963,491)**	(1,963,491)
Prepaid expenses and other current assets	(156,812)	39,141	**(312,027)**	(466,548)
Other assets	(152,165)	(3,349)	**(82,391)**	(250,629)
Accounts payable	(31,864)	5,528,544	**(1,823,602)**	5,990,320
Accrued expenses	(1,928,001)	1,258,366	**5,708,535**	9,386,636
Net cash used in operating activities	(31,826,742)	(26,890,566)	**(48,070,992)**	(119,450,253)
Cash flows from investing activities:				
Purchases of marketable securities	(29,861,162)	—	**(51,098,901)**	(111,144,188)
Maturities and sales of marketable securities	28,722,483	18,796,493	**9,083,090**	68,586,977
Purchase of fixed assets	(357,103)	(258,788)	**(834,160)**	(1,604,226)
Net cash provided by (used in) investing activities	(1,495,782)	18,537,705	**(42,849,971)**	(44,161,437)
Cash flows from financing activities:				
Proceeds from issuance of convertible notes and warrants	—	6,000,000	**13,348,779**	19,348,779
Proceeds from issuance of preferred stock, net	35,126,419	—	**6,095,338**	79,395,165
Proceeds from issuance of common stock, net	1,347	—	**101,636,356**	101,651,204
Repurchases of common stock	(148)	(77)	**(22)**	(247)
Dividends paid in cash	(6,852)	(73)	**(118)**	(11,064)
Net cash provided by financing activities	35,120,766	5,999,850	**121,080,333**	200,383,837
Effect of exchange rate changes on cash	29,928	(1,245)	**(280)**	30,209
Increase (decrease) in cash and cash equivalents	1,828,170	(2,354,256)	**30,159,090**	36,802,356
Cash and cash equivalents at beginning of period	7,169,352	8,997,522	**6,643,266**	—
Cash and cash equivalents at end of period	$ 8,997,522	$ 6,643,266	**$ 36,802,356**	$ 36,802,356
Non-cash transactions:				
Dividends on preferred stock	$ 1,686,000	$ 5,351,178	**$ 31,894,474**	$ 40,106,652
Supplemental disclosure of cash flow information:				
Interest paid	$ —	$ —	**$ 255,781**	$ 285,016

See accompanying notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2000

1. Nature of Business

The Medicines Company (the Company) was incorporated in Delaware on July 31, 1996. The Company is a pharmaceutical company engaged in the acquisition, development and commercialization of late-stage development drugs. The Company is a development stage enterprise, as defined in Statement of Financial Accounting Standards No. 7, and has, since inception, been developing business plans, acquiring product rights, conducting initial commercialization activities, obtaining financing, performing research and development, conducting regulatory activities and recruiting and training personnel. In December 2000, The U.S. Food and Drug Administration (FDA) approved Angiomax® (bivalirudin), the Company's lead product, for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA).

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Risks and Uncertainties

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to regulatory approvals, dependence on key products, and protection of proprietary rights.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents and marketable securities. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing investments in high-quality financial instruments. At December 31, 2000, approximately $23,300,000 of the cash and cash equivalents balance was invested in the Merrill Lynch Premier Institutional Fund, a no-load money market fund.

Cash, Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist of investments in money market funds, corporate bonds and taxable auction securities. These investments are carried at cost, which approximates fair value.

Marketable securities consist of securities with original maturities of greater than three months. The Company classifies its marketable securities as available-for-sale. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. The estimated fair value of the marketable securities is determined based on quoted market prices or rates for similar instruments. At December 31, 1999 and 2000, marketable securities consisted of investments in corporate bonds with maturities of less than one year and are summarized as follows:

	Cost	Unrealized Gain (Loss)	Fair Value
December 31, 1999	$ 541,400	$ (2,126)	$ 539,274
December 31, 2000	$42,559,337	$(36,608)	$42,522,729

There were no sales of available-for-sale securities during the years ended December 31, 1999 and 2000, although there were maturities of such securities as disclosed in the accompanying consolidated statement of cash flows.

The Medicines Company currently holds a $3.0 million principal investment in Southern California Edison 5⅞% bonds due January 15, 2001, which is accounted for in accordance with Statement of Financial Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." We classify these securities as available-for-sale and carry them at fair market value based on the quoted market price. We have exposure to market risk related to the fluctuation of the Southern California Edison bonds' price, which fluctuation has increased significantly as a result of events which occurred after December 31, 2000, including the non-payment of principal and interest on the bonds at maturity on January 15, 2001. At March 28, 2001, the value of the Company's investment in these Southern California Edison bonds had declined to approximately $2.5 million.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs were approximately $1,491,000, $484,000 and $807,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

Inventory

The Company records inventory upon the transfer of title from its vendor. Inventory is stated at the lower of cost or market with cost determined using a weighted average of actual costs. All costs associated with the manufacture of Angiomax bulk drug product and finished product to which title transferred to the Company prior to FDA approval of Angiomax was expensed as research and development. On

December 15, 2000, the Company received FDA approval for Angiomax and any Angiomax bulk drug product to which the Company took title after that date is recorded as inventory.

Fixed Assets

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms.

Stock-Based Compensation

Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") encourages, but does not require, companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has elected to account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25").

Translation of Foreign Currencies

The functional currencies of the Company's foreign subsidiaries are the local currencies; British pound sterling, Swiss franc and New Zealand dollar. The Company translates its foreign operations using a current exchange rate. In accordance with Statement of Financial Accounting Standards No. 52, assets and liabilities are exchanged using the current exchange rate as of the balance sheet date. Expenses and items of income are exchanged using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' deficit. Foreign exchange transaction gains and losses are included in the results of operations and are not material to the Company's consolidated financial statements.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with ultimate realization.

Comprehensive Income/(Loss)

The Company reports comprehensive income/(loss) and its components in accordance with the provisions of SFAS No. 130, "Reporting Comprehensive Income." Comprehensive income/(loss) includes all changes in equity for cumulative translations adjustments resulting from the consolidation of foreign subsidiaries' financial statements and unrealized gains and losses on available-for-sale securities.

Recent Accounting Pronouncements

In December 1999, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 101, "Revenue Recognition in Financial Statements" ("SAB 101"), which provides guidance related to revenue recognition based on interpretations and practices followed by the SEC. SAB 101, as amended, is effective beginning the fourth quarter of calendar fiscal years beginning after December 15, 1999 and requires companies to report any changes in revenue recognition as a cumulative change in accounting principle at the time of implementation. Adoption of SAB 101 did not have a material impact on the Company's financial position or results of operations, since the Company has no revenues to date.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The effective date of this statement was deferred to fiscal years beginning after June 15, 2000 by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities—Deferral of the Effective Date of SFAS No. 133." The adoption of this new standard is not expected to have a material impact on the Company's financial condition or results of operations.

Net Loss Per Share

Basic net loss per share is computed using the weighted average number of shares of common stock outstanding during the period reduced, where applicable, for outstanding, yet unvested, shares. Diluted net loss per share includes the effect of stock options, warrants and redeemable convertible preferred stock and convertible notes outstanding during the period, if dilutive. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share are the same.

Unaudited Pro Forma Net Loss Per Share

Unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding, including the pro forma effects of automatic conversion of all outstanding redeemable convertible preferred stock and accrued dividends and convertible notes and accrued interest through each balance sheet date into shares of the Company's common stock effective upon the closing of the Company's initial public offering, as if such conversion had occurred at the date of original issuance.

Segments

The Company is a development stage company focused on the acquisition, development and commercialization of late-stage development drugs. The Company has license rights to three potential products, Angiomax, CTV-05 and IS-159. The

Company manages its business and operations as one segment. There are no revenues to date for any potential products and the Company's assets are not identifiable to its three potential products.

3. Management's Plans and Financing

The Company is a development stage company and has incurred substantial losses since inception. To date, the Company has funded its operations through the issuance of debt and equity. The Company expects to continue to expend substantial amounts for continued product research, development and initial commercialization activities for the foreseeable future and management's plans with respect to funding this development are to secure additional equity, if possible, and to secure collaborative partnering arrangements that will provide available cash funding for operations.

Should additional equity financing or collaborative partnering arrangements be unavailable to the Company, management will restrict certain of the Company's planned activities and operations, as necessary, to sustain operations and conserve cash resources.

4. Fixed Assets

Fixed assets consist of the following:

	Estimated Life (Years)	December 31, 1999	December 31, 2000
Furniture, fixtures and equipment	3	$ 323,685	$ 547,748
Computer hardware and software	3	213,376	728,333
Leasehold improvements	5	216,064	243,060
		753,125	1,519,141
Less: Accumulated depreciation		(323,064)	(553,309)
		$ 430,061	$ 965,832

Depreciation expense was approximately $98,000, $208,000 and $277,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

5. Accrued Expenses

Accrued expenses consist of the following at December 31:

	1999	2000
Development services	$3,283,767	$5,998,117
Other	396,526	3,138,817
	$3,680,293	$9,136,934

6. Convertible Notes

In October 1999, the Company issued $6,000,000 of 8% Convertible Notes ("the Notes") and 1,013,877 Common Stock Purchase Warrants ("the Warrants") to existing investors, raising proceeds of $6,000,000. The Notes were redeemable on January 15, 2001 and pay interest semi-annually at a rate of 8% per annum. The Notes were convertible into shares of stock of the Company upon a subsequent sale of stock of the Company provided that such sale resulted in aggregate gross proceeds of at least $6,000,000. The Notes were convertible into a number of shares of stock determined by dividing the outstanding principal and interest on the date of the subsequent sale by the price per share of such sale. Each Warrant provides the holder with the right to purchase one share of Common Stock of the Company at a price of $5.92 per share at any time prior to October 19, 2004. The exercise price and the number of shares underlying the Warrants could be adjusted in certain circumstances related to future issuances of capital stock. The Company recorded $325,355 as the fair value of the Warrants using the Black-Scholes method and the estimated fair value of the Company's Common Stock on the date of the issuance of warrants, and $5,674,645 as the value of the Notes on the issuance date. The discount on the Notes was amortized to interest expense over the expected term of the Notes, which the Company anticipated to be to June 2000. Since the Notes were issued in October 1999, the carrying amount approximates their fair value at December 31, 1999. Upon completion of the Company's sale of Series IV Preferred Stock in May 2000, the principal and accrued interest on the Notes was converted into 1,393,909 shares of Series IV Preferred Stock.

In March 2000, the Company issued $13,348,779 of 8% Convertible Notes ("the Notes") and 2,255,687 Common Stock Purchase Warrants ("the Warrants") to current stockholders, raising proceeds of $13,348,779. The Notes were redeemable on January 15, 2001 and accrue interest semi-annually at a rate of 8% per annum. The Notes were convertible into shares of stock of the Company upon a subsequent private sale of stock of the Company provided that such sale results in aggregate gross proceeds of at least $6,000,000. The Notes were convertible into a number of shares of stock determined by dividing the outstanding principal and interest on the date of the subsequent sale by the price per share of such sale. Each Warrant provides the holder with the right to purchase one share of Common Stock of the Company at a price of $5.92 per share at any time prior to March 2005. The exercise price and the number of shares underlying the Warrants could be adjusted in certain circumstances related to future issuances of stock. The Company recorded approximately $18,800,000 as the value of the Warrants using the Black-Scholes method and the estimated fair value of the Company's Common Stock on the date of the issuance of the warrants. The discount on the Notes was amortized over the expected term of the Notes, which the Company anticipated to be to June 2000. For the year ended December 31, 2000, amortization of the

discount was approximately $18,800,000 and is included with the interest expense in the accompanying financial statements. Upon completion of the Company's sale of Series IV Preferred Stock in May 2000, the principal and accrued interest on the Notes was converted into 3,141,457 shares of Series IV Preferred Stock.

7. Redeemable Preferred Stock and Stockholders' Equity

On June 29, 2000, the Company's Board of Directors approved a reverse split of 0.73 shares for every one share of common stock then outstanding. The reverse stock split became effective on August 4, 2000. The accompanying financial statements and footnotes, including all share and per share amounts, reflect the reverse stock split.

Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock

During 1999 and 2000, the Company had designated four series of redeemable convertible preferred stock. A summary of the Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock is as follows.

	December 31,	
	1999	2000
Series I, $1 par value, 3,550,000 shares authorized at December 31, 1999 and none at December 31, 2000, 2,678,005 shares and none issued and outstanding as of December 31, 1999 and 2000, respectively ($5,512,225 liquidation value at December 31, 1999 and $0 at December 31, 2000)	$ 5,512,225	$ —
Series II, $1 par value, 15,850,000 shares authorized at December 31, 1999 and none at December 31, 2000, 11,290,928 shares and none issued and outstanding as of December 31, 1999 and 2000, respectively ($40,670,864 liquidation value at December 31, 1999 and $0 at December 31, 2000)	40,670,864	—
Series III, $1 par value, 12,150,000 shares authorized at December 31, 1999 and none at December 31, 2000, 8,993,417 shares and none issued and outstanding as of December 31, 1999 and 2000, respectively ($39,984,732 liquidation value at December 31, 1999 and $0 at December 31, 2000)	39,094,324	—
Series IV, $1 par value, 12,150,000 shares authorized during December 31, 2000 and none at December 31, 1999, none issued and outstanding as of December 31, 2000	—	—
Total	$85,277,413	$ —

In August 1998, the Company executed an agreement (the "Exchange Agreement") under which 8,892,912 shares of common stock and 41,992 shares of Series A Redeemable Preferred Stock were exchanged for 2,506,000 shares of Series I Redeemable Convertible Preferred Stock and 10,565,714 shares of Series II Redeemable Convertible Preferred Stock. Holders of Series A Redeemable Preferred Stock were entitled to receive preferential cumulative annual dividends payable in additional shares of Series A Redeemable Preferred Stock at the rate of 7% per annum of the stated value. Prior to the Exchange Agreement, dividends earned from January 1, 1998 through the date of the Exchange Agreement were paid to the holders of Series A Redeemable Preferred Stock. During 1997, certain preferred shareholders waived their right to a portion of earned dividends and the Company paid agreed-upon amounts through December 31, 1997. To the extent that all or any part of the Stock would have resulted in the issuance of a fractional share of the Series A Preferred stock, the amount of such fraction, multiplied by the stated value, was paid in cash.

On May 17, 2000, the Company issued 1,411,000 shares of Series IV Redeemable Convertible Preferred Stock for net proceeds of $6,095,520. In addition, on May 17, 2000, the convertible notes and accrued interest were converted into 4,535,366 shares of Series IV Redeemable convertible Preferred Stock. The Series IV preferred stock carries terms and conditions similar to the Series I, II, III preferred stock. The Series IV preferred stock was convertible into common stock at a 1-for-0.73 conversion rate and automatically converted upon the closing of the sale of shares of common stock in an underwritten public offering. The Series IV Redeemable Convertible Preferred Stock issued on May 17, 2000 contained a beneficial conversion feature based on the estimated fair market value of common stock into which it is convertible. In accordance with EITF 98-5, the total amount of such beneficial conversion is approximately $25,450,000. The beneficial conversion is analogous to a dividend and was recognized during 2000 when issued. Simultaneously with the closing of the Company's initial public offering, 30,659,957 shares of Redeemable Convertible Preferred Stock then outstanding (including accrued dividends for the period August 1, 2000 to August 11, 2000) were converted into 22,381,735 shares of common stock.

A summary of the rights, preferences and privileges of the Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock ("Series Preferred Stock") is as follows:

Dividends. The holders of each series of Series Preferred Stock are entitled to receive, prior to any distribution to the holders of Common Stock, preferential cumulative dividends payable in additional shares of such series of Series Preferred Stock at a rate of 7% per share per annum of the liquidation value of such series of Series Preferred Stock. Such dividends were paid annually commencing on July 31, 1999.

Liquidation. In the event of any liquidation, dissolution or winding up of the Company (either voluntary or involuntary), the holders of Series Preferred Stock are entitled to receive, out of the assets of the Company available for distribution to its stockholders, a per share amount equal to $2.00 per share in the case of the Series I Preferred Stock, $3.50 per share in the case of the Series II Preferred Stock and $4.32 in the case of the Series III and Series IV Preferred Stock, plus any accrued but unpaid dividends (the liquidation value). These distributions will be made prior to any distributions to other stockholders. Any amounts remaining after making such distributions will be distributed to the holders of Common Stock and Series Preferred Stock on parity with each other. If the remaining assets of the Company available for distribution to its stockholders are insufficient to pay all of the holders of Series Preferred Stock, distributions will be made first to the Series IV Preferred Stockholders, then to Series III Preferred Stockholders and then to the Series I and II Preferred Stockholders on a pro-rata basis.

Conversion. Holders of shares of Series Preferred Stock have the right to convert their shares at any time into shares of Common Stock. The conversion rate for each series of Series Preferred Stock is 0.73-for-1. The conversion rate for each series of Series Preferred Stock is subject (i) to proportional adjustments for splits, reverse splits, recapitalizations, etc., and (ii) to formula-weighted average adjustments in the event that the Company issues additional shares of Common Stock or securities convertible into or exercisable for Common Stock at a purchase price less than the applicable conversion price then in effect, other than the issuance of shares to directors, officers, employees and consultants pursuant to stock plans approved by the Board of Directors and certain other exceptions. Each share of Series Preferred Stock will be automatically converted into shares of Common Stock upon the closing of the sale of shares of Common Stock at a price of at least $8.90 per share (subject to appropriate adjustment for stock dividends, stock splits, combinations and other similar recapitalizations affecting such shares) in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, resulting in at least $15,000,000 of gross proceeds to the Company.

Redemption. The Company will redeem the outstanding shares of Series Preferred Stock in three equal annual installments commencing July 31, 2002 at a price equal to the liquidation value of such shares.

Voting. Generally, holders of shares of Series Preferred Stock vote on all matters, including the election of directors, with the holders of shares of Common Stock on an as-converted basis, except where a class vote is required by law.

Accretion. Series Preferred Stock is accreted to its redemption value to recognize issuance costs over the period from issuance to redemption using the interest method and to reflect accrued but unpaid dividends.

Common Stock

Common Stockholders are entitled to one vote per share and dividends when declared by the Board of Directors, subject to the preferential rights of preferred stockholders.

Upon the completion of its Initial Public Offering ("IPO") on August 11, 2000, the Company sold 6,000,000 shares of its common stock at a price of $16.00 per share. In addition, on September 8, 2000, the underwriters of the IPO exercised their over-allotment option and purchased an additional 900,000 shares of common stock at a price of $16.00 per share. The Company received proceeds of approximately $101.4 million, net of underwriting discounts and commissions, and expenses. Simultaneously with the closing of the IPO, 30,659,957 shares of Redeemable Convertible Preferred Stock then outstanding (including accrued dividends for the period August 1, 2000 to August 11, 2000) were converted into 22,381,735 shares of common stock.

During 1996, 1997 and 1998, certain employees of the Company purchased 335,800, 627,070 and 32,850 shares of common stock, respectively, for $0.001 per share. These shares are subject to restriction and vesting agreements that limit transferability and allow the Company to repurchase unvested shares at the original purchase price. The shares vest ratably over a four-year period that generally begins on each employee's hire date. During 1998, 1999 and 2000, the Company repurchased 107,979, 56,378 and 22,205 shares, respectively, of unvested common stock for $0.001 per share. There were 62,722 shares of common stock unvested at December 31, 2000.

Stock Plans

In April 1998, the Company adopted the 1998 Stock Incentive Plan (the "Plan"), which provides for the grant of stock options, restricted stock and other stock-based awards to employees, directors and consultants. The plan allows for the issuance of up to 1,083,259 shares of common stock through April 2008. The Board of Directors determines the term of each option, the option price, the number of shares for which each option is granted and the rate at which each option is exercisable. During 1999, the Board of Directors amended all outstanding grants to allow holders the opportunity to exercise options prior to vesting. Exercised options that are unvested are subject to repurchase by the Company at the original exercise price. Options granted under the plan generally vest in increments over four years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS *(continued)*

December 31, 2000

In January 2000, the Board of Directors approved an amendment to the Plan to increase the number of shares available under the Plan to 1,448,259. In May 2000, the Board of Directors approved an amendment to the Plan to increase the number of shares available under the Plan to 4,368,259. In addition, the Board of Directors also approved the 2000 Employee Stock Purchase Plan which provides for the issuance of up to 255,500 shares of common stock to participating employees and the 2000 Directors Stock Option Plan which provides for the issuance of up to 250,000 shares of common stock to the Company's directors. Both the 2000 Employee Stock Purchase Plan and the 2000 Directors Stock Option Plan have received stockholder approval.

Prior to the Company's initial public offering, the Board of Directors of the Company determined the fair value of the Company's common stock in its good faith judgment at each option grant date for grants under the Plan considering a number of factors including the financial and operating performance of the Company, recent transactions in the Company's common and preferred stock, if any, the values of similarly situated companies and the lack of marketability of the Company's common stock. Following the Company's initial public offering, the fair value is determined based on the traded value of the Company's common stock.

During the period January 1, 2000 to September 31, 2000, the Company issued 2,273,624 options at exercise prices below the estimated fair value of the Company's common stock as of the date of grant of such options based on the price of the Company's common stock in connection with the Company's initial public offering. The total deferred compensation associated with these options is approximately $17.3 million. Included in the results of operations for the year ended December 31, 2000 is compensation expense of approximately $3.7 million associated with such options.

The Company has elected to follow APB 25 in accounting for its stock options granted to employees because the alternative fair value accounting provided for under SFAS 123, requires the use of option valuation models that were not developed for use in valuing employee stock options. Because the exercise price of the Company's stock options generally equals the market price of the underlying stock on the date of grant, no compensation is recognized under APB 25. Had compensation costs for the Plan been determined based on the fair value at the grant dates as calculated in accordance with SFAS 123, the Company's net loss for the year ended December 31, 1999 and 2000 would have been increased to the pro forma amounts indicated below.

	Years Ended December 31,		
	1998	1999	2000
Net loss attributable to common stockholders— As reported	$32,909,701	$40,605,911	$101,635,158
Net loss attributable to common stockholders— Pro forma	$32,965,764	$40,771,828	$106,150,604
Net loss per share attributable to common stockholders— As reported	$ (6.03)	$ (80.08)	$ (8.43)
Net loss per share attributable to common stockholders— Pro forma	$ (6.04)	$ (80.41)	$ (8.80)

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Years Ended December 31,		
	1998	1999	2000
Expected dividend yield	0%	0%	0%
Expected stock price volatility	70%	70%	70%
Risk-free interest rate	4.70%	5.45%	6.32%
Expected option term	3.38 years	3.30 years	3.35 years

A summary of stock option activity under the 1998 Stock Incentive Plan and the 2000 Directors Stock Option Plan are as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 1997	—	$ —
Granted	734,745	1.11
Exercised	(2,037)	0.64
Canceled	(27,437)	0.88
Outstanding, December 31, 1998	705,271	1.12
Granted	239,075	1.23
Canceled	(175,380)	1.05
Outstanding, December 31, 1999	768,966	1.16
Granted	3,080,424	9.80
Exercised	(227,523)	1.26
Canceled	(406,713)	1.22
Outstanding, December 31, 2000	3,215,154	$9.43
Available for future grant at December 31, 2000	1,173,545	

The weighted average per share fair value of options granted during 1998, 1999 and 2000 was $0.55, $0.62 and $10.34, respectively. The weighted average fair value and exercise price of options granted during 2000 which were granted with exercise prices below the fair market value were $9.35 and $4.68, respectively. The weighted average fair value and exercise price of options granted during 2000 which were granted with exercise prices equal to the fair market value were $13.19 and $24.96, respectively.

The following table summarizes information about stock options from the 1998 Stock Incentive Plan and the 2000 Directors Stock Option Plan outstanding at December 31, 2000:

	Options Outstanding			Options Vested	
Range of Exercise Prices	Number Outstanding at 12/31/00	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Outstanding at 12/31/00	Weighted Average Exercise Price
$ 0.69–$ 3.08	911,673	8.72	$ 1.63	363,052	$1.46
$ 4.79–$ 4.79	850,450	9.39	$ 4.79	115,582	$4.79
$ 5.92–$12.00	631,231	9.52	$ 6.69	3,815	$5.92
$19.88–$24.00	183,750	9.85	$22.76	—	—
$24.13–$30.63	638,050	9.93	$25.60	—	—
	3,215,154	9.36	$ 9.43	482,449	$2.29

Common Stock Reserved for Future Issuance

At December 31, 2000, there were 7,913,763 shares of common stock reserved for future issuance under the Employee Stock Purchase Plan, for conversion of the Common Stock Warrants and for grants made under the 1998 Stock Incentive Plan and the 2000 Director Stock Option Plan.

8. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of basic and diluted, and unaudited pro forma basic and diluted net loss per share for the respective periods. The unaudited pro forma basic and diluted net loss per share gives effect to the conversion of the redeemable convertible preferred stock and the convertible notes and accrued interest as if converted at the date of original issuance.

	Year Ended December 31,		
	1998	1999	2000
Basic and Diluted			
Net loss	$(28,950,798)	$(34,712,895)	$ (71,292,170)
Dividends and accretion on redeemable convertible preferred stock	(3,958,903)	(5,893,016)	(30,342,988)
Net loss attributable to common stockholders	$(32,909,701)	$(40,605,911)	$(101,635,158)
Weighted average common shares outstanding	6,075,948	850,238	12,225,537
Less: unvested restricted common shares outstanding	(621,295)	(343,173)	(166,262)
Weighted average common shares used to compute net loss per share	5,454,653	507,065	12,059,275
Basic and diluted net loss per share	$ (6.03)	$ (80.08)	$ (8.43)

	Year Ended December 31,	
	1999	2000
Unaudited Pro Forma Basic and Diluted		
Net loss	$(34,712,895)	$(71,292,170)
Interest expense on convertible notes	197,455	19,390,414
Net loss used to compute pro forma net loss per share	$(34,515,440)	$(51,901,756)
Weighted average common shares used to compute net loss per share	507,065	12,059,275
Weighted average number of common shares assuming the conversion of all redeemable convertible preferred stock and convertible notes and accrued interest at the date of original issuance	17,292,811	12,659,800
Weighted average common shares used to compute pro forma net loss per share	17,799,876	24,719,075
Unaudited pro forma basic and diluted net loss per share	$ (1.94)	$ (2.10)

Options to purchase 768,966 and 3,215,154 shares of common stock have not been included in the computation of diluted net loss per share for the years ended December 31, 1999 and 2000, respectively, as their effects would have been antidilutive. Warrants to purchase 1,013,877 and 3,269,564 shares of common stock were excluded from the computation of diluted net loss per share for the year ended December 31, 1999 and 2000, respectively, as their effect would be antidilutive.

9. Income Taxes

The significant components of the Company's deferred tax assets are as follows:

	December 31,	
	1999	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 30,864,000	$ 48,494,000
Research and development credit	2,074,000	3,576,000
Intangible assets	1,139,000	1,233,000
Other	36,000	86,000
	34,113,000	53,389,000
Valuation allowance	(34,113,000)	(53,389,000)
Net deferred tax assets	$ —	$ —

The Company has increased its valuation allowance by $19,276,000 in 2000 to provide a full valuation allowance for deferred tax assets since the realization of these future benefits is not considered more likely than not. The amount of the deferred tax asset considered realizable is subject to change based on estimates of future taxable income during the carryforward period. If the Company achieves profitability, these deferred tax assets would be available to offset future income taxes. The future utilization of net operating losses and credits may be subject to limitation based upon changes in ownership under the rules of the Internal Revenue Code. The Company will assess the need for the valuation allowance at each balance sheet date based on all available evidence.

At December 31, 2000, the Company had federal net operating loss carryforwards available to reduce taxable income, and federal research and development tax credit carryforwards available to reduce future tax liabilities, which expire as follows:

Year of Expiration	Federal Net Operating Loss Carryforwards	Federal Research and Development Tax Credit Carryforwards
2011	$ 930,000	$ 22,000
2012	15,260,000	527,000
2018	27,876,000	425,000
2019	33,802,000	1,002,000
2020	44,282,000	1,300,000
	$122,150,000	$3,276,000

For state purposes, net operating loss carryforwards of approximately $116,042,000 expire in the years 2001 through 2004. State research and development tax credit carryforwards are approximately $300,000.

10. License Agreements

Angiomax

In March 1997, the Company entered into an agreement with Biogen, Inc. for the license of the anticoagulant pharmaceutical, bivalirudin (now known as Angiomax). Under the terms of the agreement, the Company acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, the Company paid $2 million on the closing date and is obligated to pay up to an additional $8 million upon reaching certain Angiomax sales milestones, including the first commercial sale of Angiomax for the treatment of AMI in the United States and Europe. In addition, the Company shall pay royalties on future sales of Angiomax and on any sublicense royalties earned until the later of (1) 12 years after the date of the first commercial sale of the product in a country or (2) the date in which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent right in such country. The agreement also stipulates that the Company use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least $20 million for certain development and commercialization activities, which we met in 1998. The license and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate for material breach, and the Company may terminate the agreement for any reason upon 90 days prior written notice. During December 2000, the Company received approval from the U.S. Food and Drug Administration (FDA) for the sale of Angiomax for certain indications.

CTV-05

In August 1999, the Company entered into an agreement with Gynelogix, Inc. for the license of the biotherapeutic agent CTV-05, a strain of human lactobacillus currently under clinical investigation for applications in the areas of urogenital and reproductive health. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the patents and know-how related to CTV-05. In exchange for the license, the Company has paid $400,000 and is obligated to pay an additional $100,000 upon reaching certain development and regulatory milestones and to fund agreed-upon operational costs of Gynelogix related to the development of CTV-05 on a monthly basis subject to a limitation of $50,000 per month. In addition, the Company is obligated to pay royalties on future sales of CTV-05 and on any sublicense royalties

earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that the Company must use commercially reasonable efforts in pursuing the development, commercialization and marketing of CTV-05 to maintain the license. The license and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and may terminate the agreement for any reason upon 60 days prior written notice.

IS-159

In July 1998, the Company entered into an agreement with Immunotech S.A. for the license of the pharmaceutical IS-159 for the treatment of acute migraine headache. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the patents and know-how related to IS-159. In exchange for the license, the Company paid $1 million on the closing date and is obligated to pay up to an additional $4.5 million upon reaching certain development and regulatory milestones. In addition, the Company shall pay royalties on future sales of IS-159 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that the Company must use commercially reasonable efforts in pursuing the development, commercialization and marketing of IS-159 and meet certain development and regulatory milestones to maintain the license. The licenses and rights under the agreement remain in force until the Company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and the Company may terminate the agreement for any reason upon 60 days prior written notice.

11. Strategic Alliances

UCB

In December 1999, the Company entered into a commercial supply agreement with UCB-Bioproducts S.A. ("UCB") to develop and supply Angiomax bulk drug substance. Under the terms of the agreement, UCB Bioproducts is also responsible for developing the Chemilog process in coordination with the Company and obtaining regulatory approval for use of the process. The Company has agreed to partially fund UCB Bioproducts' development activities. The funding is due upon the completion by UCB Bioproducts of development milestones. If UCB Bioproducts successfully completes each of these development milestones, the Company anticipates total development funding to be approximately $9.1 million. During 1999 and 2000, expenses incurred for such services were approximately $811,000 and $560,000, respectively, of which approximately $469,000 and $789,000 was recorded in accounts payable and accrued expenses at December 31, 1999 and 2000, respectively. In addition, the Company has agreed to purchase Angiomax bulk drug product exclusively from UCB Bioproducts at agreed upon prices for a period of seven years from the date of the first commercial sale of Angiomax produced under the Chemilog process. Following the expiration of the agreement, or if the Company terminates the agreement prior to its expiration, UCB Bioproducts will transfer the development technology to the Company. If the Company engages a third party to manufacture Angiomax using this technology, the Company will be obligated to pay UCB Bioproducts a royalty based on the amount paid by the Company to the third-party manufacturer.

During 1999, the Company placed an order with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Manufacture of $14.2 million of this material was completed in 2000, of which $12.2 million was expensed during the period. All costs associated with the manufacture of Angiomax bulk drug product and finished products to which title was transferred to the Company prior to the date of FDA approval of Angiomax were expensed as research and development. The Company recorded Angiomax bulk drug product to which title transferred after the date of FDA approval of Angiomax as inventory. In November 2000, the Company placed additional orders with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Under the terms of these orders, the Company is scheduled to take title to material and become obligated to make payments totaling approximately $24.0 million in fiscal 2001 and early fiscal 2002.

Lonza

In September 1997, the Company entered into an agreement with Lonza AG ("Lonza") for the development of a new commercial manufacturing process for an advanced intermediate compound used in the manufacturing of Angiomax ("Angiomax intermediate"). In November 1998, the Company entered into an additional agreement with Lonza for the engineering, procurement and installation of equipment for the initial manufacturing of the Angiomax intermediate using the new process. The agreement also contemplated the purchase of the Angiomax intermediate from Lonza at specified prices for an anticipated two-year period following initial production and stipulated the basic principles of a long-term commercial supply contract. In January 2000, the Company notified Lonza of its intention to terminate the agreement. As a result of the termination, the Company retained certain ownership rights to intellectual property and was responsible for reimbursement of all costs incurred under the terms of the agreement through the date of notice. Approximately

$1,572,000 was recorded in accounts payable and accrued expenses at December 31, 1999. There was no outstanding obligation to Lonza at December 31, 2000.

PharmaBio

In August 1996, the Company entered into a strategic alliance with one of its stockholders, PharmaBio Development Inc. ("PharmaBio"), a wholly-owned subsidiary of Quintiles Transnational Corporation ("Quintiles"). Under the terms of the strategic alliance agreement, PharmaBio and any of its affiliates who work on the Company's projects will, at no cost to the Company, review and evaluate, jointly with the Company, development programs designed by the Company related to potential or actual product acquisitions. The purpose of this collaboration is to optimize the duration, cost, specifications and quality aspects of such programs. PharmaBio and its affiliates have also agreed to perform other services with respect to our products, including clinical and non-clinical development services, project management, project implementation, pharmacoeconomic services, regulatory affairs and post marketing surveillance services and statistical, statistical programming, data processing and data management services pursuant to work orders agreed to by the Company and PharmaBio from time to time. Through December 31, 2000, the Company has entered in approximately 40 work orders with PharmaBio and has paid PharmaBio a total of $10.9 million. During 1998, 1999 and 2000, expenses incurred for such services were approximately $1.7 million, $3.7 million and $2.3 million, respectively, of which approximately $1.2 million and $813,000 was recorded in accounts payable and accrued expenses at December 31, 1999 and 2000, respectively. At December 31, 2000, the Company had open orders with PharmaBio for such services that reflect estimated aggregate future payments of approximately $3.4 million.

Innovex

In January 1997, the Company entered into a consulting agreement with Innovex, Inc. ("Innovex"), a subsidiary of Quintiles, which was subsequently superceded by a consulting agreement executed with Innovex in December 1998. Pursuant to the terms of the agreement, Innovex provides the Company with consulting services with respect to pharmaceutical marketing and sales. Since December 1997, the Company has also entered into various clinical services agreements with Innovex pursuant to which Innovex has provided project management, clinical monitoring, site management, medical monitoring, regulatory affairs, data management and quality assurance services with respect to clinical trials of Angiomax. None of the clinical services agreements is currently outstanding. Through December 31, 2000 the Company has paid Innovex $1.8 million under these agreements.

In December 2000, the Company signed a master services agreement and a work order with Innovex under which Innovex agreed to provide contract sales, marketing and commercialization services relating to Angiomax. Under the master services agreement, Innovex may provide additional services unrelated to Angiomax pursuant to work orders entered into from time to time. Under the master services agreement and the Angiomax work order, Innovex will provide the Angiomax sales force of 52 representatives, a sales territory management system and operational support for the launch of Angiomax. The Company will provide the marketing plan and marketing materials for the sales force and other sales and marketing support and direction for the sales force. For Innovex services, the Company has agreed to a daily fee for each day worked by the members of the sales force. The Company will reimburse Innovex for expenses incurred in providing the services and for the incentive compensation paid to the sales force of Innovex. The Company has the right to terminate the work order and the master services agreement at any time upon 90 days prior written notice. The Company may hire members of the sales force, although the Company may incur additional fees to Innovex. Through December 31, 2000, the Company had paid Innovex $1.1 million for its services under the master services agreement and work order. Total fees for 2001 under this agreement are estimated to be approximately $8.2 million subject to adjustments in the size of the sales force and other commercial factors.

During 1998, 1999 and 2000, expenses incurred for services provided by Innovex were approximately $943,000, $616,000 and $1.7 million, respectively, of which approximately $102,000, $280,000 and $440,000 were recorded in accounts payable and accrued expenses at December 31, 1998, 1999 and 2000, respectively.

Stack Pharmaceuticals

In April 2000, the Company entered into an agreement with Stack Pharmaceuticals, an entity controlled by David Stack, one of the Company's senior vice presidents, which was amended in August 2000. Pursuant to the terms of this agreement, as amended, Stack Pharmaceuticals will perform infrastructure services for us, which includes providing office facilities, equipment and supplies for the Company's employees based in New Jersey, and such consulting, advisory and related services for the Company as may be agreed upon from time to time. For the infrastructure services, the Company has agreed to pay Stack Pharmaceuticals a service fee of $20,100 per month. The term of this agreement continues until April 1, 2001, but either party may terminate it earlier upon 90 days prior written notice. From January 2000 through March 2000, Stack Pharmaceuticals provided the Company with consulting

services under a consulting agreement that expired on March 31, 2000. Through December 31, 2000, the Company had paid Stack Pharmaceuticals $407,000 under these agreements. The was no outstanding obligation to Stack Pharmaceuticals at December 31, 2000.

12. Commitments and Contingencies

The Company leases its facilities in Cambridge, Massachusetts and Parsippany, New Jersey and certain office furniture and equipment at those facilities under operating leases. The leases for the Cambridge and Parsippany facilities expire in August 2003 and September 2005, respectively. Future annual minimum payments under all non-cancelable operating leases are $590,000, $712,000, $429,000, $210,000 and $160,000 in 2001, 2002, 2003, 2004 and 2005, respectively. Rent expense was approximately $326,000, $442,000 and $504,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

The Company is involved in ordinary and routine matters and litigation incidental to its business. There are no such matters pending that the Company expects to be material in relation to its financial condition or results of operations.

13. Employee Benefit Plan

401(k) Plan

The Company has an employee savings and retirement plan which is qualified under Section 401 of the Internal Revenue Code. Our employees may elect to reduce their current compensation by up to the statutorily prescribed limit and have the amount of such reduction contributed to the 401(k) plan. The Company may make matching or additional contributions to the 401(k) plan in amounts to be determined annually by the board of directors. The Company has not made any matching or additional contributions to date.

14. Selected Quarterly Financial Data (Unaudited)

The following table presents selected quarterly financial data for the years ended December 31, 1999 and 2000.

	Three Months Ended							
	Mar. 31, 1999	June 30, 1999	Sept. 30, 1999	Dec. 31, 1999	Mar. 31, 2000	June 30, 2000	Sept. 30, 2000	Dec. 31, 2000
	In thousands, except per share data							
Total operating expenses	$ 8,483	$ 11,715	$ 9,000	$ 6,155	$ 11,840	$ 8,706	$ 10,297	$ 23,763
Net loss	(8,137)	(11,369)	(8,877)	(6,330)	(19,243)	(20,408)	(9,459)	(22,182)
Net loss attributable to common stockholders	(9,573)	(12,806)	(10,375)	(7,852)	(20,773)	(47,596)	(11,083)	(22,182)
Basic and diluted net loss attributable to common stockholders per common share	$(21.09)	$ (25.62)	$ (19.21)	$(13.45)	$ (32.91)	$ (68.65)	$ (0.67)	$ (0.74)
Pro forma basic and diluted net loss attributable to common stockholders per common share	(0.48)	(0.66)	(0.49)	(0.33)	(0.55)	(0.38)	(0.34)	(0.74)

The net loss for each quarter of 2000 was higher compared to the corresponding quarter of 1999. There were higher research and development costs in every quarter of 2000 associated with increased enrollment rates in the HERO-2 trial in AMI, in the third and fourth quarters of 2000 related to the initiation of the REPLACE clinical trial program in angioplasty, and in the first and fourth quarters of 2000 in connection with the receipt of Angiomax bulk drug substance to which title was taken prior to FDA approval. These increases in research and development costs were partly offset by lower development costs in all quarters of 2000 related to the discontinuation of the semilog manufacturing program and reduction in the IS-159 activities. Higher selling, general and administrative expenses associated with the commercial launch of Angiomax also contributed to the higher net loss in the last three quarters of 2000 as compared to the corresponding quarters of 1999. Higher interest expense in the first two quarters of 2000 resulted from the amortization of the discount on convertible notes issued in October 1999 and March 2000. In the second quarter of 2000, we recorded a dividend on the beneficial conversion associated with the issuance of convertible preferred stock in May 2000. In addition, in all the quarters of 2000, amortization of deferred compensation on the grant of stock options also contributed to the higher 2000 quarterly losses.

Report of Independent Auditors

Board of Directors and Stockholders
The Medicines Company

We have audited the accompanying consolidated balance sheets of The Medicines Company (a company in the development stage) as of December 31, 1999 and 2000, and the related consolidated statements of operations, redeemable preferred stock and stockholders' equity/(deficit), and cash flows, for each of the three years in the period ending December 31, 2000, and for the period July 31, 1996 (date of inception) to December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of The Medicines Company at December 31, 1999 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, and for the period July 31, 1996 (date of inception) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

Ernst & Young LLP

Boston, Massachusetts
February 13, 2001,
except for the eighth paragraph of Note 2,
as to which the date is February 20, 2001

CORPORATE INFORMATION

Officers and Directors

Clive A. Meanwell, M.D., Ph.D.
Chief Executive Officer, President and Director

Peyton J. Marshall, Ph.D.
Senior Vice President and Chief Financial Officer

Glenn P. Sblendorio, M.B.A.
Senior Vice President

David M. Stack
Senior Vice President

John M. Nystrom, Ph.D.
Vice President and Chief Technical Officer

David C. Mitchell
Vice President

Frederick K. Paster, M.Sc., M.B.A.
Vice President

Thomas P. Quinn
Vice President

John D. Richards, D.Phil.
Vice President

Fred M. Ryan, M.B.A.
Vice President

John W. Villiger, Ph.D.
Vice President

Leonard Bell, M.D.
President and Chief Executive Officer
Alexion Pharmaceuticals, Inc.

David B. Gillings, Ph.D.
Chairman and Chief Executive Officer
Quintiles Transnational Corp.

Stewart J. Hen, M.B.A., M.S.
Vice President
E.M. Warburg, Pincus & Co., LLC

Anders D. Hove, M.D., M.Sc., M.B.A.
Member
The Bellevue Group

M. Fazle Husain, M.B.A.
General Partner
Morgan Stanley Venture Partners, L.P.

T. Scott Johnson, M.D.
Partner and Co-Founder
JSB Partners L.P.

Armin M. Kessler, Dh.c.
Former Chief Operating Officer and
Head of the Pharmaceutical Division

Nicholas J. Lowcock, M.B.A.
Managing Director
E.M. Warburg, Pincus & Co., LLC

James E. Thomas, M.Sc.
Managing Partner
Thomas, McNerney & Partners, LLC

Corporate Offices

(617) 225-9099
www.themedicinescompany.com

One Cambridge Center
Cambridge, MA 02142

5 Sylvan Way, Suite 200
Parsippany, NJ 07054

Oxford, England

Auckland, New Zealand

Stock Listing

The Medicines Company common stock is traded on the Nasdaq National Market® under the symbol "MDCO."

Transfer Agent

Mellon Investor Services
111 Founders Plaza, 11th Floor
E. Hartford, CT 06108
(800) 288-9541

Independent Auditors

Ernst & Young LLP
200 Clarendon Street
Boston, MA 02116
(617) 266-2000

Corporate Counsel

Hale and Dorr LLP
60 State Street
Boston, MA 02109

Annual Meeting

The Annual Meeting of Stockholders will take place on May 31, 2001 at the offices of Hale and Dorr LLP.

A formal notice of the meeting, along with a proxy statement and a form of proxy, is being mailed to each stockholder with this annual report.

Investor Relations

Call (617) 225-9099 or email
investor.relations@themedco.com

Form 10-K

This annual report contains the 2000 Annual Report on Form 10-K filed with the Securities and Exchange Commission. Upon request, The Medicines Company will provide without charge to each stockholder of record additional copies of the Company's Annual Report on Form 10-K. Please send your request to:

Investor Relations
The Medicines Company
One Cambridge Center
Cambridge, MA 02142
(617) 225-9099

Stock Information

The total number of registered holders of The Medicines Company's common stock as of April 9, 2001 was 104. The Company believes the number of beneficial stockholders is in excess of 2,800.

The following table sets forth, for the periods indicated, the high and low intraday sales prices per share, as quoted by Nasdaq, of the Company's common stock.

2000	HIGH	LOW
Third Quarter (since August 8, 2000)	$35.38	$16.50
Fourth Quarter	$34.75	$17.13
2001		
First Quarter	$20.48	$ 8.75

The Medicines Company has never declared or paid cash dividends on the Company's common stock. The Company anticipates that it will retain all future earnings, if any, for use in the expansion and operation of its business and does not anticipate paying cash dividends in the foreseeable future.

We own or have rights to various trademarks and trade names use din our business, including The Medicines Company name and logo and Angiomax®.

*When used in this report, the words "believes," "anticipates," "plans," "expects," "intends," "may" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by the forward-looking statements contained in this report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Readers are also urged to review carefully and consider the various disclosures made by the Company that attempt to advise interested parties of the factors that affect the Company's business, including the disclosures made under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors Which May Affect Future Results" in this report, as well as the Company's periodic reports on Forms 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission.

Designed by Curran & Connors, Inc. / www.curran-connors.com

Attachment 2

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MAY , 2001

REGISTRATION NO. 333-

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

THE MEDICINES COMPANY
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE (STATE OF INCORPORATION)	2834 (PRIMARY STANDARD INDUSTRIAL CLASSIFICATION CODE NUMBER)	04-3324394 (I.R.S. EMPLOYER IDENTIFICATION NUMBER)

ONE CAMBRIDGE CENTER
CAMBRIDGE, MASSACHUSETTS 02142
(617) 225-9099
(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER,
INCLUDING AREA CODE, OF REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

CLIVE A. MEANWELL
CHIEF EXECUTIVE OFFICER
THE MEDICINES COMPANY
ONE CAMBRIDGE CENTER
CAMBRIDGE, MASSACHUSETTS 02142
(617) 225-9099
(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER,
INCLUDING AREA CODE, OF AGENT FOR SERVICE)

COPIES TO:

STUART M. FALBER, ESQ.
HALE AND DORR LLP
60 STATE STREET
BOSTON, MASSACHUSETTS 02109
(617) 526-6000

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [X]

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]
If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

TITLE OF SHARES TO BE REGISTERED	AMOUNT TO BE REGISTERED	PROPOSED MAXIMUM OFFERING PRICE PER SHARE(1)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE(1)(2)	AMOUNT OF REGISTRATION FEE(2)(3)
Common Stock, $0.01 par value per share.....	4,000,000	$13.43	$53,720,000	$13,430.00

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act and based upon the average of the high and low prices on the Nasdaq National Market on May 21, 2001.

(2) Calculated pursuant to Rule 457(c) based on an estimate of the proposed maximum aggregate offering price.

(3) Pursuant to Rule 457(p), the full amount of the filing fee due with respect to this registration statement is being paid by applying a portion of the $19,982 filing fee paid in connection with the Registration Statement on Form S-1 filed on January 5, 2001 (File No. 333-53280), which was subsequently withdrawn.

THE COMPANY HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE COMPANY SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), SHALL DETERMINE.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THE SELLING STOCKHOLDERS NAMED IN THIS PROSPECTUS MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE

SECURITIES AND NEITHER WE NOR THE SELLING STOCKHOLDERS NAMED IN THIS PROSPECTUS ARE SOLICITING OFFERS TO BUY THESE SECURITIES IN ANY JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED MAY 22, 2001

COMPANY LOGO

4,000,000 Shares of Common Stock

This prospectus relates to resales of shares of common stock previously issued by The Medicines Company. We will not receive any proceeds from the sale of the shares.

The selling stockholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders may not sell any or all of the shares offered by this prospectus.

Our common stock is traded on the Nasdaq National Market under the symbol "MDCO." On May 21, 2001, the closing sale price of the common stock on Nasdaq was $13.27 per share. You are urged to obtain current market quotations for the common stock.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 5.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is , 2001.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before buying shares of our common stock. You should read the entire prospectus carefully.

THE MEDICINES COMPANY

We acquire, develop and commercialize biopharmaceutical products that are in late stages of development or have been approved for marketing. In December 2000, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for Angiomax, our lead product, for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. Coronary angioplasty is a procedure used to restore normal blood flow in an obstructed artery in the heart. We began selling Angiomax in the United States in January 2001.

We are also developing Angiomax for additional potential applications for use in the treatment of ischemic heart disease, a condition which occurs when organs receive an inadequate supply of oxygen as a result of decreased blood flow. As of May 15, 2001, clinical investigators had administered Angiomax to approximately 13,100 patients in clinical trials for the treatment and prevention of blood clots in a wide range of hospital applications. We believe that Angiomax will become the leading replacement for heparin in hospital care. In the United States, heparin is the most widely-used acute care anticoagulant, a type of drug used to prevent or slow the formation of blood clots, and is used to treat approximately five million hospitalized patients per year.

ANGIOMAX

Angiomax directly blocks or inhibits the actions of thrombin, a key component in the formation and growth of blood clots. By blocking thrombin directly, rather than indirectly like heparin, Angiomax inhibits the actions of thrombin both in the clot and in the blood. Angiomax's inhibition of thrombin is reversible, which means that its thrombin blocking effect wears off over time, allowing thrombin to again work in the clotting process. This reversibility is associated with a reduced risk of bleeding.

In the clinical trials in angioplasty, Angiomax has:

- reduced the frequency of life-threatening coronary events including heart attack and the need for emergency coronary procedures;

- reduced the likelihood of major bleeding and the need for blood transfusion;

- demonstrated a predictable anticoagulant response to a specific Angiomax dose, which enables simplified dosing; and

- been used in combination with glycoprotein IIb/IIIa, also known as GP IIb/IIIa, inhibitors and demonstrated no evidence of significant interactions.

Our development programs are designed to expand the applications of Angiomax for the treatment of ischemic heart disease. As of May 15, 2001, we had:

- a randomized, open-label Phase 3b trial program in angioplasty underway comparing Angiomax to heparin, with and without GP IIb/IIIa inhibitors;

- a 17,000 patient Phase 3 trial program underway studying the use of Angiomax for the treatment of patients who have suffered a heart attack;

- a Phase 3 trial program underway studying the use of Angiomax for the treatment of patients undergoing angioplasty who experience reduced platelet count and clotting due to an allergic, or immunological, reaction to heparin;

- a Phase 2 trial program underway studying the use of Angiomax as an anticoagulant in patients undergoing coronary artery bypass graft surgery without the use of a bypass pump; and

- plans to commence a Phase 3 trial program to evaluate the use of Angiomax in patients with unstable angina, a coronary condition in which patients experience the new onset of severe chest pain, increasingly frequent chest pain or chest pain that occurs while they are at rest.

STRATEGY

Our strategy is to build a commercial biopharmaceutical operation by acquiring, developing and commercializing products in late-stage clinical development, which we refer to as our product candidates, and approved products. We will actively manage the development and commercialization of these product candidates and approved products. We expect our first product, Angiomax, to become the cornerstone product of an acute hospital product franchise that we plan to build. We market Angiomax in the United States using a sales force contracted from Innovex, Inc., which we manage.

We are also focused on specialty anti-infectives and are developing a second product candidate, CTV-05, a proprietary biotherapeutic agent with a potentially broad range of applications in the treatment of gynecological and reproductive infections. We are currently studying CTV-05 in a double-blind placebo controlled Phase 2 trial program examining the safety and effectiveness of the compound as an adjunct to antibiotic therapy in the treatment of bacterial vaginosis, the most common gynecological infection in women of childbearing age. We intend to market CTV-05 and our other products in the United States by supplementing our existing commercial organization, contracting with external organizations, which we would manage, or collaborating with other biopharmaceutical companies.

Our principal objectives include:

- commercializing Angiomax for use in patients with unstable angina undergoing angioplasty;

- developing and commercializing Angiomax as the leading replacement for heparin for use in the hospital treatment of ischemic heart disease;

- acquiring additional products with (1) existing clinical data which provides reasonable evidence of safety and efficacy, (2) an anticipated time to market of four years or less and (3) potential cost savings to payors or improved efficiency of patient care; and

- making the best use of our resources through our relationships with contract development, manufacturing and sales companies.

CORPORATE INFORMATION

The Medicines Company was incorporated in Delaware in July 1996. Our corporate website is located at www.themedicinescompany.com. We do not intend for information found on our website to be incorporated by reference in this prospectus. We own or have rights to various trademarks and trade names used in our business, including The Medicines Company name and logo and Angiomax(R).

Our executive offices are located at One Cambridge Center, Cambridge, Massachusetts 02142, and our telephone number is (617) 225-9099.

THE OFFERING

Common stock offered by selling stockholders.....	4,000,000 shares
Use of proceeds.....	The Medicines Company will not receive any proceeds from the sale of shares in this offering.
Nasdaq National Market Symbol.....	"MDCO"

SUMMARY CONSOLIDATED FINANCIAL DATA

In the table below, we provide you with our summary consolidated financial data. We have prepared this information using our audited consolidated financial statements for the period from July 31, 1996 (date of inception) to December 31, 1996 and for the years ended December 31, 1997, 1998, 1999 and 2000 and our unaudited consolidated financial statements for the three months ended March 31, 2000 and 2001. The pro forma net loss per share data reflects the conversion of our convertible notes and accrued interest, and the conversion of our outstanding convertible preferred stock and accrued dividends into common stock upon the closing of our initial public offering in August 2000. The pro forma balance sheet data as of March 31, 2001 reflect the sale of 4,000,000 shares of common stock on May 16, 2001 at a price of $11.00 per share for net proceeds of approximately $41.8 million. The pro forma net loss per share data and the pro forma balance sheet data do not include the effect of any options or warrants outstanding. The following data should be read in conjunction with our consolidated financial statements, including the accompanying notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	PERIOD FROM INCEPTION (JULY 31, 1996) THROUGH DECEMBER 31, 1996	YEAR ENDED DECEMBER 31, 1997	1998	1999	2000	THREE MONTHS ENDED MARCH 31, 2000	2001
In thousands, except share and per share data							
STATEMENTS OF OPERATIONS DATA							
Net revenue	$ --	$ --	$ --	$ --	$ --	$ --	$ 1,861
Operating expenses:							
Cost of revenues	--	--	--	--	--	--	332
Research and development	827	16,044	24,005	30,345	39,572	10,642	12,595
Selling, general and administrative	702	2,421	6,248	5,008	15,034	1,198	9,059
Total operating expenses	1,529	18,465	30,253	35,353	54,606	11,840	21,986
Loss from operations	(1,529)	(18,465)	(30,253)	(35,353)	(54,606)	(11,840)	(20,125)
Interest income (expense), net	62	659	1,302	640	(16,686)	(7,403)	1,069
Net loss	(1,467)	(17,806)	(28,951)	(34,713)	(71,292)	(19,243)	(19,056)
Dividends and accretion to redemption value of redeemable convertible preferred stock	(118)	(2,018)	(3,959)	(5,893)	(30,343)	(1,530)	--
Net loss attributable to common stockholders	$ (1,585)	$ (19,824)	$ (32,910)	$ (40,606)	$ (101,635)	$ (20,773)	$ (19,056)
Net loss attributable to common stockholders per common share, basic and diluted	$ (2.85)	$ (4.06)	$ (6.03)	$ (80.08)	$ (8.43)	$ (32.91)	$ (0.63)
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	557,178	4,887,230	5,454,653	507,065	12,059,275	631,276	30,247,599
Unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted				$ (1.94)	$ (2.10)	$ (0.55)	$ (0.63)
Shares used in computing unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted				17,799,876	24,719,075	21,407,651	30,247,599

	AS OF MARCH 31, 2001 ACTUAL	PRO FORMA
In thousands		
BALANCE SHEET DATA		
Cash, cash equivalents, marketable securities and accrued interest receivable	$ 60,153	$ 101,956
Working capital	49,670	91,473
Total assets	65,801	107,604
Accumulated deficit	(215,616)	(215,616)
Total stockholders' equity	51,080	92,883

RISK FACTORS

You should carefully consider the following risk factors and all other information contained in this prospectus before purchasing our common stock. Investing in our common stock involves a high degree of risk and you may lose all or part of your investment. Please read "Special Note Regarding Forward-Looking Statements."

RISKS RELATED TO OUR BUSINESS

WE HAVE A HISTORY OF NET LOSSES, AND WE EXPECT TO CONTINUE TO INCUR NET LOSSES AND MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY

We have incurred net losses since our inception, including net losses of approximately $19.1 million for the three months ended March 31, 2001. As of March 31, 2001, we had an accumulated deficit of approximately $215.6 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approval and commercialization of products. As a result, we are unsure when we will become profitable, if at all.

OUR BUSINESS IS VERY DEPENDENT ON THE COMMERCIAL SUCCESS OF ANGIOMAX

Other than Angiomax, our products are in clinical phases of development and, even if approved by the FDA, are a number of years away from entering the market. As a result, Angiomax will account for almost all of our revenues for the foreseeable future. The commercial success of Angiomax will depend upon its acceptance by physicians, patients and other key decision-makers as a therapeutic and cost-effective alternative to heparin and other products used in current practice. If Angiomax is not commercially successful, we will have to find additional sources of revenues or curtail or cease operations.

FAILURE TO RAISE ADDITIONAL FUNDS IN THE FUTURE MAY AFFECT THE DEVELOPMENT, MANUFACTURE AND SALE OF OUR PRODUCTS

Our operations to date have generated substantial and increasing needs for cash. Our negative cash flow from operations is expected to continue into the foreseeable future. The clinical development of Angiomax for additional indications, the development of our other product candidates and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors and may be significantly greater than we expect.

We believe, based on our current operating plan, including anticipated sales of Angiomax, that our cash, cash equivalents and marketable securities as of May 16, 2001 will be sufficient to fund our operations for at least 18 months. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax or otherwise, or if we acquire additional product candidates, we may need to sell additional equity or debt securities. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

WE CANNOT EXPAND THE INDICATIONS FOR ANGIOMAX UNLESS WE RECEIVE FDA APPROVAL FOR EACH ADDITIONAL INDICATION. FAILURE TO EXPAND THESE INDICATIONS WILL LIMIT THE SIZE OF THE COMMERCIAL MARKET FOR ANGIOMAX

We received in December 2000 approval from the FDA of the use of Angiomax as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. One of our key objectives is to expand the indications for which the FDA will approve Angiomax. In order to do this, we will need to conduct additional clinical trials and obtain FDA approval for each proposed indication. If we are unsuccessful in expanding the approved indication for the use of Angiomax, the size of the commercial market for Angiomax will be limited.

FAILURE TO OBTAIN REGULATORY APPROVAL IN FOREIGN JURISDICTIONS WILL PREVENT US FROM MARKETING ANGIOMAX ABROAD

We intend to market our products in international markets, including Europe. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. In February 1998, we submitted a Marketing Authorization Application to the European Agency for the Evaluation of Medicinal Products, or EMEA, for use of Angiomax in unstable angina patients undergoing angioplasty. Following extended interaction with European regulatory authorities, the Committee of Proprietary Medicinal Products of the EMEA voted in October 1999 not to recommend Angiomax for approval in angioplasty. The United Kingdom and Ireland dissented from this decision. We have withdrawn our application to the EMEA and are in active dialog with European regulators to determine our course of action. We may not be able to obtain approval from any or all of the jurisdictions in which we seek approval to market Angiomax. Obtaining foreign approvals may require additional trials and additional expense.

THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS MAY BE TERMINATED OR DELAYED, AND THE COSTS OF DEVELOPMENT AND COMMERCIALIZATION MAY INCREASE, IF THIRD PARTIES WHO WE RELY ON TO MANUFACTURE AND SUPPORT THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS DO NOT FULFILL THEIR OBLIGATIONS

Our development and commercialization strategy entails entering into arrangements with corporate and academic collaborators, contract research organizations, contract sales organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage our clinical trials and manufacture, market and sell our products. Although we manage these services, we do not have the expertise or the resources to conduct such activities on our own and, as a result, are particularly dependent on third parties in most areas.

We may not be able to maintain our existing arrangements with respect to the commercialization of Angiomax or establish and maintain arrangements to develop and commercialize any additional products on terms that are acceptable to us. Any current or future arrangements for the development and commercialization of our products may not be successful. If we are not able to establish or maintain our agreements relating to Angiomax or any additional products on terms which we deem favorable, our financial condition would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products may not be within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive. If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely manner, such breach, termination or failure could:

- delay the development or commercialization of Angiomax, our other product candidates or any additional product candidates that we may acquire or develop;

- require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

- result in the termination of the development or commercialization of our products.

WE ARE CURRENTLY DEPENDENT ON A SINGLE SUPPLIER FOR THE PRODUCTION OF ANGIOMAX BULK DRUG SUBSTANCE AND A DIFFERENT SINGLE SUPPLIER TO CARRY OUT ALL FILL-FINISH ACTIVITIES FOR ANGIOMAX

Currently, we obtain all of our Angiomax bulk drug substance from one manufacturer, UCB Bioproducts S.A., and rely on another manufacturer, Ben Venue Laboratories, Inc., to carry out all fill-finish activities for Angiomax, which includes final formulation and transfer of the drug into vials where it is then freeze-dried and sealed. The FDA requires that all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's current Good Manufacturing Practice, or cGMP, regulations and guidelines. There are a limited number of manufacturers that operate under cGMP regulations

capable of manufacturing Angiomax. The FDA has inspected Ben Venue Laboratories for cGMP compliance for the manufacture of Angiomax and UCB Bioproducts for cGMP compliance in the manufacture of pharmaceutical ingredients generally. Ben Venue Laboratories and UCB Bioproducts have informed us that they have no material deficiencies in cGMP compliance. We do not currently have alternative sources for production of Angiomax bulk drug substance or to carry out fill-finish activities. In the event that either of our current manufacturers is unable to carry out its respective manufacturing obligations to our satisfaction, we may be unable to obtain alternative manufacturing, or obtain such manufacturing on commercially reasonable terms or on a timely basis.

Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Angiomax on a timely basis and supply product for clinical trials of Angiomax.

IF WE DO NOT SUCCEED IN DEVELOPING A SECOND GENERATION PROCESS FOR THE PRODUCTION OF BULK ANGIOMAX DRUG SUBSTANCE, OUR GROSS MARGINS MAY BE BELOW INDUSTRY AVERAGES

We are currently developing with UCB Bioproducts a second generation process for the production of bulk Angiomax drug substance. This process involves limited changes to the early manufacturing steps of our current process in order to improve our gross margins on the future sales of Angiomax. If we cannot develop the process successfully or regulatory approval of the process is not obtained or is delayed, then our ability to improve our gross margins on future sales of Angiomax may be limited.

CLINICAL TRIALS OF OUR PRODUCT CANDIDATES ARE EXPENSIVE AND TIME CONSUMING, AND THE RESULTS OF THESE TRIALS ARE UNCERTAIN

Before we can obtain regulatory approvals for the commercial sale of any product which we wish to develop, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product. We are currently conducting four clinical trials of Angiomax for use in the treatment of ischemic heart disease. There are numerous factors which could delay our clinical trials or prevent us from completing these trials successfully. We, or the FDA, may suspend a clinical trial at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient population targeted by some of our clinical trials may be small. Delays in future planned patient enrollment may result in increased costs and program delays.

In addition, clinical trials, if completed, may not show any potential product to be safe or effective. Results obtained in pre-clinical studies or early clinical trials are not always indicative of results that will be obtained in later clinical trials. Moreover, data obtained from pre-clinical studies and clinical trials may be subject to varying interpretations. As a result, the FDA or other applicable regulatory authorities may not approve a product in a timely fashion, or at all.

OUR FAILURE TO ACQUIRE AND DEVELOP ADDITIONAL PRODUCT CANDIDATES OR APPROVED PRODUCTS WILL IMPAIR OUR ABILITY TO GROW

As part of our growth strategy, we intend to acquire and develop additional pharmaceutical product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire pharmaceutical products in late-stage development or that have been approved that meet the criteria we have established. Because we do not have, nor intend to establish, internal scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us.

Identifying suitable product candidates and approved products and proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. In addition, other companies,

including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

IF WE BREACH ANY OF THE AGREEMENTS UNDER WHICH WE LICENSE COMMERCIALIZATION RIGHTS TO PRODUCTS OR TECHNOLOGY FROM OTHERS, WE COULD LOSE LICENSE RIGHTS THAT ARE IMPORTANT TO OUR BUSINESS

We license commercialization rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we acquired our first three products through exclusive licensing arrangements. See "Business -- License Agreements" for a description of the terms of these licenses. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. In addition, upon the termination of the license we may be required to license to the licensor the intellectual property that we developed.

OUR ABILITY TO MANAGE OUR BUSINESS EFFECTIVELY COULD BE HAMPERED IF WE ARE UNABLE TO ATTRACT AND RETAIN KEY PERSONNEL AND CONSULTANTS

The biopharmaceutical industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our chief executive officer, Dr. Clive A. Meanwell, or other key employees or consultants, our business and operating results could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in the biotechnology industry with the breadth of skills and experience required to develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

WE FACE SUBSTANTIAL COMPETITION, WHICH MAY RESULT IN OTHERS DISCOVERING, DEVELOPING OR COMMERCIALIZING COMPETING PRODUCTS BEFORE OR MORE SUCCESSFULLY THAN WE DO

The biopharmaceutical industry is highly competitive. Our success will depend on our ability to develop products and apply technology and our ability to establish and maintain a market for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources than we do. Accordingly, our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that have been competing or are being developed by us or may obtain FDA approval for products more rapidly than we are able. Technological development by others may render our products or product candidates noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

BECAUSE THE MARKET FOR THROMBIN INHIBITORS IS COMPETITIVE, OUR PRODUCT MAY NOT OBTAIN WIDESPREAD USE

We are positioning Angiomax as a replacement to heparin, which is widely-used and inexpensive, for use in patients with ischemic heart disease. Because heparin is inexpensive and has been widely used for many years, medical decision-makers may be hesitant to adopt our alternative treatment. In addition, due to the high incidence and severity of cardiovascular diseases, the market for thrombin inhibitors is large and competition is intense and growing. There are a number of thrombin inhibitors currently on the market, awaiting regulatory approval and in development, including orally administered agents.

THE LIMITED RESOURCES OF THIRD-PARTY PAYORS MAY LIMIT THE USE OF OUR PRODUCTS

In general, anticoagulant drugs may be classified in three groups: drugs that directly or indirectly target and inhibit thrombin, drugs that target and inhibit platelets and drugs that break down fibrin. Because each group of anticoagulants acts on different components of the clotting process, we believe that there will be continued clinical work to determine the best combination of drugs for clinical use. We expect Angiomax to be used with aspirin alone or in conjunction with other therapies. Although we do not plan to position Angiomax as a direct competitor to platelet inhibitors or fibrinolytic drugs, platelet inhibitors and fibrinolytic drugs may compete with Angiomax for the use of hospital financial resources. Many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. Because this amount is not based on the actual expenses the hospital incurs, U.S. hospitals may have to choose among Angiomax, platelet inhibitors and fibrinolytic drugs.

FLUCTUATIONS IN OUR OPERATING RESULTS COULD AFFECT THE PRICE OF OUR COMMON STOCK

Our operating results may vary from period to period based on the amount and timing of sales of Angiomax to customers in the United States, the availability and timely delivery of a sufficient supply of Angiomax, the timing and expenses of clinical trials, the availability and timing of third-party reimbursement and the timing of approval for our product candidates. If our operating results do not match the expectations of securities analysts and investors as a result of these and other factors, the trading price of our common stock may fluctuate.

RISKS RELATED TO OUR INDUSTRY

IF WE DO NOT OBTAIN FDA APPROVALS FOR OUR PRODUCTS OR COMPLY WITH GOVERNMENT REGULATIONS, WE MAY NOT BE ABLE TO MARKET OUR PRODUCTS AND MAY BE SUBJECT TO STRINGENT PENALTIES

Except for Angiomax, which has been approved for sale in the United States and New Zealand, we do not have a product approved for sale in the United States or any foreign market. We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. We must successfully complete our clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell our products. The FDA could require us to repeat clinical trials as part of the regulatory review process. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of our product candidates;

- diminish our competitive advantage; and

- defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical data, clinical data and supporting information must be submitted to the FDA for each additional indication to obtain such approvals, and we cannot be certain when we will receive these regulatory approvals, if ever.

In addition to initial regulatory approval, our products and product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation, as we discuss in more detail in "Business -- Government Regulation." Any approvals, once obtained, may be withdrawn if compliance with regulatory requirements is not maintained or safety problems are identified. Failure to comply with these requirements may also subject us to stringent penalties.

WE MAY NOT BE ABLE TO OBTAIN OR MAINTAIN PATENT PROTECTION FOR OUR PRODUCTS, AND WE MAY INFRINGE THE PATENT RIGHTS OF OTHERS

The patent positions of pharmaceutical and biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

- obtain patents;

- protect trade secrets;

- operate without infringing the proprietary rights of others; and

- prevent others from infringing our proprietary rights.

We may not have any patents issued from any patent applications that we own or license. If patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States are maintained in secrecy until patents issue, others may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications. In all, as of May 15, 2001 we exclusively licensed 10 issued United States patents and a broadly filed portfolio of corresponding foreign patents and patent applications. We have not yet filed any independent patent applications.

We may not hold proprietary rights to some patents related to our product candidates. In some cases, others may own or control these patents. As a result, we may be required to obtain licenses under third-party patents to market some of our product candidates. If licenses are not available to us on acceptable terms, we will not be able to market these products.

We may become a party to patent litigation or other proceedings regarding intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. If any patent litigation or other intellectual property proceeding in which we are involved is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products and services without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms, or at all.

IF WE ARE NOT ABLE TO KEEP OUR TRADE SECRETS CONFIDENTIAL, OUR TECHNOLOGY AND INFORMATION MAY BE USED BY OTHERS TO COMPETE AGAINST US

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements. In addition, our competitors may learn or independently develop our trade secrets.

WE COULD BE EXPOSED TO SIGNIFICANT LIABILITY CLAIMS IF WE ARE UNABLE TO OBTAIN INSURANCE AT ACCEPTABLE COSTS AND ADEQUATE LEVELS OR OTHERWISE PROTECT OURSELVES AGAINST POTENTIAL PRODUCT LIABILITY CLAIMS

Our business exposes us to potential product liability risks which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise possess regulatory approval for commercial sale.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. As of May 15, 2001, we were covered, with respect to our commercial sales in the United States and New Zealand and our clinical trials, by primary product liability

insurance in the amount of $20.0 million per occurrence and $20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover any product liability claims. As we commercialize our products, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

RISKS RELATING TO THE OFFERING

OUR STOCK PRICE HAS BEEN VOLATILE, WHICH COULD RESULT IN SUBSTANTIAL LOSSES FOR INVESTORS PURCHASING SHARES IN THIS OFFERING

The market price of our common stock, like that of the common stock of many other biotechnology companies, has been and may continue to be highly volatile. The stock market has experienced extreme price and volume fluctuations. This volatility has significantly affected the market prices of securities of many biotechnology and pharmaceutical companies for reasons frequently unrelated, or disproportionate, to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. Factors that may have a significant effect on the market price of our common stock include announcements of technological innovations or new commercial products by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, developments in patent or other proprietary rights, including as a result of any public policy concerns and public concern as to the safety of products developed by us.

OUR OFFICERS AND DIRECTORS, AND CERTAIN ENTITIES WITH WHICH THEY ARE AFFILIATED, MAY BE ABLE TO CONTROL THE OUTCOME OF MOST CORPORATE ACTIONS REQUIRING STOCKHOLDER APPROVAL

Following the completion of the private placement of 4,000,000 shares of our common stock on May 16, 2001, our directors and executive officers, and certain entities with which they are affiliated, beneficially owned, in the aggregate, approximately 61.0% of our outstanding common stock. Due to this concentration of ownership, these stockholders as a group will be able to elect the directors and officers of our company, control the management and affairs of our company and control most matters requiring a stockholder vote, including:

- the amendment of our organizational documents; or

- the approval of any merger, consolidation, sale or assets or other major corporate transaction.

WE HAVE ANTI-TAKEOVER DEFENSES THAT COULD DELAY OR PREVENT AN ACQUISITION AND COULD ADVERSELY AFFECT THE PRICE OF OUR COMMON STOCK

Provisions of our certificate of incorporation and bylaws and of Delaware law could have the effect of delaying, deferring or preventing an acquisition of our company. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock, our stockholders may not take actions by written consent and may not call special meetings of stockholders, and our stockholders are limited in their ability to introduce proposals at stockholder meetings.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading "Risk Factors", that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares offered pursuant to this prospectus.

The selling stockholders will pay any expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares covered by this prospectus. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees and fees and expenses of our counsel and our accountants.

SELLING STOCKHOLDERS

We issued the shares of common stock covered by this prospectus in a private placement on May 16, 2001. The following table sets forth, to our knowledge, certain information about the selling stockholders as of May 16, 2001.

We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders may not sell any or all of the shares offered by this prospectus. Because the selling stockholders may sell all or some of the shares offered by this prospectus, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of shares that will be held by the selling stockholders after completion of the offering. For purposes of this table, however, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders.

Beneficial ownership is determined in accordance with the rules of Securities and Exchange Commission, or the SEC, and includes voting or investment power with respect to shares. Shares of common stock issuable upon exercise of warrants and/or stock options that are exercisable within 60 days after May 16, 2001 are deemed outstanding for computing the percentage ownership of the person holding the warrants and/or options but are not deemed outstanding for computing the percentage ownership of any other person. Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

NAME OF SELLING STOCKHOLDER(1)	SHARES OF COMMON STOCK BENEFICIALLY OWNED PRIOR TO OFFERING		NUMBER OF SHARES OF COMMON STOCK BEING OFFERED	SHARES OF COMMON STOCK TO BE BENEFICIALLY OWNED AFTER OFFERING	
	NUMBER	PERCENTAGE		NUMBER	PERCENTAGE
Warburg, Pincus Ventures, L.P.(2)	10,655,256	29.9%	1,050,000	9,605,256	26.9%
T. Rowe Price New Horizons Fund, Inc.	425,000	1.2%	425,000	--	--
T. Rowe Price Health Sciences Fund, Inc.	400,000	1.2%	400,000	--	--
Deerfield Partners, L.P.	353,000	1.0%	353,000	--	--
Alta BioPharma Partners, L.P.(3)	1,604,581	4.6%	279,714	1,324,867	3.8%
PharmaBio Development Inc.(4)	2,178,630	6.3%	200,000	1,978,630	5.7%
Green Line Health Sciences Fund	161,400	*	161,400	--	--
The Medicines Company Chase Partners (Alta Bio), L.L.C.(5)	916,367	2.7%	159,743	756,624	2.2%
Deerfield International, LTD	147,000	*	147,000	--	--
BayStar Capital, L.P.	105,000	*	105,000	--	--
S.A.C. Capital Associates, L.L.C.	100,000	*	100,000	--	--
Chelsey Capital	100,000	*	100,000	--	--
Sands Point Partners	100,000	*	100,000	--	--
Orion Biomedical Fund, L.P.	82,150	*	82,150	--	--

NAME OF SELLING STOCKHOLDER(1)	SHARES OF COMMON STOCK BENEFICIALLY OWNED PRIOR TO OFFERING		NUMBER OF SHARES OF COMMON STOCK BEING OFFERED	SHARES OF COMMON STOCK TO BE BENEFICIALLY OWNED AFTER OFFERING	
	NUMBER	PERCENTAGE		NUMBER	PERCENTAGE
MAM Luxembourg	79,800	*	79,800	--	--
Mercury Master Trust	70,800	*	70,800	--	--
MPM BioEquities Master Fund, L.P.	108,500	*	50,000	58,500	*
BayStar International, LTD	35,000	*	35,000	--	--
MAM Main A/C	24,400	*	24,400	--	--
Orion BioMedical Offshore Fund, L.P.	17,850	*	17,850	--	--
Alta Embarcadero BioPharma Partners, L.L.C(6)	60,477	*	10,543	49,934	*
Jay Silverman	10,000	*	10,000	--	--
Clive A. Meanwell(7)(8)	770,273	2.2%	10,000	760,273	2.2%
T. Rowe Price Health Services Fund	10,000	*	10,000	--	--
Glenn Sblendorio(7)(9)	51,982	*	5,000	46,982	
Gary Dickinson(7)	5,000	*	5,000	--	*
T. Scott Johnson(10)	109,823	*	5,000	104,823	*
Manufacturers Investment Trust -- Health Sciences Trust	2,000	*	2,000	--	--
T. Rowe Price Health Sciences Portfolio, Inc	1,600	*	1,600	1,600	--

* Less than one percent.

(1) The term "selling stockholders" includes donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other non-sale related transfer.

(2) Includes warrants to purchase 1,275,810 shares of common stock.

(3) Includes warrants to purchase 178,987 shares of common stock.

(4) Includes warrants to purchase 282,385 shares of common stock.

(5) Includes warrants to purchase 102,218 shares of common stock.

(6) Includes warrants to purchase 6,746 shares of common stock.

(7) Employee of The Medicines Company.

(8) Includes 221,580 shares issuable upon exercise of stock options and warrants prior to July 15, 2001.

(9) Includes 45,982 shares issuable upon exercise of stock options prior to July 15, 2001.

(10) Includes warrants to purchase 13,744 shares of common stock.

None of the selling stockholders has held any position or office with, or has otherwise had a material relationship with, us or any of our subsidiaries within the past three years, except that:

- the selling stockholders indicated have been employed by us; and

- T. Scott Johnson serves as one of our directors.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock has been quoted on the Nasdaq National Market under the symbol "MDCO" since August 8, 2000. The following table sets forth, for the periods indicated, the high and low intraday sales prices per share of our common stock as reported on the Nasdaq National Market.

	HIGH	LOW
2000		
Third Quarter (since August 7, 2000)	$35.38	$16.50
Fourth Quarter	$34.75	$17.13
2001		
First Quarter	$20.48	$ 8.75
Second Quarter (through May 21, 2001)	$15.18	$ 9.10

On May 21, 2001, the last reported sale price of our common stock on the Nasdaq National Market was $13.27 per share. As of the close of business on May 15, 2001, we had 127 holders of record of our common stock.

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

CAPITALIZATION

The following table summarizes as of March 31, 2001 our cash, cash equivalents, marketable securities and accrued interest receivable and our capitalization:

- on an actual basis; and

- on a pro forma basis to give effect to the sale of 4,000,000 shares of common stock on May 16, 2001 at a price of $11.00 per share and the receipt of net proceeds of approximately $41.8 million from the sale of the shares.

This table does not include:

- 3,287,175 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2001 at a weighted average exercise price of $9.74 per share or any stock options issued subsequent to March 31, 2001;

- 3,269,564 shares of common stock issuable upon exercise of common stock purchase warrants outstanding as of March 31, 2001 at an exercise price of $5.92 per share; or

- 1,274,384 additional shares of common stock that we could issue under our stock plans as of March 31, 2001 or any additional shares available for grants subsequent to March 31, 2001 under our stock plans.

This table should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and accompanying notes appearing elsewhere in this prospectus.

	MARCH 31, 2001	
	ACTUAL	PRO FORMA
In thousands, except share data		
Cash, cash equivalents, marketable securities and accrued interest receivable	$ 60,153	$ 101,956
Preferred stock, $1.00 par value, 5,000,000 shares authorized; none issued actual and pro forma	--	--
Stockholders' equity:		
Common Stock, $0.001 par value, 75,000,000 shares authorized at March 31, 2001, actual and pro forma; 30,391,948 shares issued and outstanding at March 31, 2001, actual and 34,391,948 shares issued and outstanding, pro forma	30	34
Additional paid-in capital	279,298	321,097
Deferred stock compensation	(12,235)	(12,235)
Accumulated deficit	(215,616)	(215,616)
Accumulated other comprehensive income, principally foreign currency translation	(397)	(397)
Total stockholders' equity	51,080	92,883
Total capitalization	$ 51,080	$ 92,883

DILUTION

This offering is for sales of stock by our existing stockholders on a continuous or delayed basis in the future. Sales of common stock by stockholders will not result in a change to the net tangible book value per share before and after the distribution of shares by the selling stockholders. There will be no change in net tangible book value per share attributable to cash payments made by purchasers of the shares being offered. Prospective investors should be aware, however, that the market price of our shares may not bear any rational relationship to net tangible book value per share.

SELECTED CONSOLIDATED FINANCIAL DATA

In the table below, we provide you with our selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the period from July 31, 1996 (date of inception) to December 31, 1996 and for the years ended December 31, 1997, 1998, 1999 and 2000 and our unaudited consolidated financial statements for the three months ended March 31, 2000 and 2001. The consolidated financial statements for each of the three years in the period ended December 31, 2000 which are included in this prospectus have been audited by Ernst & Young LLP, independent auditors. The consolidated statements of operations data for the three months ended March 31, 2000 and 2001 and the consolidated balance sheet data as of March 31, 2001 have been derived from our unaudited consolidated financial statements that appear elsewhere in this prospectus. The unaudited consolidated financial statements include all adjustments, consisting of normal recurring accruals, which we consider necessary for a fair presentation of the financial position and the results of operations for these periods. Operating results for the three months ended March 31, 2001 are not necessarily indicative of results that may be expected for the full year.

The pro forma net loss per share data reflects the conversion of our convertible notes and accrued interest and the conversion of our outstanding convertible preferred stock and accrued dividends into common stock upon the closing of our initial public offering in August 2000. The pro forma net loss per share data does not include the effect of any options or warrants outstanding.

The following data should be read in conjunction with our consolidated financial statements, including the accompanying notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	PERIOD FROM INCEPTION (JULY 31, 1996) THROUGH DECEMBER 31,	YEAR ENDED DECEMBER 31,				THREE MONTHS ENDED MARCH 31,	
	1996	1997	1998	1999	2000	2000	2001
In thousands, except share and per share data							
STATEMENTS OF OPERATIONS DATA							
Net revenue	$ --	$ --	$ --	$ --	$ --	$ --	$ 1,861
Operating expenses							
Cost of revenues	--	--	--	--	--	--	332
Research and development	827	16,044	24,005	30,345	39,572	10,642	12,595
Selling, general and administrative	702	2,421	6,248	5,008	15,034	1,198	9,059
Total operating expenses	1,529	18,465	30,253	35,353	54,606	11,840	21,986
Loss from operations	(1,529)	(18,465)	(30,253)	(35,353)	(54,606)	(11,840)	(20,125)
Interest income (expense), net	62	659	1,302	640	(16,686)	(7,403)	1,069
Net loss	(1,467)	(17,806)	(28,951)	(34,713)	(71,292)	(19,243)	(19,056)
Dividends and accretion to redemption value of redeemable convertible preferred stock	(118)	(2,018)	(3,959)	(5,893)	(30,343)	(1,530)	--
Net loss attributable to common stockholders	$ (1,585	$ (19,824)	$ (32,910)	$ (40,606)	$ (101,635)	$ (20,773)	$ (19,056)
Net loss attributable to common stockholders per common share, basic and diluted	$ (2.85)	$ (4.06)	$ (6.03)	$ (80.08)	$ (8.43)	$ (32.91)	$ (0.63)
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	557,178	4,887,230	5,454,653	507,065	12,059,275	631,276	30,247,599
Unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted				$ (1.94)	$ (2.10)	$ (0.55)	$ (0.63)
Shares used in computing unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted				17,799,876	24,719,075	21,407,651	30,247,599

In thousands	AS OF DECEMBER 31, 1996	1997	1998	1999	2000	AS OF MARCH 31, 2001
BALANCE SHEET DATA						
Cash, cash equivalents, marketable securities and accrued interest receivable	$ 3,421	$ 25,416	$ 29,086	$ 7,238	$ 80,718	$ 60,153
Working capital (deficit)	3,174	18,779	24,570	(4,103)	68,023	49,670
Total assets	3,473	25,595	29,831	7,991	84,363	65,801
Convertible notes	--	--	--	5,776	--	--
Redeemable convertible preferred stock	4,793	40,306	79,384	85,277	--	--
Accumulated deficit	(1,585)	(21,409)	(54,319)	(94,925)	(196,560)	(215,616)
Total stockholders' (deficit) equity	(1,582)	(21,387)	(54,266)	(94,558)	69,239	51,080

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read with "Selected Consolidated Financial Data" and our consolidated financial statements and notes included elsewhere in this prospectus.

OVERVIEW

We acquire, develop and commercialize biopharmaceutical products that are in late stages of development or have been approved for marketing. In December 2000, we received marketing approval from the FDA for Angiomax, our lead product, for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. Coronary angioplasty is a procedure used to restore normal blood flow in an obstructed artery in the heart. We began selling Angiomax in the United States in January 2001. In August and September 2000, we consummated our initial public offering resulting in $101.4 million in net proceeds.

Since our inception, we have incurred significant losses. Most of our expenditures to date have been for research and development activities, selling, general and administrative expenses. Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. We generally outsource our clinical and manufacturing development activities to independent organizations to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with product marketing activities. Interest expense consists of costs associated with convertible notes which were issued in 2000 and 1999 to fund our business activities.

We expect to continue to incur operating losses during the balance of fiscal 2001 and for the foreseeable future as a result of research and development activities attributable to new and existing products and costs associated with the commercialization and launch of our products. In 2001, we expect increased cash outlays for research and development costs associated with our ongoing clinical trials and manufacturing development activities. We also expect increased outlays during 2001 for sales, general and administrative costs related to selling and marketing activities of Angiomax, our lead product. We will need to generate significant revenues to achieve and maintain profitability. During the first quarter of 2001, we recorded revenue for the initial shipments of Angiomax.

In March 1997, we acquired exclusive worldwide commercial rights from Biogen, Inc., to the technology, patents, trademarks, inventories, know-how and all regulatory and clinical information related to Angiomax. Under the Biogen license, we paid $2.0 million upon execution of the license agreement and are obligated to pay up to an additional $8.0 million upon reaching certain milestones, including the first sale of Angiomax for certain indications. In addition, we will pay royalties on future sales of Angiomax and on any sublicense royalties earned.

In August 1999, we acquired exclusive worldwide rights from GyneLogix, Inc. to the patents and know-how related to the biotherapeutic agent CTV-05. Under the GyneLogix license, we have paid $400,000 and are obligated to pay up to an additional $100,000 upon reaching certain development and regulatory milestones and to fund agreed-upon operational costs of GyneLogix related to the development of CTV-05 on a monthly basis subject to a limitation of $50,000 per month. In addition, we will pay royalties on future sales of CTV-05 and on any sublicense royalties earned.

In July 1998, we acquired from Immunotech S.A., a wholly-owned subsidiary of Beckman Coulter, Inc., exclusive worldwide rights to IS-159, which is under clinical investigation for the treatment of acute migraine headache. Under the Immunotech license, we paid $1.0 million upon execution of the license agreement and are obligated to pay up to an additional $4.5 million upon reaching certain development and regulatory milestones. In addition, we will pay royalties on future sales of IS-159 and on any sublicense royalties earned. We are seeking a collaborator to develop IS-159 and do not intend to initiate further studies of IS-159 until we enter into a collaborative agreement.

During the three months ended March 31, 2000, we recorded deferred stock compensation on the grant of stock options of approximately $3.9 million, representing the difference between the exercise price of such options and the fair market value of our common stock at the date of grant of such options. The exercise prices of these options were below the estimated fair market value of our common stock as of the date of grant based on the estimated initial public offering price of our common stock.

We amortize deferred stock compensation over the respective vesting periods of the individual stock options. We recorded amortization expense for deferred compensation of approximately $1.1 million and $150,000 for the three months ended March 31, 2001 and 2000, respectively. We expect to record amortization expense for the deferred compensation as follows: approximately $3.1 million for the remainder of 2001, approximately $3.9 million for 2002, approximately $3.9 million for 2003 and approximately $1.4 million for 2004.

We have not generated taxable income to date. At December 31, 2000, net operating losses available to offset future taxable income for federal income tax purposes were approximately $122.2 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2011 and ending 2020. We have not recognized the potential tax benefit of our net operating losses in our statements of operations. The future utilization of our net operating loss carryforwards may be limited pursuant to regulations promulgated under the U.S. Internal Revenue Code of 1986, as amended.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2001 and 2000

Product Revenue. With the commercial launch of the Company's lead product, Angiomax, in January 2001, the Company reported product revenue of $1.9 million for the three months ended March 31, 2001. The Company had not reported revenue prior to this time.

Cost of Revenue. Cost of revenue for the three months ended March 31, 2001 was $332,000, or 18% as a percentage of product revenue. Cost of revenue includes cost of manufacturing Angiomax, logistical costs associated with distributing Angiomax, and accrued royalties. The cost of manufacturing as a percentage of product revenue was low in the first quarter of 2001 and is expected to continue to run at, or near, this level through most of 2001 because cost associated with the manufacture of Angiomax incurred by the Company prior to date of FDA approval of Angiomax in December 2000 was expensed as research and development expense.

Research and Development Expenses. Research and development expenses increased 18% to $12.6 million for the three months ended March 31, 2000, from $10.6 million for the three months ended March 31, 2000. The increase in research and development expenses of $2.0 million was primarily due to increased enrollment rates of the Company's Phase 3 clinical trial of Angiomax in acute myocardial infraction, called HERO-2, and our Phase 3b trial of Angiomax in angioplasty, called REPLACE. Also contributing to the increase was the manufacture of Angiomax bulk product produced using the Chemilog process, which we will continue to expense as research and development until the process is approved by the FDA. The increase in research and development expenses was partly offset by a reduction in manufacturing development expenses given the receipt of the first batch of pre-FDA approved Angiomax bulk drug substance manufactured by UCB Bioproducts during the first quarter of 2000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased 656% to $9.1 million for the three months ended March 31, 2001, from $1.2 million for the three months ended March 31, 2000. The increase in selling, general and administrative expenses of $7.9 million was primarily due to an increase in marketing and selling expenses and corporate infrastructure costs arising from an increase in activity relating to the commercial launch of Angiomax during the three months ended March 31, 2001.

Interest Income and Interest Expense. Interest income increased 930% to $1.1 million for the three months ended March 31, 2001, from $104,000 for the three months ended March 31, 2000. The increase in

interest income of $965,000 was primarily due to interest income arising from investment of the proceeds of the Company's IPO in August 2000.

Interest expense was $7.5 million for the three months ended March 31, 2000 and related to interest charges and amortization of discount on our convertible notes issued in October 1999 and March 2000.

Years Ended December 31, 2000 and 1999

Research and Development Expenses. Research and development expenses increased 30% from $30.3 million in 1999 to $39.6 million in 2000. The increase of $9.3 million was primarily due to the increased enrollment rate of our Phase 3 clinical trial in AMI, called HERO-2 during 2000, initiation in 2000 of a Phase 3b trial in angioplasty called REPLACE and by the recognition of $12.2 million of research and development costs in connection with the completion of UCB Bioproduct's manufacture of Angiomax bulk drug substance prior to FDA approval. The increase in costs was partly offset by reduced development expenses reflecting our termination of the semilog manufacturing development program with Lonza AG in the fourth quarter of 1999 and a reduction in development activity for IS-159 in 2000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased 200% from $5.0 million in 1999 to $15.0 million in 2000. The increase of $10.0 million was primarily due to an increase in marketing and selling expenses and corporate infrastructure costs arising from an increase in activity in preparation for the commercial launch of Angiomax.

Interest Income and Interest Expense. Interest income increased 223% from $838,000 in 1999 to $2.7 million in 2000. The increase of $1.9 million was primarily due to interest income arising from investment of the proceeds of our initial public offering.

Interest expense was $19.4 million in 2000 and was related to interest charges and the amortization of the discount on our convertible notes issued in October 1999 and March 2000. The notes were converted into series IV convertible preferred stock in May 2000, accelerating the remaining unamortized discount.

Years Ended December 31, 1999 and 1998

Research and Development Expenses. Research and development expenses increased 26% from $24.0 million in 1998 to $30.3 million in 1999. The increase of $6.3 million was due to the expansion in 1999 of our clinical development programs, primarily those relating to our Angiomax HERO-2 Phase 3 clinical trial in AMI which commenced in late 1998, our IS-159 development program and our Angiomax trials in angioplasty.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased 20% from $6.2 million in 1998 to $5.0 million in 1999. The decrease of $1.2 million was primarily due to a decrease in Angiomax-related marketing expenses.

Interest Income and Interest Expense. Interest income decreased 36% from $1.3 million in 1998 to $838,000 in 1999 due to a lower level of cash and marketable securities available for investment during 1999 as compared to 1998. Interest expense was $197,000 in 1999 and related to interest expense and amortization of the discount on our convertible notes issued in the aggregate principal amount of $6.0 million in October 1999.

LIQUIDITY AND CAPITAL RESOURCES

On May 16, 2001, we received approximately $41.8 million in net proceeds from the sale of shares of common stock in a private placement to new and existing investors.

As of March 31, 2001, we had $59.0 million in cash, cash equivalents and marketable securities, as compared to $79.3 million as of December 31, 2000.

For the three months ended March 31, 2001, we used net cash of $20.0 million in operating activities. This consisted of a net loss of $19.1 million, combined with a decrease in accounts payable of $2.3 million and an increase in accounts receivable of $1.8 million, partly offset by an increase in accrued expenses of $1.9 million, and non-cash amortization of deferred compensation of $1.1 million. We generated approximately

$9.4 million of cash from net investing activities, which consisted principally of the maturity or sale of marketable securities, partly offset by the purchase of fixed assets of $95,000. We received $171,000 from financing activities, primarily from purchases of stock by employees.

In August and September 2000, we received $101.4 million in net proceeds from the sale of common stock in our initial public offering, or IPO, at a price of $16.00 per share. Prior to the IPO, we had received net proceeds of $79.4 million from the private placement of equity securities, primarily redeemable convertible preferred stock, and $19.4 million from the issuance of convertible notes and warrants.

As of December 31, 2000, we had $79.3 million in cash, cash equivalents and marketable securities, as compared to $7.2 million and $28.3 million as of December 31, 1999 and 1998, respectively.

During 2000, we used net cash of $48.1 million in operating activities. This consisted of a net loss for the period of $71.3 million, combined with a decrease in accounts payable of $1.8 million, an increase in inventory of $2.0 million and an increase in accrued interest receivable of $1.3 million, partly offset by an increase in accrued expenses of $5.7 million, non-cash amortization of discount on convertible notes of $19.0 million and deferred compensation of $3.7 million. We spent $42.8 million for investing activities, which consisted principally of purchases of marketable securities with net proceeds from our initial public offering. We received $121.1 million from financing activities, primarily from our initial public offering, which resulted in net proceeds of $101.4 million, and from the issuance of convertible notes and preferred stock, which resulted in proceeds of $19.4 million during 2000.

During 1999, we placed an order with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Manufacture of $14.2 million of this material was completed in 2000, of which $12.2 million was expensed during that period. All costs associated with the manufacture of Angiomax bulk drug product and finished products to which title has transferred to us prior to the date of FDA approval of Angiomax were expensed as research and development. We recorded Angiomax bulk drug product to which we took title after the date of FDA approval of Angiomax as inventory, which will increase our cost of sales in 2001 and possibly the following year. In November 2000, we placed additional orders with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Under the terms of these purchase orders, we are scheduled to take title to material and become obligated to make payments totaling approximately $24.0 million in 2001 and early 2002.

As of December 31, 2000, we had net operating loss carryforwards of approximately $122.2 million, to offset future federal taxable income expiring in 2011 through 2020 and approximately $116.0 million to offset future state taxable income expiring in 2001 through 2004. Due to the degree of uncertainty related to the ultimate realization of such net operating losses, no benefit has been recognized in the financial statements as of December 31, 2000. If we achieve profitability, such tax benefits would be recognized when their realization was considered more likely than not. Our ability to utilize these losses in future years, however, may be subject to limitation based upon changes in ownership under the rules of the Internal Revenue Code.

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with the commercialization of our products. Our funding requirements will depend on numerous factors, including whether Angiomax is commercially successful, the progress, level and timing of our research and development activities, the cost and outcomes of regulatory reviews, the continuation or termination of third party manufacturing or sales and marketing arrangements, the cost and effectiveness of our sales and marketing programs, the status of competitive products, our ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

We believe, based on our current operating plan, including anticipated sales of Angiomax, that our cash, cash equivalents and marketable securities as of May 16, 2001 will be sufficient to fund our operations for approximately 18 months. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax or otherwise, or if we acquire additional product candidates, we may need to sell additional equity or debt securities. The sale of additional equity and debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be

available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

DISCLOSURE ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We place our investments in high-quality financial instruments, primarily money market funds and corporate debt securities with maturities or auction dates of less than one year, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. At March 31, 2001, we held $59.0 million in cash, cash equivalents, and marketable securities, all due within one year, which had an average interest rate of approximately 6.5%.

As of March 31, 2001, we held a $3.0 million principal investment in Southern California Edison 5 7/8% bonds which was due January 15, 2001, which is accounted for in accordance with Statement of Financial Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." On May 16, 2001, we sold $1.0 million of the Southern California Edison bonds, which will result in a realized loss of $270,000 that will be recognized in the second quarter of 2001, and accordingly, we had a $2.0 million principal investment remaining as of May 16, 2001. As of May 16, 2001, the value of our investment in these Southern California Edison bonds had declined to approximately $1.5 million. We classify these securities as available-for-sale and carry them at fair market value based on the quoted market price. We have exposure to market risk related to the fluctuation of the Southern California Edison bonds' price, which fluctuation has increased significantly as a result of events which occurred after December 31, 2000, including the non-payment of principal and interest on the bonds at maturity on January 15, 2001. Payment of interest was resumed on the Southern California Edison bonds subsequent to March 31, 2001.

Most of our transactions are conducted in U.S. dollars. We do have certain development and commercialization agreements with vendors located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. If the applicable exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

BUSINESS

OVERVIEW

We acquire, develop and commercialize biopharmaceutical products that are in late stages of development or have been approved for marketing. In December 2000, we received marketing approval from the FDA for Angiomax, our lead product, for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. Coronary angioplasty is a procedure used to restore normal blood flow in an obstructed artery in the heart. We began selling Angiomax in the United States in January 2001.

We are also developing Angiomax for additional potential applications for use in the treatment of ischemic heart disease. As of May 15, 2001, clinical investigators had administered Angiomax to approximately 13,100 patients in clinical trials in the treatment and prevention of blood clots in a wide range of hospital applications. We believe that Angiomax will become the leading replacement for heparin in hospital care. In the United States, heparin is the most widely-used acute care anticoagulant and is used to treat approximately five million hospitalized patients per year.

Angiomax directly blocks or inhibits the actions of thrombin, a key component in the formation and growth of blood clots. By blocking thrombin directly, rather than indirectly like heparin, Angiomax inhibits the actions of thrombin both in the clot and in the blood. Angiomax's inhibition of thrombin is reversible, which means that its thrombin-blocking effect wears off over time, allowing thrombin to again work in the clotting process. This reversibility is associated with a reduced risk of bleeding.

In the clinical trials in angioplasty, Angiomax has:

- reduced the frequency of life-threatening coronary events including heart attack and the need for emergency coronary procedures;

- reduced the likelihood of major bleeding and the need for blood transfusion;

- demonstrated a predictable anticoagulant response to a specific Angiomax dose, which enables simplified dosing; and

- been used in combination with GP IIb/IIIa inhibitors and demonstrated no evidence of significant interactions.

Our strategy is to build a commercial biopharmaceutical operation by acquiring, developing and commercializing product candidates. We will actively manage the development and commercialization of these product candidates. Our principal objectives include:

- commercializing Angiomax for use in patients with unstable angina undergoing angioplasty;

- developing and commercializing Angiomax as the leading replacement for heparin for use in the hospital treatment of ischemic heart disease;

- acquiring additional products with (1) existing clinical data which provides reasonable evidence of safety and efficacy, (2) an anticipated time to market of four years or less and (3) potential cost savings to payors or improved efficiency of patient care; and

- making the best use of our resources through our relationships with contract development, manufacturing and sales companies.

We market Angiomax in the United States using a sales force contracted from Innovex, Inc., which we manage. We intend to market our other products in the United States by contracting with external organizations, which we would manage, or by collaborating with other biopharmaceutical companies.

ANGIOMAX

In December 2000, we received marketing approval from the FDA for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. We began selling Angiomax in the United States in January 2001. In September 1999, Angiomax was approved in New Zealand for use in the treatment of patients undergoing coronary balloon angioplasty.

We believe Angiomax will be a valuable replacement to heparin, an anticoagulant used in almost all angioplasty procedures performed in the United States and administered to a majority of patients treated in hospitals in the United States for acute coronary syndromes, including heart attack. As of May 15, 2001, clinical investigators had administered Angiomax to approximately 13,100 patients in clinical trials for the treatment and prevention of blood clots in a wide range of hospital applications. In clinical trials in angioplasty, use of Angiomax has resulted in fewer life-threatening coronary events and fewer bleeding events, including the need for blood transfusion. The therapeutic effect of Angiomax is more predictable than heparin, which enables simplified dosing. Angiomax's therapeutic benefit is strongest in high-risk patients who have previously experienced a heart attack or unstable angina.

We believe that Angiomax has additional potential applications for the treatment of ischemic heart disease. As of May 15, 2001, we:

- had a randomized, open-label Phase 3b trial program in angioplasty underway comparing Angiomax to heparin, with and without GP IIb/IIIa inhibitors;

- had a 17,000 patient Phase 3 trial program underway studying the use of Angiomax for the treatment of patients who have suffered a heart attack, otherwise known as AMI;

- had a Phase 3 trial program underway studying the use of Angiomax in the treatment of patients undergoing angioplasty who experience reduced platelet count and clotting due to an immunological reaction to heparin, known as heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS;

- had a Phase 2 trial program underway studying the use of Angiomax as an anticoagulant in patients undergoing coronary artery bypass graft surgery, or CABG, without the use of a bypass pump; and

- planned to commence a Phase 3 trial program to study the use of Angiomax in patients with unstable angina, a condition in which patients experience the new onset of severe chest pain, increasingly frequent chest pain or chest pain that occurs while they are at rest.

Background

Clotting. Normally, blood loss at the site of an injury is limited by the formation of blood clots, or thrombosis. In general, clotting serves a life-saving function by reducing bleeding, but sometimes unwanted clots in arteries can lead to heart attack, stroke or organ failure. A blood clot is a collection of cross-linked strands of a protein called fibrin that forms a mesh around activated platelets and red blood cells. Blood clots are formed through precisely regulated interactions among the blood vessel wall, plasma clotting factors, including thrombin and fibrinogen, and platelets.

The trigger for the clotting process in an artery is typically a tearing or spontaneous rupture which exposes cholesterol and fat deposited on a blood vessel wall to the bloodstream. This may happen without an apparent cause or may be caused as a direct result of, for example, an angioplasty procedure. In parallel, the clotting factor, thrombin, is activated, and a thin protective layer of platelets is deposited at the rupture site. Thrombin and platelets interact, and thrombin formation, fibrin formation and platelet clumping take place. A full-blown clot may form rapidly as clot blocks the blood vessel and may then cut off blood supply to the heart muscle. If this occurs, the muscle stops working either in part, which is a heart attack, or myocardial infarction, or completely, which may lead to cardiac arrest as the heart stops beating. This may result in irreversible damage to the heart or death.

During medical procedures such as coronary angioplasty, the blood clotting process must be slowed to avoid unwanted clotting in the coronary artery, and the potential growth or movement of a clot along blood vessels to new sites.

The trigger for clotting in veins is usually slower than that in arteries. In general, venous clots are caused by slow blood flow, which typically occurs when patients are immobilized, such as after surgery and during pregnancy, or when patients experience changes in the blood as a result of diseases such as cancer. When a clot develops in large, deep veins, which return blood to the heart by way of the lungs, this condition is referred to as deep vein thrombosis. In some cases of deep vein thrombosis, part of the clot may break off and move to the lungs with potentially fatal results.

Anticoagulation Therapy. Anticoagulation therapy attempts to modify actions of the components in the blood system that cause clot-forming factors leading to blood clots. The most important approach to the prevention and management of arterial and venous clots is diet and exercise. When the risks of clot formation cannot be avoided, or when medical procedures such as angioplasty almost guarantee some degree of increased risk of clots, anticoagulation therapy is indicated. Anticoagulation therapy involves the use of drugs to inhibit one or more components of the clotting process, thereby reducing the risk of clots. Anticoagulation therapy is usually started immediately after a diagnosis of blood clots or after risk factors for clotting are identified. Because anticoagulation therapy reduces clotting, it also may cause excessive bleeding.

To date, three principal components of the clotting process, thrombin, fibrin and platelets, have been targeted for anticoagulation therapy:

- The actions of thrombin in the clotting process may be inhibited by indirect thrombin inhibitors, such as heparin, which act to turn off coagulation factors and turn on natural anti-clotting factors such as antithrombin-III, or AT-III. The actions of thrombin in the clotting process also may be inhibited by direct thrombin inhibitors, which act directly on thrombin.

- Fibrin may be dissolved after clotting has occurred by products called fibrinolytics.

- The aggregation of platelets in the clotting process may be inhibited by products called platelet inhibitors, which act on different pathways, including specific enzyme pathways like the cyclo-oxygenase and the adenosine diphosphate, or ADP, pathways and surface sites like the GP IIb/IIIa receptor.

Drugs are currently used alone or in combination with other anticoagulant therapy to target one or more components of the clotting process. These drugs have anticoagulant effects but also increase the patient's risk of bleeding. Excess bleeding is often a risk associated with these drugs due to the high doses needed to produce anticoagulant effects. In order to reduce this risk, physicians increasingly use combinations of drugs targeted at different components of the clotting process at lower doses, which reduce the risk of thrombosis while minimizing the risk of bleeding.

Indirect Thrombin Inhibitors. In the hospital environment, most patients undergoing anticoagulation therapy for the prevention and treatment of arterial and venous thrombosis receive heparin or low molecular weight heparin. In the United States, approximately five million patients annually receive heparin. Heparin is a standard component of acute anticoagulation therapy because of the central role of thrombin in clotting and heparin's rapid anticoagulant effect.

Heparin's properties as an anticoagulant were discovered in 1916. It is prepared from the intestines of pigs or cows. Heparin is a complex mixture of animal-derived sugars with variable anticoagulant potencies. The anticoagulant effects of heparin on any given patient are difficult to predict because heparin binds non-specifically to human cells and circulating substances in the blood. For these and other reasons, heparin, as a non-specific, indirect thrombin inhibitor, presents a variety of clinical challenges including:

- Weak effect in clots. Because it is an indirect thrombin inhibitor, heparin is ineffective on thrombin when clots have formed.

- Risk of bleeding. Patients who receive heparin have a high incidence of bleeding. This is particularly the case with patients who are elderly, female or underweight. Recent clinical trials have shown that bleeding risk may also be increased when heparin is used in combination with intravenous platelet inhibitors.

- Unpredictability. The anticoagulant effect of a given dose of heparin is unpredictable and therefore requires close monitoring.

- Adverse reaction risk. Heparin can cause HIT/HITTS, a dangerous immunological reaction.

- Diminished effect in sick patients. Heparin's effect may be reduced in the presence of blood factors found in patients stressed by disease, such as heart attack patients.

- Requires other factors for effect. Heparin can only bind to thrombin by first binding to a blood factor called antithrombin-III, which may be absent or present in insufficient amounts in some patients.

Physicians are increasingly using low molecular weight heparins as an alternative to heparin, especially as chronic therapy. In contrast to heparin, low molecular weight heparins tend to be more specific in their effect and may be administered once or twice daily by subcutaneous injection on an outpatient basis. Despite these advantages, low molecular weight heparins exhibit similar clinical challenges to those of heparin, including a weak effect in clot that has already formed and a comparable risk of bleeding. In addition, clinicians are currently unable to monitor the anticoagulant effects of low molecular weight heparins, making their use in angioplasty problematic.

Angiomax Potential Advantages

Angiomax is a peptide of 20 amino acids that is a quick-acting, direct and specific inhibitor of thrombin and is administered by intravenous injection. Angiomax is specific in that it only binds to thrombin and does not bind to any other blood factors or cells.

Angiomax was engineered based on the biochemical structure of hirudin, a natural 65-amino acid protein anticoagulant. However, Angiomax is reversible while hirudin is not. This reversibility is associated with a reduced risk of bleeding.

Angiomax has numerous clinical advantages over heparin including:

- Effective in clots. Angiomax, as a direct thrombin inhibitor, is equally effective on thrombin in the clot as well as thrombin circulating in the blood;

- Reduced bleeding risk. As a reversible thrombin inhibitor, Angiomax has consistently shown clinically meaningful reductions in bleeding as compared to heparin;

- Predictability. A specified dose of Angiomax results in a predictable level of anticoagulation;

- Diminished adverse reaction risk. To date, Angiomax has not caused dangerous immunological reactions in clinical trials;

- Effective in sick patients. Angiomax is effective even in the presence of blood factors found in patients stressed by disease, for example heart attack patients; and

- Independent of other factors for effect. Unlike heparin, Angiomax's effect does not require the presence of antithrombin-III or any other factors to act on thrombin.

Angiomax Potential Applications

We believe that Angiomax will become the leading replacement for heparin in acute cardiovascular care. We plan to commercialize Angiomax first for use in patients undergoing coronary angioplasty. In addition, we are developing Angiomax for use as an alternative to heparin for the treatment of acute coronary syndromes, with a Phase 3b trial called REPLACE underway in angioplasty, a Phase 3 trial underway in AMI, a Phase 3 trial underway in HIT/HITTS, a Phase 2 trial underway in CABG without the use of a bypass pump and a

Phase 3 trial planned in patients with unstable angina. Our development plan is designed to highlight the clinical benefits of Angiomax initially in broad patient populations treated with heparin at high risk of clots or bleeding. We are also investigating other applications of Angiomax as an acute care product.

Use of Angiomax in Angioplasty

Angioplasty. Angioplasty is a procedure involving the inflation of a balloon or deployment of a stent or other device inside an obstructed artery to restore normal blood flow. The coronary angioplasty procedure itself increases the risk of coronary clotting potentially leading to myocardial infarction, or MI, CABG, or death.

Based on hospital discharge data, in the United States, there were approximately 686,000 inpatient angioplasty procedures performed in 1997 and approximately 55,000 outpatient angioplasty procedures performed in 1996. We believe approximately one half of patients undergoing angioplasty in an inpatient hospital setting were admitted through the emergency room and may be categorized as high risk. Many of these high-risk patients have previously experienced a heart attack or have unstable angina.

To prevent clotting, anticoagulation therapy is routinely administered to patients undergoing angioplasty. Heparin is currently used as an anticoagulant in virtually all patients undergoing angioplasty. In addition, platelet inhibitors such as aspirin, an ADP inhibitor or a GP IIb/IIIa inhibitor are often administered.

A segment of patients undergoing angioplasty and receiving anticoagulation therapy are at risk of significant bleeding. For example, the risk is greater for patients who are elderly, female or underweight.

Angiomax Clinical Experience in Angioplasty. As of May 15, 2001, we and the licensor of Angiomax, Biogen, had conducted clinical trials of Angiomax in over 6,100 patients undergoing angioplasty. These trials have shown that Angiomax is a predictable anticoagulant, which can be used in combination with other therapies and which results in fewer adverse clinical events when compared to heparin.

ANGIOPLASTY TRIALS OF ANGIOMAX AS OF MAY 15, 2001

LEAD INVESTIGATORS	COMPLETED	PATIENTS	PHASE	TRIAL/STUDY DESCRIPTION
E. Topol	1992	291	2	Angiomax dose-ranging trial
J. Bittl	1994	4,312	3	Pivotal angioplasty trials comparing Angiomax with high dose heparin in unstable angina patients
M. Abernathy, P. Aylward	1999	30	3	Interaction study of Angiomax with Ticlid
L. Wallentin	1999	40	3	Trial comparing Angiomax with heparin in patients switched from low molecular weight heparin
H. White, P. Aylward	2000	26	2	Trial of Angiomax dosing in patients with normal to moderately impaired kidney function
N. Kleiman	2000	42	3b	Interaction study of Angiomax with Integrilin
E. Topol, N. Kleiman, A.M. Lincoff, R. Harrington	1999	60	3	CACHET-A trial comparing Angiomax with heparin in full-dose ReoPro patients
E. Topol, N. Kleiman, A.M. Lincoff, R. Harrington	2000	210	3	CACHET-B/C trial comparing Angiomax with ReoPro plus heparin in broad patient group

ANGIOPLASTY TRIALS OF ANGIOMAX AS OF MAY 15, 2001

LEAD INVESTIGATORS	COMPLETED	PATIENTS	PHASE	TRIAL/STUDY DESCRIPTION
R. Califf, K. Mahaffey.....	Ongoing	19	3	Study of Angiomax in HIT/HITTS patients
J. Ormiston.....	2000	49	3b	Angiomax single intravenous dose trial
J. Ormiston.....	2000	33	3b	Interaction study of Angiomax with Aggrastat
A.M. Lincoff.....	Ongoing	1,057	3b	REPLACE trial comparing Angiomax to heparin, with and without GP IIb/IIIa inhibitors

Phase 3 Pivotal Trials in Angioplasty. Two similar, randomized double blind clinical trials compared the use of Angiomax to heparin in a total of 4,312 patients with unstable angina undergoing coronary balloon angioplasty. High doses of heparin were used in the trials. When measured seven days after treatment in the hospital, in comparison to heparin-treated patients in the trials, Angiomax-treated patients experienced:

- 43% fewer clinical events as measured by death, MI, revascularization procedures or major bleeding;

- 22% fewer ischemic events as measured by death, revascularization or MI; and

- 62% or 65% less bleeding, as measured by a protocol-defined end point of major bleeding or the transfusion of two or more units of blood, respectively.

The following table summarizes the combined clinical results for all unstable angina patients in the pivotal Phase 3 angioplasty trials.

	ANGIOMAX	HEPARIN	PERCENTAGE REDUCTION IN ADVERSE CLINICAL EVENTS	P-VALUE*
Number of patients.....	2,161	2,151		
In hospital up to 7 days				
Death, MI, revascularization or major bleeding.....	8.3%	14.5%	43%	<0.001
Death, MI or revascularization.....	6.2%	7.9%	22%	0.039
Major bleeding.....	3.5%	9.3%	62%	<0.001
Transfusion.....	2.0%	5.7%	65%	<0.001
At 90 days				
Death, MI or revascularization.....	15.7%	18.5%	15%	0.012

* The statistical significance of clinical results is determined by a widely-used statistical method that establishes the p-value of clinical results. For example, a p-value of less than 0.01 ($p<0.01$) means that the chance of the clinical results occurring by accident is less than 1 in 100.

The trials included a prospectively defined and separately stratified group of 741 patients, who had experienced an MI during the two weeks prior to angioplasty. The benefits of Angiomax as a direct thrombin inhibitor, compared to heparin as an indirect thrombin inhibitor, were more pronounced for this group of 741 patients who had experienced an MI during the two weeks prior to angioplasty. When measured seven days after treatment in the hospital, the Angiomax-treated patients experienced the following benefits:

- 64% fewer clinical events as measured by death, MI, revascularization procedures or major bleeding;

- 51% fewer ischemic events as measured by death, revascularization or MI; and

- 76% or 80% less bleeding, as measured by a protocol-defined major bleeding or as measured by a transfusion of two or more units of blood.

The following table summarizes the combined clinical results of the group of patients who had experienced a heart attack or MI during the two weeks prior to angioplasty in the pivotal Phase 3 angioplasty trials.

	ANGIOMAX	HEPARIN	PERCENTAGE REDUCTION IN ADVERSE CLINICAL EVENTS	P-VALUE
Number of patients	369	372		
In hospital up to 7 days				
Death, MI, revascularization or major bleeding	6.5%	18.3%	64%	<0.001
Death, MI or revascularization	4.9%	9.9%	51%	0.009
Major bleeding	2.4%	11.8%	80%	<0.001
Transfusion	1.6%	6.7%	76%	<0.001
At 90 days				
Death, MI or revascularization	11.7%	20.2%	42%	<0.003

Recent trends in interventional cardiology have resulted in heparin doses lower than those used in the Angiomax pivotal Phase 3 trials in angioplasty. We believe that this trend has been encouraged by the increasing combined use of platelet inhibitors and heparin in angioplasty. In most recent major angioplasty trials with GP IIb/IIIa inhibitors, lower heparin doses were used than in the Angiomax pivotal Phase 3 trials.

Heparin Dosing in Pivotal Phase 3 Angioplasty Trial. Analyses of data from a wide array of recent angioplasty trials show that the bleeding rates for the heparin patients in our trials were not higher than the bleeding rates for other trials where lower doses of heparin were used. Ischemic event rates for patients in the Angiomax pivotal Phase 3 trials were lower than for patients receiving lower doses of heparin without a GP IIb/IIIa inhibitor in other clinical studies.

CACHET-B/C Trials in Angioplasty. In February 2000, we completed the CACHET-B/C study, a 210 patient randomized, multicenter study, in angioplasty. The trial analyzed the use of Angiomax versus low-dose heparin. All heparin patients also received ReoPro. Although Angiomax patients could receive ReoPro under certain circumstances, physicians in the trial opted not to use ReoPro in 76% of the Angiomax patients.

The CACHET-B/C patient study population was broader than in earlier Angiomax trials, targeting lower risk patients undergoing angioplasty with expected stenting. Heparin and Angiomax doses were designed to achieve similar levels of anticoagulation. Aspirin with Ticlid or Plavix was used in most patients. As in previous trials, Angiomax provided predictable levels of dose response anticoagulation.

The combined incidence of death, MI, revascularization or major bleeding reported within seven days was 3.5% in Angiomax patients and 14.3% in heparin and ReoPro patients with a p-value of 0.013.

Low platelet count, or thrombocytopenia, was significantly less frequent among Angiomax patients than among heparin/ReoPro patients with a p-value of
0.012. Other adverse events occurred with similar frequency in both groups. Angiomax showed no apparent pharmacological interaction with ReoPro.

The results of the CACHET-B/C study provides more support for the use of Angiomax as a foundation anticoagulant for angioplasty. In this study, Angiomax demonstrated predictable reversible anticoagulation and improved net clinical benefit over heparin. In addition, by decreasing major bleeds and reducing the need for revascularization and drug costs, we believe that, on average, substantial cost savings are possible for hospitals treating patients with Angiomax.

Interaction Studies. Specific interaction studies of Angiomax with GP IIb/IIIa inhibitors ReoPro, Integrilin and Aggrastat have not revealed any drug-drug interactions.

REPLACE Trial in Angioplasty. In November 2000, we began a randomized, two-part Phase 3b trial of the use of Angiomax in angioplasty. We expect that the trial will be conducted at approximately 200 sites in the United States. The first part of the trial, in which we have enrolled 1,057 patients, is designed to assess the clinical outcomes and health economics of Angiomax compared to heparin, with and without GP IIb/IIIa

inhibitors. The second part of the trial, which may include up to 10,000 patients who have been referred for angioplasty, may include three randomized arms:

- heparin with a GP IIb/IIIa inhibitor;

- Angiomax with the provisional use of a GP IIb/IIIa inhibitor at the choice of the physician; and

- Angiomax with a GP IIb/IIIa inhibitor.

Angiomax Commercialization Plans for Angioplasty. We began selling Angiomax in the United States in January 2001 using a sales force contracted from Innovex, Inc., which we manage. In December 2000, we signed a master services agreement and a work order with Innovex under which Innovex agreed to provide the sales force, a sales territory management system and operational support for the launch of Angiomax.

We are focusing our Angiomax marketing efforts on interventional cardiologists and other key clinical decision-makers for Angiomax. Our sales force has been configured to target the relatively small number of cardiac catheterization laboratories in which most of the angioplasty procedures in the United States are performed.

We expect Angiomax to provide cost savings to medical decision-makers using Angiomax as part of a safe and effective anticoagulant therapy. Many United States hospitals receive a fixed reimbursement amount for the angioplasties they perform. Because this amount is not based on the actual expenses the hospital incurs, the use of Angiomax has the potential to reduce a hospital's cost of treating an angioplasty patient by reducing bleeding and ischemic events and reducing the need for other treatment therapies. From 1995 to 1997, the incremental costs to a hospital averaged the following: approximately $12,000 for an angioplasty patient receiving a 2-unit transfusion; approximately $4,000 for revascularization in the form of a repeat angioplasty; and approximately $17,000 for an angioplasty patient revascularized by means of coronary artery bypass graft surgery. Our pricing structure for Angiomax is designed to provide hospitals with cost savings based on reductions in clinical events and reductions in drug costs.

If Angiomax is approved for use in other indications, such as AMI or unstable angina, we intend to market Angiomax for these indications in the United States by supplementing our commercial organization, or by collaborating with other biopharmaceutical companies.

We are seeking commercial partners outside of the United Stated to market, sell and distribute Angiomax. As of May 17, 2001, we had entered into a marketing and distribution agreement with Medison Pharma Ltd. for the registration, distribution and promotion of Angiomax in Israel.

Acute Myocardial Infarction

Acute myocardial infarction is a leading cause of death. AMI occurs when coronary arteries, which supply blood to the heart, become completely blocked with clot. AMI patients are routinely treated with heparin, with and without fibrinolytics. Heart attack patients are increasingly undergoing angioplasty as a primary treatment to unblock clotted arteries.

Based on hospital discharge data, in 1997, there were approximately 871,000 AMI patients in the United States who were treated in a hospital.

Angiomax Clinical Experience in AMI. As of May 15, 2001, we and Biogen had conducted clinical trials comparing Angiomax and heparin in over 17,600 AMI patients.

LEAD INVESTIGATORS	COMPLETED	PATIENTS	PHASE	TRIAL/STUDY DESCRIPTION
P. Theroux.....	1992	45	2	Dose-ranging trial comparing Angiomax with heparin administered prior to a fibrinolytic
P. Theroux.....	1993	68	2	Dose-ranging trial comparing Angiomax with heparin administered prior to a fibrinolytic
H. White.....	1996	412	2	HERO-1: Dose-ranging trial comparing Angiomax with heparin administered following a fibrinolytic
H. White, R. Califf, F. Van de Werf, P. Aylward.....	Enrollment	17,090	3	HERO-2: Mortality trial comparing Angiomax with heparin administered prior to a fibrinolytic in 17,000 patients

The first two trials compared the effect of two doses of Angiomax with heparin as therapy administered in advance of streptokinase, a fibrinolytic, in heart attack patients. The trials were designed to compare the difference in rates of blood flow following therapy. The third trial, the Hirulog Early Reperfusion/Occlusion-1 trial, or the HERO-1 trial, was a multi-center, randomized, double blind comparison involving 412 patients. In this trial, patients with AMI were administered heparin or one of two doses of Angiomax as therapy following the administration of streptokinase and aspirin. Blood flow rates after therapy were evaluated using a standard measure of coronary artery blood flow.

The three Phase 2 trials demonstrated that use of Angiomax:

- resulted in normal blood flow in at least 34% more patients than heparin; and

- resulted in substantially less bleeding and the need for fewer transfusions than heparin.

The following table summarizes the clinical results for AMI patients in the Phase 2 clinical trials comparing Angiomax to heparin as combined with a fibrinolytic:

	ANGIOMAX PATIENTS	HEPARIN PATIENTS	PERCENTAGE IMPROVEMENT	P-VALUE*
Theroux Montreal Heart Institute Study 1 (45 patients)				
Full blood flow at 90 minutes.....	67%	40%	67%	0.08
Theroux Montreal Heart Institute Study 2 (68 patients)				
Full blood flow at 90 minutes.....	71%	31%	129%	0.006
Transfusion.....	5%	31%	84%	<0.02
HERO-1 Trial (412 patients)				
Full blood flow at 90 minutes.....	47%	35%	34%	0.024
Major bleeding.....	17%	28%	39%	<0.01

Based on the results of these Phase 2 trials, we are conducting a worldwide 17,000 patient Phase 3 clinical trial in AMI. In this HERO-2 Phase 3 trial, AMI patients receive Angiomax or heparin prior to treatment with a fibrinolytic. All patients receive aspirin and Streptase, a fibrinolytic. This trial is designed to demonstrate statistically significant improvement in 30-day cumulative mortality among patients receiving Angiomax, thus establishing Angiomax as the only direct thrombin inhibitor with mortality benefit compared to heparin in the management of AMI.

We are coordinating the HERO-2 trial with the Virtual Coordinating Center for Global Collaborative Cardiovascular Research Organization, commonly referred to as VIGOUR, an academic consortium of leading cardiologists and their affiliated institutions established to coordinate the efforts of large global clinical

trials in cardiology. As of May 15, 2001, the trial had completed enrollment of the 17,000 patients. We expect the analysis of the data to be completed by the end of the third quarter.

Following enrollment of approximately 2,000, 5,000, 8,000 and 12,500 patients, an independent panel, the Drug Safety Monitoring Board, reviewed safety data from the trial to determine whether there were safety issues that would warrant modification or early termination of the trial. The Board completed the fourth planned review in January 2001, and the trial is proceeding without modification. In contrast, two previous trials using high doses of hirudin in patients including heart attack patients were stopped early because of excessive bleeding in the hirudin patients.

Acute Coronary Syndromes/Unstable Angina

Unstable angina is a condition in which patients experience the new onset of severe chest pain, increasingly frequent chest pain or chest pain that occurs while they are resting. Unstable angina is caused most often by a rupture of plaque on an arterial wall that ultimately decreases coronary blood flow but does not cause complete blockage of the artery. There are approximately 948,000 cases of unstable angina in the United States reported each year. Unstable angina is often treated in hospitals with anticoagulation therapy that may include aspirin, indirect thrombin inhibitors such as heparin or low molecular weight heparin and GP IIb/IIIa inhibitors. Many unstable angina patients undergo angioplasty or CABG.

Angiomax Clinical Experience in Unstable Angina. As of May 15, 2001, we and Biogen had completed five Phase 2 trials of Angiomax in patients with unstable angina or who had experienced a less serious form of MI known as non Q-wave MI. These trials enrolled a total of 630 patients, of whom 553 received various doses of Angiomax. These studies have demonstrated that Angiomax is an anticoagulant which can be administered safely in patients with unstable angina.

The largest of these Phase 2 trials was a multicenter, double blind, placebo-controlled and randomized study in 410 patients with unstable angina or who had experienced non Q-wave MI. The trial compared the effect of three active dose levels and one placebo dose level of Angiomax with respect to death, MI, recurrent angina and major bleeding. Angiomax demonstrated a significant correlation between dose and anticoagulant effect.

In comparison to 160 patients treated with placebo doses in the trial, 250 patients treated with active doses of Angiomax experienced:

- a 68% reduction in death or MI in hospital with a p-value equal to 0.009; and

- a 59% reduction in death or MI after six weeks with a p-value equal to 0.014.

We have plans to commence a Phase 3 trial program to study the use of Angiomax in patients with unstable angina.

Other Indications

We and Biogen have conducted a number of additional clinical trials of Angiomax for other indications.

HIT/HITTS. Approximately one to three percent of patients who have received heparin for seven to 14 days experience a condition known as HIT/HITTS. The underlying mechanism for the condition appears to be an immunological response to a complex formed by heparin and another factor, resulting in the lowering of platelet counts, commonly referred to as thrombocytopenia, and in some cases in arterial or venous clotting, which may result in the need for limb amputation, or death. Because further administration of heparin is not possible, an alternative anticoagulant is necessary.

Prior to 1997, Angiomax was administered to a total of 39 HIT/HITTS patients undergoing angioplasty requiring anticoagulation for invasive coronary procedures or treatment of thrombosis. For those patients undergoing angioplasty and other procedures, Angiomax provided adequate anticoagulation, was well- tolerated and rarely resulted in bleeding complications.

Based upon the encouraging data in 39 patients, we are currently enrolling patients in a trial designed to evaluate the use of Angiomax for treatment of HIT/HITTS patients undergoing angioplasty. The trial has enrolled 19 patients to date and plans to enroll 50 patients in total.

CABG. We have initiated a 100 patient Phase 2 trial of Angiomax comparing Angiomax to heparin in patients undergoing off pump CABG. The trial was initiated in November 2000 and 32 patients had been enrolled in the trial as of May 15, 2001.

Deep Venous Thrombosis. Thirty-one patients with clots in the veins in their legs and 222 patients undergoing orthopedic surgical procedures were treated with Angiomax in two open-label, dose-ranging Phase 2 trials in 1990. Both studies established that Angiomax was an active and well-tolerated anticoagulant and that the anticoagulant effects correlated with the dose of Angiomax.

We are actively considering further development plans to expand the uses of Angiomax in venous thrombosis and other indications.

Regulatory Status

In December 2000, we received approval from the FDA for the use of Angiomax in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. In connection with this approval, the FDA has required us to complete our ongoing trial evaluating the use of Angiomax for the treatment of HIT/HITTS patients undergoing angioplasty. Angiomax is intended for use with aspirin and has been studied only in patients also receiving aspirin.

In February 1998, we submitted a Marketing Authorization Application, or MAA, to the European Agency for the Evaluation of Medicinal Products, or EMEA, for use in unstable angina patients undergoing angioplasty. Following extended interaction with European regulatory authorities, the Committee of Proprietary Medicinal Products, or CPMP, of the EMEA voted in October 1999 not to recommend Angiomax for approval in angioplasty. The United Kingdom and Ireland dissented from this decision. We have withdrawn our application to the EMEA and are in active dialogue with European regulators to determine our alternative courses of action.

Angiomax was approved in New Zealand in September 1999 for use as an anticoagulant in patients undergoing coronary balloon angioplasty, and we began selling Angiomax in New Zealand in June 2000. We have submitted an application in Canada to market Angiomax for use in unstable angina patients undergoing angioplasty and are in active dialogue with Canadian regulators.

CTV-05

In 1999, we acquired from GyneLogix, Inc. exclusive worldwide rights to CTV-05, a strain of bacteria under clinical investigation for a broad range of applications in the areas of gynecological and reproductive health. We have entered into a clinical trial agreement with the National Institutes of Allergy and Infectious Diseases, a division of the National Institutes of Health, commonly referred to as NIH, to conduct a Phase 2 trial of CTV-05, a proprietary biotherapeutic agent for the treatment of bacterial vaginosis, or BV. BV, the most common gynecological infection in women of childbearing age, is an imbalance of naturally occurring organisms in the vagina.

Bacterial Vaginosis

BV develops when certain bacteria normally present in the vagina in low levels multiply to infectious levels. BV is associated with serious health risks such as pelvic inflammatory disease, pre-term birth, post-surgical infection and an increased susceptibility to sexually transmitted diseases, including AIDS. The standard treatments currently prescribed for BV are oral or topical antibiotics including metronidazole and clindamycin. These treatments are not optimal, having significant recurrence rates. Moreover, antibiotic use depletes a beneficial bacteria called lactobacilli.

CTV-05: Rationale, Product Profile and Clinical Studies

A healthy vagina is principally populated by lactobacilli. The presence of lactobacilli in the vagina, particularly those that produce hydrogen peroxide, has been linked to decreased incidence of BV and other urinary tract and gynecological infections. However, many women lack sufficient populations of hydrogen peroxide-producing lactobacilli to maintain vaginal health, making them more susceptible to infection.

Studies have shown that the CTV-05 strain of lactobacillus is able to restore the natural balance of the bacteria in the vagina and produce both hydrogen peroxide and lactic acid, substances which are active against disease-causing bacteria and serve a protective role. Because of this, CTV-05 has the potential to improve cure rates when used in conjunction with approved antibiotics, to prevent BV recurrence and thus to reduce serious health risks.

In the Phase 2 safety and efficacy trial, funded by NIH, CTV-05 is administered topically to BV patients. The study is primarily designed to show whether CTV-05 improves cure rates of BV at 30 days. The study is the first large trial to look at recurrence rates of BV at 90 days. As of May 15, 2001, we had enrolled over 260 patients in a 400 patient trial at three sites and expect to conclude the trial in 2001.

Other Indications

Recently completed studies by GyneLogix under a Center for Disease Control and Prevention grant, have shown that CTV-05 is active against the organisms which cause yeast infections and gonorrhea. We plan to conduct pilot clinical studies in these indications.

IS-159

In 1998, we acquired from Immunotech S.A. exclusive worldwide rights to IS-159, a selective chemical that reacts with receptors found on cerebral blood vessels and nerve terminals. We are seeking a collaborator to develop IS-159 and do not intend to initiate further studies of IS-159 until we enter into a collaborative arrangement.

PRODUCT ACQUISITION STRATEGY

We plan to continue to acquire, develop and commercialize late-stage product candidates or approved products that make a clinical difference to patients managed by focused groups of medical decision-makers. Our strategy is to acquire late-stage development product candidates with an anticipated time to market of four years or less and existing clinical data which provides reasonable evidence of safety and efficacy. In addition, we aim to acquire approved products that can be marketed by our commercial organization. In making our acquisition decisions we attempt to select products that meet these criteria and achieve high investment returns by:

- understanding the market opportunity for initially-targeted uses of the drug;

- assessing the investment and development programs that will be necessary to achieve a marketable product profile in these initial uses; and

- attempting to structure the design of our development programs to obtain critical information relating to the clinical and economic performance of the product early in the development process, so that we can make key development decisions.

As of May 15, 2001, we have implemented this strategy with Angiomax, CTV-05 and IS-159.

We intend to acquire products and product candidates with possible uses and markets beyond those on which our initial investment program will be focused. We plan to acquire other products that will enhance the acute hospital product franchise we are building around Angiomax. We are also seeking other specialty anti-infective products and product candidates that will fit into the franchise we expect to build around CTV-05.

We have assembled a management team with significant experience in drug development and in drug product launches and commercialization.

MANUFACTURING

We do not intend to build or operate manufacturing facilities but instead intend to enter into contracts for manufacturing development and/or commercial supply.

Angiomax

All Angiomax bulk drug substance used in non-clinical and clinical work performed to date has been produced by UCB Bioproducts by means of a chemical synthesis process. We have ordered, and for the foreseeable future will order, Angiomax bulk drug substance from UCB Bioproducts under the validated manufacturing process. Using this process, UCB Bioproducts has successfully completed the manufacture of bulk drug substance to meet anticipated commercial supply requirements in 2001.

Together with UCB Bioproducts, we have developed a second generation chemical synthesis process to improve the economics of the manufacturing of Angiomax bulk drug substance. This process, which must be approved by the FDA before it can be used, is known as the Chemilog process and involves limited changes to the early manufacturing steps of our current process in order to improve process economics. We expect the Chemilog process to produce material that is chemically equivalent to that produced using the current process. UCB Bioproducts has completed initial development of the process and is currently manufacturing validation batches.

We have entered into a commercial development and supply agreement with UCB Bioproducts for production of Angiomax bulk drug substance utilizing the Chemilog process. Under terms of the agreement, UCB Bioproducts will prepare and file the necessary drug master file for regulatory approval of the Chemilog process. If the Chemilog process is successfully developed and regulatory approval is obtained, we expect this process will result in a reduced cost of manufacturing.

We have developed reproducible analytical methods and processes for the manufacture of Angiomax drug product by Ben Venue Laboratories. Ben Venue Laboratories has carried out all of our Angiomax fill-finish activities and has released product for clinical trials and commercial sale.

CTV-05

As of May 15, 2001, GyneLogix had manufactured all CTV-05 material used in clinical trials. In order to scale up production to produce sufficient materials for later phase clinical trials, we have entered into a manufacturing arrangement with The Dow Chemical Company. We are currently in the process of transferring the CTV-05 manufacturing technology to Dow.

STRATEGIC RELATIONSHIPS

In order to develop and commercialize our products, we leverage our resources by utilizing contract product development, manufacturing and sales companies.

UCB Bioproducts

In December 1999, we entered into a commercial development and supply agreement with UCB Bioproducts for the development and supply of Angiomax bulk drug substance. Under the terms of the agreement, UCB Bioproducts is also responsible for developing the Chemilog process in coordination with us and obtaining regulatory approval for use of the process. We have agreed to partially fund UCB Bioproducts' development activities. This funding is due upon the completion by UCB Bioproducts of development milestones. If UCB Bioproducts successfully completes each of these development milestones, we anticipate that total development funding paid by us will equal approximately $9.1 million. Of this $9.1 million, $7.7 million will be paid to UCB Bioproducts for validation batches of Angiomax manufactured using the Chemilog process, which we may use for commercial sale following regulatory approval of the Chemilog process. In addition, following successful development and regulatory approval of the Chemilog process, we have agreed to purchase Angiomax bulk drug substance exclusively from UCB Bioproducts at agreed upon prices for a period of seven years from the date of the first commercial sale of Angiomax produced under the

Chemilog process. Following the expiration of the agreement, or if we terminate the agreement prior to its expiration, UCB Bioproducts will transfer the development technology to us. If we engage a third party to manufacture Angiomax for us using this technology, we will be obligated to pay UCB Bioproducts a royalty based on the amount paid by us to the third-party manufacturer.

PharmaBio/Quintiles

In August 1996, we entered into a strategic alliance with PharmaBio Development, Inc., a wholly owned subsidiary of Quintiles Transnational Corp. Under the terms of the strategic alliance agreement, PharmaBio and any of its affiliates who work on our projects will, at no cost to us, review and evaluate, jointly with us, development programs we design related to potential or actual product acquisitions. The purpose of this collaboration is to optimize the duration, cost, specifications and quality aspects of such programs. PharmaBio and its affiliates have also agreed to perform certain other services with respect to our products, including clinical and non-clinical development services, project management, project implementation, pharmacoeconomic services, regulatory affairs and post-marketing surveillance services and statistical, statistical programming, data processing and data management services. We have agreed to pay PharmaBio its standard fee for these other services, with certain exceptions for exceptional performance by PharmaBio. For more information regarding this alliance, please see "Transactions with Executive Officers, Directors and Five Percent Stockholders."

Innovex

In January 1997, we entered into a consulting agreement with Innovex, Inc., a subsidiary of Quintiles, which was subsequently superseded by a consulting agreement we executed with Innovex in December 1998. Pursuant to the terms of these agreements, Innovex has provided us with consulting services with respect to pharmaceutical marketing and sales.

In December 2000, we signed a master services agreement and a work order with Innovex to promote Angiomax. Under the agreement and work order, Innovex will provide a sales force of up to 52 sales representatives, a sales territory management system and operational support for the launch of Angiomax. Under the terms of the agreement and work order, we have paid Innovex a total of approximately $3.0 million for its services through April 30, 2001.

COMPETITION

The development and commercialization of new drugs is competitive and we will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that have been or are being developed by us, or may obtain FDA approval for their products more rapidly than we may obtain approval for ours.

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense and growing. We are developing Angiomax as an anticoagulant therapy for the treatment of ischemic heart disease. There are a number of anticoagulant therapies currently on the market, awaiting regulatory approval or in development.

In general, anticoagulant drugs may be classified in three groups: drugs that directly or indirectly target and inhibit thrombin or its formation, drugs that target and inhibit platelets activation and aggregation and drugs that break down fibrin. Indirect thrombin inhibitors include heparin and low molecular weight heparins such as Lovenox, Fragmin and pentasaccharide. Direct thrombin inhibitors include Angiomax, Argatroban, Melagatran and hirudins such as Refludan. Platelet inhibitors include aspirin, Ticlid Plavix. GP IIb/IIIa inhibitors include ReoPro, Integrilin and Aggrastat. Fibrinolytics include Streptase, Activase, Retevase and TNKase.

Because each group of anticoagulants acts on different clotting factors, we believe that there will be continued clinical work to determine the best combination of drugs for clinical use. We plan to position

Angiomax as an alternative to heparin as baseline anticoagulation therapy for use in patients with ischemic heart disease. We expect Angiomax to be used with aspirin alone or in conjunction with other fibrinolytic drugs or platelet inhibitors. We will compete with indirect and direct thrombin inhibitors on the basis of efficacy and safety, ease of administration and economic value. Heparin's widespread use and low cost to hospitals will provide a selling challenge.

We do not plan to position Angiomax as a direct competitor to platelet inhibitors such as ReoPro from Centocor, Inc. and Eli Lilly and Company, Aggrastat from Merck, Inc. or Integrilin from Cor Therapeutics, Inc. and Schering-Plough Corporation. Similarly, we do not plan to position Angiomax as a competitor to fibrinolytic drugs such as Streptase from Aventis S.A., Retevase from Centocor, Inc., and Activase and TNKase from Genentech Inc. Platelet inhibitors and fibrinolytic drugs may, however, compete with Angiomax for the use of hospital financial resources. Many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform.

Because this amount is not based on the actual expenses the hospital incurs, U.S. hospitals may be forced to use either Angiomax or a platelet inhibitor or fibrinolytic drugs but not both.

The acquisition or licensing of pharmaceutical products is a competitive area, and a number of more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisition. In addition, a number of established research-based pharmaceutical and biotechnology companies may have acquired products in late stages of development to augment their internal product lines. These established companies may have a competitive advantage over us due to their size, cash flows and institutional experience.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and create value in patient therapy.

PATENTS, PROPRIETARY RIGHTS AND LICENSES

Our success will depend in part on our ability to protect the products we acquire or license by obtaining and maintaining patent protection both in the United States and in other countries. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We plan to prosecute and defend any patents or patent applications we acquire or license, as well as any proprietary technology.

We have exclusively licensed from Biogen patents and applications for patents covering Angiomax and Angiomax analogs and other novel anticoagulants as compositions of matter, and processes for using Angiomax and Angiomax analogs and other novel anticoagulants. We have exclusively licensed from GyneLogix a patent and patent applications covering formulations and uses of the biotherapeutic agent CTV-05 for the treatment of urogenital and reproductive health. We have also exclusively licensed from Immunotech a patent and patent applications covering the pharmaceutical IS-159 and its use for the treatment of acute migraine headache. In each case, we are responsible for prosecuting and maintaining such patents and patent applications. In all, as of May 15, 2001, we exclusively licensed 10 issued United States patents and a broadly filed portfolio of corresponding foreign patents and patent applications. We have not yet filed any independent patent applications. The U.S. patents licensed by us expire at various dates ranging from March 2010 to April 2017.

The patent positions of pharmaceutical and biotechnology firms like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the applications we acquire or license will result in the issuance of patents or, if any patents are issued,

whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

The development of anticoagulants is intensely competitive. A number of pharmaceutical companies, biotechnology companies, universities and research institutions have filed patent applications or received patents in this field. Some of these applications are competitive with applications we have acquired or licensed, or conflict in certain respects with claims made under such applications. Such conflict could result in a significant reduction of the coverage of the patents we have acquired or licensed, if issued, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if patents are issued to other companies that contain competitive or conflicting claims and such claims are ultimately determined to be valid, no assurance can be given that we would be able to obtain licenses to these patents at a reasonable cost, or develop or obtain alternative technology.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for the our trade secrets in the event of unauthorized use or disclosure of such information.

LICENSE AGREEMENTS

Biogen, Inc.

In March 1997, we entered into an agreement with Biogen for the license of the anticoagulant pharmaceutical bivalirudin, which we have developed as Angiomax. Under the terms of the agreement, we acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, we paid $2.0 million on the closing date and are obligated to pay up to an additional $8.0 million upon reaching certain Angiomax sales milestones, including the first commercial sales of Angiomax for the treatment of AMI in the United States and Europe. In addition, we are obligated to pay royalties on future sales of Angiomax and on any sublicense royalties earned until the later of (1) 12 years after the date of the first commercial sale of the product in a country or (2) the date in which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. The agreement also stipulates that we use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least $20.0 million for certain development and commercialization activities, which we met in 1998. The licenses and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and we may terminate the agreement for any reason upon 90 days prior written notice.

GyneLogix, Inc.

In August 1999, we entered into an agreement with GyneLogix for the license of the biotherapeutic agent CTV-05, a strain of human lactobacillus currently under clinical investigation for applications in the areas of urogenital and reproductive health. Under the terms of the agreement, we acquired exclusive worldwide rights to the patents and know-how related to CTV-05. In exchange for the license, we have paid GyneLogix $400,000 and are obligated to pay up to an additional $100,000 upon reaching certain development and regulatory milestones and to fund agreed-upon operational costs of GyneLogix related to the development of CTV-05 on a monthly basis subject to a limitation of $50,000 per month. In addition, we are obligated to pay royalties on future sales of CTV-05 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that we must use commercially reasonable efforts in pursuing the development, commercialization and marketing of CTV-05 to maintain the license. The licenses and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and we may terminate the agreement for any reason upon 60 days prior written notice.

Immunotech S.A.

In July 1998, we entered into an agreement with Immunotech for the license of the pharmaceutical IS-159 for the treatment of acute migraine headache. Under the terms of the agreement, we acquired exclusive worldwide rights to the patents and know-how related to IS-159. In exchange for the license, we paid $1.0 million on the closing date and are obligated to pay up to an additional $4.5 million upon reaching certain development and regulatory milestones. In addition, we are obligated to pay royalties on future sales of IS-159 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that we must use commercially reasonable efforts in pursuing the development, commercialization and marketing of IS-159 and meet certain development and regulatory milestones to maintain the license. The licenses and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and we may terminate the agreement for any reason upon 60 days prior written notice.

GOVERNMENT REGULATION

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing of our products. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, and, in the case of biologics, also under the Public Health Service Act, and implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as the FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

The steps required before a drug may be marketed in the United States include:

- pre-clinical laboratory tests, animal studies and formulation studies;

- submission to the FDA of an investigational new drug exemption, or IND, for human clinical testing, which must become effective before human clinical trials may begin;

- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;

- submission to the FDA of an NDA or biologics license application, or BLA;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and

- FDA review and approval of the NDA or BLA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the investigational new drug exemption.

Clinical trials typically are conducted in three sequential Phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board before it can begin. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its safety, dosage tolerance, phamacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;

- identify possible adverse effects and safety risks; and

- evaluate preliminarily the efficacy of the drug for specific indications.

Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. We cannot guarantee that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application and the manufacturing facilities are acceptable, the FDA will issue an approval letter. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

In December 2000, we received marketing approval from the FDA for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty.

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For example, as a condition of approval of an application, the FDA may require postmarketing testing and surveillance to monitor the drug's safety or efficacy. In the case of Angiomax, the FDA has required us to complete an ongoing 50 patient trial in which we are treating patients with HIT/ HITTS who need coronary balloon angioplasty.

In addition, holders of an approved NDA or BLA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with current good manufacturing practices and other aspects of regulatory compliance.

We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and we cannot be sure that future FDA inspections will not identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

FACILITIES

As of May 15, 2001, we leased approximately 9,000 square feet of office space in Cambridge, Massachusetts and approximately 6,660 square feet of office space in Parsippany, New Jersey. We believe our current facilities will be sufficient to meet our needs for the foreseeable future, but that additional space will be available on commercially reasonable terms to meet space requirements if they arise. We also have offices in Oxford, United Kingdom and Parnell, Auckland, New Zealand.

LEGAL PROCEEDINGS

From time to time we have been and expect to continue to be subject to legal proceedings and claims in the ordinary course of business. As of May 15, 2001, we were not a party to any material legal proceeding.

EMPLOYEES

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. We have assembled a management team with significant experience in drug development and commercialization.

As of May 15, 2001, we employ 75 persons, of whom 12 hold M.D. and/or Ph.D. degrees and 15 hold other advanced degrees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

MANAGEMENT

EXECUTIVE OFFICERS, KEY EMPLOYEES AND DIRECTORS

Our executive officers, key employees and directors, and their respective ages and positions as of May 15, 2001, are set forth below:

NAME	AGE	POSITION
Clive A. Meanwell, M.D., Ph.D.*	44	Chief Executive Officer, President and Director
Peyton J. Marshall, Ph.D.*	46	Senior Vice President and Chief Financial Officer
Glenn P. Sblendorio, M.B.A.*	45	Senior Vice President
David M. Stack*	50	Senior Vice President
John M. Nystrom, Ph.D.*	55	Vice President and Chief Technical Officer
Gary Dickinson	49	Vice President
David C. Mitchell	47	Vice President
Frederick K. Paster, M.Sc., M.B.A.	36	Vice President
Thomas P. Quinn*	42	Vice President
John D. Richards, D.Phil.*	44	Vice President
Fred M. Ryan, M.B.A.	49	Vice President
John W. Villiger, Ph.D.*	46	Vice President
Leonard Bell, M.D.	43	Director
Dennis B. Gillings, Ph.D.	57	Director
Stewart J. Hen, M.B.A., M.S.	34	Director
Anders D. Hove, M.D., M.Sc., M.B.A.(1)	35	Director
M. Fazle Husain, M.B.A.(1)	37	Director
T. Scott Johnson, M.D.(1)	53	Director
Armin M. Kessler, Dh.c.(2)	63	Director
Nicholas J. Lowcock, M.B.A.(2)	36	Director
James E. Thomas, M.Sc.(2)	40	Director

* Executive Officer

(1) Member of Audit Committee

(2) Member of the Compensation Committee

Set forth below is certain information regarding the business experience during the past five years for each of the above-named persons.

Clive A. Meanwell, M.D., Ph.D. has been our Chief Executive Officer and President and a director since the inception of our company in July 1996. From 1995 to 1996, Dr. Meanwell was a Partner and Managing Director at MPM Capital L.P., a venture capital firm. From 1986 to 1995, Dr. Meanwell held various positions at Hoffmann-La Roche, Inc., a pharmaceutical company, including Senior Vice President, from 1992 to 1995, Vice President from 1991 to 1992 and Director of Product Development from 1986 to 1991. Dr. Meanwell was also a member of Hoffmann-La Roche's pharmaceutical division operating board, its research and development board and its portfolio management committee. During his tenure as Director of Product Development, Dr. Meanwell had responsibility at Hoffmann-La Roche for the development and launch of Neupogen. During his tenure as Vice President, Worldwide Drug Regulatory Affairs, he had management responsibility for the regulatory approval of eight new products and nine significant line extensions of products. Dr. Meanwell also led an initiative at Hoffmann-La Roche to reengineer the drug development process with the goal of cutting the time and cost of drug development. Dr. Meanwell received his M.D. and Ph.D. from the University of Birmingham, United Kingdom.

Peyton J. Marshall, Ph.D. has been a Senior Vice President since January 2000 and our Chief Financial Officer since joining us in October 1997. From 1995 to October 1997, Dr. Marshall was based in London as a

Managing Director and head of European Corporate Financing and Risk Management Origination at Union Bank of Switzerland, an investment banking firm. From 1986 to 1995, Dr. Marshall held various investment banking positions at Goldman Sachs and Company, an investment banking firm, including head of European product development from 1987 to 1993 and Executive Director, Derivatives Origination from 1993 to 1995. From 1981 to 1986, Dr. Marshall held several product development positions at The First Boston Corporation, an investment banking firm, and was an Assistant Professor of Economics at Vanderbilt University. Dr. Marshall received his Ph.D. in economics from the Massachusetts Institute of Technology.

Glenn P. Sblendorio, M.B.A. has been a Senior Vice President since July 2000, with primary responsibility for business development. From 1998 to July 2000, Mr. Sblendorio was the Chief Executive Officer and Managing Director of MPM Capital Advisors, LLC, an investment bank specializing in healthcare related transactions. From 1997 to 1998, Mr. Sblendorio served as Managing Director at Millennium Venture Management, LLC, a strategic consulting firm. From 1996 to 1997, Mr. Sblendorio was the Executive Vice President, Chief Financial Officer and Treasurer at PlayNet Technologies, a publicly traded internet company that develops entertainment systems. From 1993 to 1996, Mr. Sblendorio was the Senior Vice President and Chief Financial Officer for Sony Interactive Entertainment Inc. From 1981 to 1993, Mr. Sblendorio held several positions at Hoffmann-La Roche, Inc., including Vice President of Finance & Administration for Roche Molecular Systems and Controller Europe for the Amgen/Roche venture. Mr. Sblendorio received his B.A. in accounting from Pace University and his M.B.A. from Fairleigh Dickinson University. Mr. Sblendorio is also a CPA.

David M. Stack has been a Senior Vice President since April 2000. Under Mr. Stack's employment agreement with us, Mr. Stack has agreed to devote at least 24 hours per week to our business. Since January 2000, Mr. Stack has also served as President and General Partner of Stack Pharmaceuticals, Inc., a commercialization, marketing and strategy consulting firm serving pharmaceutical companies, and as a Senior Advisor to the Chief Executive Officer of Innovex Inc., a contract pharmaceutical organization. Mr. Stack served as President and General Manager of Innovex Inc. from May 1995 to December 1999. From April 1993 to May 1995, Mr. Stack served as Vice President, Business Development and Marketing at Immunomedics, Inc., a biotechnology company specializing in monoclonal antibodies in diagnostics and therapeutics. From September 1981 to March 1993, Mr. Stack was employed by Roche Laboratories, a division of Hoffmann-La Roche, where he was the Rocephin Product Director from June 1989 to December 1992 and Director, Business Development and Planning, Infectious Disease, Oncology and Virology from May 1992 to March 1993. Mr. Stack currently serves as director of Bio Imaging Laboratories, Inc. Mr. Stack received his B.S. in biology from Siena College and his B.S. in pharmacy from Albany College of Pharmacy.

John M. Nystrom, Ph.D. has been a Vice President since October 1998 and our Chief Technical Officer since December 1999. From July 1979 to October 1998, Dr. Nystrom was employed by the Arthur D. Little, an international technology and management consulting firm. During his 19 years with the firm he held numerous positions consulting to the fine chemical, biotechnology and pharmaceutical industries. In 1994 he was elected a Vice President of the firm, and his last position was that of Vice President and Director. Dr. Nystrom currently serves as a director of Cangene Corp. Dr. Nystrom received his B.S. and Ph.D. in chemical engineering from the University of Rhode Island.

Gary Dickinson has been a Vice President since May 2001 with a focus on human resources activities. From April 2000 to May 2001, Mr. Dickinson was the Vice President of Human Resources and Communications at Elementis Specialties, a specialty chemicals manufacturing firm. From 1985 to March 2000, Mr. Dickinson held several senior human resources positions at Bristol-Myers Squibb Company, including Director of Human Resources for the International Medicines Group, Asia, Middle East and Africa and Director of Human Resources for Bristol-Myers Squibb Consumer Group for Europe, Middle East and Africa. Mr. Dickinson holds a B.A. from the University of Sheffield, England.

David C. Mitchell has been a Vice President since December 2000 with a focus on information technology and information systems. His responsibilities include planning and implementing worldwide information systems. From February 1999 to December 2000, Mr. Mitchell was a Vice President of

Information Technology for Innovex Americas. From July 1997 to February 1999, Mr. Mitchell was Director of Information Technology at NBC. Prior to joining NBC, Mr. Mitchell served as the Director of Programming and Technology at Walt Disney Pictures and Television for twelve years. Mr. Mitchell received his Bachelor of Music from Arizona State University.

Frederick K. Paster, M.Sc., M.B.A. has been a Vice President since September 1999, with a focus on worldwide product partnering, product development strategy and market/pricing analysis. Mr. Paster is also involved in new product acquisitions and corporate partnerships. From 1994 until he joined us in September 1998, Mr. Paster was a Manager with The Boston Consulting Group, a management consulting firm. From 1990 to 1992, Mr. Paster was located in Germany and Belgium as European Programs Manager for ESI, a computer software and services firm. Mr. Paster received his B.S. and M.Sc. degrees in engineering from the Massachusetts Institute of Technology and received his M.B.A. from the Harvard Business School.

Thomas P. Quinn has been a Vice President since April 2000, with a focus on the launch of Angiomax, business development and product in-licensing. Mr. Quinn has served as a Partner of Stack Pharmaceuticals, Inc. since January 2000 and served as the Vice President of Marketing of Stack Pharmaceuticals, Inc. from January 2000 through May 2000. From November 1997 to January 2000, Mr. Quinn was Senior Vice President, Business Development at Innovex. From January 1996 to July 1997, Mr. Quinn was employed by the Strategic Planning/New Business Development Department of Bristol-Myers Squibb Inc., a pharmaceutical company, where his responsibilities included domestic and global portfolio management and franchise development. From April 1992 to December 1995, Mr. Quinn was involved in the commercial start-up of the U.S. Therapeutics Division of Boehringer Mannheim Corporation, a pharmaceutical company. Mr. Quinn received his B.S. degree from Duquesne University.

John D. Richards, D.Phil. joined us in October 1997 and has been a Vice President since 1999, with a focus on product manufacturing and quality. From 1993 until he joined us in October 1997, Dr. Richards was Director of Process Development and Manufacturing at Immulogic Pharmaceutical Corporation, a pharmaceutical company. From 1989 to 1993, Dr. Richards was a Technical Manager at Zeneca PLC, a pharmaceutical company, where he developed and implemented processes for the manufacture of peptides as pharmaceutical active intermediates. In 1986, Dr. Richards helped establish Cambridge Research Biochemicals, a manufacturer of peptide-based products for pharmaceutical and academic customers. Dr. Richards received his M.A. and D.Phil. in organic chemistry from the University of Oxford, United Kingdom, and has carried out post-doctoral research work at the Medical Research Councils Laboratory of Molecular Biology in Cambridge, United Kingdom.

Fred M. Ryan, M.B.A. has been a Vice President since April 2000, with a focus on corporate strategic development, new product acquisitions and Angiomax commercial development. Under Mr. Ryan's employment agreement with us, Mr. Ryan has agreed to devote at least 24 hours per week to our business. Since April 2000, Mr. Ryan has also served as a Partner and the Vice President of Business Development of Stack Pharmaceuticals, Inc. From July 1991 to April 2000, he held senior management positions with Novartis Pharmaceuticals, Inc. in the United States in both the Consumer Pharmaceuticals and Prescription Pharmaceuticals businesses in the areas of Finance, Strategic Planning, Business Development and Marketing, serving from 1998 to April 2000 as Executive Director Mature Products responsible for managing sales and marketing activities for a portfolio of products having annual sales in excess of $500 million. From 1989 to 1991, he served as Assistant Controller for Alusuisse-Lonza in the United States. From 1985 to 1988, he served as Senior Financial Manager for Ciba Consumer Pharmaceuticals (Ciba). He received his B.S. and B.A. degrees from Bryant College and his M.B.A. from Fairleigh Dickinson University.

John W. Villiger, Ph.D. has been a Vice President since March 1997, with a focus on cardiovascular product development. From December 1986 until he joined us in March 1997, Dr. Villiger held various positions in product development at Hoffmann-La Roche, including Head of Global Project Management from 1995 to 1996 and International Project Director from 1991 to 1995. As Head of Global Project Management, Dr. Villiger was responsible for overseeing the development of Hoffmann-LaRoche's pharmaceutical portfolio, with management responsibility for over 50 development programs. As International Project

Director, Dr. Villiger was responsible for the global development of Tolcapone also known as tasmar. Dr. Villiger received his Ph.D. in neuropharmacology from the University of Otago.

Leonard Bell, M.D. has been a director since May 2000. Since January 1992, Dr. Bell has served as the President and Chief Executive Officer, Secretary and Treasurer of Alexion Pharmaceuticals, Inc., a pharmaceutical company. From 1991 to 1992, Dr. Bell was an Assistant Professor of Medicine and Pathology and co-Director of the Program in Vascular Biology at the Yale University School of Medicine. From 1990 to 1992, Dr. Bell was an attending physician at the Yale-New Haven Hospital and an Assistant Professor in the Department of Internal Medicine at the Yale University School of Medicine. Dr. Bell was the recipient of the Physician Scientist Award from the National Institutes of Health and Grant-in-Aid from the American Heart Association as well as various honors and awards from academic and professional organizations. Dr. Bell is the recipient of various honors and awards from academic and professional organizations and his work has resulted in more than 45 scientific publications, invited presentations and patent applications. Dr. Bell is an invited Member of the State of Connecticut Governor's Council on Economic Competitiveness and Technology and a director of Connecticut United For Research Excellence, Inc. He also served as a director of the Biotechnology Research and Development Corporation from 1993 to 1997. Dr. Bell received his A.B. from Brown University and M.D. from the Yale University School of Medicine. Dr. Bell is currently an Adjunct Assistant Professor of Medicine and Pathology at the Yale University School of Medicine. Dr. Bell also serves as a director of Alexion Pharmaceuticals, Inc.

Dennis B. Gillings, Ph.D. has been a director since September 1996. Dr. Gillings has served as Chairman of Quintiles Transnational Corp., since its founding by him in 1982. From 1982 to March 2000, Dr. Gillings also served as Chief Executive Officer of Quintiles. Quintiles provides integrated product development, commercial development and other services to the pharmaceutical, biotechnology, medical device and healthcare industries. From 1972 to 1988, Dr. Gillings was a Professor of Biostatistics at the University of North Carolina at Chapel Hill. Dr. Gillings serves as a director of WebMD Corporation and Triangle Pharmaceuticals, Inc. Dr. Gillings received his diploma in mathematical statistics from Cambridge University and his Ph.D. in mathematics from the University of Exeter, United Kingdom.

Stewart J. Hen, M.B.A., M.S. has been a director since February 2001. Since May 2000, Mr. Hen has been a Vice President of Warburg Pincus LLC. Mr. Hen focuses on investments in the emerging life sciences area, including biotechnology, specialty pharmaceuticals, drug delivery and diagnostics. From 1996 to May 2000, Mr. Hen was a consultant at McKinsey & Company, where he advised pharmaceutical and biotechnology companies on a range of strategic management issues. Mr. Hen served at Merck & Company from 1991 to 1994 in both research and development and manufacturing positions. Mr. Hen received an M.B.A. from The Wharton School, an M.S. in biochemical engineering from Massachusetts Institute of Technology and a B.S. in chemical engineering from the University of Delaware.

Anders D. Hove, M.D., M.Sc., M.B.A. has been a director since December 1998. Dr. Hove has been a member of the Bellevue Group since 1996, which focuses on investing in public and private biotechnology companies in the United States and in Europe. From 1991 to 1996, Dr. Hove held various positions at Ciba-Geigy Pharmaceuticals Division in clinical development, international marketing and business development. Dr. Hove currently serves as a director of Virologic, Inc., a biotechnology company. Dr. Hove received his M.B.A. from INSEAD and his M.D. from the University of Copenhagen.

M. Fazle Husain, M.B.A. has been a director since September 1998. Mr. Husain has been affiliated with Morgan Stanley Venture Partners since 1991 and is currently a General Partner of Morgan Stanley Venture Partners III, L.P., a private partnership affiliated with Morgan Stanley. Mr. Husain focuses primarily on investments in the health care industry, including health care services, medical technology and health care information technology. He currently serves on the board of directors of Allscripts, Inc., Healthstream, Inc. and Cardiac Pathways Corporation. Mr. Husain received his Sc.B. degree in chemical engineering from Brown University and his M.B.A. from the Harvard Graduate School of Business Administration.

T. Scott Johnson, M.D. has been a director since September 1996. In July 1999, Dr. Johnson founded JSB Partners, L.P., an investment bank focusing on mergers and acquisitions, private financings and corporate alliances within the health care sector. From July 1991 to June 1999, Dr. Johnson served as a founder and

managing director of MPM Capital, L.P. Dr. Johnson held academic positions at the Harvard Medical School from 1978 to 1996 and was actively involved in both basic science and clinical research at the Beth Israel Hospital and the Brigham and Women's Hospital. Dr. Johnson received both his B.A. and M.D. from the University of Alabama.

Armin M. Kessler, Dh.c. has been a director since October 1998. Dr. Kessler joined us after a 35-year career in the pharmaceutical industry, which included senior management positions at Sandoz Pharma Ltd., Basel, United States and Japan (now Novartis Pharma A.G.) and, most recently, at Hoffmann-La Roche, Basel where he was Chief Operating Officer and Head of the Pharmaceutical Division until 1995. Dr. Kessler has served as a director of Hoffmann-La Roche, Syntex Corporation and Genentech, Inc., and Dr. Kessler currently serves as a director of Neutherapeutics, Inc., a biopharmaceutical company. Dr. Kessler received his degrees in physics and chemistry from the University of Pretoria, his degree in chemical engineering from the University of Cape Town, his law degree from Seton Hall and his honorary doctorate in business administration from the University of Pretoria.

Nicholas J. Lowcock, M.B.A. has been a director since December 2000. He previously served as a director of the Company from September 1996 until December 1998. Mr. Lowcock has been with Warburg Pincus LLC, a venture capital firm, since 1994. Prior to joining Warburg, Pincus he was with the Boston Consulting Group and previously worked in the pharmaceutical industry in the United Kingdom. Mr. Lowcock serves as a director of Eurand Pharmaceutical Holdings, B.V., Leciva Pharmaceutical Holdings B.V., Craegmoor Healthcare Ltd., PharmaIdea B.V. and Aspect Educational Holdings Ltd. Mr. Lowcock is also a director of Project Hope U.K., a charity devoted to improving healthcare in developing nations. Mr. Lowcock received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.A. in Experimental Psychology from Oxford University.

James E. Thomas, M.Sc. has been a director since September 1996. Since March 2001, Mr. Thomas has served as Managing Director of Thomas, McNerney & Partners, LLC, a healthcare private equity investment fund. From 1989 to May 2000, Mr. Thomas served as Managing Director of E.M. Warburg, Pincus & Co., LLC, a venture capital firm. From 1984 to 1989, Mr. Thomas was a Vice President at Goldman Sachs International, an investment banking firm, in London. Mr. Thomas currently serves as a director of Transkaryotic Therapies, Inc. Mr. Thomas received his B.Sc. in finance and economics from the Wharton School at the University of Pennsylvania and his M.Sc. in economics from the London School of Economics.

BOARD COMPOSITION

We currently have ten directors, although one of our current directors, Dr. Hove, is not standing for re-election as a director at the annual meeting of stockholders to be held on May 31, 2001. Pursuant to the terms of a stockholders' voting agreement that we entered with certain of our stockholders in connection with the sale of shares of preferred stock prior to our initial public offering, Messrs. Bell, Gillings, Hen, Hove, Husain, Johnson, Lowcock and Thomas were elected to our board of directors. This agreement terminated by its terms upon the completion of our initial public offering. However, so long as any of the investors who were party to that agreement, excluding Biotech Growth, S.A., own 20% percent of our outstanding common stock, they will be entitled to nominate two individuals to serve as directors, and so long as they own 10% of our outstanding common stock, they will be able to nominate one individual to serve as a director. Warburg, Pincus is entitled to nominate two individuals to serve as directors, and Messrs. Lowcock and Hen serve on our board of directors as representatives of Warburg, Pincus.

Our board of directors is divided into three classes, each of whose members serve for a staggered three-year term. The division of the three classes, the directors and their respective election dates are as follows:

- the class 1 directors are Drs. Gillings, Hove and Johnson, and Mr. Hen, and their term will expire at the annual meeting of stockholders to be held on May 31, 2001;

- the class 2 directors are Dr. Meanwell and Messrs. Lowcock and Husain, and their term will expire at the annual meeting of stockholders to be held in 2002; and

- the class 3 directors are Drs. Kessler and Bell and Mr. Thomas, and their term will expire at the annual meeting of stockholders to be held in 2003.

At each annual meeting of stockholders, the successors to directors whose terms are to expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in control or management of our company.

BOARD COMMITTEES

Audit Committee. Our audit committee reviews our internal accounting procedures and consults with, and reviews the services provided by, our independent public accountants. As of May 15, 2001, the members of our audit committee were Drs. Hove and Johnson and Mr. Husain.

Compensation Committee. Our compensation committee reviews and recommends to the board the compensation and benefits of all of our officers and reviews general policies relating to the compensation and benefits of our employees. The compensation committee also administers the issuance of stock options and other awards under our stock plans. As of May 15, 2001, the members of the compensation committee were Dr. Kessler and Messrs. Lowcock and Thomas.

DIRECTOR COMPENSATION

Generally, our non-employee directors receive $2,500 from us for each meeting of the board of directors which they attend in person and $500 for each meeting in which they participate by telephone. The chairmen of our audit and compensation committees receive $1,000 from us for each committee meeting he or she attends in person and $500 for each committee meeting in which he or she participates by telephone. Directors are reimbursed for expenses in connection with their attendance at board meetings.

In addition, non-employee directors may receive stock options and other equity awards under our 1998 stock incentive plan and our 2000 outside director stock option plan. In 1998, we granted Dr. Kessler an option under our 1998 stock incentive plan to purchase 14,600 shares of common stock at an exercise price of $1.23 per share. In May 2000, we granted each of Dr. Bell and Mr. Thomas an option under our 1998 stock incentive plan to purchase 14,600 shares of common stock at an exercise price of $4.79 per share. In December 2000, we granted Mr. Lowcock an option under our 2000 outside director stock option plan to purchase 20,000 shares of common stock at an exercise price of $26.00 per share. In February 2001, we granted Mr. Hen an option under our 2000 outside director stock option plan to purchase 20,000 shares of common stock at an exercise price of $14.875 per share. These options vest in 48 equal monthly installments commencing one month after the date of grant.

2000 Outside Director Stock Option Plan

Our 2000 outside director stock option plan was adopted by our board of directors on May 15, 2000. Under the plan, our non-employee directors will be eligible to receive non-statutory options to purchase shares of our common stock. A total of 250,000 shares of our common stock may be issued upon the exercise of

options granted under the 2000 outside director stock option plan. As of May 15, 2001, options to purchase 40,000 shares of our common stock were outstanding under the 2000 outside director stock option plan.

Under the terms of the director stock option plan, each non-employee director will be granted an option to purchase 20,000 shares of our common stock on the date of his or her initial election to the board of directors. In addition, each non-employee director will receive an option to purchase 7,500 shares of our common stock on the date of each annual meeting of our stockholders commencing with the 2001 annual meeting of stockholders, other than a director who was initially elected to the board of directors at any such annual meeting. All options granted under the plan vest in 48 equal monthly installments commencing one month after the date of grant. The exercise price per share of all options will equal the fair market value per share of our common stock on the option grant date. Each grant under the director stock option plan will have a maximum term of ten years, subject to earlier termination following the optionee's cessation of service.

CARDIOLOGY ADVISORY BOARD

We have established a cardiology advisory board to guide and counsel us on all aspects of interventional cardiology practice. The entire cardiology advisory board meets twice a year, and we contact individual members as needed. Members of this board provide input on product research and development strategy, education and publication plans. We do not employ any of the members of the cardiology advisory board, and members may have other consulting or advisory contracts. Accordingly, members devote only a small portion of their time to us. In addition to the cardiology advisory board, we have consulting relationships with a number of scientific and medical experts who advise us on a project-specific basis. The members of the cardiology advisory board are:

NAME	AFFILIATION	TITLE
Eric J. Topol, M.D., Chair...	The Cleveland Clinic Foundation	Chairman and Professor, Department of Cardiology
Eric R. Bates, M.D.....	University of Michigan Medical Center	Professor, Internal Medicine
John A. Bittl, M.D.....	Ocala Heart Institute	Interventional Cardiologist
Robert M. Califf, M.D.....	Duke University Clinical Research Institute	Associate Vice Chancellor, Clinical Research, Professor of Medicine, CEO
Frederick Feit, M.D.....	New York University Medical Center/Tisch Hospital	Director, Cardiac Catheterization Laboratory
Bernard J. Gersh, M.B., Ch.B., D. Phil.	Mayo Clinic	Professor of Medicine
Neal S. Kleiman, M.D.....	The Methodist Hospital	Assistant Director, Cardiac Catheterization Laboratories
A. Michael Lincoff, M.D.....	The Cleveland Clinic Foundation	Director, Experimental Interventional Laboratory
Jeffrey J. Popma, M.D.....	Cardiology Research Foundation	Executive Director
Jeffrey I. Weitz, M.D.....	McMaster University, Canada	Professor of Medicine and Director, Experimental Thrombosis and Atherosclerosis Group
Harvey White, D.Sc.....	Green Lane Hospital, New Zealand	Director of Cardiovascular Research and Coronary Care

EXECUTIVE COMPENSATION

The following table presents summary information for the years ended December 31, 1999 and 2000, regarding the compensation of each of our most highly compensated executive officers.

Summary Compensation Table

NAME AND POSITION	YEAR	ANNUAL COMPENSATION		LONG-TERM COMPENSATION AWARDS
		SALARY	BONUS	SECURITIES UNDERLYING OPTIONS
Clive A. Meanwell, M.D., Ph.D.	2000	$250,000	$85,000	424,781
President and Chief Executive Officer	1999	$200,000	--	--
Peyton J. Marshall, Ph.D.	2000	$200,000	$70,000	271,446
Senior Vice President and Chief Financial Officer	1999	$150,000	--	--
John W. Villiger, Ph.D.	2000	$195,000	$60,000	188,591
Vice President	1999	$195,000	--	--
John M. Nystrom, Ph.D.	2000	$165,000	$50,000	121,101
Vice President and Chief Technical Officer	1999	$165,000	--	--
John D. Richards, D. Phil.	2000	$143,654	$42,100	51,591
Vice President	1999	$130,000	--	--

Option Grants in 2000

The following table summarizes information regarding options granted to each of the individuals listed in the summary compensation table as of December 31, 2000.

Amounts in the following table represent hypothetical gains that could be achieved for the respective options if exercised at the end of the option term. The 0%, 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by the rules of the Securities and Exchange Commission and do not represent an estimate or projection of our future common stock prices. These amounts represent certain assumed rates of appreciation in the value of our common stock from the fair market value on the date of grant. Actual gains, if any, on stock option exercises are dependent on the future performance of the common stock and overall stock market conditions. The amounts reflected in the following table may not necessarily be achieved.

NAME	INDIVIDUAL GRANTS(1) NUMBER OF SECURITIES OPTIONS GRANTED	PERCENT OF OPTIONS GRANTED TO EMPLOYEES IN 2000	EXERCISE PRICE PER SHARE	MARKET PRICE PER SHARE	EXPIRATION DATE	POTENTIAL REALIZABLE VALUE AT ASSUMED ANNUAL RATES OF STOCK PRICE APPRECIATION FOR OPTION TERM 0%	5%	10%
Clive A. Meanwell, M.D., Ph.D.	70,445(2)	.3%	$ 1.23	$ 7.00(3)	1/11/10	$ 406,265	$ 716,382	$1,192,163
	2,336(4)	0.1%	$ 1.23	$11.20(3)	3/1/10	$ 23,283	$ 39,737	$ 64,981
	292,000(5)	9.5%	$ 4.79	$12.60(3)	5/15/10	$2,279,200	$4,593,029	$8,142,897
	30,000(5)	0%	$26.00	$26.00	12/12/10	--	$ 490,538	$1,243,119
	30,000(5)	0%	$24.25	$24.25	12/15/10	--	$ 457,521	$1,159,448
Peyton J. Marshall, Ph.D.	34,310(2)	1.1%	$ 1.23	$ 7.00(3)	1/11/10	$ 197,870	$ 348,912	$ 580,639
	2,336(4)	0.1%	$ 1.23	$11.20(3)	3/1/10	$ 23,283	$ 39,737	$ 64,981
	189,800(5)	6.2%	$ 4.79	$12.60(3)	5/15/10	$1,481,480	$2,985,469	$5,292,883
	22,500(5)	0.7%	$26.00	$26.00	12/12/10	--	$ 367,903	$ 932,339
	22,500(5)	0.7%	$24.25	$24.25	12/15/10	--	$ 343,141	$ 869,586
John W. Villiger, Ph.D.	31,755(2)	1.0%	$ 1.23	$ 7.00(3)	1/11/10	$ 183,135	$ 322,929	$ 537,400
	2,336(4)	0.1%	$ 1.23	$11.20(3)	3/1/10	$ 23,283	$ 39,737	$ 64,981
	109,500(5)	3.6%	$ 4.79	$14.00(3)	6/6/10	$1,008,000	$1,972,095	$3,451,207
	22,500(5)	0.7%	$26.00	$26.00	12/12/10	--	$ 367,903	$ 932,339
	22,500(5)	0.7%	$24.25	$24.25	12/15/10	--	$ 343,141	$ 869,586
John M. Nystrom, Ph.D.	40,515(2)	1.3%	$ 1.23	$ 7.00(3)	1/11/10	$ 233,655	$ 412,013	$ 685,648
	2,336(4)	0.1%	$ 1.23	$11.20(3)	3/1/10	$ 23,283	$ 39,737	$ 64,981
	18,250(5)	0.6%	$ 3.08	$12.60(3)	3/23/10	$ 173,700	$ 318,314	$ 540,181
	30,000(5)	1.0%	$26.00	$26.00	12/12/10	--	$ 490,538	$1,243,119
	30,000(5)	1.0%	$24.25	$24.25	12/15/10	--	$ 457,521	$1,159,448
John D. Richards, D. Phil	14,783(2)	0.5%	$ 1.23	$ 7.00(3)	1/11/10	$ 85,250	$ 150,324	$ 250,161
	7,008(4)	0.2%	$ 1.23	$11.20(3)	3/1/10	$ 69,850	$ 119,211	$ 194,942
	14,600(5)	0.5%	$ 3.08	$12.60(3)	3/23/10	$ 138,960	$ 254,651	$ 432,145
	7,600(5)	0.2%	$26.00	$26.00	12/12/10	--	$ 124,270	$ 314,924
	7,600(5)	0.2%	$24.25	$24.25	12/15/10	--	$ 115,905	$ 293,727

(1) Our 1998 stock incentive plan provides that stock options which are otherwise unvested may be exercised for restricted stock which is subject to vesting and a repurchase option.

(2) Eighty percent of the shares underlying the option will vest in 48 equal monthly installments ending January 11, 2004. Twenty percent of the shares underlying the option vested upon FDA approval of Angiomax.

(3) For all options granted prior to our initial public offering in August 2000, the market price per share was determined based on the estimated initial public offering price of our common stock as used to determine compensation expense as required by the SEC.

(4) Two-thirds of the shares underlying the option vested upon FDA approval of Angiomax. One-third of the shares underlying the option will vest six months following FDA approval of Angiomax.

(5) The option will vest in 48 equal monthly installments commencing one month following the date of grant.

Option Values at December 31, 2000

The following table presents the number and value of securities underlying unexercised options that are held by each of the individuals listed in the summary compensation table as of December 31, 2000. No shares were acquired upon the exercise of stock options by these individuals during the year ended December 31, 2000.

Amounts shown under the column "Value of Unexercised In-the-Money Options at December 31, 2000" are based on the closing sale price on December 29, 2000 of $20.50 per share, without taking into account any taxes that may be payable in connection with the transaction, multiplied by the number of shares underlying the option, less the exercise price payable for these shares.

NAME	SHARES ACQUIRED ON EXERCISE	VALUE REALIZED	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT DECEMBER 31, 2000		VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT DECEMBER 31, 2000	
			EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE(1)
Clive A. Meanwell, M.D., Ph.D.	--	--	96,145	369,516	$1,709,272	$5,078,649
Peyton J. Marshall, Ph.D.	--	--	51,878	238,548	$ 900,957	$3,151,696
John W. Villiger, Ph.D.	61,648	$793,068	13,687	140,813	$ 214,961	$1,504,789
John M. Nystrom, Ph.D.	29,200	$347,670	32,826	135,725	$ 633,136	$1,450,830
John D. Richards, D. Phil.	--	--	15,812	41,253	$ 299,590	$ 480,028

(1) Our 1998 stock incentive plan provides that stock options which are otherwise unvested may be exercised for restricted stock which is subject to vesting and a repurchase option.

EMPLOYMENT AGREEMENTS

Dr. Meanwell serves as our President and Chief Executive Officer pursuant to the terms of an employment agreement dated September 5, 1996. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal. Pursuant to the terms of the agreement, Dr. Meanwell's annual compensation is determined by the board of directors. If Dr. Meanwell terminates his employment for good reason, as defined in the agreement, or if we elect to voluntarily terminate his employment, Dr. Meanwell will be entitled to three months salary and the same health, disability and other benefits as were provided during his employment for a period of three months after the date of his termination. Dr. Meanwell has agreed not to compete with us during the term of his employment and for a period of one year after his termination.

Dr. Marshall serves as our Chief Financial Officer pursuant to the terms of an employment agreement dated October 20, 1997. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal. Pursuant to the terms of the agreement, Dr. Marshall's annual compensation is determined by the board of directors. If Dr. Marshall terminates his employment for good reason, as defined in the agreement, or if we elect to voluntarily terminate his employment, Dr. Marshall will be entitled to three months salary and the same health, disability and other benefits as were provided during his employment for a period of three months after the date of his termination. Dr. Marshall has agreed not to compete with us during the term of his employment and for a period of one year after his termination.

Dr. Villiger serves as one of our vice presidents pursuant to the terms of an employment agreement dated March 10, 1997. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal. Pursuant to the terms of the agreement, Dr. Villiger's annual compensation is determined by the board of directors. If Dr. Villiger terminates his employment for good reason, as defined in the agreement, or if we elect to voluntarily terminate his employment, Dr. Villiger will be entitled to three months salary and the same health, disability and other benefits as were provided during his employment for a period of three months after the date of his termination. Dr. Villiger has agreed not to compete with us during the term of his employment and for a period of one year after his termination.

Dr. Nystrom serves as our Chief Technical Officer pursuant to the terms of an employment agreement dated September 29, 1998. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal. Pursuant to the terms of the agreement, Dr. Nystrom's annual compensation is determined by the board of directors. If Dr. Nystrom terminates his employment for good reason, as defined in the agreement, Dr. Nystrom will be entitled to up to six months salary and the same health, disability and other benefits as were provided during his employment for a period of six months after the date of his termination. If we elect to voluntarily terminate his employment, Dr. Nystrom will be entitled to up to three months salary and the same health, disability and other benefits as were provided during his employment for a period of three months after the date of his termination. Dr. Nystrom has agreed not to compete with us during the term of his employment and for a period of one year after his termination.

Dr. Richards serves as one of our vice presidents pursuant to the terms of an employment agreement dated October 16, 1997. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal. Pursuant to the terms of the agreement, Dr. Richards' annual compensation is determined by the board of directors. If Dr. Richards terminates his employment for good reason, as defined in the agreement, or if we elect to voluntarily terminate his employment, Dr. Richards will be entitled to three months salary and the same health, disability and other benefits as were provided during his employment for a period of three months after the date of his termination. Dr. Richards has agreed not to compete with us during the term of his employment and for a period of one year after his termination.

EMPLOYEE BENEFIT PLANS

1998 Stock Incentive Plan

We adopted our 1998 stock incentive plan in April 1998 and have reserved 4,368,259 shares of our common stock for issuance under the 1998 plan. As of May 15, 2001, options to purchase 3,457,581 shares of our common stock were outstanding and 318,128 shares of common stock have been issued upon the exercise of stock options.

Our 1998 plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock and other stock-based awards. Our officers, employees, directors, consultants and advisors, and those of our subsidiaries, are eligible to receive awards under the 1998 plan, however, incentive stock options may only be granted to our employees.

Our board of directors administers the 1998 plan, although it may delegate its authority to one or more of its committees and, in limited circumstances, to one or more of our executive officers. Our board of directors has authorized the compensation committee to administer the plan, including the granting of options to our executive officers. In accordance with the provisions of the 1998 plan, our compensation committee selects the recipients of awards and determines the:

- number of shares of common stock covered by options and the dates upon which such options become exercisable;

- exercise price of options;

- duration of options; and

- number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of such awards, including the conditions for repurchase, issue price and repurchase price.

In the event of a merger or other acquisition event, our board of directors must provide for all outstanding awards under the 1998 plan to be assumed or substituted for by the acquiror. If the acquiror does not assume or substitute for outstanding awards, our board of directors may provide that all unexercised options will become exercisable in full prior to the completion of the event and that these options will terminate upon completion of the event if not previously exercised. If our stockholders will receive cash in the acquisition event, any options that would become exercisable will be converted into cash. If any of these events constitutes a change in control, the assumed or substituted options will be immediately exercisable in full if the holder of the options is terminated by the acquiror within one year of the change in control.

No award may be granted under the 1998 plan after April 13, 2008 but the vesting and effectiveness of awards granted before April 13, 2008 may extend beyond those dates. Our board of directors may at any time amend, suspend or terminate the 1998 plan except that no award granted after an amendment of the plan and designated as subject to Section 162(m) of the Internal Revenue Code by our board of directors shall become exercisable, realizable or vested, to the extent such amendment was required to grant such award, unless and until such amendment is approved by our stockholders.

2000 Employee Stock Purchase Plan

Our 2000 Employee Stock Purchase Plan was adopted by our board of directors on May 15, 2000. The purchase plan became effective upon the completion of our initial public offering. The purchase plan authorizes the issuance of up to a total of 255,500 shares of our common stock to participating employees.

All of our employees, including our directors who are employees and all employees of any participating subsidiaries, whose customary employment is for more than five months in any calendar year, are eligible to participate in the purchase plan. Employees who would, immediately after an option grant, own 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries are not eligible to participate in the purchase plan. As of May 15, 2001, 24 of our employees participate in the purchase plan.

Under the purchase plan, we make offerings to our employees to purchase stock beginning on dates established by our board of directors. Each offering commencement date begins a six-month period during which payroll deductions are made and held for the purchase of our common stock at the end of the purchase plan period. The first offering period under the purchase plan commenced on September 1, 2000 and ended on February 28, 2001, at which time we issued 6,662 shares to 21 participating employees. The second offering period began on March 1, 2001 and will end on August 31, 2001.

On the first day of a designated payroll deduction period, or offering period, we will grant to each eligible employee who has elected to participate in the purchase plan an option to purchase shares of our common stock as follows: the employee may authorize between 1% and 10% of his or her base pay to be deducted by us during the offering period. On the last day of the offering period, the employee is deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the purchase plan, the option exercise price is an amount equal to 85% of the closing price, as defined in the purchase plan, per share of our common stock on either the first day or the last day of the offering period, whichever is lower. In no event may an employee purchase in any one offering period a number of shares which exceeds the number of shares determined by dividing (a) the product of $2,083 and the number or fraction of months in the offering period by (b) the closing price of a share of our common stock on the commencement date of the offering period. Our board of directors may, in its discretion, choose an offering period of 12 months or less for each offering and may choose a different offering period for each offering.

An employee who is not a participant on the last day of the offering period is not entitled to exercise any option, and the employee's accumulated payroll deductions will be refunded. An employee's rights under the purchase plan terminate upon voluntary withdrawal from the purchase plan at any time, or when the employee ceases employment for any reason, except that upon termination of employment because of death, the employee's beneficiary has certain rights to elect to exercise the option to purchase the shares that the accumulated payroll deductions in the employee's account would purchase at the date of death.

Because participation in the purchase plan is voluntary, we cannot now determine the number of shares of our common stock to be purchased by any particular current executive officer, by all current executive officers as a group or by non-executive employees as a group.

401(k) Plan

Our employee savings and retirement plan is qualified under Section 401 of the Internal Revenue Code. Our employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and have the amount of such reduction contributed to the 401(k) plan. We may make matching or additional contributions to the 401(k) plan in amounts to be determined annually by our board of directors. We have not made any matching contributions or additional contributions to date.

CHANGE IN CONTROL ARRANGEMENTS

The terms of restricted stock agreements between us and certain of our employees, as well as the option agreements evidencing the grant of options under the 1998 plan, provide that in the event that we consummate

an acquisition, as defined in the agreements, and the employee or optionholder, within a period of one year after the acquisition:

(1) is terminated without cause;

(2) is terminated as the result of death, severe physical or mental disability; or

(3) terminates his or her employment for good reason in accordance with the terms of the agreements, the shares covered by such agreements shall vest in full.

TRANSACTIONS WITH EXECUTIVE OFFICERS, DIRECTORS AND FIVE PERCENT STOCKHOLDERS

Since our incorporation in July 1996, we have engaged in the following transactions with our directors, officers and holders of more than five percent of our voting securities and affiliates of our directors, executive officers and five percent stockholders:

ISSUANCE OF SERIES A PREFERRED STOCK

In September 1996, we issued 4,675 units, each unit consisting of one share of our series A preferred stock and 365 shares of our common stock, at price per unit of $1,000 for a total purchase price of $4.7 million. Of the 4,675 units sold, 4,009 units were sold to the following directors, executive officers and five percent stockholders and their affiliates:

NAME	SERIES A PREFERRED STOCK	COMMON STOCK	PURCHASE PRICE
Warburg, Pincus Venture Partners, L.P.	2,000	730,000	$2,000,000
PharmaBio Development Inc.	1,425	520,125	1,425,000
MPM Capital L.P.	250	91,250	250,000
Clive A. Meanwell	167	60,955	167,000
T. Scott Johnson	167	60,955	167,000

In June and December 1997, we issued an aggregate of 34,456 units, each unit consisted of one share of our series A preferred stock and 208.571 shares of common stock, at price per unit of $1,000 for a total purchase price of $34.6 million. Of the 34,456 units sold, 32,670 units were sold to the following directors, executive officers and five percent stockholders and their affiliates:

NAME	SERIES A PREFERRED STOCK	COMMON STOCK	PURCHASE PRICE
Biotech Growth S.A.	15,000	3,128,571	$15,000,000
Warburg, Pincus Venture Partners, L.P.	14,000	2,920,000	14,000,000
PharmaBio Development Inc.	2,670	556,880	2,670,000
Clive A. Meanwell	550	114,714	550,000
Peyton J. Marshall	350	73,000	350,000
John W. Villiger	100	20,856	100,000

In April 1997, we issued three promissory notes in the principal amounts of $1.2 million and $610,000 to Warburg, Pincus and Biotech Target, an affiliate of Biotech Growth, respectively. The outstanding principal amount of these notes was converted into units in the June 1997 financing.

EXCHANGE

In August 1998, the holders of the units issued in 1996 and 1997 exchanged these units, as well as shares of our series A preferred stock issued as stock dividends in December 1997 and August 1998, into shares of our series I and II convertible preferred stock. Stockholders who purchased units in 1996 received shares of our series I convertible preferred stock and those who purchased units in 1997 received shares of series II

convertible preferred stock. The following directors, executive officers and five percent stockholders and their affiliates received shares in the exchange:

NAME	SERIES I PREFERRED STOCK	SERIES II PREFERRED STOCK
Biotech Growth S.A.	--	4,621,143
Warburg, Pincus Venture Partners, L.P.	1,071,000	4,283,143
PharmaBio Development Inc.	764,500	818,286
Clive A. Meanwell	87,500	165,143
MPM Capital L.P.	135,000	--
Peyton J. Marshall	--	104,000
T. Scott Johnson	90,000	--
John W. Villiger	--	29,714

All shares of series I and series II convertible preferred stock, including accrued dividends on such stock from August 1, 2000 through August 11, 2000, the date of the closing of our initial public offering, automatically converted into an aggregate of 10,932,334 shares of common stock upon the closing of our initial public offering.

ISSUANCE OF SERIES III CONVERTIBLE PREFERRED STOCK

In August 1998, we issued an aggregate of 8,399,593 shares of series III preferred stock at a price per share of $4.32 for a total purchase price of $36.3 million. Of the 8,399,593 shares, 6,643,519 shares were sold to the following directors, executive officers and five percent stockholders and their affiliates:

NAME	SERIES III CONVERTIBLE PREFERRED	PURCHASE PRICE
Warburg, Pincus Venture Partners, L.P.	2,546,296	$10,999,999
Morgan Stanley Venture Partners III, L.P. and its affiliated funds	1,851,852	8,000,001
Alta Partners	1,736,112	7,500,004
Biotech Growth S.A.	462,963	2,000,000
Clive A. Meanwell	23,148	99,999
Peyton J. Marshall	23,148	99,999

All shares of our series III convertible preferred stock, including accrued dividends on such stock from August 1, 2000 through August 11, 2000, the date of the closing of our initial public offering, automatically converted into an aggregate of 7,038,398 shares of our common stock upon the closing of our initial public offering.

1999 DIVIDEND

In July 1999, we issued a stock dividend on all outstanding shares of series I convertible preferred stock, series II convertible preferred stock and series III convertible preferred stock. In connection with the dividend, we issued 172,005 shares of series I convertible preferred stock, 725,214 shares of series II convertible preferred stock and 571,510 shares of series III convertible preferred stock. The dividend covered the period from August 8, 1998 to July 31, 1999 with respect to series I and II convertible preferred stock and August 12, 1998 to July 31, 1999 with respect to the series III convertible preferred stock.

NOTE FINANCINGS

In October 1999, we issued convertible promissory notes in the aggregate principal amount of $6.0 million. The notes bore interest at a rate of 8% per year and were redeemable on January 15, 2001. In connection with the issuance of the notes, we issued common stock purchase warrants to purchase an aggregate of 1,013,877 shares of common stock with an exercise price of $5.92 per share. The warrants must

be exercised by October 19, 2004. The following directors, executive officers and five percent stockholders and their affiliates purchased notes and warrants:

NAME	NOTES	WARRANTS TO PURCHASE COMMON STOCK
Warburg, Pincus Venture Partners, L.P.	$2,750,000	464,699
Morgan Stanley Venture Partners III, L.P. and its affiliated funds	643,959	108,877
Alta Partners	604,048	102,072
PharmaBio Development Inc.	551,103	93,126
Biotech Growth S.A.	500,000	84,490
Clive A. Meanwell	150,000	25,347
Peyton J. Marshall	60,175	10,168
T. Scott Johnson	31,357	5,295
John M. Nystrom	20,000	3,379
John W. Villiger	10,000	1,689

In March 2000, we issued convertible promissory notes in the aggregate principal amount of $13.3 million. The notes bore interest at a rate of 8% per year and were redeemable on January 15, 2001. In connection with the issuance of the notes, we issued common stock purchase warrants to purchase an aggregate of 2,255,687 shares of common stock with an exercise price of $5.92 per share. The warrants must be exercised by March 2, 2005. The following directors, executive officers and five percent stockholders and their affiliates purchased notes and warrants:

NAME	NOTES	WARRANTS TO PURCHASE COMMON STOCK
Warburg, Pincus Venture Partners, L.P.	$4,800,000	811,111
Biotech Growth S.A.	3,500,000	591,435
Morgan Stanley Venture Partners III, L.P. and its affiliated funds	1,132,279	191,333
PharmaBio Development Inc.	1,120,000	189,259
Alta Partners	1,100,000	185,879
Armin M. Kessler	200,000	33,796
Clive A. Meanwell	200,000	33,796
T. Scott Johnson	50,000	8,449
Peyton J. Marshall	50,000	8,449
John M. Nystrom	10,000	1,689
John W. Villiger	10,000	1,689

On May 17, 2000, the outstanding aggregate principal amount of the notes issued in October 1999 and March 2000, and accrued interest thereon, were converted into an aggregate of 4,535,366 shares of our

series IV convertible preferred stock. The following directors, executive officers and five percent stockholders and their affiliates received 4,100,748 shares of our series IV preferred stock in the conversion:

NAME	NOTES	SERIES IV PREFERRED STOCK
Warburg, Pincus Venture Partners, L.P.	$7,639,901	1,768,495
Biotech Growth S.A.	4,060,110	939,840
Morgan Stanley Venture Partners III, L.P. and its affiliated funds	1,797,789	416,153
Alta Partners	1,724,556	399,201
PharmaBio Development Inc	1,691,752	391,609
Clive A. Meanwell	353,874	81,915
Armin M. Kessler	203,332	47,067
Peyton J. Marshall	111,225	25,746
T. Scott Johnson	82,283	19,047
John M. Nystrom	30,239	6,999
John W. Villiger	20,203	4,676

ISSUANCE OF SERIES IV CONVERTIBLE PREFERRED STOCK

In May 2000, we issued an aggregate of 1,411,000 shares of our series IV convertible preferred stock at a price per share of $4.32 for a total purchase price of $6.1 million. Of the 1,411,000 shares, 1,275,000 shares were sold to the following directors, executive officers and five percent stockholders and their affiliates:

NAME	SERIES IV PREFERRED STOCK	PURCHASE PRICE
Warburg, Pincus Venture Partners, L.P.	555,000	$2,397,600
Biotech Growth S.A.	345,000	1,490,400
Morgan Stanley Venture Partners III, L.P. and its affiliated funds	130,000	561,600
Alta Partners	130,000	561,600
PharmaBio Development Inc.	115,000	496,800

All shares of our series IV convertible preferred stock, including the shares issued upon the conversion of the notes, including accrued dividends on such stock from August 1, 2000 through August 11, 2000, the date of the closing of our initial public offering, automatically converted into an aggregate of 4,411,003 shares of common stock upon the consummation of our initial public offering.

2000 DIVIDEND

In July 2000, we issued a stock dividend on all outstanding shares of series I convertible preferred stock, series II convertible preferred stock, series III convertible preferred stock and series IV convertible preferred stock. In connection with the dividend we issued 187,458 shares of series I convertible preferred stock, 790,358 shares of series II convertible preferred stock, 629,530 shares series III convertible preferred stock and 84,394 shares of series IV convertible preferred stock. The dividend covered the period from August 1, 1999 to July 31, 2000 with respect to the series I, II and III convertible preferred stock and May 17, 2000 to July 31, 2000 with respect to the series IV convertible preferred stock.

MAY 2001 PRIVATE PLACEMENT

In May 2001, we sold the 4,000,000 shares of our common stock covered by this prospectus at a price per share of $11.00 for a total purchase price of $44.0 million. Of the 4,000,000 shares, 1,720,000 shares were sold to the following directors, executive officers and five percent stockholders and their affiliates:

NAME	COMMON STOCK	PURCHASE PRICE
Warburg, Pincus Venture Partners, L.P.	1,050,000	$11,550,000
Alta Partners	450,000	4,950,000
PharmaBio Development Inc	200,000	2,200,000
Clive A. Meanwell	10,000	110,000
T. Scott Johnson	5,000	55,000
Glenn P. Sblendorio	5,000	55,000

CERTAIN RELATIONSHIPS

PharmaBio/Quintiles

In August 1996, we entered into a strategic alliance with PharmaBio Development, Inc., a wholly owned subsidiary of Quintiles Transnational Corp. Under the terms of the strategic alliance agreement, PharmaBio and any of its affiliates who work on our projects will, at no cost to us, review and evaluate, jointly with us, development programs we design related to potential or actual product acquisitions. The purpose of this collaboration is to optimize the duration, cost, specifications and quality aspects of such programs. PharmaBio and its affiliates have also agreed to perform other services with respect to our products, including clinical and non-clinical development services, project management, project implementation, pharmacoeconomic services, regulatory affairs and post-marketing surveillance services and statistical, statistical programming, data processing and data management services pursuant to work orders agreed to by us and PharmaBio from time to time. Through April 30, 2001, we had entered into approximately 40 work orders with PharmaBio and had paid PharmaBio a total of $11.9 million. We have outstanding obligations to PharmaBio of an additional $630,000 under outstanding work orders.

In addition, under the strategic alliance agreement, if PharmaBio and its affiliates exceed performance milestones agreed upon prior to the initiation of services under any work order, we will pay certain bonuses (not to exceed 10% of the net revenues PharmaBio and its affiliates received for such services) which, at the option of PharmaBio, may be paid in shares of our common stock. To date, performance milestones have been requested and agreed upon for one work order out of the work orders completed or outstanding, and no such agreed upon milestones remain outstanding.

Innovex

In January 1997, we entered into a consulting agreement with Innovex, Inc., a subsidiary of Quintiles, which was subsequently superseded by a consulting agreement we executed with Innovex in December 1998. Pursuant to the terms of these agreements, Innovex has provided us with consulting services with respect to pharmaceutical marketing and sales. Since December 1997, we have also entered into various clinical services agreements with Innovex pursuant to which Innovex has provided project management, clinical monitoring, site management, medical monitoring, regulatory affairs, data management and quality assurance services with respect to clinical trials of Angiomax. None of the clinical services agreements is currently outstanding. Through April 30, 2001, we had paid Innovex $1.8 million under all of these agreements.

In July 2000, we signed a letter of intent with Innovex to enter into a sales agreement under which Innovex would provide sales and marketing services in connection with Angiomax. Although the letter of intent contemplated the negotiation and execution of a binding sales agreement and could be terminated at any time by either party if no binding sales agreement was reached, we agreed in the letter of intent that Innovex would begin performing its services immediately. These services included recruiting and training up to 52 sales representatives and engaging in other agreed-upon activities.

In December 2000, we signed a master services agreement and a work order with Innovex under which Innovex agreed to provide contract sales, marketing and commercialization services relating to Angiomax. Under the master services agreement, Innovex may provide additional services unrelated to Angiomax pursuant to work orders entered into from time-to-time. Under the master services agreement and the Angiomax work order, Innovex will provide the Angiomax sales force, a sales territory management system and operational support for the launch of Angiomax. We will provide the marketing plan and marketing materials for the sales force and other sales and marketing support and direction for the sales force. For Innovex's services, we have agreed to pay a daily fee for each day worked by the members of the sales force. We will reimburse Innovex for expenses incurred in providing the services and for the incentive compensation paid to the sales force by Innovex. We have the right to terminate the work order and the master services agreement at any time upon 90 days written notice. We may hire members of the sales force, although we may incur additional fees to Innovex. Through April 30, 2001, we had paid Innovex $3.0 million for its services under the letter of intent and master services agreement and work order.

Stack Pharmaceuticals

In April 2000, we entered into an agreement with Stack Pharmaceuticals, Inc., which is an entity controlled by David Stack, one of our senior vice presidents, which we amended in August 2000. Pursuant to the terms of this agreement, as amended, Stack Pharmaceuticals will perform infrastructure services for us, which includes providing office facilities, equipment and supplies for our employees based in New Jersey, and such consulting, advisory and related services for us as we may agree from time to time. For the infrastructure services, we have agreed to pay Stack Pharmaceuticals a services fee of $20,100 per month. The fees for any additional services to be provided to us will be agreed upon with Stack Pharmaceuticals prior to the delivery of such services. The term of this agreement continues until April 1, 2001, but either party may terminate it earlier upon 90 days prior written notice. From January 2000 through March 2000, Stack Pharmaceuticals provided us with consulting services under a consulting agreement which expired on March 31, 2000. Through April 30, 2001, we had paid Stack Pharmaceuticals a total of $502,000 under these agreements.

PRINCIPAL STOCKHOLDERS

The following table presents information regarding the beneficial ownership of our common stock as of May 16, 2001 by:

- each of the individuals listed in the "Summary Compensation Table" above;

- each of our directors;

- each person, or group of affiliated persons, who is known by us to beneficially own five percent or more of our common stock; and

- all current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and includes voting or investment power with respect to shares. Shares of common stock issuable upon exercise of warrants and/or stock options that are exercisable within 60 days after May 16, 2001 are deemed outstanding for computing the percentage ownership of the person holding the warrants and/or options but are not deemed outstanding for computing the percentage ownership of any other person. Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below. Unless otherwise indicated in the footnotes, the address of each of the individuals named below is: c/o The Medicines Company, One Cambridge Center, Cambridge, Massachusetts 02142.

	BENEFICIAL OWNERSHIP		
	SHARES BENEFICIALLY OWNED AT MAY 16, 2001	SHARES UNDERLYING OPTIONS AND/OR WARRANTS EXERCISABLE WITHIN 60 DAYS PRIOR TO JULY 15, 2001	PERCENTAGE BENEFICIALLY OWNED AFTER OFFERING
5% STOCKHOLDERS:			
Warburg, Pincus Ventures, L.P.(1)	9,379,446	1,275,810	26.9%
Biotech Growth S.A.(2)	5,204,837	675,925	16.8%
Alta Partners(3)	2,293,474	287,951	6.1%
Morgan Stanley Venture Partners III, L.P. and its affiliated funds(4)	1,952,777	300,210	6.5%
PharmaBio Development, Inc.(5)	1,896,245	282,385	5.7%
DIRECTORS AND NAMED EXECUTIVE OFFICERS:			
Clive A. Meanwell	548,693	221,580	2.2%
Peyton J. Marshall(6)	271,420	112,285	1.1%
John W. Villiger(7)	209,465	39,596	*
John M. Nystrom(8)	36,925	65,611	*
John D. Richards	37,100	24,712	*
Leonard Bell(9)	--	4,258	*
Dennis B. Gillings(10)	--	--	--
Stewart J. Hen(11)	--	2,083	*
Anders D. Hove(12)	--	--	--
M. Fazle Husain(13)	--	--	--
T. Scott Johnson(14)	96,079	13,744	*
Armin M. Kessler(15)	37,914	43,806	*
Nicholas J. Lowcock(16)	9,379,446	1,278,726	26.9%
James E. Thomas(17)	10,000	4,258	*
All directors and executive officers as a group (17 persons)	10,633,042	1,970,139	31.7%

* Represents beneficial ownership of less than 1 percent.

(1) Consists of shares with respect to which Warburg, Pincus Ventures, L.P., Warburg, Pincus & Co. and Warburg Pincus LLC share ownership and voting and dispositive power. Warburg, Pincus Ventures is

managed by Warburg Pincus LLC. Lionel I. Pincus is the managing partner of Warburg, Pincus & Co. and the managing member of Warburg Pincus LLC and may be deemed to control both entities. The members of Warburg Pincus LLC are substantially the same as the partners of Warburg, Pincus & Co. The address of the Warburg, Pincus entities is 466 Lexington Avenue, New York, New York 10017. This information is based on a Schedule 13G filed by the Warburg, Pincus entities with the Commission on February 14, 2001.

(2) Consists of shares owned directly by Biotech Growth S.A. with respect to which BB Biotech AG and Biotech Growth S.A. share voting and dispositive power. Biotech Growth S.A. is a wholly owned subsidiary of BB Biotech AG. The address of Biotech Growth S.A. is Calle 53, Urbanizacion Obarrio, Torre Swiss Bank, Piso 16, Panama City, Zona 1, Republic of Panama. This information is based on a Schedule 13G filed by BB Biotech AG on behalf of Biotech Growth S.A. with the Commission on February 14, 2001.

(3) Includes 1,425,594 shares and warrants to purchase 178,987 shares held by Alta BioPharma Partners, L.P., 814,149 shares and warrants to purchase 102,218 shares held by The Medicines Company Chase Partners (Alta Bio), LLC and 53,731 shares and warrants to purchase 6,746 shares held by Alta Embarcadero BioPharma Partners, LLC. Alta Partners provides investment advisory services to several venture capital funds, including Alta BioPharma Partners L.P., The Medicines Company Chase Partners (Alta Bio), LLC and Alta Embarcadero BioPharma Partners, LLC. The respective general partner and managing members of Alta BioPharma Partners, L.P., The Medicines Company Chase Partners (Alta Bio), LLC and Alta Embarcadero BioPharma Partners, LC exercise sole voting and investment power with respect to the shares owned by such funds. The principals of Alta Partners are members of Alta BioPharma Management, LLC (which is the general partner of Alta BioPharma Partners, L.P.), and Alta/Chase BioPharma Management, LLC (which is the managing member of The Medicines Company Chase Partners (Alta Bio), LLC) and Alta Embarcadero BioPharma Partners, LLC. As general partners and managing members of such entities, they may be deemed to share voting and investment powers for the shares held by the funds. The principals of Alta Partners disclaim beneficial ownership of all such shares held by the foregoing funds, except to the extent of their proportionate pecuniary interests therein. The address of Alta Partners is One Embarcadero Center, Suite 4050, San Francisco, California 94111.

(4) Includes 1,713,322 shares and warrants to purchase 263,399 shares owned directly by Morgan Stanley Venture Partners III, L.P., 164,501 shares and warrants to purchase 25,288 shares owned directly by Morgan Stanley Venture Investors III, L.P. and 74,954 shares and warrants to purchase 11,523 shares owned directly by The Morgan Stanley Venture Partners Entrepreneur Fund, L.P. Morgan Stanley Venture Partners III, L.L.C. is the general partner of Morgan Stanley Venture Partners III, L.P., Morgan Stanley Venture Investors III, L.P. and The Morgan Stanley Venture Partners Entrepreneur Fund, L.P. (collectively, the "Funds"), and, as such, has the power to vote or direct the vote and to dispose or direct the disposition of all of the shares held by the Funds. Morgan Stanley Venture Capital III, Inc. is the institutional managing member of Morgan Stanley Venture Partners III, L.L.C., and, as such, shares, together with the remaining managing members, the power to direct the actions of Morgan Stanley Venture Partners III, L.L.C. Morgan Stanley Dean Witter & Co., as the sole stockholder of Morgan Stanley Venture Capital III, Inc., controls the actions of Morgan Stanley Venture Capital III, Inc. Therefore, Morgan Stanley Venture Capital III, L.L.C., Morgan Stanley Venture Capital III, Inc. and Morgan Stanley Dean Witter & Co. each may be deemed to have beneficial ownership of the shares held collectively by the Funds. The address of the Funds is 1221 Avenue of the Americas, New York, New York 10020. This information is based on a Schedule 13G filed by Morgan Stanley Dean Witter & Co., Morgan Stanley Venture Capital III, Inc., Morgan Stanley Venture Partners III, L.L.C. and the Funds with the Commission on January 26, 2001.

(5) Includes 1,896,245 shares held by PharmaBio Development Inc., a wholly owned subsidiary of Quintiles Transnational Corp., and warrants to purchase 282,385 shares held by Quintiles Transnational Corp. The address of PharmaBio Development Inc. is c/o Quintiles Transnational Corp., 4709 Creekstone Drive, Suite 200, Durham, North Carolina 27703. This information is based on a Schedule 13G filed by

Quintiles Transnational Corp. and PharmaBio Development Inc. with the Commission on February 14, 2001.

(6) Includes 58,400 shares held in custody for the benefit of Dr. Marshall's minor children.

(7) Includes 209,465 shares and warrants to purchase 3,378 shares held in trust for the benefit of the Villiger Family.

(8) Includes 10,820 shares held by Dr. Nystrom's children. Dr. Nystrom disclaims beneficial ownership of these shares.

(9) The address of Dr. Bell is c/o Alexion Pharmaceuticals, Inc., 25 Science Park, Suite 360, Box 15, New Haven, Connecticut 06511.

(10) Does not include 1,896,245 shares held by PharmaBio Development Inc. or warrants to purchase 282,385 shares held by Quintiles Transnational Corp., of which Dr. Gillings is the Chairman. Dr. Gillings disclaims beneficial ownership of these shares. The address of Dr. Gillings is c/o Quintiles Transactional Corp., 4709 Creekstone Drive, Suite 200, Durham, North Carolina 27703.

(11) The address of Mr. Hen is c/o Warburg, Pincus, 466 Lexington Avenue, New York, New York 10017.

(12) Does not include 5,204,837 shares or warrants to purchase 675,925 shares held by Biotech Growth S.A. Dr. Hove is affiliated with Bellevue Asset Management, which serves as the non-discretionary investment manager of Biotech Growth S.A. Dr. Hove disclaims beneficial ownership of these shares. The address of Dr. Hove is c/o Bellevue Asset Management, One Cambridge Center, Cambridge, Massachusetts 02142.

(13) Does not include 1,952,777 shares or warrants to purchase 300,210 shares held by the Funds. Mr. Husain is a vice president of Morgan Stanley Venture Partners III, Inc., which is the institutional managing member of Morgan Stanley Venture Partners III, L.L.C., which is a general partner of each of the Funds. Mr. Husain disclaims beneficial ownership of these shares. The address of Mr. Husain is c/o Morgan Stanley Venture Partners III, Inc., 1221 Avenue of the Americas, New York, New York 10020.

(14) The address of Dr. Johnson is c/o JSB Partners, 6A Damonmill Square, Concord, Massachusetts 01742.

(15) Includes 3,000 shares held by Dr. Kessler's wife.

(16) Includes 9,379,446 shares and warrants to purchase 1,275,810 shares held by Warburg, Pincus Ventures, L.P. Mr. Lowcock is a Managing Director of Warburg Pincus LLC. All shares indicated as owned by Mr. Lowcock are included because of his affiliation with the Warburg, Pincus entities. The address of Mr. Lowcock is c/o Warburg, Pincus, Almack House, 28 King Street, St. James, London SW1Y 6QW. Mr. Lowcock disclaims beneficial ownership of all shares owned by the Warburg, Pincus entities.

(17) The address of Mr. Thomas is Woods End Road, New Canaan, Connecticut 06840.

DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 75,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of undesignated preferred stock, $1.00 par value per share.

The following summary of our capital stock, and some of the provisions of our certificate of incorporation and other agreements to which we and our stockholders are parties, is not intended to be complete and is qualified by reference to our certificate of incorporation and any other agreements included as exhibits to or incorporated by reference into the registration statement of which this prospectus is a part. See "Where You Can Find More Information."

COMMON STOCK

As of May 15, 2001, the day immediately prior to the private placement of the 4,000,000 shares of common stock covered by this prospectus, there were 30,404,826 shares of our common stock outstanding held by 127 stockholders of record.

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders and do not have any cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Holders of our common stock are entitled to receive proportionally any dividends declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities, subject to the prior rights of any outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. All outstanding shares of our common stock are validly issued, fully paid and nonassessable. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock that we may designate and issue in the future.

PREFERRED STOCK

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. The board has discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock. There are currently no shares of preferred stock outstanding.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could make it more difficult for a third party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

WARRANTS

As of May 15, 2001, we had outstanding common stock purchase warrants entitling their holders to purchase an aggregate of 3,269,564 shares of common stock at an exercise price of $5.92 per share. In October 1999, we issued warrants exercisable at any time prior to October 19, 2004 for 1,013,877 shares of our common stock in connection with the sale of 8% convertible promissory notes in the aggregate principal amount of $6.0 million. In March 2000, we issued warrants exercisable at any time prior to March 2, 2005 for 2,255,687 shares of our common stock in connection with the sale of 8% convertible promissory notes in the aggregate principal amount of $13.3 million.

ANTI-TAKEOVER PROVISIONS OF DELAWARE LAW AND CHARTER AND BY-LAW PROVISIONS

Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporate Law. In general, the statute prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

- prior to the date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding those shares owned by persons who are directors and also officers, and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- in general, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Charter and By-law Provisions

Our charter and our amended and restated by-laws provide for the division of our board of directors into three classes as nearly equal in size as possible with staggered three-year terms. See "Management -- Board Composition." Under our charter and by-laws, any vacancy on the board of directors, including a vacancy resulting from an enlargement of the board of directors, may only be filled by vote of a majority of the directors then in office. The classification of the board of directors and the limitation on and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from acquiring, control of our company.

Our charter and by-laws also provide that any action required or permitted to be taken by our stockholders at an annual or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our by-laws further provide that special meetings of the stockholders may only be called by the chairman of our board of directors, our president or a majority of our board. In order for any matter to be considered "properly brought" before a meeting, a stockholder must comply with certain requirements regarding advance notice and provide us with certain information. These provisions could have the effect of delaying until the next stockholders meeting stockholder actions which are favored by the holders of a majority of our outstanding voting securities.

The General Corporation Law of Delaware provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our charter and our by-laws require the affirmative vote of holders of at least 50% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors to amend or repeal any of the provisions described in the prior two paragraphs.

Our certificate of incorporation contains certain provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. These provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, except in certain circumstances involving wrongful acts, such as the breach of a director's duty of loyalty or acts or omissions which involve intentional misconduct or a knowing violation of law. Further, our certificate of incorporation contains provisions to indemnify our directors and officers to the fullest extent permitted by the General Corporation Law of Delaware. We believe that these provisions will assist us in attracting and retaining qualified individuals to serve as directors.

TRANSFER AGENT AND REGISTRAR

Mellon Investor Services, LLC serves as the transfer agent and registrar for our common stock.

NASDAQ NATIONAL MARKET LISTING

Our shares of common stock are listed on the Nasdaq National Market under the symbol "MDCO".

SHARES ELIGIBLE FOR FUTURE SALE

Following the closing of the private placement of the 4,000,000 shares of common stock covered by this prospectus on May 16, 2001, we had outstanding an aggregate of 34,406,826 shares of common stock and currently exercisable warrants to purchase 3,269,564 shares of common stock. Of those shares, the 6,900,000 shares sold in our initial public offering and all of the 4,000,000 shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless these shares are purchased by affiliates. Generally, the balance of the outstanding shares of common stock are "restricted securities." Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under the Securities Act.

As of May 15, 2001, there were outstanding options to purchase 3,497,581 shares of common stock.

REGISTRATION RIGHTS

Pursuant to a registration rights agreement dated August 12, 1998, as amended, the holders of approximately 18,572,874 shares of common stock and warrants exercisable for 3,269,564 shares of common stock are entitled to require us to register their shares under the Securities Act. Under this agreement, if we propose to register any of our securities under the Securities Act, either for our account or for the account of other security holders exercising registration rights, the holders are entitled to notice of the registration and to include their shares of common stock in the registration. Additionally, such holders may, on up to three occasions, require us to register their shares of common stock under the Securities Act, and we are required to use our best efforts to effect any such registration. We are responsible for paying the expense of any such registration. Further, such holders may require us to file nine additional registration statements on Form S-3 at our expense. These registration rights are subject to conditions and limitations, including
(i) the right of the underwriters of an offering to limit the number of shares included in such registration (ii) the right of the underwriters to lock-up the share's of such holders for a period of 120 days after the effective date of any registration statement filed by us and (iii) our right not to effect a requested registration within 180 days following an offering of our securities pursuant to a Form S-3. The parties to the registration rights agreement waived their rights to notice of, and to include their shares of common stock in, this registration.

Pursuant to stock purchase agreements dated as of May 11, 2001, we granted registration rights with respect to 4,000,000 shares of our common stock sold in a private placement. This prospectus is a part of the registration statement filed with the SEC to register the resale of these shares. We are obligated to keep the registration statement effective until the earlier of (i) May 16, 2003,
(ii) the date on which the selling stockholders may sell all of the shares covered by this prospectus without restriction by the volume limitations of Rule 144(e) of the Securities Act, or (iii) such time as all of the shares covered by this prospectus have been sold pursuant to and in accordance with the registration statement.

PLAN OF DISTRIBUTION

The shares covered by this prospectus may be offered and sold from time to time by the selling stockholders. The term "selling stockholders" includes donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other non-sale related transfer. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholders may sell their shares by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;

- ordinary brokerage transactions and transactions in which the broker solicits purchasers;

- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

- an over-the-counter distribution in accordance with the rules of the Nasdaq National Market;

- in privately negotiated transactions; and

- in options transactions.

In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with selling stockholders. The selling stockholders may also sell the common stock short and redeliver the shares to close out such short positions. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In effecting sales, broker-dealers or agents engaged by the selling stockholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholders in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the selling stockholders and any broker-dealers who execute sales for the selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. Any profits realized by the selling stockholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus available to the selling stockholders for the

purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, a prospectus supplement will be distributed that will set forth the number of shares being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallowed or paid to any dealer, and the proposed selling price to the public.

We have agreed to indemnify the selling stockholders against certain liabilities, including certain liabilities under the Securities Act.

We have agreed with the selling stockholders to keep the Registration Statement of which this prospectus constitutes a part effective until the earlier of (i) May 16, 2003, (ii) the date on which the selling stockholders may sell all the shares covered by this prospectus without restriction by the volume limitations of Rule 144(e) of the Securities Act, or (iii) such time as all of the shares covered by this prospectus have been sold pursuant to and in accordance with the registration statement.

LEGAL MATTERS

Certain legal matters with respect to the validity of the shares of common stock offered hereby has been passed upon us by Hale and Dorr LLP, Boston, Massachusetts. Partners of Hale and Dorr LLP beneficially own an aggregate of 19,292 shares of our common stock and warrants exercisable for 1,554 additional shares of common stock.

EXPERTS

Ernst & Young LLP, independent auditors, have audited our consolidated financial statements as of December 31, 1999 and 2000 and for each of the three years in the period ended December 31, 2000, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC's public reference room at Judiciary Plaza Building, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC's Internet site at http://www.sec.gov.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet site.

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THE MEDICINES COMPANY

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REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders
The Medicines Company

We have audited the accompanying consolidated balance sheets of The Medicines Company (a company in the development stage) as of December 31, 1999 and 2000, and the related consolidated statements of operations, redeemable preferred stock and stockholders' equity/(deficit), and cash flows, for each of the three years in the period ending December 31, 2000, and for the period July 31, 1996 (date of inception) to December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of The Medicines Company at December 31, 1999 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, and for the period July 31, 1996 (date of inception) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
February 13, 2001, except
for the eighth paragraph
of Note 2, as to which
the date is February 20, 2001

THE MEDICINES COMPANY
(A COMPANY IN THE DEVELOPMENT STAGE)

CONSOLIDATED BALANCE SHEETS

	DECEMBER 31, 1999	DECEMBER 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,643,266	$ 36,802,356
Marketable securities	539,274	42,522,729
Accrued interest receivable	55,225	1,392,928
	7,237,765	80,718,013
Inventory	--	1,963,491
Prepaid expenses and other current assets	154,967	465,650
Total current assets	7,392,732	83,147,154
Fixed assets, net	430,061	965,832
Other assets	168,605	250,144
Total assets	$ 7,991,398	$ 84,363,130
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 7,815,028	$ 5,987,213
Accrued expenses	3,680,293	9,136,934
Total current liabilities	11,495,321	15,124,147
Convertible notes	5,776,319	--
Commitments and contingencies		
Redeemable Convertible Preferred Stock, $1 par value; 31,550,000 and 5,000,000 shares authorized at December 31, 1999 and 2000, respectively; shares issued and outstanding: 22,962,350 and none at December 31, 1999 and 2000, respectively; at redemption value (Liquidation value of $86,167,821 and $0 at December 31, 1999 and 2000, respectively)	85,277,413	--
Stockholders' equity/(deficit):		
Common stock, $.001 par value, 36,000,000 and 75,000,000 shares authorized at December 31, 1999 and 2000, respectively; shares issued and outstanding: 833,400 and 30,320,455 at December 31, 1999 and 2000, respectively	834	30,320
Additional paid-in capital	339,144	279,126,337
Deferred stock compensation	--	(13,355,694)
Deficit accumulated during the development stage	(94,925,028)	(196,560,034)
Accumulated other comprehensive income (loss)	27,395	(1,946)
Total stockholders' equity (deficit)	(94,557,655)	69,238,983
Total liabilities and stockholders' equity (deficit)	$ 7,991,398	$ 84,363,130

See accompanying notes.

THE MEDICINES COMPANY
(A COMPANY IN THE DEVELOPMENT STAGE)

CONSOLIDATED STATEMENTS OF OPERATIONS

	YEAR ENDED DECEMBER 31,			PERIOD JULY 31, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2000
	1998	1999	2000	
Operating expenses:				
Research and development	$ 24,004,606	$ 30,344,892	$ 39,572,297	$ 110,793,397
Selling, general and administrative	6,248,265	5,008,387	15,033,585	29,411,917
Total operating expenses	30,252,871	35,353,279	54,605,882	140,205,314
Loss from operations	(30,252,871)	(35,353,279)	(54,605,882)	(140,205,314)
Other income (expense):				
Interest income	1,302,073	837,839	2,704,126	5,593,904
Interest expense	--	(197,455)	(19,390,414)	(19,617,104)
Net loss	(28,950,798)	(34,712,895)	(71,292,170)	(154,228,514)
Dividends and accretion to redemption value of redeemable preferred stock	(3,958,903)	(5,893,016)	(30,342,988)	(42,331,520)
Net loss attributable to common stockholders	$(32,909,701)	$(40,605,911)	$(101,635,158)	$(196,560,034)
Basic and diluted net loss attributable to common stockholders per common share	$ (6.03)	$ (80.08)	$ (8.43)	
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share	$ --	$ (1.94)	$ (2.10)	
Shares used in computing net loss attributable to common stockholders per common share:				
Basic and diluted	5,454,653	507,065	12,059,275	
Unaudited pro forma basic and diluted	--	17,799,876	24,719,075	

See accompanying notes.

THE MEDICINES COMPANY
(A COMPANY IN THE DEVELOPMENT STAGE)

CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) FOR THE PERIOD JULY 31, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2000

	REDEEMABLE PREFERRED STOCK		REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK	
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT
Issuance of common stock				$ --	2,042,175	$ 2,042
Issuance of redeemable preferred stock	4,675	$ 4,675,000				
Accretion of preferred stock to redemption value		118,348				
Net loss						
Balance at December 31, 1996	4,675	4,793,348	--	--	2,042,175	2,042
Employee stock purchases					627,070	627
Issuance of common stock					7,186,537	7,187
Issuance of redeemable preferred stock	34,456	33,498,408				
Dividends on preferred stock	1,175	1,056,652				
Accretion of preferred stock to redemption value		957,592				
Net loss						
Currency translation adjustment						
Unrealized gain on marketable securities						
Comprehensive loss						
Balance at December 31, 1997	40,306	40,306,000	--	--	9,855,782	9,856
Employee stock purchases					34,887	35
Repurchase of common stock					(107,979)	(108)
Exchange of redeemable preferred stock for redeemable convertible preferred stock	(41,992)	(41,992,000)	13,071,714	41,992,000	(8,892,912)	(8,893)
Issuance of redeemable convertible preferred stock			8,421,907	35,126,419		
Dividends on preferred stock	1,686	1,686,0000				
Accretion of preferred stock to redemption value				2,266,051		
Net loss						
Currency translation adjustment						
Unrealized loss on marketable securities						
Comprehensive loss						
Balance at December 31, 1998	--	--	21,493,621	79,384,470	889,778	890

	ADDITIONAL PAID-IN CAPITAL	DEFERRED STOCK COMPENSATION	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	COMPREHENSIVE INCOME (LOSS)	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
Issuance of common stock	$ 755	$ --		$ --	$ 2,797
Issuance of redeemable preferred stock					
Accretion of preferred stock to redemption value			$ (118,348)		(118,348)
Net loss			(1,466,877)		(1,466,877)
Balance at December 31, 1996	755	--	(1,585,225)	--	(1,582,428)
Employee stock purchases	232				859
Issuance of common stock	2,658				9,845
Issuance of redeemable preferred stock					
Dividends on preferred stock			(1,060,673)		(1,060,673)
Accretion of preferred stock to redemption value			(957,592)		(957,592)
Net loss			(17,805,926)		(17,805,926)
Currency translation adjustment				1,806	1,806
Unrealized gain on marketable securities				7,274	7,274
Comprehensive loss					(17,796,846)
Balance at December 31, 1997	3,645	--	(21,409,416)	9,080	(21,386,835)
Employee stock purchases	1,312				1,347
Repurchase of common stock	(40)				(148)
Exchange of redeemable preferred stock for redeemable convertible preferred stock	8,893				--
Issuance of redeemable convertible preferred stock					
Dividends on preferred stock			(1,692,852)		(1,692,852)
Accretion of preferred stock to redemption value			(2,266,051)		(2,266,051)
Net loss			(28,950,798)		(28,950,798)
Currency translation adjustment				31,562	31,562
Unrealized loss on marketable securities				(1,984)	(1,984)
Comprehensive loss					(28,921,220)
Balance at December 31, 1998	13,810	--	(54,319,117)	38,658	(54,265,759)

See accompanying notes.

THE MEDICINES COMPANY
(A COMPANY IN THE DEVELOPMENT STAGE)

CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) -- (CONTINUED)

	REDEEMABLE PREFERRED STOCK		REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	
Repurchase of common stock					(56,378)	(56)	(21)
Dividends on preferred stock			1,468,729	5,351,178			
Accretion of preferred stock to redemption value				541,765			
Issuance of warrants associated with convertible notes							325,355
Net loss							
Currency translation adjustment							
Unrealized loss on marketable securities							
Comprehensive loss							
Balance at December 31, 1999	--	--	22,962,350	85,277,413	833,400	834	339,144
Repurchase of common stock					(22,205)	(22)	
Employee Stock purchases					227,525	226	286,068
Issuance of redeemable convertible preferred stock			5,946,366	25,688,284			
Accretion and dividend on preferred stock			1,751,241	4,898,537			
Beneficial conversion of redeemable convertible preferred stock							25,444,299
Issuance of warrants associated with convertible notes							18,789,805
Issuance of common stock through initial public offering					6,900,000	6,900	101,343,162
Conversion of preferred stock to common stock			(30,659,957)	(115,864,234)	22,381,735	22,382	115,841,732
Deferred compensation expense associated with stock options							17,279,612
Adjustments to deferred compensation for terminations							(197,485)
Amortization of deferred compensation							
Net loss							
Currency translation adjustment							
Unrealized loss on marketable securities							
Comprehensive loss							
Balance at December 31, 2000	--	$ --	--	$ --	30,320,455	$30,320	$279,126,337

	DEFERRED STOCK COMPENSATION	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	COMPREHENSIVE INCOME (LOSS)	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
Repurchase of common stock				(77)
Dividends on preferred stock		(5,351,251)		(5,351,251)
Accretion of preferred stock to redemption value		(541,765)		(541,765)
Issuance of warrants associated with convertible notes				325,355
Net loss		(34,712,895)		(34,712,895)
Currency translation adjustment			(3,847)	(3,847)
Unrealized loss on marketable securities			(7,416)	(7,416)
Comprehensive loss				(34,724,158)
Balance at December 31, 1999	--	(94,925,028)	27,395	(94,557,655)
Repurchase of common stock				(22)
Employee Stock purchases				286,294
Issuance of redeemable convertible preferred stock				--
Accretion and dividend on preferred stock		(4,898,537)		(4,898,537)
Beneficial conversion of redeemable convertible preferred stock		(25,444,299)		--
Issuance of warrants associated with convertible notes				18,789,805
Issuance of common stock through initial public offering				101,350,062
Conversion of preferred stock to common stock				115,864,114
Deferred compensation expense associated with stock options	(17,279,612)			--
Adjustments to deferred compensation for terminations	197,485			--
Amortization of deferred compensation	3,726,433			3,726,433

Net loss		(71,292,170)		(71,292,170)
Currency translation adjustment			5,141	5,141
Unrealized loss on marketable securities			(34,482)	(34,482)
Comprehensive loss				(71,321,511)
Balance at December 31, 2000	$(13,355,694)	$(196,560,034)	$ (1,946)	$ 69,238,983

See accompanying notes.

THE MEDICINES COMPANY
(A COMPANY IN THE DEVELOPMENT STAGE)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEAR ENDED DECEMBER 31,			PERIOD JULY 31, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2000
	1998	1999	2000	
Cash flows from operating activities:				
Net loss	$(28,950,798)	$(34,712,895)	$(71,292,170)	$(154,228,514)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	98,413	207,663	277,307	618,677
Amortization of discount on convertible notes	--	101,674	19,013,486	19,115,160
Amortization of deferred stock compensation	--	--	3,726,433	3,726,433
Loss on sales of fixed assets	--	--	14,631	14,631
Changes in operating assets and liabilities:				
Accrued interest receivable	(705,515)	690,290	(1,337,703)	(1,392,928)
Inventory	--		(1,963,491)	(1,963,491)
Prepaid expenses and other current assets	(156,812)	39,141	(312,027)	(466,548)
Other assets	(152,165)	(3,349)	(82,391)	(250,629)
Accounts payable	(31,864)	5,528,544	(1,823,602)	5,990,320
Accrued expenses	(1,928,001)	1,258,366	5,708,535	9,386,636
Net cash used in operating activities	(31,826,742)	(26,890,566)	(48,070,992)	(119,450,253)
Cash flows from investing activities:				
Purchases of marketable securities	(29,861,162)	--	(51,098,901)	(111,144,188)
Maturities and sales of marketable securities	28,722,483	18,796,493	9,083,090	68,586,977
Purchase of fixed assets	(357,103)	(258,788)	(834,160)	(1,604,226)
Net cash provided by (used in) investing activities	(1,495,782)	18,537,705	(42,849,971)	(44,161,437)
Cash flows from financing activities:				
Proceeds from issuance of convertible notes and warrants	--	6,000,000	13,348,779	19,348,779
Proceeds from issuance of preferred stock, net	35,126,419	--	6,095,338	79,395,165
Proceeds from issuance of common stock, net	1,347	--	101,636,356	101,651,204
Repurchases of common stock	(148)	(77)	(22)	(247)
Dividends paid in cash	(6,852)	(73)	(118)	(11,064)
Net cash provided by financing activities	35,120,766	5,999,850	121,080,333	200,383,837
Effect of exchange rate changes on cash	29,928	(1,245)	(280)	30,209
Increase (decrease) in cash and cash equivalents	1,828,170	(2,354,256)	30,159,090	36,802,356
Cash and cash equivalents at beginning of period	7,169,352	8,997,522	6,643,266	--
Cash and cash equivalents at end of period	$ 8,997,522	$ 6,643,266	$ 36,802,356	$ 36,802,356
Non-cash transactions:				
Dividends on preferred stock	$ 1,686,000	$ 5,351,178	$ 31,894,474	$ 40,106,652
Supplemental disclosure of cash flow information:				
Interest paid	$ --	$ --	$ 255,781	$ 285,016

See accompanying notes.

1. NATURE OF BUSINESS

The Medicines Company (the Company) was incorporated in Delaware on July 31, 1996. The Company is a pharmaceutical company engaged in the acquisition, development and commercialization of late-stage development drugs. The Company is a development-stage enterprise, as defined in Statement of Financial Accounting Standards No. 7, and has, since inception, been developing business plans, acquiring product rights, conducting initial commercialization activities, obtaining financing, performing research and development, conducting regulatory activities and recruiting and training personnel. In December 2000, The U.S. Food and Drug Administration (FDA) approved Angiomax(R) (bivalirudin), the Company's lead product, for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA).

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Risks and Uncertainties

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to regulatory approvals, dependence on key products, and protection of proprietary rights.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents and marketable securities. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing investments in high-quality financial instruments. At December 31, 2000, approximately $23,300,000 of the cash and cash equivalents balance was invested in the Merrill Lynch Premier Institutional Fund, a no-load money market fund.

Cash, Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist of investments in money market funds, corporate bonds and taxable auction securities. These investments are carried at cost, which approximates fair value.

Marketable securities consist of securities with original maturities of greater than three months. The Company classifies its marketable securities as available-for-sale. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. The estimated fair value of the marketable securities is determined based on quoted market prices or rates for similar instruments. At December 31, 1999 and 2000, marketable securities

consisted of investments in corporate bonds with maturities of less than one year and are summarized as follows:

	COST	UNREALIZED GAIN (LOSS)	FAIR VALUE
December 31, 1999	$ 541,400	$ (2,126)	$ 539,274
December 31, 2000	$42,559,337	$(36,608)	$42,522,729

There were no sales of available-for-sale securities during the years ended December 31, 1999 and 2000, although there were maturities of such securities as disclosed in the accompanying consolidated statement of cash flows.

The Medicines Company currently holds a $3.0 million principal investment in Southern California Edison 5 7/8% bonds due January 15, 2001, which is accounted for in accordance with Statement of Financial Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." We classify these securities as available-for-sale and carry them at fair market value based on the quoted market price. We have exposure to market risk related to the fluctuation of the Southern California Edison bonds' price, which fluctuation has increased significantly as a result of events which occurred after December 31, 2000, including the non-payment of principal and interest on the bonds at maturity on January 15, 2001. At March 28, 2001, the value of the Company's investment in these Southern California Edison bonds had declined to approximately $2.5 million.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs were approximately $1,491,000, $484,000 and $807,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

Inventory

The Company records inventory upon the transfer of title from its vendor. Inventory is stated at the lower of cost or market with cost determined using a weighted average of actual costs. All costs associated with the manufacture of Angiomax bulk drug product and finished product to which title transferred to the Company prior to FDA approval of Angiomax was expensed as research and development. On December 15, 2000, the Company received FDA approval for Angiomax and any Angiomax bulk drug product to which the Company took title after that date is recorded as inventory.

Fixed Assets

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms.

Stock-Based Compensation

Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") encourages, but does not require, companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has elected to account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25").

Translation of Foreign Currencies

The functional currencies of the Company's foreign subsidiaries are the local currencies; British pound sterling, Swiss franc and New Zealand dollar. The Company translates its foreign operations using a current exchange rate. In accordance with Statement of Financial Accounting Standards No. 52, assets and liabilities are exchanged using the current exchange rate as of the balance sheet date. Expenses and items of income are exchanged using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' deficit. Foreign exchange transaction gains and losses are included in the results of operations and are not material to the Company's consolidated financial statements.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with ultimate realization.

Comprehensive Income/(Loss)

The Company reports comprehensive income/loss and its components in accordance with the provisions of SFAS No. 130, "Reporting Comprehensive Income." Comprehensive income/loss includes all changes in equity for cumulative translations adjustments resulting from the consolidation of foreign subsidiaries' financial statements and unrealized gains and losses on available-for-sale securities.

Recent Accounting Pronouncements

In December 1999, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 101, "Revenue Recognition in Financial Statements" (SAB 101), which provides guidance related to revenue recognition based on interpretations and practices followed by the SEC. SAB 101, as amended, is effective beginning the fourth quarter of calendar fiscal years beginning after December 15, 1999 and requires companies to report any changes in revenue recognition as a cumulative change in accounting principle at the time of implementation. Adoption of SAB 101 did not have a material impact on the Company's financial position or results of operations, since the Company has no revenues to date.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The effective date of this statement was deferred to fiscal years beginning after June 15, 2000 by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities -- Deferral of the Effective Date of SFAS No. 133." The adoption of this new standard is not expected to have a material impact on the Company's financial condition or results of operations.

Net Loss Per Share

Basic net loss per share is computed using the weighted average number of shares of common stock outstanding during the period reduced, where applicable, for outstanding, yet unvested, shares. Diluted net loss per share includes the effect of stock options, warrants and redeemable convertible preferred stock and convertible notes outstanding during the period, if dilutive. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share are the same.

Unaudited Pro Forma Net Loss Per Share

Unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding, including the pro forma effects of automatic conversion of all outstanding redeemable convertible preferred stock and accrued dividends and convertible notes and accrued interest through each balance sheet date into shares of the Company's common stock effective upon the closing of the Company's initial public offering, as if such conversion had occurred at the date of original issuance.

Segments

The Company is a development stage company focused on the acquisition, development and commercialization of late-stage development drugs. The Company has license rights to three potential products, Angiomax, CTV-05 and IS-159. The Company manages its business and operations as one segment. There are no revenues to date for any potential products and the Company's assets are not identifiable to its three potential products.

3. MANAGEMENT'S PLANS AND FINANCING

The Company is a development stage company and has incurred substantial losses since inception. To date, the Company has funded its operations through the issuance of debt and equity. The Company expects to continue to expend substantial amounts for continued product research, development and initial commercialization activities for the foreseeable future and management's plans with respect to funding this development are to secure additional equity, if possible, and to secure collaborative partnering arrangements that will provide available cash funding for operations.

Should additional equity financing or collaborative partnering arrangements be unavailable to the Company, management will restrict certain of the Company's planned activities and operations, as necessary, to sustain operations and conserve cash resources.

4. FIXED ASSETS

Fixed assets consist of the following:

	ESTIMATED LIFE (YEARS)	DECEMBER 31, 1999	DECEMBER 31, 2000
Furniture, fixtures and equipment	3	$ 323,685	$ 547,748
Computer hardware and software	3	213,376	728,333
Leasehold improvements	5	216,064	243,060
		753,125	1,519,141
Less: Accumulated depreciation		(323,064)	(553,309)
		$ 430,061	$ 965,832

Depreciation expense was approximately $98,000, $208,000 and $277,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

5. ACCRUED EXPENSES

Accrued expenses consist of the following at December 31:

	1999	2000
Development services	$3,283,767	$5,998,117
Other	396,526	3,138,817
	$3,680,293	$9,136,934

6. CONVERTIBLE NOTES

In October 1999, the Company issued $6,000,000 of 8% Convertible Notes ("the Notes") and 1,013,877 Common Stock Purchase Warrants ("the Warrants") to existing investors, raising proceeds of $6,000,000. The Notes were redeemable on January 15, 2001 and pay interest semi-annually at a rate of 8% per annum. The Notes were convertible into shares of stock of the Company upon a subsequent sale of stock of the Company provided that such sale resulted in aggregate gross proceeds of at least $6,000,000. The Notes were convertible into a number of shares of stock determined by dividing the outstanding principal and interest on the date of the subsequent sale by the price per share of such sale. Each Warrant provides the holder with the right to purchase one share of Common Stock of the Company at a price of $5.92 per share at any time prior to October 19, 2004. The exercise price and the number of shares underlying the Warrants could be adjusted in certain circumstances related to future issuances of capital stock. The Company recorded $325,355 as the fair value of the Warrants using the Black-Scholes method and the estimated fair value of the Company's Common Stock on the date of the issuance of warrants, and $5,674,645 as the value of the Notes on the issuance date. The discount on the Notes was amortized to interest expense over the expected term of the Notes, which the Company anticipated to be to June 2000. Since the Notes were issued in October 1999, the carrying amount approximates their fair value at December 31, 1999. Upon completion of the Company's sale of Series IV Preferred Stock in May 2000, the principal and accrued interest on the Notes was converted into 1,393,909 shares of Series IV Preferred Stock.

In March 2000, the Company issued $13,348,779 of 8% Convertible Notes ("the Notes") and 2,255,687 Common Stock Purchase Warrants ("the Warrants") to current stockholders, raising proceeds of $13,348,779. The Notes were redeemable on January 15, 2001 and accrue interest semi-annually at a rate of 8% per annum. The Notes were convertible into shares of stock of the Company upon a subsequent private sale of stock of the Company provided that such sale results in aggregate gross proceeds of at least $6,000,000. The Notes were convertible into a number of shares of stock determined by dividing the outstanding principal and interest on the date of the subsequent sale by the price per share of such sale. Each Warrant provides the holder with the right to purchase one share of Common Stock of the Company at a price of $5.92 per share at any time prior to March 2005. The exercise price and the number of shares underlying the Warrants could be adjusted in certain circumstances related to future issuances of stock. The Company recorded approximately $18,800,000 as the value of the Warrants using the Black-Scholes method and the estimated fair value of the Company's common stock on the date of the issuance of the warrants. The discount on the Notes was amortized over the expected term of the Notes, which the Company anticipated to be to June 2000. For the year ended December 31, 2000, amortization of the discount was approximately $18,800,000 and is included with the interest expense in the accompanying financial statements. Upon completion of the Company's sale of Series IV Preferred Stock in May 2000, the principal and accrued interest on the Notes was converted into 3,141,457 shares of Series IV Preferred Stock.

7. REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

On June 29, 2000, the Company's Board of Directors approved a reverse split of .73 shares for every one share of common stock then outstanding. The reverse stock split became effective on August 4, 2000. The accompanying financial statements and footnotes, including all share and per share amounts, reflect the reverse stock split.

Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock

During 1999 and 2000, the Company had designated four series of redeemable convertible preferred stock. A summary of the Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock is as follows.

	DECEMBER 31,	
	1999	2000
Series I, $1 par value, 3,550,000 shares authorized at December 31, 1999 and none at December 31, 2000, 2,678,005 shares and none issued and outstanding as of December 31, 1999 and 2000, respectively ($5,512,225 liquidation value at December 31, 1999 and $0 at December 31, 2000)	$ 5,512,225	$ --
Series II, $1 par value, 15,850,000 shares authorized at December 31, 1999 and none at December 31, 2000, 11,290,928 shares and none issued and outstanding as of December 31, 1999 and 2000, respectively ($40,670,864 liquidation value at December 31, 1999 and $0 at December 31, 2000)	40,670,864	--
Series III, $1 par value, 12,150,000 shares authorized at December 31, 1999 and none at December 31, 2000, 8,993,417 shares and none issued and outstanding as of December 31, 1999 and 2000, respectively ($39,984,732 liquidation value at December 31, 1999 and $0 at December 31, 2000)	39,094,324	--
Series IV, $1 par value, 12,150,000 shares authorized during December 31, 2000 and none at December 31, 1999, none issued and outstanding as of December 31, 2000	--	--
Total	$85,277,413	$ --

In August 1998, the Company executed an agreement (the "Exchange Agreement") under which 8,892,912 shares of common stock and 41,992 shares of Series A Redeemable Preferred Stock were exchanged for 2,506,000 shares of Series I Redeemable Convertible Preferred Stock and 10,565,714 shares of Series II Redeemable Convertible Preferred Stock. Holders of Series A Redeemable Preferred Stock were entitled to receive preferential cumulative annual dividends payable in additional shares of Series A Redeemable Preferred Stock at the rate of 7% per annum of the stated value. Prior to the Exchange Agreement, dividends earned from January 1, 1998 through the date of the Exchange Agreement were paid to the holders of Series A Redeemable Preferred Stock. During 1997, certain preferred shareholders waived their right to a portion of earned dividends and the Company paid agreed-upon amounts through December 31, 1997. To the extent that all or any part of the Stock would have resulted in the issuance of a fractional share of the Series A Preferred stock, the amount of such fraction, multiplied by the stated value, was paid in cash.

On May 17, 2000, the Company issued 1,411,000 shares of Series IV Redeemable Convertible Preferred Stock for net proceeds of $6,095,520. In addition, on May 17, 2000, the convertible notes and accrued interest were converted into 4,535,366 shares of Series IV Redeemable convertible Preferred Stock. The Series IV preferred stock carries terms and conditions similar to the Series I, II, III preferred stock. The Series IV preferred stock was convertible into common stock at a 1-for-0.73 conversion rate and automatically converted upon the closing of the sale of shares of common stock in an underwritten public offering. The Series IV Redeemable Convertible Preferred Stock issued on May 17, 2000 contained a beneficial conversion feature

based on the estimated fair market value of common stock into which it is convertible. In accordance with EITF 98-5, the total amount of such beneficial conversion is approximately $25,450,000. The beneficial conversion is analogous to a dividend and was recognized during 2000 when issued. Simultaneously with the closing of the Company's initial public offering, 30,659,957 shares of Redeemable Convertible Preferred Stock then outstanding (including accrued dividends for the period August 1, 2000 to August 11, 2000) were converted into 22,381,735 shares of common stock.

A summary of the rights, preferences and privileges of the Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock ("Series Preferred Stock") is as follows:

Dividends. The holders of each series of Series Preferred Stock are entitled to receive, prior to any distribution to the holders of Common Stock, preferential cumulative dividends payable in additional shares of such series of Series Preferred Stock at a rate of 7% per share per annum of the liquidation value of such series of Series Preferred Stock. Such dividends were paid annually commencing on July 31, 1999.

Liquidation. In the event of any liquidation, dissolution or winding up of the Company (either voluntary or involuntary), the holders of Series Preferred Stock are entitled to receive, out of the assets of the Company available for distribution to its stockholders, a per share amount equal to $2.00 per share in the case of the Series I Preferred Stock, $3.50 per share in the case of the Series II Preferred Stock and $4.32 in the case of the Series III and Series IV Preferred Stock, plus any accrued but unpaid dividends (the liquidation value). These distributions will be made prior to any distributions to other stockholders. Any amounts remaining after making such distributions will be distributed to the holders of Common Stock and Series Preferred Stock on parity with each other. If the remaining assets of the Company available for distribution to its stockholders are insufficient to pay all of the holders of Series Preferred Stock, distributions will be made first to the Series IV Preferred Stockholders, then to Series III Preferred Stockholders and then to the Series I and II Preferred Stockholders on a pro-rata basis.

Conversion. Holders of shares of Series Preferred Stock have the right to convert their shares at any time into shares of Common Stock. The conversion rate for each series of Series Preferred Stock is 0.73-for-1. The conversion rate for each series of Series Preferred Stock is subject (i) to proportional adjustments for splits, reverse splits, recapitalizations, etc., and (ii) to formula-weighted average adjustments in the event that the Company issues additional shares of Common Stock or securities convertible into or exercisable for Common Stock at a purchase price less than the applicable conversion price then in effect, other than the issuance of shares to directors, officers, employees and consultants pursuant to stock plans approved by the Board of Directors and certain other exceptions. Each share of Series Preferred Stock will be automatically converted into shares of Common Stock upon the closing of the sale of shares of Common Stock at a price of at least $8.90 per share (subject to appropriate adjustment for stock dividends, stock splits, combinations and other similar recapitalizations affecting such shares) in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, resulting in at least $15,000,000 of gross proceeds to the Company.

Redemption. The Company will redeem the outstanding shares of Series Preferred Stock in three equal annual installments commencing July 31, 2002 at a price equal to the liquidation value of such shares.

Voting. Generally, holders of shares of Series Preferred Stock vote on all matters, including the election of directors, with the holders of shares of Common Stock on an as-converted basis, except where a class vote is required by law.

Accretion. Series Preferred Stock is accreted to its redemption value to recognize issuance costs over the period from issuance to redemption using the interest method and to reflect accrued but unpaid dividends.

Common Stock

Common Stockholders are entitled to one vote per share and dividends when declared by the Board of Directors, subject to the preferential rights of preferred stockholders.

Upon the completion of its Initial Public Offering ("IPO") on August 11, 2000, the Company sold 6,000,000 shares of its common stock at a price of $16.00 per share. In addition, on September 8, 2000, the underwriters of the IPO exercised their over-allotment option and purchased an additional 900,000 shares of common stock at a price of $16.00 per share. The company received proceeds of approximately $101.4 million, net of underwriting discounts and commissions, and expenses. Simultaneously with the closing of the IPO, 30,659,957 shares of Redeemable Convertible Preferred Stock then outstanding (including accrued dividends for the period August 1, 2000 to August 11, 2000) were converted into 22,381,735 shares of common stock.

During 1996, 1997 and 1998, certain employees of the Company purchased 335,800, 627,070 and 32,850 shares of common stock, respectively, for $0.001 per share. These shares are subject to restriction and vesting agreements that limit transferability and allow the Company to repurchase unvested shares at the original purchase price. The shares vest ratably over a four-year period that generally begins on each employee's hire date. During 1998, 1999 and 2000, the Company repurchased 107,979, 56,378 and 22,205 shares, respectively, of unvested common stock for $0.001 per share. There were 62,722 shares of common stock unvested at December 31, 2000.

Stock Plans

In April 1998, the Company adopted the 1998 Stock Incentive Plan (the "Plan"), which provides for the grant of stock options, restricted stock and other stock-based awards to employees, directors and consultants. The plan allows for the issuance of up to 1,083,259 shares of common stock through April 2008. The Board of Directors determines the term of each option, the option price, the number of shares for which each option is granted and the rate at which each option is exercisable. During 1999, the Board of Directors amended all outstanding grants to allow holders the opportunity to exercise options prior to vesting. Exercised options that are unvested are subject to repurchase by the Company at the original exercise price. Options granted under the plan generally vest in increments over four years.

In January 2000, the Board of Directors approved an amendment to the Plan to increase the number of shares available under the Plan to 1,448,259. In May 2000, the Board of Directors approved an amendment to the Plan to increase the number of shares available under the Plan to 4,368,259. In addition, the Board of Directors also approved the 2000 Employee Stock Purchase Plan which provides for the issuance of up to 255,500 shares of common stock to participating employees and the 2000 Directors Stock Option Plan which provides for the issuance of up to 250,000 shares of common stock to the Company's directors. Both the 2000 Employee Stock Purchase Plan and the 2000 Directors Stock Option Plan have received stockholder approval.

Prior to the Company's initial public offering, the Board of Directors of the company determined the fair value of the Company's common stock in its good faith judgment at each option grant date for grants under the Plan considering a number of factors including the financial and operating performance of the company, recent transactions in the Company's common and preferred stock, if any, the values of similarly situated companies and the lack of marketability of the company's common stock. Following the Company's initial public offering, the fair value is determined based on the traded value of the Company's common stock.

During the period January 1, 2000 to September 31, 2000, the Company issued 2,273,624 options at exercise prices below the estimated fair value of the Company's common stock as of the date of grant of such options based on the price of the Company's common stock in connection with the Company's initial public offering. The total deferred compensation associated with these options is approximately $17.3 million. Included in the results of operations for the year ended December 31, 2000 is compensation expense of approximately $3.7 million associated with such options.

The Company has elected to follow APB 25 in accounting for its stock options granted to employees because the alternative fair value accounting provided for under SFAS 123, requires the use of option valuation models that were not developed for use in valuing employee stock options. Because the exercise price of the Company's stock options generally equals the market price of the underlying stock on the date of grant, no compensation is recognized under APB 25. Had compensation costs for the Plan been determined based on the fair value at the grant dates as calculated in accordance with SFAS 123, the Company's net loss for the year ended December 31, 1999 and 2000 would have been increased to the pro forma amounts indicated below.

	YEARS ENDED DECEMBER 31,		
	1998	1999	2000
Net loss attributable to common stockholders -- As reported	$32,909,701	$40,605,911	$101,635,158
Net loss attributable to common stockholders -- Pro forma	$32,965,764	$40,771,828	$106,150,604
Net loss per share attributable to common stockholders -- As reported	$ (6.03)	$ (80.08)	$ (8.43)
Net loss per share attributable to common stockholders -- Pro forma	$ (6.04)	$ (80.41)	$ (8.80)

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	YEARS ENDED DECEMBER 31,		
	1998	1999	2000
Expected dividend yield	0%	0%	0%
Expected stock price volatility	70%	70%	70%
Risk-free interest rate	4.70%	5.45%	6.32%
Expected option term	3.38 years	3.30 years	3.35 years

A summary of stock option activity under the 1998 Stock Incentive Plan and the 2000 Directors Stock Option Plan are as follows:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding, December 31, 1997	--	$ --
Granted	734,745	1.11
Exercised	(2,037)	0.64
Canceled	(27,437)	0.88
Outstanding, December 31, 1998	705,271	1.12
Granted	239,075	1.23
Canceled	(175,380)	1.05
Outstanding, December 31, 1999	768,966	1.16
Granted	3,080,424	9.80
Exercised	(227,523)	1.26
Canceled	(406,713)	1.22
Outstanding, December 31, 2000	3,215,154	$9.43
Available for future grant at December 31, 2000	1,173,545	

The weighted average per share fair value of options granted during 1998, 1999 and 2000 was $0.55, $0.62 and $10.34, respectively. The weighted average fair value and exercise price of options granted during 2000 which were granted with exercise prices below the fair market value were $9.35 and $4.68, respectively. The weighted average fair value and exercise price of options granted during 2000 which were granted with exercise prices equal to the fair market value were $13.19 and $24.96, respectively.

The following table summarizes information about stock options from the 1998 Stock Incentive Plan and the 2000 Directors Stock Option Plan outstanding at December 31, 2000:

	OPTIONS OUTSTANDING			OPTIONS VESTED	
RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING AT 12/31/00	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER OUTSTANDING AT 12/31/00	WEIGHTED AVERAGE EXERCISE PRICE
$ 0.69 -- $ 3.08	911,673	8.72	$ 1.63	363,052	$1.46
$ 4.79 -- $ 4.79	850,450	9.39	$ 4.79	115,582	$4.79
$ 5.92 -- $12.00	631,231	9.52	$ 6.69	3,815	$5.92
$19.88 -- $24.00	183,750	9.85	$22.76	--	--
$24.13 -- $30.63	638,050	9.93	$25.60	--	--
	3,215,154	9.36	$ 9.43	482,449	$2.29

Common Stock Reserved for Future Issuance

At December 31, 2000, there were 7,913,763 shares of common stock reserved for future issuance under the Employee Stock Purchase Plan, for conversion of the Common Stock Warrants and for grants made under the 1998 Stock Incentive Plan and the 2000 Director Stock Option Plan.

8. NET LOSS AND UNAUDITED PRO FORMA NET LOSS PER SHARE

The following table sets forth the computation of basic and diluted, and unaudited pro forma basic and diluted net loss per share for the respective periods. The unaudited pro forma basic and diluted net loss per share gives effect to the conversion of the redeemable convertible preferred stock and the convertible notes and accrued interest as if converted at the date of original issuance.

	YEAR ENDED DECEMBER 31,		
	1998	1999	2000
Basic and Diluted			
Net loss	$(28,950,798)	$(34,712,895)	$ (71,292,170)
Dividends and accretion on redeemable convertible preferred stock	(3,958,903)	(5,893,016)	(30,342,988)
Net loss attributable to common stockholders	$(32,909,701)	$(40,605,911)	$(101,635,158)
Weighted average common shares outstanding	6,075,948	850,238	12,225,537
Less: unvested restricted common shares outstanding	(621,295)	(343,173)	(166,262)
Weighted average common shares used to compute net loss per share	5,454,653	507,065	12,059,275
Basic and diluted net loss per share	$ (6.03)	$ (80.08)	$ (8.43)
Unaudited Pro forma basic and diluted			
Net loss		$(34,712,895)	$ (71,292,170)
Interest expense on convertible notes		197,455	19,390,414
Net loss used to compute pro forma net loss per share		$(34,515,440)	$ (51,901,756)
Weighted average common shares used to compute net loss per share		507,065	12,059,275
Weighted average number of common shares assuming the conversion of all redeemable convertible preferred stock and convertible notes and accrued interest at the date of original issuance		17,292,811	12,659,800
Weighted average common shares used to compute pro forma net loss per share		17,799,876	24,719,075
Unaudited pro forma basic and diluted net loss per share		$ (1.94)	$ (2.10)

Options to purchase 768,966 and 3,215,154 shares of common stock have not been included in the computation of diluted net loss per share for the years ended December 31, 1999 and 2000, respectively, as their effects would have been antidilutive. Warrants to purchase 1,013,877 and 3,269,564 shares of common stock were excluded from the computation of diluted net loss per share for the year ended December 31, 1999 and 2000, respectively, as their effect would be antidilutive.

9. INCOME TAXES

The significant components of the Company's deferred tax assets are as follows:

	DECEMBER 31,	
	1999	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 30,864,000	$ 48,494,000
Research and development credit	2,074,000	3,576,000
Intangible assets	1,139,000	1,233,000
Other	36,000	86,000
	34,113,000	53,389,000
Valuation allowance	(34,113,000)	(53,389,000)
Net deferred tax assets	$ --	$ --

The Company has increased its valuation allowance by $19,276,000 in 2000 to provide a full valuation allowance for deferred tax assets since the realization of these future benefits is not considered more likely than not. The amount of the deferred tax asset considered realizable is subject to change based on estimates of future taxable income during the carryforward period. If the Company achieves profitability, these deferred tax assets would be available to offset future income taxes. The future utilization of net operating losses and credits may be subject to limitation based upon changes in ownership under the rules of the Internal Revenue Code. The Company will assess the need for the valuation allowance at each balance sheet date based on all available evidence.

At December 31, 2000, the Company had federal net operating loss carryforwards available to reduce taxable income, and federal research and development tax credit carryforwards available to reduce future tax liabilities, which expire as follows:

YEAR OF EXPIRATION	FEDERAL NET OPERATING LOSS CARRYFORWARDS	FEDERAL RESEARCH AND DEVELOPMENT TAX CREDIT CARRYFORWARDS
2011	$ 930,000	$ 22,000
2012	15,260,000	527,000
2018	27,876,000	425,000
2019	33,802,000	1,002,000
2020	44,282,000	1,300,000
	$122,150,000	$3,276,000

For state purposes, net operating loss carryforwards of approximately $116,042,000 expire in the years 2001 through 2004. State research and development tax credit carryforwards are approximately $300,000.

10. LICENSE AGREEMENTS

Angiomax

In March 1997, the Company entered into an agreement with Biogen, Inc. for the license of the anticoagulant pharmaceutical, bivalirudin (now known as Angiomax). Under the terms of the agreement, the Company acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know- how related to Angiomax. In exchange for the license, the Company paid $2 million on the closing date and is

obligated to pay up to an additional $8 million upon reaching certain Angiomax sales milestones, including the first commercial sale of Angiomax for the treatment of AMI in the United States and Europe. In addition, the Company shall pay royalties on future sales of Angiomax and on any sublicense royalties earned until the later of (1) 12 years after the date of the first commercial sale of the product in a country or (2) the date in which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent right in such country. The agreement also stipulates that the Company use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least $20 million for certain development and commercialization activities, which we met in 1998. The license and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate for material breach, and the Company may terminate the agreement for any reason upon 90 days prior written notice. During December 2000, the Company received approval from the U.S. Food and Drug Administration (FDA) for the sale of Angiomax for certain indications.

CTV-05

In August 1999, the Company entered into an agreement with Gynelogix, Inc. for the license of the biotherapeutic agent CTV-05, a strain of human lactobacillus currently under clinical investigation for applications in the areas of urogenital and reproductive health. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the patents and know-how related to CTV-05. In exchange for the license, the Company has paid $400,000 and is obligated to pay an additional $100,000 upon reaching certain development and regulatory milestones and to fund agreed-upon operational costs of Gynelogix related to the development of CTV-05 on a monthly basis subject to a limitation of $50,000 per month. In addition, the Company is obligated to pay royalties on future sales of CTV-05 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that the Company must use commercially reasonable efforts in pursuing the development, commercialization and marketing of CTV-05 to maintain the license. The license and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and may terminate the agreement for any reason upon 60 days prior written notice.

IS-159

In July 1998, the Company entered into an agreement with Immunotech S.A. for the license of the pharmaceutical IS-159 for the treatment of acute migraine headache. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the patents and know-how related to IS-159. In exchange for the license, the Company paid $1 million on the closing date and is obligated to pay up to an additional $4.5 million upon reaching certain development and regulatory milestones. In addition, the Company shall pay royalties on future sales of IS-159 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that the Company must use commercially reasonable efforts in pursuing the development, commercialization and marketing of IS-159 and meet certain development and regulatory milestones to maintain the license. The licenses and rights under the agreement remain in force until the company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and the Company may terminate the agreement for any reason upon 60 days prior written notice.

11. STRATEGIC ALLIANCES

UCB

In December 1999, the Company entered into a commercial supply agreement with UCB-Bioproducts S.A. ("UCB") to develop and supply Angiomax bulk drug substance. Under the terms of the agreement, UCB Bioproducts is also responsible for developing the Chemilog process in coordination with the Company and obtaining regulatory approval for use of the process. The Company has agreed to partially fund UCB Bioproducts' development activities. The funding is due upon the completion by UCB Bioproducts of development milestones. If UCB Bioproducts successfully completes each of these development milestones, the Company anticipates total development funding to be approximately $9.1 million. During 1999 and 2000, expenses incurred for such services were approximately $811,000 and $560,000, respectively, of which approximately $469,000 and $789,000 was recorded in accounts payable and accrued expenses at December 31, 1999 and 2000, respectively. In addition, the Company has agreed to purchase Angiomax bulk drug product exclusively from UCB Bioproducts at agreed upon prices for a period of seven years from the date of the first commercial sale of Angiomax produced under the Chemilog process. Following the expiration of the agreement, or if the Company terminates the agreement prior to its expiration, UCB Bioproducts will transfer the development technology to the Company. If the Company engages a third party to manufacture Angiomax using this technology, the Company will be obligated to pay UCB Bioproducts a royalty based on the amount paid by the Company to the third-party manufacturer.

During 1999, the Company placed an order with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Manufacture of $14.2 million of this material was completed in 2000, of which $12.2 million was expensed during the period. All costs associated with the manufacture of Angiomax bulk drug product and finished products to which title was transferred to the Company prior to the date of FDA approval of Angiomax were expensed as research and development. The Company recorded Angiomax bulk drug product to which title transferred after the date of FDA approval of Angiomax as inventory. In November 2000, the Company placed additional orders with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Under the terms of these orders, the Company is scheduled to take title to material and become obligated to make payments totaling approximately $24.0 million in fiscal 2001 and early fiscal 2002.

Lonza

In September 1997, the Company entered into an agreement with Lonza AG ("Lonza") for the development of a new commercial manufacturing process for an advanced intermediate compound used in the manufacturing of Angiomax ("Angiomax intermediate"). In November 1998, the Company entered into an additional agreement with Lonza for the engineering, procurement and installation of equipment for the initial manufacturing of the Angiomax intermediate using the new process. The agreement also contemplated the purchase of the Angiomax intermediate from Lonza at specified prices for an anticipated two-year period following initial production and stipulated the basic principles of a long-term commercial supply contract. In January 2000, the Company notified Lonza of its intention to terminate the agreement. As a result of the termination, the Company retained certain ownership rights to intellectual property and was responsible for reimbursement of all costs incurred under the terms of the agreement through the date of notice. Approximately $1,572,000 was recorded in accounts payable and accrued expenses at December 31, 1999. There was no outstanding obligation to Lonza at December 31, 2000.

PharmaBio

In August 1996, the Company entered into a strategic alliance with one of its stockholders, PharmaBio Development Inc. ("PharmaBio"), a wholly owned subsidiary of Quintiles Transnational Corporation ("Quintiles"). Under the terms of the strategic alliance agreement, PharmaBio and any of its affiliates who

work on the Company's projects will, at no cost to the Company, review and evaluate, jointly with the Company, development programs designed by the Company related to potential or actual product acquisitions. The purpose of this collaboration is to optimize the duration, cost, specifications and quality aspects of such programs. PharmaBio and its affiliates have also agreed to perform other services with respect to our products, including clinical and non-clinical development services, project management, project implementation, pharmacoeconomic services, regulatory affairs and post marketing surveillance services and statistical, statistical programming, data processing and data management services pursuant to work orders agreed to by the Company and PharmaBio from time to time. Through December 31, 2000, the Company has entered in approximately 40 work orders with PharmaBio and has paid PharmaBio a total of $10.9 million. During 1998, 1999 and 2000, expenses incurred for such services were approximately $1.7 million, $3.7 million and $2.3 million, respectively, of which approximately $1.2 million and $813,000 was recorded in accounts payable and accrued expenses at December 31, 1999 and 2000, respectively. At December 31, 2000, the Company had open orders with PharmaBio for such services that reflect estimated aggregate future payments of approximately $3.4 million.

Innovex

In January 1997, the Company entered into a consulting agreement with Innovex, Inc. ("Innovex"), a subsidiary of Quintiles, which was subsequently superceded by a consulting agreement executed with Innovex in December 1998. Pursuant to the terms of the agreement, Innovex provides the Company with consulting services with respect to pharmaceutical marketing and sales. Since December 1997, the Company has also entered into various clinical services agreements with Innovex pursuant to which Innovex has provided project management, clinical monitoring, site management, medical monitoring, regulatory affairs, data management and quality assurance services with respect to clinical trials of Angiomax. None of the clinical services agreements is currently outstanding. Through December 31, 2000 the Company has paid Innovex $1.8 million under these agreements.

In December 2000, the Company signed a master services agreement and a work order with Innovex under which Innovex agreed to provide contract sales, marketing and commercialization services relating to Angiomax. Under the master services agreement, Innovex may provide additional services unrelated to Angiomax pursuant to work orders entered into from time to time. Under the master services agreement and the Angiomax work order, Innovex will provide the Angiomax sales force of 52 representatives, a sales territory management system and operational support for the launch of Angiomax. The Company will provide the marketing plan and marketing materials for the sales force and other sales and marketing support and direction for the sales force. For Innovex services, the Company has agreed to a daily fee for each day worked by the members of the sales force. The Company will reimburse Innovex for expenses incurred in providing the services and for the incentive compensation paid to the sales force of Innovex. The company has the right to terminate the work order and the master services agreement at any time upon 90 days prior written notice. The Company may hire members of the sales force, although the Company may incur additional fees to Innovex. Through December 31, 2000, the Company had paid Innovex $1.1 million for its services under the master services agreement and work order. Total fees for 2001 under this agreement are estimated to be approximately $8.2 million subject to adjustments in the size of the sales force and other commercial factors.

During 1998, 1999 and 2000, expenses incurred for services provided by Innovex were approximately $943,000, $616,000 and $1.7 million respectively, of which approximately $102,000, $280,000 and $440,000 were recorded in accounts payable and accrued expenses at December 31, 1998, 1999 and 2000, respectively.

Stack Pharmaceuticals

In April 2000, the Company entered into an agreement with Stack Pharmaceuticals, an entity controlled by David Stack, one of the Company's senior vice presidents, which was amended in August 2000. Pursuant to the terms of this agreement, as amended, Stack Pharmaceuticals will perform infrastructure services for us, which includes providing office facilities, equipment and supplies for the Company's employees based in New Jersey, and such consulting, advisory and related services for the Company as may be agreed upon from time to time. For the infrastructure services, the Company has agreed to pay Stack Pharmaceuticals a service fee of $20,100 per month. The term of this agreement continues until April 1, 2001, but either party may terminate it earlier upon 90 days prior written notice. From January 2000 through March 2000, Stack Pharmaceuticals provided the Company with consulting services under a consulting agreement that expired on March 31, 2000. Through December 31, 2000, the Company had paid Stack Pharmaceuticals $407,000 under these agreements. The was no outstanding obligation to Stack Pharmaceuticals at December 31, 2000.

12. COMMITMENTS AND CONTINGENCIES

The Company leases its facilities in Cambridge, Massachusetts and Parsippany, New Jersey and certain office furniture and equipment at those facilities under operating leases. The leases for the Cambridge and Parsippany facilities expire in August 2003 and September 2005, respectively. Future annual minimum payments under all non-cancelable operating leases are $590,000, $712,000, $429,000, $210,000 and $160,000 in 2001, 2002, 2003, 2004 and 2005, respectively. Rent expense was approximately $326,000, $442,000 and $504,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

The Company is involved in ordinary and routine matters and litigation incidental to its business. There are no such matters pending that the Company expects to be material in relation to its financial condition or results of operations.

13. EMPLOYEE BENEFIT PLAN

401(k) Plan

The Company has an employee savings and retirement plan which is qualified under Section 401 of the Internal Revenue Code. Our employees may elect to reduce their current compensation by up to the statutorily prescribed limit and have the amount of such reduction contributed to the 401(k) plan. The Company may make matching or additional contributions to the 401(k) plan in amounts to be determined annually by the board of directors. The Company has not made any matching or additional contributions to date.

14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table presents selected quarterly financial data for the years ended December 31, 1999 and 2000.

	THREE MONTHS ENDED							
	MARCH 31, 1999	JUNE 30, 1999	SEPT. 30, 1999	DEC. 31, 1999	MARCH 31, 2000	JUNE 30, 2000	SEPT. 30, 2000	DEC. 31, 2000
	(IN THOUSANDS, EXCEPT PER SHARE DATA)							
Total operating expenses	$ 8,483	$ 11,715	$ 9,000	$ 6,155	$ 11,840	$ 8,706	$ 10,297	$ 23,763
Net loss	(8,137)	(11,369)	(8,877)	(6,330)	(19,243)	(20,408)	(9,459)	(22,182)
Net loss attributable to common stockholders	(9,573)	(12,806)	(10,375)	(7,852)	(20,773)	(47,596)	(11,083)	(22,182)
Basic and diluted net loss attributable to common stockholders per common share	$(21.09)	$ (25.62)	$ (19.21)	$(13.45)	$ (32.91)	$ (68.65)	$ (0.67)	$ (0.74)
Pro forma basic and diluted net loss attributable to common stockholders per common share	(0.48)	(0.66)	(0.49)	(0.33)	(0.55)	(0.38)	(0.34)	(0.74)

The net loss for each quarter of 2000 was higher compared to the corresponding quarter of 1999. There were higher research and development costs in every quarter of 2000 associated with increased enrollment rates in the HERO-2 trial in AMI, in the third and fourth quarters of 2000 related to the initiation of the REPLACE clinical trial program in angioplasty, and in the first and fourth quarters of 2000 in connection with the receipt of Angiomax bulk drug substance to which title was taken prior to FDA approval. These increases in research and development costs were partly offset by lower development costs in all quarters of 2000 related to the discontinuation of the semilog manufacturing program and reduction in the IS-159 activities. Higher selling, general and administrative expenses associated with the commercial launch of Angiomax also contributed to the higher net loss in the last three quarters of 2000 as compared to the corresponding quarters of 1999. Higher interest expense in the first two quarters of 2000 resulted from the amortization of the discount on convertible notes issued in October 1999 and March 2000. In the second quarter of 2000, we recorded a dividend on the beneficial conversion associated with the issuance of convertible preferred stock in May 2000. In addition, in all the quarters of 2000, amortization of deferred compensation on the grant of stock options also contributed to the higher 2000 quarterly losses.

THE MEDICINES COMPANY

CONDENSED CONSOLIDATED BALANCE SHEET
(UNAUDITED)

	MARCH 31, 2001
ASSETS	
Current assets:	
Cash and cash equivalents	$ 26,299,211
Marketable securities	32,670,642
Accrued interest receivable	1,183,528
	60,153,381
Accounts receivable	1,792,124
Inventory	2,050,500
Prepaid expenses and other current assets	394,450
Total current assets	64,390,455
Fixed assets, net	947,718
Other assets	462,661
Total assets	$ 65,800,834
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	$ 3,706,243
Accrued expenses	11,014,368
Total current liabilities	14,720,611
Stockholders' equity:	
Common stock, $.001 par value, 75,000,000 shares authorized at March 31, 2001; 30,391,948 issued and outstanding at March 31, 2001	30,392
Additional paid-in capital	279,297,727
Deferred compensation	(12,234,762)
Accumulated deficit	(215,616,020)
Accumulated other comprehensive loss	(397,114)
Total stockholders' equity	51,080,223
Total liabilities and stockholders' equity	$ 65,800,834

See accompanying notes to condensed consolidated financial statements.

THE MEDICINES COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2000	2001
Net revenue	$ --	$ 1,861,288
Operating expenses:		
Cost of revenue	--	332,400
Research and development	10,641,866	12,595,197
Selling, general and administrative	1,197,971	9,058,936
Total operating expenses	11,839,837	21,986,533
Loss from operations	(11,839,837)	(20,125,245)
Other income (expense):		
Interest income	103,835	1,069,259
Interest expense	(7,507,025)	--
Net loss	(19,243,027)	(19,055,986)
Dividends and accretion to redemption value of redeemable preferred stock	(1,529,756)	--
Net loss attributable to common stockholders	$(20,772,783)	$(19,055,986)
Basic and diluted net loss attributable to common stockholders per common share	$ (32.91)	$ (0.63)
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share	$ (0.55)	$ (0.63)
Shares used in computing net loss attributable to common stockholders per common share:		
Basic and diluted	631,276	30,247,599
Unaudited pro forma basic and diluted	21,407,651	30,247,599

See accompanying notes to condensed consolidated financial statements.

THE MEDICINES COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
Cash flows from operating activities:		
Net loss	$(19,055,986)	$(19,243,027)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	104,829	62,994
Amortization of discount on convertible notes	--	7,320,267
Amortization of deferred stock compensation	1,120,932	150,000
Loss on sales of fixed assets	251	--
Changes in operating assets and liabilities:		
Accrued interest receivable	209,400	28,547
Accounts receivable	(1,792,124)	--
Inventory	(87,009)	--
Prepaid expenses and other current assets	69,762	(92,073)
Other assets	(212,102)	(1,422)
Accounts payable	(2,280,050)	2,159,075
Accrued expenses	1,885,622	1,412,312
Net cash used in operating activities	(20,036,475)	(8,203,327)
Cash flows from investing activities:		
Purchases of marketable securities	(1,457,913)	--
Maturities and sales of marketable securities	10,926,379	541,400
Purchase of fixed assets	(94,658)	(23,200)
Net cash provided by investing activities	9,373,808	518,200
Cash flows from financing activities:		
Proceeds from issuance of convertible notes and warrants	--	13,348,779
Proceeds from issuances of common stock, net	171,472	--
Repurchases of common stock	(10)	(20)
Net cash provided by financing activities	171,462	13,348,759
Effect of exchange rate changes on cash	(11,940)	(11,695)
Increase (decrease) in cash and cash equivalents	(10,503,145)	5,651,937
Cash and cash equivalents at beginning of period	36,802,356	6,643,266
Cash and cash equivalents at end of period	$ 26,299,211	$ 12,295,203

See accompanying notes to condensed consolidated financial statements.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

The Medicines Company (the Company) was incorporated in Delaware on July 31, 1996. The Company is a pharmaceutical company engaged in the acquisition, development and commercialization of late-stage development drugs. As a result of the U.S. Food and Drug Administration approval of Angiomax (bivalirudin) for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty in December 2000, and the commencement of sales of Angiomax in the first quarter of 2001, the Company is no longer considered to be a development-stage enterprise, as defined in Statement of Financial Accounting Standards No. 7.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, including normal recurring accruals, considered necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented.

The results of operations for the three months ended March 31, 2001 are not necessarily indicative of the results that may be expected for the entire fiscal year ended December 31, 2001. These condensed consolidated financial statements should be read in conjunction with the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

Cash, Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist of investments in money market funds, corporate bonds and taxable auction securities. These investments are carried at cost, which approximates fair value. Marketable securities consist of securities with original maturities of greater than three months. The Company classifies its marketable securities as available-for-sale. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity.

The Medicines Company currently holds a $3.0 million principal investment in Southern California Edison 5 7/8% bonds which was due January 15, 2001, which is accounted for in accordance with Statement of Financial Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." The Company classifies these securities as available-for-sale and carries them at fair market value based on the quoted market price. The Company has exposure to market risk related to the fluctuation of the Southern California Edison bonds' price, which fluctuation has increased significantly as a result of events which occurred after December 31, 2000, including the non-payment of principal and interest on the bonds at maturity on January 15, 2001. At March 31, 2001, the value of the Company's investment in these Southern California Edison bonds had declined to approximately $2.5 million. Subsequent to March 31, 2001, payment of interest was resumed on the Southern California Edison bonds.

Revenue Recognition

The Company recognizes revenue from product sales when there is pervasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Revenue is recorded net of applicable allowances, including estimated allowances for returns, rebates and other discounts.

3. NET LOSS AND UNAUDITED PRO FORMA NET LOSS PER SHARE

The following table sets forth the computation of basic and diluted, and unaudited pro forma basic and diluted, net loss per share for the three months ended March 31, 2001 and 2000. The unaudited pro forma basic and diluted net loss per share for the three months ended March 31, 2000 gives effect to the conversion of redeemable convertible preferred stock and accrued dividends and convertible notes and accrued interest as if converted at the date of original issuance. All redeemable convertible preferred stock and convertible notes were converted during 2000. Accordingly, the basic and diluted net loss per share and unaudited pro forma basic and diluted net loss per share for the three months ended March 31, 2001 are the same.

	THREE MONTHS ENDED MAR. 31,	
	2001	2000
Basic and diluted		
Net loss	$(19,055,986)	$(19,243,027)
Dividends and accretion to redemption value of redeemable preferred stock	--	(1,529,756)
Net loss attributable to common stockholders	$(19,055,986)	$(20,772,783)
Weighted average common shares outstanding	30,335,939	832,277
Less: unvested restricted common shares Outstanding	(88,340)	(201,001)
Weighted average common shares used to compute net loss per share	30,247,599	631,276
Basic and diluted net loss per share	$ (0.63)	$ (32.91)
Unaudited pro forma basic and diluted net loss	$(19,055,986)	$(19,243,027)
Interest expense on convertible notes	--	7,507,025
Dividends and accretion to redemption value of redeemable preferred stock	--	--
Net loss used to compute pro forma net loss per share	$(19,055,986)	$(11,736,002)
Weighted average common shares used to compute net loss per share	30,247,599	631,276
Weighted average number of common shares assuming the conversion of all redeemable convertible preferred stock and convertible notes and accrued interest at the date of original issuance	--	20,776,375
Weighted average common shares used to compute pro forma net loss per share	30,247,599	21,407,651
Unaudited pro forma basic and diluted pro forma net loss per share	$ (0.63)	$ (0.55)

Options to purchase 3,287,175 and 1,159,355 shares of common stock as of March 31, 2001 and 2000, respectively, have not been included in the computation of diluted net loss per share as their effect would have been antidilutive. Outstanding warrants to purchase 3,269,564 shares of common stock as of March 31, 2001 were also excluded from the computation of diluted net loss per share as their effect would have been antidilutive.

During the three months ended March 31, 2000, the Company issued options to purchase 587,942 shares of common stock, respectively, at exercise prices below the estimated fair value of the Company's common stock as of the date of grant of such options, based on the estimated price (as of the date of grant) of the Company's common stock in connection with the Company's initial public offering. The total deferred compensation associated with options granted during the three months ended March 31, 2000 was approximately $3.9 million.

Included in the results of operations for the three months ended March 31, 2001 and 2000 is compensation expense of approximately $1.1 million and $150,000, respectively, associated with options issued in 2000 at exercise prices below the estimated fair value of the Company's common stock as of the date of grant of such options.

4. COMPREHENSIVE INCOME LOSS

Comprehensive losses for the three months ended March 31, 2001 and 2000 were $19,451,000 and $19,253,000 respectively. Comprehensive loss is comprised primarily of net loss and unrealized losses on marketable securities.

5. RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The effective date of this statement was deferred to fiscal years beginning after June 15, 2000 by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities -- Deferral of the Effective Date of SFAS No. 133." The Company adopted this new standard and it did not have a material impact on the Company's financial condition or results of operations.

6. SUBSEQUENT EVENTS

On May 16, 2001, the Company sold 4,000,000 shares of common stock in a private placement at $11.00 per share. The net proceeds from this sale were approximately $41.8 million. The Company expects to register the shares of common stock sold in the private placement.

On May 16, 2001, the Company sold approximately $1.0 million of Southern California Edison 5 7/8% bonds and realized a loss of approximately $270,000. The Company continues to hold approximately $2.0 million of these bonds.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses, incurred by the Registrant in connection with the sale of Common Stock being registered. All amounts are estimated except the SEC registration fee.

	AMOUNT TO BE PAID
SEC registration fee	$ 13,430
Printing and mailing	15,000
Legal fees and expenses	50,000
Accounting fees and expenses	20,000
Miscellaneous	11,570
Total	$110,000

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The Registrant's Certificate of Incorporation (the "Certificate") provides that, except to the extent prohibited by the Delaware General Corporation Law (the "DGCL"), the Registrant's directors shall not be personally liable to the Registrant or its stockholders for monetary damages for any breach of fiduciary duty as directors of the Registrant. Under the DGCL, the directors have a fiduciary duty to the Registrant which is not eliminated by this provision of the Certificate and, in appropriate circumstances, equitable remedies such as injunctive or other forms of nonmonetary relief will remain available. In addition, each director will continue to be subject to liability under the DGCL for breach of the director's duty of loyalty to the Registrant, for acts or omissions which are found by a court of competent jurisdiction to be not in good faith or involving intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the director, and for payment of dividends or approval of stock repurchases or redemptions that are prohibited by DGCL. This provision also does not affect the directors' responsibilities under any other laws, such as the Federal securities laws or state or Federal environmental laws. The Registrant has obtained liability insurance for its officers and directors.

Section 145 of the DGCL empowers and corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of their capacity or status as directors and officers, provided that this provision shall not eliminate or limit the liability of a director: (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) arising under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, nay agreement, a vote of stockholders or otherwise. The Certificate eliminates the personal liability of directors to the fullest extent permitted by Section 102(b)(7) of the DGCL and provides that the Registrant shall fully indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was a director or officer of the Registrant, or is or was serving at the request of the Registrant as a director or officer of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding.

At present, there is no pending litigation or proceeding involving any director, officer, employee or agent as to which indemnification will be required or permitted under the Certificate. The Registrant is not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

Set forth below in chronological order is a description of the Registrant's sales of unregistered securities since January 1, 1998. The sales made to investors were made in accordance with Section 4(2) or Regulation D of the Securities Act. Sales to all of our employees, directors and officers were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 promulgated under Section 3(b) of the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation provided under Rule 701.

In August 1998, we declared a stock dividend on all outstanding shares series A preferred stock and issued an additional 1,686 shares of series A preferred stock. The dividend covered the period from June 1, 1998 through August 31, 1998.

In August 1998, the holders of our series A preferred stock exchanged the shares of series A preferred stock and common stock issued to them as part of the transaction which occurred in 1996 and 1997 and the shares of series A preferred stock issued to them in connection with the dividends declared in 1997 and 1998 for shares of series I convertible preferred stock and series II convertible preferred stock. In connection with the exchanges, we issued an aggregate of 2,506,000 shares of series I preferred stock and 10,565,714 shares of series II preferred stock.

In August 1998, we issued an aggregate of 8,399,593 shares of series III convertible preferred stock for an aggregate purchase price of $36,286,241, or $4.32 per share, to investors, including Warburg, Pincus, Morgan Stanley, Hanseatic, Biotech Growth S.A., Alta Partners, Clive Meanwell and Peyton Marshall.

In July 1999, we issued a stock dividend on all outstanding shares of series I preferred stock, series II preferred stock and series III preferred stock. In connection with the dividend we issued 172,005 shares of series I preferred stock, 725,214 shares of series II preferred stock and 571,510 shares of series III preferred stock. The dividend covered the period from August 8, 1998 with respect to the series I and II preferred stock and August 12, 1998 with respect to the series III preferred stock, to July 31, 1999.

In October 1999, we issued 8% convertible promissory notes in the aggregate original principal amount of $6,000,000 to existing investors. In connection with the issuance of these notes, we also issued common stock purchase warrants to purchase 1,013,877 shares of common stock at a price of $5.92 per share at any time prior to October 19, 2004.

In March 2000, we issued 8% convertible promissory notes in the aggregate original principal amount of $13,348,779 to existing investors. In connection with the issuance of these notes, we also issued common stock purchase warrants to purchase 2,255,687 shares of common stock at a price of $5.92 per share at any time prior to March 2, 2005.

In May 2000, the outstanding principal amount of the notes issued in October 1999 and March 2000 and the accrued interest thereon were converted into an aggregate of 4,535,366 shares of our series IV convertible preferred stock.

In May 2000, we issued an aggregate of 1,411,000 shares of series IV convertible preferred stock for an aggregate purchase price of $6,095,520 to Warburg, Pincus, Biotech Growth S.A., Morgan Stanley, Alta Partners, PharmaBio and Hanseatic.

In July 2000, we issued a stock dividend on all outstanding shares of series I preferred stock, series II preferred stock, series III preferred stock and series IV preferred stock. In connection with the dividend we issued 187,458 shares of series I preferred stock, 790,358 shares of series II preferred stock, 629,530 shares of series III preferred stock and 84,394 shares of series IV preferred stock. The dividend covered the period from August 1, 1999 to July 31, 2000 with respect to the series I, II and III preferred stock and May 17, 2000 to July 31, 2000 with respect to the series IV preferred stock.

In August 2000, we issued a stock dividend on all outstanding shares of series I preferred stock, series II preferred stock, series III preferred stock and series IV preferred stock. In connection with the dividend we issued 5,572 shares of series I preferred stock, 23,491 shares of series II preferred stock, 18,711 shares of

series III preferred stock and 11,726 shares of series IV preferred stock. The dividend covered the period from August 1, 2000 to August 11, 2000, the date of the closing of our initial public offering. On August 11, 2000, all outstanding shares of series I preferred stock, series II preferred stock, series III preferred stock and series IV preferred stock automatically converted into an aggregate of 22,381,735 shares of common stock upon the consummation of our initial public offering.

In May 2001, we issued an aggregate of 4,000,000 shares of common stock for an aggregate purchase price of $44.0 million, or $11.00 per share, to investors, including Warburg, Pinus, Alta Partners, PharmaBio Development Inc., Clive A. Meanwell, T. Scott Johnson and Glenn P. Sblendorio.

As of May 15, 2001, 58,138 shares of common stock outstanding were subject to our right of repurchase. The shares were purchased for $0.001 per share. We have issued 318,128 shares of common stock upon the exercise of stock options at a weighted average exercise price of $1.33. In addition, options to purchase 3,497,581 shares of common stock were outstanding under our 1998 stock incentive plan and our 2000 outside director stock option plan.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Exhibits

NUMBER	DESCRIPTION
3.1**	Third Amended and Restated Certificate of Incorporation of the registrant
3.2**	Amended and Restated By-laws of the registrant
5.1	Opinion of Hale and Dorr LLP
10.1**	1998 Stock Incentive Plan
10.2**	Form of 2000 Employee Stock Purchase Plan
10.3**	Amended and Restated Registration Rights Agreement, dated as of August 12, 1998, as amended to date, by and among the registrant and the other parties set forth on the signature pages thereto
10.4**	Third Amended and Restated Stockholders' Agreement, dated as of August 12, 1998, as amended to date, by and among the registrant and the other parties set forth on the signature pages thereto
+10.5**	Chemilog Development and Supply Agreement, dated as of December 20, 1999, by and between the registrant and UCB Bioproducts S.A.
+10.6**	License Agreement, dated as of June 6, 1990, by and between Biogen, Inc. and Health Research, Inc., as assigned to the registrant
+10.7**	License Agreement dated March 21, 1997, by and between the registrant and Biogen, Inc.
+10.8**	Development and Commercialization Agreement, dated August 16, 1999, by and between the registrant and GyneLogix, Inc.
10.9**	Consulting Agreement, dated December 1, 1998, by and between Innovex Inc. and the registrant
10.10**	Alliance Agreement, dated August 1996, by and between the registrant and PharmaBio Development Inc., as amended
10.11**	Services Agreement dated April 1, 2000 by and between the registrant and Stack Pharmaceuticals, Inc.
10.12**	Employment agreement dated September 5, 1996 by and between the registrant and Clive Meanwell
10.13**	Employment agreement dated March 10, 1997 by and between the registrant and John Villiger
10.14**	Employment agreement dated September 29, 1998 by and between the registrant and John Nystrom
10.15**	Employment agreement dated October 20, 1997 by and between the registrant and Peyton Marshall
10.16**	Employment agreement dated March 30, 2000 by and between the registrant and David Stack

NUMBER	DESCRIPTION
10.17**	Lease for One Cambridge Center dated March 15, 1997 by and between Boston Properties, Inc. and the registrant, as amended
10.18**	Form of Common Stock Purchase Warrant dated October 19, 1999
10.19**	Form of Common Stock Purchase Warrant dated March 2, 2000
10.20*	Form of 2000 Outside Director Stock Option Plan
10.21**	Letter of Intent dated July 20, 2000 by and between Innovex Inc. and the registrant
10.22***	Amendment No. 1 dated as of August 8, 2000 to the Services Agreement between the registrant and Stack Pharmaceuticals, Inc.
10.23*	Master Services Agreement effective as of November 17, 2000 between Innovex Inc. and the registrant
++10.24****	Sales Force Work Order #8475 effective as of November 17, 2000 between Innovex Inc. and the registrant
10.25*	Employment Agreement dated as of April 1, 2000 by and between the registrant and Thomas P. Quinn, as amended
10.26*	Employment Agreement dated October 16, 1997 by and between the registrant and John D. Richards
10.27*	Lease for 5 Sylvan Way dated August 15, 2000 by and between the registrant and Mack-Cali Morris Realty L.L.C.
10.28	Form of Stock Purchase Agreement between the registrant and the selling stockholders dated May 11, 2001
21.1*	Subsidiaries of the registrant
23.1	Consent of Ernst & Young LLP, Independent Auditors
23.2	Consent of Hale and Dorr LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on page II-6)

+ Confidential treatment was granted for certain portions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act.

++ Confidential treatment has been sought for certain portions of this Exhibit pursuant to Rule 24(b) promulgated under the Securities Exchange Act.

* Incorporated by reference to the registration statement on Form S-1 (registration no. 333-53280)

** Incorporated by reference from the exhibits to the registration statement on Form S-1 (registration no. 333-37404).

*** Incorporated by reference from the exhibits to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2000.

**** Incorporated by reference from the exhibits to the registrant's annual report on Form 10-K for the year ended December 31, 2000.

(b) Financial Statement Schedules.

None.

ITEM 17. UNDERTAKINGS

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;

provided, however, that paragraph (1)(i) and (1)(ii) do not apply if the information required to be included is a post-effective amendment by those paragraphs is contained in periodic reports filed by the Company pursuant to
Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in this Registration Statement.

(2) That, for the purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Insofar as indemnification to liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the Delaware General Corporation Law, the Certificate of Incorporation of the Registrant, the Underwriting Agreement, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of counsel the matter has been settled by the controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the act and will be governed by the final adjudication of such issue.

SIGNATURE

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Cambridge, Commonwealth of Massachusetts, on this 23 day of May, 2001.

THE MEDICINES COMPANY

By: /s/ CLIVE A. MEANWELL
Clive A. Meanwell
Chief Executive Officer and President

POWER OF ATTORNEY

We, the undersigned directors and/or officers of The Medicines Company (the "Company"), hereby severally constitute and appoint Clive A. Meanwell, Chief Executive Officer, and Peyton J. Marshall, Chief Financial Officer, and each of them individually, our true and lawful attorneys, with full powers to any of them, and to each of them singly, to sign for us and in our names in the capacities indicated below the Registration Statement on Form S-1 filed herewith, and any and all pre-effective and post-effective amendments to said Registration Statement (including any post-effective amendment to convert this Registration Statement to a Registration Statement on Form S-3), and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of them might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities indicated on May 23, 2001:

SIGNATURE	TITLE(S)
/s/ CLIVE A. MEANWELL Clive A. Meanwell	Chief Executive Officer and President (Principal Executive Officer)
/s/ PEYTON J. MARSHALL Peyton J. Marshall	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ LEONARD BELL Leonard Bell	Director
/s/ DENNIS B. GILLINGS Dennis B. Gillings	Director
/s/ STEWART J. HEN Stewart J. Hen	Director
/s/ ANDERS D. HOVE Anders D. Hove	Director
/s/ M. FAZLE HUSAIN M. Fazle Husain	Director

SIGNATURE	TITLE(S)
T. Scott Johnson	Director
Armin M. Kessler	Director
/s/ NICHOLAS J. LOWCOCK Nicholas J. Lowcock	Director
/s/ JAMES E. THOMAS James E. Thomas	Director

EXHIBIT INDEX

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* Incorporated by reference from the exhibits to the registration statement on Form S-1 (registration no. 333-53280)

** Incorporated by reference from the exhibits to the registration statement on Form S-1 (registration no. 333-37404).

*** Incorporated by reference from the exhibits to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2000.

**** Incorporated by reference from the exhibits to the registrant's annual

report on Form 10-K for the year ended December 31, 2000.

Exhibit 5.1

[HALE AND DORR LLP LETTERHEAD]

May 22, 2001

The Medicines Company
One Cambridge Center
Cambridge, MA 02142

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

This opinion is furnished to you in connection with a Registration Statement on Form S-1 (the "Registration Statement") to be filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), for the registration of an aggregate of 4,000,000 shares of Common Stock, $0.001 par value per share (the "Shares"), of The Medicines Company, a Delaware corporation (the "Company"). All of the Shares are being registered on behalf of certain stockholders of the Company (the "Selling Stockholders").

We are acting as counsel for the Company in connection with the registration for resale of the Shares. We have examined signed copies of the Registration Statement to be filed with the Commission. We have also examined and relied upon the minutes of meetings of the stockholders and the Board of Directors of the Company as provided to us by the Company, stock record books of the Company as provided to us by the Company, the Certificate of Incorporation and By-Laws of the Company, each as restated and/or amended to date, and such other documents as we have deemed necessary for purposes of rendering the opinion hereinafter set forth.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

Our opinion below, insofar as it relates to the Shares being fully paid, is based solely on a certificate of the Chief Financial Officer of the Company confirming the Company's receipt of the consideration called for by the applicable resolutions authorizing the issuance of the Shares.

We assume that the appropriate action will be taken, prior to the offer and sale of the Shares, to register and qualify the Shares for sale under all applicable state securities or "blue sky" laws.

We express no opinion herein as to the laws of any state or jurisdiction other than the state laws of the Commonwealth of Massachusetts, the General Corporation Law of the State of Delaware and the federal laws of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that the Shares have been duly authorized for issuance and are validly issued, fully paid and nonassessable.

It is understood that this opinion is to be used only in connection with the offer and sale of the Shares while the Registration Statement is in effect.

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act and to the use of our name therein and in the related prospectus under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

Very truly yours,

/s/ Hale and Dorr LLP

HALE AND DORR LLP

Exhibit 10.28

STOCK PURCHASE AGREEMENT

The Medicines Company
One Cambridge Center
Cambridge, Massachusetts 02142

Ladies & Gentlemen:

The undersigned, _____(the "Investor"), hereby confirms its agreement with you as follows:

1. This Stock Purchase Agreement (the "Agreement") is made as of May 11, 2001 between The Medicines Company, a Delaware corporation (the "Company"), and the Investor.

2. The Company has authorized the sale and issuance of up to 4,000,000 shares (the "Shares") of common stock of the Company, $0.001 par value per share (the "Common Stock"), to certain investors in a private placement (the "Offering").

3. The Company and the Investor agree that the Investor will purchase from the Company and the Company will issue and sell to the Investor _____ Shares, for a purchase price of $11.00 per share, or an aggregate purchase price of $_____, pursuant to the Terms and Conditions for Purchase of Shares attached hereto as Annex I and incorporated herein by reference as if fully set forth herein. Unless otherwise requested by the Investor, certificates representing the Shares purchased by the Investor will be registered in the Investor's name and address as set forth below.

4. The Investor represents that, except as set forth below, (a) it has had no position, office or other material relationship within the past three years with the Company or persons known to it to be affiliates of the Company, (b) neither it, nor any group of which it is a member or to which it is related, beneficially owns (including the right to acquire or vote) any securities of the Company and (c) it has no direct or indirect affiliation or association with any NASD member as of the date hereof. Exceptions:

---.
(If no exceptions, write "none." If left blank, response will be deemed to be "none.")

Please confirm that the foregoing correctly sets forth the agreement between us by signing in the space provided below for that purpose. By executing this Agreement, you acknowledge that the Company may use the information in paragraph 4 above and the name and address information below in preparation of the Registration Statement (as defined in Annex 1).

[Remainder of Page Intentionally Left Blank]

[SIGNATURE PAGE TO STOCK PURCHASE AGREEMENT]

AGREED AND ACCEPTED:

THE MEDICINES COMPANY

By:
Title:

Investor: _____

By: _____

Print Name: _____

Title: _____

Address: _____

_____

Tax ID No.: _____

Contact name: _____

Telephone: _____

Name in which shares should be registered (if different):

_____

ANNEX I

TERMS AND CONDITIONS FOR PURCHASE OF SHARES

1. AUTHORIZATION AND SALE OF THE SHARES. Subject to these Terms and Conditions for Purchase of Shares (the "Terms and Conditions"), the Company has authorized the sale of up to 4,000,000 Shares. The Company reserves the right to increase or decrease this number.

2. AGREEMENT TO SELL AND PURCHASE THE SHARES; SUBSCRIPTION DATE.

2.1 At the Closing (as defined in Section 3), the Company will sell to the Investor, and the Investor will purchase from the Company, upon the terms and conditions hereinafter set forth, the number of Shares set forth in Section 3 of the Stock Purchase Agreement to which these Terms and Conditions are attached at the purchase price set forth therein.

2.2 The Company may enter into the same form of Stock Purchase Agreement, including these Terms and Conditions, with certain other investors (the "Other Investors") and expects to complete sales of Shares to them. (The Investor and the Other Investors are hereinafter sometimes collectively referred to as the "Investors," and the Stock Purchase Agreement to which these Terms and Conditions are attached and the Stock Purchase Agreements (including attached Terms and Conditions) executed by the Other Investors are hereinafter sometimes collectively referred to as the "Agreements.") The Company may accept executed Agreements from Investors for the purchase of Shares commencing upon the date on which the Company provides the Investors with the proposed purchase price per Share and concluding upon the date (the "Subscription Date") on which the Company has (i) executed Agreements with Investors for the purchase of at least 4,000,000 Shares, and (ii) notified the Investors in writing that it is no longer accepting additional Agreements from Investors for the purchase of Shares. The Company may not enter into any Agreements after the Subscription Date.

3. DELIVERY OF THE SHARES AT CLOSING. The completion of the purchase and sale of the Shares (the "Closing") shall occur (the "Closing Date") on May 16, 2001, at the offices of the Company's counsel. At the Closing, the Company shall deliver to the Investor one or more stock certificates representing the number of Shares set forth in Section 3 of the Stock Purchase Agreement, each such certificate to be registered in the name of the Investor or, if so indicated on the signature page hereto, in the name of a nominee designated by the Investor.

The Company's obligation to issue the Shares to the Investor shall be subject to the following conditions, any one or more of which may be waived by the Company: (a) receipt by the Company of a certified or official bank check or wire transfer of funds in the full amount of the purchase price for the Shares being purchased hereunder as set forth in Section 3 of the Stock Purchase Agreement; (b) completion of the purchases and sales under the Agreements with the Other Investors; and (c) the accuracy of the representations and warranties made by the Investors and the fulfillment of those undertakings of the Investors to be fulfilled prior to the Closing.

The Investor's obligation to purchase the Shares shall be subject to the following conditions, any one or more of which may be waived by the Investor:
(a) Investors shall have executed Agreements for the purchase of at least 4,000,000 Shares, (b) the representations and warranties of the Company set forth herein shall be true and correct as of the Closing Date in all material respects and (c) the Investor shall have received such documents as such Investor shall reasonably have requested, including, a standard opinion of Company Counsel as to the matters set forth in Section 4.2 and as to exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), of the sale of the Shares.

4. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY. The Company hereby represents and warrants to, and covenants with, the Investor, as follows:

4.1 ORGANIZATION. The Company is duly organized and validly existing in good standing under the laws of the jurisdiction of its organization. Each of the Company and its Subsidiaries (as defined in Rule 405 under the Securities Act) has full power and authority to own, operate and occupy its properties and to conduct its business as presently conducted and as described in the documents filed by the Company under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), since the end of its most recently completed fiscal year through the date hereof, including, without limitation, its report on Form

10-K for the year ended December 31, 2000 and its current report on Form 10-Q for the quarter ended March 31, 2001 (the "Exchange Act Documents"), and is registered or qualified to do business and in good standing in each jurisdiction in which the nature of the business conducted by it or the location of its properties owned or leased by it requires such qualification and where the failure to be so qualified would have a material adverse effect upon the condition (financial or otherwise), earnings, business or business prospects, properties or operations of the Company and its Subsidiaries, considered as one enterprise (a "Material Adverse Effect"), and no proceeding has been instituted in any such jurisdiction, revoking, limiting or curtailing, or seeking to revoke, limit or curtail, such power and authority or qualification.

4.2 DUE AUTHORIZATION AND VALID ISSUANCE. The Company has all requisite power and authority to execute, deliver and perform its obligations under the Agreements, and the Agreements have been duly authorized and validly executed and delivered by the Company and constitute legal, valid and binding agreements of the Company enforceable against the Company in accordance with their terms, except as rights to indemnity and contribution may be limited by state or federal securities laws or the public policy underlying such laws, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). The Shares being purchased by the Investor hereunder will, upon issuance and payment therefor pursuant to the terms hereof, be duly authorized, validly issued, fully-paid and nonassessable.

4.3 NON-CONTRAVENTION. The execution and delivery of the Agreements, the issuance and sale of the Shares under the Agreements, the fulfillment of the terms of the Agreements and the consummation of the transactions contemplated thereby will not (A) conflict with or constitute a violation of, or default (with the passage of time or otherwise) under, (i) any material bond, debenture, note or other evidence of indebtedness, lease, contract, indenture, mortgage, deed of trust, loan agreement, joint venture or other agreement or instrument to which the Company or any Subsidiary is a party or by which it or any of its Subsidiaries or their respective properties are bound, (ii) the charter, by-laws or other organizational documents of the Company or any Subsidiary, or (iii) any law, administrative regulation, ordinance or order of any court or governmental agency, arbitration panel or authority applicable to the Company or any Subsidiary or their respective properties, except in the case of clauses (i) and
(iii) for any such conflicts, violations or defaults which are not reasonably likely to have a Material Adverse Effect or (B) result in the creation or imposition of any lien, encumbrance, claim, security interest or restriction whatsoever upon any of the material properties or assets of the Company or any Subsidiary or an acceleration of indebtedness pursuant to any obligation, agreement or condition contained in any material bond, debenture, note or any other evidence of indebtedness or any material indenture, mortgage, deed of trust or any other agreement or instrument to which the Company or any Subsidiary is a party or by which any of them is bound or to which any of the material property or assets of the Company or any Subsidiary is subject. No consent, approval, authorization or other order of, or registration, qualification or filing with, any regulatory body, administrative agency, or other governmental body in the United States or any other person is required for the execution and delivery of the Agreements and the valid issuance and sale of the Shares to be sold pursuant to the Agreements, other than such as have been made or obtained, and except for any post-closing securities filings or notifications required to be made under federal or state securities laws.

4.4 CAPITALIZATION. The capitalization of the Company as of March 31, 2001 is as set forth in the most recent applicable Exchange Act Documents, increased as set forth in the next sentence. The Company has not issued any capital stock since that date other than pursuant to (i) employee benefit plans disclosed in the Exchange Act Documents, or (ii) outstanding warrants, options or other securities disclosed in the Exchange Act Documents. The Shares to be sold pursuant to the Agreements have been duly authorized, and when issued and paid for in accordance with the terms of the Agreements will be duly and validly issued, fully paid and nonassessable. The outstanding shares of capital stock of the Company have been duly and validly issued and are fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and were not issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. Except as set forth in or contemplated by the Exchange Act Documents or options granted after March 31, 2001, there are no outstanding rights (including, without limitation, preemptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any unissued shares of capital stock or other equity interest in the Company or any Subsidiary, or any contract, commitment, agreement, understanding or arrangement of any kind to which the Company is a party or of which the Company has knowledge and relating to the issuance or sale of any capital stock of the Company or any Subsidiary, any such convertible or exchangeable securities or any such rights, warrants or options. Without limiting the foregoing, except as set forth in the Exchange Act Documents, no preemptive right, co-sale right, right of first refusal, registration right, or other similar right exists with respect to the Shares or the issuance and sale thereof. No further approval or authorization of any stockholder, the Board of Directors of the

Company or others is required for the issuance and sale of the Shares. The Company owns the entire equity interest in each of its Subsidiaries, free and clear of any pledge, lien, security interest, encumbrance, claim or equitable interest, other than as described in the Exchange Act Documents. Except as disclosed in the Exchange Act Documents, there are no stockholders agreements, voting agreements or other similar agreements with respect to the Common Stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

4.5 LEGAL PROCEEDINGS. There is no material legal or governmental proceeding pending or, to the knowledge of the Company, threatened to which the Company or any Subsidiary is or may be a party or of which the business or property of the Company or any Subsidiary is subject that is not disclosed in the Exchange Act Documents.

4.6 NO VIOLATIONS. Neither the Company nor any Subsidiary is in violation of its charter, bylaws, or other organizational document, or in violation of any law, administrative regulation, ordinance or order of any court or governmental agency, arbitration panel or authority applicable to the Company or any Subsidiary, which violation, individually or in the aggregate, would be reasonably likely to have a Material Adverse Effect, or is in default (and there exists no condition which, with the passage of time or otherwise, would constitute a default) in any material respect in the performance of any bond, debenture, note or any other evidence of indebtedness in any indenture, mortgage, deed of trust or any other material agreement or instrument to which the Company or any Subsidiary is a party or by which the Company or any Subsidiary is bound or by which the properties of the Company or any Subsidiary are bound, which would be reasonably likely to have a Material Adverse Effect upon the business or financial condition of the Company and its Subsidiaries, considered as one enterprise.

4.7 GOVERNMENTAL PERMITS, ETC. Each of the Company and its Subsidiaries has all necessary franchises, licenses, certificates, permits and other authorizations from any foreign, federal, state or local government or governmental agency, department, or body that are currently necessary for the operation of the business of the Company and its Subsidiaries as currently conducted and as described in the Exchange Act Documents except where the failure to currently possess could not reasonably be expected to have a Material Adverse Effect.

4.8 INTELLECTUAL PROPERTY. Except as specifically disclosed in the Exchange Act Documents (i) each of the Company and its Subsidiaries owns or possesses sufficient rights to use all material patents, patent rights, trademarks, copyrights, licenses, inventions, trade secrets, trade names and know-how (collectively, "Intellectual Property") described or referred to in the Exchange Act Documents as owned or possessed by it or that are necessary for the conduct of its business as now conducted or as proposed to be conducted as described in the Exchange Act Documents except where the failure to currently own or possess would not have a Material Adverse Effect, (ii) neither the Company nor any of its Subsidiaries has received any notice of infringement, or to the best knowledge of the Company after due inquiry neither the Company nor any of its Subsidiaries is infringing, or has any knowledge of, any asserted infringement by the Company or any of its Subsidiaries of, any rights of a third party with respect to any Intellectual Property that, individually or in the aggregate, would have a Material Adverse Effect and (iii) neither the Company nor any of its Subsidiaries has received any notice of, or has any knowledge of, infringement by a third party with respect to any Intellectual Property rights of the Company or of any Subsidiary that, individually or in the aggregate, would have a Material Adverse Effect.

4.9 FINANCIAL STATEMENTS. The financial statements of the Company and the related notes contained in the Exchange Act Documents present fairly, in accordance with generally accepted accounting principles, the financial position of the Company and its Subsidiaries as of the dates indicated, and the results of its operations and cash flows for the periods therein specified consistent with the books and records of the Company and its Subsidiaries except that unaudited interim financial statements were or are subject to normal and recurring year-end adjustments which are not expected to be material in amount. Such financial statements (including the related notes) have been prepared in accordance with generally accepted accounting principles applied on a consistent basis throughout the periods therein specified, except as may be included in the notes to such financial statements, or the case of unaudited statements, as may be permitted by the SEC on Form 10-Q under the Exchange Act and except as disclosed in the Exchange Act Documents. The other financial information contained in the Exchange Act Documents has been prepared on a basis consistent with the financial statements of the Company.

4.10 NO MATERIAL ADVERSE CHANGE. Except as disclosed in the Exchange Act Documents, since March 31, 2001, there has not been (i) any material adverse change in the financial condition or earnings of the Company and its Subsidiaries considered as one enterprise, (ii) any material adverse event affecting the Company or its Subsidiaries, (iii) any obligation, direct or contingent, that is material to the Company and its Subsidiaries considered as one enterprise, incurred by the Company, except

obligations incurred in the ordinary course of business, (iv) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or any of its Subsidiaries, or (v) any loss or damage (whether or not insured) to the physical property of the Company or any of its Subsidiaries which has been sustained which has a Material Adverse Effect.

4.11 DISCLOSURE. The representations and warranties of the Company contained in this Section 4 as of the date hereof and as of the Closing Date, did not and shall not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. In addition, since January 5, 2001, the date that the Company filed its registration statement on Form S-1 which was subsequently withdrawn on March 19, 2001, there have been no changes in the Company's business or financial condition that are material to the investment decision of the Investor in the Offering and have not been disclosed in the Exchange Act Documents.

4.12 NASDAQ COMPLIANCE. The Company's Common Stock is registered pursuant to Section 12(g) of the Exchange Act and is listed on The Nasdaq Stock Market, Inc. National Market (the "Nasdaq National Market"), and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or de-listing the Common Stock from the Nasdaq National Market, nor has the Company received any notification that the Securities and Exchange Commission (the "SEC") or the National Association of Securities Dealers, Inc. ("NASD") is contemplating terminating such registration or listing.

4.13 REPORTING STATUS. The Company has filed in a timely manner all documents that the Company was required to file under the Exchange Act during the period from August 8, 2000, the closing date of the Company's initial public offering, to the date of this Agreement. The following documents complied in all material respects with the SEC's requirements as of their respective filing dates, and the information contained therein as of the date thereof did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein in light of the circumstances under which they were made not misleading:

(a) amendment no. 1 to the proxy statement pursuant to Section 14(a) of the Exchange Act, filed on May 3, 2001;

(b) the proxy statement pursuant to Section 14(a) of the Exchange Act, filed on April 30, 2001;

(c) the annual report on Form 10-K for the year ended December 31, 2000, filed on April 2, 2001;

(d) the quarterly report on Form 10-Q for the quarter ended March 31, 2001 filed on May 10, 2001;

(e) the quarterly report on Form 10-Q for the quarter ended September 30, 2001, filed on November 8, 2001;

(f) the quarterly report on Form 10-Q for the quarter ended June 30, 2000, filed on September 19, 2000;

(g) the registration on Form 8-A, under the Exchange Act, filed July 28, 2000; and

(h) All other documents, if any, filed by the Company with the SEC since August 8, 2000 pursuant to the reporting requirements of the Exchange Act.

4.14 LISTING. The Company shall comply with all requirements of the National Association of Securities Dealers, Inc. with respect to the issuance of the Shares and the listing thereof on the Nasdaq National Market.

4.15 NO MANIPULATION OF STOCK. The Company has not taken and will not, in violation of applicable law, take, any action designed to or that might reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock to facilitate the sale or resale of the Shares.

4.16 COMPANY NOT AN "INVESTMENT COMPANY". The Company has been advised of the rules and requirements under the Investment Company Act of 1940, as amended (the "Investment Company Act"). The Company is not, and immediately after receipt of payment for the Shares will not be, an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act and shall conduct its business in a manner so that it will not become subject to the Investment Company Act.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE INVESTOR.

5.1 The Investor represents and warrants to, and covenants with, the Company that: (i) the Investor is an "accredited investor" as defined in Regulation D under the Securities Act and the Investor is also knowledgeable, sophisticated and experienced in making, and is qualified to make decisions with respect to investments in shares presenting an investment decision like that involved in the purchase of the Shares, including investments in securities issued by the Company and investments in comparable companies, and has requested, received, reviewed and considered all information it deemed relevant in making an informed decision to purchase the Shares; (ii) the Investor is acquiring the number of Shares set forth in Section 3 of the Stock Purchase Agreement in the ordinary course of its business and for its own account for investment only and with no present intention of distributing any of such Shares or any arrangement or understanding with any other persons regarding the distribution of such Shares; (iii) the Investor will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the Shares except in compliance with the Securities Act, applicable state securities laws and the respective rules and regulations promulgated thereunder; (iv) the Investor has answered all questions on the Investor Questionnaire for use in preparation of the Registration Statement and the answers thereto are true, correct and complete as of the date hereof and will be true, correct and complete as of the Closing Date; (v) the Investor will notify the Company immediately of any change in any of such information until such time as the Investor has sold all of its Shares or until the Company is no longer required to keep the Registration Statement effective; and (vi) the Investor has, in connection with its decision to purchase the number of Shares set forth in Section 3 of the Stock Purchase Agreement, relied only upon the Exchange Act Documents and the representations and warranties of the Company contained herein. The Investor understands that its acquisition of the Shares has not been registered under the Securities Act or registered or qualified under any state securities law in reliance on specific exemptions therefrom, which exemptions may depend upon, among other things, the bona fide nature of the Investor's investment intent as expressed herein. Investor has completed or caused to be completed and delivered to the Company the Investor Questionnaire, which questionnaire is true, correct and complete in all material respects.

5.2 The Investor acknowledges, represents and agrees that no action has been or will be taken in any jurisdiction outside the United States by the Company that would permit an offering of the Shares, or possession or distribution of offering materials in connection with the issue of the Shares, in any jurisdiction outside the United States where legal action by the Company for that purpose is required. Each Investor outside the United States will comply with all applicable laws and regulations in each foreign jurisdiction in which it purchases, offers, sells or delivers Shares or has in its possession or distributes any offering material, in all cases at its own expense.

5.3 The Investor hereby covenants with the Company not to make any sale of the Shares without complying with the provisions of this Agreement and without causing the prospectus delivery requirement under the Securities Act to be satisfied, and the Investor acknowledges that the certificates evidencing the Shares will be imprinted with a legend that prohibits their transfer except in accordance therewith. The Investor acknowledges that there may occasionally be times when the Company determines that it must suspend the use of the Prospectus forming a part of the Registration Statement, as set forth in Section 7.2(c).

5.4 The Investor further represents and warrants to, and covenants with, the Company that (i) the Investor has full right, power, authority and capacity to enter into this Agreement and to consummate the transactions contemplated hereby and has taken all necessary action to authorize the execution, delivery and performance of this Agreement, and (ii) this Agreement constitutes a valid and binding obligation of the Investor enforceable against the Investor in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law) and except as the indemnification agreements of the Investors herein may be legally unenforceable.

5.5 Investor will not use any of the restricted Shares acquired pursuant to this Agreement to cover any short position in the Common Stock of the Company if doing so would be in violation of applicable securities laws.

5.6 The Investor understands that nothing in the Exchange Act Documents, this Agreement or any other materials presented to the Investor in connection with the purchase and sale of the Shares constitutes legal, tax or investment advice. The Investor has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of Shares.

5.7 The Investor understands that the Company filed a registration statement on Form S-1 under the Securities Act on January 5, 2001, as amended on January 26, 2001 and February 23, 2001, for a public offering of shares of the Company's Common Stock, that such public offering was never completed and has been abandoned and that such registration statement was withdrawn on March 19, 2001. The Investor understands that the Shares have not been registered under the Securities Act by reason of their issuance in a transaction exempt from the registration requirements of the Securities Act pursuant to Section 4(2) or Regulation D promulgated thereunder and, as a result, the Investor will not have the protection of Section 11 of the Securities Act (15 U.S.C. 77k) with respect to the purchase of the Shares.

6. SURVIVAL OF REPRESENTATIONS, WARRANTIES AND AGREEMENTS. Notwithstanding any investigation made by any party to this Agreement, all covenants, agreements, representations and warranties made by the Company and the Investor herein shall survive the execution of this Agreement, the delivery to the Investor of the Shares being purchased and the payment therefor.

7. REGISTRATION OF THE SHARES; COMPLIANCE WITH THE SECURITIES ACT.

7.1 REGISTRATION PROCEDURES AND OTHER MATTERS. The Company shall:

(a) subject to receipt of necessary information from the Investors after prompt request from the Company to the Investors to provide such information, prepare and file with the SEC, within 10 days after the Closing Date, a registration statement on Form S-1 (the "S-1 Registration Statement") to enable the resale of the Shares by the Investors from time to time through the automated quotation system of the Nasdaq National Market or in privately-negotiated transactions;

(b) use its reasonable best efforts, subject to receipt of necessary information from the Investors after prompt request from the Company to the Investors to provide such information, to cause the S-1 Registration Statement to become effective within 30 days after the S-1 Registration Statement is filed by the Company such efforts to include, without limiting the generality of the foregoing, preparing and filing with the SEC in such 30-day period any financial statements that are required to be filed prior to the effectiveness of such S-1 Registration Statement;

(c) use its reasonable best efforts, subject to receipt of necessary information from the Investors after prompt request from the Company to the Investors to provide such information, to prepare and file with the SEC, within 10 days after the Company first becomes eligible to file a registration statement on Form S-3, a registration statement on Form S-3 (the "S-3 Registration Statement") to enable the resale of the Shares by the Investors from time to time through the automated quotation system of the Nasdaq National Market or in privately-negotiated transactions; and to use its reasonable best efforts to cause the S-3 Registration Statement to become effective as soon as practicable thereafter, such efforts to include, without limiting the generality of the foregoing, preparing and filing with the SEC as promptly as practicable any financial statements that are required to be filed prior to the effectiveness of such S-3 Registration Statement (the term "Registration Statement" shall mean the S-1 Registration Statement until the S-3 Registration Statement is declared effective by the SEC, after which time it shall mean the S-3 Registration Statement).

(d) use its reasonable best efforts to prepare and file with the SEC such amendments and supplements to the Registration Statement and the Prospectus used in connection therewith as may be necessary to keep the Registration Statement current, effective and free from any material misstatement or omission to state a material fact for a period not exceeding, with respect to each Investor's Shares purchased hereunder, the earlier of (i) the second anniversary of the Closing Date, (ii) the date on which the Investor may sell all Shares then held by the Investor without restriction by the volume limitations of Rule 144(e) of the Securities Act, or (iii) such time as all Shares purchased by such Investor in this Offering have been sold pursuant to a registration statement;

(e) furnish to the Investor with respect to the Shares registered under the Registration Statement such number of copies of the Registration Statement, Prospectuses and Preliminary Prospectuses in conformity with the requirements of the Securities Act and such other documents as the Investor may reasonably request, in order to facilitate the public sale or other disposition of all or any of the Shares by the Investor; provided, however, that the obligation of the Company to deliver copies of Prospectuses or Preliminary Prospectuses to the Investor shall be subject to the receipt by the Company of reasonable assurances from the Investor that the Investor will comply with the applicable provisions of the Securities Act and of such other securities or blue sky laws as may be applicable in connection with any use of such Prospectuses or Preliminary Prospectuses;

(f) file documents required of the Company for normal blue sky clearance in states specified in writing by the Investor and use its reasonable best efforts to maintain such blue sky qualifications during the period the Company is required to maintain the effectiveness of the Registration Statement pursuant to Section 7.1(d); provided, however, that the Company shall not be required to qualify to do business or consent to service of process in any jurisdiction in which it is not now so qualified or has not so consented;

(g) bear all expenses in connection with the procedures in paragraph (a) through (f) of this Section 7.1 and the registration of the Shares pursuant to the Registration Statement; and

(h) advise the Investor, promptly after it shall receive notice or obtain knowledge of the issuance of any stop order by the SEC delaying or suspending the effectiveness of the Registration Statement or of the initiation or threat of any proceeding for that purpose; and it will promptly use its reasonable best efforts to prevent the issuance of any stop order or to obtain its withdrawal at the earliest possible moment if such stop order should be issued.

Notwithstanding anything to the contrary herein, the Registration Statement shall cover only the Shares. In no event at any time before the Registration Statement becomes effective with respect to the Shares shall the Company publicly announce or file any other registration statement, other than registration statements on Form S-8, without the prior written consent of a majority in interest of the Investors.

The Company understands that the Investor disclaims being an underwriter, but the Investor being deemed an underwriter by the SEC shall not relieve the Company of any obligations it has hereunder; PROVIDED, HOWEVER that if the Company receives notification from the SEC that the Investor is deemed an underwriter, then the period by which the Company is obligated to submit an acceleration request to the SEC shall be extended to the earlier of (i) the 90th day after such SEC notification, or (ii) 120 days after the initial filing of the Registration Statement with the SEC.

7.2 TRANSFER OF SHARES AFTER REGISTRATION; SUSPENSION.

(a) The Investor agrees that it will not effect any disposition of the Shares or its right to purchase the Shares that would constitute a sale within the meaning of the Securities Act except as contemplated in the Registration Statement referred to in Section 7.1 and as described below or as otherwise permitted by law, and that it will promptly notify the Company of any changes in the information set forth in the Registration Statement regarding the Investor or its plan of distribution.

(b) Except in the event that paragraph (c) below applies, the Company shall (i) if deemed necessary by the Company, prepare and file from time to time with the SEC a post-effective amendment to the Registration Statement or a supplement to the related Prospectus or a supplement or amendment to any document incorporated therein by reference or file any other required document so that such Registration Statement will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and so that, as thereafter delivered to purchasers of the Shares being sold thereunder, such Prospectus will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; (ii) provide the Investor copies of any documents filed pursuant to Section 7.2(b)(i); and (iii) inform each Investor that the Company has complied with its obligations in Section 7.2(b)(i) (or that, if the Company has filed a post-effective amendment to the Registration Statement which has not yet been declared effective, the Company will notify the Investor to that effect, will use its reasonable best efforts to secure the effectiveness of such

post-effective amendment as promptly as possible and will promptly notify the Investor pursuant to Section 7.2(b)(i) hereof when the amendment has become effective).

(c) Subject to paragraph (d) below, in the event (i) of any request by the SEC or any other federal or state governmental authority during the period of effectiveness of the Registration Statement for amendments or supplements to a Registration Statement or related Prospectus or for additional information; (ii) of the issuance by the SEC or any other federal or state governmental authority of any stop order suspending the effectiveness of a Registration Statement or the initiation of any proceedings for that purpose;
(iii) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) of any event or circumstance which, upon the advice of its counsel, necessitates the making of any changes in the Registration Statement or Prospectus, or any document incorporated or deemed to be incorporated therein by reference, so that, in the case of the Registration Statement, it will not contain any untrue statement of a material fact or any omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and that in the case of the Prospectus, it will not contain any untrue statement of a material fact or any omission to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; then the Company shall deliver a certificate in writing to the Investor (the "Suspension Notice") to the effect of the foregoing and, upon receipt of such Suspension Notice, the Investor will refrain from selling any Shares pursuant to the Registration Statement (a "Suspension") until the Investor's receipt of copies of a supplemented or amended Prospectus prepared and filed by the Company, or until it is advised in writing by the Company that the current Prospectus may be used, and has received copies of any additional or supplemental filings that are incorporated or deemed incorporated by reference in any such Prospectus. In the event of any Suspension, the Company will use its reasonable best efforts to cause the use of the Prospectus so suspended to be resumed as soon as reasonably practicable within 20 business days after the delivery of a Suspension Notice to the Investor. In addition to and without limiting any other remedies (including, without limitation, at law or at equity) available to the Investor, the Investor shall be entitled to specific performance in the event that the Company fails to comply with the provisions of this Section 7.2(c).

(d) Notwithstanding the foregoing paragraphs of this Section 7.2, the Investor shall not be prohibited from selling Shares under the Registration Statement as a result of Suspensions on more than two occasions of not more than 30 days each in any twelve month period, unless, in the good faith judgment of the Company's Board of Directors, upon the written opinion of counsel of counsel, the sale of Shares under the Registration Statement in reliance on this paragraph 7.2(d) would be reasonably likely to cause a violation of the Securities Act or the Exchange Act and result in liability to the Company.

(e) Provided that a Suspension is not then in effect, the Investor may sell Shares under the Registration Statement, provided that it arranges for delivery of a current Prospectus to the transferee of such Shares. Upon receipt of a request therefor, the Company has agreed to provide an adequate number of current Prospectuses to the Investor and to supply copies to any other parties requiring such Prospectuses.

(f) In the event of a sale of Shares by the Investor pursuant to the Registration Statement, the Investor must also deliver to the Company's transfer agent, with a copy to the Company, a Certificate of Subsequent Sale substantially in the form attached hereto as EXHIBIT A, so that the Shares may be properly transferred.

7.3 INDEMNIFICATION. For the purpose of this Section 7.3:

(i) the term "Selling Stockholder" shall include the Investor and any affiliate of such Investor;

(ii) the term "Registration Statement" shall include the Prospectus in the form first filed with the SEC pursuant to Rule 424(b) of the Securities Act or filed as part of the Registration Statement at the time of effectiveness if no Rule 424(b) filing is required, exhibit, supplement or amendment included in or relating to the Registration Statement referred to in Section 7.1; and

(iii) the term "untrue statement" shall include any untrue statement or alleged untrue statement, or any omission or alleged omission to state in the Registration Statement a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(a) The Company agrees to indemnify and hold harmless each Selling Stockholder from and against any losses, claims, damages or liabilities to which such Selling Stockholder may become subject (under the Securities Act or otherwise) insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of, or are based upon (i) any breach of the representations or warranties of the Company contained herein or failure to comply with the covenants and agreements of the Company contained herein, (ii) any untrue statement of a material fact contained in the Registration Statement as amended at the time of effectiveness or any omission of a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any failure by the Company to fulfill any undertaking included in the Registration Statement as amended at the time of effectiveness, and the Company will reimburse such Selling Stockholder for any reasonable legal or other expenses reasonably incurred in investigating, defending or preparing to defend any such action, proceeding or claim, or preparing to defend any such action, proceeding or claim, PROVIDED, HOWEVER, that the Company shall not be liable in any such case to the extent that such loss, claim, damage or liability arises out of, or is based upon, an untrue statement made in such Registration Statement or any omission of a material fact required to be stated therein or necessary to make the statements therein not misleading in reliance upon and in conformity with written information furnished to the Company by or on behalf of such Selling Stockholder specifically for use in preparation of the Registration Statement or the failure of such Selling Stockholder to comply with its covenants and agreements contained in Section 7.2 hereof respecting sale of the Shares or any statement or omission in any Prospectus that is corrected in any subsequent Prospectus that was delivered to the Selling Stockholder prior to the pertinent sale or sales by the Selling Stockholder. The Company shall reimburse each Selling Stockholder for the amounts provided for herein on demand as such expenses are incurred.

(b) The Investor agrees to indemnify and hold harmless the Company (and each person, if any, who controls the Company within the meaning of
Section 15 of the Securities Act, each officer of the Company who signs the Registration Statement and each director of the Company) from and against any losses, claims, damages or liabilities to which the Company (or any such officer, director or controlling person) may become subject (under the Securities Act or otherwise), insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of, or are based upon, (i) any failure to comply with the covenants and agreements contained in Section 7.2 hereof respecting sale of the Shares, or (ii) any untrue statement of a material fact contained in the Registration Statement or any omission of a material fact required to be stated therein or necessary to make the statements therein not misleading if such untrue statement or omission was made in reliance upon and in conformity with written information furnished by or on behalf of the Investor specifically for use in preparation of the Registration Statement, and the Investor will reimburse the Company (or such officer, director or controlling person), as the case may be, for any legal or other expenses reasonably incurred in investigating, defending or preparing to defend any such action, proceeding or claim; provided that the Investor's obligation to indemnify the Company shall be limited to the net amount received by the Investor from the sale of the Shares.

(c) Promptly after receipt by any indemnified person of a notice of a claim or the beginning of any action in respect of which indemnity is to be sought against an indemnifying person pursuant to this Section 7.3, such indemnified person shall notify the indemnifying person in writing of such claim or of the commencement of such action, but the omission to so notify the indemnifying person will not relieve it from any liability which it may have to any indemnified person under this Section 7.3 (except to the extent that such omission materially and adversely affects the indemnifying person's ability to defend such action) or from any liability otherwise than under this Section 7.3. Subject to the provisions hereinafter stated, in case any such action shall be brought against an indemnified person, the indemnifying person shall be entitled to participate therein, and, to the extent that it shall elect by written notice delivered to the indemnified person promptly after receiving the aforesaid notice from such indemnified person, shall be entitled to assume the defense thereof, with counsel reasonably satisfactory to such indemnified person. After notice from the indemnifying person to such indemnified person of its election to assume the defense thereof, such indemnifying person shall not be liable to such indemnified person for any legal expenses subsequently incurred by such indemnified person in connection with the defense thereof, PROVIDED, HOWEVER, that if there exists or shall exist a conflict of interest that would make it inappropriate, in the opinion of counsel to the indemnified person, for the same counsel to represent both the indemnified person and such indemnifying person or any affiliate or associate thereof, the indemnified person shall be entitled to retain its own counsel at the expense of such indemnifying person; provided, however, that no indemnifying person shall be responsible for the fees and expenses of more than one separate counsel (together with appropriate local counsel) for all indemnified parties. In no event shall any indemnifying person be liable in respect of any amounts paid in settlement of any action unless the indemnifying person shall have approved the terms of such settlement; PROVIDED that such consent shall not be unreasonably withheld. No indemnifying person shall, without the prior written consent of the indemnified person, effect any settlement of any pending or threatened proceeding in respect of which any indemnified person is or could have been a party and

indemnification could have been sought hereunder by such indemnified person, unless such settlement includes an unconditional release of such indemnified person from all liability on claims that are the subject matter of such proceeding.

(d) If the indemnification provided for in this Section 7.3 is unavailable to or insufficient to hold harmless an indemnified person under subsection (a) or (b) above in respect of any losses, claims, damages or liabilities (or actions or proceedings in respect thereof) referred to therein, then each indemnifying person shall contribute to the amount paid or payable by such indemnified person as a result of such losses, claims, damages or liabilities (or actions in respect thereof) in such proportion as is appropriate to reflect the relative fault of the Company on the one hand and the Investor, as well as any other Selling Shareholders under such registration statement on the other in connection with the statements or omissions or other matters which resulted in such losses, claims, damages or liabilities (or actions in respect thereof), as well as any other relevant equitable considerations. The relative fault shall be determined by reference to, among other things, in the case of an untrue statement, whether the untrue statement relates to information supplied by the Company on the one hand or an Investor or other Selling Shareholder on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such untrue statement. The Company and the Investor agree that it would not be just and equitable if contribution pursuant to this subsection (d) were determined by pro rata allocation (even if the Investor and other Selling Shareholders were treated as one entity for such purpose) or by any other method of allocation which does not take into account the equitable considerations referred to above in this subsection (d). The amount paid or payable by an indemnified person as a result of the losses, claims, damages or liabilities (or actions in respect thereof) referred to above in this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified person in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this subsection (d), the Investor shall not be required to contribute any amount in excess of the amount by which the net amount received by the Investor from the sale of the Shares to which such loss relates exceeds the amount of any damages which such Investor has otherwise been required to pay by reason of such untrue statement. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Investor's obligations in this subsection to contribute shall be in proportion to its Investor sale of Shares to which such loss relates and shall not be joint with any other Selling Shareholders.

(e) The parties to this Agreement hereby acknowledge that they are sophisticated business persons who were represented by counsel during the negotiations regarding the provisions hereof including, without limitation, the provisions of this Section 7.3, and are fully informed regarding said provisions. They further acknowledge that the provisions of this Section 7.3 fairly allocate the risks in light of the ability of the parties to investigate the Company and its business in order to assure that adequate disclosure is made in the Registration Statement as required by the Act and the Exchange Act. The parties are advised that federal or state public policy as interpreted by the courts in certain jurisdictions may be contrary to certain of the provisions of this Section 7.3, and the parties hereto hereby expressly waive and relinquish any right or ability to assert such public policy as a defense to a claim under this Section 7.3 and further agree not to attempt to assert any such defense.

7.4 TERMINATION OF CONDITIONS AND OBLIGATIONS. The conditions precedent imposed by Section 5 or this Section 7 upon the transferability of the Shares shall cease and terminate as to any particular number of the Shares when such Shares shall have been effectively registered under the Securities Act and sold or otherwise disposed of in accordance with the intended method of disposition set forth in the Registration Statement covering such Shares or at such time as an opinion of counsel reasonably satisfactory to the Company shall have been rendered to the effect that such conditions are not necessary in order to comply with the Securities Act.

7.5 INFORMATION AVAILABLE. So long as the Registration Statement is effective covering the resale of Shares owned by the Investor, the Company will furnish to the Investor:

(a) as soon as practicable after it is available, one copy of
(i) its Annual Report to Stockholders (which Annual Report shall contain financial statements audited in accordance with generally accepted accounting principles by a national firm of certified public accountants), (ii) its Annual Report on Form 10-K and (iii) its Quarterly Reports on Form 10-Q (the foregoing, in each case, excluding exhibits);

(b) upon the request of the Investor, all exhibits excluded by the parenthetical to subparagraph (a) of this Section 7.5 as filed with the SEC and all other information that is made available to shareholders; and

(c) upon the reasonable request of the Investor, an adequate number of copies of the Prospectuses to supply to any other party requiring such Prospectuses; and upon the reasonable request of the Investor, the President or the Chief Financial Officer of the Company (or an appropriate designee thereof) will meet with the Investor or a representative thereof at the Company's headquarters to discuss all information relevant for disclosure in the Registration Statement covering the Shares and will otherwise cooperate with any Investor conducting an investigation for the purpose of reducing or eliminating such Investor's exposure to liability under the Securities Act, including the reasonable production of information at the Company's headquarters; provided, that the Company shall not be required to disclose any confidential information to or meet at its headquarters with any Investor until and unless the Investor shall have entered into a confidentiality agreement in form and substance reasonably satisfactory to the Company with the Company with respect thereto.

8. NOTICES. All notices, requests, consents and other communications hereunder shall be in writing, shall be mailed (A) if within the United States by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, or by facsimile, or (B) if delivered from outside the United States, by International Federal Express or facsimile, and shall be deemed given (i) if delivered by first-class registered or certified mail, three business days after so mailed, (ii) if delivered by nationally recognized overnight carrier, one business day after so mailed, (iii) if delivered by International Federal Express, two business days after so mailed, (iv) if delivered by facsimile, upon electronic confirmation of receipt and shall be delivered as addressed as follows:

(a) if to the Company, to:

The Medicines Company
One Cambridge Center
Cambridge, Massachusetts 02142 Attn: Clive A. Meanwell

(b) with a copy to:

Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109 Attn: Stuart M. Falber, Esq.

(c) if to the Investor, at its address on the signature page hereto, or at such other address or addresses as may have been furnished to the Company in writing.

9. CHANGES. This Agreement may not be modified or amended except pursuant to an instrument in writing signed by the Company and the Investor.

10. HEADINGS. The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

11. SEVERABILITY. In case any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

12. GOVERNING LAW. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without giving effect to the principles of conflicts of law.

13. COUNTERPARTS. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute but one instrument, and shall become effective when one or more counterparts have been signed by each party hereto and delivered to the other parties.

14. RULE 144. The Company covenants that it will timely file the reports required to be filed by it under the Securities Act and the Exchange Act and the rules and regulations adopted by the SEC thereunder (or, if the Company is not required to file such reports, it will, upon the request of any Investor holding Shares purchased hereunder made after the first anniversary of the Closing Date, make publicly available such information as necessary to permit sales pursuant to Rule 144 under the Securities Act), and it will take such further action as any such Investor may reasonably request, all to the extent required from time to time to enable such Investor to sell Shares purchased hereunder without registration under the Securities Act within the limitation of the exemptions provided by (a) Rule 144 under the Securities Act, as such Rule may be amended from time to time, or (b) any similar rule or regulation hereafter adopted by the SEC. Upon the request of the Investor, the Company will deliver to such holder a written statement as to whether it has complied with such information and requirements.

15. CONFIDENTIAL INFORMATION. The Investor represents to the Company that, at all times during the Company's offering of the Shares, the Investor has maintained in confidence all non-public information regarding the Company received by the Investor from the Company or its agents, and covenants that it will continue to maintain in confidence such information until such information
(a) becomes generally publicly available other than through a violation of this provision by the Investor or its agents or (b) is required to be disclosed in legal proceedings (such as by deposition, interrogatory, request for documents, subpoena, civil investigation demand, filing with any governmental authority or similar process), PROVIDED, HOWEVER, that before making any use or disclosure in reliance on this subparagraph (b) the Investor shall give the Company at least fifteen (15) days prior written notice (or such shorter period as required by law) specifying the circumstances giving rise thereto and will furnish only that portion of the non-public information which is legally required and will exercise its reasonable best efforts to obtain reliable assurance that confidential treatment will be accorded any non-public information so furnished.

Exhibit 23.1

CONSENT OF INDEPENDENT AUDITORS

We consent to the reference to our firm under the captions "Selected Consolidated Financial Data" and "Experts" and to the use of our report dated February 13, 2001, except for the eighth paragraph of Note 2, as to which the date is February 20, 2001, in the Registration Statement (Form S-1) and related Prospectus of The Medicines Company for the registration of 4,000,000 shares of its common stock.

/s/ Ernst & Young LLP

Boston, Massachusetts

May 21, 2001

Attachment 3

A BILL TO AMEND TITLE 35, UNITED STATES CODE, TO CONFORM CERTAIN FILING PROVISIONS WITHIN THE PATENT AND TRADEMARK OFFICE

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

ON

H.R. 5120

SEPTEMBER 14, 2006

Serial No. 109–150

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A BILL TO AMEND TITLE 35, UNITED STATES CODE, TO CONFORM CERTAIN FILING PROVISIONS WITHIN THE PATENT AND TRADEMARK OFFICE

THURSDAY, SEPTEMBER 14, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, THE INTERNET,
AND INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 11:14 a.m., in Room 2141, Rayburn House Office Building, the Honorable Lamar Smith (Chairman of the Subcommittee) presiding.

Mr. SMITH. The Subcommittee on Courts, the Internet, and Intellectual Property will come to order.

I am going to recognize myself for an opening statement, then the Ranking Member of the full Judiciary Committee, Mr. Conyers, as well as Mr. Berman and as well as Mr. Jenkins, the author of the legislation on which we are having the hearing today.

Thank you all for your interest. And we will proceed and then get to questions for our panelists as soon as we can.

I will recognize myself for an opening statement.

Today we begin an examination of H.R. 5120, a bill to amend title 35 of United States Code to conform certain filing provisions within the Patent and Trademark Office.

This is an important hearing on a serious subject, and I look forward to the testimony of our witnesses.

It is the tradition of our Subcommittee to ensure all stakeholders have an opportunity to be heard and have their concerns placed on the record. This is a critical step to take before we begin to consider what further steps, if any, may be appropriate.

H.R. 5120 is a highly unusual bill. Its enactment will single out a specific company and their legal counsel for special consideration. I believe the proponents of the legislation have the burden to establish that a change in public law is necessary. At the same time, I want to compliment the company for its commitment to the regular legislative process.

And I appreciate Dr. Meanwell's willingness to respond to tough questions in a public forum, which I believe is necessary to assist the Members of the Subcommittee in understanding the circumstances that led this company and their counsel to this point.

Their view is that the law is inflexible and, in their words, should be conformed to other provisions of the patent code that per-

mit parties who have failed to meet statutory deadlines to be granted an extension. Further, they believe the public interest in spurring innovation and promoting public health is best served by providing for the retroactive application of such a change in the law in their case.

Not unexpectedly, there are countervailing arguments. Opponents of this measure maintain there is no good reason the law requires amendment. They note that since this provision was first enacted more than two decades ago, only three of more than 700 applications have ever been denied in any part for having missed the 60-day filing deadline.

Further, they assert there is substantial precedent in the Patent Act to support the view that no relief should be granted when certain statutory deadlines are not met and that relief should extend only to circumstances where it is objectively demonstrated that the failure to file was unavoidable rather than merely unintentional. In other words, they believe the proposed change would actually make this deadline inconsistent with other precedents in the Patent Act. This is just a preview of the various arguments that the Subcommittee Members will soon hear and need to weigh for themselves.

That concludes my opening remarks. And the gentleman from Michigan, Mr. Conyers, is recognized for his.

Mr. CONYERS. I thank you, Chairman Smith. And I join you in welcoming all the witnesses: the Honorable Jon Dudas, a very dear friend of ours, Dr. Meanwell, and President Jaeger of Generic Pharmaceutical Association, and Professor Thomas.

I wanted you to know as I head for the floor on a judiciary bill that is currently up for consideration that the proposal before us, legislation that would permit the Patent and Trademark Office to consider late applications for an extended term of patent protection or marketing exclusivity, currently if a patent owner files for an extension even 1 day late, then the PTO has no discretion to consider it.

I understand that The Medicines Company faced this problem directly in 2002 when it sought patent term extension for its heart drug, Angiomax. If it was granted, the extension would have permitted the company to exclude competition to Angiomax for a longer period.

The application for additional patent protection was due 60 days after the Food and Drug Administration approved the drug. But the application was filed on the 61st day. Because it has no discretion to review late filings, the PTO summarily rejected its consideration.

Before us today is a proposal that would allow the PTO to consider the application. Contrary to how it has been portrayed, it would not automatically extend the term of exclusivity or automatically prevent competitors from entering the market. And in that regard, the bill appears equitable.

And I look forward to returning to continue the discussion with these very able witnesses that are before us.

And I thank you for your courtesy, Chairman Smith.

Mr. SMITH. Would the gentleman from Michigan yield to the gentleman from California, Mr. Berman, for his opening statement as well?

Mr. CONYERS. Absolutely.

Mr. BERMAN. Thank you, Mr. Chairman.

And thank you, Mr. Ranking Member, for yielding.

I appreciate scheduling this hearing on a bill giving the USPTO additional discretion to extend certain patent deadlines. While similar measures, bills that have specifically extended the Angiomax patent, have been attached to legislative vehicles in the past, I am glad that this issue is finally being reviewed by the Committee with jurisdiction over patent matters. It is important that this Subcommittee be able to analyze the impact of any changes this bill may make on the patent system.

Patents are a cornerstone of innovation. The Constitution provides a limited period of time of protection in order to promote innovation. Therefore, the patent process provides the exclusive right for an invention for 17 to 20 years generating incentives for an inventor to continue to create after which the invention becomes available for public use.

There is a delicate balance here: providing enough of an incentive to the inventor to spend the time, energy and money to create new inventions and on the other hand, the value of allowing the invention to be used by the public enabling others to develop new products or provide similar products for lower cost. Therefore, when considering the effect of allowing the PTO discretion to extend certain patent deadlines there is a natural tension between providing the flexibility to extend the deadline and maintaining a hard date for specific types of filings.

While providing greater elasticity may prevent Draconian results, does that come at the expense of stability in the market? There are to be other instances—there appears to be other instances where the PTO has discretion to extend deadlines. But the situation in this bill is designed to address is not one of those sections. Why? Is there something different about this type of filing that the PTO should not have discretion in this case?

Unfortunately, the PTO, I am sorry to say, Jon, hasn't provided much guidance in its response to the letter from the Chairman and myself about the policy questions posed by this bill. So I look forward to this hearing to hear the witnesses discuss the policy implications of this bill on the patent system and possibly on Hatch-Waxman.

Just to conclude, originally this legislation began as an effort to address one particular late filing of one patent. There has been no demonstrated need or request from any other patent owners, as far as I know, to provide discretion to the PTO for these types of filings. Moreover, from the way the bill has been written, it is clear this bill would affect the late filing of a particular company, which occurred about over 4 years ago. Some have even suggested that the better alternative to this bill is a private bill.

However, this bill and this particular circumstance does raise some questions about why there are inconsistencies in the discretion afforded to the PTO to determine when filings are timely. I look forward to this opportunity to explore those issues.

I yield back, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Berman.

The gentleman from Tennessee, Mr. Jenkins, is recognized for an opening statement.

Mr. JENKINS. Thank you, Chairman Smith, for holding this hearing.

And thank you, Mr. Berman, for your participation. I look forward to the views of our witnesses, like you, sir. And I am grateful for their appearance this morning.

H.R. 5120 has drawn bipartisan sponsorship from 23 of our colleagues, including three Members of the full Judiciary Committee: Mr. Hyde, Mr. Delahunt, and Mr. Meehan. I introduced this measure because I believe it is both good patent policy and sound health care policy. It corrects an inequity in the patent law and will encourage important innovation in medical research, precisely the purpose that Congress sought to accomplish in enacting the Hatch-Waxman Act.

In the course of this hearing, I hope that you will hear several examples of relief that is available for late payments, late filings and deficient filings. By enacting H.R. 5120 we are continuing to promote the basic purpose of Hatch-Waxman, and we are strengthening Hatch-Waxman. It is important to do this so that our nation will continue to lead the way in medical research and so that patients will not be denied promising new, innovative developments.

Mr. Chairman, I am submitting letters from leading medical practitioners and consumer groups, including a letter from the Cleveland Clinic, the University of California at Los Angeles, and the Emory Health Care Center in Atlanta, Georgia, from across our country endorsing H.R. 5120 to include in the Committee report.

Their credentials and their views are impressive. They emphasize the health care advantages of this measure, particularly its effect on opening up new avenues of medical research to prevent and treat strokes.

Mr. Chairman, I would like to ask unanimous consent to introduce these letters and that they be made a part of the record.

Mr. SMITH. Okay. Without objection, those letters will be made a part of the record.

[The letters follow in the Appendix]

Mr. JENKINS. Thank you.

H.R. 5120 is a narrowly tailored bill. It simply confers discretion on the patent office to consider an unintentionally late filed patent term restoration application submitted to the patent office within 5 days of the 60-day deadline in current law. It does not confer any substantive rights on any applicant but merely allows the applicant to present the facts surrounding the late filing to the patent office.

The director of the patent office then has 30 days to rule on the petition. Honest mistakes should not cause irreparable hardship for innovators or patients. A few days unintentional late filing mistake at the patent office should not be a cause for blocking promising medical research that could lead to important health care advances.

Mr. Chairman, I appreciate all the efforts you and the Subcommittee have invested in preparing for this hearing. I hope that

we can move as quickly as possible through the Committee process and proceed with the enactment of H.R. 5120. Thank you.

Mr. SMITH. Thank you, Mr. Jenkins.

And, without objection, other Members' opening statements will be made a part of the record, as well as a statement by Representative Elton Gallegly, a letter from Lawrence Goffney and testimony by Thomas Schatz, president of Citizens Against Government Waste.

Mr. SMITH. Before I introduce our witnesses, I would like to ask you all to stand and be sworn in.

[Witnesses sworn.]

Thank you. Please be seated.

Our first witness is Jon Dudas, who is the Undersecretary for Intellectual Property and Director of the United States Patent and Trademark Office. Mr. Dudas is the lead policy adviser to the Secretary of Commerce, the President of the United States and Administration agencies on intellectual property matters.

As Director of the USPTO, he is responsible for administering the laws that relate to the issuance of patents and trademarks and day-to-day management of the agency's $1.7 billion budget and 8,000 employees.

Prior to joining the Administration, Mr. Dudas served 6 years as Counsel to this Subcommittee and as Staff Director and Deputy General Counsel to the Committee on the Judiciary. Mr. Dudas is a summa cum laude graduate of the University of Illinois where he earned a bachelor of science in finance. He is an honors law graduate from the University of Chicago.

Our second witness is Clive Meanwell, who is the Chairman and Chief Executive Officer of The Medicines Company, a pharmaceutical company based in Parsippany, New Jersey that specializes in acute care hospital medicines. In 1996, Dr. Meanwell co-founded TMC to develop medicines for specialized patient populations.

TMC's only product is marketed under the name Angiomax and is used to prevent blood clots in patients from cardiovascular disease. Dr. Meanwell oversaw the acquisition, development and successful regulatory review of Angiomax, which culminated with the Food and Drug Administration's approval in 2000. Dr. Meanwell holds both an M.D. and a Ph.D. from the University of Birmingham in the United Kingdom.

Our next witness is Kathleen D. Jaeger, who has served as the President and CEO of the Generic Pharmaceutical Association since 2002. Before joining that organization, Ms. Jaeger was a partner in the Washington office of several law firms where she developed a specialty in food and drug practice. In addition to earning her J.D. from Catholic University Law School, Ms. Jaeger also has a bachelor of science in pharmacy and a minor in chemistry, which she earned at the University of Rhode Island.

Our final witness is John R. Thomas, who is a professor of law at the Georgetown University Law Center. Professor Thomas formerly served as an associate or visiting professor on the faculties of George Washington University, Cornell Law School and the University of Tokyo. Professor Thomas has written extensively on intellectual property law co-authoring both a patent law case book and a one-volume treatise on intellectual property.

Welcome to you all.

As you know, we have your entire written statements, which, without objection, will be made a part of the record. But please limit your testimony to 5 minutes.

And, Mr. Dudas, we will begin with you.

TESTIMONY OF JON DUDAS, UNDERSECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY, DIRECTOR OF THE U.S. PATENT AND TRADEMARK OFFICE

Mr. DUDAS. Thank you, Mr. Chairman, Ranking Member Berman, Congressman Jenkins and Congressmen Meehan and Delahunt, for inviting me to testify today on H.R. 5120.

This bill would amend patent law to permit the USPTO to consider certain late-filed applications for patent extension under Hatch-Waxman if such applications are filed no later than 5 days after the current 60-day time period and applicants file a petition showing that the delay was unintentional.

Mr. Chairman, the USPTO does not at this point have a position on this bill. Certainly, there could be some benefits and at least one direct beneficiary of providing the flexibility proposed in the bill. But there are also benefits to maintaining a certainty inherent in the current law.

While we have a sense of the potential impact on the possible direct beneficiary to this legislation and while we know very well our own abilities to enforce the law, we do not yet have a full sense of the impact on other interested parties. Therefore, I commend you for holding this hearing to help determine the potential impact and to otherwise examine the possible merits and limitations of this proposal.

Although I am unable to give you a clear reading of support or opposition, I would like to share with you a number of observations that may be helpful to the Subcommittee as it reviews the bill.

First, this type of legislation is not without precedent. As indicated in my written statement, current patent and trademark law provides the USPTO with discretionary authority to accept late-filed submissions in a number of situations.

Also, while we currently do not believe the legislation requires additional restrictions or limitations in order to ensure a neutral application if enacted, further review of the issue may be helpful as the legislative process continues.

In terms of application, we are aware of one current application for patent term extension that would immediately benefit from enactment of the bill. You will be hearing from the owner of that patent shortly. But our review of the over 700 applications for patent term extensions filed since 1984 indicates that one other application filed 5 days late may have benefited from this bill if it had been in effect.

So after a review of 700 applications since 1984, there are a total of four patent term extension requests that were over 60 days, two that were within 65 days but older than 60 days and one that is currently pending.

I should note that it is not unprecedented for newly enacted patent legislation to apply to issued patents and pending applications. But prospective or retrospective discretionary authority as pro-

posed in this bill should involve a careful balancing of all relevant interests involved. Again, we are pleased that the Subcommittee is reviewing input with an eye toward that balancing.

Mr. Chairman, if granted the authority proposed in the bill, I would not foresee any implementation problems at the USPTO. The USPTO would, of course, follow the policies reflected in our administration of areas currently subject to discretionary review of delayed filings.

Mr. Chairman, in closing I want to thank you, Ranking Member Berman, and the Members of this Subcommittee for your continuing and strong support for the USPTO operations and for your efforts to maintain and improve our system of intellectual property protection and enforcement. And I look forward to answering your questions.

[The prepared statement of Mr. Dudas follows:]

PREPARED STATEMENT OF THE HONORABLE JON W. DUDAS

Chairman Smith, Ranking Member Berman, and Members of the Subcommittee:

Thank you for inviting me to testify today on H.R. 5120, a bill "to amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office."

The bill would amend patent law to permit the USPTO to consider certain late-filed applications for patent extension under section 156 of title 35 if such applications are filed not later than five days after the current 60-day time period and the applicants file a petition that shows that the delay in filing the application was unintentional.

Mr. Chairman, as indicated in our recent letters to you and Ranking Member Berman, the United States Patent and Trademark Office (USPTO) does not at this time have a position on this proposed legislation.

While there could be some benefits, and at least one direct beneficiary, of providing the type of additional flexibility provided by the proposal, there are also benefits to maintaining the certainty inherent in the current law in this area.

While we have a sense of the potential impacts on the possible direct beneficiary to this legislation, we do not yet have a full sense of the impact on others in the invention, manufacturing, consumer, and intellectual property communities.

Accordingly, we commend you for holding this hearing to help determine the potential impact on all interested parties and to otherwise examine the possible merits and limitations of the proposal.

I am pleased to share with you a number of our observations that may be helpful as the Subcommittee reviews the bill.

PRECEDENT

This type of legislation is not without precedent. Currently, patent laws provide the USPTO with discretionary authority to accept late-filed submissions in a number of situations, including: payment of maintenance fees (35 USC § 41(c)(1)); abandonment of applications (35 USC § 133); and payment of issue fees (35 USC § 151). The trademark laws have similar language, for example, regarding timely filing of a verified statement of use (15 USC § 1051(d)(4)) and abandonment of an application for failure to reply or amend (15 USC § 1062(b)).

Similarly, while we currently do not believe the legislation requires additional restrictions or limitations in order to ensure neutral application if enacted, further exploration of the issue may be informative as the legislative process continues.

PREVIOUS APPLICANTS THAT WOULD BENEFIT FROM ENACTMENT

We are aware of one current application for patent term extension that would immediately benefit from enactment of the bill. That application is related to patent number 5,196,404 owned by the company represented at the table here today. More generally, a review of our records indicates that, of the over 700 applications for patent term extension filed since 1984, three other applications were not granted due, at least in part, to timeliness issues. One of these applications was filed within 65 days of the "approval date," and thus may have been eligible for a petition to have the delay excused, if the proposed provision had been in effect.

PROSPECTIVE VS. RETROSPECTIVE

It is not unprecedented for newly enacted patent legislation to apply to issued patents and pending applications. That fact noted, prospective or retrospective discretionary authority, as proposed in the bill, would have to involve a careful balancing of all relevant interests involved. We are unable to make a particular recommendation in this regard because we are unaware of any substantive input by interested parties, other than the 404 patent owner.

EXERCISE OF DISCRETION

With respect to the circumstances under which we would expect to exercise discretion under this bill, we believe it is premature to attempt to list or identify particular examples at this point. We would, of course, if granted the subject authority, be likely to follow the policies reflected in the administration of areas currently subject to discretionary review of delayed filings.

PATENT REFORM

Although our survey of patent term extension applications reveals few issues related to timeliness, this legislation would be of use to at least one current applicant and could be utilized by future applicants who miss the patent term extension application deadline due to unintentional delay. As noted above, the discretionary authority contemplated by H.R. 5120 is similar to other deadline-extending provisions in patent law.

As indicated in testimony before your Subcommittee in April, the USPTO supports enactment of two patent proposals pending before the Subcommittee that are widely supported throughout the intellectual property community, namely, a post-grant review procedure and a new procedure for submission of prior art. We continue to review other proposals before the Subcommittee.

Thank you.

Mr. SMITH. Thank you, Mr. Dudas.

Dr. Meanwell.

TESTIMONY OF CLIVE MEANWELL, CHIEF EXECUTIVE OFFICER, THE MEDICINES COMPANY

Mr. MEANWELL. Thank you, Mr. Chairman and Members of the Committee. I am pleased to be here and appreciate the Committee's invitation to testify. My name is Clive Meanwell. I come before you today both as a physician and as the chairman and CEO of The Medicines Company, a young company devoted to developing medicines for acutely ill patients.

The subject of today's hearing may seem dry and technical, but, as you know, it is actually about ensuring the potential to save lives and reduce health care costs. Our company serves as a poster child for why this legislation is needed. Relying on incentives in the patent law, we spent more than $200 million developing Angiomax, an intravenous blood thinner that has proven to be effective and safe for patients while actually saving hospitals an average of $400 per use compared with more established therapies.

Once FDA approved Angiomax, we applied for patent term restoration to recover time lost while seeking approval. The 60-day deadline was mistaken for a 2-month limit, and the application was filed 1 day late. Unlike most other patent provisions, current law gives the PTO no discretion to accept a late filing. So our application was denied.

This drastic penalty took away 4½ years of patent rights we had earned and cut off our ability to invest tens of millions of dollars more in research to confirm promising new uses of Angiomax in open heart surgery and stroke.

Mr. Chairman, this is a good bill for three principle reasons.

First, the existing deadline provision imposes hugely disproportionate penalty like having your home repossessed when you are a day late with the last mortgage payment. Deadlines are important, but most patent law provisions like Federal court rules recognize that human beings make mistakes and that catastrophic consequences should not flow from them.

Second, this legislation is consistent with most patent laws and regulations, which allow minor mistakes to be excused.

Third, the bill could benefit millions of seriously ill patients. Only companies with a period of exclusivity can make the large-scale investments necessary to develop new uses of the drug beyond the scope of its initial FDA approval.

Some critics suggest this bill will disrupt the decision making process of generic manufacturers who pursue their own applications on relatively tight timelines. I am on the board of a company that sells generics, and I know how important these tight timelines are. But they have nothing to do with the patent term restoration—with when patent term restoration applications are filed. The only dates really important to a generic firm are the date of FDA approval and the date a patent expires.

Similarly, the claim that this bill might interfere with settled expectations is a fallacy. There are no settled expectations 60 days after a drug has been approved, nor would the time added by this bill, a maximum of 35 days, have the slightest impact on a generic's business plans. It is the pioneers' settled expectations that get blown to bits if its patent rights are lost over a minor filing error.

It is also suggested that since the filing of Hatch-Waxman application triggers an elaborate sequence for calculating the registration period—the restoration period, ensuring that this triggering event happens in a seasonable manner is somehow important. But calculating the restoration term typically takes 3 years after the application is filed. So the few extra days this bill could add at the start of the process are just trivial.

This bill will not—and let me repeat that—will not upset the delicate balance that Hatch-Waxman strikes between innovators and generics. In fact, it preserves the balance. Generics retain all their rights. And the patent owners get nothing more than the restoration period that they already earned under Hatch-Waxman. Without this bill, however, an innovator who makes an unintentional filing mistake loses what Congress intended to provide: an opportunity to recover time lost during FDA approval.

I just don't believe that Congress intended to throw this careful balance overboard in the event that an innovator trips on their way to the patent office. Some say this is a single company bill. But that is a red herring. This bill would fix a legal pothole for all other patent holders and could potentially help millions of patients who will benefit from new drugs and new uses of drugs.

In summary, this bill enhances the fundamental bargain struck by Hatch-Waxman. It removes a Draconian penalty for minor error. It is consistent with current law. And it will potentially improve the lives of millions of needy patients.

Thank you very much.

[The prepared statement of Mr. Meanwell follows:]

PREPARED STATEMENT OF CLIVE MEANWELL

Thank you Mr. Chairman and Members of the Committee.

My name is Clive Meanwell, and I am the Chairman and Chief Executive Officer of The Medicines Company, a young pharmaceutical company based in New Jersey where we develop acute care medicines for hospital patients, a small segment of the market often considered unattractive by big drug companies. I am also a doctor. And I am pleased to be here and appreciate the Committee's invitation to testify.

Mr. Chairman, the subject of today's hearing—filing deadlines for certain patent applications—might seem like a dry and technical one, but it is actually about creating the potential to save lives. It is about amending a provision of the Hatch-Waxman Act that, if left unchanged, will right now kill the further development of a drug that is helping thousands of heart disease patients every month and has the promise to help hundreds of thousands more patients with life-threatening cardiovascular conditions, including stroke victims. Beyond our case, if the provision is left unchanged, it will also put at risk the development of other drugs that will save lives in the future.

The purpose of this hearing, at least as I see it, is to weigh the distinct benefit of the proposed filing amendment against whatever benefit there may be to retaining the existing, inflexible provision. In my view, what H.R. 5120 does, in a nutshell, is to preserve the fundamentally sound bargain Congress struck in the Hatch-Waxman Act between encouraging innovation and bringing generic drugs to market. In preserving Hatch-Waxman's incentive to develop new drugs and new uses for drugs—without curtailing provisions that benefit generic manufacturers—this bill also stands solidly on the side of patients.

BACKGROUND

To date, The Medicines Company's only marketed product is a new blood thinning drug called Angiomax. The FDA has already approved Angiomax for use in angioplasty—a procedure often used to treat coronary artery disease, including heart attacks. Catheters, inflatable balloons, and stents are used to open up a coronary artery that is narrowed or blocked by arteriosclerosis or blood clots. Approximately one million angioplasties are performed each year in the United States, and in this setting Angiomax has been shown effective and safe, and is also associated with a significant reduction in bleeding complications compared to other treatments. More than 250,000 patients benefited from Angiomax last year alone. These positive results have been seen in both clinical trials and real-world use, in many different groups of patients, from diverse ethnic backgrounds, with a range of risk factors and a variety of life-threatening coronary artery disease states. And Angiomax—a product of high technology research—is particularly useful for people who cannot tolerate heparin, an extract of pig intestines discovered in 1916, that until the last decade was the only injectable anticoagulant available.

In addition to its established effectiveness in coronary angioplasty, Angiomax may also have important uses in patients undergoing cardiac surgery, those with pre-heart attacks and those with strokes. Each of these conditions represents enormous public health problems in the United States today. Coronary artery disease and stroke combine to kill well over a half million Americans each year—more than the deaths caused by all cancers combined, and therefore by far the leading cause of death in this country. The initial promise of Angiomax in these new research areas is exciting. For example, results of an Angiomax pilot trial in open heart surgery were reported in the *Annals of Thoracic Surgery* in 2004, where an expert commentator stated, "bivalirudin [*i.e.,* Angiomax] could be the 'holy grail' eagerly sought by cardiac surgeons and anesthesiologists (and hematologists). . . ." Ann. Thorac. Surg. 2004; 77:925–31. In another example, early studies involving carotid artery stenting—a procedure used to unblock the arteries in the neck that can throw off blood clots to the brain—have shown that Angiomax can reduce the risks of bleeding and effectively prevent embolic strokes during this delicate life-saving procedure.

We have already committed, and hope to continue committing, substantial resources to research and development of these significant new uses for Angiomax. And that brings me to the point of my testimony today.

Our company serves, I am sorry to say, as a poster child for why this bill is needed.

In developing Angiomax, we did what research-based biotech and pharmaceutical companies regularly do in responding to the incentives of the U.S. patent system: we spent large amounts of time and money to bring a new product to market. In total, development of Angiomax for angioplasty took eight years and cost more than $200 million. We anticipate that the clinical trials needed to establish the safety and effectiveness of Angiomax in patients for cardiac surgery and for stroke will take

at least 4 more years and cost tens of millions of dollars. These investments are not viable without the patent exclusivity provided by the Hatch-Waxman Act.

As you know, the U.S. patent law framework—including Hatch-Waxman—is designed to provide incentives for the investment of such time and money. Hatch-Waxman, of course, enables research-based pharmaceutical companies to recoup some of the time spent in the FDA approval process so that the patent exclusivity period is not unfairly curtailed. Often, it is the possibility of qualifying for Hatch-Waxman patent term restoration that provides innovators with the incentive to invest in drugs that no one else wants to develop. Moreover, once such restoration has been granted, innovators have added incentive to pursue further research on drugs to broaden their approved use, an important step in the development process, since it is not unusual for FDA to grant a narrow approval in the first instance.

The FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000. Under the Hatch-Waxman formula, we calculated that we were entitled to a restoration period of approximately 4½ years. We quickly set about preparing our application for patent restoration, completing a first draft of the 100-plus page application package by the first week of January 2001 and then working steadily along with our counsel on further drafts. But then human error intervened. The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, but one day late for the actual 60-day deadline. Unlike other filing provisions of the patent laws, this provision of Hatch-Waxman does not allow for any discretion to accept late applications, no matter the reason and no matter how close to the actual deadline. So, the Patent and Trademark Office denied the petition as untimely. We filed a motion for reconsideration which is still pending, but the PTO lacks the authority to grant it.

So, because of an inadvertent administrative error, The Medicines Company—and the patients who could be helped by Angiomax—are facing a drastic and disproportionate penalty. The basis for a $200 million investment that powered development of a life-saving drug in coronary angioplasty has been completely cut out from under us. And our hope of extending the benefit of Angiomax into critically important new areas is in tatters. Without patent restoration, our patent will expire in 2010, not nearly enough time to make possible the investment of years and tens of millions of dollars needed to confirm the efficacy of Angiomax in treating stroke and serious heart disease to the satisfaction of ourselves, the FDA and medical practitioners. And others who make accidental filing mistakes in the future, may face a similar predicament.

Making the consequences of a minor mistake so catastrophic, both to a patent owner and the public, simply cannot be good or wise public policy.

H.R. 5120-WEIGHING THE BENEFITS

H.R. 5120 is a modest bill that would correct this unduly harsh result for us and for any other innovators who make the same mistake. The bill would not give a patent owner anything other than what it has already earned under the Hatch-Waxman system—a credit for the portion of a patent term effectively lost while seeking FDA approval. The bill would not, by its own terms, grant patent term restoration. It would simply give the PTO authority to accept an application that was filed late on account of an unintentional error.

Mr. Chairman, I think a reasoned analysis of the potential costs and benefits of this legislation argues powerfully in its favor. Let me begin with the benefits of modifying the existing deadline provision.

First, the effect of the existing provision is like having your home repossessed for making your mortgage payment a day late—a completely disproportionate punishment for a minor, administrative mistake. As a matter of wise public policy, this does not make sense. Years of highly valuable, hard earned patent rights—in our case more than a third of our total patent period—should not be forfeited on account of a minor clerical error.

Second, this legislation is entirely consistent with typical patent law and practice and supports the purpose of Hatch-Waxman. Recognizing the obvious importance of patent rights and the national interest in promoting pharmaceutical innovation, the great majority of relevant patent laws and regulations actually do give the PTO discretion to excuse inadvertent mistakes. For example: if an applicant files an incomplete application for patent term restoration, the PTO can grant up to two extra months to correct the errors in the application. This is not an isolated example. There are more than 30 such examples where the PTO has the authority

to excuse errors that could otherwise deprive an applicant of its rights. We have submitted a memorandum detailing these examples to the Committee. Thus, the rigid statutory 60-day deadline, allowing PTO no discretion to excuse an inadvertent error is, in fact, an anomaly, which this bill would rightly correct. Moreover, by preventing the automatic forfeit of years of patent protection for minor clerical errors, the bill supports an important purpose of the Hatch-Waxman system—to make sure patent owners have an opportunity to recover the portion of their exclusivity period that would otherwise be lost while awaiting FDA approval.

Third, this bill would potentially benefit millions of seriously ill patients. Only a company that can assure itself of a significant period of exclusivity will take the risks and make the substantial investment necessary to obtain the approval of new uses of a drug beyond the scope of its initial FDA approval. In our case, no generic manufacturer would do what we are prepared to do—invest years and tens of millions of dollars to test promising new uses of Angiomax for heart disease and stroke—because the manufacturer would have no financial incentive to do so. If the initial promise we have seen for such applications is realized, Angiomax could potentially provide vital help to hundreds of thousands of seriously ill patients. And what is true for us will be true for others in the future. So this is an important, potentially life-saving bill for patients.

Now, I understand that concerns have also been raised about this bill, but they do not, individually or together, begin to measure up to the bill's substantial benefits.

Settled expectations/certainty. First, it has been said that H.R. 5120 might interfere with settled expectations about when a drug would come off patent, and that there are legitimate benefits to maintaining the certainty inherent in current law. In principle, there are of course benefits to certainty in laws. But the interest of "settled expectations" is more effectively served by this bill than by the status quo.

The fact that a patent owner might get an additional 5 days to file a patent restoration application, and that the PTO could take 30 days to decide whether to grant this additional time, will not have the slightest impact on the business plans a generic manufacturer has or has not made to enter a new market. The truth is that neither generics manufacturers nor anyone else can know what the duration of a possible patent term restoration period might be until the proposed patent term extension is published for public comment, often years after the application is filed. That is the first notice that a generic manufacturer is likely to rely on in terms of its own planning, and this bill would have no impact on the content or timing of such notice.

I am very sympathetic to the value of generics companies in our healthcare system—indeed I sit on the board of directors of one, and I am proud of what we do there. But the claimed disturbance to certainty and settled expectations entailed in H.R. 5120 would not even amount to a ripple upon the water for a generic firm.

By contrast, the settled business expectations that are obliterated are those of a patent holder that devises its business and investment strategy in reliance on the opportunity for Hatch-Waxman restoration, if those rights are lost on account of a minor filing error.

The delicate balance. Second, some have said that enacting this bill would upset the delicate balance in Hatch-Waxman between (a) spurring innovation by assuring that a patent holder retains its exclusivity rights despite the years it takes to get FDA approval, and (b) allowing generic manufacturers to produce cheaper drugs. I'm neither a lawyer nor a legislator, but it seems to me that the "balance" argument cuts in favor of H.R. 5120, not against it.

The Hatch-Waxman balance was premised, as I understand it, on the following five elements: first, a generic manufacturer can study a drug during the patent term without infringing the patent; second, a generic manufacturer can rely upon the investment and testing done by the innovator, rather than incurring the time and expense required to test the drug itself; third, a generic manufacturer who files an ANDA (Abbreviated New Drug Application) successfully challenging an existing patent is eligible for a six-month period of marketing exclusivity; and fourth, generic manufacturers benefit from the five-year limit on the patent restoration term and the 14-year cap on the overall patent term; while, fifth, the innovator is provided an incentive—through the grant of patent term restoration—to undertake the risk, expense, and delay of drug testing and FDA approval.

Under H.R. 5120, this balance is fully preserved. Generic manufacturers would retain all of the benefits I just described—study during patent term, benefiting from others' R&D investments, ANDA opportunity, and limited patent terms—and the innovator would retain its benefit of term restoration in exchange for conducting clinical testing. *Without* this bill, however, an innovator who makes a minor, inad-

vertent filing error loses its entire Hatch-Waxman benefit—the opportunity to seek the patent term restoration that was already earned.

I simply cannot believe that, as Congress constructed this careful balance, it meant to throw it overboard in the event that the innovator tripped on the way to the Patent Office. That was manifestly not part of the bargain Congress intended to strike.

Deadlines. Third, some say simply that 60 days means 60 days, full stop. I understand the importance of deadlines, and I understand that penalties are an important way to enforce deadlines. But, the problem here is that the punishment does not remotely fit the crime. As I have noted, the PTO has extensive discretion to extend deadlines in most situations encountered in patent examinations. And I understand that a similar rule applies in federal civil litigation, where the relevant rule (6(b)) gives judges broad discretion to extend a deadline or permit a filing "where the failure to act was the result of excusable neglect." The flexibility found in the patent law and the rules of civil procedure is built on a fundamental and simple recognition—that people are human and sometimes make inadvertent mistakes, and thus draconian consequences ought not to flow from such errors. An argument that comes down to the claim that a rule is a rule and should not be changed no matter how inappropriate its effect seems to me unworthy of this great legislative body. The PTO, of course, cannot change such a rule in a statute, but Congress can if it concludes, as a matter of policy, that a wise amendment is available. I think H.R. 5120 constitutes just such an amendment.

Single company. Fourth, the notion that this is just a bill to help one company is a red herring. Of course, our company would potentially be helped by the bill, since the PTO would then have the discretion to accept our filing and consider our application on the merits if it so chose. But, as the PTO has noted, others in the past have had timeliness problems with regard to Hatch-Waxman filings, and, because people will always make mistakes, others will have this problem in the future. Our company is the one that has stumbled, inadvertently, into this legal pothole. But that does not change the reality that the pothole ought to be fixed. Most laws passed by Congress benefit some companies and disadvantage others—that is just a fact of life. If there is any difference here, it is that most of the beneficiaries of this law will be found in the future and no one is likely to be disadvantaged.

Going to court. Finally, some have said to me that we should just file a lawsuit rather than advocating an amendment to Hatch-Waxman. But that course of action would fail in fundamental ways that I care about a great deal. First, there is a *bona fide* public policy problem here. This really is not just one company's concern. The immense disproportion between a relatively trivial mistake and the enormous consequences that flow from it is just not right—not for us and not for any other companies that follow in our wake.

In addition, I care deeply about pursuing the promise of Angiomax to heart and stroke applications, which as I have explained, we will not be able to do absent patent term restoration. As I said at the outset, I am not just a businessman, I am also a doctor. I have made a lifelong commitment to improve patient care, and I would hate to let that promise go unexplored. Money that we might recover in a lawsuit would be useful to the company, but it would not save a single life. So that is not the answer to this problem even for us, much less for future patent owners.

CONCLUSION

In summary, this is a small but important piece of legislation. I think the answer to the question I posed at the start of my of my testimony—whether the benefits of the bill outweigh the benefits of the status quo—is clear. H.R. 5120 would provide palpable benefits both to innovators and to patients in a manner that is fully consistent with patent law and practice. The only harms identified—a negligible effect on certainty and the loss of an unintended, unplanned and unearned windfall for generic manufacturers—in my judgment are definitively outweighed by those benefits.

Mr. Chairman, I have been impressed by the thorough and diligent manner in which this Subcommittee has carried on its work. I hope that, with a single-minded focus on the public interest, the Subcommittee will see fit to move the bill forward toward ultimate enactment.

Thank you very much and I look forward to your questions.

Mr. SMITH. Thank you, Dr. Meanwell.

Ms. Jaeger.

TESTIMONY OF KATHLEEN JAEGER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENERIC PHARMACEUTICAL ASSOCIATION

Ms. JAEGER. Chairman Smith, Ranking Member Berman and Members of this Committee, my name is Kathleen Jaeger, and I am the president and CEO of the Generic Pharmaceutical Association. On behalf of GPhA and our 130 members, I want to thank you for convening this hearing and allowing GPhA to express its views on H.R. 5120.

Mr. Chairman and Members of this Committee, what we are essentially discussing here this morning is playing by the rules and whether Congress is willing to turn its back on the rules because one company decided it just didn't want to play by those rules.

The fact is that Congress established specific criteria in both title 1 and title 2 of the Hatch-Waxman amendments on how brand and generic pharmaceutical companies should operate when in the Hatch-Waxman system, including how and when a brand company could apply for a patent term extension, or a PTE.

Congress worked hard to ensure that they established a system that addressed two competing yet equally important goals: encouraging innovation and expediting the public's access to more affordable generic medicine. The system was designed to foster both goals, and a process was put in place that hundreds of companies have been following since 1984.

As with any system, the Hatch-Waxman system is replete with rules and deadlines. And they need to be followed to achieve these important public health goals. In the case of The Medicines Company, it simply chose not to follow the rules that says there is a deadline for submitting the PTE application. And now it is asking for a change of the rules because it didn't follow them.

Mr. Chairman, that is simply not the way the system works. We all know the rules, and we all know that if we don't play by them we could be benched, we could be penalized or lose an extraordinary opportunity.

Congress cannot create a system where if a company misses a deadline it can come running to Congress to fix it. If that was the case, I daresay this Committee would have an even busier hearing calendar than it does now.

For example, several brand companies have lost the opportunity to secure a 30-month automatic stay under title 1 of Hatch-Waxman because the brand companies failed to file a lawsuit against a generic patent challenger within the statutory mandated 45-day deadline.

Likewise on our side of the industry, a generic company is eligible for 180 days of generic exclusivity provided that among other things, the company is the first to file a generic application with FDA that contains a paragraph four patent challenge. If another company files 1 day after the first generic company filed its application, that subsequent firm gets nothing because those are the rules.

If Congress approves this legislation, rules go out the window. You would basically be saying that the deadlines don't mean anything. Under this legislation, the PTO would be given a discretion to accept a P.T. application filed up to 5 days after expiration of

statutory deadline. And by its terms, this bill would have the practical effect of automatically extending a deadline to 65 days.

This extension not only undermines the intent of Congress, it ultimately delays the ability of more affordable generic drugs to be brought to consumers. And this Committee needs to ask itself what happens when some other company misses the new deadline and files on day 66. Do we extend the deadline again? And what are the consequences to the health care system when several of the Hatch-Waxman system deadlines get extended and the system unravels?

Now, this legislation has been labeled, "Sorry I am Late, the Dog Ate My Homework Act," by Citizens Against Government Waste. While this label is quite amusing, there is nothing funny about the consequences of this legislation. It isn't as simple as saying my dog ate my homework.

This is a major change in the law with enormous negative implications, a change that would offset the delicate balance Congress created under the Hatch-Waxman Act between the brand and generic pharmaceutical companies. That balance has stimulated pharmaceutical innovation while ensuring that consumers are able to receive safe, effective and affordable medicines in a timely manner.

In the end, statutory deadlines have meaning. They have consequences. Allowing 5 extra days to file a patent term extension application renders that deadline meaningless and treats certain patentees differently than everyone else who respects statutory deadlines. And all to the benefit of one company who by its own inactions failed to file a simple form within the statutory timeframe.

Mr. Chairman and Members of this Committee, we thank you for giving GPHA the opportunity to present our concerns about this legislation. This legislation opens a Pandora's Box that simply should not be opened because one company didn't get its paperwork done on time. Thank you.

[The prepared statement of Ms. Jaeger follows:]

PREPARED STATEMENT OF KATHLEEN JAEGER

TESTIMONY OF
KATHLEEN JAEGER

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET AND INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
U.S. HOUSE OF REPRESENTATIVES, CONGRESS OF THE UNITED STATES

INTRODUCTION

Chairman Smith, Ranking Member Berman, and members of the Committee, my name is Kathleen Jaeger and I am the President of the Generic Pharmaceutical Association ("GPhA"). I am pleased to testify today on behalf of GPhA.

On behalf of the Association and its nearly 130 members, I want to thank you for convening this hearing and allowing GPhA to express its views on H.R. 5120, a bill introduced to benefit a single brand pharmaceutical company at significant expense to all Americans, as well as the generic pharmaceutical industry. Specifically, H.R. 5120 would give the U.S. Patent & Trademark Office ("PTO") discretion to accept an application for a patent term extension ("PTE") filed up to five days *after* expiration of the statutory deadline for the submission of such applications. By its terms, the proposal would, in practice, automatically extend the 60-day filing deadline by five days. Before enacting legislation that would severely harm consumers and taxpayers, both Congress and the public should understand the genesis of H.R. 5120, a bill that the Council for Citizens Against Government Waste has appropriately labeled the "Sorry I'm Late, the Dog Ate My Homework Act."

BACKGROUND

In 1997, The Medicines Company filed a new drug application ("NDA") for Angiomax™ (bivalirudin) injection. On December 15, 2000, FDA approved that application, and The Medicines Company began marketing in January 2001. While it began marketing promptly after receiving approval, the company inexplicably waited to file its request for a PTE with the PTO. Not until February 14, 2001 did The Medicines Company finally get around to submitting an application seeking a PTE for U.S. Patent No. 5,196,404 ("the '404 patent"). Unfortunately, waiting until what it thought was the last day had significant consequences for The Medicines Company.

February 14, 2001 is 61 days from the date of NDA approval. As a result, after confirming the NDA approval date with FDA, the PTO correctly determined that the '404 patent is not eligible for a PTE under 35 U.S.C. § 156 because that statutory provision requires PTE applications to be filed within 60 days of NDA approval. *See* 35 U.S.C. § 156(d)(1).

Upon learning of the PTO's decision, The Medicines Company immediately sought to avoid the consequences of its delayed filing. Specifically, The Medicines Company attempted to convince the PTO that the application had been timely filed. The Medicines Company could not deny that FDA had, in fact, approved the NDA on December 15, 2000. Nor could The Medicines Company argue that they lacked the information necessary to submit the application on time, or that the application was too complicated to complete within 60. Instead, the company could only argue that FDA allegedly had not signed the approval letter until after the agency's normal business hours on December 15, 2000 and that, as a result, the approval date should be considered December 18, 2000, the next business day. Changing the approval date in this way would have made The Medicines Company's application timely. Nearly four years

later, The Medicines Company's October 2002 request for reconsideration apparently remains pending before the PTO.

In the years since its untimely PTE filing, The Medicines Company has acknowledged that, despite having 60 days to complete this simple application, its representatives failed to get the application in on time. As GPhA understands it, The Medicines Company's representative assumed that the company had two months to file the PTE application. But as the statute says on its face, such applications must be filed within *60 days* of NDA approval. Two months and 60 days are not the same thing and, in this case, The Medicines Company's decision to wait until the very last minute and to rely on an assumption, rather than consult the statute itself, caused the company to miss the filing deadline by a day. While a mistake and, perhaps, even an understandable mistake, mistakes have consequences.

With hundreds of millions of dollars in sales at stake, and a dubious request for reconsideration pending, The Medicines Company embarked on a more ambiguous plan to secure a PTE – lobbying heavily for new federal legislation to fix the company's mistake. While The Medicines Company undoubtedly has made other efforts, GPhA knows that the company attempted to have language included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"). Those efforts failed, however, when various members of Congress refused to support such a proposal.

Apparently, The Medicines Company decided not to give up its legislative efforts. Now, some three years later, Congress is again entertaining legislative language that would allow The Medicines Company to avoid the consequences of its admitted failure to comply with the plain language of § 156 to the detriment of consumers and taxpayers. This time, unfortunately, the harm to the public would be astronomically higher. The 2003 proposal that Congress rejected only would have applied to The Medicines Company's PTE on the '404 patent. In stark contrast, H.R. 5120 would apply to any late-filed PTE application, in essence extending the statutory deadline from 60 days to 65 days. Such a statutory change would have serious anti-consumer consequences when the American public can least afford it. GPhA strongly urges Congress not to enact H.R. 5120, or any similar legislation.

DISCUSSION

Congress should not enact H.R. 5120. First, the legislation would disrupt the balance created with the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act in a way that harms consumers and the generic drug companies. Second, the legislation is unnecessary. As discussed above, it came about solely because one brand company failed to meet a clear-cut filing deadline established by statute back in 1984. Third, the legislation would put more pressure on the generic pharmaceutical industry – an industry already under attack by such brand company tactics as "authorized generics" and abuse of the FDA's citizen petition process. Fourth, amending the PTE provisions in the way The Medicines Company seeks runs contrary Congress' historical treatment of statutory deadlines for the expansion or extension of

patent rights. Indeed, by setting a firm deadline (one that the PTO cannot extend), the PTE filing deadline of § 156 is consistent with other statutory provisions that establish deadlines for patentees seeking to expand the scope or lengthen the terms of their patents.

I. Congress Must Preserve The Balance Created By The Hatch-Waxman Amendments.

H.R. 5120 would disturb the delicate balance that Congress struck between generic and brand pharmaceutical companies in the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Amendments or Hatch-Waxman.

Hatch-Waxman represents a carefully-crafted balance between two competing, yet equally important goals - encouraging innovation and expediting the public's access to more-affordable generic drug products. Congress enacted Hatch-Waxman as "the best possible compromise between [these] two competing economic interests." (H.R. Rep. No. 98-857, pt. II at 7 (1984)). To expedite generic market entry, Congress created a statutory scheme whereby generic companies could file Abbreviated New Drug Applications ("ANDAs") and litigate patent infringement during FDA review. Congress also enacted a 180-day generic exclusivity period as the incentive needed to get generic companies to challenge drug patents. To encourage innovation, Congress enacted many benefits for brand companies, including a wide variety of regulatory exclusivity periods and the opportunity to extend the terms of certain patents. Disturbing these provisions threatens the balance that Congress created and, in the process, threatens to harm a public that desperately needs increased and expedited access to lower-priced generic drug products.

A. H.R. 5120 Would Upset Hatch-Waxman's Balance At A Time When Consumers And Taxpayers Need Increased Access To Affordable Generic Medicines.

GPhA fully supports both of the intended purposes of Hatch-Waxman. The public needs both innovative new medicines and increased access to affordable generic drug products. This precisely is why Congress should reject H.R. 5120.

The PTE application deadlines of 35 U.S.C. § 156 are part of the "encouraging innovation" portion of the Hatch-Waxman Amendments. H.R. 5120 would enlarge the benefits found in that provision by allowing more brand companies to obtain PTEs. Allowing brand companies greater opportunities to obtain PTEs necessarily threatens the public's access to lower-priced generic alternatives because more patents – patents that block generic competition – will be entitled to extensions. H.R. 5120 also unbalances Hatch-Waxman in that it changes just one of many deadlines found in those amendments. Before enacting such legislation, Congress must ask at least two questions: first, whether such legislation truly is necessary and, second, whether this is the best course of action now, at a time when the need for affordable health care and prescription medication is so great.

First, the legislation most assuredly is not necessary. As discussed above, H.R. 5120 came about because a single brand company failed to meet the 60-day PTE filing deadline after (1) waiting until the last minute to file a simple, 7-page application; and (2) making an incorrect assumption about the law, rather than consulting the statutory language which has remained the same since September 1984.[1] An attorney myself, I personally am sympathetic to The Medicines Company's plight. Indeed, every practicing attorney can understand how The Medicines Company and its representatives feel, as we all fear of making the same type of mistake made here. But deadlines are a key part of the balanced statutory scheme that Congress created with Hatch-Waxman. Sympathy and understanding simply are not sufficient reasons to pass a law that would have such enormous, negative consequences for consumers and taxpayers for the sole purpose of rectifying a mistake that never should have happened.

Further, any sympathy felt for The Medicines Company should be tempered by the knowledge that company has legal recourse to obtain compensation for any damage that it believes that it has suffered. According to the company's public SEC filings, The Medicines Company has "entered into agreements with the counsel involved in the filing that suspend the statute of limitations on our claims against them for failing to make a timely filing."[2] And, of course, The Medicines Company's Angiomax™ already has generated sales exceeding over half a billion dollars since launch, according to IMS Health data, and the '404 patent does not expire until March 2010, even without the extension that the company seeks.[3]

Second, now is not the time for such blatant special interest legislation. Everyone recognizes that America today faces a healthcare crisis, with the skyrocketing cost of prescription drugs eating up an ever-increasing part of the available funds. For example, in one recent survey, 26% of senior citizens surveyed stated that that they did not fill a prescription, skipped doses, or took smaller doses of medications due to the high cost of drugs.[4] Generic pharmaceuticals, which provide the same medicines and the same results, are critical to helping contain healthcare costs. Specifically, while generic drugs provide the same results, they do so at prices ranging from 30 to 80 percent *less* than their brand counterparts.[5] Thus, "[w]hile generics accounted for 56 percent of prescriptions dispensed, Americans spent $22.3 billion on them last year, compared with $229.5 billion for branded drugs . . . ."[6] Such savings add up to billions and billions of dollars each year.[7] As a result, the availability of generic pharmaceuticals is of the

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[1] The Medicines Company would benefit from H.R. 5120 because the PTO apparently has not ruled upon the company's 2002 request for reconsideration. GPhA finds it unusual that the PTO has not acted on this request at some point over the last four years. If the PTO has not, in fact, ruled on the reconsideration request. GPhA encourages the Committee to look into why the PTO apparently is assisting The Medicines Company in its effort to obtain a PTE for the '404 patent.

[2] The Medicines Company 12/31/05 10-K at 33.

[3] The Medicines Company seeks to extend the '404 patent's term by 1,773 days, until January 29, 2015.

[4] *See* National Survey of Seniors and Prescription Drugs, April 19, 2005, The Kaiser Family Foundation.

[5] *See* GPhA Press Release, 8/16/05.

[6] "Dose of Relief: Are Generic Drugs Just What the Cost-cutters Ordered? As Healthcare Prices Spiral Upward, Some Are Encouraged by an Emerging Trend: Key Drugs Are Losing Patent Protection. Now They Look to the FDA to Unclog the Approval Pipeline for Generics," *The Boston Globe*, April 30, 2006).

[7] *See, e.g.*, Express Scripts Research Study Findings, 2005 Generic Drug Usage Report, available at www.express-scripts.com (finding that consumers had the potential to save $21.7 billion in 2005, and an estimated $24.7 billion in 2006, through the use of generic drugs).

utmost importance to consumers, taxpayers, and federal and state governments.[8] Indeed, as one member of Congress recently explained: "***It is now more important than ever that we speed less expensive generic drugs to market.***"[9]

As of January 2006, the MMA's prescription drug benefit was estimated to account for roughly 4 out of every 10 prescriptions dispensed in the United States.[10] The Congressional Budget Office has estimated the plan will cost $850 billion over its 10-year life span, although some lawmakers have predicted the costs will top $1 trillion.[11] Because generic drugs are critical both to consumers and taxpayers, Congress must carefully consider any legislation that would make it harder for affordable medicines to reach the market. This is especially true for special interest legislation like H.R. 5120.

In the end, statutory deadlines have meaning. They must be followed and failing to do so has consequences. Here, rather than face the consequences of its mistakes, The Medicines Company has spent considerable time and money lobbying for federal legislation that would harm consumers and taxpayers. Because the legislation reaches all PTE applications, the negative consequences for the public would, of course, extend far beyond just this one patent and this one drug.

B. H.R. 5120 Would Add To The Growing Number Of Forces Currently Working Against Hatch-Waxman's Goal Of Providing Timely Consumer Access To Generic Pharmaceuticals.

Generic pharmaceutical companies' ability to provide consumers with access to affordable generic drugs increasingly has come under attack. This special interest legislation is just another tool that would delay generic pharmaceuticals from timely entering the market.

In recent years, brand companies have employed various tactics to undermine the purpose of Hatch-Waxman. Such tactics include the marketing of authorized generics, the filing of frivolous citizen petitions with FDA, and failure to bring suit on listed patents during FDA's review of the ANDA. Moreover, other forces impede consumer access to lower priced generic drugs. For example, currently, the United States Trade Representative ("USTR") is including provisions in Free Trade Agreements ("FTAs") that fail to promote access to lower-priced generics. Congress should not add to the impediments to the introduction of affordable generic medicines by enacting H.R. 5120.

In recent years, the brands embarked on a widespread practice of launching "authorized generics" during the 180-day generic exclusivity period that Congress created as a

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[8] *See* Congressional Budget Office report, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998), available at www.cbo.gov.

[9] "Sen. Kohl Pushes HHS Secretary Leavitt to Accelerate Generic Drug Approvals," *US Fed News* (May 3, 2006) (emphasis added).

[10] *See* "Medicare Rx Formularies Likely to Satisfy Drugmakers," *FDANews Drug Daily Bulletin*, 6/23/05, Vol. 2, No. 123; "Lawmakers Push Bush to Repeal Medicare Part D," *FDANews Drug Daily Bulletin*, 10/10/05, Vol. 2, No. 199.

[11] *See* "Lawmakers Push Bush to Repeal Medicare Part D," *FDANews Drug Daily Bulletin*, 10/10/05, Vol. 2, No. 199.

reward for the first company to challenge the patents blocking the entry of generic drugs. *See* 21 U.S.C. § 355(j)(5)(B)(iv). An authorized generic merely is the brand's own product repackaged and sold through traditional generic drug distribution channels. By diminishing Hatch-Waxman's incentive for generic drug companies to develop generic drugs and to challenge suspect brand patents, authorized generics have a chilling effect on the patent challenges that must happen for generics to enter the market prior to patent expiration. More specifically, when brands sell authorized generics during the 180-day exclusivity period, they compete with the true ANDA generic and siphon off funds and other market advantages that Congress intended the true generic to receive. In this way, authorized generics create a disincentive for generics to challenge patents and get their products on the market sooner. In the long run, this tactic slows competition, to the disadvantage of the public.

Unfortunately, as AARP recently has explained, the "practice of authorized generics is just one growing trend in the industry's arsenal of anticompetitive practices."[12] Another anti-competitive tactic that has re-emerged in recent years is rampant brand company abuse of FDA's citizen petition. These generic blocking petitions ask FDA to withhold ANDA approval unless applicants carry out time-consuming and scientifically unnecessary tests and studies. Because FDA virtually always delays ANDA approval until it deals with even the most frivolous petitions, ANDA approvals are significantly delayed, as it takes the Agency months and even years to complete its evaluation. In the meantime, the public is forced to pay millions of dollars for brand name products because FDA has not approved a generic alternative. While the brand petitions are without merit, the delay they cause is very real. For example, of the 35 or so generic blocking petitions that brand representatives filed in 2004 and 2005, FDA had only ruled on about half as of the end of July 2006. Yet, because no one has held brand companies accountable for this anti-competitive behavior, they have everything to gain and nothing to lose by continuing to file these blocking petitions. Indeed, as one GPhA member aptly explained in recent Congressional testimony, "[f]rivolous citizen petitions given brand companies an undeserved patent extension, at no cost and with no consequences" to the brand.

Yet another delay tactic involves brand companies obtaining and listing patents with FDA, but refusing to bring suit when confronted with a generic applicant seeking immediate ANDA approval. Brand companies have found that delaying suit can delay generic market entry because few generic companies will launch product before patent issues have been fully resolved. The reason a generic would delay launch is a matter of simple economics – infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs would ruin most generic companies. As a result, few generic companies can risk going to market before a final judicial resolution of its patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows them to continue selling drugs at monopoly prices.

As this Committee is aware, Congress recognized this problem and sought to prevent such a scenario by specifically providing generic applicants with the right to bring declaratory judgment actions if they are not sued by the patentee or NDA-holder within 45 days of receiving the generic applicant's notice that the Orange Book listed patent is invalid and/or

[12] AARP's 6/5/06 Comments to FTC's Authorized Generic Study at 2; *see also* Prescription Access Litigation Project's 6/5/06 Comments to FTC Study at 4.

not infringed. *See* Medicare Act § 1101(a)(2)(C) (codified at 21 U.S.C. § 355(j)(5)(C)). In doing so, Congress directed the courts to exercise jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution." *Id.* § 1101(d) (codified at 35 U.S.C. § 271(e)(5)). The Federal Circuit, however, issued a decision in 2005 that effectively guts these important declaratory judgment provision. Thus, despite Congress' attempt to provide the generic industry with a mechanism for obtaining patent certainty and avoiding delays in marketing, generic companies nevertheless have been unable to take advantage of these provisions.

Finally, other forces are working against generic drug companies and, in turn, against the introduction of affordable medicines. For instance, the USTR is including provisions in FTAs that fail to promote access to lower-priced generics. Moreover, these provisions often are inconsistent with U.S. law. Such provisions serve to: (1) block generic drug exports in foreign territories; (2) significantly delay the availability of affordable drugs in those territories; and (3) create an avenue to delay domestic generic competition. Many FTAs, for example, have provisions that require patent "linkage" provisions. In other words, these provisions mandate that the United States' trading partner establish a generic approval system that is identical to the one in the United States. But these same provisions do not provide a means for generic companies to challenge drug patents and, as a result, block generic competition. Thus, there is no incentive for the early resolution of patent disputes, nor is there a limit on the types of drug patents that can be listed for a drug product. Such measures grant brand companies *de facto* patent extensions, encourage lower quality patents, and unnecessarily delay the availability of affordable generic drugs. They not only are inconsistent with U.S. law, but they also thwart generic competition both domestically and abroad. The USTR should be required to modify provisions in current and future FTAs so that they are consistent with U.S. law and ensure that foreign and domestic consumers have timely access to affordable drugs.

As this discussion amply demonstrates, generic companies currently face significant obstacles. H.R. 5120 only would serve as yet another barrier to generic market entry – a barrier created because one brand company failed to comply with a statutory deadline in existence since 1984. Neither the public nor the generic drug industry upon which the public relies so heavily deserve better.

II. The Current Statutory Deadline Is Consistent With Other Statutory Provisions Setting Deadlines For Patentees.

As GPhA understands it, proponents of H.R. 5120 have argued that "the hard and fast 60-day deadline for filing Hatch-Waxman applications for patent term restoration runs counter to" the PTO's "general philosophy" of giving extensions to patent applicants. Not so. As an initial matter, if the PTO has a "general philosophy" of granting extensions to patent applicants, that philosophy is limited to deadlines in PTO rules, and *not* to the deadlines found in statutory enactments of Congress. The PTO created its rules and the deadlines contained therein. Should it wish to give extensions, the PTO can do so. The PTO cannot, however, extend statutory deadlines set by Congress. Indeed, the rule which allows the PTO to extend deadlines states that "in no situation may an applicant reply later than the maximum period set by statute"

and must reply at "the earlier of any maximum period set by statute or five months after the time period set for reply." 37 U.S.C. § 1.136.

More importantly, Congress historically has set firm statutory deadlines by which a patentee must act in order to expand or extend patent rights. The patent term extension statute of 35 U.S.C. § 156 is no exception. That statute mandates that a party seeking to extend the term of its patent must submit an application for extension "within the sixty day period" proscribed. 35 U.S.C. § 156(d)(1). In this material respect, PTE filing deadline is entirely consistent with other substantive, statutory provisions that establish deadlines for patentees seeking to *expand the scope or lengthen the terms* of their patents. For example, a patentee seeking to enlarge the scope of the claims of its original patent by invoking the PTO's reissue procedure must apply within two years from the grant of the original patent. *See* 35 U.S.C. § 251. Similarly, a patentee seeking to claim priority to the date of an earlier-filed foreign patent must file its patent application in the U.S. within twelve months from the earliest date on which such foreign application was filed. *See* 35 U.S.C. § 119(a). The governing statutes do not allow the PTO to extend these deadlines. Thus, while Congress has seen fit to provide the PTO with discretion as to the purely ministerial act of paying a patent maintenance fee (35 U.S.C. § 41), such leniency is in stark contrast to the statutes which set deadlines for patentees to act to substantively expand or extend their patent rights. Congress should give careful consideration to changing this precedent in the manner found in H.R. 5120.

In the end, statutory deadlines have meaning. They have consequences. Either they are followed or penalties ensue. Citizens, for example, must file their tax returns or ask for an extension by April 15. Here, allowing five extra days to file an application makes the deadline essentially meaningless, and treats patentees differently than anyone else to whom statutory deadlines apply. And all to benefit one company that, by choice, waited until the last minute to file a simple form that hundreds and hundreds of other companies have timely filed since 1984.

CONCLUSION

Thank you, Mr. Chairman, Ranking Member Berman, and Members of the Committee, for giving GPhA the opportunity to explain its views and concerns about this important issue. The Association again urges Congress to refuse to enact this special interest legislation that does nothing but help one company to the detriment of all consumers and taxpayers.

Mr. SMITH. Thank you, Ms. Jaeger.
Professor Thomas.

TESTIMONY OF JOHN THOMAS, PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER

Mr. THOMAS. Thank you, Mr. Chairman and other distinguished Members of the Subcommittee. I am pleased to testify today on my personal behalf. My views are my own rather than those of Georgetown University or other institutions with which I am affiliated.

The Hatch-Waxman Act represents an effort to refine within the pharmaceutical industry the central problem of any intellectual property regime: encouraging the labors that lead to innovation on one hand and disseminating the fruits of those labors on the other. Thus the Hatch-Waxman Act created an expedited generic marketing approval protocol, but also called for term extensions for patents on approved drugs.

Patent term extension is unquestionably a fundamental part of the Hatch-Waxman Act, a statute that for all its perceived flaws has been highly successful in both encouraging the generic drug industry and promoting the discovery and development of new drugs by brand name firms.

As the Committee considers modifications to the 60-day period provided by section 156, the term extension statute, a few basic subjects and points may be worthy of review.

First, the Federal circuit has long interpreted the 60-day deadline strictly. Its 1989 decision in *Unimed v. Quigg* held that an NDA holder was not entitled to patent term extension even though it filed promptly after having the drug cleared by the Drug Enforcement Administration.

It held that, in fact, the date for term extension calculation was the FDA approval date, which had occurred more than a year before. It is a 17-year-old case, and I simply know of no other circumstance during that period in which anyone has come to Congress requesting a term extension.

Second, U.S. PTO regulations already provide some flexibility in meeting the deadline standards. And so, there is already some ability for NDA holders to follow an expedited application that can then be filled out.

Third, term extension determinations do not entail merely a ministerial calculation. The filing of an application for term extension potentially triggers a fairly elaborate proceeding potentially involving the USPTO, Secretary of Health and Human Services, Secretary of Agriculture, the patent proprietor and third hearings—third parties. There may even be an informal hearing to discuss qualifications for the term extension.

And that somewhat distinguishes this case from other sorts of deadlines that the USPTO deals with, for example, responding to an office action. So ensuring that these deadlines are met promptly would arguably serve important administrative goals.

Finally, it is true that some deadlines of the USPTO can be waived or extended. Though, of course, many of those extensions entail third party rights, for example, user rights in favor of those who may have a reliance interest on the expiration of diminution of patent rights.

As you know, the Patent Reform Act of 2005 retains the 1-year deadline. Anyone who discloses an invention more than a year before filing forfeits their patent rights. And that is a provision that can work very hard against independent inventors and small firms.

The Hatch-Waxman Act is replete with deadlines that impose even tighter timeframes. A brand name firm has to file a patent infringement suit within 45 days of receipt of notice of a paragraph four ANDA, otherwise it loses its entitlement to a 3-month stay by the FDA.

On the generic side, a paragraph four ANDA applicant who files 1 day after another such applicant potentially loses its entitlement to a 180-day period of generic exclusivity. So there already are a lot of tight deadlines and even shorter deadlines in the Hatch-Waxman Act.

Now, in view of those principles, allow me to offer a few observations.

First, one question is the extent of the problem. How many times has this occurred? Is this a recurring issue or one that we think might change?

Second, what is the standard for the USPTO to resolve whether there ought to be an extension or not? The statute right now says the delay in—or the bill says that whether the delay in filing the application is unintentional.

I am sort of reminded of Aristotle and the Nicomedian ethics. No one can suffer injustice voluntarily because no one can wish to be harmed, Aristotle says. Well, if that is so, what does this mean? Is this an automatic 5-day deadline for everyone? If that is so, better just to change the period to 61 days, 65 days or something else.

If, in fact, the USPTO is supposed to do a malpractice style inquiry, I would suggest this is not a situation where the USPTO is well suited. And it ought to retain its core responsibilities.

There are a lot of other section 156 issues that seem to me to be more compelling. For example, the applicability of patent term extension to combination therapies. And the Committee may wish to consider that.

Thank you again for the opportunity to submit this testimony. I would be delighted to answer any questions.

[The prepared statement of Mr. Thomas follows:]

PREPARED STATEMENT OF JOHN R. THOMAS

United States House of Representatives
Committee on the Judiciary
Subcommittee on Courts, the Internet, and Intellectual Property

Legislative Hearing on H.R. 5120, "To amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office."
September 14, 2006

Statement of John R. Thomas
Professor of Law
Georgetown University

Thank you for the opportunity to submit this statement before the subcommittee today. These comments reflect my personal views, rather than those of Georgetown University or other institutions with which I am affiliated.

Patent Term Extension Within the Hatch-Waxman Act

The Hatch-Waxman Act represents an effort to refine, within the pharmaceutical industry, the central problem of any intellectual property regime: Encouraging the labors that lead to innovation, on one hand, and disseminating the fruits of those labors, on the other. Thus, the Hatch-Waxman Act codified an expedited generic marketing approval protocol, but also provided for term extension for patents on approved drugs.[1] Patent term extension is unquestionably a fundamental part of a statute that, for all of its perceived flaws, has been highly successful in both encouraging the generic drug industry and promoting the discovery and development of new drugs by brand-name firms.

Codified at 35 U.S.C. § 156, the patent term extension provision of the Hatch-Waxman Act stands among the most unwieldy statutes in the federal code. One portion of that statute is relatively clear, however. An application for term extension "may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use."[2]

As this Committee considers modifications to this period, a few basic substantive points may be worthy of review. First, the Federal Circuit has interpreted the 60-day deadline strictly. Second, provided that an application is filed within the statutory period, existing USPTO rules already accord

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[1] I use the phrase "patent term extension" loosely. The Hatch-Waxman Act does not go so far as to provide a patent term extension in the usual sense–that is to say, a temporal extension of the original right to exclude others from practicing the patented invention. During the period of term extension, the rights provided by the patent are instead limited, generally speaking, to the specific use that the FDA has approved. *See* 35 U.S.C. § 156(b)(1) (2006). *See* John R. Thomas, PHARMACEUTICAL PATENT LAW 299-300 (Bureau of National Affairs 2005).

[2] 35 U.S.C. § 156(d)(1) (2006).

applicants for term extension some relief in complying with regulatory requirements. Third, term extension determinations do not entail merely a ministerial calculation. The filing of an application for patent term extension potentially triggers a fairly elaborate proceeding involving the USPTO, FDA, and patent proprietor and possibly third parties as well. Fourth, generic firms reach decisions about pursuing their own applications, along with patent challenges, in a relatively tight time frame that is governed by FDA-administered marketing exclusivities. Because the duration of proprietary rights is obviously significant concern for these stakeholders, determining entitlement to patent term extension in a seasonable manner serves important regulatory goals. Finally, both the Patent Act in general, and the Hatch-Waxman Act in particular, provide that failure to meet certain deadlines is irremediable. These comments discuss each of these points in further detail below.

Judicial Precedent. Longstanding judicial precedent has interpreted the 60-day statutory time period strictly. Notably, in its 1989 decision in *Unimed, Inc. v. Quigg*,[3] the Court of Appeals for the Federal Circuit considered an application for term extension of U.S. Patent No. 3,668,224. The '224 patent described and claimed a process for making dibenzo-pyran. That compound, known under the trademark MARINOL®, is the synthetic equivalent of an isomer of delta-9-tetrahydrocannabinol (THC), the principal psychoactive substance in *Cannabis sativa L.* marijuana.

The exclusive licensee of the '224 patent, Unimed, submitted an NDA to the FDA on June 24, 1981, pursuant to the Federal Food, Drug, and Cosmetic Act.[4] The FDA approved the NDA on May 31, 1985, but reminded Unimed that "MARINOL may not be legally marketed until the Drug Enforcement Administration has completed rescheduling activities as required by the Controlled Substances Act."[5] This latter step took place on May 13, 1986, when the Drug Enforcement Administration ("DEA") finalized the removal of MARINOL® from Schedule I to Schedule II of the Controlled Substances Act.[6] Unimed filed its application for extension of the '224 patent term under 35 U.S.C. § 156 at the USPTO 14 days later. By that point, more than one year had elapsed since the FDA had issued marketing approval for MARINOL®.[7]

The USPTO denied Unimed's application, concluding that it had not been filed within sixty days of receipt of FDA marketing approval. Although the District Court for the District of Columbia reversed the USPTO's decision,[8] on appeal the Federal Circuit again reversed. Judge Mayer stated

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[3] 888 F.2d 826 (Fed. Cir. 1999).

[4] *See* 21 U.S.C. § 355 (2006).

[5] 888 F.2d at 827.

[6] 21 U.S.C. § 812 (2006).

[7] 888 F.2d at 827.

[8] 707 F. Supp. 17 (D.D.C. 1989).

the issue crisply: "The timeliness issue boils down to whether the 60-day period specified in section 156(d)(1) began, as the [USPTO] Commissioner argues, when the FDA sent its approval letter, on May 31, 1985, or, as Unimed argues, when the DEA rescheduled Marinol nearly a year later."[9] Siding with the USPTO, the Court of Appeals reasoned that the sixty-day period identified in 35 U.S.C. § 156(d)(1) commenced "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." 35 U.S.C. § 156(g)(1)(B) in turn defined the "applicable regulatory review period" as section 505 of the Federal Food, Drug, and Cosmetic Act, which governs the approval of new drugs by the FDA, and nowhere mentioned the role of the DEA. The Federal Circuit therefore agreed with the USPTO that the 60-day period began upon the FDA approval date. As a result, the '224 patent term extension application was considered to have been untimely filed and was therefore rejected.[10]

It should be appreciated that both the patent laws and food and drug laws have been amended numerous times during the 17-year period since the Federal Circuit decided *Unimed v. Quigg*. Further, this subcommittee has spent significant time in recent years contemplated further reforms to the patent laws. To my knowledge, this is the first occasion where the Congress has considered altering 35 U.S.C. § 156.

USPTO Regulations. Agency regulations allow New Drug Application (NDA) holders to assemble somewhat truncated applications for term extension, with the remainder of the material to follow. Rulemaking therefore already affords brand-name drug companies the ability to submit a somewhat condensed application that is more readily prepared during the 60-day statutory period.

In particular, the USPTO has employed its rule-making authority[11] to provide that each application for term extension under 35 U.S.C. § 156 include some fifteen elements.[12] The USPTO will assign a filing date to an application for term extension that falls somewhat short of its regulatory standards, however. If the application (1) identifies the approved product; (2) identifies each federal statute under which regulatory review occurred; (3) identifies the patent for which an extension is being sought; (4) identifies each claim of the patent which claims the approved product or a method of using or manufacturing the approved product; (5) provides sufficient information to enable the USPTO to determine whether the patent is eligible for extension, and the rights that will be derived from the extension, and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and (6) includes a brief description of the activities undertaken by the marketing applicant

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[9] 888 F.2d at 828.

[10] *Id.* at 828-29.

[11] 35 U.S.C. § 156(d)(1)(E) (2006).

[12] 37 C.F.R. § 1.740(a) (2006).

during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities, then the USPTO will accord the application a filing date.[13] This USPTO policy is based on the obligatory nature of these six elements in a term extension application under 35 U.S.C. § 156(d)(1)(A)-(D), while the remainder of the USPTO requirements were established via regulation.

If the USPTO determines that the term extension application should be accorded a filing date, but that it does not fully comply with its regulations, the applicant ordinarily has two months to complete the application.[14] The applicant may extend this period through the payment of additional surcharges in accordance with usual USPTO practice.

The USPTO therefore already provides NDA holders with some flexibility in assembling their term extension applications, provided of course that the 60-day deadline is met.

Subsequent Proceedings. The submission of a complete application for term extension under 35 U.S.C. § 156 commences a fairly elaborate proceeding involving the USPTO, FDA, and patent proprietor and possibly third parties as well. In short, within 60 days of receiving the application, the USPTO will request either the Secretary of Agriculture (if the product is subject to the Virus-Serum-Toxin Act) or the Secretary of Health and Human Services (in all other cases) to calculate the applicable "regulatory review period," which is then published in the *Federal Register*.[15]

The date of publication is followed by a 180-day period during which any interested party may file a petition contending that the applicant has not acted with due diligence.[16] The appropriate secretary must determine within 90 days of filing whether the applicant has acted with due diligence or not, and then publish this determination in the *Federal Register*.[17] An interested person may then request an informal hearing on this determination within 60 days of publication, which is held within 60 days of the request.[18] Following the hearing, the appropriate Secretary is allotted 30 days to

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[13] 37 C.F.R. § 1.741 (2006).

[14] 37 C.F.R. § 1.741(b) (2006)

[15] 35 U.S.C. § 156(d)(2)(A) (2006). *See* Aktiebolaget Astra v. Lehman, 71 F.3d 1578, 1580-81 (Fed. Cir. 1995).

[16] 35 U.S.C. § 156(d)(2)(B)(i) (2006).

[17] *Id.*

[18] 35 U.S.C. § 156(d)(2)(B)(ii) (2006).

affirm or modify its original decision and then notify the USPTO Director.[19]

The USPTO then forwards a Notice of Final Determination to the applicant. The applicant may make a single request for reconsideration of the determination within one month, or such other time period set forth in the determination.[20] If no such request for reconsideration is filed, or upon the completion of its review of such a request, the USPTO will then issue a Certificate of Extension of Patent Term to the applicant.[21]

In view of these statutory procedures, it should be appreciated that the filing of an application under 35 U.S.C. § 156 does not merely trigger the ministerial calculation of a particular number of days. Rather, such a filing potentially commences an elaborate multi-party proceeding. Ensuring that the triggering event for this procedure commences in a seasonable manner would appear to be an important administrative aspiration.

Generic Responses. FDA approval of an NDA in many cases triggers a response by generic firms that might be interested in entering that market. Although the Hatch-Waxman Act includes provisions that create marketing exclusivity for certain FDA-approved drugs,[22] these periods are relatively short in view of the time required for preparation and regulatory review of an ANDA or § 505(b)(2) application. As a result, generic firms reach decisions about pursuing their own applications, along with patent challenges, within a relatively tight time frame. Between the duration of proprietary rights is obviously significant concern for these stakeholders, determining entitlement to patent term extension in a prompt manner serves important regulatory goals.

Timeliness Within the Patent Law. Given its focus upon novelty, and its requirement of government intervention to secure rights, the patent law is a temporally focused discipline. The Patent Act includes numerous deadlines that, if not followed, lead to the irrevocable forfeiture of

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[19] *Id.*

[20] USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 2755 (May 2004).

[21] 37 C.F.R. § 1.780 (2006).

[22] In brief, the length of marketing exclusivity is contingent on whether or not the drug is considered a "new chemical entity" (NCE). The Hatch-Waxman Act defines an NCE drug as an approved drug that consists of active ingredients, including the ester or salt of an active ingredient, none of which has been approved in any other full NDA. 21 U.S.C. § 355(j)(4)(D)(i), (ii) (2006). If the approved drug is not an NCE, then the FDA may not approve an ANDA for a generic version of the approved drug until three years after the approval date of the pioneer NDA. 21 U.S.C. § 355(j)(4)(D)(iii) (2006). In contrast, if the approved drug is an NCE, then a would-be generic manufacturer cannot submit an ANDA until five years after the date of the approval of the pioneer NDA. The effect of this provision is to restrict a potential generic manufacturer from bringing a product to market for five years plus the length of the FDA review of the ANDA. 21 U.S.C. § 355(c)(3)(d)(ii) (2006).

patent rights. Most significant among these is the one-year grace period of 35 U.S.C. § 102(b). That public disclosure even one day outside that grace period voids all patent rights has a severe impact upon individuals unfamiliar with the patent system, including individuals, small firms, and academics. In contrast, applications for patent term extension are commonly filed by sophisticated enterprises that have just achieved obtained FDA marketing approval–an occasion that is often a watershed in the life of their firms.

The Hatch-Waxman Act further conditions a number of other benefits upon observance of fairly tight deadlines. For example, a brand-name firm must file a patent infringement suit against a paragraph IV ANDA or § 505(b)(2) applicant within 45 days in order to obtain the right to a 30-month stay of marketing approval.[23] A generic applicant must notify the NDA holder and patent proprietor within 20 days of filing its paragraph IV ANDA or § 505(b)(2) application; otherwise, that application will presumably be considered incomplete.[24] A paragraph IV ANDA applicant that files even one day after another may forfeit entitlement to a 180-day period of generic marketing exclusivity.[25] In the context of the Hatch-Waxman Act, the 60-day period established by 35 U.S.C. § 156 stands as just one relatively short time frame among many.

Comments on H.R. 5120

In view of this statutory, regulatory, and industrial backdrop, allow me to offer some observations on H.R. 5120.

The Extent of the Problem. Although I am unsure how many applicants the 60-day filing deadline for term extension has impacted, to the best of my knowledge this issue has not been a recurring one. I am uncertain that legislative intervention is required with respect to this issue. It should also be appreciated that the Hatch-Waxman Act stipulates numerous deadlines that impose significant obligations over even more compact time frames. The creation of an additional 5-day window for complying this deadline, as compared to many others, may strike many observers as anomalous.

The Standard for Obtaining 5-Day Period. H.R. 5120 would require the USPTO to determine whether "the delay in filing the application was unintentional." Although I have no doubt

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[23] 21 U.S.C. § 355(c)(3)(C) (2006) (with respect to § 505(b)(2) applications); 21 U.S.C. § 355(j)(5)(B)(iii) (2006) (with respect to ANDAs).

[24] 21 U.S.C. § 355(b)(3)(B)(I) (2006) (with respect to § 505(b)(2) applications); 21 U.S.C. § 355(j)(2)(B)(ii)(I) (2006) (with respect to ANDAs).

[25] 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

that the USPTO will administer any standard that Congress stipulates at a high level of professional ability, the lack of an objective basis for assessing entitlements to patent term extension strikes me as troubling. If the Congress means to say that obviously no rational actor would intentionally waive valuable periods of term extension, then I would encourage a simple extension of the deadline to 61, 65, or some other period of days that is greater than 60. Alternatively, if Congress wishes to compel a substantive inquiry into the fulfillment of professional obligations by the applicant or its counsel, I would suggest that this inquiry would undoubtedly be a thorny one. The USPTO plainly has more important tasks at hand, and should be allowed to pursue its core responsibilities without having to engage in this manner of endeavor.

The Potential Advantages of Prospective Application. I am unsure how many other stakeholders have established a reliance interest based upon the events of any one failure to comply with the statutory deadline. To the extent that legislation is considered desirable, the common mandate that the legislation applies only on a prospective basis strikes me as a superior alternative.

Other Section 156 Issues. Now that the subcommittee has extended its gaze to 35 U.S.C. § 156, it should be aware that this statute has raised other thorny issues that may be amenable to legislative reform. Following the Federal Circuit opinion in *Cardiac Pacemakers, Inc. v. St. Jude Medical*,[26] brand-name firms possess a greater ability to select individual patents for term extension with respect to medical devices than with respect to pharmaceuticals. In addition, in *Arnold Partnership v. Dudas*,[27] the Federal Circuit has interpreted the statute in such a way effectively to eliminate the possibility of patent term extension for combination therapies. Although the court of appeals read the precise language of § 156 fairly in both cases, in my opinion this reading unfairly limits the availability of term extension both for pharmaceuticals in general, and for combination therapies in particular. The subcommittee may wish to address these issues as it considers reforming the Hatch-Waxman Act's term extension provisions.

Legislative Alternatives. Finally, to the extent that H.R. 5120 is motivated by a single incident, a different legislative alternative might be more appropriate. Another option is to promote a private term extension bill in favor of the particular patent involved. Such legislation might more effectively convey to the public the motivation for the legislation and focus attention upon relevant stakeholders in this particular circumstance.

Thank you again for the opportunity to submit this statement.

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[26] 381 F.3d 1371 (Fed. Cir. 2004).

[27] 362 F.3d 1338 (Fed. Cir. 2004).

Mr. SMITH. Thank you. Thank you, Professor Thomas.

And let me say this is the first panel where every witness has kept within their 5-minute limit. So that is appreciated. It is appreciated in part because we have a Judiciary Committee bill on the House floor right now. We are actually trying to expedite this hearing.

Mr. Dudas, let me direct my first question to you. The PTO has had under consideration for 4 years now a request by The Medicines Company for reconsideration. You have also said that the statute is clear and you have your hands tied. Why is it that the PTO has not acted in 4 years on the request by The Medicines Company?

Mr. DUDAS. Thank you. We have acted within 4 years, and I will explain.

This is a rather administrative procedure back and forth between the USPTO and other agencies, the FDA and Department of Agriculture. But that question came up in my mind as well. How many of these do we have that are over 4 years old? How long does this process take?

I talked to the woman who is in charge of this process. The average time period is a little bit over 3 years. It is a series of back and forths with the FDA and the Department of Agriculture. We now have 30 cases. I have a list of them that I had compiled—30 cases where they are active over 4 years old.

The second question is, well, do we want things to be active for 4 years. We are very careful in every case measuring everything at the USPTO to make certain we protect rights.

Mr. SMITH. And you are just as careful in issuing patents as well, right?

Mr. DUDAS. Absolutely, absolutely. And so, the answer to that is basically both referred to it here. These are patent term extensions. The date that really matters is when the patent term originally expires. So you look at this case. It is the year 2010, 2015, et cetera.

Mr. SMITH. Yes, right.

Mr. DUDAS. So the back and forth—certainly, if we get close to that time period we accelerate the process.

Mr. SMITH. Okay. Thank you, Mr. Dudas.

Mr. DUDAS. Sure.

Mr. SMITH. Dr. Meanwell, this is a particularly litigious society that we have today. I am sure there are any number of plaintiff's attorneys who would be happy to file a malpractice suit, contingency fee or not, on your behalf. Why haven't you simply resorted to those means and filed a malpractice suit?

Mr. MEANWELL. Mr. Chairman, a lawsuit won't solve this problem. We will still be left with the underlying pothole in the law. I think there is a real policy problem to solve here.

Of course, I would like the money. The money would be useful to help me build my company. But it wouldn't save a single life. I don't think at this stage that a lawsuit is going to move any of us forward. Certainly, it is not going to move forward the well-being of any patient.

So for us, at this point, we would rather come here and debate the merits of fixing this hole in the law than suing our law firm.

Mr. SMITH. Okay. Thank you, Dr. Meanwell.

Ms. Jaeger, you said in your written and opening statement that severe harm would be caused to both consumers and taxpayers if this legislation were to be passed. That is in distinction to what Dr. Meanwell has said where he said that actually consumers would be benefited by having an extension to the patent.

You made that assertion. Can you support it with evidence that consumers and taxpayers would be harmed by passing this legislation?

Ms. JAEGER. Absolutely, Mr. Chairman.

There are two issues here. The first one is the broader piece on harm having to do with the statutory framework of Hatch-Waxman. As I said in my testimony, the Hatch-Waxman system is a very complex system. And it is based on an intellectual property-based generic approval system. In that system, there are numerous rules and deadlines.

We were very concerned that with respect to this particular issue we start moving deadlines, they start to be very clouded. We do not, well, actually we will not have a system. The system will totally unravel to the detriment of the generic industry and to consumers. These deadlines need to be met, and they need to be there for the administration of the orderly conduct of all parties in the system.

Mr. SMITH. Right. But wouldn't consumers be benefited by the continuing research and development of additional benefits that might accrue from this particular type of drug? And would that be halted by The Medicines Company not getting their extension or reconsideration?

Ms. JAEGER. I think the broader issue is that the rules need to be followed is more imperative to consumers. Again, we have had situations where other deadlines in the Hatch-Waxman system have been missed by brand companies even by 1 day. Yet they did not get the benefit and the opportunity of that other provision.

And again, it goes to the benefit of consumers and ensuring that everyone plays by the rules. And in this instance, what we are talking about also, getting down to more of a specific issue, is we do have a situation where the patent will expire in 2010.

Our members do a lot of research and development many years prior to bringing a generic to the marketplace. They rely on that information that has been posted. They are relying on the information that the PTE extension has been rejected. They have made business decisions on reliance on that decision.

Mr. SMITH. Okay. Thank you, Ms. Jaeger.

Professor Thomas, would you respond to two issues that I brought up so far, that being the possibility of and the advisement of filing a malpractice suit? And second of all, whether you think real harm is being done to consumers if we do not grant discretion to the patent holder.

Mr. THOMAS. Yes, sir. The malpractice suit is part of patent practice. As someone who used to spend his time prosecuting patent applications, my experience was the docketing clerk was the most important colleague I had. And he would come and tell me, "Look, you have got a deadline up here, and it is irremediable."

And so, any first-year associate at a patent law firm is advised about this in no uncertain terms. And you can read the law books.

They are full of malpractice cases where regrettably deadlines have been missed. So that has traditionally been the method of compensation for those who have missed deadlines. Alternatively, shareholder suits against company management——

Mr. SMITH. And what about harm?

Mr. THOMAS. Harm to patients?

Mr. SMITH. Harm to consumers if extension is not granted.

Mr. THOMAS. Well, we are deciding here, I guess, essentially is wealth transfer between patient populations that will pay lower prices for generic versions of drugs versus, you know, surplus that would go to the firm due to its super-competitive profits that are based on a patent. Harm to patients, it is hard to say. We have already got this medication in hand.

But the patent law is about incentives. We have got the patent in hand. The question is how The Medicines Company chooses to use its resources and whether, in fact, it is the best actor to further develop this medication.

Mr. SMITH. Okay. Thank you, Professor Thomas.

The gentleman from California, Mr. Berman, is recognized for his questions.

Mr. BERMAN. Well, thank you, Mr. Chairman. I guess I have a set of questions for Dr. Meanwell and Ms. Jaeger.

Ms. Jaeger, I thought maybe your testimony went a little far in saying that the company chose not to meet the deadline. My guess is they don't feel they chose not to meet the deadline. Somebody screwed up big time. Maybe somebody at the company screwed up by not watching who was in charge of not screwing up. And bad things happened. And this is clearly a case.

But the central public policy point from not the company's well-being or the shareholders' well-being—but, Dr. Meanwell, when you came a long time ago, I think it was, to my office, you made the point, which you have repeated here, that not having what was your settled expectation regarding the delays caused by the FDA and added on to your patent term is going to keep you from investing the funds to do the trials and the research in the trials to find where you think there are beneficial uses from this drug or some slight variation of this drug and that you believe that that is the real harm to the public in a way that you see, apart from your own interests, your company's interests, your shareholders' interests, that a new use of this drug will be precluded.

And I guess what I am asking is you originally developed Angiomax based on raising funds to do the research and trial runs for the blood thinning use that it is now used for. Why can't you do that same process for the new uses of this particular drug, even though I recognize a huge amount of revenue, if nothing changes, is going to be lost to you by not having what was your settled expectation of exclusivity?

And maybe, because my time might run out, let me just ask Ms. Jaeger very specifically. Apart from all the generalized talk, what generic drug company thought that this patent term would expire 4, 4½ years earlier than you would have normally assumed and has made an investment based on what didn't happen on the 60th day to produce an alternative that is going to end up in a lower cost drug?

I would like you to be specific about your members that you sort of generalized have made investments based on their, what you claim to be, their settled expectation of when this thing would come on the market, especially given that at least for, it seems like, years, but maybe it is only two since there has been a great deal of public discussion about this issue that would unsettle anyone's expectations about anything.

So those are my two questions.

Mr. MEANWELL. Thank you for the question. Indeed, there has been quite a lot of public disclosure about this. It is not so much the loss of money and revenue, Mr. Berman. It is the loss of time that is the critical component in research here.

By not having the extension that we had expected, I cannot launch the kind of programs that are required today to prove that this drug, to my satisfaction, to the satisfaction of the FDA, to the satisfaction of doctors and their patients, will meet the needs of patients with, for example, stroke or undergoing open heart surgery. I need several years to do that in.

It was our plan that we would follow—and this is not unusual for hospital products—the initial research program with the FDA.

Mr. BERMAN. Explain that to me.

Mr. MEANWELL. Yes, sir.

Mr. BERMAN. Why does the fact that the patent will expire in 2010 if nothing is done have anything to do with the time needed to run the clinical tests to determine if there are other uses?

Mr. MEANWELL. Because, sir, if I start the trials today—and some of them have preliminarily started—and then we held it, I would have 2, 3, 4 years to do it, 1 year to get it through the FDA and, at that point, would happily hand over those indications to my colleagues in the generic industry. I would not benefit from them at all. And I simply don't have time to get them done.

Mr. BERMAN. Don't you need a patent for new uses of——

Mr. MEANWELL. No, sir. But I need an FDA approval in order to promote those new uses, and I don't have that today. I need to work hard to get a new indication for the drug beyond its existing use. And I don't have time to do that unless the patent term is restored, which, of course, is what under Hatch-Waxman we believe we had earned in the normal way.

So our expectations were to get that. We set our programs up sequentially. We now cannot pursue that research in what looked like very promising new indications in important illnesses.

Mr. BERMAN. Thank you. I have to say, I think it is me, but I am not fully understanding why. But just to get my second question answered——

Ms. JAEGER. May I just add, Ranking Member Berman, regarding that issue, is that a number of companies, a lot of brand companies, do actually pursue their brand products to subsequent clinical trials and do get new indications of use. When they do bring those indications of use, and the Food and Drug Administration does approve those new indications of use, they will get 3 years of exclusivity under the Hatch-Waxman system.

At the same time, there are also generally speaking, on average, there are also some patents that also will be issued protecting that particular product for that new indication of use. Generally speak-

ing, there will be new I.P. protection for those new indications of use as they bring those products to the marketplace.

As to your question, I cannot sit here and tell you specifically one company, or if there are 10 companies in our industry. Unfortunately, our pipelines, our companies' pipelines, are proprietary information.

What I can tell you is what they do utilize for business decisions and that is the CEOs and their R&D teams are looking at what we call the Orange Book, which is a publication by FDA that puts forth all the products as approved by FDA, the market exclusivity that is generated that protects the brand company, the 5 years to 3 years, as well as all patents that the brand company claimed this particular—that claim to protect this particular product and that are eligible for listing in that system. We look at those patents based upon that information, we then turn around and make business decisions on what products we will start our R&D investment on.

A 2010 product is something our companies are considering and have been considering for many years. That is something they are now looking at and will bring a product through the appropriate R&D process and do the necessary application process to have something ready to go when that, when that patent expires in 2010.

Mr. BERMAN. —perhaps 10 generic drug companies are spending money on research in developing this generic product in the hope that one of those 10—each one of those 10 will be the first guy to file that thing and get the 180 days exclusivity? That seems like high-risk ventures.

Ms. JAEGER. No, there is two different issues here in Hatch-Waxman. What happens is there is a patent challenge process. And what the patent challenge process is, that Congress, in their wisdom, basically said the brand companies are to file all patents they deem that claim that particular drug product with FDA.

If there is a patent that gets filed with the Food and Drug Administration that a generic company believes is either filed wrongly, or it is frivolous, or it is questionable, meaning that they believe their product will be outside the scope of that patent, then they will file a paragraph four challenge, which means they are challenging the patent. And then we go into a very complicated Hatch-Waxman patent challenge process. However, if a generic company looks at a patent and believes it is valid, it may not challenge it.

What the companies are going to do then is under the statute file a paragraph three patent certification, which basically says to the Food and Drug Administration, we will not be seeking approval until that patent expires. But indeed, these companies are looking at the patents. They are looking at the market, and they are making determinations many years prior to the patent expiring.

As you imagine, our generic companies want to get FDA approval the day the relevant patent expires. So they are going to back in at least 2 years of FDA review of a generic application, which is 2008.

Their application has to be in by 2008. We are in 2006 now. That means a lot of R&D work has to be done now or could have been done last year as well.

So our systems are, we back in from where patent expiration and the market exclusivity periods will expire. We back in at least 2 years for FDA review of a generic application. And then we back in our R&D schedules.

Mr. SMITH. Thank you, Mr. Berman.

The gentleman from Tennessee, Mr. Jenkins, is recognized for his questions.

Mr. JENKINS. Thank you, Mr. Chairman.

Mr. Dudas, you mentioned several instances in which relief can be given for the late payment of fees, late filings or deficient filings. I have been told that there may be as many as 30 instances under our patent law in which this is the case. Is that a pretty accurate number of cases where relief can be given for late filings?

Mr. DUDAS. We have not compiled each and every one of them, but that seems very much a reasonable estimate of how many there are.

Mr. JENKINS. Now, well, let me ask Ms. Jaeger.

Ms. Jaeger, you have been in law school much more recently than I have. But my memory is—and I am sure you will correct me if I misspeak—but in England, there was a court known as the keeper of the king's conscience. What was it, exchequer came to us in our country as the chancellory system. And it was basically a system where there was no laches adequate remedy at law. And it brought with it the doctrine of—now, I am not recommending that be applied in this instance.

But I would ask you with the prospect of this particular medicine—and it has not been denied, and there is ample medical evidence that the prospects for it in the treatment of strokes and heart disease are very promising.

So I would ask you, what is wrong with 30 instances under our patent laws where relief can be given, what is wrong with us departing from the rigidity that you stick with and going to a more humane situation where we can go ahead, this company can spend those tens of millions of dollars that they spoke about and get on with the prospect of benefiting?

You know, some of us—and you may feel this way when you get older, but some of us have family backgrounds that kind of indicate that we need to be on the lookout for strokes coming on one of these days. And millions and millions of Americans would welcome any prospect to have their prospects for the future improved.

So what is wrong with us departing from rigidity? We already have flexibility in the law in, I say, at least 30 instances. So what is wrong with us departing and seizing this opportunity that we have? We seize too few in this country in advancing genuine and good. We seize many, but there are many that we miss.

What is wrong with us departing from rigidity and going to a more humane system? Would you not, would you not be an advocate of a—and perhaps we are the keeper in this instance of the king's conscience. And so, would you fault us then if we went to a more humane system?

Ms. JAEGER. To that question I have three points. And I think the first point is, it is quite important that with respect to the PTE filing deadline, it is truly consistent with other substantive statu-

tory provisions that establish deadlines for patentees seeking to expand the scope or lengthen the term of the patent.

For example, a patentee seeking to enlarge the scope of the claims in the original patent by invoking PTO's reissuance proceedings must apply within 2 years from the grant of the original patent. Likewise, a patentee seeking to claim priority to the date of an early filed foreign patent must file with the U.S. within 12 months of the earliest day on such foreign application was filed. And these governing statutes do not allow PTO to extend those deadlines much like the PTE applications.

And then, too, these statutes don't have what we call equitable tolling provisions. Now, GPHA is not supporting nor endorsing the concept of moving forward an equitable tolling statute for this particular situation. But even assuming that there was an equitable tolling statute here, this situation would not rise to that level.

Unfortunately, it is an administrative error. An administrative error would not rise to a level of inequitable conduct, in an equitable tolling statute, much like that for the Federal circuit, and there we are talking about the Federal rules of civil procedures, which state a failure to take the proper steps at the proper time not in consequence of the party's own carelessness, inattention or willful disregard of the process of the court but in consequence of some unexpected or unavoidable hindrance or accident or reliance on the care of his counsel or a promise made by an adverse party. In that situation, we apply just a general equitable tolling statute or this particular civil rule of procedure.

Under either scenario, this situation doesn't rise to that level. And therefore, redress was not appropriate. We do believe—my third point is that redress should not be found here with respect to a retroactive amendment, but that there are other recourses that the company can pursue outside this Committee.

Mr. SMITH. Thank you, Mr. Jenkins.

The gentleman from Massachusetts, Mr. Meehan?

Mr. MEEHAN. Thank you, Mr. Chairman.

And to the Ranking Member, thank you very much for putting this hearing together. I think we all can agree that somebody didn't file a form on time, whether it is incompetently or—I doubt they intentionally didn't file it. And I can only assume that whoever failed to file is somewhere in an unemployment line somewhere.

I am interested—because we all agree it wasn't filed on time. And we could go on and on about that, although I am—it is interesting how when we have a Conference Committee how we reach these magical numbers, whether it be 50 or 60 or 45. I can assure you it is usually the House wants one number, the Senate wants another, and we split the difference in the middle.

But in any event, I think it would be important, Dr. Meanwell, just for the record, that you could talk about the public health benefits of this drug and what it means for the future. Because I really haven't heard it for the record here. And if you could do that.

Mr. MEANWELL. Yes, I will do that. I would like to also add something I said to Mr. Berman, which I missed in my attempt to be brief. But let me first get to the point of the drug.

This is an intravenous blood thinner. It is a very unique, high-technology product. It is one which has proven in heart procedures

called angioplasty to be highly effective and to substantially reduce the risk of bleeding among these patients. Typically patients today are receiving a mix of powerful blood thinners in a hospital intravenously. And the big risk is bleeding. And the other big risk is having a heart attack. And then there is a minor risk, if you wish, of dying.

This drug has reduced all of those: bleeding, dying and heart attacks relative to the alternative therapy, which in this case is heparin, which is a 60-year-old product made of pig intestines and which has a lot of side effects, most notably, bleeding and allergies. We have basically knocked out all of those issues.

Now, we found in the course of our research in coronary angioplasty that doctors started to try to experiment with the drug in stroke and cardiac surgery. One report from a doctor described this drug as—and I quote, and I am willing to put this into the record—"the holy grail of drugs for cardiac surgery in patients who are allergic to heparin."

We cannot complete that research right now because we don't have the money, the time, the incentive that Hatch-Waxman originally saw we would and which we expected to get but for our error in filing.

As far as stroke is concerned, it is one of the biggest causes of death in Americans today. It affects all ethnic groups, particularly African-Americans, as we know. It is a deadly disease, of course, and something that really needs to be worked on. We have shown that this drug in preliminary trials can enable the positioning of the carotid stents, stents in the neck to prevent stroke better than any other product that is currently out there. Most experts believe this is a drug that should be developed extensively in that situation.

Mr. MEEHAN. Thank you.

Secretary Dudas, I want to make sure that I understand the current law correctly. As I understand it, an application which contains a number of technical errors submitted on time within the 60 days can be returned to the applicant who has a number of months to correct these mistakes. But a perfectly filed and complete patent resolution application mistakenly filed 1 day late—and I have been counting how many days have—how many months have 30 days and how many have 31, which apparently is part of the problem. Do you know quickly how many have 30 days?

Mr. DUDAS. I have to count it on my hand.

Mr. MEEHAN. Right. But I am interested is that case. In other words, in other words, if you file an application with mistakes on time, can you make corrections?

Mr. DUDAS. Yes, you can.

Mr. MEEHAN. How does that work?

Mr. DUDAS. Well, there is a variety of different instances.

Mr. MEEHAN. So, in other words, so even if somebody files with mistakes, as long as they file within the 60 days, they will get a period of months to correct those mistakes?

Mr. DUDAS. There is an opportunity to correct mistakes in some cases with applications and also in other areas in the office, yes.

Mr. MEEHAN. Do you, do you believe that PTO can waive the 60-day filing requirement on its own inherent authority? Or is it your

belief that an extension must be legislated through a measure such as H.R. 5120?

Mr. DUDAS. It is our belief that it would have to be legislated.

Mr. MEEHAN. Do you agree with the discretionary authority in 5120? Do you agree that it is similar to other deadline-extending provisions presently in patent law? And if so, approximate—well, I think the question was asked. But you said maybe 30. But you agree that there is already discretionary authority with other deadlines?

Mr. DUDAS. There is definitely discretionary authority with some other deadlines. And this is not in some way that we find to be fundamentally inconsistent with some of the other deadlines.

Mr. MEEHAN. Okay. So there are other deadlines that it is okay, this discretion that you guys have? There are other mistakes that are filed that somebody has a period of months to correct. Would you agree with the description of H.R. 5120 that the bill simply gives the PTO the discretion to review a patent term restoration application filed a few days late to determine whether that filing was delayed intentionally? Would you agree?

Mr. DUDAS. I think that is correct, as I read it. It would depend on what—and I am not familiar with the legal standard of unintentional. And we have folks in our office that could determine, whether or not it would be automatic. But the bill on its face says discretion to determine whether it is unintentional.

Mr. MEEHAN. Would you agree that the legislation doesn't by itself add any additional patent term restoration?

Mr. DUDAS. The bill itself does not add any patent term restoration.

Mr. MEEHAN. Finally, some people have characterized this bill as automatically extending—I heard some of the witnesses say that it automatically extends the 60-day filing deadline by 5 days. Do you agree with that?

Mr. DUDAS. I think the only way that would be true is if the term unintentional—no, it can't be that, because if someone did it intentionally it wouldn't be automatic, either. So I think a lot depends on the standard of unintentional. But, no, there is at least that standard there.

Mr. MEEHAN. And I read it, and I share Mr. Berman's feeling. I read the material from you, the letter from you. One thing I think we can be clear is the PTO doesn't have any reason to oppose this legislation. Is that correct?

Mr. DUDAS. From a PTO perspective, an administrative perspective and an ability to carry it out, no, we don't have a reason to oppose.

Mr. MEEHAN. Thank you, Mr. Chairman.

Mr. SMITH. Okay. Thank you, Mr. Meehan.

I am going to ask, Mr. Dudas, you another question and in doing so, give other witnesses, if they so desire, an opportunity to answer the question as well. And what I am trying to do here in asking a question about precedent is to find out exactly what the facts are, and be a little bit more specific when we talk about those precedents.

I have a list in front of me which may or may not be entirely comprehensive of all the instances where discretion has been al-

lowed in the case of unintentional mistakes. And so far as I can see from this list in front of me, which, as I say, may not be completely extensive, is that in all the instances where discretion has been allowed in the case of unintentional mistakes that deal with the statute as opposed to PTO rules generally fall into two categories: discretion being allowed in the case of late fees and discretion being allowed in the case of failure to reference earlier applications.

Clearly, discretion in those instances don't rise to the level of significance of discretion in the case of extending a patent. Do you know of any instance where there would be a precedent directly on point where discretion would be allowed in the case of an unintentional mistake dealing with the approval of a patent and dealing with discretion being allowed in the case of the statute as opposed to PTO rules?

Mr. DUDAS. I am not aware of that, but I would give the following caveat that we have in our deputy office of operations and policy within Patent and Trademark Office—I would like to follow-up——

Mr. SMITH. Okay. It would probably be useful to the Committee to realize two things. One, most of the discretion that is being given is of relatively minor infractions or deadlines dealing with PTO rules, not the statute. And if you have any case in point, I think that would be helpful. But there is precedent perhaps on both sides. I just haven't seen the precedent yet on the side of extending a patent.

Dr. Meanwell, do you have any examples you could give? And then we will ask Ms. Jaeger and Professor Thomas.

Mr. MEANWELL. I would like to say that the hard and fast deadlines that we have reviewed—and I am no patent attorney, so I am——

Mr. SMITH. Neither am I.

Mr. MEANWELL. The ones that seek to expand the scope of a patent, the breadth of the intellectual property, are indeed often hard and fast. I know at least of three. In fact, they were mentioned earlier, I think, 102-B, 251 and 119-A are the things related to establishing a patent, either here or in foreign territories. But actually, that is establishing new grounds for a patent. That is establishing the breadth of a patent.

Here we are talking about the time life of a patent. We are not talking about the breadth of the patent in any way. The breadth of the Angiomax patent will remain exactly the same.

And one of the things I should have said to Mr. Berman is that that means that we are not looking for a new patent to do what we are doing. We are hoping to use this one as long as we need. And we will need to invest $100 million to do so. So we obviously would like to recoup that with exclusivity thereafter. So just to clarify.

But there are certainly situations where expanded the scope of a patent is hard and fast. But this is a procedural situation, in my opinion, not expanding the scope of the patent in any way. And by the way, the revision here would not in any way give us a single day more on our term than would be normally envisioned under Hatch-Waxman. And, you know, frankly for such a Draconian pen-

alty to be hammered out for the sake of this dumb mistake, we feel would be, would be inequitable.

Mr. SMITH. Okay. Thank you, Dr. Meanwell.

Ms. Jaeger or Professor Thomas, any precedents to cite or examples to give?

Mr. THOMAS. Mr. Chairman, I believe the most apt analogy would be with respect to maintenance fees, which may well be the first element on the chart you have referenced. As you know, the patent 20-year term is not automatic. You have to pay periodic annuities essentially to the patent office to retain the term and the 3 and-a-half, 7 and-a-half and 11 and-a-half years from the date of issuance. Some of those deadlines aren't met, so there are provisions for coming in late and asking for your patent to be maintained in a sense, sort of a term extension.

Mr. SMITH. You are right. Okay.

Mr. THOMAS. However, and those applications are entertained by the U.S. PTO. However, if there is a late maintenance fee accepted, that gives some right with respect to third parties that are rather vaguely defined by the statute, for example, something that would be akin to the first inventor Defense Act, which you are considering modifying to encompass all sorts of inventions, not just——

Mr. SMITH. Okay. Thank you, Professor Thomas.

Mr. THOMAS. You are welcome.

Mr. SMITH. Ms. Jaeger?

Ms. JAEGER. I just want to reiterate for the record, I know we see three particular situations where patentees are seeking to expand the scope or lengthen the term that do not, do not have any discretion for PTO. And, of course, that is the——

Mr. BERMAN. Expand the scope.

Ms. JAEGER. Expand the scope of patent with a reissuance proceeding or a PTE, which is extending the length of the patent as well as, of course, you know, the foreign early filed foreign patent provision as well.

Mr. SMITH. Okay, okay. Thank you, Ms. Jaeger.

Let me explain to the panelists that I have to leave for another engagement. I am going to ask the gentleman from Tennessee to chair the rest of the hearing. And thank you all again for being here.

Mr. JENKINS. [Presiding.] Mr. Berman, were you finished?

I am sorry. Go ahead.

Mr. BERMAN. I was just interrupting somebody else.

Actually, now I understand, Dr. Meanwell, you are not seeking a new patent. You will need to get FDA approval for the new uses. You won't need to get a new patent. And it makes a heck of a difference whether it expires in 2010 or 2014 whether you have some exclusive period for marketing this drug that FDA would have approved for additional uses. Okay. I have got it. It is not about a new patent.

Professor Thomas, you made a point in your initial testimony. I forget exactly how you put it, but a policy reason perhaps to not provide discretion in this provision is because it implicates not just the patent office, but the Secretary of HHS and the head of FDA and the Secretary of Agriculture. And I don't know what other agencies you mentioned.

But realistically, what is the difference if under the limited nature of this extension in terms—I am trying to understand why is that a policy argument against doing it when in the limited nature of the relief proposed in this legislation.

Mr. THOMAS. It is a good point. It is only 5 days. But it does create a lot of reliance interest upon other actors. And that is something that is not as commonly the case with other missed PTO deadlines. So in short, there are a host of actors out there that have to engage in a fair amount of steps.

Another distinction that may be salient to you—and again, let me first once more acknowledge you are right about the 5 days. It is only 5 days from that perspective. But there are any number of other deadlines that if missed are irremediable under the Patent Act. And again, they often impact small entities that are not sophisticated players in the patent system. They have long been a part of our law. That really——

Mr. BERMAN. That are not, that are not——

Mr. THOMAS. That cannot be correctable. And that is really not the case here. Right? We are really talking about very sophisticated actors that are well-advised. And that may be why this is not a situation that has recurred.

One of my colleagues at Georgetown often uses the phrase "big boys" that I don't like because of its gender implications. But nonetheless, do we need in a sense really a protection statute for sophisticated actors who have just been gifted with a watershed event for their firm, FDA marketing approval?

Mr. BERMAN. Well, no, look, one cannot help but avoid the notion that in life there are a lot of deadlines that every day because some little person or company or whatever missed them and opportunity was lost or harm was done and, I mean, you can't, you can't but avoid thinking at this. And at the same time, it is hard to avoid thinking about the enormity of, you know—I mean, there is a disproportional aspect of what has happened here, too, on the other side in terms of just nature of mistake versus money lost. So I guess that is part of the consideration.

Ms. Jaeger, my last question—in the context of, somewhere companies in your association, unknown to you because of the proprietary interests may have spent money, and in some cases considerable money, thinking that notwithstanding all the hullabaloo in 2010 this thing is coming out there and we want to be ready to fill that void with a lower cost consumer benefit therefore protection.

Are there situations—somebody mentioned in the context of some other statute the maintenance fees. In the context of things, are compensation for money spent in reliance on something that Congress subsequently changed—is there any precedent for those kinds of arrangements?

Ms. JAEGER. Well, I think when we are looking at this retroactively—we are looking at this retroactive bill. And in so doing, the job, I think, of everyone here is to sort of do the analysis of weighing the benefits and the risks.

And here, yes, absolutely, the benefit would inure to The Medicines Company and would provide them with 5 additional years of market exclusivity in the United States. It is adding to their patent that they have today, which expires in 2010. It is not taking away

their patent. It is just going to extend the terms of that particular patent and give them this extraordinary benefit.

At the same time, the burden that would be placed on our industry would be that we relied upon the 2010 patent expiration date. We went through and did some performance research and development, which costs money from our industry side.

At the same time, we also have a downstream effect of the others in the health care distribution channel, which are the insurers and the PBMs and the consumers, that have relied upon that date as well for forecasting and in trying to figure out what health insurance premiums will be in 2010 and the like. So this does have a negative implication downstream in the health care distribution channels.

At the same time, among the broader issue, we are just very concerned about the many, many deadlines in Hatch-Waxman. And, you know, we say, we all hope to move the deadline to, 65 days. When we get to another situation when someone comes in at 67, 68, are we going to move it again? And then do we move the 45-day window? And does that move——

Mr. BERMAN. We are very good at saying it is this time only, never again until——

Ms. JAEGER. And we think it is a Pandora's Box that doesn't need to be opened, sir.

Mr. BERMAN. Just in closing, Mr. Chairman, as I heard Dr. Meanwell describe the drug, I realized that this fit perfectly with what happened to my father, who died from an allergic reaction to heparin during a heart surgery where he had to have a blood thinner at that time. This is 16 years ago or something. Not from the heart surgery, not from the heart attack, but from not having—so I could personally testify there is something valuable about what you have produced here.

And I yield back.

Mr. JENKINS. Professor Thomas, let me go back to the flexibility that you spoke about with respect to the payment of fees for continuation. If that flexibility was not in the law, then this patent continuation would be just as dead as any of the other instances that could kill its continued life. Isn't that true? If we had the same rigidity in the law with respect to the payment of those fees that we have, let us say, in this instance, then that would put an end to that patent and its continuation just as surely.

Mr. THOMAS. Sir, I don't know all the facts of the case. I am not aware of how long the patent has been extant and whether they have paid maintenance fees or not. So in good faith I can't answer that, sir.

Mr. JENKINS. Well, let me ask it not on a comparative basis, but just on the basis of if the law was different and said you had to pay these fees on time, you couldn't pay them a day late, then your continuation would be just as dead, would it not? It would be dead.

Mr. THOMAS. That is right, if the maintenance fees were paid late, right.

Mr. JENKINS. Okay.

Mr. Meehan, do you have any questions, sir?

Mr. MEEHAN. Mr. Chairman, I just want to point out on this issue of unintentional error in standards that are, that are used by

the PTO, there is a letter in the record from Lawrence Goffney that specifically says that the agency is extremely familiar with the unintentional error standard that is being proposed in H.R. 2150. Indeed, this is a standard most commonly used by the PTO in determining whether to accept late filings under the statutory provisions. And I would refer that to Members of the Committee.

Just one more thing that I want to ask Ms. Jaeger. So you can't provide us with a company that is ready to develop this drug or has had an investment or anything of that nature?

Ms. JAEGER. No, sir, not at this time I cannot because, again, our companies' pipelines are proprietary. As you can imagine, they are fierce competitors. And so, it is not something they are about to disclose, what products they are or are not going to bring to the market in a few years.

Mr. MEEHAN. Right. And that is basically for some of us—the question is, you know, what is the future going to be of this particular drug and the advances that have been made?

It is my understanding that clinical data demonstrates that up to 23,000 transfusions could be saved if these results move forward, more than 1 million of these performed each year, these procedures. So from my perspective, that is why we are balancing interests here.

We are balancing a lawyer at a firm who messed up with what the public health effect would be in the end. And for me, that is a significant thing that we should weigh.

So I thank the Chairman. I just want to point out those unintentional error standards into the record.

Mr. JENKINS. Thank you, Mr. Meehan.

Does any other Member of the Committee have any additional questions?

Mr. Berman?

Mr. BERMAN. No.

Mr. JENKINS. Any?

Well, the Chairman has already complimented this panel of witnesses. And let me add to that and say that your remarks were very informative. Your answers were very direct and cogent, and we certainly appreciate that.

I think that this Committee has learned quite a bit today. I hope that we can use it to the benefit of the people across the United States of America. It is a difficult situation.

And, Ms. Jaeger, let me say I have the utmost respect for you and what your association members are doing. We shouldn't let it pass without saying that your members provide a really valuable service to millions and millions of Americans.

As I understand it, Dr. Meanwell is also on the board of directors of a generic company. Was that brought out? Is that true?

Mr. MEANWELL. Yes, I am, sir. I am on the board of a company that sells generics. I absolutely agree with your remarks.

Mr. JENKINS. All right. Well, thank you very much for coming. And the Committee will be adjourned.

[Whereupon, at 12:35 p.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

STATEMENT OF THE HONORABLE HOWARD BERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND RANKING MEMBER, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

Mr. Chairman,

Thank you for scheduling this hearing on a bill giving the USPTO additional discretion to extend certain patent deadlines. While similar measures (bills that have specifically extended the Angiomax patent) have been attached to legislative vehicles in the past, I am glad that this issue is finally being reviewed by the committee with jurisdiction over patent matters. It is important that this Subcommittee be able to analyze the impact of any changes this bill may make on the patent system.

Patents are the cornerstone of innovation. The Constitution provides for a limited period of time of protection in order to promote innovation. Therefore, the patent process provides the exclusive right for an invention (for 17 to 20 years) generating incentives for an inventor to continue to create after which the invention becomes available for public use. There is a delicate balance of - on the one hand- providing enough of an incentive to the inventor to spend the time, energy and money to create new inventions - and on the other- the value of allowing the invention to be used by the public enabling others to develop new products or provide similar products for lower cost.

Therefore, when considering the effect of allowing the PTO discretion to extend certain patent deadlines, there is a natural tension between providing the flexibility to extend a deadline and maintaining a hard date for specific types of filings. While providing greater elasticity may prevent seemingly draconian results does it come at the expense of stability in the market? There appear to be other instances where the PTO has discretion to extend deadlines but the situation this bill is designed to address is not among them. WHY? Is there something different about this type of filing that the PTO should NOT have discretion in this case?

Unfortunately, the PTO has not provided much guidance in its response to the (letter from the Chairman and myself about the) policy questions posed by this bill. I look forward to hearing from the other witnesses to discuss the policy implications of this bill on the patent system and possibly Hatch-Waxman.

Originally this legislation began as an effort to address one particular late filing, of one patent - there has been no demonstrated need nor request from any other patent owners to provide discretion to the PTO for these type of filings. Moreover, from the way the bill has been written it is clear that this bill would effect the late filing of a particular company which occurred over 4 years ago. Some have even suggested that the better alternative to this bill is a private bill. However, this bill and this particular circumstance does raise some questions about why there are inconsistencies in the discretion afforded to the PTO to determine when filings are timely. As such I look forward to further exploring the issues.

STATEMENT OF THE HONORABLE ELTON GALLEGLY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND MEMBER, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

Mr. Chairman, I would like to begin by thanking you for holding this hearing on H.R. 5120. I appreciate your interest in this important issue. I would also like to commend Congressman Jenkins for the introduction of this legislation.

H.R. 5120, which I strongly support, deals with what seems to be a narrow issue in our nation's patent law, namely the question of patent term restoration applica-

tions submitted to the Patent and Trademark Office. However, although the change to the law is relatively minor, the passage of this legislation would both provide greater fairness to patent holders and encourage innovation by companies in the medical research field and in other industries.

H.R. 5120 would amend the Hatch-Waxman Act to provide the U.S. Patent and Trademark Office with modest discretion to accept late-filed patent term restoration applications. In a recent letter to the Subcommittee, the Director of the Patent and Trademark office confirmed that under current law the PTO already enjoys discretion in numerous instances to accept late-filed applications. However, Congress has not given the PTO similar discretion to accept late-filed patent restoration applications.

This strikes me, and other cosponsors of H.R. 5120, as an unfortunate and undeserved inconsistency in our patent law.

Mr. Chairman, failure to allow an innovator that has earned patent term restoration to qualify merely because of a clerical or other unintentional error discourages innovation and ultimately harms patients who rely on research into new medicines. We must keep in mind that for a company to qualify for patent term restoration, it must already have successfully completed an incredibly rigorous drug testing and development regime, ultimately obtaining FDA approval of its drug. The Hatch-Waxman Act offers patent term restoration as an incentive for innovators to invest their time, effort, and resources in this arduous drug development and approval process.

I can think of no area in the patent law where permitting discretion on the part of the PTO too accept late-filed applications is more important that in the case of patent restoration applications. Yet, this is one area where Congress has not granted the PTO such discretion. It is imperative that we correct this situation by the passage of H.R. 5120.

I understand that some oppose H.R. 5120, arguing that giving the PTO any discretion will somehow disadvantage generic manufacturers.

In my view, the Hatch-Waxman Act provides generic manufacturers with clear, enumerated benefits. However, Congress never intended one of those benefits to be the ability to take advantage of unintentional clerical errors, thereby gaining years of marketing time at the expense of innovative companies that have satisfied all of the many processes required by Hatch-Waxman.

Mr. Chairman, I want to thank you again for holding this hearing today.

A LETTER TO THE HONORABLE JONATHAN W. DUDAS, UNDER SECRETARY FOR INTELLECTUAL PROPERTY AND DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE (USPTO) FROM THE HONORABLE LAMAR SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS AND CHAIRMAN, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY, AND THE HONORABLE HOWARD BERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND RANKING MEMBER, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

ONE HUNDRED NINTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON THE JUDICIARY

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May 23, 2006

The Honorable Jonathan W. Dudas
Under Secretary for Intellectual Property and Director
U.S. Patent and Trademark Office (USPTO)
Madison West Building
600 Dulany Street
Suite AW 10-d-44
Alexandria, Virginia 22313

Dear Jon:

Please find enclosed a copy of H.R.5120, a bill referred to the Subcommittee, which seeks to amend the Patent Act to provide the Director of the United States Patent & Trademark Office (USPTO) with new authority to waive the operation of title 35 U.S.C. §156(d)(1).

Specifically, H.R. 5120 proposes, under circumstances shown "to the satisfaction of the Director" to permit the Director to declare such delay to be "unintentional" and "accept" an application for extended patent term that is filed:

1) "not later than 5 days after the expiration of the 60-day period" specified by statute[1] for applications not submitted on the date of enactment ;or
2) "not later than 5 days after [the] date of enactment" in the case of an application that is pending at USPTO, subject to a request for reconsideration, or has been denied an extension under this section but whose period for seeking reconsideration has not expired.

[1] 35 U.S.C. § 156(d)(1) provides, "[t]o obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use."

In support of this proposal, proponents have noted that the USPTO has ex ante discretionary authority[2] to permit an application, which is incompletely or improperly filed within the 60-day statutory period, to be deemed "informal" and to grant the applicant additional time to make corrections.

They assert that the USPTO has no authority under statute or regulation to permit a properly completed application, which was filed late due to an applicant's inadvertence[3], to be granted an extension. In their view, the interests of equity would be served if Congress granted the Director with statutory discretion to waive or extend the deadline in certain instances.

In considering amendments to the Patent Act, we are mindful that ensuring the predictable application of our law can promote a number of beneficial purposes. The presence of clearly articulated standards contributes to increased entrepreneurial activity, which can lead to the availability of innovative new products and technologies.

The certainty associated with a clearly defined statute may act as an incentive for parties to conduct their affairs in reliance upon the occurrence of outcomes that are reasonably foreseeable. And a demonstrably consistent application of the law inspires public confidence in the objectivity of administrative decision-making.

In sum, the reliance upon variable and uncertain factors may result in unsettling the reasonable expectations of parties, as a disincentive to innovation, and as a bar to potential competition.

Notwithstanding the considerations above, there are those who believe the USPTO needs new administrative flexibility to waive the requirements of 35 U.S.C. §156(d)(1). It is argued this is required to ensure that the strict application of a "bright line" rule in every circumstance does not lead to counter-productive outcomes that have the unintended and undesired effects of actually discouraging innovation and imposing on inventors draconian and unforeseeable costs.

Due to the technical nature of these issues and the importance we attach to ensuring all relevant views are fully and properly considered, we would appreciate your providing the Subcommittee with your analysis and assessment of H.R. 5120.

If, as the Director of the USPTO, you determine that you wish to request that Congress grant the authority intended by H.R. 5120, then we would appreciate your providing us with a written response that includes recommendations for any restrictions or limitations that you believe ought to be included to ensure the neutral application of such a provision, a discussion of

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[2] 37 CFR § 1.740

[3] A non-dispositive but arguably persuasive authority for similar equitable principles may be found in FED. R. CIV P. 6(b), which provides, subject to some restrictions that a "court for cause shown may at any time in its discretion ... order the period [of time for an act to be done] enlarged, or ... permit the act to be done where the failure to act was the result of excusable neglect."

the status of any pending matter that USPTO foresees may be impacted by such a change, the identification of any parties who may be aggrieved by such a change, and an explanation of the manner in which the USPTO would anticipate implementing such a proposal.

We are aware of one instance where a company might benefit from the enactment of legislation and the exercise of administrative flexibility in this area. The Medicines Company manufactures the pharmaceutical Angiomax® (bivalirudin), an anticoagulant approved in the U.S. for use by patients who are undergoing coronary angioplasty procedures. The company believes Angiomax® may be useful in treating other conditions. Due to uncertainty over the final expiration date of the underlying patent the company has, thus far, been reluctant to fund new clinical trials. The current patent for Angiomax®, U.S. Patent No. 5,196,404, (herinafter the "404" patent) was issued March 23, 1993. Absent an extension, it will expire in 2010.

We understand that attorneys who represent The Medicines Company applied for an additional 4.5 years of extended patent term but that the request was denied due to a failure to meet the 60-day statutory filing requirement contained in 35 U.S.C. §156(d)(1). We are told that an attorney filed a motion for reconsideration in this matter with the USPTO on October 4, 2002, and that the motion, as of today's date, has not yet been acted upon by the USPTO.

Further, we understand that the law, as of December 2004, permits a generic manufacturer to be eligible to file a "paragraph 4 certification" to challenge the validity of the "404" patent.

While we are not aware of an expressed intention by a generic manufacturer to file such a challenge, we are concerned about the possible effect that the operation of such a statutory and administrative change could have on the inchoate interests of potential generic competitors.

We would appreciate your analysis and opinion as to whether the changes proposed in H.R. 5120 could, under any circumstances, operate to retroactively delay the ability of a generic manufacturer to file a challenge to a patent granted by the USPTO.

In addressing our concerns, please be sure to include answers to the following specific questions:

- If USPTO was granted statutory discretion to extend the deadline of an application for an extended patent term, how many previous applicants could benefit? How many current applicants could be expected to take advantage of such discretion?
- If discretion was granted, should it be prospective and not apply to any current case rather than retroactive since that would be consistent with the way new laws are generally applied?
- What are examples of the USPTO's having been "given wide discretion to excuse late filings" in other areas?

- Under what circumstance would you expect such discretion to be exercised in regard to patent term restoration applications filed in an "untimely manner"? What are specific examples of "unintentional delay" in filing such applications? Would "unintentional delay" cover "human error"?

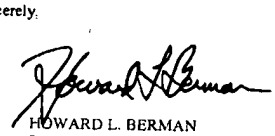
- Finally, do you feel this legislation is needed?

After conducting a thorough review of H.R. 5120 and the circumstances it is intended to address, we would appreciate your recommendations, if any.

The Committee's points of contact for this matter are David Whitney, Counsel to the House Judiciary Committee's Subcommittee on Courts, the Internet, and Intellectual Property and Shanna Winters, Minority Counsel to the Subcommittee on Courts, the Internet, and Intellectual Property.

Sincerely,

LAMAR SMITH
Chairman, Subcommittee on Courts,
The Internet, and Intellectual Property



HOWARD L. BERMAN
Ranking Member, Subcommittee on Courts,
The Internet, and Intellectual Property

109TH CONGRESS
2D SESSION

H. R. 5120

To amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2006

Mr. JENKINS (for himself, Mr. DELAHUNT, Mr. DUNCAN, and Mr. MEEHAN) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. FINDINGS.**
4 The Congress finds the following:
5 (1) The Congress historically has provided vig-
6 orous support for innovation in the useful arts by es-
7 tablishing a system of patent protection for products
8 and processes.
9 (2) Through section 156 of title 35, United
10 States Code, the Congress sought to promote the de-

1 velopment of innovative drugs by granting patent
2 term restoration to companies to recover a portion
3 of the patent term for such drugs that was con-
4 sumed during the approval process conducted by the
5 Food and Drug Administration.
6 (3) Consistent with the historic purpose of pro-
7 moting innovation, patent legislation, and subse-
8 quent rules promulgated by the United States Pat-
9 ent and Trademark Office (PTO), have routinely
10 given the PTO wide discretion to excuse late filings
11 and other mistakes that might otherwise result in
12 the forfeiture of underlying patent rights.
13 (4) Contrary to this routine practice, however,
14 under section 156 of title 35, United States Code,
15 the PTO has no discretion to excuse a filing that is
16 even one day late.
17 (5) In order to be consistent with the intent of
18 protecting patent rights and promoting further inno-
19 vation, the PTO should be granted limited, cir-
20 cumscribed discretion to consider patent term res-
21 toration applications filed in an untimely manner.

1 **SEC. 2. FILING OF APPLICATIONS FOR EXTENSIONS OF A**
2 **PATENT TERM.**

3 (a) IN GENERAL.—Section 156 of title 35, United
4 States Code, is amended by adding at the end the fol-
5 lowing new subsection:

6 "(i) UNINTENTIONAL DELAY.—The Director may ac-
7 cept an application under this section that is filed not later
8 than 5 days after the expiration of the 60-day period pro-
9 vided in subsection (d)(1) if the applicant files a petition
10 showing, to the satisfaction of the Director, that the delay
11 in filing the application was unintentional. Such petition
12 must be filed with the application in the case of an appli-
13 cation filed on or after the date of the enactment of this
14 subsection and must be filed not later than 5 days after
15 such date of enactment in the case of an application
16 which, on such date of enactment, is pending, is the sub-
17 ject of a request for reconsideration of a denial of a patent
18 term extension under this section, or has been denied a
19 patent term extension under this section in a case in which
20 the period for seeking reconsideration of such denial has
21 not yet expired. The Director shall make a determination
22 on a petition under this subsection not later than 30 days
23 after the date on which the petition is received. If no de-
24 termination has been made on the petition within that 30-
25 day period, the petition shall be deemed to be denied.".

1 (b) REVIVAL FEES.—Section 41(a)(7) of title 35,
2 United States Code, is amended—
3 (1) by striking "or for an" and inserting "for
4 an"; and
5 (2) by inserting after "reexamination pro-
6 ceeding," the following: "or for an unintentionally
7 delayed application for patent term extension,".
8 (c) EFFECTIVE DATE.—The amendments made by
9 this section shall take effect on the date of the enactment
10 of this Act, and shall apply to any application for patent
11 term extension under section 156 of title 35, United
12 States Code, which—
13 (1) is filed on or after the date of the enact-
14 ment of this Act; or
15 (2) on such date of enactment—
16 (A) is pending;
17 (B) is the subject of a request for reconsid-
18 eration of a denial of a patent term extension
19 under section 156; or
20 (C) has been denied a patent term exten-
21 sion under such section 156 in a case in which
22 the period for seeking reconsideration of such
23 denial has not yet expired.

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A LETTER TO THE HONORABLE LAMAR SMITH, A REPRESETATIVE IN CONGRESS FROM THE STATE OF TEXAS, AND CHAIRMAN, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY, IN RESPONSE TO A LETTER REQUESTING THE UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO) ANALYSIS AND ASSESSMENT OF H.R. 5120

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

AUG 30 2006

The Honorable Lamar Smith
Chairman, Subcommittee on Courts,
The Internet, and Intellectual Property
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your co-signed letter requesting the United States Patent and Trademark Office's (USPTO) analysis and assessment of H.R. 5120, a bill "to amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office."

We appreciate the Committee's interest in the USPTO's views on this bill. This type of legislation is not without precedent. Currently, patent laws provide the USPTO with discretionary authority to accept late-filed submissions in a number of situations, including: payment of maintenance fees (35 U.S.C. § 41(c)(1)), abandonment of applications (35 U.S.C. § 133); and payment of issue fees (35 U.S.C. § 151). The trademark laws have similar language, for example, regarding timely filing of a verified statement of use (15 U.S.C. § 1051(d)(4)) and abandonment of an application for failure to reply or amend (15 U.S.C. § 1062(b)).

At this time, however, we do not have a position on this proposal. As the Committee recognizes, there could be some benefits, and at least one direct beneficiary, of providing the type of additional flexibility provided by the proposal. However, as the Committee also recognizes, there are also benefits to maintaining the certainty inherent in current law in this area. While we have a sense of the potential impacts on the possible direct beneficiary to this legislation, we do not yet have a full sense of the impact on others in the invention, manufacturing, consumer, and intellectual property communities. As the legislative process continues, we would encourage the Committee to explore these issues, as the views of a range of parties may help elucidate the merits and limitations of the proposal. Similarly, while we currently do not believe the legislation requires additional restrictions or limitations in order to ensure neutral application if enacted, further exploration of the issue may help inform this question as well.

We are pleased to provide information below that is responsive to various questions posed in your letter.

P.O. Box 1450, Alexandria, Virginia 22313-1450 - www.uspto.gov

Previous Applicants that Would Benefit from Enactment
We are aware of one current application for patent term extension that would immediately benefit from enactment of the bill. That application is related to patent number 5,196,404 owned by the company named in your letter. More generally, a review of our records indicates that, of the over 700 applications for patent term extension filed since 1984, three other applications were not granted due, at least in part, to timeliness issues. One of these applications was filed within 65 days of the "approval date," and thus may have been eligible for a petition to have the delay excused, if the proposed provision had been in effect.

Prospective vs. Retrospective
It is not unprecedented for newly enacted patent legislation to apply to issued patents and pending applications. That fact noted, prospective or retrospective discretionary authority, as proposed in the bill, would have to involve a careful balancing of all relevant interests involved. We are unable to make a particular recommendation in this regard because we are unaware of any substantive input by interested parties, other than the '404 patent owner.

Exercise of Discretion
With respect to the circumstances under which we would expect to exercise discretion, we believe it is premature to attempt to list or identify particular examples at this point. We would, of course, if granted the subject authority, be likely to follow the policies reflected in the administration of areas currently subject to discretionary review of delayed filings.

Patent Reform
Although our survey of patent term extension applications reveals few issues related to timeliness, this legislation would be of use to at least one current applicant and could be utilized by future applicants who miss the patent term extension application deadline due to unintentional delay. As noted above, the discretionary authority contemplated by H.R. 5120 is similar to other deadline-extending provisions in patent law.

As indicated in testimony before your Subcommittee in April, the USPTO supports enactment of two patent proposals pending before the Subcommittee that are widely supported throughout the intellectual property community, namely, a post-grant review procedure and a new procedure for submission of prior art. We continue to review other proposals before the Subcommittee.

The Office of Management and Budget has advised that there is no objection to the transmittal of these views from the standpoint of the Administration's program.

Sincerely,

JON W. DUDAS
Under Secretary and Director

A LETTER TO THE HONORABLE JON W. DUDAS, UNDER SECRETARY FOR INTELLECTUAL PROPERTY AND DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE (USPTO) FROM JANE A. AXELRAD, ASSOCIATE DIRECTOR FOR POLICY, CENTER FROM DRUG EVALUATION AND RESEARCH, DEPARTMENT OF HEALTH & HUMAN SERVICES IN REGARD TO THE MARCH 24, 2003 LETTER FROM KARIN FERRITER REQUESTING FDA'S ASSISTANCE IN PREPARING A RESPONSE TO A REQUEST FOR RECONSIDERATION IN THE APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5, 196, 404 FILED BY THE MEDICINES COMPANY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 2 2006

Re: Angiomax
Docket No. 01E-0213

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the March 24, 2003, letter from Karin Ferriter requesting FDA's assistance in preparing a response to a request for reconsideration in the application for patent term extension for U.S. Patent No. 5,196,404 filed by The Medicine Company under 35 U.S.C. § 156. The human drug product claimed by the patent is Angiomax (bivalirudin), which was assigned new drug application (NDA) No. 20-873.

The applicant argues that the approval date for NDA 20-873 should be December 18, 2000, not December 15, 2000 (a Friday), because the approval letter was signed after FDA's normal business hours on December 15.

The FDA reiterates that NDA 20-873 for Angiomax was approved on December 15, 2000.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Hollie Baker
Wilmer, Cutler, Pickering, Hale and Dorr, LLP
60 State Street
Boston, MA 02109

Paul Antinori
The Medicine Company
8 Campus Drive
Parsippany, NJ 07054

Bcc:
BCC:
Chron
Hard Copy to B.Friedman for Patent File : Angiomax Patent No. 5,196,404

Scanned Copy to:

J. Axelrad
L. Jaffe/G. Ortega/J. Butler for Docket # 20016-0213
Mary_Till@PTO.gov for Angiomax Patent No. 5,196,404

I:\Patent98\PRODUCTS\Angiomax\Response to request for reconsideration\2.doc

A PAPER ON CRITICAL ACTIONS THAT RELATE TO THE MEDICINES COMPANY APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT 5, 196, 404

Critical Actions That Relate to The Medicines Company Application for Patent Term Extension for U.S. Patent 5,196,404

DAY	DATE	ACTION
0	December 15, 2000	FDA approves New Drug Application (NDA).
3-19	December 18, 2000 – January 3, 2001	Application preparations underway (drafting, beg collection and preparation of appendices); meetin on January 3, 2001 at The Medicines Company (MDCO) w/ Hale & Dorr (H&D) to discuss application.
21	January 5, 2001	First draft of (substantially complete) 100 + page application prepared and sent by H&D to MDCO for review.
42	January 26, 2001	Meeting at H&D to review application.
56	February 9, 2001	Review next to final draft of application at MDCC
59	February 12, 2001	Application sent by Hale & Dorr to Fish & Neave (patent counsel of record) for filing.
60	February 13, 2001	Application arrived at Fish & Neave.
61	February 14, 2001	Fish & Neave files application with PTO (by Express Mail procedure).
	March 2, 2001	PTO asks FDA to confirm that PTE application w. not filed within sixty days after the product was approved as required by 35 USC §156(d)(1).
	September 6, 2001	FDA transmits letter confirming that PTE was file untimely.
	March 4, 2002	Final Determination of Ineligibility issued.
	October 2, 2002	H&D Counsel files MDCO Request for Reconsideration for Patent Term Extension by USPS with Commissioner for Patents.

REQUESTED SUBMISSION FROM THE HONORABLE WILLIAM JENKINS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE; LETTERS FROM LEADING MEDICAL PRACTITIONERS AND CONSUMER GROUPS

EMORY HEALTHCARE
HEART CENTER

The Carlyle Fraser Heart Center
at Crawford Long Hospital
[illegible]
Atlanta [illegible]
Phone [illegible]

June 15, 2006

Congressman John Lewis
United States House of Representatives
343 Cannon House Office Building
Washington, DC 20515

Dear Representative Lewis,

I received a phone call today from Clive Meanwell, Chief Executive Officer of The Medicines Company, regarding HR 5120, relating to the patent restoration provisions of the Hatch-Waxman law I am the Director of Interventional Cardiology at Emory Crawford Long Hospital and have been on the faculty of Emory University School of Medicine for thirteen years I am also the President of the Greater Atlanta Division of the American Heart Association (A.H.A.), and a medical reporter for FOX-5 television The major focus of my profession is the care of patients with advanced and complex cardiovascular disease, particularly those undergoing interventional procedures (commonly known as stents) of the arteries of their heart and elsewhere in the body

I am writing in support of HR 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. Angiomax is a critically important product which is used in the overwhelming majority (thousands) of the interventional procedures at Emory Angiomax is an important therapy because it provides safe, effective, and cost-effective anticoagulation during interventional procedures In addition, several Emory physicians have performed extensive research on Angiomax. Emory was one of the leading U.S. centers in a recent trial studying this product. I am perhaps one of the nation's leading experts and researchers in this area and have lectured internationally and published extensively in this area Within the last month, we submitted approximately twenty individual research abstracts on Angiomax to the American Heart Association and Transcatheter Cardiovascular Therapeutics national meetings Our research shows that Angiomax provides equal efficacy to other drugs, costs less, is easier to use, and causes less risk of bleeding complications Bleeding complications have been shown to increase mortality and are particularly common in

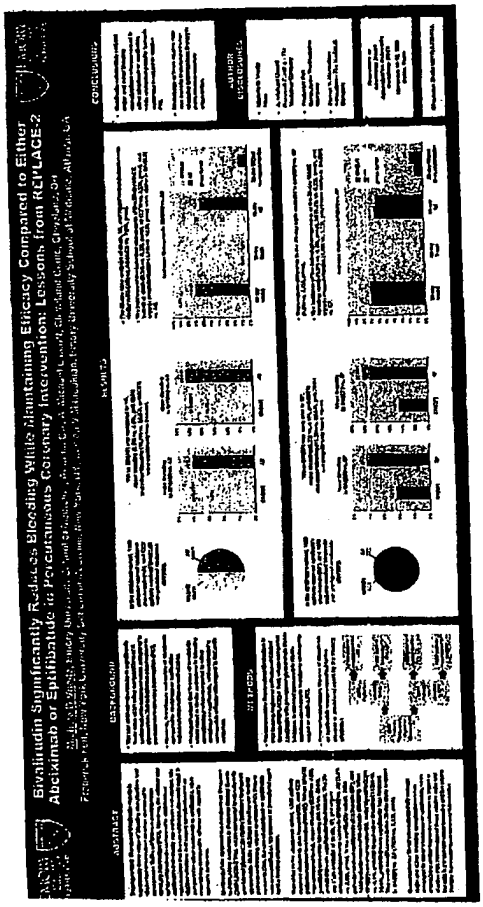
patients who are: elderly, female, African-American, and those with kidney disease, anemia, and high-blood pressure. I have attached two of our abstracts highlighting the consequences of bleeding complications. These types of patients make up the majority of the patients at our institution. Better outcomes and a reduction in healthcare costs with Angiomax is what we want for the patients of our community.

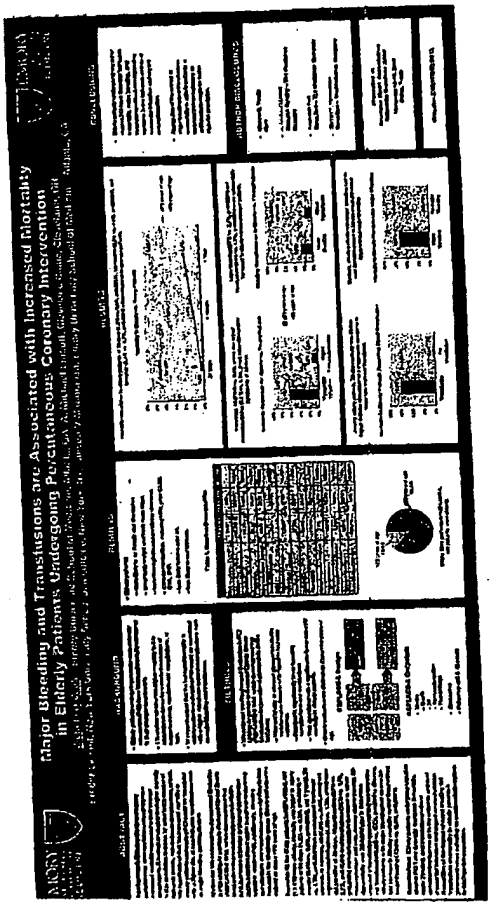
But that is only part of the story. Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year—one every 45 seconds; over 165,000 die and many thousands more are disabled for life. I know that you are aware that Georgia is part of the high-risk "stroke belt" In my capacity with the A.H.A., one of our major initiatives is reducing the risk of stroke. Unfortunately, the blood thinning and clot-busting agents currently utilized to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer bleeding side effects. But the very costly and time-consuming clinical trials (which Emory will likely be involved with) which will be needed to explore this and other promising new uses (such as patients undergoing open-heart surgery) will not be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that HR 5120 be enacted so that research in stroke is undertaken to evaluate the use of Angiomax in the treatment and prevention of this debilitating disease. I would be happy to discuss this matter further with you at your convenience; my direct office number is 404-686-2663.

Very truly yours,

Steven V. Manoukian, M.D., F.A.C.C
Director, Interventional Cardiology
Emory Crawford Long Hospital
Emory University School of Medicine


Bivalirudin Significantly Reduces Bleeding While Maintaining Efficacy Compared to Either Abciximab or Epifibatide in Percutaneous Coronary Intervention: Lessons from REPLAGE-2
ABSTRACT
BACKGROUND
RESULTS
METHODS
CONCLUSIONS
AUTHOR DISCLOSURES


Major Bleeding and Transfusions are Associated with Increased Mortality in Elderly Patients Undergoing Percutaneous Coronary Intervention

THE CLEVELAND CLINIC FOUNDATION

Heart Center

April 24, 2006

Deepak L. Bhatt, MD, FACC, FSCAI, FESC
Director, Interventional Cardiology Fellowship
Cardiac, Peripheral, and Carotid Intervention
Department of Cardiovascular Medicine / F25
Office: 216/445-6042
Appt.: 216/444-6697
Fax: 216/445-6531

Congresswoman Stephanie Tubbs Jones
United States House of Representatives
1009 Longworth House Office Building
Washington, DC 20515

Dear Representative Tubbs Jones:

I understand that you are considering a bill, HR 5120, related to the patent restoration provisions of the Hatch-Waxman law. I am an interventional cardiologist practicing at the Cleveland Clinic. I engage in the clinical care of patients with cardiovascular disease as well as in clinical research related to this complex and unique group of patients.

I am writing in support of HR 5120 because I understand that, if it passes, the anticoagulant drug Anglomax may become eligible for patent term restoration. This would allow for further investment in clinical development. I use Anglomax and have been involved in the study of Anglomax in acute care cardiovascular procedures, including heart attack and angina. Anglomax is an important therapy that provides safe and effective anticoagulation in interventional procedures with less bleeding than other treatments. These advantages also save the health care system money by reducing bleeding and providing single drug therapy versus combination drug therapy.

Patent term restoration for Anglomax is important because preliminary experience suggests that Anglomax may be useful in preventing and treating stroke, but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year--one every 45 seconds; over 165,000 die and many thousands more are disabled for life. Unfortunately, the blood thinning and clot-busting agents now available to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Anglomax may be useful in the prevention and treatment of strokes with fewer side effects. But the very costly and time-consuming clinical trials needed to explore this promising new use won't be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

9500 Euclid Avenue, Cleveland, OH 44195

It is vital that HR 5120 be enacted so that research on Angiomax in the prevention and treatment of strokes is undertaken to evaluate the drug in the treatment and prevention of this debilitating disease. I am available to discuss this matter further with you at your convenience.

Very truly yours,

Deepak L. Bhatt, M.D.

Deepak L. Bhatt, MD, FACC, FSCAI, FESC, FACP
Associate Director, Cleveland Clinic Cardiovascular Coordinating Center
Staff, Cardiac, Peripheral, and Carotid Intervention
Associate Professor of Medicine
Department of Cardiovascular Medicine
Cleveland Clinic Foundation
Cleveland, OH 44195 USA
Office: 216-445-4042
FAX: 216-445-8531

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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SANTA BARBARA • SANTA CRUZ

DEPARTMENT OF MEDICINE
UCLA SCHOOL OF MEDICINE
CENTER FOR THE HEALTH SCIENCES

Please Reply to:

CARDIOLOGY SECTION (111E)
V.A. HOSPITAL (WADSWORTH)
11301 WILSHIRE BOULEVARD
LOS ANGELES, CALIFORNIA 90073

September 6, 2006

Congresswoman Nancy Pelosi
United States House of Representatives
H-204 The Capitol
Washington, DC 20515-6537
Fax: 202 225-4188

Dear Congresswoman:

I understand that the Subcommittee on Courts, the Internet and Intellectual Property of the Judiciary Committee of the House of Representatives is considering a bill, HR 5120, relating to the patent restoration provisions of the Hatch-Waxman law. I am an interventional cardiologist practicing at The UCLA Medical Center and the Greater Los Angeles Veterans Administration Medical Center. I engage in the clinical care of patients with cardiovascular disease as well as in clinical research related to this complex and unique group of patients.

I am writing in support of HR 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. I use Angiomax and have been involved in the study of Angiomax in acute care cardiovascular procedures. Angiomax is an important therapy that provides safe and effective anticoagulation in interventional procedures with less bleeding than other treatments. These advantages also save money by reducing bleeding and providing single drug therapy versus combination drug therapy.

Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year—one every 45 seconds; over 165,000 die and many thousands more are disabled for life. Unfortunately, the blood thinning and clot-busting agents now available to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer side effects. But the very costly and time-consuming clinical trials needed to explore this promising new use won't be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that HR 5120 be enacted so that research in stroke is undertaken to evaluate the use of Angiomax in the treatment and prevention of this debilitating disease. I am available to discuss this matter further with you at your convenience.

Very truly yours,

Ramin Ebrahimi, M.D., FACC, FCCP, FSCAI
Associate Clinical Professor University of California Los Angeles
Director Cardiac Catheterization Laboratory Greater Los Angeles VA Medical Center
Assistant Director Nuclear Cardiology Greater Los Angeles VA Medical Center

September 13, 2006

The Honorable F. James Sensenbrenner, Jr.
Chairman, Committee on the Judiciary
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, DC 20515

The Honorable John Conyers, Jr.
Ranking Member, Committee on the Judiciary
2426 Rayburn Building
Washington, DC 20515

Dear Chairman Sensenbrenner and Ranking Member Conyers,

On behalf of the 800,000 members of FreedomWorks, I am writing to urge your support for H.R. 5120, a bill that would address a concern that has arisen in patent law and provide an environment that facilitates innovation and continued development of products that are beneficial to potentially millions of Americans. FreedomWorks has a long history of involvement with issues arising from the drug approval process, promoting policies that eliminate unnecessary delays that limit consumer access to important new therapies. In addition, FreedomWorks believes that at times the patent process may be abused and generics provide an important source of competition that generates substantial benefits to consumers. This legislation, however, is not an abuse of the system; it is an adjustment to the process that will ensure continued research and development. This issue also highlights the burden imposed by the drug approval process and I would urge Congress to also consider reforms in this area as well to ensure Americans have the access to the best care possible.

Briefly, H.R. 5120 would grant the U.S. Patent Office the discretion to consider an application for patent term restoration that unintentionally has been filed late, but within five days of the expiration of the 60-day filing period established in the Hatch-Waxman Act (see 35 U.S.C. Section 156(d)(1). The U.S. Patent Office has the discretion to accept late-filed submissions in a variety of patent and trademark proceedings, but it does not in instances of patent term restoration filings. H.R. 5120 would correct this anomaly.

Under the Hatch-Waxman Act, patent term restoration is an inducement for innovators and firms to undertake risky, time-consuming, and costly drug development and the FDA approval processes. Without patent term restoration, incentives for drug innovation are diminished and consumers would bear the costs as fewer resources are devoted to important lifesaving drug therapies.

As an example, the Medicines Company failed to receive patent restoration because its filing was unintentionally filed one day late. The firm was in the process of conducting important additional research on Angiomax, a drug initially approved as a blood thinning agent. New research, however, suggests that Angiomax may be beneficial for use in the prevention and treatment of stroke, which is the leading cause of disability and third leading cause of death in the

1775 Pennsylvania Ave., NW, 11th Floor Washington, DC 20006 PH: 202.783.3870 www.freedomworks.org

United States. Unfortunately, without patent restoration, the ability to conduct the additional research and commit to the costly approval process are eliminated, leaving consumers with fewer choices for critical health care decisions.

Unlike other areas of patent law, the inflexible filing deadline is clearly draconian. The Hatch-Waxman act provides incentives to invest in the costly and time-consuming drug approval process, yet the inflexibility built into the current law can destroy those incentives and have a disproportionate impact on the process, and reduce opportunities for innovation. H.R. 5120 brings this application of patent law more in line with the broader process for patent and trademark proceedings. Given the importance of innovation in the field of health care, and the potential impact on the lives of Americans, I urge you to support this important legislation.

Sincerely,

Matt Kibbe
President and CEO
FreedomWorks

cc: Subcommittee on Courts, the Internet, and Intellectual Property

Hon. Lamar S. Smith, Chairman	Hon. Howard L. Berman, Ranking Member
Hon. Henry J. Hyde	Hon. Rick Boucher
Hon. Elton Gallegly	Hon. Zoe Lofgren
Hon. Bob Goodlatte	Hon. Maxine Waters
Hon. William L. Jenkins	Hon. Martin T. Meehan
Hon. Spencer Bachus	Hon. Robert Wexler
Hon. Robert D. Inglis	Hon. Anthony D. Weiner
Hon. Ric Keller	Hon. Adam B. Schiff
Hon Darrell E. Issa	Hon. Linda T. Sánchez
Hon. Chris Cannon	
Hon. Mike Pence	
Hon. J. Randy Forbes	

RetireSafe

Preserving Your Retirement. Securing Your Benefits.

September 13, 2006

The Honorable F. James Sensenbrenner
Chairman
House Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Sensenbrenner,

On behalf of the almost 400,000 senior citizens represented by RetireSafe, I am writing to inform you of our support of H.R. 5120, legislation that would correct a troubling anomaly in the patent law that can hinder innovation and stymie life-saving research. Currently, the Hatch Waxman Act allows the owner of a drug patent to obtain time restored to its patent to make up for time lost while awaiting FDA approval. H.R. 5120 would permit the Patent and Trademark Office to accept an application within five days of the deadline if the PTO determines the filing de ay was unintentional.

RetireSafe urges the House Judiciary Committee to support this much needed legislation that can benefit millions of seriously ill patents It's unfortunate, but when years of patent protection on a drug are forfeited due to a minor clerical error, the benefits of further research and development of critical drugs is often lost. Ironically, there are more than 30 patent laws and regulations on the books giving the PTO the discretion to accept minor application errors and late filings, but not under Hatch-Waxman. We believe such rigid rules undermine the intent and basic purposes of the patent law.

Furthermore, there are absolutely no downsides to fixing this problem. The bill would not upset the balance of Hatch-Waxman; it would simply avoid a premature cutoff of earned patent rights due to minor clerical error. Generic manufactures will also still have the same right they now enjoy to file an application to bring out a new drug, and this right would still be keyed to the date FDA approves the patent owner's drug use.

For instance, take the case of the drug Angiomax, made by a small drug company, which had earned the right to patent restoration but missed the filing deadline by *one* day. Research into promising new applications of Angiomax for cardiac and stroke patients – applications which are critical to older Americans – will be cut short if this legislation is not passed. If Angiomax loses its patent protection prematurely, this critical research opportunity will be lost entirely as it will *never* be conducted by generic manufacturers. The end result will mean that 13 million Americans including the millions of seniors with coronary artery disease will never benefit from this potentially life-saving drug.

Angiomax is just one example of a drug that has faced this filing deadline issue. Two

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www.retiresafe.org

other companies have missed the Hatch-Waxman filing deadline by *one* day and others will doubtless make minor filing errors in the future. Cardiac and stroke patients will clearly benefit from this bill. H.R. 5120 is good public policy that will help save lives and provide a better quality of life for seriously ill patients, and it should be enacted immediately.

In short, H.R. 5120 does not give anything to patent owners that the Hatch-Waxman law did not intend to give them and does not take anything away from the generic manufactures that the Hatch-Waxman law intended to provide. It merely gives PTO the discretion to consider whether or not to accept an application for patent term restoration after hearing all the facts.

I urge you and your committee to support H.R. 5120 and help millions of seniors in this country who are currently suffering or at risk for coronary artery disease and need innovative life-saving medications. It is my hope you will agree that H.R. 5120 is good public policy with an overriding public health benefit.

Sincerely,

Michelle Plasari

Michelle Plasari
RetireSafe

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CENTER FOR INDIVIDUAL FREEDOM

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September 12, 2006

Chairman F. James Sensenbrenner, Jr.
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

Congressman John Conyers, Jr.
Ranking Member
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Sensenbrenner and Congressman Conyers:

On behalf of the Center for Individual Freedom and its more than 250,000 supporters and activists nationwide, I am writing to urge you to support H.R. 5120. This bill grants the Patent and Trade Office Director the discretion, where fair and appropriate, to accept slightly overdue patent-term restoration applications under the Hatch-Waxman law.

Under current law, an application unintentionally filed even one day late *must* be denied – the Director possesses absolutely no discretion whatsoever. Such a rigid command creates unfair outcomes, and arbitrarily jeopardizes enormously valuable property rights.

Throughout other realms of business, legal, and personal life, equitable grace periods exist. For example, other federal agencies such as the Internal Revenue Service possess discretion to accept slightly overdue submissions. If even the "Tax Man" can have a heart, the Patent and Trademark Office should also be allowed similar discretion.

It is also important to put H.R. 5120 into perspective: the bottom line is that a company should not have to pay the price of millions or even billions of dollars in revenue due to a simple and unintentional clerical error. Companies invest billions of dollars in product research and development, and recouping those investments through patent protection is what allows our innovative economy to thrive.

Moreover, other patent laws and regulations allow the Patent and Trade Office discretion to excuse minor mistakes, such as filing documents or making payments. Thus the current Hatch-Waxman deadline provision stands as an anomaly by prohibiting any type of discretion. In our view, this anomaly should be fixed, and H.R. 5120 does just that.

If an individual unintentionally pays their mortgage payment one day late, does the bank seize their home? No. If property taxes are paid one day late due to a bank disbursement error,

does the government automatically seize your property? Obviously not. Should a different standard apply to a company whose very existence depends upon a patent that they hold?

Opponents of this rational legislation claim that it would somehow benefit one particular company, but that is incorrect. Rather, any company that can prove that its slight delay was unintentional would be treated more fairly. This is simply good public policy.

Indeed, the only beneficiaries of perpetuating the current regulations are generic companies who stand to gain an unfair windfall by pounding whenever a patent owner accidentally files a few days late. Perpetuating such inequitable windfalls for generic companies is an inappropriate public policy result. Maintaining the Hatch-Waxman mandate as-is will lead to the further loss of highly valuable patent rights for no good reason. In contrast, fixing it through H.R. 5120 will help all innovators, both present and future.

Further, H.R. 5120 does not give the patent holder a "carte blanche, no questions asked" grace period. It does not allow for indefinite patents, nor does it imply continued protections due to intentional negligence. Rather, it allows a five-day grace period for a patent restoration filing that was unintentionally delayed. Five days.

Finally, Congress routinely revisits statutes in order to fix loopholes and anomalies. Very simply, mistakes happen, as does the law of unintended consequences. In the case of Hatch-Waxman, allowing a simple five-day grace period will not undermine or compromise the growth of the generics market in the United States. Rather, H.R 5120 will merely align patent restoration filing rules with the other discretions enjoyed by the Patent and Trademark Office.

Accordingly, the Center for Individual Freedom urges you and all members of the Judiciary Committee to pass H.R. 5120, allowing it full consideration by the U.S. House of Representatives. Fairness and equity demands it, and we will monitor members' votes on this critical matter and communicate them to our constituency.

Thank you very much for your time and consideration.

Sincerely,

Timothy H. Lee, Esq.
Director of Legal and Public Affairs

CC:
The Honorable Lamar S. Smith
The Honorable Henry J. Hyde
The Honorable Elton Gallegly
The Honorable Bob Goodlatte
The Honorable William L. Jenkins
The Honorable Spencer Bachus
The Honorable Bob Inglis
The Honorable Ric Keller
The Honorable Darrell Issa
The Honorable Chris Cannon
The Honorable Howard L. Berman
The Honorable Mike Pence
The Honorable Randy Forbes
The Honorable Rick Boucher
The Honorable Zoe Lofgren
The Honorable Maxine Waters
The Honorable Marty Meehan
The Honorable Robert I. Wexler
The Honorable Anthony D. Weiner
The Honorable Adam Schiff
The Honorable Linda T. Sanchez

LETTER FROM LAWRENCE GOFFNEY

Lawrence J. Goffney
120 Waterford Place
Alexandria, VA 22314-3860

(703) 518-0214
LGoffney@comcast.net

September 13, 2006

The Honorable Lamar Smith, Chairman
The Honorable Howard Berman, Ranking Member
Subcommittee on Courts, The Internet, and Intellectual Property
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman and Mr. Berman,

My name is Lawrence J. Goffney, Jr., perhaps I am better known as "Larry Goffney." I am a former Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks and a former Assistant Commissioner for Patents (now known as the "Commissioner of Patents") with the United States Patent and Trademark Office (the "PTO"). In connection with the hearing that you are holding tomorrow on H.R. 5120, it has come to my attention that there are a number of issues that warrant clarification with respect to this legislation.

Simply put, H.R. 5120 is perfectly consistent with both the Hatch-Waxman system and the general authority to excuse unintentional errors in patent practice.

The bill would provide the Director with the authority to excuse a late filing under 35 U.S.C. § 156 caused by an unintentional error. This authority, however, is limited to filings within a very short period of five days after the original due date that are accompanied with a petition explaining to the Director's satisfaction the unintentional error. The short window for forgiveness in the bill ensures that errors that could be corrected by this authority will in no way disrupt the handling of patent term extension applications within the PTO. Indeed, virtually no formal or substantive review will have occurred within the PTO within five days of the original deadline for filing of a § 156 application.

The provision of a 5-day grace period to address an unintentional late filing will not affect, in any manner, the decision-making process that generic firms follow regarding filing of Abbreviated New Drug Applications ("ANDA"), the marketing of generic drugs, or the initiation of patent challenges under the Hatch-Waxman system. Simply put, the date on which an application for patent term restoration is filed has no relevance to the decisions made by the generic company as to whether to market a generic drug. Rather, those decisions are based on factors such as the size of the market of a pioneer drug, the strength or coverage of a patent, and

the business risks the generic manufacturer is willing to undertake in seeking early marketing of a generic copy of a drug product.

In addition, the precedent for an "unintentional error" standard for § 156 applications in the rest of the patent system is overwhelming. Few firm deadlines are present in the patent laws; instead the PTO has been granted the discretion to extend deadlines that would affect substantive rights in a number of circumstances. The agency is extremely familiar with the "unintentional error" standard being proposed in H.R. 5120. Indeed, this is the standard most commonly used by the PTO in determining whether to accept late filings under other statutory provisions. There is thus little basis for concluding that H.R. 5120 is inconsistent with or anomalous to the patent laws or that the "unintentional error" is not an objective standard that will prove difficult for the PTO to apply.

Finally, there is considerable precedent for having patent legislation apply to issued patents and pending applications rather than having only a prospective effect. Most patent legislation that Congress has passed in the last twenty years has applied at least in part to pending applications or existing patents.

1. The Present Statutory Scheme Contemplates Delays Greater Than 60 Days in the Filing of a Completed Patent Term Restoration Request

The PTO has exercised its rule-making authority to provide that an application for patent term extension must include 15 elements. 37 C.F.R. § 1.740(a). Notwithstanding this exercise of its rule-making authority, the PTO has further exercised its rule-making authority to provide that an application containing less than all of the required 15 elements will be treated as timely filed if it provides certain of the required information. These elements roughly correspond to those specified in 35 U.S.C. § 156(d)(1). If that information is provided, the patentee has two months—plus the additional time available upon the payment of surcharges pursuant to the PTO's usual practice—to provide the missing or incomplete elements of the application. 37 C.F.R. § 1.741(b).

Arguments that the five day grace period that would be provided by H.R. 5120 will disrupt the orderly processing of § 156 applications, or will cause other unprecedented disruptions, ignore both the existing authority to correct informal errors already in the system, and the broader experience under PTO practice. H.R. 5120 would provide a grace period of 5 days (and would afford the PTO 30 days to determine whether the patentee is entitled to the grace period). This period is significantly shorter than the period already allotted for initial review of §156 applications. For example, the system already contemplates a potential delay in processing of two months, plus the additional time available upon the payment of a surcharge, before the request for patent term extension will be substantively processed. Moreover, 37 C.F.R. § 1.741(b)'s use of two months to establish the time within which the application must be completed underscores that a difference of a few days is inconsequential to the process. For example, if the two-month period includes December and January, 62 days are afforded the patentee. If, on the other hand, the two-month period is measured by January and February the patentee is afforded 58 days in the normal year but 59 days in a leap year. Indeed, it is likely that nothing more than initial processing by the PTO mailroom will have occurred within 5 days of the 60 day statutory deadline provided by 35 U.S.C. § 156.

2. Determining the Amount of Patent Term Restoration is a Lengthy Process.

Similarly, introducing a 5-day grace period will not lengthen the time it takes to process a request for patent term restoration. That is because, although the Secretary of the Department of Agriculture (for certain veterinary drugs) or the Secretary of Health and Human Services (in the case of human drugs) must be asked to calculate the applicable "regulatory review period" within 60 days of receiving the application, there is no set period within which that calculation must be made.

Research into the average time it takes to make that calculation reveals the calculation period is far longer than the fixed time periods specified in these regulations. For example, a review of all of the available requests for patent term extension filed between 1996 and 2005 reveals that the average time taken by the Secretary of Health and Human Service to make a determination was 1121 days—3.08 years. In context, the 5-day grace period provided by H.R. 5120 is 0.44% of that period. Those who point to the deadlines for subsequent proceedings frequently omit the fact that by far the largest amount of time consumed in that process is the period taken by the Secretary of Health and Human Services to make its determination.

3. The Date of Filing of A Request for Patent Term Restoration is Irrelevant to Generics.

Suggestions that the *timely* filing of a § 156 application somehow factors into the decision-making process of a generic drug manufacturer are disingenuous. The only dates having any importance to third parties, such as generics, are the dates of FDA approval of the drug (from which the time to file a paragraph 4 certification under Hatch-Waxman is computed) or the date on which the patent (including any restored term) expires. In fact, until recently, there was virtually no information made available to the public about these filings. A person wishing to determine if a § 156 application has been filed at that date had to travel to a small filing room at the Office of Patent Legal Administration at the PTO and hand search the paper records. Today, information on patent term extension applications is still only sporadically available through the PTO's Patent Application Information Retrieval system. The lack of ready access to the information is hardly surprising in light of the fact that the mere filing of a § 156 application has no significance.

4. Granting The PTO The Discretion To Accept A Late Extension Filing Would Align The Patent Term Extension Process With Other Patent Deadlines

One of the other main clarifications to make about H.R. 5120 is that it corrects an anomaly in the patent law. It has been noted by some of the opponents of the bill that certain provisions of the Patent Act and the Hatch-Waxman Act include deadlines that are not flexible. Contrary to these suggestions, the norm is flexibility, not punitive inflexibility.

The few fixed deadlines that exist in the Patent Act are directed almost exclusively to a person's decision to pursue patent protection or from obligations the United States has under treaties. When it comes to granting an inventor the right to exclude the public from an invention, or the right to claim an even broader invention than what was claimed in his original patent, the patent laws require prompt action. Statutes such as 35 U.S.C. § 102(b) and 35 U.S.C. § 251

force the prospective patentee to file a patent or an amendment to a patent within a specific time frame to avoid upsetting settled expectations of the public, who had access to the invention for over a year before the application claiming the invention was filed, in the case of 35 U.S.C. § 102(b), or had access to a patent limiting the scope of its claims for two years, in the case of 35 U.S.C. § 251. The patent laws are therefore protective of the public when information is being removed from the public domain.

The patent term extension provision of 35 U.S.C. § 156 is not analogous to statutes that increase the scope of the patent owned by an inventor. There is no new intellectual knowledge that is removed from the public or called into question when a patent applicant files for an extension. Instead, the term of the patent increases in order to compensate the patentee for the delay it experienced during the FDA approval process. Congress approved this increase in the patent term as part of the Hatch-Waxman Act in 1984; it thus has already decided that the extension is worth the cost to the public.

Once a patent application has been filed, the Patent Act provides for extraordinary flexibility in the prosecution and administration of the patent. As noted by the PTO in its letter dated August 30, 2006, the PTO currently has discretionary authority in a "number of situations" to accept late-filed submissions. This discretion extends to the ability to correct patent term extension applications, as discussed above, 37 C.F.R. § 1.741(b); revive abandoned applications, 37 C.F.R. § 1.137; pay required maintenance fees, 35 U.S.C. § 41, and claim the benefit of earlier foreign filing or priority dates, 35 U.S.C. § 119(b)(2), 35 U.S.C. § 120. Research has shown that there are at least thirty examples of such flexibility in the patent laws and regulations, most of which could otherwise result in the loss of substantive rights due to an unintentional error.

With respect to the Hatch-Waxman Act, the consequence for failing to file a patent term extension with 60 days is orders of magnitude more harsh than the penalties incurred by missing the other fixed deadlines in the Act. For example, Section 505(b)(2) requires the patentee to file a lawsuit against an ANDA applicant within 45 days of receiving notice that the application has been filed. The consequence for missing that deadline is not to eliminate the right to sue, however. Instead, the patentee is not granted an automatic 30-month stay of approval of the ANDA that challenges the patent. The loss of the 30-month stay does not foreclose the ability of the patentee to sue the generic manufacturer or enjoin its marketing of the generic product. Similarly, while the ANDA applicant has 20 days to give notice to the patent holder, there are no prescribed consequences if this deadline is not met. The other provision of the Hatch-Waxman Act that has been identified –the 180-day generic exclusivity period granted to the first ANDA filer to include a patent challenge–is more aptly termed a "race to the FDA" than a deadline. Indeed, the failure of an ANDA filer to file its ANDA with a patent challenge on the first day possible does not automatically lead to an inability of that filer to receive 180-day exclusivity. Instead, exclusivity remains a possibility as long as there is no earlier filer. Comparing a race to win exclusivity to a loss of an earned patent term restoration period attempts to compare apples and oranges.

5. **The PTO Is Familiar With The Standard Used In H.R. 5120.**

The PTO is not only familiar with having discretion to accept late-filed submissions, it is also familiar with the standard that H.R. 5120 asks them to apply: unintentional delay. Contrary to concerns raised by some commentators, unintentional delay has a well-defined meaning within the PTO. According to our research, the unintentional error standard is the most common standard used by the PTO to determine whether to excuse a late filing. The standard is used by the PTO for example to determine whether to revive an abandoned patent, 37 C.F.R. § 1.137(b); revive a patent that has expired because of a failure to pay maintenance fees, 35 U.S.C. § 41(c); file tardy responses in reexamination proceedings, 37 C.F.R. § 1.550 and § 1.958, among others. The term "unintentional delay" has even been defined in the MPEP, which is the authority for handling applications for patents within the PTO. The MPEP definition is that such a delay is one that is not the result of a "deliberately chosen course of action on the part of the applicant." M.P.E.P. § 711.03(c). With all such standards, the agency has ample experience in evaluating the merits of the case before it and applying the appropriate standard.

6. **The PTO Is Familiar With The Standard Used In H.R. 5120.**

H.R. 5120 has also been questioned because it applies not only to prospective applications, but also to applications that are currently pending. This is common practice in patent legislation, however—Congress routinely permits patent holders and patent applications to take advantages of the benefits granted by new legislation. Research has shown that nearly every bill amending the patent statute has applied to pending applications and pending patents in at least some respects. This includes provisions in the Cooperative Research and Technology Enhancement Act ("CREATE") (Pub.L.108-453); the American Inventors Protection Act ("AIPA") of 1999 (Pub. L. 106-113); Biotechnology Process Patent Amendments Act (Pub. L. 104-41), and the Uruguay Round Agreements Act ("URAA") (Pub. L. 103-465).

Sincerely,

Lawrence K. Goffney, Jr.

Lawrence J. Goffney, Jr. has, since January 2000, consulted on intellectual property and serves as an expert witness on patent issues, including proceedings before the United States Patent and Trademark Office. Since January 2000, he has testified in court or by deposition in over 50 cases, many involving ANDA litigation. He is registered to practice before the U.S. Patent and Trademark Office, and he is licensed to practice before the state and federal courts in the State of Michigan and before other federal courts, including the U.S. Court of Appeals for the Federal Circuit

Until January 2000,he was a partner with Akin, Gump, Strauss, Hauer & Feld, L.L.P., in Washington, where he was a member of the firm's intellectual property practice.

From 1996 until 1998, prior to joining Akin, Gump, Mr. Goffney was the Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks at the USPTO, a position to which he had been designated by the Secretary of Commerce.

In 1994, he had been appointed by the President and confirmed by the Senate to the position of Assistant Commissioner for Patents, in which capacity he ran the entire U.S. official patent process (the "Patent Office") from application to issue. In this capacity, and later as Deputy Commissioner, he attended Trilateral Meetings officials

Prior to entering government service as a senior official in January, 1994, Mr. Goffney was a partner in the Michigan based law firm of Dykema Gossett. From 1974 until 1983, he was a law professor on the faculties of the University of Texas and the University of Detroit, a visiting professor at the University of Wisconsin and a Harvard Fellow in Law and the Humanities.

Mr. Goffney received a B.S. with honors in 1970 from Oakland University. He attended Carnegie Institute of Technology (now Carnegie-Mellon University). He received a J.D. in 1974 from the University of Detroit and an LL.M. in 1974 from Columbia University, where he was a Burton Fellow in Intellectual Property. In 1975, Mr. Goffney received a certificate from the Parker School in Foreign and Comparative Law at Columbia University.

TESTIMONY FROM THOMAS SCHATZ, PRESIDENT, CITIZENS AGAINST GOVERNMENT WASTE

Testimony

Thomas A. Schatz,
President,
Citizens Against Government Waste
before the
House Committee on the Judiciary,
Subcommittee on Courts, the Internet, and Intellectual Property
September 14, 2006

H.R. 5120
A bill to amend title 35 of the United States Code, to conform certain filing provisions within the Patent and Trademark Office

or

"The Dog Ate my Homework Act"

1301 Connecticut Avenue, N.W.
Suite 400
Washington, D.C. 20036
202-467-5300

1

Mr. Chairman, members of the subcommittee, thank you for having this hearing to discuss H.R. 5120 and allowing me to submit testimony on behalf of the more than 1.2 million members and supporters of Citizens Against Government Waste (CAGW). We hope that this hearing will shed light on what we believe is an irresponsible attempt to change U.S. patent law and throw a cog into the wheel of the landmark Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, that governs the approval process for generic drugs. Hatch-Waxman seeks to balance two important but highly competitive goals: provide quick market access for generic manufacturers and encourage brand-name drug manufacturers to incur the high cost of drug research by providing patent term restoration to compensate for the Food and Drug Administration (FDA) regulatory review time.

CAGW was created in 1984 By J. Peter Grace and Jack Anderson after Mr. Grace presented to President Ronald Reagan the 2,478 findings and recommendations of the Grace Commission (formally known as the President's Private Sector Survey on Cost Control). If all of the Grace Commission's recommendations had been implemented, it would have saved $424.4 billion over three years. In fact, savings from Grace Commission and other CAGW-proposed recommendations have saved $825 billion over 22 years.

CAGW is classified as a Section 501(c)(3) organization under the Internal Revenue Code of 1954, has not received any federal money, and does not plan to receive any federal funds in the future.

H.R. 5120 has no specific title, but should be called, "The Dog Ate My Homework Act." Simply put, this legislation will allow the Director of the U.S. Patent and Trademark Office (PTO) to accept an application for an extension of the term of a patent if an application is filed no more than 5 days late and if the applicant files a petition showing that the delay in filing the application was unintentional. If no attention had been paid to this legislation, it might have been added to an appropriations bill in the dead of night. There would have been no hearing or analysis of how it would drastically change current drug approval law. We therefore appreciate the effort being made to address this matter in an open hearing.

As you know, The Medicines Company acquired the anti-coagulant drug Angiomax from Biogen in 1997, received their New Drug Application (NDA) from the FDA on December 15, 2000, and began to sell the drug in January 2001. The company filed for a patent extension until December 15, 2014. Current patent law states that a company has 60 days from the day of NDA approval to file a patent term extension. That day came and went on February 13, 2001. Unfortunately for The Medicines Company,

their representative waited until they thought was the last minute to file this simple application. By filing the extension on February 14, 2001, The Medicines Company missed the statutory deadline. The PTO said precisely this in a letter to the company, dated March 4, 2002: "The NDA was approved on December 15, 2000, which makes the submission of the patent term extension application on February 14, 2001, untimely within the meaning of 35 U.S.C. 156(d)(1)..."

CAGW is concerned that the PTO has left this matter pending for several years in order to provide The Medicines Company with the opportunity to explore avenues to extend the term of its patent. According to patent lawyers with whom we have spoken, this is unusual. CAGW is also concerned that the PTO is under pressure to keep this application open, possibly anticipating that H.R. 5120 will be enacted.

H.R. 5120 is special interest legislation at its worst. It would allow the Director of the PTO to accept an application for an extension of the term of a patent if an application is filed no more than 5 days late, if the applicant files a petition showing that the delay in filing the application was unintentional. Why? Because one company missed a statutory deadline that has existed since 1984. As it states in H.R. 5120, it would apply to any application that, "is pending on the date of enactment, is the subject of a request for reconsideration of a denial of a patent extension, or has been denied a patent term extension in a case in which the period for seeking reconsideration of such denial has not yet expired." The PTO admits as much when it states in its letter to the Subcommittee on Courts, the Internet, and Intellectual Property that, "We are aware of one current application for patent term extension that would immediately benefit from enactment of the bill."

Of further concern is the legislative language that states, "if the applicant files a petition showing, to the satisfaction of the Director, that the delay in filing the application was unintentional." How does one prove that a delay was "unintentional?" Talk about opening up a can of worms and prompting numerous lawsuits! At best, the phrase exposes PTO to all sorts of political shenanigans and lobbying pressure. At worse, it is an automatic 5-day extension on patent term extension applications. It is far better to have certainty on patent extension applications. The current statute provides that certainty without burdening the public with additional patent extensions – extensions that delay generic competition.

As CAGW stated in a June 19 letter to the Judiciary Committee, timelines written into laws have meaning. Furthermore, how likely is it that a company that has its product regulated under the Food, Drug, and Cosmetic Act will miss this kind of important deadline? Again, the PTO provides insight. Of the 700 applications for patent term

extensions filed since 1984, when Hatch-Waxman was enacted, only three other applications were not granted due, at least in part, to timeliness issues. That is 0.4 percent of total applications. Surely this doesn't warrant legislation that will provide a window to cover delays in patent extension filings. In other words, making a law to cover an exception benefits the one to the detriment of the many who have complied with the regulatory deadlines.

CAGW understands and appreciates the importance of patents, property rights and the role research pharmaceutical companies play in our nation's health and economy. We have long fought against legislation that jeopardizes the vital work pharmaceutical companies do, such as price controls and the re-importation of prescription drugs.

But CAGW also appreciates the vital role that the generic industry plays in health care. Generics encourage competition and lower the price of pharmaceuticals for all Americans.

The bottom line is H.R. 5120 gives an unfair advantage to one company and dramatically changes patent law. It is in fact private relief legislation disguised as public law.

CAGW believes any changes to Hatch-Waxman and patent exclusivity deserve close examination. We appreciate this hearing, but other committees need to review this legislation before it goes forward, such as the House Energy and Commerce Committee, and it deserves a full review in the appropriate Senate committees.

Neither Congress, nor taxpayers and consumers, should be used to cover-up and correct any company's errors. H.R. 5120 sets a dangerous precedent and it should not become law.

○

Attachment 4

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MAY - 1 2000

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,911,920 was filed on April 26, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, BETAXON™ (levobetaxolol), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156, unless levobetaxolol[1] has been previously approved.[2]

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[1]The chemical name of levobetaxolol hydrochloride is 2-Propanol, 1-[4-[2-(cyclopropylmethoxy)ethyl]phenoxy]-3-[(1-methylethyl)amino]-hydrochloride(S)- and its empiric formula is $C_{18}H_{29}NO_3.HCl$.

[2]It is noted that the New Drug Approvals list for February, 2000 at http://www.fda.gov/cder/da/da0200.htm shows that levobetaxolol hydrochloride is not considered a new chemical entity. The entry for NDA 02-1114, BETAXON, Active Ingredient(s): levobetaxolol hydrochloride states that the product is chemical type 2 (New derivative: A chemical derived from an active ingredient already marketed (a "parent" drug)). Betaxolol hydrochloride (racemic, includes levobetaxolol hydrochloride) was previously approved in the products Kerlone, on October 27, 1989, and Kerledex, on October 30, 1992, for example, but no record has been found of a prior approval of levobetaxolol hydrochloride alone. (See enclosure.)

Any correspondence, especially any change of address from applicant, with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

By FAX: (703) 308-6916 or (703)941-8711
Attn: Karin Tyson

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson

Karin Tyson, Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

cc: Sally S. Yeager
R&D Counsel, Q-148
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth TX 76134

Enclosure: USP Dictionary of USAN and International Drug Names (1998), Page 95
Prescription and OTC Drug Product, Patent and Exclusivity Data, Page AD22
Prescription Drug Product List, pages 3-44 and 3-45

Attachment 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 17 2001

Re: Betaxon
Docket No. 00E-1402

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,911,920 filed by Alcon Laboratories under 35 U.S.C. § 156. The human drug product claimed by the patent is Betaxon (levobetaxolol), which was assigned new drug application (NDA) No. 21,114.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

Under 35 U.S.C. § 156(d)(1), the patent term extension must be submitted within 60 days of the product's approval, or on the next business day after the sixtieth day if the sixtieth day falls on a weekend or holiday. In the case of Betaxon, the NDA was approved on February 23, 2000. The sixtieth day after approval fell on Sunday, April 23, 2000, so the deadline for submission of the patent term extension application was the next business day, April 24, 2000. However, the patent term extension application was not submitted until April 26, 2000, which is not timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Sally Yeager
Alcon Laboratories, Inc.
R&D Counsel, Q-148
6201 South Freeway 76134
Fort Worth, TX 76134

Attachment 6

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

MAR 13 2002

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,911,920. The application was filed on April 19, 2000, under 35 U.S.C. § 156. The application was received by the undersigned on April 26, 2000, but was mailed by Express Mail on April 19, 2000, and is entitled to a filing date of April 19, 2000. As a result, the application was timely filed.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Sally Yeager
Alcon Laboratories Inc.
R&D Counsel Q-148
6201 South Freeway 76134
Fort Worth TX 76134

kt

Attachment 7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-873

DEC 15 2000

The Medicines Company - 617-225-9099
Attention: Sonja Loar, Pharm. D.
One Cambridge Center
Cambridge, Massachusetts 02142

Dear Ms. Loar:

Please refer to your new drug application (NDA) dated December 23, 1997, received December 23, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Angiomax™ (bivalirudin) Injection.

We acknowledge receipt of your submissions dated April 6, May 12 and 17, July 14, October 9, November 9, and December 1, 2000. Your submission of July 14, 2000, constituted a complete response to our May 11, 2000, action letter.

This new drug application provides for the use of Angiomax™ (bivalirudin) Injection as an anticoagulant in conjunction with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA).

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted draft labeling (immediate container and carton labels submitted July 14, 2000). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-873." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing commitment in your submission dated December 1, 2000. This commitment is listed below.

Commit to completing Study TMC 98-10 entitled "Anticoagulant Therapy with Bivalirudin to Assist in the Performance of Percutaneous Coronary Intervention in Patients with Heparin-Induced Thrombocytopenia: An Open Label Study of Bivalirudin for Heparin-Induced Thrombocytopenia (HIT) or Heparin-Induced Thrombocytopenia and Thrombosis Syndrome (HITTS)" and submitting the full report for that study.

Final Report Submission: Within 36 months of the date of this letter.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Gastrointestinal and Coagulation Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Julicann DuBeau, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Victor F.C. Raykowski 12/15/00 FOR FH

Florence Houn, M.D., M.P.H., F.A.C.P.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

Attachment 8

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

FEB 8 1993

In re Sankyo Company Limited	:	
Request for Patent Term Extension	:	DECISION DENYING
U.S. Patent No. 4,486,425	:	APPLICATION
	:	

An application for extension of the patent term of U.S. Patent No. 4,486,425 granted on December 4, 1984, was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on December 7, 1992. The application for extension was filed by the assignee of record Sankyo Company Limited through its duly authorized agent, The Upjohn Company. Applicant requests a 3.2 year extension of the '425 patent on the basis of new drug applications (NDAs) simultaneously approved by the Food and Drug Administration (FDA) for a product containing the active ingredient cefpodoxime proxetil. The '425 patent claims the active ingredient cefpodoxime proxetil in the drugs VANTIN Tablets, VANTIN Oral Suspension, BANAN Tablets, and BANAN Oral Suspension.

The FDA official records indicate that the product was subject to a regulatory review period before its commercial marketing or use, as required under 35 USC § 156 (a)(4), and that it represents the first permitted commercial marketing or use of the active ingredient cefpodoxime proxetil.

The New Drug Applications were approved on August 7, 1992, which makes the submission of the patent term extension application outside the sixty-day period beginning on the day the NDAs were approved, and accordingly, untimely within the meaning of 35 USC § 156 (d)(1). However, applicant requests that the application be considered as timely filed since the failure to file within the sixty days was "unintentional". Applicant claims that due to a misunderstanding between it and its U.S. licensee, The Upjohn Company, applicant was not aware until December 4, 1992, that the patent extension application had not been filed. Therefore, applicant requests that the sixty-day period referred to in 35 USC § 156 (d)(1) be interpreted as commencing on the date that applicant first became aware of an "unintentional" failure to file an application for extension.

Applicant maintains that public policy supports the requested remedial interpretation of the duration of the sixty-day period, arguing that Congress has twice in the last ten years (1982 and 1992) amended the patent statutes to remedy unintentional failures to act. Applicant notes the court in Unimed v. Quigg, 12 USPQ2d 1644, 1646 (Fed. Cir. 1989) stated that the sixty-day period in section 156 (d)(1) begins on the FDA approval date, but argues the court's decision was before the latest statement from Congress evincing a remedial approach to such matters, and involved different facts than those herein.

Section 156 (a)(3) provides that an application for patent term extension must be submitted by the owner of record of the patent or its agent in accordance with the requirements of subsection (d). Subsection 156 (d)(1) provides:

> (1) To obtain an extension of the term of the patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. ... (emphasis added).

The starting point for statutory interpretation is the plain language of the statute. The statute itself must be regarded as conclusive of the meaning absent a clearly contrary legislative intent. Burlington Northern R.R. Co. v. Oklahoma Tax Comm'n, 481 U.S. 545, 461 (1987); Ethicon v. Quigg, 849 F.2d 1422, 7 USPQ2d 1152 (Fed. Cir. 1988). Statutory words are normally presumed, unless the contrary appears, to be used in their ordinary and usual sense, and with the meaning commonly attributed with them. Calminetti v. United States, 242 U.S. 470, 485 (1917) [the meaning of a statute must, in the first instance, be sought in the language in which the act is framed and, if that is plain, the sole function of the court is to enforce it according to its terms].

The plain language of the statute states that an application for patent term extension is timely only if submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. Read in the light of the definition of "regulatory review period", this language is crystal clear. Unimed v. Quigg, supra at 1646. Applicant's application was filed outside the sixty-day period. Clearly it would be inconsistent with the plain language of the statute to make the sixty-day requirement a subjective test based on remedial considerations or on the patent owner's

intent, knowledge or inaction, as the clarity of the statute admits of no other meaning than that the sixty-day period begins on the FDA approval date. Accordingly, the application for patent term extension must be denied because it was not filed within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use.

For the reasons advanced above, the term of U.S. Patent 4,486,425 is not eligible to be extended under 35 USC § 156.

C. E. Van Horn

Charles E. VanHorn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Re: Vantin Tablets

Docket No. 93E-0009

Lawrence T. Welch
Corporate Intellectual Property Law
The Upjohn Company
301 Henrietta Street
Kalamazoo, MI 49001

(For Applicant)

Attachment 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-114

FEB 23 2000

Alcon Research, Ltd.
Attention: Scott Krueger
Senior Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Mr. Krueger:

Please refer to Alcon Universal, Limited's new drug application (NDA) dated August 25, 1999, received August 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betaxon (levobetaxolol hydrochloride ophthalmic suspension) 0.5%.

We acknowledge receipt of your submissions dated May 25 and 26, October 1, 15 and 20, December 2, 7, 8, 13, 17, and 20, 1999, and January 12, 18 and 24, and February 15 and 17, 2000.

This new drug application provides for the use of Betaxon for lowering intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submission dated February 17, 2000. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted February 17, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved NDA 21-114.**" Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies until October 1, 2002. However, in the interim, please submit your pediatric drug development plans and we will review your plans.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). A written request for pediatric information on levobetaxolol hydrochloride for the treatment of elevated intraocular pressure was issued on October 15, 1999. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Attachment 10

DEPARTMENT OF HEALTH & HUMAN SERVICES

EXHIBIT VII

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103949 (replaces Ref. No. 99-1488)

January 19, 2001

JAN 2001
RECEIVED
JOSEPH F. LAMENDOLA, Ph.D.

Nicholas J. Pelliccione, Ph.D.
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Pelliccione:

Your biologics license application for Peginterferon alfa-2b is approved effective this date. Schering Corporation, Kenilworth, New Jersey, is hereby authorized to introduce or deliver for introduction into interstate commerce, Peginterferon alfa-2b under Department of Health and Human Services U.S. License No. 0994.

Peginterferon alfa-2b is indicated for the treatment of chronic hepatitis C in patients not previously treated with interferon alfa who have compensated liver disease and are at least 18 years of age. Under this authorization, you are approved to manufacture Peginterferon alfa-2b at your facility in Innishannon County Cork, Ireland. Final formulated drug product will be filled at Innishannon County Cork and unlabeled vials of drug product will be shipped to Kenilworth, New Jersey, for labeling, packaging and distribution. In accordance with approved labeling, your product will bear the trade name PEG-Intron, and will be marketed in 100 µg /mL, 160 µg /mL, 240 µg /mL and 300 µg /mL vials of lyophilized powder, supplied with a 5-mL vial of PEG-Intron Diluent (Sterile Water for Injection), two disposable 1-mL (Becton Dickenson Safety-Lok) syringes with needles and needle guards, and alcohol swabs.

The dating period for Peginterferon alfa-2b shall be 24 months from the date of manufacture when stored at 25 °C (77 ° F). The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The bulk drug substance may be stored for up to 36 months at -80 °C. Results of ongoing stability studies should be submitted throughout the dating period, as they become available, including the results of stability studies from the first three production lots. The stability protocol in your license application is considered approved for the purpose of extending the expiration dating period of your drug substance and drug product as specified in 21 CFR 601.12.

You are not currently required to submit samples of future lots of Peginterferon alfa-2b to the Center for Biologics Evaluation and Research (CBER) for release by the Director, CBER, under 21 CFR 610.2. FDA will continue to monitor compliance with 21 CFR 610.1 requiring assay and release of only those lots that meet release specifications.

Any changes in the manufacturing, testing, packaging or labeling of Peginterferon alfa-2b, or in the manufacturing facilities will require the submission of information to your biologics license application for our review and written approval consistent with 21 CFR 601.12.

Any changes in the manufacturing, testing, packaging or labeling of Peginterferon alfa-2b, or in the manufacturing facilities will require the submission of information to your biologics license application for our review and written approval consistent with 21 CFR 601.12.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We do not concur with your request, as submitted to your application on February 4, 2000, to waive the requirement to conduct pediatric studies. As communicated during the December 14, 2000, meeting, we are deferring the submission of your pediatric studies until June 30, 2001, subsequent to discussion at an open session of an FDA advisory committee meeting.

Pursuant to 21 CFR Part 208, FDA has determined that this product poses a serious and significant public health concern requiring the distribution of a Medication Guide. Distribution of a Medication Guide is necessary for safe and effective use of this product. FDA has determined that Peginterferon alfa-2b is a product for which patient labeling could help prevent serious adverse effects and inform the patient of serious risks relative to benefit that could affect their decisions to use, or continue to use the product. *See* 21 CFR 208.1. FDA hereby approves the Medication Guide you submitted January 19, 2001. In accordance with 21 CFR 208, you are responsible for ensuring that this Medication Guide is available for every patient who is dispensed a prescription for this product. In addition, you are responsible for ensuring that the label of each package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided.

We acknowledge your written commitments to provide additional information and to conduct post marketing studies as described in your letters of November 28, 2000, and January 12, 2001, as outlined below:

1. To address the safety and efficacy of Peginterferon alfa-2b in African Americans by submitting the data from a study of 100 previously untreated patients with chronic hepatitis C who will receive 1.5 μg/kg PEG-Intron and 800, 1000 or 1200 mg ribavirin, depending on their weight. The final protocol for this study will be submitted to CBER by April 1, 2001. Patient accrual will be completed by June 1, 2002, the study completed by December 1, 2003 and a final study report submitted to CBER by June 1, 2004.

2. To evaluate, in patients diagnosed with chronic hepatitis C and compensated liver disease, the effects of single and multiple doses of Peginterferon alfa-2b on the disposition of drugs known to be metabolized by hepatic cytochrome P450 enzymes. The final protocol for this study will be submitted to CBER by February 22, 2001. Patient accrual will be completed by February 19, 2002, the study completed by April 19, 2002, and a final study report submitted to CBER by November 20, 2002.

3. To evaluate the pharmacokinetic, pharmacodynamic and clinical effects of Peginterferon alfa-2b when given chronically to patients with renal dysfunction (creatinine clearance <50 mL/min). The final protocol for this study will be submitted to CBER by March 1, 2001. Patient accrual will be completed by March 1, 2002, the study completed by April 29, 2002, and a final study report submitted to CBER by October 21, 2002.

4. To evaluate the pharmacokinetic, pharmacodynamic and clinical effects of Peginterferon alfa-2b when administered to patients receiving methadone. The final protocol for this study will be submitted to CBER by May 15, 2001. Patient accrual will be completed by May 12, 2004, the study completed by July 12, 2004, and a final study report submitted to CBER by January 18, 2005.

5. To replace the 5-mL vial of diluent that is packaged with Peginterferon alfa-2b with a 1-mL vial of diluent. The supplement supporting this change will be submitted by December 31, 2001.

It is requested that adverse experience reports be submitted in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80) and that distribution reports be submitted as described (21 CFR 600.81). All adverse experience reports should be prominently identified according to 21 CFR 600.80 and be submitted to the Center for Biologics Evaluation and Research, HFM-210, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2567 or Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by a FDA Form 2567 or Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

Sincerely yours,

Shawn L Risso

for Jay P. Siegel, M.D., FACP
Director
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

Attachment 11

2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-001

Pharmacia and Upjohn Co.
Attn: Marcia Rogers
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Rogers:

Please refer to your new drug application (NDA) dated December 17, 1999, received December 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Axert (almotriptan malate) tablets.

We acknowledge receipt of your submissions dated January 5, 2001, January 23, 2001, March 6, 2001, March 13, 2001, March 28, 2001, April 9, 2001 and April 30, 2001. Your submission of March 6, 2001 constituted a complete response to our December 20, 2000 action letter.

This new drug application provides for the use of Axert (almotriptan malate) tablets for the acute treatment of migraine.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-001." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified. In order that we may complete the methods validation process in an orderly fashion, please submit a corrected methods validation package. The necessary corrections were detailed in our fax of May 4, 2001.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We note your March 28, 2001 submission includes your Pediatric Development Plan and Proposed Pediatric Study Request. That submission remains under review. We are deferring submission of your pediatric studies until approximately 2 years after approval.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

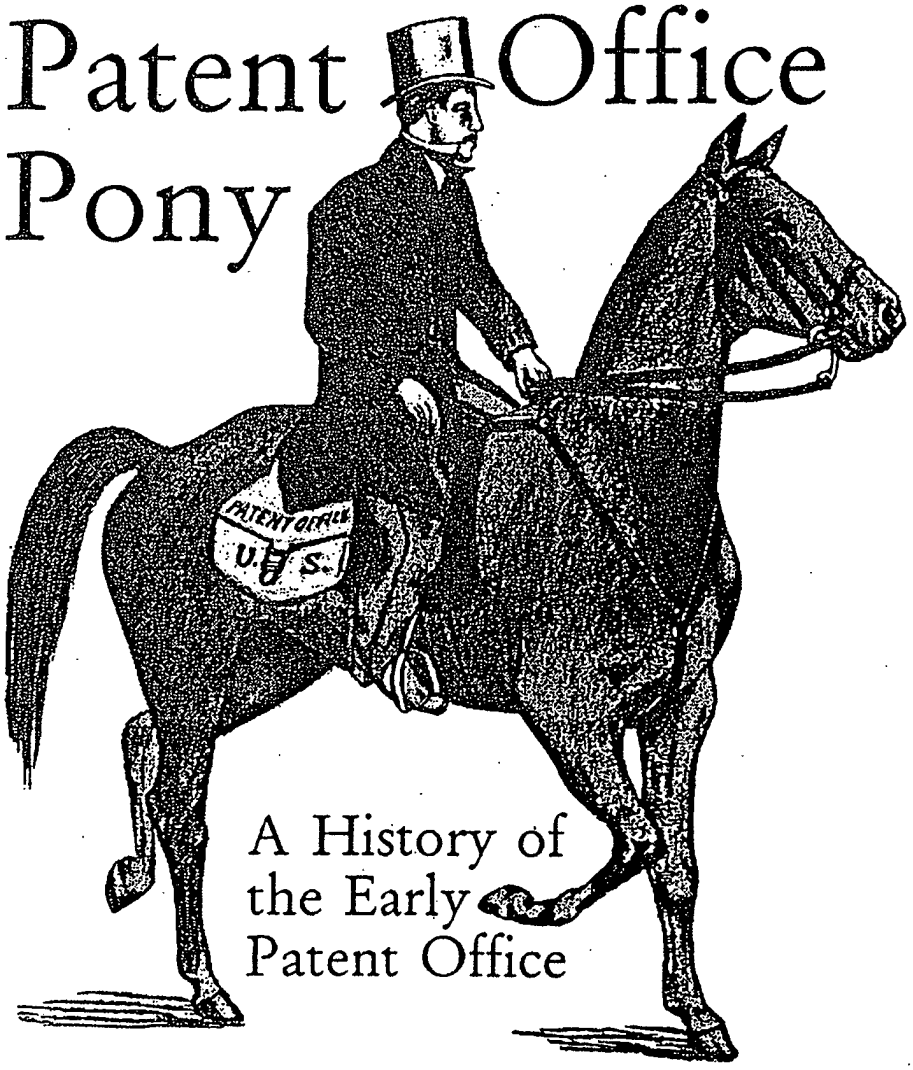
/s/

Robert Temple
5/7/01 05:02:11 PM

Attachment 12

US PATENT & TRADEMARK OFFICE
3 0402 00115 3446

The Patent Office Pony



A History of the Early Patent Office

Kenneth W. Dobyns

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Cass, the 1848 Democratic candidate for President, would have better connections.

While his application was pending, Mr. Peale heard that assistant examiner Thomas G. Clinton had filed charges against Mr. Burke. Indeed, this was so, because Mr. Burke had suspended examiner Clinton pending his removal, and then when he was removed had refused to pay him his salary during the period of suspension. Dr. Clinton then appealed to the President, and Secretary of State James Buchanan sided with Dr. Clinton as to his right to receive pay during the suspension period.[9]

THOMAS EWING

Titian Peale was offered an appointment as assistant examiner, and he initially declined it, even though he had no other prospects.[10] However, on advice of Joseph Henry and others,[11] he did accept the position in August 1848.[12] By May 1849, Peale was settled in and liked his duties, but found his salary insufficient to overcome debts. He had received his first confirmation of a rumor that Commissioner Burke was about to leave by seeing packing boxes lined up in front of his room.[13]

Prior to 1848, patents could issue on any day, but beginning in early 1848 and continuing to date, patents have issued at noon every Tuesday, and only on Tuesday, come fire, flood, war, riot, or national holiday.

On March 11, 1848, *Journal of the Franklin Institute* editor-for-life Thomas P. Jones gave up his editorship at death. The journal continued despite loss of its first editor.

As far back as 1812, some officials had advocated a Home Department in the Government to handle non-foreign affairs, leaving the State Department to handle foreign affairs. It was to comprise territorial governments, national highways and canals, the General Post Office, the Patent Office, and the Indian Affairs Office.[14] A Home Department was founded by the Act of March 3, 1849. Its first Secretary was Thomas Ewing, and its name was the Interior Department by early April. The 1849 act also appropriated $600,000 to complete the east wing of the Patent Office Building, of which $250,000 was to come from the Patent Fund. The Patent Office was placed within the Home Department, and the Home Department, lacking a building of its own, moved into the Patent Office Building and began elbowing for space.

The conflict between the Patent Office and the Interior Department for space in the building continued for many years and would continue to cause hard feelings among the nation's inventors and their representatives.

Attachment 13

United States Patent and Trademark Office OG Notices: 01 February 2005

Relocation of Customer Service Windows for Patent-Related Correspondence; Establishment of Drop Box in South Tower for Certain Patent-Related Correspondence; Hand Carry and Mailing Address for Trademark-Related Correspondence

Effective January 14, 2005, a new Customer Service Window for patent-related correspondence will open at 8:30 a.m. at the USPTO Alexandria campus. The Customer Service Window (Lobby, Room 1B03) and the PCT Customer Service Window (8th floor) currently located at 220 20th Street South, Crystal Plaza Two, Arlington, VA 22202 will close at 12:00 midnight on January 13, 2005 and will be consolidated at the Alexandria campus.

Customer Service Window for Patent-Related Correspondence

The location for the new Customer Service Window is on the first floor of the south side of the Randolph Building, with street level access from Ballenger Avenue. The specific hand carry or delivery address is:

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

If the appropriate mail stop is known, the mail stop should also be included in the address. Documents for the Customer Service Window or the PCT Customer Service Window may be hand carried or delivered to the new Customer Service Window at the above Alexandria address on or after January 14, 2005. No application numbers will be assigned by window staff at the time of delivery. Hours of Operation will be 8:30 a.m. through 12 midnight, Monday through Friday, except holidays and if the USPTO is closed for inclement weather or an emergency.

Drop Box in South Tower for Certain Patent-Related Correspondence

Additionally, a satellite drop location will be established in the lobby of the South Tower building in Crystal City (2900 Crystal Drive, Arlington, Virginia), effective January 14, 2005. This location will not be staffed but will be monitored by the building guard. Applications and application-related papers may be left at this location during the hours of 8:30 a.m. and 7:00 p.m., Monday through Friday, except holidays and if the USPTO is closed for inclement weather or an emergency. The guard will not allow materials to be left except during those hours. No postcard receipts will be stamped at time of drop off, nor will the guard answer any processing questions. Materials will be retrieved periodically throughout the day and taken to the appropriate location for processing.

Other Information Regarding Patent-Related Correspondence

The new customer service window and new drop box must not be used for correspondence that is required to be mailed to post office boxes other than P.O. Box 1450, Alexandria, VA 22313-1450, filed by facsimile, filed electronically, or hand-delivered to a different address.

PCT customer service offices will provide file inspection for files located in PCT PALM locations. The PCT file inspection location is Room 4A22, 2900 Crystal Drive, Arlington, Virginia (South Tower). Customers should call 703-305-3165 in advance to make arrangements to inspect a file. Requests to inspect files located in OIPE PALM locations should be directed to the File Information Unit (FIU) at 703-308-2733. The FIU is located in Room 2E04, 2900 Crystal Drive, Arlington, Virginia (South Tower).

Patent-related correspondence sent through the United States Postal Service should continue to be directed to the addresses set forth in 37 CFR 1.1 (revised effective September 13, 2004) (e.g., P.O. Box 1450, Alexandria, VA 22313-1450).

Hand Delivery and Mailing Address for Trademark-Related Correspondence

Use of any patent boxes for trademark-related correspondence is strongly discouraged, and may result in delayed processing. Most trademark-related correspondence, including Madrid Protocol-related correspondence, may be filed electronically using the Trademark Electronic Application System (TEAS), at www.uspto.gov. The USPTO prefers that filers use TEAS where possible.

Trademark-related correspondence also may be hand-delivered to the Trademark Assistance Center (TAC) located at:

Trademark Assistance Center
James Madison Building - East Wing
Concourse Level
600 Dulany Street
Alexandria, VA 22314

Hand deliveries of Madrid Protocol-related correspondence should also include the notation "Attention: MPU".

Hours of operation for TAC are 8:30 a.m. - 5:00 p.m. Monday through Friday, except holidays or days the USPTO is closed for inclement weather or emergency.

Trademark-related correspondence sent through the United States Postal Service, except documents sent to the Assignment Services Division for recordation, requests for copies of trademark documents, and documents filed under the Madrid Protocol, should be mailed to:

Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451

Madrid Protocol-related documents sent through the United States Postal Service should be mailed to:

Commissioner for Trademarks
P.O. Box 16471
Arlington, VA 22215-1471
Attn: MPU

Questions regarding this notice may be e-mailed to PatentPractice@uspto.gov, or directed to the Inventors' Assistance Center (formerly the Patent Assistance Center (PAC)) by telephone at (800)786-9199, or (703)308-4357.

January 12, 2005

JOHN D. HASSETT
Director
Administrative Services

Attachment 14

LEGAL FRAMEWORK FOR EFS-WEB

September 2008

I. Introduction - Scope of Document

This Legal Framework provides guidance on the background statutes, regulations and policies that support the Electronic Filing System – Web (EFS-Web) project. The document is provided as a reference for applicants, parties in reexamination proceedings, attorneys, and agents, as well as their staffs using the system.

II. Background

From October 2000 through October 2006, the USPTO provided eFiling software including two client-side components. Those components were EFS-ABX for patent application specification authoring and ePAVE for form generation, validation, and submission to the USPTO. EFS-ABX generated an .abx package that contained the Portable Document Format (PDF) version of the file and an XML version with all associated files needed for rendering in a browser. ePAVE generated XML forms based on user input, allowed for the .abx file to be attached, validated the package, and submitted it to the USPTO for processing. Due to low adoption rates of eFiling, the USPTO requested feedback from the IP community and found that users prefer filing applications using PDF, as well as being free from downloading and installing software on their workstations.

As a result of these user requests, the USPTO created EFS-Web, a PDF-based Internet patent application filing system. The use of a web browser on the client side answered requests for a "light" client, that is a system that does not require a user to download a substantial amount of software onto his/her computer. As a result of the highly favorable reception of the EFS-Web filing system and the low adoption rate of the ePAVE and ABX filing components, the ePAVE and ABX filing components were retired by the USPTO in the Fall of 2006.

III. EFS-Web

EFS-Web is a PDF-based filing system. Accordingly, all EFS-Web submissions are required to be in PDF format unless otherwise indicated below. In addition, PDF files created from scanned documents and submitted via EFS-Web must be created using a scanning resolution no lower than 300 dpi. Lower resolution scans have significantly delayed processing and publication of applications, e.g. resubmission has been required for documents failing to comply with the legibility requirements. See 37 CFR 1.52(a)(1)(v) and (a)(5) regarding document legibility requirements.

EFS-Web collects data elements from on-screen entries made through the EFS-Web graphical user interface (GUI) data collection screens. Needed patent information, however, is also collected on form fillable PDF, or user created PDF files attached to the submission.

The user and the USPTO benefit greatly from such automated processing by increasing the accuracy and timeliness of data going from one system to another, while eliminating the need for the user to prepare paper submissions (which may be extensive) and eliminating the need for the USPTO to process large volumes of paper submissions. An applicant need not provide a duplicate copy of any document filed through EFS-Web unless the Office specifically requires the filing of a duplicate in a particular situation.

The USPTO provides users with PDF Web-based fillable forms. Currently there are several fillable forms including the Provisional Cover Sheet, the Information Disclosure Statement, the Application Data Sheet, Petition to Make Special Under Accelerated Examination Program, Petition to Accept Unintentionally Delayed Payment of Maintenance Fee in an Expired Patent, Request for Continued Examination (RCE), and Petition to Make Special Based on Age. The USPTO will continue to convert additional forms to the PDF form-fillable format over time.

EFS-Web permits a legal assistant or paralegal to submit an application/request for reexamination previously reviewed by a registered practitioner without the registered practitioner being present.

IV. Relevant Statutes and Rules

35 USC 111 – filing a patent application
35 USC 302, 311 – filing a request for reexamination
37 CFR 1.52 – form of an application/reexamination
37 CFR 1.4 – signatures
37 CFR 1.6 – receipt of correspondence

Electronic Filing System Available to Public 1240 OG 45 (14 November 2000) indicates that to the extent that any USPTO regulation is inconsistent with EFS procedures, the regulation will be interpreted in a manner to support EFS.

Improper Use of EFS-Web:

Use of EFS-Web in a manner significantly in violation of the instructions proscribed by the Legal Framework may result in non-entry of the submission or failure to accord a filing date in the event the USPTO does not fully, successfully, and officially receive all of the elements necessary to obtain a filing date for an intended submission once the applicant/patent owner clicks the SUBMIT button on the Confirm and Submit screen.

V. Legal Advantages to the Filer of the EFS-Web Approach

Major Innovations of EFS-Web:

a. Web access from anywhere using web browser.

b. Standard PDF accepted, from commercial and free PDF converters.

c. Portable PDF forms, can be passed around for collaboration.

d. Responsible attorney or agent need not be present for submission.

e. Real time fee payments.

f. An Acknowledgement Receipt received upon making an electronic filing is the legal equivalent of a post card receipt described in MPEP 503.

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VI. Legal Issues & Policies

This initiative does not depend upon, or require, statutory changes. PDF files when submitted as part of a Patent Application Specification via EFS-Web are used to create the official record.

The following are policies of the Office concerning e-filed patent applications/requests for reexamination under EFS-Web, as well as follow-on papers in applications and reexamination proceedings.

VII. Subscriber Agreement/ Signature Policy

A practitioner or an employee acting under the direction and control of a practitioner may, as a general rule, file documents signed by either the practitioner exercising the direction and control or another practitioner via EFS. Filing of a document that is unauthorized to be filed via EFS (e.g., a withdrawal from issue by a third party) is inconsistent with the subscriber agreement. Thus, the certificate holder and employee acting under the direction and control of a registered attorney (or agent) must make sure that documents being submitted are authorized to be filed via EFS, regardless of whether the document is signed by the practitioner exercising the direction and control or another practitioner.

VIII. Acknowledgement Receipt Policy

The Acknowledgement Receipt establishes the date of receipt by the USPTO of electronic documents itemized in the receipt. Under EFS-Web, the Acknowledgement Receipt will contain a full listing of the documents submitted to the USPTO as described by applicant or a reexamination party (patent owner or reexamination requester) during the submission process, including the count of pages and/or byte sizes for each document. Thus, the Acknowledgement Receipt is the electronic equivalent of the post card receipt described in MPEP 503.

The official application filing date will be noted on the Filing Receipt (37 CFR 1.54), PTO Form-103X, after the submitted application parts are reviewed for compliance with 35 U.S.C. § 111. The filing date is based on the dates indicated on the Acknowledgement Receipt assuming that, after review, the documents submitted are found to be entitled to an application filing date. Likewise the official reexamination filing date will be noted on the "Notice of ... Reexamination

Request Filing Date," after Central Reexamination Unit (CRU) review for filing date compliance and is based on the dates indicated on the Acknowledgement Receipt.

If the official version of any document received by the EFS-Web is lost, damaged or rendered unreadable by the USPTO and if it cannot be recovered from the stored files received by electronic submission, then the applicant/reexamination party will be promptly notified. In that situation, the applicant/reexamination party may have to resubmit the document(s) or portion of the document that are lost and petition for the original filing date. Such events are expected to be rare, indeed since inception of the EFS project no documents submitted using USPTO EFS software and received in EFS have been lost. In most cases a phone call to the Electronic Business Center (EBC) will resolve the issue. But if that is not sufficient, the applicant/reexamination party would present: (1) the Acknowledgement Receipt; (2) a copy of the missing files as submitted; and (3) a signed petition and statement verifying that the attached files are the same as mentioned in the Acknowledgement Receipt for that application number. The Acknowledgement Receipt and statement will serve as *prima facie* evidence that the resubmitted documents are the same as those submitted on the date of receipt. Note the Acknowledgement Receipt only indicates that the USPTO received what was actually sent, as opposed to what may have been intended to be transmitted. Applicants/ reexamination parties should exercise the same care in preparing and preserving a copy of a submission in electronic form as in paper.

IX. Entry in the US national stage under 35 USC 371

It is recommended that applicants continue to use the Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Submission Under 35 USC 371 (Form PTO-1390) when electronically filing documents for entry into the US national stage under 35 USC 371. The PTO-1390 Form includes useful information that is not otherwise collected by EFS-Web at this time.

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 USC 371 and other applicable requirements, Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 USC 371 will be issued in addition to the Filing Receipt.

X. Security

The USPTO requires Public Key Infrastructure (PKI) certificates to meet federal government computer system authentication guidelines as defined by the National Institute of Standards and Technology (NIST) and the Office of Management and Budget (OMB). The required evaluation of EFS and PAIR determined that level 3 authentication was needed which is met by the USPTO's PKI.

Only PKI registered users (or persons under their direction and control) can submit follow on papers. This preserves confidentiality, and is consistent with power of attorney and correspondence regulations. In order to obtain a PKI certificate the user must already be a registered attorney (or equivalent) or inventor and complete the appropriate paperwork. Once the user has a PKI certificate, the user can authenticate himself/herself to the USPTO through the

EFS-Web sign-on. This will generate a secure, encrypted, connection with the USPTO. While an inventor and his/her attorney may obtain a PKI certificate, only a single PKI certificate associated with a single customer number is allowed access to a particular application in Private PAIR.

For filers that do not have or do not wish to use a PKI certificate to authenticate to the USPTO, they may still submit new filings only via a non-authenticated workflow. The user would go to the EFS-Web page and choose to submit without a PKI certificate as an unregistered user, which would generate a Transit Layer Security (TLS) connection for the session, thus allowing secure data transmission to the USPTO. Non-authenticated users have the same level of protection for filing as a registered user, but are limited to submission of initial filings. This practice minimizes the risk of improperly filed third party petitions and other papers.

Note: Users are advised that the USPTO may revoke a user's digital PKI certificate if the user makes an improper submission through EFS-Web. See section XXXI (Documents Policy) at page 17. See also paragraph 4 of the "United States Patent and Trademark Office Public Key Infrastructure Subscriber Agreement" located at [http://www.uspto.gov/ebc/documents/subscribersagreement.pdf].

XI. Policy of Annex F of the PCT Administrative Instructions

EFS-Web employs a Web based approach to document submission which is different from the Annex F "wrapped, bundled and signed package" approach. Thus EFS-Web does not meet Annex F requirements. See Annex F of the PCT Administrative Instructions located at [http://www.wipo.int/pct/en/texts/]. While EFS-Web is not required to meet Annex F requirements at this time, work will commence to expand Annex F as a world standard.

XII. What is the official record of documents submitted by EFS-Web?

The Official Record for application files and reexamination proceeding documents (e.g., reexamination requests) submitted via EFS comprises (1) ASCII text documents as well as color and grayscale drawings in PDF format as stored in the Supplemental Complex Repository for Examiners (SCORE) and (2) TIFF images of all other original documents as stored in the Image File Wrapper system as well as the Electronic Acknowledgement Receipt and the Electronic Patent Application Fee Transmittal both of which contain information entered via the EFS-Web graphical user interface (GUI). The original documents submitted via EFS, e.g., applications and, reexamination proceeding documents are stored exactly as filed, for reference, in an independent location.

XIII. May biotechnology sequence listings, large tables, or computer program listing appendices be submitted as text files via EFS-Web?

Yes, all of these types of documents may be submitted as text files for national applications (other than international applications filed under the Patent Cooperation Treaty (PCT)) and reexamination proceeding documents. The CD practice of 37 CFR 1.52(e) and 37 CFR 1.821 remains as a filing option. The filing of international applications under the PCT via EFS-Web is discussed in Part XVIII below.

A filer may submit the following document types, as specified in 37 CFR 1.52(e), as text files via EFS-Web instead of on compact disc provided such files are in compliance with the American Standard Code of Information Interchange (ASCII):

A computer program listing (see 37 CFR 1.96);

A "Sequence Listing" (submitted under 37 CFR 1.821); or

Any individual table (see 37 CFR 1.58) if the table is more than 50 pages in length, or if the total number of pages of all of the tables in an application exceeds 100 pages in length, wherein a table page is a page printed on paper in conformance with 37 CFR 1.52(b) and 37 CFR 1.58(c).

The requirements of 37 CFR 1.52(e)(3)(ii), (4), and (6) are not applicable to computer program listings, sequence listings, and tables submitted as text files via EFS-Web. Further, the specification must contain an incorporation-by-reference of the material in the text file in a separate paragraph identifying the name of the text file, the date of creation, and the size of the text file in bytes as per 37 CFR 1.52(e)(5).

Pursuant to 37 CFR 1.821, a patent application which discloses nucleotide and/or amino acid sequences must contain both "a paper copy" of the sequence listing (37 CFR 1.821(c)) and a computer readable form (CRF) of the sequence listing (37 CFR 1.821(e)). If a sequence listing text file submitted via EFS-Web complies with the requirements of 37 CFR 1.824(a)(2)-(6) and (b) (i.e., is a compliant sequence listing ASCII text file), the text file will serve as both the paper copy required by 37 CFR 1.821(c) and the CRF required by 37 CFR 1.821(e). Thus a statement under 37 CFR 1.821(f) (indicating that the paper copy and CRF copy of the sequence listing are identical) is unnecessary. Furthermore, the filer need not submit any additional copies of the sequence listing pursuant to 37 CFR 1.821(e). If a filer submits a compliant sequence listing ASCII text file via EFS-Web, the filer should not request the use of a compliant computer readable "Sequence Listing" that is already on file for another application pursuant to 37 CFR 1.821(e). If such a request is filed, the Office will not carry out the request but will use the sequence listing submitted with the application as originally filed via EFS. Checker software that may be used to check a sequence listing for compliance with the requirements of 37 CFR 1.824 is available on the USPTO web site at http://www.uspto.gov/web/offices/pac/checker/.

If a filer submits a sequence listing (under 37 CFR 1.821(c) and (e)) as a text file via EFS-Web in response to a requirement under 37 CFR 1.821(g) or (h), the sequence listing text file must be accompanied by a statement that the submission does not include any new matter which goes beyond the disclosure of the application as filed. However, if the sequence listing text file complies with the requirements of 37 CFR 1.824(a)(2)-(6) and (b), the filer need not submit (i) any additional copies of the sequence listing pursuant to 37 CFR 1.821(e) nor (ii) the statement described in 37 CFR 1.821(f) and any request under 37 CFR 1.821(e) for the use of a compliant

computer readable "Sequence Listing" that is already on file for another application is unnecessary and will not be carried out.

XIV. How are text files counted for application size fee purposes?

Any sequence listing submitted as a text file via EFS-Web that is otherwise in compliance with 37 CFR 1.52(e) and 1.821(c) or (e), and any computer program listing submitted as a text file via EFS-Web that is otherwise in compliance with 37 CFR 1.52(e) and 1.96, will be excluded when determining the application size fee required by 37 CFR 1.16(s) or 1.492(j) as per 37 CFR 1.52(f)(1).

Regarding a table submitted as a text file via EFS-Web that is part of the specification or drawings, each three kilobytes of content submitted will be counted as a sheet of paper for purposes of determining the application size fee required by 37 CFR 1.16(s) or 1.492(j). Each table should be submitted as a separate text file. Further, the file name for each table should indicate which table is contained therein.

XV. What is the size limit for text files?

100 megabytes is the size limit for sequence listing text files submitted via EFS-Web. If a filer wishes to submit an electronic copy of a sequence listing text file that exceeds 100 megabytes, it is recommended that the electronic copy be submitted on compact disc via Express Mail in accordance with 37 CFR 1.10 on the date of the corresponding EFS-Web filing in accordance with 37 CFR 1.52(e) if the filer wishes the electronic copy to be considered part of the application as filed. Alternatively, a filer may submit the application in paper and include the electronic copy of the sequence listing text file on compact disc in accordance with 37 CFR 1.52(e). Sequence listing text files may not be partitioned into multiple files for filing via EFS-Web as the EFS-Web electronic filing system is not currently capable of handling such submissions. If the sequence listing is filed on a compact disc, the sequence listing must be a single document, but the document may be split using software designed to divide a file, that is too large to fit on a single compact disc, into multiple concatenated files. If the filer breaks up a sequence listing so that it may be submitted on multiple compact discs, the compact discs must be labeled to indicate their order (e.g., "1 of X", "2 of X", etc.).

For all other file types, 25 megabytes is the size limit. If a filer wishes to submit an electronic copy of a computer program listing or table that is larger than 25 megabytes, it is recommended that the electronic copy be submitted on compact disc via Express Mail in accordance with 37 CFR 1.10 on the date of the corresponding EFS-Web filing in accordance with 37 CFR 1.52(e) if the filer wishes the electronic copy to be considered to be part of the application as filed. Alternatively the applicant/patent owner may submit the application in paper and include the electronic copies on compact disc in accordance with 37 CFR 1.52(e). Another alternative would be for the filer to break up a computer program listing or table file that is larger than 25 megabytes into multiple files that are no larger than 25 megabytes each and submit those smaller

files via EFS-Web. If the filer chooses to break up a large computer program listing or table file so that it may be submitted electronically, the file names must indicate their order (e.g., "1 of X", "2 of X", etc.).

XVI. What is the limit on the number of electronic files submitted via EFS-Web?

60 electronic files is the file number limit, as EFS-Web is not currently capable of accepting more than 60 electronic files in any one submission. Accordingly, if an application file is comprised of more than 60 electronic files, it is recommended that the filer submit 60 or fewer files in an initial filing via EFS-Web at which time the application will be assigned an application number. Note that regarding the 60 electronic file limit, an applicant may upload and validate in sets up to 20 files each, with a limit of three sets of 20 files. If applicant chooses to divide a file into multiple parts using the multi-doc feature, each part is counted as one file. Then the filer may submit any additional electronic files as follow-on documents later on the same day as the initial filing. This will allow all of the electronic files making up the application to receive the same filing date.

XVII. May international applications filed under the Patent Cooperation Treaty (PCT) with the US Receiving Office (RO/US) be electronically submitted via EFS-Web?

Yes, EFS-Web enables a user to electronically file international applications under the Patent Cooperation Treaty (PCT) with the United States Receiving Office (RO/US).

XVIII. May EFS-Web be used to file international applications containing nucleotide/amino acid sequence listings and/or tables related thereto in the United States Receiving Office?

Yes, applicants may file international applications under the PCT that contain nucleotide/amino acid sequence listings and/or tables related thereto with the United States Receiving Office (RO/US) via the EFS-Web filing system of the USPTO. However, computer program listings may not be included in international applications filed under the PCT.

Applicants are advised that EFS-Web may be used to file either: (1) international applications in fully electronic form or (2) follow-on papers to previously filed international applications. Applications containing large sequence listings and/or tables related thereto (i.e. 400 or more combined sequence listing and/or tables pages) may qualify for a reduced filing fee under Section 707(a-*bis*) of the PCT Administrative Instructions (AI) as discussed below.

Applicants should note that AI Part 8 does not apply to applications filed via EFS-Web, because AI Part 8 is reserved for applications filed partly on paper and partly on electronic media.

A. Sequence Listing:

Under PCT Rule 5.2(a), the sequence listing part must always be presented as a separate part of the description. The sequence listing part of the description should be submitted as a single ASCII text file with a ".txt" extension (e.g. "seqlist.txt"). Submission of the sequence listing part in PDF format is not recommended because applicant would still be required to supply a copy of the sequence listing in text format in accordance with AI Annex C, ¶39. If the sequence listing part is submitted as a text file, applicant need not submit any additional copies. The text file will serve both as the written portion of the sequence listing under PCT Rule 5.2 and the electronic form under PCT Rule 13ter.1(a). Furthermore, the required statement in paragraph 40 of Annex C that "the information recorded in the electronic form is identical to the sequence listing in the application" is not required. .

B. Tables Related to a Sequence Listing:

Tables related to a sequence listing may be either interspersed with the rest of the description or consolidated into a separate part of the description. Description pages, which contain interspersed tables, must be submitted in PDF format. Table pages which are consolidated into a separate part of the description may be submitted in either PDF or text format when using EFS-Web, although text format is preferred. For consolidated tables, each table must be contained in a separate file with the appropriate extension (i.e. ".txt" for text files and ".pdf" for PDF files). Furthermore, each table file must have a filename which indicates the name of the table contained therein (e.g. "table-1.txt", "table-2.txt", "table-3.txt" etc. or "table-1.pdf", "table-2.pdf", "table-3.pdf", etc.). Regardless of the file format used, the spatial relationships (e.g., columns and rows) of the table elements must be maintained.

C. File Size and Quantity Limits

100 megabytes is the size limit for sequence listing text files. For all other file types (including tables related to a sequence listing) EFS-Web is currently not capable of accepting files that are larger than 25 megabytes. Additionally, a single EFS-Web submission may include no more than 60 electronic files. Note that regarding the 60 electronic file limit, an applicant may upload and validate in sets up to 20 files each, with a limit of three sets of 20. If applicant chooses to divide a file into multiple parts using the multi-doc feature, each part is counted as one file. Unusually large or numerous sequence listings and/or tables may prevent applicant from making a complete international application filing in a single EFS-Web submission. In such instances, applicant may use EFS-Web to file part of the international application and to obtain the international application number and the confirmation number. The remainder of

the international application must then be submitted on the same day as one or more follow-on submissions using EFS-Web, Express Mail from the United States Postal Service (USPS) in accordance with 37 CFR 1.10, or hand delivery, as appropriate, in order to secure the same filing date for all parts of the international application. However, sequence listing text files may not be partitioned into multiple files for filing via EFS-Web as the EFS-Web electronic filing system is not currently capable of handling such submissions. In addition, USPS Express Mail and hand carried submissions may not contain PDF files and must fully comply with the guidelines for filing a sequence listing and/or tables related thereto on electronic media as set forth in MPEP 1823.02, except that only one copy of the sequence listing and/or tables is required, and applicant need not make any reference to AI Part 8 or AI § 801. If a sequence listing is filed on a compact disc, the sequence listing must be a single document, but the document may be split using software designed to divide a file, that is too large to fit on a single compact disc, into multiple concatenated files. If the filer breaks up a sequence listing into multiple concatenated files so that it may be submitted on multiple compact discs, the compact discs must be labeled to indicate their order (e.g., "1 of X", "2 of X", etc.).

As an alternative to using USPS Express Mail or a hand carried submission to submit a table file related to a sequence listing that exceeds the EFS-Web 25 megabyte limit, applicant may partition the oversize table file into multiple files, each of which is smaller than 25 megabytes. If applicant chooses to partition an oversize table file, the filenames of the resulting segments must indicate their proper order (e.g. "table-35-part1of3.txt", "table-35-part2of3.txt", etc.).

D. Fee Determination for International Applications Containing a Sequence Listing.

The calculation of the international filing fee shall take into account only the first 400 pages of the combination of any sequence listing and any tables related thereto which are individually consolidated in separate parts of the description. Tables that are not related to a sequence listing will not qualify for any potential fee reduction.

Pursuant to AI § 707(a), the international filing fee, subject to the 400 page limit described above, is calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the physical requirements prescribed in PCT Rule 11. For text files, each three kilobytes of content as measured by USPTO computer systems shall be counted as one printed page for fee calculation purposes.

XIX. Follow-on Submissions for International Applications.

As noted above, a sequence listing part and/or tables related thereto may be submitted using one or more follow-on EFS-Web submissions. Such follow-on submissions will form part of the international application if filed on the same date on which the international application was

filed. Note that follow-on submissions may change the number of pages in the international application and therefore may affect the international filing fee.

EFS-Web may also be used to submit a sequence listing in text format after the international filing date in response to a requirement under 37 CFR 1.821(h) and PCT Rule 13*ter*. Such sequence listing will not form part of the international application as set forth in PCT Rule 13*ter*.1(e).

XX. May a reissue application or a request for reexamination, and follow on papers be submitted via EFS-Web?

Yes, EFS-Web permits a user to electronically submit a reissue application under 35 USC 251 and follow-on papers, a request for ex parte reexamination under 35 USC 302 and follow-on papers, or a request for inter partes reexamination under 35 USC 311 and follow-on papers. In reexamination, both the reexamination requester and the patent owner may file via EFS-Web.

XXI. May pre-grant publication requests be submitted via EFS-Web?

Yes, EFS-Web enables users to electronically submit pre-grant publication requests for amended publication, redacted publication, voluntary publication, or republication under 37 CFR §§ 1.215, 1.217, 1.219, and 1.221(a) via EFS-Web. When filing pre-grant publication requests via EFS-Web, the form fillable application data sheet (PTO/SB/14) is required to be used for fulfilling the bibliographic data requirements. An electronic submission for voluntary publication, amended publication, republication (37 CFR § 1.221(a)) or redacted publication must be submitted as a "Pre-Grant Publication" by selecting the "Pre-Grant Publication" radio button on the EFS-Web data collection screen. It is not sufficient for a filer to merely submit a document via EFS-Web requesting voluntary publication, amended publication, republication or redacted publication without also selecting the "Pre-Grant Publication" radio button on the EFS-Web data collection screen.

XXII. May color drawings for design applications be submitted via EFS-Web?

Yes, all design application drawings may be submitted via EFS-Web. However, the Office will treat color drawings in design applications as informal drawings unless accompanied by a grantable petition filed under 37 CFR § 1.84(a)(2) explaining why the color drawings are necessary.

The requirement for three (3) sets of color drawings under 37 CFR 1.84(a)(2)(ii) is not applicable to color design drawings submitted via EFS-Web. Only one set of such color design drawings is sufficient when filing via EFS-Web.

Drawings submitted via EFS-Web in application types other than design applications must be in bitonal black and white only.

XXIII. What is the date of receipt of an application received under the EFS-Web?

35 USC 111(a)(4) states in part (emphasis added):

> The filing date of an application shall be the date on which the specification and any required drawing are **received in the Patent and Trademark Office**.

Thus, the filing date of an application is the date of receipt of the application in the USPTO. Further, the USPTO is located in the Eastern Standard Time zone. Accordingly, the date of filing of an application officially submitted through EFS-Web will be the date in the Eastern Standard Time zone at the time of submission. As such, the submission's "date of receipt", as shown on the Acknowledgement Receipt, is the Eastern Standard Time date that the documents are fully, successfully, and officially received at the USPTO as indicated by pressing the Submit Button on the Confirm and Submit screen. This date is controlling for filing date purposes of your newly filed application. There is no "certificate of transmission" practice for new application e-filings (37 CFR 1.8). This applies by analogy to reexamination proceedings.

To be very specific, the EFS-Web system records as the date of receipt of documents the local date in Eastern Standard Time on which it receives an electronic indication that the SUBMIT button has been clicked on the Confirm and Submit screen for those documents.

So, for example, if an applicant in California officially files a patent application with the USPTO through EFS-Web by clicking on the SUBMIT button at 10:00 PM Pacific Time in California on May 1, that application would be officially received by the USPTO at 1:00 AM Eastern Standard Time on May 2. Accordingly, the application would receive a filing date of May 2. However, the applicant could alternatively file the application using the "Express Mail Post Office to Addressee" service of the United States Postal Service in accordance with 37 CFR 1.10 in which case the applicant would have until midnight on May 1 in his/her local time zone to file the application and obtain a filing date of May 1.

XXIV. What if the applicant electronically files an application via EFS-Web, and on that same day, realizes that they have inadvertently omitted a document from the application?

One advantage of filing an application via EFS-Web is that the applicant may view the submission in PAIR and file a paper directly into the application on the same day as the filing

date of the application. In certain situations, applicant may correct an error by filing a missing item(s) on the same day as the filing date of the application. Applicant, however, may wish to file another new application in other certain situations. For example:

(1) Oath or Declaration - Applicant may file an executed oath or declaration on the same day as the filing date as the application via EFS-Web. The oath or declaration will not be considered late and thus a surcharge for filing a late oath or declaration will not be required.

(2) Filing Fees - Applicant may file the filing fees (e.g., the basic filing fee, search and examination fees, application size fee, or excess claims fee) on the same day as the filing date of the application via EFS-Web. The fees will not be considered late and thus a surcharge for filing the filing fees will not be required.

(3) Non-publication request - Since 37 CFR 1.213(a)(1) requires any non-publication request to be filed with the application, applicant cannot simply file the non-publication request to correct the error. If applicant does not wish to have the application publish, applicant must file: (a) a new application with a nonpublication request; and (b) file a petition for express abandonment to avoid publication under 37 CFR 1.138(c) and fee under 37 CFR 1.17(h) in sufficient time to permit the appropriate officials in Pre-Grant Publication Division to recognize the abandonment and remove the application from the publication process.

(4) Drawings - Applicant may file the missing drawings as a preliminary amendment on the same day as the filing date of the application. The drawings will be considered as part of the original disclosure of the application. See 37 CFR 1.115(a)(2). If the application, however, were filed with the "wrong drawings," the "wrong drawings" would still be part of the original disclosure. A preliminary amendment could be filed on the same day as the filing date of the application adding the correct drawings and deleting the "wrong drawings." An amendment adding new drawings and deleting the "wrong drawings," filed on a day after the filing date of the application, may raise new matter issues. Certainly, if applicant wishes to have an application without the "wrong drawings" being a part of the original disclosure, applicant should file a totally new application (e.g., new specification including claims(s) and fees) comprising the correct drawings, and, if desired, expressly abandon the original application.

(5) Claims - Applicant may file the claims as a preliminary amendment on the same day that applicant filed the application papers. Please note that the application will not be entitled to a filing date until applicant files at least one claim in the application.

(6) Part of the specification - Applicant may file the missing portion of the written description as a preliminary amendment on the filing date of the application. Such amendment will be considered as part of the original disclosure.

If applicant files another new application to correct the error, applicant will have two applications. Applicant may continue to prosecute the first application that has the error or abandon the first application by filing a declaration of express abandonment. Please note that any fees paid in the first application will not be refunded or applied to the second application. Applicant may request refund of the search fee and any excess claims fees (but not the basic filing fee, examination fee, and application size fee) paid in the first application if the application was filed under 35 USC 111(a) on or after December 8, 2004 and the applicant files a declaration of express abandonment in accordance with 37 CFR § 1.138(d).

XXV. What is the date of receipt of follow-on correspondence received by the USPTO through EFS-Web?

Patent application/reexamination proceeding correspondence filed after the initial application filing (i.e. follow-on correspondence) will receive as an official filing date the date the follow-on correspondence is received at the USPTO. However, follow-on correspondence that is required to be filed within a set time period will be considered timely if the correspondence is officially submitted through EFS-Web prior to the expiration of the set time period, and the correspondence includes a certificate for each piece of correspondence stating the local date of submission. See 37 CFR 1.8(a)(1)(i)(C).

XXVI. Hours of Operation

Hours of operation of the EFS-Web will be clearly provided in the EFS-Web instructions. If a transmission is attempted during a down time, the Office cannot accept it and will, if possible, transmit back a notice that the Office is not accepting submissions. No Acknowledgement Receipt will be sent. Instead a notice will advise the applicant/reexamination party to use alternative filing methods, such as hand delivery of paper to the USPTO or Express Mail (under 37 CFR 1.10), to establish the filing date. Note that most applications filed under 37 CFR 1.53, and reexamination requests, cannot be submitted by fax (37 CFR 1.6(d)(3) and (5)), and that normal certificate of mailing procedures do not apply to new applications and reexamination requests (37 CFR 1.8(a)(2)(i)(A) and (D)). Users are strongly advised to transmit their electronic filings sufficiently early in the day to allow time for alternative paper filing when transmission cannot be initiated or correctly completed.

If the submission is successfully received on a Saturday, Sunday or Federal holiday within the District of Columbia, the Office will assign that receipt date at the USPTO to the submission.

XXVII. Are there any legal consequences of the Office's accepting electronic patent applications on Saturday and Sunday?

The USPTO will be open for receiving applications in electronic form during scheduled hours every day of the week. Hours will be announced on the Patents Electronic Business Center Web Page, at the USPTO Website: http://www.uspto.gov/ebc.

Electronic filing will provide applicants with the opportunity to receive a filing date on any day of the week, including Saturday, Sunday, and Federal holidays. In addition, 35 USC 21(b) states:

> When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a Federal holiday within the District of Columbia, the action may be taken, or fee paid, on the next succeeding secular or business day.

Further, 35 USC 119((e)(3)) states:

> If the day that is 12 months after the filing date of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, the period of pendency of the provisional application shall be extended to the next succeeding secular or business day.

Thus, under United States law, applicants will be permitted to take action on the next business day when the last day for taking action falls on a weekend or Federal holiday, regardless of the mode or form of filing.

However, Article 4 of the Paris Convention addresses the priority period and in Article 4(c)(3) it states:

> If the last day of the period is an official holiday, or a day when the Office is not open for the filing of applications in the country where protection is claimed, the period shall be extended until the first following working day.

Further, as stated above, the USPTO is capable of accepting electronic patent application filings every day of the week, including weekends and holidays, through EFS-Web. Thus, applicants are cautioned to consider possible adverse consequences regarding the determination in other countries of priority periods under Article 4(C)(3) of the Paris Convention when filing international applications with the United States Receiving Office (RO/US). Specifically, the ability to file applications electronically on weekends and holidays in the USPTO *may* result in loss of priority rights in foreign jurisdictions designated in international applications filed with the RO/US, if applicants elect, in accordance with 35 USC 21(b) or 119(e)(3), to file an international application on the next succeeding business day in the event that the twelve month Paris Convention priority period set out in Article 4(C)(1) falls on a Saturday, Sunday, or Federal Holiday. In such circumstances, other Patent Offices *may* deny the priority claim on the basis that the international application was not timely filed if their national law strictly incorporates the provision of Paris Convention Article 4(c)(3) and considers the USPTO to be open for the filing of applications on weekends and holidays. For this reason, applicants may prefer not to rely upon the "next business day" provisions of sections 21(b) and 119(e)(3) of title 35 when filing applications with the USPTO, and instead file the application before the Paris Convention twelve-month priority period has expired.

XXVIII. Under what authority does an authorized assistant of the digital certificate holder submit signed documents?

Subscriber Agreements and Certificate Action Forms have been written to permit Assistants under the direction and control of the digital certificate holder (applicant/reexamination party or attorney) to submit documents under EFS-Web. The Assistant will use the Certificate Holder's certificate to make the submission.

The Assistant will serve the ministerial function of pickup and delivery of documents that have been electronically or ink signed by the applicant/reexamination party or the attorney. (Ink signed documents can be electronically scanned and then e-filed.) The Assistant, not being a

registered attorney or the applicant/reexamination party, does not have the authority to sign or be responsible for the content of the documents submitted. However, they may view and retrieve documents from Private PAIR, or submit documents under EFS-Web under the direction of a registered practitioner.

In the submission process, the Assistant is required to specify certain "locator information" so the documents can be associated with the proper electronic File Wrapper in the IFW system. That locator information may include the application's title, first named inventor, docket number, application number, confirmation number, correspondence address and filing date, all if available. The type of application (e.g. 111(a), 371, international application, etc) and information necessary for the payment of fees are not considered to be locator information. This information is entered on submission to assure that the documents are placed in the proper file, and do not constitute a signed submission of bibliographic data on behalf of the applicant/reexamination party. Errors made in the "locator information" may be corrected by the Office on its own initiative, or by the applicant/reexamination party, similar to the way they are corrected in paper processing.

It also should be noted that the assistant could pay the fees associated with the submission in the EFS-Web solution. This is comparable to the paper practice in which law firms designate individuals to pay fees.

XXIX. Under what conditions will the EFS-Web allow refunds?

The USPTO will grant refunds to e-filers when, due to a malfunction with the EFS-Web system, the EFS-Web system has misled a filer into paying a fee in error. If it cannot be determined that a malfunction occurred, but rather seems only to be an e-filer error, no refund will be given. The filer should contact the EBC if there are any issues associated with their submission.

XXX. Signature Policy

Signatures, other than handwritten signatures meeting the standard of 37 CFR 1.4(d)(1), included in image attachments submitted via EFS-Web are governed by the S-signature requirements of 37 CFR 1.4(d)(2) (See also 69 FR 56186, Sept. 21, 2004).

If the signer is submitting an application through EFS-Web in image-based PDF format, he or she should apply either a handwritten signature in compliance with 37 CFR 1.4(d)(1) or an S-signature in compliance with 37 CFR 1.4(d)(2) before scanning the document or converting it to image-based PDF form. It is noted that when filing a new application by EFS-Web, a signed transmittal form or a signed application data sheet (ADS) is recommended for identification purposes. It should be noted, however, that a signature is not required to obtain a filing date for a new patent application.

A legible electronic image of a handwritten signature inserted, or copied and pasted by the person signing the correspondence into an application document may be considered to be an

acceptable signature. The legible image of the handwritten signature of the person signing the correspondence must be inserted by the person. Additionally, the signature must be surrounded by a first single forward slash mark before the electronic image and a second single forward slash mark after the electronic image. That is, the legible electronic image of a handwritten signature must be enclosed between two single forward slashes and the signer's name is indicated below or adjacent the signature as per 37 CFR 1.4(d)(2). The slashes may be inserted into the document prior to the insertion of the signature.

The presentation to the USPTO (whether by signing, filing, submitting, or later advocating) of any document constitutes a certification under 37 CFR 10.18(b)(2). See 37 CFR 1.4(d)(4).

XXXI. Documents Policy

EFS-Web will allow registered users to file both new submissions and follow-on documents. The following is a list of submission types that are not allowed to be filed using EFS-Web:

1) Correspondence concerning **Registration Practice** submitted under 37 CFR 1.4(e), which states:
Correspondence requiring a person's signature and relating to registration practice before the Patent and Trademark Office in patent cases, enrollment and disciplinary investigations, or disciplinary proceedings must be submitted with an original hand written signature personally signed in permanent dark ink or its equivalent by that person. See 37 CFR 1.6(d)(1)

2) **Certified Copies** submitted under 37 CFR 1.4(f), which states:
When a document that is required by statute to be certified must be filed, a copy, including a photocopy or facsimile transmission, of the certification is not acceptable. See 37 CFR 1.6(d)(2). An example of such a submission is a certified copy of a foreign patent application filed pursuant to 35 USC 119 or a certified copy of an international application filed pursuant to 35 USC 365.

3) Correspondence to be filed in a patent application subject to a **secrecy order** under §§ 5.1 through 5.5 of this chapter. See 37 CFR 1.6(d)(6).

4) Submissions in contested cases before the **Board of Patent Appeals and Interferences**, except as the Board may expressly authorize. See 37 CFR 1.6(d)(9).

5) Papers filed in contested cases before the **Board of Patent Appeals and Interferences**, which are governed by 37 CFR 41.106(f). See 37 CFR 1.6(d)(3).

6) Correspondence filed in connection with a **disciplinary proceeding** under 37 CFR part 10. See 37 CFR 1.6(d)(3).

7) Submissions that are **not associated with an application/reexamination proceeding.**

8) **Third party papers** under 37 CFR 1.99.

9) **Protests** under 37 CFR 1.291.

10) **Public use hearing papers** under 37 CFR 1.292.

11) **Maintenance fees** submitted under 37 CFR 1.366. See MPEP 2510 for information regarding the proper methods for submitting maintenance fees.

12) Assignment documents under 35 USC 261, which may be electronically filed using the Electronic Patent Assignment System (EPAS) or the Electronic Trademark Assignment System (ETAS). Information regarding EPAS is available at: http://epas.uspto.gov. Information regarding ETAS is available at: http://etas.uspto.gov.

13) Submissions under 35 USC 161 associated with **plant applications**.

14) Initial submissions for Patent Term Extension under 35 USC 156.

For more information on these policies, please contact Diana Oleksa, Legal Advisor – IT Projects, PCT Legal Administration, at Diana.Oleksa@uspto.gov .

John J. Love
Deputy Commissioner for Patent Examination Policy

September, 2008

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 19 2010

Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

Dear Mr. Steinberg :

Pursuant to order by the United States District Court for the Eastern District of Virginia, Alexandria Division in The Medicines Company v. David Kappos et al. in civil action no. 01:10-cv-81, the USPTO issued an interim extension under the provision of 35 U.S.C. § 156(e)(2) on March 18, 2010. The attached document corrects an error in the Interim Extension granted on March 18, 2010. The order granting the interim extension was revised to read as follows:

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,196,404 is granted for a period of 61 days from the original expiration date of the patent, to and including May 23, 2010.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: Angiomax
FDA Docket No.: 01E-0213

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Biogen Idec MA Inc. Request for Patent Term Extension U.S. Patent No. 5,196,404	:	CORRECTION TO THE ORDER GRANTING INTERIM EXTENSION

Biogen Idec MA Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,196,404 (the '404 patent), through its authorized agent, The Medicines Company, filed an application for patent term extension under 35 U.S.C. § 156 on ~~February 14, 2001. The original term of the patent is due to expire on March 23, 2010. The~~ patent claims the active ingredient bivalirudin, in the human drug product Angiomax®, which was approved by the Food and Drug Administration for commercial marketing or use on December 15, 2000. An extension of 1,728 days is requested.

Pursuant to order by the United States District Court for the Eastern District of Virginia, Alexandria Division in The Medicines Company v. David Kappos et al. in civil action no. 01:10-cv-81, the USPTO issued an interim extension under the provision of 35 U.S.C. § 156(e)(2) on March 18, 2010. The order granting the interim extension is revised to read as follows:

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,196,404 is granted for a period of 61 days from the original expiration date of the patent, to and including May 23, 2010.

3/19/2010
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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MAR 19 2010

Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

Dear Mr. Steinberg :

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Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: Angiomax
FDA Docket No.: 01E-0213

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Biogen Idec MA Inc.	:	CORRECTION TO THE
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 5,196,404	:	INTERIM EXTENSION

Biogen Idec MA Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,196,404 (the '404 patent), through its authorized agent, The Medicines Company, filed an application for patent term extension under 35 U.S.C. § 156 on February 14, 2001. The original term of the patent is due to expire on March 23, 2010. The patent claims the active ingredient bivalirudin, in the human drug product Angiomax®, which was approved by the Food and Drug Administration for commercial marketing or use on December 15, 2000. An extension of 1,728 days is requested.

Pursuant to order by the United States District Court for the Eastern District of Virginia, Alexandria Division in The Medicines Company v. David Kappos et al. in civil action no. 01:10-cv-81, the USPTO issued an interim extension under the provision of 35 U.S.C. § 156(e)(2) on March 18, 2010. The order granting the interim extension is revised to read as follows:

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,196,404 is granted for a period of 61 days from the original expiration date of the patent, to and including May 23, 2010.

3/19/2010
Date

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

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MAY 21 2010

Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

Dear Mr. Steinberg :

Pursuant to Order by the United States District Court for the Eastern District of Virginia, Alexandria, Division in *The Medicines Company v. David Kappos et al.* in Civil Action No. 01:10-cv-286, the USPTO issued an interim extension extending the term of U.S. Patent No. 5,196,404 from May 23, 2010, through and including the day ten (10) days after the district court issues and Order deciding the pending cross motions for summary judgment in the above-identified civil action.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: ANGIOMAX® (bivalirudin)
FDA Docket No.: 01E-0213

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Biogen Idec MA Inc.	:	ORDER GRANTING
U.S. Patent No. 5,196,404	:	INTERIM EXTENSION

Biogen Idec MA Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,196,404 (the '404 patent), through its authorized agent, The Medicines Company, filed an application for patent term extension under 35 U.S.C. § 156 on February 14, 2001. The '404 patent claims the active ingredient bivalirudin, in the human drug product Angiomax®, which was approved by the Food and Drug Administration for commercial marketing or use on December 15, 2000. An extension of 1,728 days is requested.

The original term of the patent was due to expire on March 23, 2010. On March 18, 2010, the USPTO granted an interim extension extending the term of the '404 patent through May 23, 2010.

Pursuant to the May 21, 2010 Order of the United States District Court for the Eastern District of Virginia, Alexandria Division, in *The Medicines Company v. David Kappos et al.*, Civil Action No. 01:10-cv-286, directing the USPTO to further extend the term of the '404 patent, the USPTO is issuing a second interim extension.

An interim extension extending the term of U.S. Patent No. 5,196,404 is granted from the previously extended expiration date of May 23, 2010, through and including the day ten (10) days after the District Court issues an Order deciding the pending cross motions for summary judgment in the above-identified civil action.

May 21, 2010

Date

David J. Kappos

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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In re Gynelab Products, Inc. U.S. Patent No. 5,105,808	:	DISMISSAL OF PATENT TERM EXTENSION APPLICATION

An application for patent term extension of U.S. Patent No. 5,105,808 based upon the medical device ThermaChoice™ was filed by Gynelab Products, Inc. in the Patent and Trademark Office on February 6, 1998. An application for patent term extension of U.S. Patent No. 4,949,718, based upon the same product, was also filed on June 11, 1997.

On May 31, 2000, the PTO mailed a Notice of Final Determination in both of the above-noted applications stating that both patents qualify for patent term extension but for the fact that 35 U.S.C. § 156(c)(4), only one patent may be extended for the same regulatory review period for a product. Applicant was given a period of one-month to elect the patent for which term extension is desired.

On June 30, 2000, applicant filed a paper electing to have the term of U.S. Patent No. 4,949,718 extended. Accordingly, the application for patent term extension of the term of U.S. Patent No. 5,105,808 is dismissed under 35 U.S.C. 156(c)(4).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: ThermaChoice™
FDA Docket No.: 98E-0850

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

THOMAS R. MORRISON, ESQ.
145 NORTH FIFTH AVE.
MT VERNON NY 10550

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APR 27 2007

OFFICE OF PETITIONS

Patentee: Nakamichi et al.

Patent No. 5,123,001

Application No. 07/572,050
Filed: August 23, 1990

Issue Date: June 16, 1992
Title of Invention: Disk Playback Device

ON PETITION

This is a decision on the petition filed August 10, 2006, under 37 CFR 1.378(b), to accept the unavoidably delayed payment of a maintenance fee for the above-identified patent.

The petition is **DISMISSED**.

The patent issued June 16, 1992. The 11.5 year maintenance fee could have been paid from June 16, 2003 to December 16, 2003, or with a surcharge during the period from December 17, 2003 to June 16, 2004. Petitioner did not do so. Accordingly, the patent expired at midnight on June 16, 2004.

A grantable petition under 37 CFR 1.378(b) must be accompanied by a showing to the satisfaction of the Director that the entire delay in paying the required maintenance fee from the due date for the fee until the filing of grantable petition pursuant to this paragraph was unavoidable.

Pursuant to 37 CFR 1.378(b) a petition to accept an unavoidably delayed payment of a

maintenance fee must include:

(1) The required maintenance fee set forth in §1.20 (e) through (g);

(2) The surcharge set forth in §1.20(l)(1); and

(3) A showing that the delay was unavoidable since reasonable care was taken to ensure the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date and the manner in which patentee became aware of the expiration of the patent and the steps taken to file the petition promptly.

As to item (3), the showing of record is not sufficient to establish to the satisfaction of the Director that delay was unavoidable within the meaning of 37 CFR 1.378(b).

The general standard applied by the Office requires petitioner to establish that petitioner treated the patent the same as a reasonable and prudent person would treat his or her most important business.[1] However, " The question of whether an applicant's delay in prosecuting an application was unavoidable [will] be decided on a case by case basis, taking all of the facts and circumstances into account."[2] Nonawareness of the content of, or misunderstanding of PTO statues, PTO rules, the MPEP or Official Gazette notices, do not constitute unavoidable delay.[3] The statue requires a "showing" by petitioner. Therefore, petitioner has the burden of proof.

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[1] The Director is responsible for determining the standard for unavoidable delay and for applying that standard 35 U.S.C. 41(c)(1) states, "The Director may accept the payment of any maintenance fee...at any time...if the delay is shown to the *satisfaction of the Director* to have been unavoidable (emphasis added).

[2] Smith v. Mossinghoff, 671 F.2d 533,538, 213 U.S.P.Q. (BNA) 977 (1982). (citing Potter v. Dann, 201 U.S.P.Q. (BNA) 574 (D.D.C. 1978) for the proposition that counsel's nonawareness of PTO rules does not constitute unavoidable delay)); Vincent v. Mossinghoff, 1985 U.S. Dist. Lexis 23119, 13 230 U.S.P.Q. (BNA) 621 (D.D.C. 1985) (Plaintiffs through their counsel's actions or their own must be held responsible for having noted the MPEP section and Official Gazette notices expressly stating that the certified mailing procedures outlined in 37 CFR 1.8(a) do not apply to continuation applications).

[3] Id.

The word 'unavoidable' ... is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business.[4]

Application of the unavoidable standard to the present facts

In the instant petition, petitioner contends the delay in timely submitting the 11.5 year maintenance fee was unavoidable.

* The law firm of Banner and Witcoff "herein after B anner tracks maintenance fees through a docketing system and Computer Patent Annuities (CPA).

* The docketing system generates reminders.

* A reissue application for the above-identified application was filed on May 27, 1994.

* The attorney who was responsible for the reissue application left the Morrison Law firm and joined Banner in 1997.

* The reissue application transferred to Banner on March 1998 and was assigned reference number 004076.73577. At this time the parent application 5,123,001 was not transferred.

* In July 1999 the assignee requested Banner pay the 7.5 maintenance fee. The correspondence address of record was changed to that of Banner.

* No separate matter was opened for the above-identified patent in the Banner docket system.

* The clerk who handled renewals was responsible for opening a corresponding file for the above-identified patent to ensure the payment of the all future maintenance fee.

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[4] In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(*quoting* Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 U.S.P.Q. 666, 167-68 (D.D.C. 1963), aff'd, 143 U.S.P.Q. 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

* The clerk was subsequently terminated.

* Based on a correspondence log it was determined a Notice of patent expiration was received in July 2004.

* Petitioner contends there is no record of the Notice of Expiration was placed in the reissue application 08/250,667 docket record .

* The standard procedure would have required the clerk to have attempted to resolve why Banner received the expiration Notice for which there was no reference number.

* The clerk should have determined the assignee, determined if other matters are being handled for the assignee, and timely brought the Notice of Expiration to the billing attorney in charge of the matters for the assignee.

* Petitioner contends if the clerk had done the above the maintenance fee would have been paid.

* The clerk who was in charge of maintenance fees in 2004 is no longer with the firm.

*The first petitioner was aware that the 11.5 year maintenance fee had not been paid was when an order to show cause was mailed in the reissue application.

* General instructions to any clerk have always been to obtain instructions from a supervisory clerk.

* Petitioner contends the 11.5 year maintenance fee was unavoidable due to the failure of two clerks.

* The declaration of Janet Herring an employee of Banner has also been provided.

Petitioner's arguments have been considered but are unpersuasive to establish unavoidable delay. In general a grantable petition under 37 CFR 1.378 (b) must show 1) petitioner knew of the need to make the maintenance fee payment, 2) implemented a reliable docketing system to track the relevant dates 3) treated the payment of the maintenance fee (and later the filing of a petition to reinstate) as his most important business 4) was prevented from making the payment and 5) must show the entire delay in making the payment and

submitting a grantable petition was unavoidable. Petitioner has failed to demonstrate (2) that a reliable docketing system was implemented, (3) the payment of the maintenance fee was treated as their most important business and that (4) petitioner was prevented from making the maintenance fee payment due to the failure of two clerks resulted in the expiration of the above-identified patent.

As set forth in MPEP 711.03(c), a delay resulting from an error on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown :

> *A) the error was the cause of the delay;*
>
> *B) there was in place a business routine for performing the clerical function which could reasonably be relied upon to avoid errors in its performance; and*
>
> *C) the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care.*

Assuming the error was caused by docket error, petitioner has failed establish that there was a business routine in place that could reasonably be relied upon and that the employees were sufficiently trained and experienced with regard to the clerical function.

Petitioner states that general instructions to clerks are to always to obtain instructions from a supervisory clerk. More specifically the clerk was to see if they could match correspondence with an assignee and bing any Notices of Expiration to the billing attorney in charge. Petitioner has however failed to demonstrate that this was a business routine which could reasonably be relied upon considering for this one application there were two separate clerks who failed to follow this routine.

Further the errors purportedly caused by the clerks fail to show that the clerks were sufficiently trained, experienced and supervised. Petitioner has failed to provide sufficient information regarding the clerks in question. The Office is interested in finding out how long the clerks were employed with Banner, why was the one clerk terminated. Did either clerk have a history of failing to adhere to the business routine? Since at least one clerk was terminated was a review of her/his work conducted to locate any errors.

An adequate showing of unavoidable delay due to docket/clerical error may include but not limited to:

> *1) statements by all parties with direct knowledge of the circumstances surrounding the delay;*
>
> *2) a through explanation of the docketing system in use;*
>
> *3) identification of the types of records kept;*
>
> *4) identification of the persons responsible for the maintenance of the system, copies of mail ledger, docket sheets, file wrappers;*
>
> *6)an indication why the system failed; and*
>
> *5)information regarding the training provided to the clerk(s) responsible for the docketing error, the degree of supervision of their work.*

Petitioner has failed to provide a through explanation of the docketing system. What type of docketing system is used, do only clerks enter new records. When is information transferred to CPA? Petitioner mentions two clerks but has not provided enough information as to the clerical duties that were to be performed. Specifically petitioner should state why a docket record was not opened in July 1999 when the 7.5 year maintenance fee was paid and the correspondence address was changed to Banner. Since part of petitioner's system in place included reliance on CPA did petitioner notify CPA to pay the 7.5 year maintenance fee.

Petitioner has failed to provide any information regarding the training provided to a subordinate clerk beyond stating general instructions given to clerks. Nor is there any information regarding the type of supervision provided to junior clerks. It is evident there was at least one supervisory clerk but little else has been provided. Further a statement from the attorney who was responsible for the payment of the 7.5 year maintenance fee should be provided.

Accordingly, petitioner has not presented sufficient facts to establish the delay in submitting the 11.5 year maintenance fee was "unavoidable".

There is no indication that Petitioner herein was ever empowered to prosecute the application. If Petitioner desires to receive future correspondence regarding this patent, the appropriate power of attorney documentation and change of correspondence address must be submitted. A courtesy copy of this decision will be mailed to Petitioner. However, all future correspondence will be directed to the address of record until such time as appropriate instructions are received to the contrary.

Petitioner's current options

I. Petitioner may file a request for reconsideration.

Any request for reconsideration of this decision must be filed within **TWO MONTHS** of the mailing date of this decision. Any such petition for reconsideration must be accompanied by the $400 petition fee set forth in §1.17(h). After decision on the petition for reconsideration, no further reconsideration or review of the matter will be undertaken by the Director. Accordingly, on request for reconsideration, it is extremely important the petitioner supply **any** and **all** relevant information and documentation in order to meet his burden of showing unavoidable delay. This includes statements by all persons with direct knowledge of the cause of the delay, setting forth the facts as they know them. If a request for reconsideration is filed, it must establish that the entire delay in the submission of the maintenance fee was unavoidable.

II. Petitioner may request a refund of the maintenance fee and surcharge which accompanied the petition.

Petitioner may a request a refund of the maintenance fee and surcharge by writing to the Office of Finance, Commissioner for Patents, P.O. Box 1450,Alexandria, VA 22313. A copy of this decision should accompany petitioner's request.

Further correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
By facsimile:	(571) 273-8300
By delivery service: (FedEx, UPS, DHL, etc.)	U.S. Patent and Trademark Office Customer Window, Mail Stop Petition Randolph Building 401 Dulany Street

Alexandria, VA 22314

Telephone inquiries should be directed to the undersigned at (571) 272-3215.

Charlema R. Grant

Charlema R. Grant
Petitions Attorney
Office of Petitions

cc: Christopher R. Glembocki
Banner & Witcoff LTD
1001 G St. Suite 1100
Washington, DC 20001

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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OFFICE OF PETITIONS

In re Patent No. 5,123,001	:	
Issued: June 16 1992	:	
Application No. 07/572,050	:	ON PETITION
Filed: August 23, 1990	:	
Title: Disk Playback Device	:	
	:	

This is a decision on the petition under 37 CFR 1.378(e), filed June 27, 2007.[1]

The petition is **DENIED**[2].

BACKGROUND

The patent issued June 16, 1992. The 11.5 year maintenance fee could have been paid from June 16, 2003 to December 16, 2003, or with a surcharge during the period from December 17, 2003 to June 16, 2004. Petitioner did not do so. Accordingly, the patent expired at midnight on June 16, 2004.

A petition under 37 C.F.R. § 1.378(b) to accept late payment of the maintenance fee was filed August 10, 2006. A decision dismissing the petition under 37 CFR 1.378(b) was mailed April 27, 2007 and is hereby incorporated by reference. Petitioner timely submitted this request for reconsideration on June 27, 2007. In support of the request for reconsideration petitioner has provided statements from Gary Fedorochko, Carolyn Lewis, Scott Fisher, Sherman Miranda and Johnathan Dunn.

Petitioners assert that the entire delay was unavoidable since reasonable care was taken to ensure that the third maintenance fee would be paid. Petitioners frequently used the services of Computer Patent Annuities ("hereinafter CPA"). However, petitioner states there were instances where the firm Banner Witcoff paid maintenance fees on their own. Petitioner contends

[1] The required petition fee of $400.00 has been charged to petitioners' deposit account as authorized.
[2] This decision may be viewed as a final agency action within the meaning of 5 U.S.C. § 704 for purposes of seeking judicial review. *See*, MPEP 1002.02.

that contrary to the first petition, only one clerk, Ms. Florence Burgess failed to adequately perform her duties. Petitioners state that the clerks were adequately trained and were provided the firm's Docketing Policies and Procedures Manual, the International Department's Policy Procedures Manual and CPA's Inproma docketing Software System Manual. (Copies of the manuals have been submitted as evidence).

Petitioners' procedure as it existed until July 2005 involved US Maintenance fee correspondence being forwarded to a single US Maintenance Fee person in the Washington, DC Office. The US maintenance fee person's sole responsibility was to research and pay maintenance fees, annuity fees and renewal fees.

Petitioner states that Ms. Burgess, the U.S. Maintenance Fee person, failed to enter the 11.5 year maintenance fee due date for the above-identified patent in the docket system.

Although the firm's PTO Log shows that a Notice of Patent Expiration was received on July 29, 2004, the clerk responsible at that time Mr. Miranda, does not recall receiving the Notice of Expiration. The Notice of Expiration was never associated with the reissue application.

Lastly, petitioners insist that any delay in the submission of the original petition was unavoidable because they did not become aware of the expiration until July 11, 2006 upon receipt of the Notice to Show Cause.

OPINION

The Director may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Director to have been "unavoidable.[3]" Moreover, a late maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 U.S.C. 133 because 35 U.S.C. 41(c)(1) uses the identical language, i.e., "unavoidable" delay[4]. Decisions on reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable[5]. Further, decisions on revival are made on a

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[3] 35 U.S.C. 41(c)(1).

[4] See, Ray v. Lehman, 55 F3d 606, 608-609, 34 USPQ2d 1786, 1787 (Fed. Cir. 1995)(quoting In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (Comm'r Pat. 1988)).

[5] See, Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by

"case-by-case basis, taking all the fact and circumstances into account[6]." Finally, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay[7].

A delay resulting from an error (e.g., a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown that: (A) the error was the cause of the delay at issue; (B) there was in place a business routine for performing the clerical function that could reasonably be relied upon to avoid errors in its performance; and (C) the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care. See, In re Egbers, 6 USPQ2d 1869, 1872 (Comm'r Pat. 1988), rev 'd on other grounds sub nom., Theodor Groz & Sohne & Ernst Bechert Nadelfabrik KG v. Quigg, 10 USPQ2d 1787 (D.D.C. 1988); In re Katrapat, 6 USPQ2d 1863, 1867-68 (Comm'r Pat. 1988).

Petitioners have failed to establish that the docketing error complained of was the requisite cause of the failure to timely remit the maintenance fee. Petitioners state that the maintenance fee due date for the instant patent was not docketed for action because Ms. Burgess failed to inform the docketing staff of the dates and/or open a separate matter for tracking the dates of the above-identified patent.

Although petitioner has provided evidence about the training the firm provides to clerks in general, no information regarding the training specifically provided to Ms. Burgess has been provided.

Petitioners have failed to establish that docket error on the part of a clerical staff resulted in the failure to submit the 11.5 year maintenance fee. Petitioners have provided evidence that a system was in place to track and monitor maintenance fee due dates. However, petitioners have failed to establish that the required documents, which would trigger updating the docketing system, were ever provided to Ms. Burgess. The clerical functions can only be expected to be relied upon, if

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prudent and careful men in relation to their most important business"; In re Mattullath, 38 App. D.C. 497, 514-515 (D.C. Cir. 1912), Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (Comm'r Pat. 1913).

[6] See, Smith v. Mossinghoff, 671 F.2d 533, 213 USPQ 977, 982 (D.C. Cir. 1982).

[7] See, Haines v. Quigg, 673 F.Supp. 314, 5 USPQ2d 1130 (N.D. Ind. 1987).

Ms. Burgess was directed to enter the information into the system.

In this instance petitioner states that the firm was working on reissue application no. 08/760,706 for which they received the physical file from former counsel the Morrison Law firm. Banner & Witcoff did not receive the patent application file for patent '001. In response to a request from the assignee on November 16, 1999 attorney Fedorochko reviewed and signed the submission of the 7.5 year maintenance fee after it was prepared by Ms. Burgess. However, no evidence has been provided to establish that this was not a one time request and that Ms. Burgess was directed to enter the future due date for the 11.5 year maintenance fee. It is noted that the manner in which assignee conveyed the request to pay the maintenance fee has not been provided.

Further, insufficient evidence was provided to establish that Ms. Burgess's clerical duties were ever reviewed or supervised and thus there appears to be no checks in place to ensure proper execution of the payment of maintenance fees. Although petitioner states Ms. Burgess was knowledgeable and performed her responsibilities, she was terminated based on her overall productivity. The subsequent termination and her inability to meet the firm's productivity levels calls into question whether it was reasonable to rely on Ms. Burgess without an adequate degree of supervision. To the extent Ms. Burgess neglected to include the patent in the docket system a review by a supervisor may have revealed the parent application had not been included in the docketing system. It is further noted that a statement from Ms. Burgess has not been provided. The failure to procure the statement goes to the failure to make an adequate showing of unavoidable delay. Nor has petitioner provided a showing of the training specifically given to Ms. Burgess.

Contrary to petitioner's argument, the failure to address the Notice of Expiration upon receipt on July 29, 2004 was avoidable. Further it shows that the clerks (Mr. Miranda and Mr. Fisher) failed to follow the procedures in place. According to petitioner's procedure, if a maintenance fee form was received and could not be resolved, it was to be bought to a senior clerk's attention and thereafter an attorney if the issue could not be resolved. If it was determined that Banner & Witcoff was not responsible for the maintenance issue, the sheet was to be returned to the USPTO. The record is devoid of any evidence that this procedure was followed. Instead it appears that the Notice

of Expiration was just ignored. Thus, the failure to take action resulted in the failure to promptly file the original petition.

In view of the totality of the evidence of record, including the exhibits submitted herewith, it cannot be found that the entire time, from the time that the maintenance fee was due until the filing of the instant petition, was unavoidable.

DECISION

The prior decision dismissing petition under 37 CFR 1.378(b) to accept the delayed payment of maintenance fee has been reconsidered. For the reasons set forth herein the delay in payment of the maintenance fee cannot be regarded as unavoidable within the meaning of 35 USC 41 and 37 CFR 1.378(b). Accordingly, the offer to pay the delayed maintenance fee will not be accepted and this patent will not be reinstated.

Since this patent will not be reinstated, a refund covering the maintenance fee and surcharge fee will be forwarded to petitioner.

This file is being forwarded to files repository.

Telephone inquiries concerning this matter may be directed to the Petitions Attorney Charlema Grant at 571-272-3215.

Charles Pearson
Director
Office of Petitions

CC:

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

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OFFICE OF PETITIONS

In re Application of	:	
Martin LEMPERLE	:	
Application No. 07/572,975	:	DECISION ON PETITION
Filed: August 6, 1990	:	TO WITHDRAW
Attorney Docket No. 095004-0230	:	FROM RECORD
	:	

This is a decision on the Request to Withdraw as attorney or agent of record under 37 C.F.R. § 1.36(b), filed January 28, 2009.

The request is **APPROVED**.

A grantable request to withdraw as attorney/agent of record must be signed by every attorney/agent seeking to withdraw or contain a clear indication that one attorney is signing on behalf of another/others. The Office requires the practitioner(s) requesting withdrawal to certify that he, she, or they have: (1) given reasonable notice to the client, prior to the expiration of the response period, that the practitioner(s) intends to withdraw from employment; (2) delivered to the client or a duly authorized representative of the client all papers and property (including funds) to which the client is entitled; and (3) notified the client of any responses that may be due and the time frame within which the client must respond, pursuant 37 CFR 10.40(c).

The request was signed by G. Peter Albert Jr. on behalf of the attorneys of record associated with Customer No. 30542.

The attorneys of record associated with Customer No. 30542 have been withdrawn.

Applicant is reminded that there is no attorney of record at this time.

All future correspondence will be directed to the inventor at the address indicated below until otherwise properly notified by the applicant.

Telephone inquiries concerning this decision should be directed to the undersigned at 571-272-6735.

Diane Goodwyn
Petitions Examiner
Office of Petitions

cc: MARTIN LEMPERLE
RODERBERGQWEQ 43
D-6000 FRANKFURT 1
GERMANY

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: 30

DATE : 3-6-07

EXPEDITE

TO SPE OF : ART UNIT ~~1700~~ 1615

SUBJECT : Request for Certificate of Correction on Patent No.: 5202128

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within **7** days to:
Palm location **7580, Certificates of Correction Branch – South Tower – 9A22**
If response is for an IFW, **return to employee (named below) via PUBSCofC Team in MADRAS.**
With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction (COCIN)? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

PLEASE FORWARD CASE BACK CERTITICATE OF CORRECTION BRANCH, AS SOON AS POSSIBLE!!!

Michelle Williams

Thank You For Your Assistance

Certificates of Correction Branch
Tel. No. 703-308-9390 ext. 118

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

- ☒ **Approved** — **All** changes apply.
- ☐ **Approved in Part** — Specify below which changes **do not** apply.
- ☐ **Denied** — State the reasons for denial below.

Comments:

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SPE **Art Unit**

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,202,128
APPLICATION NO. : 07/574551
DATED : April 13, 1993
INVENTOR(S) : Angelo M. Morella

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 23 lines 65-68 + Col. 24 lines 1-13, should read,

2. The sustained release pharmaceutical pellet composition of claim 1 wherein the coating contains:

as component (a), ethyl cellulose, a quaternary ammonium acrylic or methacrylic polymer, an acrylic or a methacrylic ester copolymer or a mixture thereof;

as component (b), cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid:acrylic acid ester copolymer, hydroxypropyl methylcellulose acetate succinate, shellac, cellulose acetate trimellitate or mixtures thereof; and

as component (c), polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol having a molecular weight of from 1700 to 20,000, polyvinyl alcohol and monomers therefor or mixtures thereof.

Col. 24 lines 14-26 should read,

3. The sustained release pharmaceutical pellet composition of claim 1 wherein the active ingredient is selected from the group consisting of antihistamines, antibiotics, antituberculosis agents, cholinergic agents, antimuscarinics, sympathomimetics, sympatholytic agents, autonomic drugs, iron preparations, haemostatics, cardiac drugs, antihypertensive agents, vasodilators, non-steroidal antiinflammatory agents, opiate agonists, anticonvulsants, tranquilizers, stimulants, barbiturates, sedatives, expectorants, antiemetics, gastrointestinal drugs, heavy metal antagonists, antithyroid agents, genitourinary smooth muscle relaxants and vitamins.

Col. 25 lines 5-34 should read,

10. A pH-dependent sustained release pharmaceutical pellet composition for administration to a patient at a predetermined dosage and interval which comprises: a core element containing a therapeutically effective amount of an acid addition salt of morphine and a coating on said core element which comprises the following components:

(a) at least 35% by weight of a matrix polymer which is insoluble at a pH of from 1 to 7.5 and contributes to the control of the rate of release of the acid addition salt of morphine in the stomach and intestines;

(b) from 1 to 30% of an enteric polymer which is substantially insoluble at a pH of from 1 to 4, sufficient to delay the release of the acid addition salt of morphine in the stomach, but which is soluble at a pH of from 6 to 7.5 so as not to substantially delay release in the intestines;

CERTIFICATE OF CORRECTION

PATENT NO. : 5,202,128
APPLICATION NO. : 07/574551
DATED : April 13, 1993
INVENTOR(S) : Angelo M. Morella

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 25 lines 17-48 (cont'd)

(c) from 1 to 60% of a compound soluble at a pH of from 1 to 4, sufficient to enable initiation of release of the acid addition salt of morphine in the stomach; said percentages being by weight based on the total weight of components (a), (b), and (c); the ratio of the components (a), (b), and (c) in said coating being effective to allow the initiation of the release of the acid addition salt of morphine in the stomach at a slow rate and to control the release in the intestines at a rate faster than that in the stomach such that a dose of the pellet composition delivers to the patient a therapeutically effective amount of said acid addition salt of morphine over the course of said predetermined interval.

Col. 25 lines 52-68 should read,

15. The sustained release pharmaceutical pellet composition of claim 10 wherein the coating contains:

as component (a), ethyl cellulose, a quaternary ammonium acrylic or methacrylic polymer, an acrylic or a methacrylic ester copolymer or a mixture thereof;

as component (b), cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid ester copolymer, hydroxypropyl methylcellulose acetate succinate, shellac, cellulose acetate trimellitate or mixtures thereof; and

as component (c), polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol having a molecular weight of from 1700 to 20,000, polyvinyl alcohol and monomers therefor or mixtures thereof.

17. The sustained release pharmaceutical pellet composition of claim 15 wherein the coating comprises:

[TABLE OMITTED].

Col. 26 lines 17-48 should read

18. A method for treating a pain associated with a condition in a patient which comprises administering to said patient at a predetermined dosage and interval a pH-dependent sustained release pharmaceutical pellet composition which comprises: a core element containing a therapeutically effective amount of an active compound having an aqueous solubility of at least 1 in 30 and a coating on said core element which comprises the following components:

(a) at least 35% by weight of a matrix polymer which is insoluble at a pH of from 1 to 7.5 and contributes to the control of the rate of release of the active ingredient in the stomach and intestines;

CERTIFICATE OF CORRECTION

PATENT NO. : 5,202,128
APPLICATION NO. : 07/574551
DATED : April 13, 1993
INVENTOR(S) : Angelo M. Morella

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 26 lines 17-48 (cont'd)

(b) from 1 to 30% of an enteric polymer which is substantially insoluble at a pH of from 1 to 4, sufficient to delay the release of the active ingredient in the stomach, but which is soluble at a pH of from 6 to 7.5 so as not to substantially delay release in the intestines;

(c) from 1 to 60% of a compound soluble at a pH of from 1 to 4, sufficient to enable initiation of release of the active ingredient in the stomach;

said percentages being by weight based on the total weight of components (a), (b), and (c); the ratio of the components (a), (b), and (c) in said coating being effective to allow the initiation of the release of the active ingredient in the stomach at a slow rate and to control the release in the intestines at a rate faster than that in the stomach such that a dose of the pellet composition delivers to the patient a therapeutically effective amount of said active ingredient over the course of said predetermined interval.

Col. 27 lines 29-49 should read,

25. A pH-dependent sustained release pharmaceutical pellet composition for administration to a patient at a predetermined dosage and interval which comprises: a core element containing a therapeutically effective amount of an acid addition salt of morphine and a coating on said core element which comprises the following components:

(a) at least 35% by weight of a matrix polymer which is insoluble at a pH of from 1 to 7.5 and is composed of ethyl cellulose, a quaternary ammonium acrylic or methacrylic polymer, an acrylic or a methacrylic ester copolymer or a mixture thereof which contributes to the control of the release of the acid addition salt of morphine in the stomach and intestines;

(b) from 1 to 30% of an enteric polymer which is substantially insoluble at a pH of from 1 to 4, sufficient to delay the release of the acid addition salt of morphine in the stomach, but which is soluble at a pH of from 6 to 7.5 so as not to substantially delay release in the intestines;

(c) from 1 to 60% of a compound soluble at a pH of from 1 to 4, sufficient to enable initiation of release of the acid addition salt of morphine in the stomach;

said percentages being by weight based on the total weight of components (a), (b), and (c); the ratio of the components (a), (b), and (c) in said coating being effective to allow the initiation of the release of the acid addition salt of morphine in the stomach at a slow rate and to control the release in the intestines at a rate faster than that in the stomach such that a dose of the pellet composition delivers to the patient a therapeutically effective amount of said acid addition salt of morphine over the course of said predetermined interval.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,202,128
APPLICATION NO. : 07/574551
DATED : April 13, 1993
INVENTOR(S) : Angelo M. Morella

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 28 lines 14-48 should read,

26. A method for treating a pain associated with a condition in a patient which comprises administering to said patient at a predetermined dosage and interval a pH-dependent sustained release pharmaceutical pellet composition which comprises: a core element containing a therapeutically effective amount of an active compound having an aqueous solubility of at least 1 in 30 and a coating on said core element which comprises the following components:

(a) at least 35% by weight of a matrix polymer which is insoluble at a pH of from 1 to 7.5 and is composed of ethyl cellulose, a quaternary ammonium acrylic or methacrylic polymer, an acrylic or a methacrylic ester copolymer or a mixture thereof which contributes to the control of the release of the active ingredient in the stomach and intestines;

(b) from 1 to 30% of an enteric polymer which is substantially insoluble at a pH of from 1 to 4, sufficient to delay the release of the active ingredient in the stomach, but which is soluble at a pH of from 6 to 7.5 so as not to substantially delay release in the intestines;

(c) from 1 to 60% of a compound soluble at a pH of from 1 to 4, sufficient to enable initiation of release of the active ingredient in the stomach;

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,202,128
APPLICATION NO. : 07/574551
DATED : April 13, 1993
INVENTOR(S) : Angelo M. Morella

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 28 lines 14-48 (cont'd)

said percentages being by weight based on the total weight of components (a), (b), and (c); the ratio of the components (a), (b), and (c) in said coating being effective to allow the initiation of the release of the active ingredient in the stomach at a slow rate and to control the release in the intestines at a rate faster than that in the stomach such that a dose of the pellet composition delivers to the patient a therapeutically effective amount of said active ingredient over the course of said predetermined interval.

Signed and Sealed this

Tenth Day of April, 2007

Jon W. Dudas

JON W. DUDAS
Director of the United States Patent and Trademark Office

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.:20080624

DATE : June 24, 2008

TO SPE OF : ART UNIT 1638

SUBJECT : Request for Certificate of Correction on Patent No.: 5,159,135

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within **7** days to:
Certificates of Correction Branch - ST (South Tower) 9A22
Palm location **7590** - Tel. No. (703) 305-8309

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Thank You For Your Assistance **Certificates of Correction Branch**

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriated box.

☒ **Approved** All changes apply.

☐ **Approved in Part** Specify below which changes **do not** apply.

☐ **Denied** State the reasons for denial below.

Comments:

The petition to add an inventor under 37 CFR 1.324 of 09 April 2008 has been GRANTED.

SPE: Anne Marie Grunberg Art Unit 1638

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON DC 20044-4300

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MAR 2 3 2007

OFFICE OF PETITIONS

In re Application of :
Matich, et al. :
Application No. 07/578,515 : ON PETITION
Filed: August 16, 1990 :
Attorney Docket No. 100123/50879/02589 :

This is a decision on the petition, filed March 2, 2007, under 37 CFR 1.181 to withdraw the holding of abandonment.

The petition under 37 CFR 1.181 to withdraw the holding of abandonment is **GRANTED**.

The Office contended that the above-identified application became abandoned for failure to timely reply to the Notice Regarding Drawings, mailed August 4, 2006, which set non-extendable period for reply of two (2) months. In addition, applicants did not timely respond to the Notice of Allowance and Fee(s) Due, mailed July 12, 2006, which set a three month period for reply. Having received no drawings, the application became abandoned on October 5, 2006. A Notice of Abandonment was mailed on January 23, 2007.

The Office received a proper Revocation of Previous Power of Attorney and Appointment of New Attorneys on June 17, 2004. Unfortunately, the Office did not promptly enter the requested changes, including a change in correspondence address. This error resulted in all later mailed correspondence being directed to the previous correspondence address of record and the subsequent return of the correspondence. The Revocation of Previous Power of Attorney and Appointment of New Attorneys, filed June 17, 2004, was entered into Office databases in time for the mailing of a Notice of Abandonment.

The petition under 37 CFR 1.181 is granted, the holding of abandonment is withdrawn, and the January 23, 2007 Notice of Abandonment is vacated. No petition fee has been or will be charged in connection with this matter.

After the mailing of this decision, the application will be forwarded to Technology Center AU 3662 for the re-mailing of the July 12, 2006 Notice of Allowance and Fee(s) Due and Notice of Allowability. It is noted that applicants did not receive the Notice Regarding Drawings, mailed August 4, 2006. The undersigned hopes the issues raised in the August 4, 2006 Notice will be

included in a revised Notice of Allowability. If not, Publications Division will have to re-mail the August 4, 2006 Notice Regarding Drawings. Of course, new periods for reply must be set.

Telephone inquiries may be directed to the undersigned at (571) 272-3230.

Shirene Willis Brantley

Shirene Willis Brantley
Senior Petitions Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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Crowell & Moring, L.L.P.
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300

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JUN 14 2006

OFFICE OF PETITIONS

In re Application of	:
Ramsey	:
U.S. Patent No. 6,989,783	: Decision on Petition for
Issue Date: January 24, 2006	: Patent Term Extension
Application No. 07/578,517	:
Filed: August 16, 1990	:
For: Multiple Target Ranging System	:

The above-identified application has been forwarded to the undersigned for consideration on a petition for patent term extension entitled "Petition Regarding Patent Term Extension Under 37 CFR 1.181" received May 2, 2006.

The petition is granted.

Petitioner notes that the above-identified application was filed on August 16, 1990, and therefor not eligible for patent term extension under 35 U.S.C. 154.

The Notice of Allowance and Issue Fee Due mailed on July 9, 2005, correctly indicated that the patent to issue from the application 07/578,517 was not eligible for a patent term extension. The front page of the patent incorrectly indicates that the term of the patent is extended for 1,826 days.

After mailing of this decision, the application will be forwarded to the Certificate of Correction Branch. The Office will issue a certificate of correction in order to rectify the error regarding the patent term extension information. See 35 U.S.C. 254 and 37 CFR 1.322. The Office will issue a certificate of correction indicating that the patent term is extended by **0 days.**

Petitioner's deposit account has not been charged a petition fee.

Inquiries with regard to this communication should be directed to Mark O. Polutta at (571) 272-7709.

Mark O. Polutta
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

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SCULLY, SCOTT, MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY NY 11530

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FEB 28 2006

OFFICE OF PETITIONS

In re Application of: :
Huffman et al. :
Application No. 07/580,246 : ON PETITION
Filed: September 10, 1990 :

This application is before this office in view of a petition filed August 2, 2005, self-styled as requesting relief under 37 CFR 1.181, 1.182, and 1.183, which is being treated by this Office as a petition under 37 CFR 1.181 only, to refer the above-identified application to the attention of the Office of the Director, Technology Center 1700, for a review of the examiner's actions in this case.

The petition is granted under 37 CFR 1.181 **solely** to the preliminary, procedural extent that the petition is being referred to the Group Director of Technology Center 1700, for a decision on the merits of the petition under 37 CFR 1.181.

Petitioner complains that he has been prejudiced by the examiner's inclusion of an alleged, but unlabeled, new grounds of rejection in the Examiner's Answer mailed June 3, 2005

A review of an examiner's action or inaction in a given application, in the first instance, is by way of the Group Director under the provisions of 37 CFR 1.181. See MPEP 1002.02(c), ¶ 3. Should an applicant, in turn, seek review of an adverse decision of the Director, that review will come before this office under the provisions of 37 CFR 1.181. See MPEP 1002.02(b), ¶ 15.

Since 37 CFR 1.181 entirely provides for the question then 37 CFR 1.182 by its express terms does not provide for the question, and as such, it is facially unnecessary to consider the petition under 37 CFR 1.182.

As to the petition under 37 CFR 1.183, since it is facially not necessary to consider waiver of any requirement of the rules of practice for the Group Director to treat the petition on its merits under 37 CFR 1.181, the question of waiver need not be considered.

This application is being referred to the office of the Group Director for Technology Center 1700, for treatment of the petition filed August 5, 2005 considered only under the provisions of 37 CFR 1.181(a).

Telephone inquiries related to this communication should be directed to the undersigned at (571) 272-3217.

Brian Hearn
Petitions Examiner
Office of Petitions

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MAR 17 2008

SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY NY 11530

In re Application of	:	
Huffman,et al.	:	
Application No. 07/580,246	:	DECISION
Filed: 10 September, 1990	:	
Attorney Docket No. 7913Z	:	

This is a decision on the petition filed on 12 October, 2007, and considered as a request to withdraw the holding of abandonment under 37 C.F.R. §1.181.

The Office regrets the delay in addressing this matter, however, the petition was presented to the attorneys in the Office of Petitions only at this writing.

The petition as considered under 37 C.F.R. §1.181 is **GRANTED**.

BACKGROUND

The record reflects that:

- Petitioner failed to reply timely and properly to the Office Communication mailed on 8 June, 2007 (the June 2007 Communication), with reply due absent extension of time on or before 8 September, 2007;
- the application went abandoned after midnight 8 September, 2007;
- it does not appear that the Office mailed the Notice of Abandonment before the instant petition was filed;

- on 24 July, 2007, Petitioner filed a Notice of Change of Address as associated with Customer Number 23389, and the Office appears to have acknowledged that Notice;

- 12 October, 2007, Petitioner filed, *inter alia*, the instant petition, and averred that the Examiner contacted him 1 October, 2007 (and indicated that the reply was not in the file and questioned whether the reply had been filed), however that there was timely filing of the reply to the June 2007 Communication in the form, *inter alia*, of Communication page and three separate Declarations—specifically those of Harold W. Kroto (with thirteen associated exhibits attached thereto), Mauricio Terrones (with three associated exhibits attached thereto) and Adam Darwish (with sixteen associated exhibits attached thereto), and in support of this averment, Petitioner evidences that the papers in question were transmitted over Petitioner's signed and dated Certificate of Mailing (37 C.F.R. §1.8), along with a date-stamped ("SEP 07 2007") receipt card in support of that averment, and what are averred as true copies of the papers previously filed.

The availability of applications and application papers online to applicants/practitioners who diligently associate their Customer Number with the respective application(s) now provides an applicant/practitioner on-demand information as to events/transactions in an application. Thus, now if one wishes to know the progress in and/or status of an application or the accuracy of the data therein, one need only look at the file online.

Out of an abundance of caution, Petitioners always are reminded that the filing of a petition under 37 C.F.R. §1.181 does not toll any periods that may be running any action by the Office and a petition seeking relief under the regulation must be filed within two (2) months of the act complained of (see: 37 C.F.R. §1.181(f)), and that those registered to practice and all others who make representations before the Office are reminded to inquire into the underlying facts of representations made to the Office and support averments with the appropriate documentation–since all owe to the Office the continuing duty to disclose.[1]

STATUTES, REGULATIONS AND ANALYSIS

Congress has authorized the Commissioner to "revive an application if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable." 35 U.S.C. §133 (1994).[2]

---

[1] See supplement of 17 June, 1999. The Patent and Trademark Office is relying on petitioner's duty of candor and good faith and accepting a statement made by Petitioner. See Changes to Patent Practice and Procedure, 62 Fed. Reg. at 53160 and 53178, 1203 Off. Gaz. Pat. Office at 88 and 103 (responses to comments 64 and 109)(applicant obligated under 37 C.F.R. §10.18 to inquire into the underlying facts and circumstances when providing statements to the Patent and Trademark Office).

See specifically, the regulations at 37 C.F.R. §10.18.

[2] 35 U.S.C. §133 provides:

35 U.S.C. §133 Time for prosecuting application.

Upon failure of the applicant to prosecute the application within six months after any action therein, of which notice has been given or mailed to the applicant, or within such shorter time, not less than thirty days, as fixed by the Commissioner in such action, the application shall be regarded as abandoned by the parties thereto, unless it be shown to the satisfaction of the Commissioner that such delay was unavoidable.

The regulations at 37 C.F.R. §1.137(a) and (b) set forth the requirements for a petitioner to revive a previously unavoidably or unintentionally, respectively, abandoned application under this congressional grant of authority.

The language of 35 U.S.C. §133 and 37 C.F.R. §1.137(a) is clear, unambiguous, and without qualification: the delay in tendering the reply to the outstanding Office action, as well as filing the first petition seeking revival, must have been unavoidable for the reply now to be accepted on petition.[4]

Delays in responding properly raise the question whether delays are unavoidable.[3] Where there is a question whether the delay was unavoidable, Petitioners must meet the burden of establishing that the delay was unavoidable within the meaning of 35 U.S.C. §133 and 37 C.F.R. §1.137(a).[4]

And the Petitioner must be diligent in attending to the matter.[5] Failure to do so does not constitute the care required under Pratt, and so cannot satisfy the test for diligence and due care.

(By contrast, unintentional delays are those that do not satisfy the very strict statutory and regulatory requirements of unavoidable delay, and also, by definition, are not intentional.[6]))

Allegations as to the Request to
Withdraw the Holding of Abandonment

The courts have determined the basis for a petition seeking withdrawal of a holding of abandonment[7]—the guidance in the Commentary at MPEP §711.03(c)(A) and (B) details the requirements therein.

And the regulation requires that relief be sought within two (2) months of the act complained of.

Petitioner appears to have satisfied the burdens herein.

---

[3] See: *Changes to Patent Practice and Procedure*; *Final Rule Notice*, 62 *Fed. Reg.* at 53158-59 (October 10, 1997), 1203 *Off. Gaz. Pat. Office* at 86-87 (October 21, 1997).

[4] See: In re Application of G, 11 USPQ2d 1378, 1380 (Comm'r Pats. 1989).

[5] See: Diligence in Filing Petitions to Revive and Petitions to Withdraw the Holding of Abandonment, 1124 Off. Gaz. Pat. Office 33 (March 19, 1991). It was and is Petitioner's burden to exercise diligence in seeking either to have the holding of abandonment withdrawn or the application revived. See 1124 Off. Gaz. Pat. Office supra.

[6] Therefore, by example, an unintentional delay in the reply might occur if the reply and transmittal form are to be prepared for shipment by the US Postal Service, but other pressing matters distract one's attention and the mail is not timely deposited for shipment.

[7] See: Delgar v. Schulyer, 172 USPQ 513 (D.D.C. 1971).

CONCLUSION

Petitioner appears to have satisfied the burdens herein, and the petition as considered under 37 C.F.R. §1.181 is **granted**; there appears to be no Notice of Abandonment to be vacted.

The instant application is released to Technology Center AU 1795 for further processing in due course.

Petitioner may find it beneficial to view Private PAIR within a fortnight of the instant decision to ensure that the revival has been acknowledged by the Technology Center in response to this decision—and it is noted that all inquiries with regard to any failure of that change in status should be directed to the Technology Center where that change of status must be effected.

While telephone inquiries regarding this decision may be directed to the undersigned at (571) 272-3214, it is noted that all practice before the Office is in writing (see: 37 C.F.R. §1.2[8]) and the proper authority for action on any matter in this regard are the statutes (35 U.S.C.), regulations (37 C.F.R.) and the commentary on policy (MPEP). Therefore, no telephone discussion may be controlling or considered authority for Petitioner's action(s).

John J. Gillon, Jr.
Senior Attorney
Office of Petitions

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[8] The regulations at 37 C.F.R. §1.2 provide:

§1.2 Business to be transacted in writing.

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

UNITED STATES PATENT AND TRADEMARK OFFICE

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JOYCE A KILLEN PHD
IMAGYN MEDICAL TECHNOLOGIES INC
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1 PARK PLAZA
IRVINE, CA 92614

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OFFICE OF PETITIONS

In re Patent of	:	
Kornberg et al.	:	
Patent No. 5,111,828	:	
Application No. 07/584,614	:	
Filed: September 18, 1990	:	ON PETITION
Issued: May 12, 1992	:	
Title of Invention:	:	
DEVICE FOR PERCUTANEOUS	:	
EXCISIONAL BREAST BIOPSY	:	

This is a decision on the petition under 37 CFR § 1.378(c), filed May 9, 2006, to reinstate the above-identified patent.

The petition is **GRANTED**.

The patent issued May 12, 1992. The grace period for paying the eleven and one-half (11½) year maintenance fee expired on May 12, 1996. Therefore, since this petition was filed within twenty-four months after the six-month grace period provided in 37 CFR 1.362(e), this petition was timely filed under the provisions of 37 CFR 1.378(c).

Accordingly, the maintenance fee in this case is hereby accepted and the above-identified patent is hereby reinstated as of the mail date of this decision.

The file is being forwarded to the files repository.

Telephone inquiries concerning this matter should be directed to the undersigned at (571) 272-3232.

Derek L. Woods
Attorney
Office of Petitions

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 18

THOMAS J. SCOTT
HUNTON & WILLIAMS
1900 K STREET, N.W., SUITE 1200
WASHINGTON, D.C. 20006-1109

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SPECIAL PROGRAMS OFFICE
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In re Patent No. 5109414 :
Issue Date: April 28, 1992 :
Application No. 07/588,126 :NOTICE
Filed: September 25, 1990 :

This is a notice regarding your request for acceptance of a fee deficiency submission under 37 CFR 1.28. On September 1, 1998, the Court of Appeals for the Federal Circuit held that 37 CFR 1.28(c) is the sole provision governing the time for correction of the erroneous payment of the issue fee as a small entity. See DH Technology v. Synergystex International, Inc.. No. 97-1128, -1280, -1453, 1998 U.S. App. LEXIS 21409, at *30 (Fed. Cir. Sept. 1, 1998). Therefore, your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

Inquiries related to this communication should be directed to the Office of Petitions Staff at (703) 305-9285.

This file is being forwarded to the Files Repository.

Irvin Dingle
Petitions Examiner
Office of Petitions
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Approved for use through 04/30/2009. OMB 0651-0016
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5327290	1994-07-05	07595389	1990-10-10	ID 016208

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☐ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity			Small Entity		
	Fee	Code		Fee	Code
○	3 ½ year	(1551)	○	3 ½ year	(2551)
○	7 ½ year	(1552)	○	7 ½ year	(2552)
◉	11 ½ year	(1553)	○	11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/DJCushing/	Date (YYYY-MM-DD)	2008-04-28
Name	David J. Cushing	Registration Number	28703

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5327290
Issue Date: July 5,1994
Application No. 07595389
Filed: October 10,1990
Attorney Docket No. SAN2-AA82

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed April 28,2008 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of April 28,2008 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Mail Stop Patent Application.

Robin Torres
(Type or print name of person mailing paper)

Date: March 16, 2004

Robin Torres
(Signature of person mailing paper)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of	)	Group No. 1623
	)	
Proffitt et al	)	Docket No. 179/172
	)	
Serial No: 07/600,154	)	Examiner: Elli Peselev
	)	
Filed: October 19, 1990	)	

Title: IMPROVED AMPHOTERICIN B LIPOSOME PREPARATION

TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants received a decision on the petition to revive the above-identified application (copy attached). The petition was granted.

The decision requests an appropriate Power of Attorney. A fully executed Associate Power of Attorney accompanies this transmittal.

The decision provided a blank Issue Fee Transmittal Form and requested Applicants to complete and return this form to the Office. The completed Issue Fee Transmittal Form accompanies this transmittal.

Applicants believe that no extension of term or other fees are required. If, however, any extension or fee is required, please charge Account No. 07-1250.

Respectfully submitted,

By: _____

Mark L. Bosse
Registration No. 35,071

Date: 03/16/04

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
Telephone: (650) 522-5569
Facsimile: (650) 522-5575
email: mark_bosse@gilead.com

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UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Paper No. 58

COPY

VANESSA APPLEBY
NEXSTAR PHARMACEUTICALS INC.
2860 WILDERNESS PLACE
BOULDER, CO 80301

COPY MAILED

FEB 20 2004

OFFICE OF PETITIONS

In re Application of
Proffitt et al.
Application No. 07/600,154
Filed: October 19, 1990
Attorney Docket No. 179/172

ON PETITION

This is a decision on the petition under 37 C.F.R. § 1.137(b), filed July 15, 2003, to revive the above-identified application.

The petition is **granted.**

The above-identified application became abandoned for failure to submit the issue fee in a timely manner in reply to the Notice of Allowance mailed August 14, 2002, which set a statutory period for reply of three (3) months. Accordingly, the above-identified application became abandoned on November 15, 2002.

Petitioner has met the requirements to revive the above-identified application pursuant to 37 CFR 1.137(b).

Petitioner's deposit account will be charged an additional $1300.00 for payment of the issue fee as authorized.

There is no indication that the person signing the instant petition was ever given a power of attorney or authorization of agent to prosecute the above-identified application. If the person signing the instant petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted.

The change of correspondence address filed July 15, 2003, cannot be accepted because it was not signed by an attorney of record. See MPEP §§ 601.03 and 405. While a courtesy copy of this decision is being mailed to the person signing the instant petition, all future correspondence will be directed solely to the address currently of record until such time as appropriate instructions are received to the contrary.

There is no indication that petitioner has submitted an Issue Fee Transmittal Form (PTOL-85b). Accordingly, if petitioner desires to have the information normally found thereon printed on the patent, the attached blank Issue Fee Transmittal Form should be completed and returned to the Publishing Division within **ONE MONTH** from the mail date of this decision.

The file is now being forwarded to the Publication Division for processing into a patent.

Telephone inquiries should be directed to the undersigned at (703) 306-0482.

Liana Chase
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: PTOL-85b

cc: GILEAD SCIENCES, INC.
333 LAKESIDE DRIVE
FOSTER CITY, CA 94404

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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DIW Nov-08

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA VA 22314

COPY MAILED

NOV 12 2008

In re Patent Number: 5640458	:	
Issue Date: 06/17/1997	:	
Application Number: 07/600818	:	ON PETITION
Filing Date: 10/22/1990	:	
Attorney Docket Number:	:	
280597US6	:	

This is a decision on the "PETITION UNDER 37 C.F.R. §1.181(A)(2)," filed on June 23, 2008, which is treated as a petition under 37 CFR 1.182 and 1.183, requesting that a terminal disclaimer be withdrawn in the above-identified patent.

The petition is **dismissed**.

Petitioner requests that a terminal disclaimer filed on June 13, 1994, with a petition under 37 CFR 1.137(a), be withdrawn.

Petitioner asserts that the terminal disclaimer should be withdrawn because (a) the terminal disclaimer was filed in response to an Office error; and (b) because ambiguity results in the expiration of the patent as a result of another terminal disclaimer filed on September 13, 1995, in response to an obviousness-type double patenting rejection in the Office action mailed on July 28, 1995.

It is noted that petitioner states:

> Initially, Patentee respectfully request that 37 C.F.R. § 1.182(f) be suspended. Rule 182(f) indicates that a petition not filed within two months of the action or notice from which relief is sought may be dismissed as untimely. However, under 37 C.F.R. § 1.183, the Director, or the Director's designee, may suspend or waive a Rule in the event of extraordinary

> circumstances or when justice requires. Patentee submits that the present situation is such a case.

Petitioner's argument has been, considered, but is not persuasive.

Preliminarily, it is noted that MPEP 1490 states

> While the filing and recordation of an unnecessary terminal disclaimer has been characterized as an "un-happy circumstance" in In re Jentoft, 392 F.2d 633, 157 USPQ 363 (CCPA 1968), there is no statutory prohibition against nullifying or otherwise canceling the effect of a recorded terminal disclaimer which was erroneously filed **before the patent issues**. Since the terminal disclaimer would not take effect until the patent is granted, and the public has not had the opportunity to rely on the terminal disclaimer, relief from this unhappy circumstance may be available by way of petition or by refiling the application (other than by refiling it as a CPA).
>
> The mechanisms to correct a patent — Certificate of Correction (35 U.S.C. 255), reissue (35 U.S.C. 251), and reexamination (35 U.S.C. 305) — are **not** available to withdraw or otherwise nullify the effect of a recorded terminal disclaimer. **As a general principle, public policy does not favor the restoration to the patent owner of something that has been freely dedicated to the public**, particularly where the public interest is not protected in some manner — e.g., intervening rights in the case of a reissue patent. See, e.g., Altoona Publix Theatres v. American Tri-Ergon Corp., 294 U.S. 477, 24 USPQ 308 (1935).
>
> (emphasis added)

As such, petitioners must show why this terminal disclaimer should be withdrawn after issunce of the patent.

In support, petitioner cites Bayer AG v. Carlsbad Technology, Inc., 298 F.3d 1377 (Fed. Cir. 2002). In Bayer, the court agreed with the determination of the USPTO to change a terminal disclaimer to extend the term of a patent to resolve an ambiguity in the patent term resulting from the 1994 URAA patent harmonization laws.

Petitioner's argument has been considered, but is not persuasive. At the outset, there are significant differences in the circumstances of the filing of the terminal disclaimer at issue in this case and in the Bayer case: In Bayer, the terminal disclaimer at issue was filed to counter an allegation of obviousness-type double patenting. In this case, however, the terminal disclaimer which petitioner seeks to have withdrawn was filed with a petition to revive the application, and, as petitioner states, "in essence to correct a mistake of the Office."

In pertinent part, petitioner states that "in Bayer, the ambiguity rose out of circumstances beyond the Patentee's control: the URAA. Here the ambiguity arose beyond the Patentee's control: the Office mailed the Office Action of January 23, 1992 to the wrong address, which eventually caused two disclaimers to be filed."

A review of the record reveals that on June 13, 1994, a petition to revive the application under 37 CFR 1.137(a), along with the subject terminal disclaimer, was filed. The petition was granted on September 6, 1994.

Petitioner now asserts that the holding of abandonment was the result of an Office error in mailing an Office action to the wrong address. Petitioner's contention lacks merit, however, because petitioner stated, in the petition filed on June 13, 1994, that the application became abandoned because the delay in responding to the Office action was unavoidable. The filing of the terminal disclaimer was a condition precedent to granting the petition. Petitioner has not explained why it conceded the application was abandoned if the error was that of the Office, and why a petition to revive was filed if petitioner believes that the holding of abandonment was in error. Likewise, petitioner has not shown cause why the Office should now consider the application not to have become abandoned.

In summary, petitioner's argument is very weak: assuming the Office action mailed on January 23, 1992, was mailed in error, petitioner could have promptly requested the Office withdraw the holding of abandonment and remail the Office action. At best, the showing of record is that petitioner is attempting, after issuance of the patent, to remedy an error in prosecution.

Further, and more importantly, the Bayer petitioner promptly sought relief, by filing its petition on July 10, 1995, in response to the 1994 legislation. Id. at 1379. As the court

stated "Bayer acted in a timely manner to rectify any ambiguity." Id. at 1382.

Petitioner, to the contrary, has not demonstrated that it acted in a timely manner: This petition was filed more than 10 years after the issuance of the patent, and nearly 14 years after the filing of the subject petition and terminal disclaimer. Petitioner has not provided any showing of an urgent reason why this petition should be favorably considered at such a late date. Rather, petitioner's argument that "Patentee was merely trying to obtain a patent . . . and did so believing that Patentee would be entitled to a full patent term under which to recover Patentee's investment in the invention," suggests that petitioner is now, many years after issuance of the patent, trying to rectify mistakes that were made during prosecution.

Petitioner's attempt to differentiate this case from the recapture principle of Legett v. Avery, 101 U.S. 256 (1879), in that the terminal disclaimer at issue was not filed "voluntarily," is also unpersuasive. Contrary to petitioner's assertions, the showing of record suggests that petitioner could have filed a petition to withdraw the holding of abandonment and avoided the requirement of filing the terminal disclaimer. Further, petitioner's citation of Ex parte Anthony, 230 USPQ 467, is similarly inapposite, as the mere fact that the terminal disclaimer at issue was not filed to avoid an obviousness-type double patenting rejection does not mean that the terminal disclaimer was not filed in error, and should now be withdrawn.

Lastly, in paying the issue fee on February 13, 1997, petitioner acceded to the issuance of the patent with the terminal disclaimer and acquiesced to its limitations.

Further, considered under 37 CFR 1.183, petitioner's argument is not well taken. 37 CFR 1.183 provides that in an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed.

The facts presented on the record do not establish an extraordinary situation. Petitioners have not established any special circumstances or equities that would require suspension of the rules in the interests of justice. Petitioner has not identified any rule which if waived would provide the desired relief. Still further, as stated in MPEP 1490, as a general

principle, public policy does not favor the restoration to the patent owner of something that has been freely dedicated to the public. As discussed, *supra,* the showing of record is that petitioner did not file the instant petition until an extended period after the patent had issued, and has not provided an adequate explanation of the delay.

Lastly, to the extent that the statutory provisions of the mechanisms to correct a patent – Certificate of Correction (35 U.S.C. 255), reissue (35 U.S.C. 251), and reexamination (35 U.S.C. 305) preclude their application to withdraw a recorded terminal disclaimer in an issued patent, the USPTO simply lacks the authority or discretion to relax any requirement of law. See Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1334, 47 USPQ2d 1225, 1234-1235 (Fed. Cir. 1998)(the PTO cannot, by rule, or waiver of the rules, fashion a remedy that contravenes 35 U.S.C. §§ 112, 120); A. F. Stoddard v. Dann, 564 F.2d 556, 566, 195 USPQ 97, 105 (D.C. Cir 1977), (since the USPTO is an executive branch agency, it must follow the strict provisions of the applicable statute).

In summary, the balance of equities does not merit the Director overruling the well-settled public policy precluding restoration to the patent owner of something that has been freely dedicated to the public in favor of correcting, after issuance of the patent and an extended period of delay. Further, petitioner has not demonstrated the existence of an extraordinary situation in which justice requires waiver of the rules.

The petition is **dismissed**.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-8300
Attn: Office of Petitions

By hand: Customer Service Window
Mail Stop Petition
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Telephone inquires should be directed to the undersigned at 571.272.3231.

D Wood

Douglas Wood
Senior Petitions Attorney
Office of Petitions

Conferee: Anthony Knight, Supervisor

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5235437	1993-08-10	07624729	1990-12-11	ID 01797 -JLR

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☐ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity		Small Entity	
Fee	Code	Fee	Code
○ 3 ½ year	(1551)	○ 3 ½ year	(2551)
○ 7 ½ year	(1552)	○ 7 ½ year	(2552)
◉ 11 ½ year	(1553)	○ 11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/DJCushing/	Date (YYYY-MM-DD)	2007-03-20
Name	David J. Cushing	Registration Number	28703

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5235437
Issue Date: August 10,1993
Application No. 07624729
Filed: December 11,1990
Attorney Docket No. 110-303

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed March 20,2007 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of March 20,2007 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5198743	1993-03-30	07625346	1990-12-11	37264 (8125/8)

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☐ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity		Small Entity	
Fee	Code	Fee	Code
○ 3 ½ year	(1551)	○ 3 ½ year	(2551)
○ 7 ½ year	(1552)	○ 7 ½ year	(2552)
◉ 11 ½ year	(1553)	○ 11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/Frank C. Nicholas/	Date (YYYY-MM-DD)	2006-12-01
Name	Frank C. Nicholas	Registration Number	33983

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5198743
Issue Date: March 30,1993
Application No. 07625346
Filed: December 11,1990
Attorney Docket No. 37624

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed December 1,2006 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of December 1,2006 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5198743
Issue Date: March 30,1993
Application No. 07625346
Filed: December 11,1990
Attorney Docket No.37624

:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)

This is a decision on the electronic petition, filed December 1,2006 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of December 1,2006 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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William K. Turner
Union Oil Company of California
P.O. Box 6006
San Ramon, CA 94583-0806

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OFFICE OF PETITIONS

In re Patent No. 5,288,393	:	
Issue Date: February 22, 1994	:	
Application No. 07/628,488	:	ON PETITION
Filed: December 13, 1990	:	
Attorney Docket No. N/A	:	

This is a decision on the petition under 37 CFR 1.182, filed by facsimile transmission on December 14, 2005, requesting issuance of a duplicate Letters Patent for the above-identified patent.

There is no indication that the person signing the instant petition was ever given a power of attorney or authorization of agent to prosecute the above-identified application. In accordance with 37 CFR 1.34(a), the signature appearing on the petition shall constitute a representation to the United States Patent and Trademark Office that he/she is authorized to represent the particular party in whose behalf he/she acts.

The petition is **granted**.

The Publishing Division is directed to issue duplicate Letters Patent.

A copy of this decision is being forwarded to Publishing Division for issuance of the duplicate Letters Patent.

This patented file is being referred to the Files Repository.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3226. Any questions concerning issuance of the duplicate Letters Patent should be directed to Krystal Paige at (703) 308-9250 ext 139.

Andrea Smith
Petitions Examiner
Office of Petitions

cc: Krystal Paige, P/OPPD, South Tower 8th Floor, Room C-32 (FAX 571-273-9740)

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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Paper No.

DANIEL G. FEDER
15460 LAGUNA CANYON ROAD
MAIL CODE 1650-7006
IRVINE, CA 92618

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AUG 2 6 2005

OFFICE OF PETITIONS

ON PETITION

In re Patent No. 5,119,382 :
Issue Date: June 2, 1992 :
Application No. 07/632,974 :
Filed: December 24, 1990 :
Patentee(s): Chandler Kennedy et al :

This is a decision on the petition under 37 CFR 1.378(c), filed October 15, 2004, to accept the delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED**.

The maintenance fee is hereby accepted and the above-identified patent is reinstated as of the mail date of this decision.

It is not apparent whether the person signing the statement of unintentional delay was in a position to have firsthand or direct knowledge of the facts and circumstances of the delay at issue. Nevertheless, such statement is being treated as having been made as the result of a reasonable inquiry into the facts and circumstances of such delay. In the event that such an inquiry has not been made, petitioner must make such an inquiry. If such inquiry results in the discovery that the delay in paying the maintenance fee under 37 CFR 1.378(c) was intentional, petitioner must notify the Office.

Telephone inquiries concerning this decision should be directed to Wan Laymon at (571) 272-3220.

The patent file is being forwarded to Files Repository.

Wan Laymon
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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RANDALL J. KNUTH PC
1507 YUMA COURT
MUFREESBORO, TN 37129

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OCT 0 5 2006

OFFICE OF PETITIONS

In re Patent No. 5,160,429	:
Issue Date: November 3, 1992	:DECISION GRANTING PETITION
Application No. 07/635,590	:UNDER 37 CFR 1.378(c)
Filed: December 31, 1990	:
Patentee(s): Tadahiro OHMI et al	:

This is a decision on the petition, filed May 23, 2005, under 37 CFR 1.378(c) to accept the unintentionally delayed payment of a maintenance fee for the above-identified patent.

The petition is **GRANTED**.

Initially, it is noted that a petition was filed on January 10, 2005, which alleges that the twelfth year maintenance fee was paid on April 26, 2004. The proper avenue of relief where an allegation is made that a maintenance fee was timely paid is more appropriately a petition under 37 CFR 1.377, which requires a fee of $130 for its consideration. As the petition was not accompanied by the required fee, no consideration will be given on the merits of that petition.

A subsequent petition under 37 CFR 1.378(c) was received by facsimile on September 25, 2006 by the law firm of Young & Thompson. The petition provides evidence that a previous petition was filed on March 23, 2006; however, this petition has not to date been located, although the Office processed the $1,640 surcharge reinstatement fee and the twelfth year $1,900 maintenance fee payment. As these fees were previously paid with the petition filed on May 23, 2005, these fees have been refunded to the deposit account of Young & Thompson. Also, a courtesy copy of this decision is being mailed to the firm of Young & Thompson at the address noted below.

This patent issued November 3, 1992. The grace period for paying the third maintenance fee expired at midnight on November 3, 2004. Therefore, since this petition was filed within twenty-four months after the six-month grace period provided in 37 CFR 1.362(e), this petition was timely filed under the provisions of 37 CFR 1.378(c).

Accordingly, the maintenance fee in this case is hereby accepted and the above-identified patent is hereby reinstated as of the mail date of this decision.

Telephone inquiries concerning this matter may be directed to the undersigned at (571) 272-3218.

Frances Hicks
Petitions Examiner
Office of Petitions

cc:

Benoit Castel
Young & Thompson
745 South 23rd Street
Arlington, VA 22202

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

EDWARD S. WRIGHT
1100 Alma Street
Suite 207
Menlo Park CA 94025

COPY MAILED
MAR 18 2010

In re Application of	:	
Beasley	:	
Application No. 07/636,839	:	
Filed: January 2, 1991	:	DECISION ON PETITION
U.S. Patent No. 7,095,909	:	
Issue Date: August 22, 2006	:	
Attorney Docket No. A-53661 ESW	:	
For: Light Pen System and Method	:	

The above-identified application has been forwarded to the undersigned for consideration on a petition for patent term extension entitled "Petition re Patent Term Extension," received on April 5, 2006. The petition is being treated under 37 CFR 1.181 and 37 CFR 1.701, as a petition for patent term extension.

The petition is GRANTED.

Petitioner asserts that the Notice of Allowance mailed by the Office on February 7, 2006 is incorrect, as it states that the application is not eligible for patent term extension because the application was filed prior to June 8, 1995. Petitioner states that while the application was originally filed on January 2, 1991, a continued prosecution application (CPA) was filed on July 30, 1999, thus the application has a filing date on or after June 8, 1995 and is eligible for patent term extension under 35 U.S.C. 154. Petitioner asserts that the patent should get a patent term extension because the Panel Remand is a decision in favor of applicants.

35 U.S.C. § 154(b) provides for patent term extension for appellate review, interference and secrecy order delays in applications filed on or after June 8, 1995 and before May 29, 2000, and, as amended by the "American Inventors Protection Act of 1999," enacted November 29, 1999, as part of Public Law 106-113, for those delays and others in applications filed on or after May 29, 2000.

The above-identified application was filed on July 30, 1999. [1] Accordingly it is entitled to patent term extension based upon the conditions in 35 U.S.C. § 154(b), in effect on June 8, 1995.

A Notice of Appeal was filed in the above-identified application on September 19, 2000. On March 23, 2005, the Board of Patent Appeals and Interferences (BPAI) remanded the application to the examiner in the above-identified application. Since the above-identified application was filed after June 7, 1995, there is no terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review, and issuance of the application as a patent was delayed due to appellate review resulting in a remand by a panel of the BPAI to the Examiner, the patent to issue from the application is entitled to an extension of the patent term. [2] The period of delay in the above-identified application is the period beginning on September 19, 2000, the date that the Notice of Appeal was filed and ending on march 23, 2005, the date of the remand by a panel of the BPAI, which is a final decision in favor of the applicant. Three years after the earliest effective filing date of the application is January 2, 1994. Accordingly, the period of extension is not required to be reduced pursuant to 37 CFR 1.701(d)(1) by the amount of time prior to three years after the filing date of the application. As a result, the first period of extension is 1647 days, the period from September 19, 2000 to March 23, 2005, including the beginning and end dates.

After mailing of this decision, the above-identified application will be forwarded to Office of Publications for further processing.

The Office proposes to issue a certificate of correction in order to rectify the error regarding the patent term extension information. See 35 U.S.C. 254 and 37 CFR 1.322. The Office will issue a certificate of correction indicating that the patent term is extended for 1647 days under 35 U.S.C. 154(b) and that the patent is subject to the twenty year patent term provisions.

A telephone conversation was had with Mr. Wright on March 11, 2010 confirming the PTE.

Petitioner's deposit account has not been charged a petition fee.

Telephone inquiries with regard to this communication should be directed to Mark O. Polutta at (571) 272-7709.

Mark Polutta
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

---

[1] The filing date of a CPA is the date on which the CPA reques is received.See MPEP 201.06(d).

[2] Revision of Patent Term Extension and Patent Term Adjustment Provisions, 78 FR 21704, 21705 (April 22, 2004), 1282 Off. Gaz. Pat. Office Notices 100 (May 18, 2004) (final rule).

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 7,095,909 B1

DATED : **August 22, 2006**

INVENTOR(S) : Beasley

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,
Insert:

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 1647 days.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Date: 04/27/09

Patent No. : 5199436 C1
Ser. No. : 07/646,855
Inventor(s) : POMPEI, FRANCESCO
Issued : 08/21/07
Title : **RADIATION DETECTOR HAVING IMPROVED ACCURACY**
Docket No. : **EX87-01AZ**

Re: Request for Certificate of Correction

Consideration has been given your request for the issuance of a certificate of correction for the above-identified patent under the provisions of Rule(s) 1.322 and/or 1.323.

Assignees' names and addresses (assignment data) printed in a patent, are based *solely* on information supplied in the appropriate space for identifying the assignment data, i.e., item 3 of the Issue Fee Transmittal Form PTOL-85B. Granting of a request under 37 CFR 3.81(b) is required to correct applicant's error providing ***incorrect or erroneous*** assignment data, *before* issuance of a Certificate of Correction, under 37 CFR 1.323 *(see Manual of Patent Examining Procedures (M.P.E.P) Chp.1400, sect. 1481).* This procedure is required *at any time after the issue fee is paid*, including after issuance of the patent.

In view of the foregoing, your request, in this mater, is hereby denied.

A request to correct the Assignee under 37 CFR 3.81(b) should include:

A. **the processing fee set forth in 37 CFR 1.117(h) (currently $130);**
B. a statement that the failure to include the correct assignee name on the PTOL-85B was inadvertent; and
C. a copy of the Notice of Recordation of Assignment Document, reflecting the reel and frame number where the assignment(s) is recorded and/or reflecting proof of *the date* the assignment was submitted for recordation.

In the Request, Applicant(s) may request that the file be forwarded to Certificates of Correction Branch, for issuance of a Certificate of Correction, if the Request is granted.

Any request under 37 CFR 3.81(b) should be directed to the following address or facsimile number:

By mail: Mail Stop PETITIONS
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Service Window
Mail Stop Petitions
Randolph Building
401 Dulany Street
Alexandria, VA 22314

By fax: (571) 273-0025
ATTN: Office of Petitions

If a fee (currently $100) was previously submitted for consideration of a Request for Certificate of Correction, under CFR 1.323, to correct assignment data, no additional fee is required.

Lamonte M. Newsome

Lamonte M. Newsome
For Mary Diggs, Supervisor
Decisions & Certificates
Of Correction Branch
(703) 305-8309 or (703) 308-9390 #112

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD MA 01742-9133

LMN

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United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

MAILED

JUN 14 2010

OFFICE OF PETITIONS

In re Patent of Buhr et al.	:	
Patent No. 5,672,697	:	
Issue Date: September 30, 1997	:	Letter
Application No. 07/652,978	:	
Filing Date: February 8, 1991	:	
Attorney Docket No. GLIS-0064	:	

Request for Information

This is a response to the "Petition for Reconsideration Under 37 C.F.R. § 1.378(e)" filed December 4, 2007.

The Office requests petitioner supply additional information concerning the delay in the submission of maintenance fees in this case.

Petitioner should submit the requested information within **TWO MONTHS** of the mailing date of this letter. Extensions of time may not be obtained. No additional fee is due for a response to the instant request for information. The response to this Requirement for Information should include a cover letter entitled "Response to Request for Information." *The failure to file a reply to the instant Request for Information will be interpreted as a desire to no longer pursue reinstatement of the patent and the Office will give no further consideration to the matter.*

Any response to the instant Request for Information should be filed electronically using the Office's Electronic Filing System (EFS-Web).

Procedural Background

Application No. 07/652,978 was filed February 8, 1991. The application issued as Patent No. 5,672,697 on September 30, 1997.

An application for reissue of the instant patent was filed September 29, 1999. The reissue application was assigned Application No. 09/408,396.

The 3.5 year maintenance fee for the instant patent could have been paid from September 30, 2000, to March 30, 2001, or with a surcharge from March 31, 2001, to Monday, October 1, 2001. The fee was not timely paid. As a result, the patent expired on October 1, 2001.

An Order to Show Cause was mailed in Application No. 09/408,396 on May 16, 2006. The order indicated Patent No. 5,672,697 had expired due to non-receipt of the 3.5 year maintenance fee. The order also indicated the 7.5 year maintenance fee had not been paid for the patent.

A "Response to Order to Show Cause and Petition for Delayed Payment of Maintenance Fees Pursuant to 37 CFR § 1.378(b)" ("Response") was filed in Application No. 09/408,396 on June 6, 2006.

A Second Order to Show Cause was mailed in Application No. 09/408,396 on November 13, 2006. The Second Order to Show Cause did not directly address the merits of the petition under 37 C.F.R. § 1.378(b) filed as part of the response.

A petition under 37 C.F.R. § 1.378(b) directed to the instant patent, not the reissue application, was filed December 11, 2006. The petition was accompanied by payment of $4,860 for the following fees:

(1) $900 for the 3.5 year maintenance fee,
(2) $130 for the grace period fee set forth in 37 C.F.R. § 1.20(h) for the 3.5 year maintenance fee,
(3) $2,300 for the 7.5 year maintenance fee,
(4) $130 for the grace period fee set forth in 37 C.F.R. § 1.20(h) for the 7.5 year maintenance fee, and
(5) $700 for the surcharge set forth in 37 C.F.R. § 1.20(i).

The December 11, 2006 petition stated,

> ISIS Pharmaceuticals, Inc. acquired a portfolio of patents and patent applications including the [instant] patent in 1998. Since that time, ISIS has used a computerized docketing system to monitor due dates and other activities related to the portfolio....
>
> [T]he paralegal who entered ... information into the database after ISIS acquired the patent mistakenly identified its status as "inactive." That this error was simply one of data entry is indicated by the fact that other patents in the acquired portfolio are not identified in the database as "inactive." Because the docketing system understood the [instant] patent to be inactive, none of the prompts or reports that the system subsequently generated concerning the acquired portfolio identified maintenance fees that were due in connection with the patent. Although the paralegal appears to have received a notice of patent expiration in the March, 2002, timeframe, no such notice can be found in Applicants' files, nor is the undersigned or anyone currently employed in ISIS' patent department aware of ever having seen it.

On May 4, 2007, the Office mailed a decision dismissing the petition. The decision stated,

> [S]ince this case involves importation of a patent from a previous owner[,] the routine for such transfer should be explained. If there occurred in this instance one or more clerical errors, petitioner should supply information regarding the training provided to the [person who made the error], degree of supervision of their work, examples of other work

> functions carried out and checks on the described work which were used to assure proper execution of assigned tasks. An adequate showing requires where possible statements by all persons with direct knowledge of the circumstances surrounding the delay....
>
> As noted above, statements from all persons who have firsthand knowledge of the circumstances which caused or contributed to the delay are required.

A "Petition for Reconsideration Under 37 C.F.R. § 1.378(e)" was filed December 4, 2007. The request includes a declaration by Herb Boswell, an Executive Director in the patent department of ISIS.

Facts

ISIS hired Jill Kathleen Joe as a Patent Docketing Coordinator in March 1998. At the time she was hired, Ms. Joe had a total of approximately nine years of experience working in various positions at different law firms.

ISIS began using a PCMaster computer database program during mid-1998.

"During [Ms Joe's] employment at ISIS, Ms. Joe had various file clerk assistants who reported to her; however, from Ms. Joe's hire date until at least 2002, she opened the majority of new file records in the database."[1]

During 1998, ISIS acquired a portfolio including the instant patent and several other patents and patent applications.

The PCMaster record for the instant patent was created on February 12, 1999. Boswell asserts the database record "appears" to have been created by Ms. Joe.

The PCMaster record for Reissue Application No. 09/408,396 was created on November 3, 1999. Boswell asserts the record "appears" to have been created by Ms. Joe.

Boswell asserts the status for the instant patent was either listed as inactive in PCMaster when the record for the instant patent was created on February 12, 1999, or changed to inactive when the record for the reissue application was created on November 13, 1999.

Exhibit B for the Boswell declaration includes a screenshot showing information in the PCMaster database for the instant patent.

1. The "Comment" section states, "SEE GLIS-0128 for REISSUE."
2. The "Status" section states, "INACTIVE."
3. The "Sub Status" section states, "Surrendered (Reissue)."
4. The "Sub Status Date" section states, "9/29/1999."

---

[1] Boswell Declaration, ¶ 5.

The screenshot indicates the record for the instant patent was last updated on April 10, 2002, by "CRGW." The screenshot fails to identify the specific changes made by CRGW.

Boswell's declaration states various factors have led him to conclude the error in the docketing system "was simply one of data entry."[2]

Boswell asserts Ms. Joe had considerable experience involving patents and was experienced at using the PCMaster program as of the date the error was made.

Boswell states,

> While employed by ISIS[,] Ms. Joe opened hundreds (and perhaps even thousands) of records in the ISIS patent database.... To [the best of] my knowledge, this instance relating to the [instant patent] is the first time that a due date has been missed due to incorrect data entry for any of the several thousand records that currently are in ISIS' PCMaster database.[3]

Boswell states,

> The "Status" code in the PCMaster database is entered by selecting one of four choices from a "dropdown menu" or by entering a shorthand code. The shorthand codes and choices are: D and DOCKETED, F and FILED, G and GRANTED, and I and INACTIVE.... [On the dropdown menu,] the "INACTIVE" choice is adjacent to and immediately below the "GRANTED" choice, thus increasing the likelihood of making a mistaken selection amount them.[4]

Boswell asserts none of the other patents ISIS has surrendered for reissue in the past are identified in the database as inactive.

Information Requested

The record fails to clearly identify the individual who created the database record for the instant patent on February 12, 1999. Although Boswell's declaration states Ms. Joe "appears" to have been the individual who created the record, such a statement is not the equivalent of a statement asserting Ms. Joe was the individual who created the record. The Office acknowledges Boswell's assertion Ms. Joe opened the majority of file records during her employment with ISIS. However, the fact she opened the majority of file records is not proof she was the individual who created the record on February 12, 1999.

---

[2] Id. at ¶ 10.

[3] Id. at ¶ 11.

[4] Id. at ¶ 8.

If petitioner is completely certain Ms. Joe is the individual who created the record for the instant patent, any response to the instant request should *fully* discuss the basis for such certainty.

If petitioner is not completely certain Ms. Joe is the individual who created the record on February 12, 1999, any response to the instant request should identify all the other individuals who may have created the record. The response should discuss, for each of the other individuals, the training the individual received, the degree of supervision of the individual's work, examples of other work functions carried out by the employee, and checks on the employee's work which were used to assure proper execution of assigned tasks.

The record fails to clearly identify the individual who made changes to the record for the instant patent on November 13, 1999. Although Boswell's declaration states Ms. Joe "appears" to have been the individual who made the changes, such a statement is not the equivalent of a statement asserting Ms. Joe was the individual who made the changes.

If petitioner is completely certain Ms. Joe is the individual who made changes to the record on November 13, 1999, any response to the instant request should *fully* discuss the basis for such certainty.

If petitioner is not completely certain Ms. Joe is the individual who made changes to the record on November 13, 1999, the response to the instant request should identify all the other individuals who may have created the record. The response should discuss, for each of the other individuals, the training the individual received, the degree of supervision of the individual's work, examples of other work functions carried out by the employee, and checks on the employee's work which were used to assure proper execution of assigned tasks.

Any response to the instant request for information should fully discuss the extent to which the law firm was, or was not, reasonable in relying on the individual who may be asserted to have made a mistake in a reissue application prior to November 13, 1999. For example, the discussion should indicate whether or not the individual who made the mistake had ever been informed maintenance fees must continue to be paid for a patent, *even if the patent has been surrendered*, up until the date a reissue patent is granted. If the identity of the individual who made the mistake is uncertain, the response should set forth the reissue training received by each of the employees who might have made the mistake.

The petition does not identify the exact changes made to the record for the instant patent on November 13, 1999. What changes were made on November 13, 1999? Was the "Comment" section changed to state, "SEE GLIS-0128 for REISSUE," on November 13, 1999? Was the "Sub Status" section changed to state, "Surrendered (Reissue)," on November 13, 1999? Was the "Sub Status Date" section changed to state, "9/29/1999," on November 13, 1999?

The screenshot of the record for the instant patent indicates the record was last updated on April 10, 2002, by "CRGW." Who is CRGW? What information, if any, did CRGW add to the record? What information, if any, did CRGW delete from the record? What information, if any, did CRGW change?

When evaluating the reliability of an individual's work, one may reasonably consider whether or not the employee has made similar errors when handling other cases. In this case, Boswell asserts a factor supporting his belief the error was simply a data entry error is the fact none of the other patents that ISIS has surrendered for reissue are identified in the database as inactive.

Any response to the instant request for information should explicitly identify *all* the reissue applications filed by ISIS starting from the date ISIS first implemented PCMaster and ending on January 1, 2005. For each reissue application, petitioner should,

(1) Identify the date the reissue application was filed,
(2) Identify the original patent by patent number,
(3) Identify the approximate date, or exact date if possible, changes were made to the record for the original patent as a result of the filing of the reissue application,
(4) Identify all changes made to the record for the original patent when the reissue application was filed, and
(5) Identify the individual who made the changes.

As stated in the decision mailed by the Office on May 4, 2007, a petition under 37 C.F.R. § 1.378(b) should be accompanied by "statements from all persons who have firsthand knowledge of the circumstances which caused or contributed to the delay." The instant renewed petition does not include a statement from Ms. Joe or any other employee who may have created or changed the record for the patent. If petitioner is certain Ms. Joe created the record and made the changes to the record on November 13, 1999, a statement from Ms. Joe should be filed. If one or more other individuals may have created the record and/or made the changes to the record on November 13, 1999, then a statement from each such individual should be supplied. If a statement from Ms. Joe or any other individual who may have created the record and/or changed the record on November 13, 1999, cannot be obtained, petitioner should fully discuss all reasons ISIS was unable to obtain the statement(s).

Fees

Payment of the 11.5 year maintenance fee is now necessary in order for the Office to reinstate the patent. Therefore, any response to the instant request for information should include payment of $4,110 for the 11.5 year maintenance fee.

Petitioner has submitted the $130 surcharge set forth in 37 C.F.R. § 1.20(h) for the 3.5 year maintenance fee. Petitioner has also submitted the $130 surcharge set forth in 37 C.F.R. § 1.20(h) for the 7.5 year maintenance fee. The only surcharge necessary when filing a petition under 37 C.F.R. § 1.378(b) is the $700 surcharge set forth in 37 C.F.R. § 1.20(i). Therefore, the Office has credited $260 to Deposit Account No. 23-3050.

Petitioner submitted a $700 surcharge for the 3.5 year maintenance fee and a $700 surcharge for the 7.5 year maintenance fee. The $700 surcharge only needs to be paid a single time when filing a petition under 37 C.F.R. § 1.378(b) even if more than one maintenance fee was not timely paid. Therefore, $700 has been credited to Deposit Account No. 23-3050.

Telephone inquiries regarding this communication should be directed to Petitions Attorney Steven Brantley at (571) 272-3203.

Charles Steven Brantley
Senior Petitions Attorney
Office of Petitions

PTO/SB/66 (03-09)
Approved for use through 03/31/2012. OMB 0651-0016
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5,485,884	1996-01-23	07/658,427	1991-02-20	ERG 049 US

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☒ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity			Small Entity		
	Fee	Code		Fee	Code
○	3 ½ year	(1551)	○	3 ½ year	(2551)
○	7 ½ year	(1552)	○	7 ½ year	(2552)
○	11 ½ year	(1553)	◉	11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/Vangelis Economou/	Date (YYYY-MM-DD)	2010-01-22
Name	Vangelis Economou	Registration Number	32341

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5485884
Issue Date: January 23,1996
Application No. 07658427
Filed: February 20,1991
Attorney Docket No. ERGENICS104C

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed January 22,2010 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is **GRANTED**.

The maintenance fee is accepted, and the above-identified patent reinstated as of January 22,2010 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in the Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy.

Telephone inquiries related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OLE K. NILSSEN
200 N HARRISON STREET
SUITE 103
ALGONQUIN, IL 60102

COPY MAILED
MAY 2 3 2006
OFFICE OF PETITIONS

In re Patent No. 5,185,560	:	
Issue Date: February 9, 1993	:	
Application No. 07/663,566	:	LETTER
Filed: March 4, 1991	:	
For: ELECTRONIC FLUORESCENT LAMP	:	
BALLAST	:	

This is a notice regarding your request for acceptance of a fee deficiency submission under 37 CFR 1.28. On September 1, 1998, the Court of Appeals for the Federal Circuit held that 37 CFR 1.28(c) is the sole provision governing the time for correction of the erroneous payment of the issue fee as a small entity. **See DH Technology v. Synergystex International, Inc. 154 F.3d 1333, 47 USPQ2d 1865 (Fed. Cir. Sept. 1, 1998).**

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

The patent file is being referred to Files Repository.

Wan Laymon
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DYAX CORP.
C/O WOLF, GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON MA 02210-2206

COPY MAILED

JUN 2 4 2009

OFFICE OF PETITIONS

In re Patent No. 5,223,409 :
Issue Date: June 29, 1993 :
Application No. 07/664,989 : NOTICE
Filed: March 1, 1991 :
For: DIRECTED EVOLUTION OF NOVEL :
BINDING PROTEINS :

This is in response to the communication filed December 19, 2008 entitled, "Petition Under 37 CFR § 1.182 and/or Submission of Fee Deficiency under § 1.28(c)," which is being treated as a notice regarding request for acceptance of a fee deficiency submission under 37 CFR 1.28.

The Office no longer investigates or rejects original or reissue patent under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

A review of the maintenance fee transmittal letter submitted with the maintenance fee payment on December 3, 2004, indicates that applicant did note YES for small entity status. However, in view of the above communication, this patent is not entitled to small entity status and is therefore, large entity status.

The petition fee submitted with the above on December 19, 2008, is not necessary. Therefore, the $400.00 petition fee is being credited to deposit account no. 23/2825 as authorized.

Inquiries related to this communication should be directed to the undersigned at (571) 272-3208.

/Karen Creasy/
Karen Creasy
Petitions Examiner
Office of Petitions

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5497841	1996-03-12	07669879	1991-03-14	134550-8628

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☒ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity			Small Entity		
	Fee	Code		Fee	Code
○	3 ½ year	(1551)	○	3 ½ year	(2551)
○	7 ½ year	(1552)	○	7 ½ year	(2552)
○	11 ½ year	(1553)	◉	11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

○ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

◉ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

A Joint Patentee and I certify that I am authorized to sign this submission on behalf of all the other patentees			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.			
Signature	/Robert cox /	Date (YYYY-MM-DD)	2008-04-21
Name	Robert Cox		

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 5497841
Issue Date: March 12,1996
Application No. 07669879
Filed: March 14,1991
Attorney Docket No. 134550-8628

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed April 21,2008 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of April 21,2008 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office

P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,159,451	:	
Issue Date: October 27, 1992	:	
Application No. 07/671,478	:	DECISION ON PETITION
Filed: March 19, 1991	:	
Inventor: Yves C. Faroudja et al	:	

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '451 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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DIW Jan-07

EXXONMOBIL CHEMICAL COMPANY
5200 BAYWAY DRIVE
P.O. BOX 2149
BAYTOWN TX 77522-2149

COPY MAILED

JAN 09 2007

OFFICE OF PETITIONS

In re Application of	:	
Jo Ann M. Canich	:	DECISION ON PETITION
Application No. 07/676,690	:	
Filed: 03/28/1991	:	
Atty Docket No. P-1733	:	

This is a decision on the petition filed on 15 November, 2006, which requests under 37 C.F.R. §1.182 that a previously filed terminal disclaimer be withdrawn. As the paper filed on 15 November, 2006 requests expedited treatment, it is also treated as a petition requesting expedited treatment under 37 C.F.R. § 1.182 of the above-identified petition. The petition fee has been received.

The petitions are granted.

Petitioner asserts that the terminal disclaimer filed 27 July, 1992, is no longer required. As the examiner has concurred, the requested relief can be favorably considered.

The fee for expedited consideration of the petition will be charged to counsel's deposit account.

The address on the petition is different than the correspondence address of record. A courtesy copy of this decision will be mailed to the address on the petition. All future correspondence, however, will be mailed solely to the address of record.

This application is being referred to Technology Center Art Unit 1713 for correction of PALM and file records consistent with this decision.

Telephone inquiries relative to this decision should be directed to the undersigned at (571) 272-3231.

D Wood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc: HESHKOVITZ & ASSOCIATES
2845 DUKE STREET
ALEXANDRIA VA 22314

#53
DW

UNITED STATES PATENT and TRADEMARK OFFICE
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
WWW.USPTO.GOV

JUN 13 2001

MAILED
JUN 13 2001
Office of the Director
Group 3600

Stephen John Gough
P.O. Box 205
Avon, NJ 07717

In re application of	: DECISION ON
Stephen John Gough	: PETITION UNDER
Serial No. 07/683,484	: 37 C.F.R. 1.181,
Filed : April 9, 1991	: TO VACATE AN OFFICE
For : EASY WAGON/EASY	: ACTION AND
CART/BICYCLE WHEEL	: REFUND FEES
MOUNTING BRACKETS SYSTEM	: PAID

This is in response to a petition filed on October 10, 2000, which is being treated as a petition under 37 C.F.R. 1.181. The petition requests a vacating of an office action and the refunding of fees paid.

STATEMENT OF FACTS

On November 25, 1994, (Paper No. 29) a decision was rendered by the Board of Patent Appeals and Interferences (BPAI) on the then pending claims 88-107. The decision (1) affirmed the final rejection of all claims (88-107) on the applied art and (2) applied a new rejection under 37 C.F.R. 1.196(b) to claims 88-107.

On January 6, 1995, (Paper No. 30) a "Request for Reconsideration of (11/25/94) Affirmed Rejection" was filed requesting reconsideration of the BPAI's earlier decision.

#53

On February 3, 1995, (Paper No. 31) an Amendment in Response to (11/25/94) "NEW REJECTION" by the Board of Patent Appeals and Interferences was filed which added new claims 108-127.

On November 30, 1995 (Paper No. 34) a Final Rejection was issued by the examiner rejecting claims 108-127. (The Examiner through oversight had, in error, assumed that claims 88-107 had been canceled.)

On February 13, 1996, (Paper No. 35) a supplemental Final Rejection was issued by the Examiner addressing and rejecting all claims 88-127. This action was made Final.

On May 16, 1996, (Paper No. 36) a Notice of Appeal to the BPAI was filed. (This was the second appeal in the application.)

On September 17, 1996 (Paper No. 37) a two- (2) month extension of time was requested, and was granted.

On September 17, 1996, (Paper No. 38) applicant filed a copy of his brief.

On March 28, 1997, (Paper No. 39) an Examiner's Answer was issued in response to applicant's brief.

On May 22, 1997, (Paper No. 40) a Reply Brief was filed by applicant.

On May 4, 2000, (Paper No. 49) the application was Remanded by the BPAI back "to the Examiner for taking action discussed with regard to appellant's amendment filed February 3, 1995 (Paper No. 31) (Hereinafter referred to as amendment F) following this Board's decision dated November 25, 1994 (Paper No. 29)." The Board held that "[S]ince amendment F fails to amend any of the claims 'so rejected' under 37 CFR 1.196(b)(1)(or inferentially, substitute new claims for the claims 'so rejected') amendment F is not an 'appropriate amendment' under 37 CFR 1.196(b)(1). The examiner therefor lacked authority to enter the portion of amendment F adding those claims. On remand, the examiner should issue an advisory letter vacating his decision entering the portion of amendment F adding claims 108-127 on the ground that such portion does not comply with 37 CFR 1.196(b)(1) and MPEP 1214.01."

Thereupon the only remaining claims were claims 88-107. The final rejection of these claims became moot since they were the only remaining claims, the rejection of which had been affirmed in the first appeal. The Examiner then appropriately vacated the Final Rejection. Upon vacating the Final Rejection of November 30, 1995, appellant's second appeal became moot ab initio, and was vacated.

The BPAI's Remand (Paper No. 49) then directed that the application be returned to the BPAI for consideration of the remarks made by applicant in amendment F, (Paper No. 31).

On August 11, 2000, (Paper No. 50) the Examiner vacated the Final Rejection of November 30, 1995, the supplemental Final Rejection of February 13, 1995, and the Examiner's Answer dated March 28, 1997. Further, the entry of the amendment filed February 3, 1995 (Paper No. 31) was withdrawn from entry.

On October 10, 2000, (Paper No. 51), the above petition to the Commissioner was filed.

On December 7, 2000, (Paper No. 52), an Order Remanding to Examiner to consider the petition filed October 10, 2000, was issued by the BPAI.

DECISION

On pages 3 and 4 of applicant's petition there are three items of relief requested. Both items I and II request the re-entry of Amendment F filed February 3, 1995. Title 37 C.F.R. 1.196(b)(1) clearly sets forth that an appellant may "[s]ubmit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, …" (empahsis added).

In reponse to the BPAI's new rejection under 37 C.F.R. 1.196(b), the appellant has introduced no "showing of facts" (i.e., new evidence under 37 C.F.R. 1.131 or 1.132). Amendment F merely added new claims 108-127 and did not amend or cancel any of the "claims so rejected," namely claims 88-107. The BPAI did not err in their May 4, 2000 Remand to the examiner when they stated:

> Since amendment F fails to amend any of the claims "so rejected" under CFR 1.196(b)(1) (or inferentially, substitute new claims for the claims "so rejected")

> amendment F is not an "appropriate amendment" under 37 CFR 1.196(b)(1). The examiner therefor lacked authority to enter the portion of amendment F adding those claims."

Accordingly, the relief requested under Item I and II to re-enter Amendment F is DENIED.

Under appellant's item III found on pages 3 and 4 of his petition it is requested that the following various fees be refunded:

Fee for Addional 20 Claims	$296.00
Fee For Notice of Appeal	$140.00
Fee for Filing Appeal Brief	$145.00
Fee for Extension of Time	$190.00
Fee for Oral Hearing	$130.00
Fee for Petition to Commissioner	$130.00
Total	$1031.00

It is noted that due to the Examiner's inappropriate action of issuing a new Final Rejection, the following fees were improperly incurred: Fee for Notice of Appeal, Fee for Filing Appeal Brief, Fee for Extension of Time, and Fee for Oral Hearing. Further, no fee is required for a Petition to the Commissioner under 37 C.F.R. 1.181. Accordingly, the application is being forwarded to the Head Legal Instrument Examiner for a refund of $735.00.

The Fee for the submission of the Additional 20 Claims ($296.00) was required and appropriate and this refund is DENIED.

SUMMARY

(1) The request under item I on page 3 on the petition to re-enter the Amendment filed on February 3, 1995 is DENIED; (2) The request under item II on page 3 of the petition to re-enter the Amendment filed on February 3, 1995 is DENIED; and (3) The request for refunds of fees for Notice of Appeal, Filing Appeal Brief, Extension of Time, Oral Argument and Petition to the Commissioner have been GRANTED; and the request for refund of fees for Additional 20 Claims has been DENIED.

This application is being forwarded to the Head Legal Instrument Examiner for a refund of certain of the fees as granted above. The application will then be forwarded to the Board of Patent Appeals and Interferences for consideration of Apellant's request for reconsideration of the BPAI decision of November 25, 1994.

Adjustment date: 07/16/2001 PLEWIS
10/16/2000 GTERFERA 00000016 0768484
01 FC:122 -130.00 OP

Refund Ref:
07/16/2001 PLEWIS 0000107159

CHECK Refund Total: $130.00

Refund Ref:
07/30/2001 PLEWIS 0000107680

CHECK Refund Total: $130.00

Al Lawrence Smith, Director
Patent Examining Technology Center 3600
(703)308-1020

Stephen John Gough
P.O. Box 205
Avon, NJ 07717

LAB

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COMMISSIONER FOR PATENTS
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Paper No. 70

STEPHEN GOUGH
P. O. BOX 205
ARON, NJ 07717

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DEC 09 2004
OFFICE OF PETITIONS

In re Application of :
Stephen J. Gough :
Application No. 07/683,484 :
Filed: April 9, 1991 : ON PETITION
Title of Invention: :
EASY WAGON/EASY CART/BICYCLE :
WHEEL MOUNTING BRACKETS :
SYSTEM :

This is a decision on the Petition for Revival of an Application Abandoned Unavoidably Under 37 CFR 1.137(a), filed June 25, 2004, to revive the above-identified application.

The petition is **dismissed.**

Any further petition to revive the above-identified application (under 37 CFR 1.137(a)), must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Request for Reconsideration of Petition under 37 CFR 1.137", and be addressed to Petitions Attorney Derek L. Woods. This is **not** final agency action within the meaning of 5 U.S.C. § 704.

Background

The above-identified application became abandoned for failure to timely and properly reply to the final Office action, mailed June 24, 2003. The Notices set a non-extendable three (3) month period for reply.

Applicant filed an Amendment on October 28, 2003, which failed to place the application in condition for allowance. Applicant was so notified in an Advisory Action mailed November 26, 2003. Applicant subsequently filed a Request for Continued Examination ("RCE") on December 29, 2003 and fee, and requests entry of the October 28, 2003 Amendment as the submission. The RCE fee was deficient, and the application went abandoned for failure to

timely and properly reply to the final Office action, mailed June 24, 2003.

The instant petition

Applicant files the instant petition and avers that the abandonment of the application was unavoidable because Applicant was unaware of the fee increase.

A Grantable Petition Under 37 CFR 1.137(a)

A grantable petition to revive an abandoned application under 37 CFR 1.137(a) must be accompanied by: (**1**) the required reply (unless previously filed), which may met by the filing of a notice of appeal and the requisite fee; a continuing application; an amendment or request for reconsideration which *prima facie* places the application in condition for allowance, or a first or second submission under 37 CFR 1.129(a) if the application has been pending for at least two years as of June 8, 1995, taking into account any reference made in such application to any earlier filed application under 35 USC 120, 121 and 365(c); (**2**) the petition fee as set forth in 37 CFR 1.17(l); (**3**) a showing to the satisfaction of the Commissioner that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(a) was unavoidable; and (**4**) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required pursuant to 37 CFR 1.137(c).

Applicant lacks item (**3**) as set forth above.

Applicable Law

The general standard applied by the Office requires petitioner to establish that petitioner treated the patent the same as a reasonable and prudent person would treat his or her most important business.[1] 35 U.S.C. 41(c)(1) states, "The Commissioner may accept the payment of any maintenance fee ... at any time ... if the delay is shown *to the satisfaction of the Commissioner* to have been unavoidable." (emphasis added).

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[1] The Commissioner is responsible for determining the standard for unavoidable delay and for applying that standard.

"In the specialized field of patent law, ... the Commissioner of Patent and Trademarks is primarily responsible for the application and enforcement of the various narrow and technical statutory and regulatory provisions. His interpretation of those provisions is entitled to considerable deference." Rydeen v. Quigg, 748 F.Supp. 900, 904, 16 U.S.P.Q.2d (BNA)1876 (D.D.C. 1990), aff'd without opinion (Rule 36), 937 F.2d 623 (Fed. Cir. 1991) (citing Morganroth v. Quigg, 885 F.2d 843, 848, 12 U.S.P.Q.2d (BNA) 1125 (Fed. Cir. 1989); Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1425, 7 U.S.P.Q.2d (BNA) 1152 (Fed. Cir. 1988) ("an agency' interpretation of a statute it administers is entitled to deference"); see also Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844, 81 L. Ed. 694, 104 S. Ct. 2778 (1984) ("if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.")).

"The critical phrase 'unless it be shown to the satisfaction of the Commissioner that such delay was unavoidable' has remained unchanged since first enacted in 1861." Smith v. Mossinghoff, 671 F.2d 533, 538, 213 U.S.P.Q. (BNA) 977 (D.C. Cir. 1982). The standard for "unavoidable" delay for reinstating a patent is the same as the unavoidable standard for reviving an application. See Ray v. Lehman, 55 F.3d 606, 608-609, 34 U.S.P.Q.2d (BNA) 1786, 1787 (Fed. Cir. 1995) (citing In re patent No. 4,409,763, 7 U.S.P.Q.2d (BNA) 1798, 1800 (Comm'r Pat. 1990; Smith v. Mossinghoff, 671 F.2d 533, 538, 213 U.S.P.Q. (BNA) 977 (D.C. Cir. 1982). The court in In re Mattullath, accepted the standard which had been proposed by Commissioner Hall which "requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business." In re Mattullath, 38 App. D.C. 497, 514-515 (1912) (quoting Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)). However, "The question of whether an applicant's delay in prosecuting an application was unavoidable [will] be decided on a case-by-case basis, taking all of the facts and circumstances into account."[2] Nonawareness of the content of, or a misunderstanding of, PTO statutes, PTO

[2] Smith v. Mossinghoff, 671 F.2d 533, 538, 213 U.S.P.Q. (BNA) 977 (1982).

rules, the MPEP, or Official Gazette notices, does not constitute unavoidable delay.[3] The statute requires a "showing" by petitioner. Therefore, petitioner has the burden of proof. The decision will be based solely on the written, administrative record in existence. It is not enough that the delay was unavoidable; petitioner must prove that the delay was unavoidable. A petition will not be granted if petitioner provides insufficient evidence to "show" that the delay was unavoidable.

Applicant is further advised that the Patent and Trademark Office must rely on the actions or inactions of duly authorized and voluntarily chosen representatives of the applicant, and applicant is bound by the consequences of those actions or inactions. Link v. Wabash, 370 U.S. 626, 633-34 (1962); Huston v. Ladner, 973 F.2d 1564, 1567, 23 USPQ2d 1910, 1913 (Fed. Cir. 1992); see also Haines v. Quigg, 673 F. Supp. 314, 317, 5 USPQ2d 1130, 1132 (D.N. Ind. 1987). Specifically, petitioner's delay caused by the actions or inactions of his voluntarily chosen representative does not constitute unavoidable delay within the meaning of 35 U.S.C. 133 or 37 CFR 1.137(a). Haines v. Quigg, 673 F. Supp. 314, 5 USPQ2d 1130 (D. Ind. 1987); Smith v. Diamond, 209 USPQ 1091 (D.D.C. 1981); Potter v. Dann, 201 USPQ 574 (D.D.C. 1978); Ex parte Murray, 1891 Dec. Comm'r Pat. 130, 131 (Comm'r Pat. 1891). In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(quoting Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 USPQ 666, 167-68 (D.D.C. 1963), aff'd, 143 USPQ 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

Finally, a "delay (in responding) resulting from the lack of knowledge or improper application of the patent statute,

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[3] See Smith v. Mossinghoff, 671 F.2d 533, 538, 213 U.S.P.Q. (BNA) 977 (Fed. Cir. 1982) (citing Potter v. Dann, 201 U.S.P.Q. (BNA) 574 (D. D.C. 1978) for the proposition that counsel's nonawareness of PTO rules does not constitute "unavoidable" delay)); Vincent v. Mossinghoff, 1985 U.S. Dist. LEXIS 23119, 13, 230 U.S.P.Q. (BNA) 621 (D. D.C. 1985) (Plaintiffs, through their counsel's actions, **or their own**, must be held responsible for having noted the MPEP section and Official Gazette notices expressly stating that the certified mailing procedures outlined in 37 CFR 1.8(a) do not apply to continuation applications.) (Emphasis added).

rules of practice, or MPEP, [] does not constitute unavoidable delay." MPEP 711.03(c).

Applicant's Assertion

Applicant asserts that the delay was a result of Applicant's nonawareness of the fee increase.

Analysis and Conclusion

As to item (3), Applicant has not provided an adequate showing of unavoidable delay. Applicant is reminded that "delay (in responding) resulting from the lack of knowledge or improper application of the patent statute, rules of practice, or MPEP, [] does not constitute unavoidable delay." MPEP 711.03(c). Here, the patent rules regarding payment of fees changed and the fee for filing a RCE increased. Applicant was unaware of the rule change, and such a lack of knowledge does not constitute unavoidable delay.

Alternative venue

Applicant is strongly urged to file a petition stating that the delay was unintentional. Public Law 97-247, § 3, 96 Stat. 317 (1982), which revised patent and trademark fees, amended 35 U.S.C. § 41(a)(7) to provide for the revival of an "unintentionally" abandoned application without a showing that the delay in was "unavoidable." An "unintentional" petition under 37 CFR 1.137(b) must be accompanied by the required fee, currently $750.00.

The filing of a petition under 37 CFR 1.137(b) cannot be intentionally delayed and therefore must be filed promptly. A person seeking revival due to unintentional delay can not make a statement that the delay was unintentional unless the entire delay, including the delay from the date it was discovered that the application was abandoned until the filing of the petition to revive under 37 CFR 1.137(b), was unintentional. A statement that the delay was unintentional is not appropriate if petitioner intentionally delayed the filing of a petition for revive under 37 CFR 1.137(b).

Further correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9306
Attn: Office of Petitions

By hand: 2201 South Clark Place
Customer Window
Crystal Plaza Two, Lobby Room 1B03
Arlington, VA 22202

Telephone inquiries concerning this matter should be directed to the undersigned at (571) 272-3232.

Derek L. Woods
Attorney Advisor
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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STEPHEN GOUGH
P. O. BOX 205
ARON, NJ 07717

COPY MAILED
APR 29 2005
OFFICE OF PETITIONS

In re Application of :
Stephen J. Gough :
Application No. 07/683,484 :
Filed: April 9, 1991 : ON PETITION
Title of Invention: :
EASY WAGON/EASY CART/BICYCLE :
WHEEL MOUNTING BRACKETS :
SYSTEM :

This is a decision on the Petition to Revival Under 37 CFR 1.137(b), filed January 3, 2005.

The petition is **granted.**

Background

The above-identified application became abandoned for failure to timely and properly reply to the final Office action, mailed June 24, 2003. The Notices set a non-extendable three (3) month period for reply.

Applicant filed an Amendment on October 28, 2003, which failed to place the application in condition for allowance. Applicant was so notified in an Advisory Action mailed November 26, 2003. Applicant subsequently filed a Request for Continued Examination ("RCE") on December 29, 2003 and fee, and requests entry of the October 28, 2003 Amendment as the submission. The RCE fee was deficient, and the application went abandoned for failure to timely and properly reply to the final Office action, mailed June 24, 2003.

A petition to revive the application based upon unavoidable delay and the $15.00 fee deficiency were filed November 23, 2004. The petition was dismissed in a decision mailed December 9, 2004 for failing to meet the requirements of a grantable petition under 37 CFR 1.137(a).

With the instant petition, Applicant has revived the application. The required reply, the RCE, was filed on December 29, 2003. The submission - an Amendment - was filed October 28, 2003.

Having found that all of the requirements for a grantable petition under 37 CFR 1.137(b) have been met, **this petition is hereby granted.**

This application is being referred to Technology Center 3632 for processing of the RCE and Amendment in due course.

Telephone inquiries related to this decision may be directed to the undersigned at (571) 272-3232.

Derek L. Woods
Petitions Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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DRW Feb-09

Paper No. 11

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300 PARK AVENUE
NEW YORK NY 10022-7499

COPY MAILED

FEB 1 0 2009

OFFICE OF PETITIONS

In re Patent No. 5,166,668	:	
Issue Date: 11/24/1992	:	
Application Number: 07/683,595	:	DECISION ON PETITION
Filing Date: 04/10/1991	:	
For: WIRELESS PEN-TYPE INPUT	:	
DEVICE FOR USE WITH A COMPUTER	:	

This is a decision on the petition filed on July 11, 2008, under 37 CFR § 1.378(b) to accept the delayed payment of a maintenance fee for the above-identified patent.

The petition is **dismissed**.

If reconsideration of this decision is desired, a petition for reconsideration under 37 CFR 1.378(e) must be filed within TWO (2) MONTHS from the mail date of this decision. No extension of this 2-month time limit can be granted under 37 CFR 1.136(a) or (b). Any such petition for reconsideration must be accompanied by the petition fee of $400.00 as set forth in 37 CFR 1.17(f). The petition for reconsideration should include an exhaustive attempt to provide the lacking item(s) noted below, since, after a decision on the petition for reconsideration, no further reconsideration or review of the matter will be undertaken by the Director.

The patent issued on November 24, 1992. The first and second maintenance fees were timely paid. The third maintenance fee could have been paid from November 24, 2003 through May 24, 2004, or, with a surcharge during the period from May 25 through November 24, 2004. Accordingly, the patent expired at midnight on November 24, 2004, for failure to timely submit the third maintenance fee.

Petitioners, assignee Creative Technology Ltd. (hereinafter "CTL") state that registered patent practitioner Leighton K. Chong (Chong) of Ostrager Chong and Flaherty was responsible for tracking and submitting payment of the third maintenance fee. Petitioners have provided a statement by Chong, in which he states that CTL was timely informed about the requirement to pay the third maintenance fee. On May 27, 2004, CTL submitted the funds to pay the third maintenance fee to Chong by Electronic Funds Transfer, but that due to "booking and communication errors," the maintenance fee was not timely paid.

Petitioners further aver that on May 27, 2008, Desmond Tan, a patent engineer for CTL sent an email to Chong requesting clarification as to why the patent had lapsed. A follow-up E-email was sent on May 30, 2008 by Tan to Chong. On June 3, 2008, an additional follow-up email was sent to Chong by Russ Swerdon, CTl's Director of Intellectual Property, requesting information regarding the expiration of the patent. On June 8, 2008, Chong sent a reply email stating that he was traveling outside the United States and did not have access to his office records.

Petitioners have further included an emailed letter, dated June 24, 2008, from Chong to Tan, which states, in pertinent part:

> Having returned from my trip, I have researched my files regarding the 2nd maintenance fee payment that was due in this case. My records show that I sent a letter to Mr. Masuaki Tanaka on March 24, 2004, reminding him of the fee payment. After receiving notice from him that the patent had been assigned to Creative Technologies, I sent a letter to Creative Technologies by fax and mail dated April 1, 2004, stating that the fee payment was due by May 24, 2004. My file records show that no reply that was ever sent by Creative Technologies to my letter. However, my accounting records show that funds of $3,420 equal to the amount I quoted for making the fee payment were wired to my bank account on May 27, 2004. This amount was received by my bookkeeping as a receivable to Mr. Tanaka's account, and was not marked as having been sent by Creative Technologies.
>
> Therefore, I did not receive any letter instructions from Creative Technologies to make the fee payment. Also, the payment was sent by Creative Technologies after the due date and did not include the additional surcharge for late payment. The wired funds for the

> payment did not provide me with notice that the funds were to be applied to the account of Creative Technologies for this payment.

Lastly, petitioners have supplied an email from Swerdon to Chong, dated July 1, 2008, stating that the electronic funds transfer of $3,420.00 included the invoice number appearing in Chong's communication of April 1, 2004, to CTL concerning payment of the maintenance fee.

A petition to accept the delayed maintenance fee under 35 U.S.C. § 41(c) and 37 CFR 1.378(b) must be accompanied by (1) an adequate, verified showing that the delay was unavoidable, since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent, (2) payment of the appropriate maintenance fee, unless previously submitted, and (3) payment of the surcharge set forth in 37 CFR 1.20(i)(1).

The petition lacks item (1), above.

The Director may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Director to have been "unavoidable".[1] A patent owner's failure to pay a maintenance fee may be considered to have been "unavoidable" if the patent owner "exercised the due care of a reasonably prudent person."[2] This determination is to be made on a "case-by-case basis, taking all the facts and circumstances into account."[3] Unavoidable delay under 35 U.S.C. § 41(b) is measured by the same standard as that for reviving an abandoned application under 35 U.S.C. § 133.[4] Under 35 U.S.C. § 133, the Director may revive an abandoned application if the delay in responding to the relevant outstanding Office requirement is shown to the satisfaction of the Director to have been "unavoidable". Decisions on reviving abandoned applications have adopted the reasonably prudent person standard in determining if the delay was unavoidable.[5] However,

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[1] 35 U.S.C. § 41(c)(1).

[2] Ray v. Lehman, 55 F.3d 606, 608-09 (Fed.Cir.), cert. denied, -- U.S. ---, 116 S.Ct. 304, L.Ed.2d 209 (1995).

[3] Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982).

[4] In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (PTO Comm'r 1988).

[5] Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C.

a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay.[6] In view of In re Patent No. 4,409,763, this same standard will be applied to determine whether "unavoidable" delay within the meaning of 37 CFR 1.378(b) occurred.

This petition does not satisfy the requirement of 37 CFR 1.378(b)(3). The statements presented in the petition fail to satisfy the showing required to establish unavoidable delay within the meaning of 37 CFR 1.378(b).

As 35 U.S.C. § 41(c) requires the payment of fees at specified intervals to maintain a patent in force, rather than some response to a specific action by the Office under 35 U.S.C. § 133, a reasonably prudent person in the exercise of due care and diligence would have taken steps to ensure the timely payment of such maintenance fees.[7] That is, an adequate showing that the delay was "unavoidable" within the meaning of 35 U.S.C. § 41(c) and 37 CFR 1.378(b)(3) requires a showing of the steps taken to ensure the timely payment of the maintenance fees for this patent.[8]

A delay resulting from an error (*e.g.*, a docketing error) on the part of an employee in the performance of a clerical function may provide the basis for a showing of "unavoidable" delay, provided it is shown that:

(1) the error was the cause of the delay at issue;

(2) there was in place a business routine for performing the clerical function that could reasonably be relied upon to avoid errors in its performance;

(3) and the employee was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon such employee represented the exercise of due care.[9]

An adequate showing requires:

497, 514-15 (D.C. Cir. 1912); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (Comm'r Pat. 1913).

[6] Haines v. Quigg, 673 F. Supp. 314, 5 USPQ2d 1130 (N.D. Ind. 1987).

[7] Ray, 55 F.3d at 609, 34 USPQ2d at 1788.

[8] Id.

[9] See MPEP 711.03(c)(III)(C)(2).

(A) Statements by all persons with direct knowledge of the circumstances surrounding the delay, setting forth the facts as they know them.

(B) Petitioner must supply a thorough explanation of the docketing and call-up system in use and must identify the type of records kept and the person responsible for the maintenance of the system. This showing must include copies of mail ledgers, docket sheets, filewrappers and such other records as may exist which would substantiate an error in docketing, and include an indication as to why the system failed to provide adequate notice that a reply was due.

(C) Petitioner must supply information regarding the training provided to the personnel responsible for the docketing error, degree of supervision of their work, examples of other work functions carried out, and checks on the described work which were used to assure proper execution of assigned tasks.

The present petition lacks the showing required by (1), (2), and (3) above.

The showing of record is insufficient to show that the payment of the maintenance fee resulted from a clerical error. Petitioners must provide a detailed, documented showing as described in section (A) above. Statements of first-hand knowledge, setting forth, *in detail*, the circumstances surrounding the delay, must be provided by any and all employees or attorneys responsible for tracking and paying the maintenance fee.

As such, petitioners must explain who at Chong's office (*i.e.*, his bookkeeper) was responsible for submitting the maintenance fee to the USPTO, and describe the steps in place for submitting the maintenance fee to the USPTO.

Furthermore, the information on training and supervision of personnel described in section (C) above must be provided. All statements must be made by persons with first-hand knowledge of the details surrounding the delay and set forth the facts as they know them.

With regard to the allegations that CTL did not properly notify Chong that the fee payment of May 24, 2004 intended as the maintenance fee payment for the subject patent, petitioner is reminded that failure of communication between an applicant and

counsel is not unavoidable delay.[10] Specifically, delay resulting from a lack of proper communication between a patent holder and a registered representative as to who bore the responsibility for payment of a maintenance fee does not constitute unavoidable delay within the meaning of 35 USC 41(c) and 37 CFR 1.378(b).[11] Moreover, the Office is not the proper forum for resolving a dispute as to the effectiveness of communications between parties regarding the responsibility for paying a maintenance fee.[12]

Further, petitioners must explain when and how they first became aware of the delay in payment of the maintenance fee. While Tan sent the email to Chong on May 27, 2008, noting the nonpayment of the third maintenance fee, it is unclear when exactly CTL discovered that the maintenance fee had not been paid. As petitioners must provide a showing that the entire delay, from the date the maintenance fee payment was due until the date of the filing of a grantable petition, was unavoidable, any renewed petition must explain when CTL first discovered the maintenance fee was unpaid, and, if this was prior to May 27, 2008, explain any delay in contacting Chong or filing the subject petition.

As such, the evidence proffered in the subject petition falls short of what is required in order to substantiate a claim of docketing error. Rather than unavoidable delay, the showing of record does not sufficiently explain the steps in place to docket this patent, and explain the nature of the error that led to the delayed payment of the maintenance fee. As petitioner has not shown that it exercised the standard of care observed by a reasonable person in the conduct of his or her most important business, the petition will be dismissed.[13]

In summary, the showing of record has been considered, but does not rise to the level of unavoidable delay. The showing of record is of a lack of diligence on the part of petitioner and/or petitioner's counsel. Petitioner presented insufficient documentation of the steps were taken by petitioner to ensure timely payment of the maintenance fee, and has not provided statements of facts by the docketing manager and any other persons who would have been involved in the process of docketing this patent for payment of the second maintenance fee.

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[10] In re Kim, 12 USPQ2d 1595 (Comm'r Pat. 1988).

[11] See Ray, at 610, 34 USPQ2d at 1789.

[12] Id.

[13] See note 5, supra.

Since petitioners have not shown unavoidable delay, the petition will be dismissed.

It is noted that petitioner was inadvertently charged the fee of $1,640 for a petition under 37 CFR 1.378(c) rather than the $700.00 fee for a petition under 37 CFR 1.378(b). The overpayment of $940.00 is being refunded to counsel's deposit account.

Petitioners should note that if this petition is not renewed, or if renewed and not granted, then the maintenance fee and post-expiration surcharge are refundable. The $400.00 petition fee for seeking reconsideration is not refundable. Any request for refund should be in writing to the address noted below.

The address in the petition is different than the correspondence address of record. A courtesy copy of this decision will be mailed to the address in the petition. All future correspondence, however, will be mailed solely to the address of record. A change of correspondence address should be filed if the correspondence address needs to be updated. If patentee wishes to receive any maintenance fee correspondence which **may** be mailed, a "Fee Address" should be filed.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-8300
Attn: Office of Petitions

By hand: Customer Service Window
Mail Stop Petition
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Telephone inquiries should be directed to the undersigned at 571-272-3231.

DWood

Douglas I. Wood
Senior Petitions Attorney
Office of Petitions

Cc:

SHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
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THOMAS A. GALLAGHER
100 Green Street, 3RD Floor
San Francisco, CA. 94111-1302

MAILED

MAR 30 2009

OFFICE OF PETITIONS

In re Patent No. 5,260,775 :
Issue Date: November 9, 1993 :
Application No. 07/683,807 : DECISION ON PETITION
Filed: April 11, 1991 :
Inventor: Yves C. Faroudja :

This is a corrected decision on the renewed petition filed October 7, 2008, requesting reconsideration pursuant to 37 CFR § 1.183. The petition is being properly treated as a petition under 37 CFR §1.182 to invalidate an assignment previously recorded against the above-identified patent. The decision mailed October 24, 2008, granting this renewed petition, has been reevaluated and is **VACATED.**

The petition under 37 CFR § 1.182 is **dismissed**.

Any reply must be submitted within TWO MONTHS from the mail date of this decision. Extensions of time under 37 CFR § 1.136(a) are permitted. This is not a final agency action within the meaning of 5 U.S.C. § 704.

Petitioner has requested that the assignment record be amended to reflect that petitioner is the true owner of the above-noted patent. In particular petitioner requests expungement of purportedly erroneous assignment documents at Reel 020817, Frame 0243, so that petitioner Yves C. Faroudja, may be identified as the true and correct owner of the '775 patent. Petitioner submits that the assignment submitted on April 9, 2008 was submitted with an improper document attached and therefore request expungement of the assignment.

As discussed in section 323.01(d) of the Manual of Patent Examining Procedure (MPEP), petitions to correct, modify or "expunge" assignment records are granted only if the petitioner can prove that:

(A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
(B) the integrity of the assignment records will not be affected by granting the petition.

Petitioner has not proven either item A or B.

In regard to item A, there is no evidence of record that petitioner has attempted or considered any of the corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c). Also, there is no explanation of record as to why none of these procedures would provide adequate relief.

Petitioner seeks an extraordinary remedy, properly addressed under 37 CFR § 1.182. The USPTO will not normally resort to an extraordinary remedy under 37 CFR § 1.182 if the rules of practice and the procedures before the USPTO already provide an avenue for the requested relief. See Cantello v. Rasmussen, 220 USPQ 664, (Comm'r Pats. 1982).

As background, the USPTO simply acts in a ministerial capacity in recording documents that have been submitted for recordation. See 35 USC 261 and 37 CFR § 3.11. However, the recording of a document pursuant to 37 CFR § 3.11 is **not** a determination by the USPTO of the validity of the document *per se* or the effect that document has on the title to a patent or application. See 37 CFR § 3.54. Moreover, it is USPTO policy to maintain a complete history of claimed interests in a given property, and, as such, a recorded assignment document will be retained, even if it is subsequently found to be invalid. In re Raney, 24 USPQ2d 1713 (Comm'r Pat. 1992).

As set forth in MPEP 323, an error in a recorded assignment is not corrected by invalidating the previous document, but by simply submitting a "corrective document". The "corrective document" must include 1) a copy of the original assignment document with the corrections made therein. The corrections must be initialed and dated by the party conveying the interest; and 2) a new Recordation Form Cover Sheet (form PTO-1595). The new recordation form cover sheet must identify the submission as a "corrective document" submission and indicate the reel and frame number where the incorrectly recorded assignment document appears. The person signing the new recordation form cover sheet must state that the information provided on the new cover sheet is true and correct and that any copy submitted is a true copy of the original document. The original cover sheet should be submitted with the corrective document. The corrective document will be recorded and given a new reel and frame number and recording date. The recording fee set forth in 37 CFR 1.21(h) is required for each patent application and patent against which the corrective document is being recorded. See MPEP § 302.06. Corrections may be made on the original assignment document, for example, by lining out an incorrect patent or application number in a merger or change of name (see MPEP § 314).

Therefore, the rules of practice and the procedures before the USPTO provide an avenue for the requested relief without relying upon extraordinary measures. As a request for the Office to invalidate an assignment is both extraordinary and contrary to USPTO policy, this petition must be dismissed.

In regard to item B, the statements submitted in support of the petition to expunge fails to establish that expungement will not affect the assignment records in this instance. The assignment recorded in the USPTO assignment records indicates that Faroudja Laboratories, Inc. has some rights with regard to the above mentioned patent, which suggests that the recordation may have been proper. Petitioner should note that recordation is available for numerous

documents related to a patent, not just the assignment of the entire right, title and interest in the patent. See at least MPEP § 313. Moreover, the USPTO does not determine the extent of rights transferred by the assignment papers or any recorded document. Such a determination is made by a court of relevant jurisdiction. No evidence is of record establishing that the assignment was recorded improperly. Absent sufficient evidence to support the requested expungement, the integrity of the assignment records will not be disturbed by the USPTO.

There is no indication that the person signing the petition was ever given a power of attorney or authorization of agent to prosecute the application. If the person signing the petition desires to receive future correspondence regarding this application, the appropriate power of attorney or authorization of agent must be submitted. A courtesy copy of this decision is being mailed to the person signing the petition; however, all future correspondence will be directed to the address currently of record until appropriate instructions are received.

Telephone inquiries concerning this communication should be directed to the undersigned at (571)272-0602.

Thurman K. Page
Petitions Examiner
Office of Petitions

cc: Michael J. Ferrazaro
P.O. Box 1687
Cupertino, CA 95015-1687

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

spg
Paper Number 23

Mailed: MAR 2 0 2000

In re application of Donald E. Richeson et al. Serial No. 07/686,088 Filed: April 16, 1991 For: METHOD OF MANUFACTURING PARTIALLY CRYSTALLINE POLYESTER ARTICLES	DECISION ON PETITION

This is a decision on the applicant's REQUEST FOR WITHDRAWAL OF ABANDONMENT AND PUBLICATION OF THE STATUTORY INVENTION REGISTRATION, filed January 29, 1999, and the STATUS INQUIRY, filed December 6, 1999, requesting withdrawal of the abandonment, as set forth in the Notice of Abandonment of February 16, 1995, for failure to timely respond to the non-final Office letter of July 22, 1994. The petitioner asserts that the non-final Office letter, mailed July 22, 1994, was not received at the applicant's correspondence address.

DECISION

The instant request is accepted as a timely petition under 37 C.F.R. 1.181 (no fee), and is evaluated under the procedures regarding an acceptable showing of non-receipt of an office action, TMOG 1156 O.G. 53, November 16, 1993, (see also MPEP 711.03(c) - NEW PROCEDURE TMOG 1170 O.G. 114). A review of the petitioner's evidence indicates that the request has merit. The evidence presented is sufficient to establish that the Notice of Non-compliance with 35 U.S.C. 112 of application having SIR Request (PTO-SIR-1), mailed July 22, 1994 was not received at the attorney's correspondence address. The evidence provided includes a statement by the petitioner that the office letter was not received, a statement that a search of the file and docket records was made, and a statement that the search revealed the office letter was not received. Also provided is a copy of the attorney's application docket records where the office letter would have been posted had it been timely received at the correspondence address.

Therefore, the abandonment is hereby withdrawn, and the application is returned to pending status. The application shall be forwarded to the examiner for prompt remailing of the nonreceived Notice of Non-compliance with 35 U.S.C. 112 of application having SIR Request (PTO-SIR-1) and restarting of the statutory period of response from the remail date of the Notice of Non-compliance with 35 U.S.C. 112 of application having SIR Request (PTO-SIR-1).

The Petition is **GRANTED**.

Richard V. Fisher

Richard V. Fisher, Director
Technology Center 1700
Chemical and Materials Engineering

Douglas Baldwin
Shell Oil Company
P.O. Box 2463
One Shell Plaza
Houston, TX 77252-2463

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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AUG 11 2009

Gail E. Poulos
USDA-ARS-OTT
5601 Sunnyside Avenue, Rm. 4-1183
Beltsville, Maryland 20705-5131

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,135,759

Dear Ms. Poulos :

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 5,135,759 for a period of one year from the original expiration date, i.e., until August 4, 2010. A copy of the Federal Register notice, published on August 4, 2009 at 74 Fed. Reg. 38585, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: MicroSort® Sperm Separation Technology
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States of America as represented by the Secretary of Agriculture	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 5,135,759	:	**INTERIM EXTENSION**

On June 8, 2009, patent owner, United States of America, as represented by the Secretary of Agriculture, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,135,759. The patent claims a use of the medical device, the MicroSort® Sperm Separation Technology. The application indicates, and the Food and Drug Administration has confirmed, that a Premarket Approval application (P090004) for the MicroSort® Sperm Separation Technology has been filed by the licensee of the patent owner, Genetics & IVF Institute, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (August 4, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 5,135,759 is granted for a period of one year from the expiration date of the patent, i.e., until August 4, 2010.

07/28/09
Date

John Doll
John J. Doll
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

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JUL 29 2010

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,299,569

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156 FOR U.S. PATENT NO. 5,299,569

This is in response to the application for extension of the term of U.S. Patent No. 5,299,569 ("the '569 patent") filed under 35 U.S.C. § 156 in the United States Patent and Trademark Office ("USPTO") on July 18, 2005 ("PTE Application"), the Request for Reconsideration of Final Determination of Ineligibility for Patent Term Extension Under 35 U.S.C. § 156 filed on April 27, 2007 ("Request for Reconsideration"), and the Communication Responding to FDA's Letter Regarding Applicant's Request for Reconsideration of Final Determination of Ineligibility for Patent Term Extension Under 35 U.S.C. § 156 filed on April 24, 2009 ("Communication"). Cyberonics, Inc. ("Applicant"), assignee and owner of the '569 patent, filed the PTE Application. Applicant seeks extension based upon the July 15, 2005 premarket approval of the Vagus Nerve Stimulation Therapy System ("VNS Therapy System") under Section 515 of the Federal Food Drug and Cosmetic Act ("FFDCA"). Because the USPTO has determined that the eligibility requirement set forth in 35 U.S.C. § 156(a)(5)(A) is not satisfied, the PTE Application is **DENIED** and the Request for Reconsideration, as supplemented by the Communication, is **DENIED**.

A. Factual Background

1. On April 5, 1994, the USPTO granted the '569 patent to Joachim F. Wernicke et al., who assigned their rights to Cyberonics, Inc.

2. On July 16, 1997, the FDA approved the VNS Therapy System (then called the NeuroCybernetic Prosthesis System) for use in the treatment of epilepsy.

3. On April 27, 1998, Applicant filed an original Investigational Device Exemption ("IDE") with the FDA, seeking approval to conduct a clinical (feasibility) trial using the VNS Therapy System to treat depression.

4. On July 15, 2005, the FDA approved the VNS Therapy System for the treatment of depression.

5. On July 18, 2005, Applicant filed the PTE Application. In the PTE Application,

Applicant identifies the VNS Therapy System for treatment of epilepsy as a previously-approved product. Applicant nevertheless attempts to distinguish the VNS Therapy System for treatment of depression from the previously-approved VNS Therapy System for treatment of epilepsy in two ways. First, Applicant asserts that the electrical pulses used to treat depression give a different level of electrical stimulation for treatment of depression than treatment of epilepsy. Second, Applicant asserts that the VNS Therapy System for treatment of epilepsy includes a magnetic actuator that a patient can use to interrupt the electrical stimulation during a seizure that is not used in VNS Therapy System for treatment of depression.

6. On August 29, 2005, the USPTO sent a letter to the FDA, requesting the FDA's assistance in confirming that (1) the VNS Therapy System was subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first permitted commercial marketing or use as required by § 156(a)(5)(A); and (2) the PTE application was filed within sixty days of the product receiving FDA approval as required by 35 U.S.C. § 156(d)(1).

7. On February 24, 2006, the FDA responded to the USPTO that the VNS Therapy System represents the first commercial marketing or use of the product as required by § 156(a)(5)(A) and that the PTE application was timely filed as required by § 156(d)(1).

8. On June 29, 2006, in response to the information received from the FDA, the USPTO sent a letter to the FDA, requesting that the FDA to determine the regulatory review period for the VNS Therapy System and, as required by 35 U.S.C. § 156(d)(2)(A), publish that determination in the *Federal Register*.

9. On September 18, 2006, the FDA informed the USPTO that the FDA's earlier letter dated February 24, 2006, was in error and that, in fact, the July 15, 2005 approval of the VNS Therapy System did NOT represent the first permitted commercial marketing or use of the product as required by § 156(a)(5)(A). As a result, the FDA did not determine the regulatory review period.

10. On March 1, 2007, after receiving the new information from the FDA regarding the July 15, 2005 approval of the VNS Therapy System, the USPTO mailed a Notice of Final Determination – Ineligible ("the Notice") to Applicant, informing Applicant that the '569 patent is not eligible for patent term extension because the eligibility requirement of § 156(a)(5)(A) was not met. The USPTO identified two bases for its determination of ineligibility. First, the USPTO pointed to the FDA's letter dated September 18, 2006, wherein the FDA informed the USPTO "that the VNS Therapy System approved July 15, 2005, does not represent the first permitted commercial marketing or use of the product." Second, the USPTO pointed to a statement made in Applicant's IDE, wherein Applicant informed the FDA that "[t]he investigational device for this study is the ***same device*** as that approved in P970003 and therefore, information related to device

description and manufacturing information is incorporated herein by reference to P970003 and not reproduced in this original IDE submission." (Emphasis added.)

11. On April 27, 2007, in response to the USPTO's March 1, 2007 Notice, Applicant submitted the Request for Reconsideration. Therein, Applicant explains that, due to differences in output currents and use of the patient-initiated magnetic actuator, the VNS Therapy System for treatment-resistant depression and the VNS Therapy System for epilepsy "are different 'products' within the meaning of 35 U.S.C. § 156." Thus, according to Applicant, the FDA's approval of the VNS Therapy System for treatment-resistant depression constitutes the "first permitted commercial marketing or use" as required by § 156(a)(5)(A).

12. On January 11, 2008, the USPTO sent a letter to the FDA requesting the FDA's comment on Applicant's Request for Reconsideration to assist the USPTO in its reconsideration of the final determination of ineligibility. Specifically, the USPTO in the January 11, 2008 letter requests the FDA's input on Applicant's allegation that the differences in output currents and use of the patient-initiated magnetic actuator renders the VNS Therapy System for treatment-resistant depression a different "product" from the VNS Therapy System for epilepsy within the meaning of 35 U.S.C. § 156.

13. On March 24, 2009, the FDA responded to the USPTO's January 11, 2008 letter. The FDA concluded "that the VNS Therapy System, approved July 15, 2005, as a long-term adjunctive therapy for treatment resistant depression, is the same product as approved previously in 1997 for adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures, which are refractive to antiepileptic medications." According to the FDA, "[t]he differences identified by Cyberonics in output currents and use of the patient-initiated magnetic actuator are not differences in intended use of the VNS Therapy System that amount to a different product within the meaning of 35 U.S.C. section 156."

14. On April 24, 2009, Applicant filed the Communication in response to the FDA's March 24, 2009 letter. In the Communication, Applicant reiterates the arguments it made in its Request for Reconsideration as to why the FDA's approval of the VNS Therapy System for treatment resistant depression constitutes the "first permitted commercial marketing or use" as required by § 156(a)(5)(A). The Communication also provides additional arguments as to the statutory construction of the term "product" as including a medical device and FDA's review of a device as defined in § 201(h) of the FFDCA.

B. Analysis

1. The FDA's Approval of the VNS Therapy System Product for Depression Is Not the First Permitted Commercial Marketing or Use of the Product as Required by § 156(a)(5)(A)

Section 156 of Title 35 sets forth several requirements that must be met before the Director can extend the term of a patent. *See, e.g.*, 35 U.S.C. §§ 156 (a)(1)-(a)(5), (d)(1), and (e)(1). The requirement at § 156(a)(5)(A) is the only one at issue here. Section 156(a)(5)(A) requires:

> the permission for the commercial marketing or use of the ***product*** . . . [to be] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

(Emphasis added).

In the definitional provision of § 156, the term "product" is defined as "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act." 35 U.S.C. § 156(f)(1)(B). Thus, the relevant statutory language makes clear that, so long as a medical device has been subject to a regulatory review period under the FFDCA, the medical device qualifies as a "product" for purposes of § 156.

Applicant's VNS Therapy System is a medical device, and it was subject to a regulatory review period under the FFDCA. The FDA approved the VNS Therapy System for commercial marketing and use on July 15, 2005, after undergoing regulatory review under Section 515 of the FFDCA. Therefore, Applicant's VNS Therapy System qualifies as a "product" for purposes of § 156.

Substituting the definition of "product" from § 156(f)(1)(B) directly into § 156(a)(5)(A) yields the statement that a patent is ineligible for extension if it is not the first permitted commercial marketing or use of the medical device under the provision of law under which such regulatory review period occurred. Accordingly, whether the '569 patent is eligible for a term extension hinges on whether the FDA's July 15, 2005 approval of the VNS Therapy System product is the first permitted commercial marketing or use of the VNS Therapy System product under Section 515 of the FFDCA. It is not.

In its PTE Application, Applicant identifies the VNS Therapy System for the treatment of epilepsy as a previously-approved product under Section 515 of the FFDCA. Upon receipt of Applicant's PTE application and its Request for Reconsideration, the USPTO wrote to the FDA to inquire whether the FDA's July 15, 2005 approval of the VNS Therapy System to treat depression was the first permitted commercial marketing or use of the product under Section 515 of the FFDCA. In response to the USPTO's inquiries, the FDA twice informed the USPTO that

it was not.[1] And in its second response letter dated March 24, 2009, the FDA elaborates that it considers the VNS Therapy System indicated for depression to be the "same product" as the VNS Therapy System indicated for epilepsy, which had been previously approved by the FDA in 1997.

In view of the information provided in Applicant's own PTE Application and the follow-on information provided by the FDA, the USPTO independently concludes that the requirement of § 156(a)(5)(A) is not satisfied. Specifically, the USPTO concludes that the VNS Therapy System indicated for the treatment of epilepsy and the VNS Therapy System indicated for the treatment of depression are the same products. Further, the VNS Therapy System to treat epilepsy and the VNS Therapy System to treat depression were both approved by the FDA under Section 515 of the FFDCA. Because the VNS Therapy System indicated for epilepsy was approved earlier in time than the VNS Therapy System indicated for depression (1997 and 2005, respectively), the FDA's approval of the VNS Therapy System for treating depression is *not* the first permitted commercial marketing or use of the product under Section 515 of the FFDCA.

Fisons v. Quigg, 1988 WL 150851 (D.D.C. 1988) ("*Fisons I*"), *aff'd*, 876 F.2d at 101 (Fed. Cir. 1989) ("*Fisons II*"), supports the agency's determination. There, Fisons filed three PTE applications to extend the terms of three patents protecting different formulations or uses of cromolyn sodium, all approved by the FDA under Section 505 of the FFDCA. *Fisons I*, 1998 WL 150851 at *1-3. The USPTO denied Fisons's applications for failing to meet the requirement of § 156(a)(5)(A) in view of the FDA's earlier approval of cromolyn sodium, also under Section 505 of the FFDCA. *Id.* The district court affirmed the USPTO's denial, *id.* at *10, as did the Federal Circuit, *Fisons II*, 876 F.2d at 102.

While the specific facts of *Fisons* involved human drugs as opposed to medical devices, the dispute in *Fisons* was the same as the dispute here, namely, whether the prior approval of the same product under the same regulatory review provision satisfies § 156(a)(5)(A) when the later approval is different only in use or formulation of the product. The district court answered that question in the negative, and the Federal Circuit affirmed. Accordingly, Federal Circuit precedent supports the conclusion that, in this instance, the requirement of § 156(a)(5)(A) is not met, given that the FDA approval of the VNS Therapy System in 1997 was under the same regulatory review provision as in 2005.

The Federal Circuit's recent decision in *Photocure ASA v. Kappos*, 603 F.3d 1372 (Fed.

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[1] Notably, in response to the USPTO's first request for information about the first commercial marketing or use of the VNS Therapy System to treat depression, the FDA indicated that Applicant's product satisfied the requirement of § 156(a)(5)(A). The FDA subsequently *sua sponte* corrected itself approximately seven months later, then informing the USPTO that it was mistaken when it originally indicated that the VNS Therapy System to treat depression was the first permitted commercial marketing or use of the product under the provision of law under which regulatory review occurred.

Cir. May 10, 2010), has been considered. *Photocure* is a drug product case concerning the meaning of the phrase "active ingredient" found in the ultimate definition of the term "product" in 35 U.S.C. § 156(f). *See, e.g., id.* at 1373 (stating that the "case concerns the applicability of the statute governing patent term extension, 35 U.S.C. § 156, to the drug product having as its active ingredient the chemical compound methyl aminolevulinate hydrochloride . . . "). In *Photocure*, the Federal Circuit reaffirmed its holding in *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990), that "the active ingredient is the ingredient in the drug product as administered." *Photocure*, 2010 WL 1838653 at 1376. Nothing in *Photocure* controverts the conclusion reached herein that the first approval of a medical device exhausts the patent term extension eligibility for any subsequent approval of the same device.

2. Applicant's Arguments As to Why the FDA's Second Approval of the VNS Therapy System Under the Same Provision of Law as its Earlier Approval Satisfies § 156(a)(5)(A) Are Unpersuasive

Applicant raises a host of arguments as to how the FDA's second approval of the VNS Therapy System to treat depression under Section 515 of the FFDCA satisfies the "first commercial marketing or use" provision of § 156(a)(5)(A). Each of those arguments will be considered in turn, but none is persuasive.

A. The USPTO, and Not the FDA, Made the Determination that the FDA's Approval of the VNS Therapy System for Depression on July 15, 2005 Is <u>Not</u> the First Permitted Commercial Marketing or Use of the Product under Section 515 of the FFDCA

As a preliminary matter, Applicant cites to 35 U.S.C. § 156(d)(1)(C) and states that "[u]nder § 156, as Congress intended, it is the USPTO that must make [the determination of whether the requirement of Section 156(a)(5)(A) has been fulfilled], and it is inappropriate for the USPTO to assign this determination to the FDA." Communication at 7-8. Applicant misapprehends the USPTO's process for deciding PTE applications. The USPTO alone decides eligibility for a patent term extension; it never assigns that decision to the FDA.

Section 156(d)(1)(C) states that "[t]he application [for patent term extension] shall contain . . . information to enable ***the Director*** to determine under subsections (a) and (b) the eligibility of a patent for extension . . . ." (Emphasis added.) The statute thus requires the Director to decide whether the eligibility requirements are satisfied. In the process of doing so, the Director may seek information from the FDA regarding certain eligibility requirements, like whether an approved product represents the first permitted commercial marketing or use of the product as required by § 156(a)(5)(A), to help the USPTO make its determination. The USPTO does so because the USPTO does not have the information necessary to make the determination in its own records, apart from the representations contained in a particular applicant's PTE application. Therefore, the FDA is the only independent source for the information that the USPTO may consult to confirm an applicant's representations.

Nothing in the statute precludes the Director from soliciting information from the FDA. In fact, it is the USPTO's long-standing practice to seek information from the FDA about various eligibility requirements. Shortly after the enactment of § 156, the USPTO and the FDA entered into an agreement to facilitate eligibility decisions and permit the USPTO and the FDA to carry out their respective responsibilities under § 156. *See* Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration, 52 Fed. Reg. 17830 (1987) ("hereinafter MOU"). The MOU states that "[w]hile it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied" the § 156 eligibility requirements, the "FDA possesses expertise and records regarding," *inter alia*, the requirement of § 156(a)(5)(A). *See, id.* at 17831. Accordingly, the MOU establishes a procedure whereby the FDA, upon receipt of a written request from the USPTO, conveys information to the USPTO to enable the USPTO to make an informed determination as to whether the requirement set forth in § 156(a)(5)(A) has been fulfilled.

Today, the USPTO and the FDA continue to follow the procedures laid-out in the MOU. The FDA continues to possess information pertinent to the determination of whether the requirement of § 156(a)(5)(A) has been fulfilled. Therefore, the most effective way for the USPTO to make the most informed determination concerning § 156(a)(5)(A) continues to be for the USPTO to obtain information from the FDA prior to the USPTO making its own determination.

Here, while the USPTO obtained information from the FDA about approvals of the VNS Therapy System, the USPTO – not the FDA – decided that the FDA's second approval of the VNS Therapy System on July 15, 2005, was not the first permitted commercial marketing or use of the product under Section 515 of the FFDCA. The USPTO made its determination after careful consideration of both the information provided by Applicant in its PTE application and the information provided by the FDA. Thus, the USPTO fulfilled its statutory obligation under § 156(d)(1)(C) to determine eligibility in this case.

B. Applicant's Argument That the "Product," as That Term Is Used in § 156(a)(5)(A), Does Not Have to be "New" is Misplaced

Applicant argues that when the "product" subject to regulatory review is a medical device, as in this case, the product does not have to be "new" to satisfy § 156(a)(5)(A). *See* Communication 3-4, 9-10, 15-17. Applicant alleges the requirement for the product to be "new" only applies to a drug. Applicant derives its argument from its reading of § 156(f), which sets forth a definition for the term "product" used in § 156(a)(5)(A). Applicant points out that when the "product" is a drug, the statute defines "product" to mean a "drug product," *see* 35 U.S.C. § 156(f)(1)(A), which the statute in turn defines as the active ingredient of either "a new drug, antibiotic drug, or human biological product" or "a *new* animal drug or veterinary biological product," *see id.* (f)(2)(A) & (B). By contrast, Applicant points out that when the "product' is a medical device, the statute defines "product" simply as "any medical device" as opposed to a *new* medical device. *See id.* at (f)(1)(B). Given the foregoing, Applicant contends that the FDA's

approval of the VNS Therapy System to treat depression satisfies § 156(a)(5)(A), regardless of the FDA's previous approval of the VNS Therapy System to treat epilepsy.

Applicant's argument is misplaced because the issue here is not whether the medical device was new, or whether that is a statutory requirement. The issue is simply whether FDA's July 15, 2005 approval constituted the first permitted commercial marketing or use of the device as required by § 156(a)(5)(A). It did not – the same device had already been approved on July 16, 1997. Moreover, even accepting Applicant's theory that the term "new" in § 156(f) is somehow applicable to this case, that argument is fatally flawed because it misconstrues the use of the word "new" in that section. Section 156(f) provides:

(f) For purposes of this section:

(1) the term "product" means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of –

(A) a *new* drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a *new* animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(Emphases added).

Applying a plain reading to the statutory language, the term "new" in sections 156(f)(2)(A) and (B) does *not* modify each of the possible subsequent terms, i.e., new drug, new antibiotic drug, new human biological product, new animal drug, and new veterinary biological product. Instead, the term "new" modifies only the word that immediately follows it in the statute. In § 156(f)(2)(A), the word "new" modifies "drug," i.e., "new drug," and in § 156(f)(2)(B), it modifies "animal drug," i.e., "new animal drug." If Congress had intended for

each of the types of drug products to be "new," then it likely would have placed the adjective "new" before each of them.

This reading is confirmed by the fact that the statutes provides independent definitions for the terms "new drug," "new animal drug," "antibiotic drug," and "human biological product" in the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. *See* 21 U.S.C. § 201(p) (defining "new drug"); *id.* at § 201(jj) (defining "antibiotic drug"); *id.* at § 201(p) (defining "new animal drug"); and 42 U.S.C. § 262(i) (defining "human biological product").

Under the proper statutory construction of the term "new," § 156(f) does not identify five classes of "products" (drug, antibiotic drug, human biological product, animal drug, and veterinary biological product) that must be "new" and three classes of products (medical devices, food additives, and color additives) that do not have to be "new" for purposes of § 156(a)(5)(A). Instead, § 156(f) simply defines eight separate classes of products that can support a patent term extension. One of those classes is medical devices. That the statute does not use the word "new" with "medical device" as it does with "drug" does not mean, however, that a medical device previously approved for one indication can support a patent term extension under § 156(a)(5)(A) if later approved for another indication. To support a patent term extension, § 156(a)(5)(A) expressly requires the medical device to be "the first permitted commercial marketing or use of the product under the provision of law under which [] regulatory review [] occurred." Section 156(a)(5)(A) thus is not concerned with whether the product has never been on the market before (aka, "new" as Applicant uses that term); it is concerned only with whether the "approval" of the product – "new" or "old" – was the first grant of permission for commercial marketing or use under the applicable regulatory review provision.

C. Applicant's Argument Regarding the Provision of Law Under Which Regulatory Review Occurred Is Also Misplaced

Applicant argues that a determination of whether a medical device subject to a prior FDA approval satisfies § 156(a)(5)(A) depends on whether the second request for permission to commercially market or use the device raises different safety and effectiveness issues than those that arose in connection with the prior request for permission to commercially market or use the device. *See* Communication at 4-5, 10-12, 17-23. Applicant contends that this reading of the statute comports with the legislative history in which Congress intended to benefit innovators by restoring some "lost" patent term while the product, claimed by the patent, underwent regulatory review. *Id.* at 11. Framing the determination this way, Applicant argues that the VNS Therapy System indicated for depression satisfies § 156(a)(5)(A), despite prior FDA approval of the VNS Therapy System indicated for epilepsy, because the former raised different safety and effectiveness issues from those addressed in the approval process for the latter.

Applicant misunderstands the "first permitted commercial marketing or use" requirement in §156(a)(5)(A). As noted earlier, § 156(a)(5)(A) states that the permission for commercial

marketing or use of the product must be "the ***first*** permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." (Emphasis added.) Satisfaction of this provision – by its express terms – turns exclusively on the number of approvals given to a particular product under a particular regulatory review provision as indicated by the word "first"; the statute says nothing about the safety and effectiveness issues raised during the FDA approval process. *See Burlington Northern Ry. Co. v. Oklahoma Tax Comm'n*, 107 S. Ct. 1855, 1860 (1987) (explaining that the starting point for statutory interpretation is the plain language of the statute and that it should be regarded as conclusive absent clearly contrary legislative intent).

Thus, based on the actual statutory language, a product approved under a first regulatory review provision may support a patent term extension if the product is subsequently approved under a *different* regulatory review provision, but a product approved under a first regulatory review provision will not support a patent term extension if the product is subsequently approved under the *same* regulatory review provision. For example, as stated by the FDA in a letter dated April 20, 2007, to the USPTO in the application for patent term extension of U.S. Patent No. 4,868,179, "only the first approval of an active ingredient for use in a new drug for human use reviewed under section 505 of the FFDCA would be eligible, but patent term restoration could still be available for a [previously not extended] patent in connection with review and approval under section 512 of that same active ingredient for use in a new animal drug."

The legislative history supports the USPTO's plain language reading. While Applicant is generally correct that Congress enacted the Hatch-Waxman Act to remedy the loss of effective patent term due to lengthy regulatory review delay, it does not follow that every provision within § 156 is "remedial." As the D.C. District Court explained in *Fisons*, "the legislative history reflects that the purpose of § 156 was indeed broad, but not completely magnanimous." *Fisons v. Quigg*, 1988 WL 150851, *6 (D.D.C. 1988) *aff'd*, 876 F.2d 99 (Fed. Cir. 1989). In that regard, the court elaborated "[t]hat the patent restoration provisions were not as generous as [applicant] would like is attributable to the counterveiling interests [of brand pharmaceuticals versus generics that] Congress attempted to reconcile in the legislation." *Id.* at *10.

Moreover, during the enactment of the Hatch-Waxman Act, the Committee on the Judiciary for the House of Representatives considered a proposed amendment to grant a patent term extension for each regulatory review period for a product, not just for the regulatory review period associated with the first approval of the product. *See* H.R. Rep. No. 98-857 (II) at 22 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2691-92. The Committee rejected the proposed amendment to avoid multiple patent term extensions because only the first patent is effected by substantial regulatory delay and subsequent patents "frequently" do not represent "the same magnitude of innovation." *Id.* at 8. Contrary to Congress's intent, however, Applicant's construction would make a patent term extension available for the second, third, fourth, fifth, etc. approval of the same product under the same regulatory review provision so long as different safety and effectiveness considerations were involved in those latter approvals, regardless whether they offered the same "magnitude of innovation." Accordingly, Applicant's argument

departs from the congressional intent behind § 156(a)(5)(A).

Finally, Applicant's arguments would essentially render the statutory term "first" superfluous because any change in use, effectiveness, etc., that necessitates a subsequent FDA approval would, in Applicant's view, also constitute a new "first" approval. But Congress clearly contemplated that the FDA might approve a device multiple times, and limited the availability of patent term extensions only to the first such approval. Thus, while Applicant's additional use of the device necessitated another FDA regulatory review period for that use, the subsequent approval of the device was not the "first" approval of Applicant's device.

D. The FDA Consistently Reviewed the VNS Therapy System Under Section 515 for both Treatment of Epilepsy in 1997 and Treatment of Depression in 2005

Applicant alleges that the FDA treated the VNS Therapy System to treat depression as a *different device* than the VNS Therapy System to treat epilepsy for purposes of regulatory approval under Section 515. *See* Communication at 5-6, 23-3. Applicant substantiates its allegations by pointing out that the FDA (i) twice granted expedited review of the VNS Therapy System to treat depression; (ii) demanded new safety data rather than rely on the safety data for the VNS Therapy System to treat epilepsy; and (iii) required additional effectiveness data for the VNS Therapy System to treat depression. *Id.* at 24-25. Applicant further points to the seven-year FDA regulatory review period for the VNS Therapy System to treat depression, claiming that if the FDA were simply re-reviewing the previously approved VNS Therapy System, then it would have taken less time. Request for Reconsideration at 11-12. In support of its allegations, Applicant submitted a declaration from Mr. Scott Mindrebo, Applicant's Senior Director of Regulatory Affairs, attesting to Applicant's activities during the FDA's regulatory review of the VNS Therapy System to treat depression. In highlighting how it believes the FDA treated the VNS Therapy System to treat depression, Applicant thus appears to be urging the USPTO to treat the VNS Therapy System for depression as a different device from the VNS Therapy System for epilepsy for purposes of assessing whether the first permitted commercial marketing or use provision of § 156(a)(5)(A) is met.

Applicant's argument again ignores the statutory language of § 156(a)(5)(A). Nothing in the statutory language of that provision or its legislative history creates an exception for how the FDA treated a product during regulatory review or the length of the regulatory review period. As explained, the only relevant inquiry under § 156(a)(5)(A) is whether the product has been previously granted permission for commercial marketing or use under the same provision of law for regulatory review. If it had, then the product fails under § 156(a)(5)(A), and it is undisputed here that the FDA had approved the VNS Therapy System for epilepsy before it approved the VNS Therapy System for depression under the same regulatory review provision. The first approval of a medical device exhausts the patent term extension eligibility for any subsequent approval of the same device.

Moreover, Applicant fails to point to anything that shows that the FDA regarded the VNS

Therapy System for depression as a different device than the VNS Therapy System for epilepsy for purposes of § 156(a)(5)(A). In fact, record evidence shows the opposite. The USPTO twice wrote to the FDA to inquire whether the VNS Therapy System was subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first permitted commercial marketing or use as required by § 156(a)(5)(A). The FDA twice (once in 2006 and once in 2009) responded that the VNS Therapy System for depression did not represent the first permitted commercial marketing or use of the product under § 156(a)(5)(A). Further, in its March 24, 2009 response letter, the FDA elaborates that it considers the VNS Therapy System indicated for depression to be the *same product* as the VNS Therapy System indicated for epilepsy, which had been previously approved by the FDA in 1997. The FDA stated: "[t]he differences identified by Cyberonics in output currents and use of the patient-initiated magnetic actuator are not differences in intended use of the VNS Therapy System that amount to a different product within the meaning of 35 U.S.C. section 156." Hence, plainly, the FDA did not regard the VNS Therapy System to treat depression as a different device than the VNS Therapy System to treat epilepsy, contrary to Applicant's allegations.

E. Applicant's Argument that the VNS Therapy System to Treat Depression is a Different Medical Device than the VNS Therapy System to Treat Epilepsy Is Not Persuasive

Applicant contends that the VNS Therapy System to treat depression is a different medical device from the VNS Therapy System to treat epilepsy as the term "device" is defined in section 201(h) of the FFDCA, based on the different use of the magnetic actuator when the device is used for the two different treatments. *See* Communication at 6-7; 31-35; *see also* Request for Reconsideration at 5-6, 10. In particular, Applicant argues that if any component, part, or accessory changes the intended use of a device, then it is a different device under section 201(h) from the previous device. Communication at 6. Under this theory, Applicant asserts that the actuator in the VNS Therapy System to treat depression is set to zero and cannot be used to initiate any electrical signals (it is present only to allow the patient to turn off the device), whereas the actuator in the device is set to "on demand" to treat epilepsy to be used at will by a patient to prevent, reduce, or stop a seizure by delivering electrical signals to the vagus nerve. *Id.* at 7; Request for Reconsideration at 10 (featuring diagram showing differences in operation between the VNS Therapy System to treat depression versus epilepsy).[2]

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[2] In its Request for Reconsideration, Applicant also claims that the VNS Therapy System to treat depression is a different device from the VNS Therapy System to treat epilepsy because the output currents for the two different uses are different. *See* Request for Reconsideration at 5 (providing tabular data of output currents when VNS Therapy System is used to treat depression versus epilepsy). Applicant did not continue this argument in its Communication. Applicant's output currents argument is unpersuasive because the physical composition of the VNS Therapy System indicated for depression is identical to the physical composition of the VNS Therapy System indicated for epilepsy.

Applicant's argument is not persuasive. Section 201(h) of the FFDCA defines a "device" for purposes of determining FDA's jurisdiction over the product and its classification among FDA-regulated products. Applying that definition to the facts here, the VNS Therapy System (whether indicated for epilepsy or depression or both) is a "device," since it is intended for use in the cure, mitigation, treatment, or prevention of disease and it is intended to affect the structure or function of the body. This means it is subject to the provisions of the FFDCA applicable to "devices." Contrary to Applicant's assertion, however, section 201(h) does not dictate that the VNS Therapy System indicated for epilepsy and the VNS Therapy System indicated for depression are different devices under the patent term extension statute.

In assessing patent term extension, § 156 sets forth all of the eligibility requirements as well as definitions for any terms relevant to those requirements. As explained earlier, § 156(a)(5)(A) requires "the permission for the commercial marketing or use of the *product* . . . [to be] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." Section 156(f)(1)(B) defines the term "product" as used in § 156(a)(5)(A) as "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act." Nothing in either provision accounts for how the medical device is used (i.e., magnetic actuator turned on or off) or the indications that the medical device may treat (i.e., depression or epilepsy). Substituting the relevant definition of "product" into § 156(a)(5)(A), the only consideration is whether the medical device itself was previously approved under the same provision of law. Here, there is no dispute that the VNS Therapy System was approved in 1997 and again in 2005, both under the same provision of law.

Furthermore, Applicant's argument premised on the different uses of the magnetic actuator is not persuasive, even if, for the sake of argument, it is accepted that "if any component, part, or accessory changes the intended use of a device, then under Section 201(h) it is a different device from the previous device." Communication at 6. By Applicant's own admission, the magnetic actuator included with the VNS Therapy System indicated for depression is identical to the magnetic actuator included with the VNS Therapy System indicated for epilepsy. *See* Communication at 31-35. In other words, the physical composition of the device for either indication is the same; the only difference lies in the setting on the magnetic actuator. This finding is supported, for example, by language in the Physician's Manual that indicates that the use of the magnetic actuator "is not recommended for patients with depression" and so the "Magnet Mode output current should remain at 0.0mA for patients with depression." *See* Request for Reconsideration (April 27, 2007) (quoting the Physician's Manual for the VNS Therapy System). In other words, the device used to treat Epilepsy is also used to treat depression, but when used for that latter purpose, physicians are instructed to reduce the Magnet Mode output current to 0.0mA.

Still further, the VNS Therapy System indicated for epilepsy has the same intended use as the VNS Therapy System indicated for depression, *i.e.*, delivering electrical signals to the left vagus nerve. For example, as stated at page 3 of FDA's March 24, 2009 letter, "[a]ll facets of the technology of the device, as well as site and method of implantation, are identical for the two indications and directly reflect ***the unchanged intended use of the device*** to deliver electrical

signals to the left vagus nerve using cervical access to the nerve." (Emphasis added.)

C. Conclusion

For the reasons stated above, Applicant's request for extension of the patent term of the '569 patent is **DENIED**, and Applicant's Request for Reconsideration, as supplemented by Applicant's Communication, is **DENIED**.

This is considered a final agency decision.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7728

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.

Brian E. Hanlon

Brian E. Hanlon
Director
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: VNS Therapy System
Docket No.: FDA-2006-E-0198

Attention: Beverly Friedman

SPE: S. Loke

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.: 11

DATE : 2/25/08

TO SPE OF : ART UNIT 2818

SUBJECT : Request for Certificate of Correction on Patent No.: 5140386

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within 7 days to:
Palm location **7580, Certificates of Correction Branch – South Tower – 9A22**
If response is for an IFW, **return to employee (named below) via PUBSCofC Team in MADRAS.**
With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction (COCIN)? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Thank You For Your Assistance

Lamonte M. Newsome
Certificates of Correction Branch
Tel. No. 703-305-8309

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

- ☒ **Approved** — **All** changes apply.
- ☐ **Approved in Part** — Specify below which changes **do not** apply.
- ☐ **Denied** — State the reasons for denial below.

Comments:

Steven Loke — **SPE**

2818 — **Art Unit**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays valid OMB control number.

PETITION TO ACCEPT UNINTENTIONALLY DELAYED PAYMENT OF MAINTENANCE FEE IN AN EXPIRED PATENT (37 CFR 1.378(c))

Patent Number	Issue Date (YYYY-MM-DD)	Application Number	Filing Date (YYYY-MM-DD)	Docket Number (if applicable)
5282098	1994-01-25	07698771	1991-05-13	ID 003408

CAUTION: Maintenance fee (and surcharge, if any) payment must correctly identify: (1) the patent number and (2) the application number of the actual U.S. application leading to issuance of that patent to ensure the fee(s) is/are associated with the correct patent. 37 CFR 1.366(c) and (d).

SMALL ENTITY
☐ Patentee claims, or has previously claimed, small entity status. See 37 CFR 1.27.

LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
☐ Patentee is no longer entitled to small entity status. See 37 CFR 1.27(g)

NOT Small Entity			Small Entity		
	Fee	Code		Fee	Code
○	3 ½ year	(1551)	○	3 ½ year	(2551)
○	7 ½ year	(1552)	○	7 ½ year	(2552)
◉	11 ½ year	(1553)	○	11 ½ year	(2553)

SURCHARGE
The surcharge required by 37 CFR 1.20(i)(2) (Fee Code 1558) must be paid as a condition of accepting unintentionally delayed payment of the maintenance fee.

MAINTENANCE FEE (37 CFR 1.20(e)-(g))
The appropriate maintenance fee must be submitted with this petition.

STATEMENT
THE UNDERSIGNED CERTIFIES THAT THE DELAY IN PAYMENT OF THE MAINTENANCE FEE TO THIS PATENT WAS UNINTENTIONAL

PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

37 CFR 1.378(d) states: "Any petition under this section must be signed by an attorney or agent registered to practice before the Patent and Trademark Office, or by the patentee, the assignee, or other party in interest."

I certify, in accordance with 37 CFR 1.4(d)(4) that I am

◉ An attorney or agent registered to practice before the Patent and Trademark Office

○ A sole patentee

○ A joint patentee; I certify that I am authorized to sign this submission on behalf of all the other patentees.

○ A joint patentee; all of whom are signing this e-petition

○ The assignee of record of the entire interest

Patent Practitioner			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature			
Signature	/DJCushing/	Date (YYYY-MM-DD)	2008-01-17
Name	David J. Cushing	Registration Number	28703

This collection of information is required by 37 CFR 1.378(c). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/ or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in reinstating the patent.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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P.O. Box 1450
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In re Patent No. 5282098
Issue Date: January 25,1994
Application No. 07698771
Filed: May 13,1991
Attorney Docket No. 177/515031MA

:
:DECISION GRANTING PETITION
:UNDER 37 CFR 1.378(c)
:

This is a decision on the electronic petition, filed January 17,2008 ,under 37 CFR 1.378(c) to accept the unintentionally delayed payment of the 11.5 year maintenance fee for the above-identified patent.

The petition is GRANTED.

The maintenance fee is accepted, and the above-identified patent reinstated as of January 17,2008 . This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in an Image File Wrapper. Nevertheless, petitioner should print and retain an independent copy

Telephone inquires related to this electronic decision should be directed to the Electronic Business Center at 1-866-217-9197.

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OFFICE OF PETITIONS

Thomas I. Rozsa
18757 Burbank Blvd, Ste. 220
Tarzana, CA 91356-3346

In re Patent No. 5,168,844	:	
Issue Date: December 8, 1992	:	
Application No. 07/702,407	:	DECISION ON PETITION
Filed: May 20, 1991	:	UNDER 37 CFR 1.378(b)
For: ADAPTER SYSTEM FOR USE WITH	:	
AN INTERNAL COMBUSTION ENGINE	:	
FLUSHING APPARATUS		

This is a decision on the petition under 37 CFR 1.378(c), filed January 3, 2009. This matter is also being treated under 37 CFR 1.378(b).

The patent issued December 8, 1992. The third maintenance fee could have been paid from December 8, 2003 through June 8, 2004 without a surcharge, or with a surcharge during the period from June 9, 2004 through December 8, 2004. Accordingly, the patent expired on December 8, 2004 for failure to timely submit the second maintenance fee.

DECISION UNDER 37 CFR 1.378(c)

Any petition to accept an unintentionally delayed payment of a maintenance fee filed under paragraph (a) of this section must be filed within twenty-four months after the six-month grace period provided in § 1.362(e) and must include: (1) The required maintenance fee set forth in § 1.20 (e) through (g); (2) The surcharge set forth in § 1.20(i)(2); and (3) A statement that the delay in payment of the maintenance fee was unintentional.

The instant petition was not filed within twenty-four months after the six-month grace period provided in 37 CFR 1.362(e)(3).

Accordingly, the petition under 37 CFR 1.378(c) is hereby DISMISSED.

Petitioner is entitled to a partial refund of the surcharge of $1,640.00 in the amount of $940.00. The remaining $700.00 is required for consideration of the surcharge required under 37 CFR 1.378(b)(2).

DECISION UNDER 37 CFR 1.378(b)

The petition under 37 CFR 1.378(b) for reinstatement of expired patent is hereby DISMISSED.

If reconsideration of this decision is desired, a petition for reconsideration under 37 CFR 1.378(e) must be filed within TWO (2) MONTHS from the mail date of this decision. No

extension of this 2-month time limit can be granted under 37 CFR 1.136(a) or (b). Any such petition for reconsideration must be accompanied by the petition fee of $400 as set forth in 37 CFR 1.17(f). The petition for reconsideration should include an exhaustive attempt to provide the lacking item(s) noted below, since, after a decision on the petition for reconsideration, no further reconsideration or review of the matter will be undertaken by the Director.

A petition to accept the delayed payment of a maintenance fee under 35 U.S.C. § 41(c) and 37 CFR 1.378(b) must be accompanied by (1) an adequate showing that the delay was unavoidable, since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent, (2) payment of the appropriate maintenance fee, unless previously submitted, and (3) payment of the surcharge set forth in 37 CFR 1.20(i)(1).

This petition lacks item requirement (1) set forth above.

The Director may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Director to have been "unavoidable". 35 U.S.C. § 41(c)(1).

Petitioner indicates that the third maintenance fee was mailed to the USPTO on July 31, 2003 and has provided a copy of the documents submitted on that date. Patentee further states that "[a]pparently, the Patent Office believed that the maintenance fee was paid early and therefore, returned the paperwork; however, they did not send me a notice to pay the maintenance fee."

Petitioner further states that "the USPTO mailed a notice of payment to Computer Packages, Inc. even though the Patent Office clearly had a record that the assignment of the patent was made from Krupp Bilstein of America, Inc. to MCY III Corp. and had a record that I was not the attorney of record and the notice should have been mailed to me."

Petitioner indicates that he became aware that the patent had expired on January 2, 2009.

Patentee appears to attribute the failure to timely pay the second maintenance fee to failure to receive a Maintenance Fee Due Reminder letter from the USPTO.

The showing of record is inadequate to establish unavoidable delay within the meaning of 37 CFR 1.378(b)(3).

Acceptance of late payment of a maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 U.S.C. § 133 because 35 U.S.C. § 41(c)(1) uses the identical language, i.e. "unavoidable delay". Ray v. Lehman, 55 F.3d 606, 608-09, 34 USPQ2d 1786, 1787 (Fed. Cir. 1995)(quoting In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (Comm'r Pat. 1988)). Decisions on reviving abandoned applications have adopted the "reasonably prudent person" standard in determining if the delay in responding to an Office action was unavoidable. Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-515 (D.C.

Cir. 1912); and Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141. In addition, decisions on revival are made on a "case-by-case basis, taking all the facts and circumstances into account." Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982). Finally, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay. Haines v. Quigg, 673 F. Supp. 314, 316-17, 5 USPQ2d 1130, 1131-32 (N.D. Ind. 1987).

In essence, patentee must show that he was aware of the need to pay the maintenance fee, and to that end was tracking it, or had engaged someone to track it before the expiration, but when the fee came due, was "unavoidably" prevented from making the maintenance fee payment from the time the payment was due until the filing of a grantable petition. Petitioner has failed to meet this burden.

Petitioner acknowledges that he attempted to pay the maintenance fee on July 31, 2003 and that the paperwork concerning this submission was returned to practitioner.

In accordance with 37 CFR 1.366(b), "Payment of a maintenance fee and any necessary surcharge or the authorization to charge a deposit account must be submitted within the periods set forth in § 1.362(d), (e), or (f). Any payment or authorization of maintenance fees and surcharges filed at any other time will not be accepted and will not serve as a payment of the maintenance fee except insofar as a delayed payment of the maintenance fee is accepted by the Director in an expired patent pursuant to a petition filed under § 1.378."

The time period for submitting the maintenance fee commenced December 8, 2003. As the maintenance fee was submitted too early for acceptance on or about July 31, 2003, the USPTO was precluded from accepting the fee, and, as acknowledged by petitioner, the paperwork concerning this submission was returned to practitioner and the fees were refunded.

Petitioner alleges that he first became aware that the maintenance fee was due on January 2, 2009 and contends that instead of mailing a maintenance fee due reminder letter to him, the USPTO instead mailed the reminder letter to Computer Packages, Inc.

Under the statutes and rules, the Office has no duty to notify patentee of the requirement to pay maintenance fees or to notify patentee when the maintenance fee is due. It is solely the responsibility of the patentee to ensure that the maintenance fee is paid timely to prevent expiration of the patent. The failure to receive the reminder notice will not shift the burden of monitoring the time for paying a maintenance fee from the patentee to the Office. The Office will attempt to assist patentees through the mailing of a Maintenance Fee Reminder in the grace period. However, the failure to receive a Maintenance Fee Reminder will not relieve the patentee of the obligation to timely pay the appropriate maintenance fee to prevent expiration of the patent, nor will it constitute unavoidable delay if the patentee seeks to reinstate the patent under 37 CFR 1.378(b). See, In re Patent No. 4,409,763, 7 USPQ2d 1798 (Comm'r Pat. 1988), aff 'd sub nom. Rydeen v. Quigg, 748 F. Supp. 900, 16 USPQ2d 1876 (D.D.C. 1990), aff 'd, 937 F.2d 623 (Fed. Cir. 1991) (table), cert. denied, 502 U.S. 1075 (1992). See, MPEP 2540.

Thus, the failure to receive a maintenance fee reminder from the USPTO is immaterial to the failure to timely submit the third maintenance fee.

Moreover, 37 CFR 1.378(b)(3) requires a showing of the steps in place to pay the maintenance fee, and the record currently lacks a sufficient showing that any steps were emplaced by practitioner or anyone else. In the absence of a showing that patentee or anyone else was engaged in tracking the maintenance fee due dates, and that party had in fact been tracking the due dates with a reliable tracking system, such as would be used by prudent and careful men in relation to their most important business, petitioner cannot reasonably show that the delay was unavoidable delay. In re Katrapat, 6 USPQ2d 1863, 1867-1868 (Comm'r Pat. 1988); California, supra.

The record does not establish that there were adequate steps in place to ensure timely payment of the fee. Thus, it cannot be found that the failure to timely submit the required maintenance fee, from the time that the maintenance fee was due until the filing of a grantable petition, was unavoidable.

The petition fails to establish that patentee was unavoidably delayed in making the payment. Accordingly, the Office is precluded from accepting the maintenance fee and surcharge. If reconsideration of this decision is not desired, petitioner may request a refund of this fee by writing to the Finance Office, Refund Section. A copy of this decision should accompany any request for refund.

Any renewed petition must establish that the entire period of delay from the time that the maintenance fee was due until the time of the filing of a grantable petition has been unavoidable. Petitioner is reminded that any renewed petition should entail an exhaustive effort to establish that the failure to timely pay the maintenance fee was unavoidable as after reconsideration pursuant to 37 CFR 1.378(e), no further reconsideration regarding unavoidable delay will be undertaken.

Petitioner must establish that he was aware of the need to pay the maintenance fee, and was tracking it on behalf of patentee before the expiration, but when the fee came due, was "unavoidably" prevented from making the maintenance fee payment due until the filing of a grantable petition. Petitioner must establish a nexus between the events complained of and the failure to timely remit the maintenance fee.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop PETITIONS
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Service Window
Mail Stop Petitions
Randolph Building
401 Dulany Street
Alexandria, VA 22314

By fax: (571) 273-8300
ATTN: Office of Petitions

The requested revocation of power of attorney/change of address has been entered into the record.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3205.

/ALESIA M. BROWN/

Alesia M. Brown
Petitions Attorney
Office of Petitions

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Paper No. 66

BIRCH, STEWART, KOLASCH & BIRCH
P.O. Box 747
Falls Church, VA 22040-0747

JUL 11 2002

In re Application of BAINES Application No. 07/702,615 Filed: May 17, 1991 For: ELECTRIC MOTOR	)))))	DECISION ON PETITION TO WITHDRAW HOLDING OF ABANDONMENT

This is a decision on the petition filed on May 9, 2002, and supplemented on June 17, 2002, to withdraw the holding of abandonment of the above-identified application. No fee is required for the petition.

The petition is **GRANTED** to the extent indicated below.

This application was held abandoned for failure to respond in a timely manner to the decision of the Board of Patent Appeals rendered on January 31, 2002. A Notice of Abandonment was mailed on April 10, 2002.

Petitioner states that a request for a continued prosecution application (CPA) was filed on March 28, 2002. To support this assertion, petitioner has submitted a copy of the CPA and a copy of a return postcard which acknowledges receipt of a request for a CPA by the Patent and Trademark Office on March 28, 2002. A review of the application file indicates that the original request for a CPA is not of record in the application file and cannot be located. However, M.P.E.P. § 503 states that "A post card receipt which itemizes and properly identifies the items which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO." Accordingly, it is concluded that a request for a CPA was timely received in the PTO but lost after receipt thereof.

Since a request for a CPA expressly abandons the prior application as of the filing date of the request, parent Application No. 07/702,615 was expressly abandoned in favor of a CPA on March 28, 2002. Accordingly, the mailing of a Notice of Abandonment for failure to respond to the final Office action was in error and is hereby vacated.

The application file is being forwarded to the technical support staff for Technology Center 2800 for processing of the request for a CPA.

for Hien H. Phan, Special Program Examiner
Technology Center 2800 - Semiconductors, Electrical
and Optical Systems and Components