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PATENT & TRADEMARK OFFICE

PATENT
Atty. Docket No.: ACY31682-04J

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,529,990

Issued: June 25, 1996

To: Joseph J. Hlavka, Phaik-Eng Sum, Yakov Gluzman, Ving J. Lee, Adma A. Ross

Assignee: Wyeth Holdings Corporation

For: METHOD FOR TREATING BACTERIAL INFECTION WITH NOVEL 7-SUBSTITUTED-9-SUBSTITUTED AMINO 6-DEMETHYL-6-DEOXYTETRACYCLINES

RECEIVED
AUG 1 6 2005
OFFICE OF PETITIONS

ATTN: MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR EXTENSION OF PATENT
TERM UNDER 35 U.S.C. § 156

Applicant, Wyeth Holdings Corporation, represents that it is the Assignee of the entire interest in and to United States Patent No. 5,529,990 granted to Joseph J. Hlavka, Phaik-Eng Sum, Yakov Gluzman, Ving J. Lee, and Adma A. Ross, on the 25th day of June 1996, for Method For Treating Bacterial Infection With Novel 7-Substituted-9-Substituted Amino 6-Demethyl-6-Deoxytetracyclines by virtue of an assignment from the inventors to American Cyanamid Company, recorded in the U.S. Patent and Trademark Office at Reel 6439, Frame 0109 on March 8, 1993. American Cyanamid Company has since changed its name to Wyeth Holdings Corporation. By the Power of Attorney enclosed herein (Attachment A), Applicant appoints the attorneys associated

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with Customer No. 25,291 as attorneys for Wyeth Holdings Corporation with regard to this application for extension of the term of U.S. Patent No. 5,529,990 and to transact all business in the U.S. Patent and Trademark Office in connection therewith.

Notice Regarding Multiple Applications

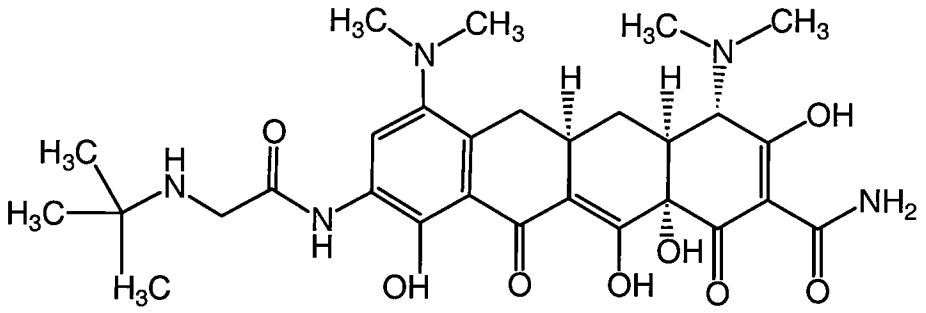
Applicant has filed another application for term extension (U.S. Patent No. 5,494,903) based on the regulatory review period for the product TYGACIL tigecycline. Applicant will make an election of only one patent in accordance with 37 C.F.R. § 1.785(b) upon receipt of a notice of final determination in these applications from the U.S. Patent and Trademark Office.

Information Required Under 37 C.F.R. § 1.740

Applicant hereby submits this application for extension of the patent term under 35 U.S.C. § 156 by providing the following information required by the rules promulgated by the U.S. Patent and Trademark Office (37 C.F.R. § 1.740). For the convenience of the U.S. Patent and Trademark Office, the information contained in this application will be presented in a format which follows the requirements of Section 1.740 of Title 37 of the Code of Federal Regulations.

(1) The approved product TYGACIL tigecycline is a glycylcycline antibacterial for intravenous infusion. The chemical name of tigecycline is (4*S*,4a*S*,5a*R*,12a*S*)-9-[2-(*tert*-butylamino)acetamido]-4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-2-naphthacenecarboxamide. The empirical formula is $C_{29}H_{39}N_5O_8$ and the molecular weight is 585.65.

The following represents the chemical structure of tigecycline:



(2) The approved product TYGACIL was subject to regulatory review under the Federal Food, Drug and Cosmetic Act Section 505.

(3) The approved product TYGACIL received permission for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act on June 15, 2005. A copy of the approval letter for NDA 21-821 is attached (Attachment B).

(4) The active ingredient in TYGACIL is tigecycline which, on information and belief, has not been approved for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act prior to the approval of NDA 21-821 by the Food and Drug Administration on June 15, 2005. A copy of the package insert describing the approved product is attached (Attachment C).

(5) This application for extension of patent term under 35 U.S.C. § 156 is being submitted within the permitted 60-day period pursuant to 37 C.F.R. § 1.720(f); said period will expire on August 14, 2005 (a Sunday).

(6) The complete identification of the patent for which a term extension is being sought is as follows:

Inventors: Joseph J. Hlavka, Phaik-Eng Sum, Yakov Gluzman, Ving J. Lee, and Adma A. Ross

Patent No.: 5,529,990

Filing Date: May 31, 1995

Issue Date: June 25, 1996

Expiration Date: June 25, 2013

(7) A true copy of the patent is attached (Attachment D).

(8) No reexamination certificate or certificate of correction has been issued on this patent. A copy of a record of maintenance fee payments under 35 U.S.C. § 41(b) is attached (Attachment E).

(9) U.S. Patent No. 5,529,990 claims a method for the treatment or control of bacterial infections in warm-blooded animals using the active ingredient (tigecycline) in TYGACIL. Claims 1 and 2 are directed to a method of using the approved product.

Claim 1 reads on a method of using the active ingredient in TYGACIL when considering the first formula listed in claim 1 (col. 141, lines 2-8) where X is NR^1R^2, R^1 and R^2 are each methyl, R is $R^4(CH_2)_nCO$- where n=1, and R^4 is a branched C_4 alkylamino.

(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

Investigational New Drug Application (IND 56518) for TYGACIL was received by the FDA on July 27, 1998, and became effective on August 26, 1998.

New Drug Application for TYGACIL (NDA 21-821) was submitted on December 15, 2004.

New Drug Application for TYGACIL was approved on June 15, 2005.

(11) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to TYGACIL and the dates applicable to these significant activities are set forth in a chronology of events in Attachment F. There are two logs of activities associated with the regulatory approval of TYGACIL.

(12)(i) Applicant is of the opinion that U.S. Patent No. 5,529,990 is eligible for extension of the patent term under 35 U.S.C. § 156 because it satisfies all requirements for such extension as follows:

(a) 35 U.S.C. § 156(a) - U.S. Patent No. 5,529,990 claims a method of using the active ingredient (tigecycline) in TYGACIL.

(b) 35 U.S.C. § 156(a)(1) - U.S. Patent No. 5,529,990 has not expired before submission of this application.

(c) 35 U.S.C. § 156(a)(2) - The term of U.S. Patent No. 5,529,990 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3) - The application for patent term extension is submitted by the owner of record of the patent in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. § 156(d) and the rules of the U.S. Patent and Trademark Office.

(e) 35 U.S.C. § 156(a)(4) - The product TYGACIL has been subjected to a regulatory review period before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A) - The commercial marketing or use of the product TYGACIL after the regulatory review period is the first permitted commercial marketing or use under the provision of the Federal Food, Drug and Cosmetic Act (i.e., Section 505) under which such regulatory review period occurred.

(g) 35 U.S.C. § 156(c)(4) - No other patent has been extended for the same regulatory review period for the product TYGACIL.

(12)(ii) Applicant respectfully submits that the length of the extension of patent term for U.S. Patent No. 5,529,990 is 3.66 years (1335 days) pursuant to 35 U.S.C. § 156(c). The length of the extension was determined pursuant to 37 C.F.R. § 1.775 as follows:

(a) The regulatory review period under 35 U.S.C. § 156(g)(1)(B) began on August 26, 1998 and ended June 15, 2005, which is a total of 2487 days, which is the sum of (1) and (2) below:

(1) The period of review under 35 U.S.C. § 156(g)(1)(B)(i), the "Testing Period," began on August 26, 1998 and ended on December 15, 2004, which is 2304 days; and

(2) The period of review under 35 U.S.C. § 156(g)(1)(B)(ii), the "Approval Period," began on December 15, 2004, and ended on June 15, 2005, which is a total of 183 days.

(b) The regulatory review period upon which the period of extension is calculated is the entire regulatory review period as determined in subparagraph 12(ii)(a) above (2487) less:

(1) The number of days in the regulatory review period which were on or before the date on which the patent issued (June 25, 1996) which is 0 days; and

(2) The number of days during which applicant did not act with due diligence, which is zero (0) days; and

(3) One-half the number of days determined in subparagraph (12)(ii)(a)(1) above after the patent issued (one-half of 2304) which is 1152 days;

(c) The number of days as determined in subparagraph (12)(ii)(b) (1335 days) when added to the original term of the patent (June 25, 2013) would result in the date of February 19, 2017.

(d) Fourteen (14) years when added to the date of the NDA approval (June 15, 2005) would result in the date of June 15, 2019;

(e) The earlier date as determined in subparagraphs (12)(ii)(c) and (12)(ii)(d) is February 19, 2017;

(f) Since U.S. Patent No. 5,529,990 issued after September 24, 1984, the period of extension may not exceed five years from the original expiration date of June 25, 2013. Five years when added to the original expiration date of the patent would result in the date of June 25, 2018.

(g) The earlier date as determined by subparagraphs (12)(ii)(e) and (12)(ii)(f) is February 19, 2017.

(13) Applicant acknowledges a duty to disclose to the Director of the U.S. Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee for receiving and acting upon this application is the amount of $1,120.00. The Director is authorized to charge this fee and any additional fees required by this application to Deposit Account No. 01-1425.

(15) All correspondence and inquiries may be directed to the undersigned, at the correspondence address associated with Customer No. 25,291:

John W. Hogan
Wyeth
Five Giralda Farms
Madison, NJ 07940

(16) Enclosed is a certification that the application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and two (2) copies thereof (Attachment G).

Respectfully submitted,

By: John W. Hogan
John W. Hogan
Reg. No. 32,703

Date: August 10, 2005

Attachments:
Power of Attorney (Attachment A)
Approval Letter (Attachment B)
Package Insert for TYGACIL (Attachment C)
U.S. Patent No. 5,529,990 (Attachment D)
Maintenance Fees Paid (Attachment E)
Chronology of Regulatory Review Period (Attachment F)
Certification of Copies of Application Papers (Attachment G)

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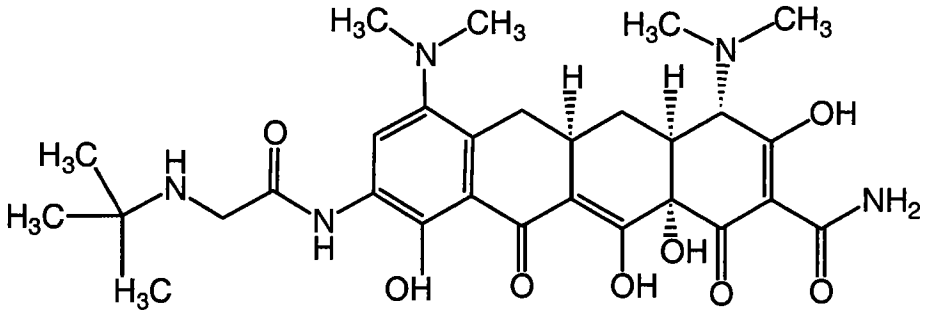

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(c) 35 U.S.C. § 156(a)(2) - The term of U.S. Patent No. 5,529,990 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3) - The application for patent term extension is submitted by the owner of record of the patent in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. § 156(d) and the rules of the U.S. Patent and Trademark Office.

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John W. Hogan
Wyeth
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(16) Enclosed is a certification that the application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and two (2) copies thereof (Attachment G).

Respectfully submitted,

By: John W. Hogan Jr.
John W. Hogan
Reg. No. 32,703

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