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CASE 4-16180/-CIP



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
<u>EL 813 00494 US</u> Express Mail Label Number	<u>October 17, 2001</u> Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE U.S. PATENT NO. 4,939,130
 ISSUED: JULY 3, 1990
 INVENTORS: KNUT A. JAEGGI AND LEO WIDLER
 FOR: SUBSTITUTED ALKANEDIPHOSPHONIC ACIDS AND
 PHARMACEUTICAL USE

Box Patent Ext.
 Assistant Commissioner for Patents
 Washington, D.C. 20231

TRANSMITTAL LETTER FOR PATENT TERM EXTENSION APPLICATION

Sir:

Enclosed in triplicate is an application for the extension of U.S. Patent No. 4,939,130 under 35 U.S.C. §156.

The Commissioner is hereby authorized to charge the Application Fee of \$1,120.00 prescribed by 37 C.F.R. §1.20(j)(1), as well as any additional fees which may be necessitated in connection with the filing of this Application for Patent Term Extension, to Applicant's Deposit Account No. 19-0134 in the name of Novartis Corporation. Two additional copies of this transmittal letter are being submitted for charging purposes.

Respectfully submitted,

Carol A. Loeschorn
 Attorney for Applicant
 Reg. No. 35,590

Novartis Corporation
 Patent and Trademark Dept.
 564 Morris Avenue
 Summit, NJ 07901-1027
 (908) 522-6932

Date: October 17, 2001

Encl.: Patent Term Extension Application including Appendices A-F in triplicate
 Two additional copies of this transmittal letter
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APP 1

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Assistant Commissioner for Patents
Washington, D.C. 20231

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

Sir:

Pursuant to 35 U.S.C. §156 and 37 C.F.R. §1.710 *et seq.*, Novartis Corporation ("Applicant"), a Corporation of the State of New York, hereby requests an extension of the patent term due to regulatory review of U.S. Patent No. 4,939,130, which was granted on July 3, 1990.

Applicant asserts that it is the owner of the entire right, title and interest in U.S. Patent No. 4,939,130 by virtue of an assignment from the inventors, Knut A. Jaeggi and Leo Widler, to Ciba-Geigy Corporation, which later changed its name to Novartis Corporation. The assignment from the inventors is recorded in the U.S. Patent and Trademark Office at Reel 5228, Frame 0929 and the change of name from Ciba-Geigy Corporation to Novartis Corporation was recorded in the U.S. Patent and Trademark Office at Reel 011089, Frame 0648. Copies of each of these documents evidencing that title to U.S. Patent No. 4,939,130 is vested in Novartis Corporation are attached hereto as Appendix A.

An originally executed Power of Attorney evidencing that the undersigned is an attorney authorized to act on behalf of Novartis Corporation is attached hereto as Appendix B.

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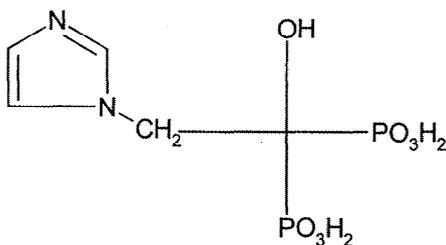
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In accordance with 35 U.S.C. §156 and 37 C.F.R. §1.740, Applicant provides the following information in support of its request for a patent term extension. The following sections are numbered analogously to 37 C.F.R. §1.740.

(1) Identification of the Approved Product

The approved product is Zometa[®], which contains the active ingredient zoledronic acid, having the chemical name 1-hydroxy-2-(imidazol-1-yl)ethane-1,1-diphosphonic acid and having the chemical structure



2. Identification of the Federal Statute under which Regulatory Review Occurred

The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, Section 505(b) (21 U.S.C. §355(b)).

3. The Date of Permission for Commercial Marketing

The approved product received permission for commercial marketing under Section 505(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(c)) on August 20, 2001. A copy of the FDA approval letter is attached hereto as Appendix C.

4. Active Ingredient Statement

The sole active ingredient in Zometa[®] is zoledronic acid, which has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum Toxin Act prior to the approval of NDA 21-223 by the United States Food and Drug Administration on August 20, 2001.

5. Statement of Timely Filing

The last day on which this application could be submitted is October 19, 2001, which is 60 days after the approval of NDA 21-223 on August 20, 2001. This application is timely filed on or prior to October 19, 2001.

6. Identification of Patent for which Extension is Sought

The patent, the term of which the instant application seeks to extend, is U.S. Patent No. 4,939,130, issued July 3, 1990, having as inventors, Knut A. Jaeggi and Leo Widler and entitled SUBSTITUTED ALKANEDIPHOSPHONIC ACIDS AND PHARMACEUTICAL USE, the term of which would otherwise expire on November 13, 2007.

7. Patent Copy

A complete copy of U.S. Patent No. 4,939,130, identified in paragraph 6 above, is attached as Appendix D.

8. Post-Issuance Activity Statement

No Certificate of Correction, Terminal Disclaimer, Reexamination Certificate or Reissue has been issued or requested with respect to U.S. Patent No. 4,939,130. The first maintenance fee for U.S. Patent No. 4,939,130 in the amount of \$930.00 was paid on December 28, 1993 and debited to Applicant's Deposit Account in January 1994. The second maintenance fee in the amount of \$2100.00 was paid on December 30, 1997 and debited to Applicant's Deposit Account on January 16, 1998. Copies of the Maintenance fee statements indicating the maintenance fees were paid are attached as Appendix E.

9. Statement Showing How the Claims of the Patent for which Extension is Sought Cover the Approved Product

Claims 1, 2, 4 and 5 claim the approved product. More specifically, claims 1 and 2 claim compounds or a compound which includes the active ingredient, zoledronic acid, in the approved product. The approved product, zoledronic acid, is the compound of claim 1 wherein R_1 is 1-imidazolyl, and R_2 is hydroxy and is the compound of claim 2. Claim 4 claims a pharmaceutical composition containing a compound of claim 1. Claim 5 claims a method of treating diseases associated with impaired calcium metabolism comprising administering a compound of claim 1.

10. Statement of the Relevant Dates to Determine the Regulatory Review Period

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:

(i) The patent for which extension of the term thereof is sought claims a human drug product, a pharmaceutical composition containing such human drug product and a method of treating diseases associated with impaired calcium metabolism using such human drug product. The human drug product is zoledronic acid.

(A) An Investigational New Drug Application for zoledronic acid was submitted on August 12, 1993, received by the Department of Health and Human Services on August 19, 1993 and was assigned IND No. 43,240 and became effective on September 18, 1993. The original IND was filed for Paget's Disease. The first submission for Hypercalcemia of Malignancy, the approved indication, was made on December 18, 1997.

(B) A New Drug Application for zoledronic acid was submitted to the Department of Health and Human Services on December 21, 1999 and granted NDA No. 21-223.

(C) NDA No. 21-223 was approved on August 20, 2001.

11. Brief Description of Activities Undertaken During the Regulatory Review Period

As a brief description of the activities undertaken during the applicable regulatory review period, attached hereto as Appendix F is a chronology of the major communications between the U.S. Food and Drug Administration and the Applicant in IND No. 43,240 and NDA No. 21-223.

12. Opinion of Eligibility for Extension

Applicant is of the opinion that U.S. Patent No. 4,939,130 is eligible for extension under 35 U.S.C. §156 and 37 C.F.R. §1.720 because it satisfies all of the requirements for such extension as follows:

(a) 35 U.S.C. §156(a) and 37 C.F.R. §1.720(a)

U.S. Patent No. 4,939,130 claims a human drug product, zoledronic acid, pharmaceutical compositions thereof and methods of use thereof.

(b) 35 U.S.C. §156(a)(1) and 37 C.F.R. §1.720(g)

The term of U.S. Patent No. 4,939,130 (expiring November 13, 2007) has not expired before the submission of this application.

(c) 35 U.S.C. §156(a)(2) and 37 C.F.R. §1.720(b)

The term of U.S. Patent No. 4,939,130 has never been extended.

(d) 35 U.S.C. §156(a)(3) and 37 C.F.R. §1.720(c)

The application for extension of the term of U.S. Patent No. 4,939,130 is submitted by the authorized attorney of the owner of record thereof in accordance with the requirements of 35 U.S.C. §156(d) and 37 C.F.R. §1.740.

(e) 35 U.S.C. §156(a)(4) and 37 C.F.R. §1.720(d)

The approved product, Zometa[®], has been subjected to a regulatory review period before its commercial marketing or use.

(f) 37 C.F.R. §1.720(h)

No other patent has been extended for the same regulatory review period for the approved product, Zometa[®].

(g) 35 U.S.C. §156(a)(5)(A) and 37 C.F.R. §1.720(e)(1)

The permission for the commercial marketing or use of the approved product, Zometa[®], is the first received permission for commercial marketing or use of Zometa[®].

(h) Length of extension claimed under 37 C.F.R. §1.740(a)(12)

The length of extension of the patent term of U.S. Patent No. 4,939,130 requested by Applicant is 1,752 days, which length was calculated in accordance with 37 C.F.R. §1.775 as follows:

(a) The regulatory review period under 35 U.S.C. §156(g)(1)(B) began on September 18, 1993 (the effective date of the IND) and ended on August 20, 2001, amounting to a total of 2,895 days which is the sum of (i) and (ii) below:

(i) The period of review under 35 U.S.C. §156(g)(1)(B)(i), the "Testing Period," began on September 18, 1993 and ended on December 21, 1999 which is 2,286 days;

(ii) The period for review under 35 U.S.C. §156(g)(1)(B)(ii), the "Application Period," began on December 21, 1999 and ended on August 20, 2001, which is 609 days;

(b) The regulatory review period upon which the period for extension is calculated is the entire regulatory review period as determined in subparagraph (13)(a) above (2,895 days) less:

(i) The number of days in the regulatory review period which were on or before the date on which the patent issued (July 3, 1990), i.e., zero days, and

(ii) The number of days during which the Applicant did not act with due diligence, i.e., zero days, and

(iii) One-half of the number of days remaining in the period in subparagraph (13)(a)(i) after subtracting the number of days in subparagraphs (13)(b)(i) and (13)(b)(ii), which is one-half of $(2,286 - [0 + 0])$ or 1,143 days;

which results in a period of $2,895 - [0 + 0 + 1,143] = 1,752$ days.

(c) The number of days as determined in subparagraph (13)(b), when added to the original term (November 13, 2007), would result in the date of August 30, 2012.

(d) Fourteen (14) years when added to the date of the NDA Approval Letter (August 20, 2001) would result in the date of August 20, 2015.

(e) The earlier date as determined by subparagraphs (13)(c) and (13)(d) is August 30, 2012.

(f) Since the original patent was issued after September 24, 1984, the extension otherwise obtainable is limited to not more than five (5) years. Five years, when added to the original expiration of U.S. Patent No. 4,939,130 (November 13, 2007), results in the date November 13, 2012.

(g) The earlier date as determined in subparagraphs (13)(e) and (13)(f) is August 30, 2012

13. Duty of Disclosure Acknowledgement Under 37 C.F.R. §1.740(a)(13)

Applicant acknowledges a duty to disclose to the Commissioner of Patent and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

14. Fee Charge

The prescribed fee for receiving and acting upon this application is to be charged to Applicant's Deposit Account No. 19-0134 as authorized in the attached transmittal letter, submitted in triplicate.

15. Correspondence Address Required by 37 C.F.R. §1.740(a)(15)

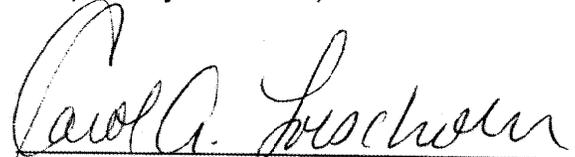
All correspondence relating to this application for patent term extension should be addressed to:

Thomas Hoxie
Novartis Pharmaceuticals Corp.
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027

16. Certification Under 37 C.F.R. §1.740(b)

The undersigned hereby certifies that the instant application, including its attachments and supporting papers, is being submitted as one original and two copies thereof in accordance with 37 C.F.R. §1.740(b).

Respectfully submitted,



Carol A. Loeschorn
Attorney for Applicant
Reg. No. 35,590

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