

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

Sir:

Applicant, AstraZeneca AB, a corporation organized and existing under the laws of Sweden, the address of which is S-151 85 Södertälje, Sweden, represents that it is the owner and assignee of the entire interest in and to Letters Patent of the United States No. 5,817,338, granted to Pontus John Arvid Bergstrand and Kurt Ingmar Lövgren on the 6th day of October, 1998, for MULTIPLE UNIT TABLETED DOSAGE FORM OF OMEPRAZOLE by virtue of assignment from Pontus John Arvid Bergstrand and Kurt Ingmar Lövgren to Astra AB, recorded June 20, 1995, at Reel 8106, Frame 0134, and from Astra AB to AstraZeneca AB, recorded November 3, 2000, at Reel 011325, Frame 0031.

The holder of marketing approval for Prilosec OTC™ (omeprazole magnesium delayed-release tablets, 20 mg), the Approved Product that is relevant to this application, is AstraZeneca LP. AstraZeneca LP and AstraZeneca AB are both owned by AstraZeneca PLC, headquartered in London, England. On January 30, 1998, The Procter & Gamble Company assumed responsibilities for managing the IND and NDA applications as the then agent of Astra Merck Inc., the original IND applicant.

Applicant, through its duly authorized attorney, hereby submits this application for extension of patent term under 35 U.S.C. § 156 by providing the following information required by the statute and by the Rules of Practice in Patent Cases, 37 C.F.R. § 1.740. For the convenience of the United States Patent and Trademark Office, the information in this application is presented in the order set forth in Section 1.740 of the Rules.

1. Identity of the Approved Product (37 C.F.R. § 1.740(a)(1))

Pursuant to 37 C.F.R. § 1.740, the chemical and generic name, physical structure or characteristics of the Approved Product, Prilosec OTC™ (omeprazole magnesium delayed-release tablets, 20 mg) (hereinafter “Prilosec OTC”), are as follows:

Prilosec OTC contains, as the active ingredient, omeprazole magnesium, which is the magnesium salt of omeprazole. The chemical name of omeprazole magnesium is 5-methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole magnesium tetrahydrate.

2. Identity of Federal Statute Under Which Regulatory Review Occurred (37 C.F.R. § 1.740(a)(2))

The Approved Product is a drug product and the submission was approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(b)).

3. Identity of Date on Which Approved Product Received Permission for Commercial Marketing or Use (37 C.F.R. § 1.740(a)(3))

The Approved Product received permission for commercial marketing or use in a letter dated June 20, 2003, from Jonca Bull, M.D., Director, Office of Drug Evaluation V, and Florence Houn, M.D., M.P.H., Director, Office of Drug Evaluation III, both of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration.

4. Identity of Active Ingredient (37 C.F.R. § 1.740(a)(4))

Applicant avers that the active ingredient of the Approved Product is omeprazole magnesium. Omeprazole magnesium has not been previously approved for commercial marketing or use under the FDCA. Please note that omeprazole magnesium is a different active ingredient from omeprazole, which is marketed as Prilosec® (NDA 019810), for which a patent term extension has previously been granted. Omeprazole magnesium is also a different active

ingredient from esomeprazole magnesium, which is marketed as Nexium® (NDA 21-153, NDA 21-154), for which a patent term extension application is pending.

5. Timely Filing of This Application (37 C.F.R. § 1.740(a)(5))

This application is filed, pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), within the permitted sixty-day (60-day) period that began on June 20, 2003, the date the product received permission under 21 U.S.C. § 355(b), and that will expire on August 19, 2003.

6. Identity of the Patent for Which an Extension Is Sought (37 C.F.R. § 1.740(a)(6))

Inventors:	Pontus John Arvid Bergstrand, Kurt Ingmar Lövgren
Patent No.:	5,817,338
Issued:	October 6, 1998
Expiration:	October 6, 2015

7. Copy of Patent Attached (37 C.F.R. § 1.740(a)(7))

A copy of the patent for which an extension is being sought, including the entire specification (with claims), is attached as Exhibit A.

8. Disclaimers, Certificates of Correction, Receipts of Maintenance Fee Payment or Reexamination Certificate (37 C.F.R. § 1.740(a)(8))

A copy of a certificate of correction dated May 11, 1999, is attached as Exhibit B. A statement showing maintenance fee payment for pay year 04 is attached as Exhibit C. Maintenance fee payments for pay years 08 and 12 are not yet due. No disclaimer or reexamination certificate has been issued with respect to the patent.

9. Statement of Patent Claim Coverage of Approved Product (37 C.F.R. § 1.740(a)(9))

U.S. Patent No. 5,817,338 claims the Approved Product and methods of using and manufacturing the Approved Product, as shown in Exhibit D. Exhibit D presents a chart showing each applicable patent claim (claims 1-7, 9-15, 17-25) and the manner in which each

such applicable patent claim reads on the Approved Product, method of using or method of manufacturing the Approved Product.

**10. Statement of Relevant Dates and Information Pursuant to 35 U.S.C. § 156(g)
(37 C.F.R. § 1.740(a)(10))**

NDA 21-229 was submitted and approved for Prilosec OTC. The relevant dates are as

follows:

- a. Effective Date of the Investigational New Drug (IND) Application:
November 14, 1997
- b. IND Number: 54,307
- c. Date on which the NDA was initially submitted:
January 27, 2000
- d. NDA Number: 21-229
- e. Date on which the NDA was approved:
June 20, 2003

11. Brief Description of Significant Activities Undertaken by Marketing Applicant During Applicable Regulatory Review Period and Respective Dates (37 C.F.R. § 1.740(a)(11))

Attached as Exhibit E is a brief description of the significant activities undertaken by the marketing applicant with respect to Prilosec OTC during the regulatory review period for NDA 21-229, November 14, 1997, to June 20, 2003.

12. Statement of Eligibility for Extension (37 C.F.R. § 1.740(a)(12))

Applicant believes that U.S. Patent No. 5,817,338 is eligible for extension under 35 U.S.C. § 156 because it satisfies all of the requirements for such extension as follows:

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

U.S. Patent No. 5,817,338 claims a product, a method of using and a method of manufacturing that product.

b. 35 U.S.C. § 156(a)(1)

The term of U.S. Patent No. 5,817,338 will not have expired before submission of this application.

c. 35 U.S.C. § 156(a)(2)

The term of U.S. Patent No. 5,817,338 has never been extended under 35 U.S.C. § 156(e)(1).

d. 35 U.S.C. § 156(a)(3)

This application for extension is submitted by an attorney for the owner of record in accordance with the requirements of 35 U.S.C. § 156(d)(1)-(4) and rules of the U.S. Patent and Trademark Office.

e. 35 U.S.C. § 156(a)(4)

The Approved Product, Prilosec OTC, has been subject 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 Approved Product, Prilosec OTC, is the first permitted commercial marketing or use of the product under the FDCA (21 U.S.C. § 355(b)), 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 Approved Product, Prilosec OTC.

13. Statement as to Length of Extension Claimed and the Determination of Such Extension (37 C.F.R. § 1.740(a)(12))

In the opinion of the Applicant, U.S. Patent No. 5,817,338 is entitled to an extension of 623 days, pursuant to 35 U.S.C. § 156 and the implementing regulations, based upon the regulatory review period for Prilosec OTC.

The claimed length of this extension of 623 days was determined pursuant to 37 C.F.R. § 1.775 as follows:

(1) The regulatory review period under 35 U.S.C. § 156(g)(1)(B), which began on November 14, 1997, and ended on June 20, 2003, and lasted 2044 days, the sum of computations in (a) and (b) below:

(a) The period of review under 35 U.S.C. § 156(g)(1)(B)(i) began on November 14, 1997, and ended on January 27, 2000, a period of 804 days; and

(b) The period of review under 35 U.S.C. § 156(g)(1)(B)(ii) began on January 27, 2000, and ended on June 20, 2003, a period of 1240 days;

(2) The regulatory review period upon which the period of extension is calculated is the entire regulatory review period as determined in subparagraph 13(1) above (2044 days) less

(a) The number of days in the regulatory review period which were on or before the date on which the patent issued, October 6, 1998, which is 326 days, and

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

(c) One-half the number of days determined in subparagraph (13)(1)(a) (804) after subtracting the number of days determined in subparagraph (13)(2)(a) (326) and (b) zero (0), or 239 days, which leaves 1479 days;

(3) The number of days as determined in subparagraph 13(2) in its entirety (1479), when added to the original term of the patent, would result in the date October 24, 2019;

(4) Fourteen (14) years when added to the date of approval (June 20, 2003) would result in the date June 20, 2017;

(5) The earlier date as determined in subparagraphs (13)(3) and (13)(4) is June 20, 2017;

(6) Since the original patent issued after September 24, 1984, five (5) years are added to the original expiration date of the patent, resulting in a date of October 6, 2020; and

(7) The earlier of the dates obtained in paragraph 13(5) and in paragraph 13(6) is June 20, 2017.

Therefore, the length of extension of patent term claimed by applicant is 623 days, which is the period of time needed to extend the original expiration of term until June 20, 2017.

**14. Statement of Acknowledgment of Duty to Disclose Material Information
(37 C.F.R. § 1.740(a)(13))**

Applicant acknowledges a duty to disclose to the Director of the United States 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 in this application.

15. Prescribed Fee (37 C.F.R. § 1.740(a)(14))

The Director is hereby authorized to charge the filing fee of \$1,120.00, as prescribed in 37 C.F.R. § 1.20(j), and any additional necessary fees which may be required by this paper to Deposit Account 23-1703.

16. Contact Information (37 C.F.R. § 1.740(a)(15))

All inquiries and correspondence relating to this application for patent term extension should be directed to:

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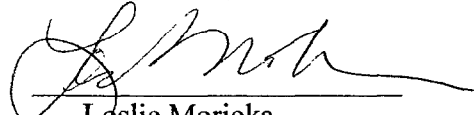
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17. Copies Enclosed (37 C.F.R. § 1.740(b))

Four duplicate copies of the present application papers are enclosed. The undersigned patent attorney certifies under penalty of perjury that the attached duplicates of the application papers are true and correct copies of such papers.

Respectfully submitted,

Dated: August 19, 2003



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