

1001 01 11 11:17

MYLAN LABORATORIES INC.

October 29, 2004

VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket Number 2003P-0366

Dear Sir/Madam:

The undersigned, Mylan Laboratories Inc. ("Mylan"), submits this comment in support of Mattingly, Stanger & Malur, P.C. citizen petition No. 2003P-0075 (the "Mattingly Petition"), pursuant to 21 C.F.R. § 10.30(d). Mylan supports Mattingly's request that FDA amend its approval of the new drug application for Prilosec OTC® to require that Procter & Gamble's OTC omeprazole magnesium product be sold under a trade name other than "Prilosec." Mylan has previously submitted comments to both FDA and DDMAC that demonstrate that P&G's OTC omeprazole magnesium product and Prilosec® (omeprazole sodium) are not the same drug product, are not bioequivalent, and are approved for different indications and, thus, that using the same "Prilosec" name for both products inevitably confuses consumers and creates the potential for misuse of the OTC product. We are especially concerned that P&G has promoted the OTC product under virtually the same name as the prescription product, and that consumers will inappropriately use the OTC product to treat more serious conditions for which prescription omeprazole has been prescribed by their physicians.

It has recently come to our attention that the maker of both prescription Prilosec® and Prilosec OTC®, AstraZeneca, in an August 2003 submission to the U.S. Patent and Trademark Office, requested a patent term extension on various patents asserting that Prilosec OTC® and prescription Prilosec® contain "different active ingredients." A copy of AstraZeneca's public submission to the PTO is attached as **Exhibit A**.

This remarkable admission by the maker of both products that the drugs contain "different active ingredients" compels a name change for the OTC omeprazole magnesium product. A name is improper under FDA's regulations, and FDA cannot allow a name to be used, if "similarity in spelling or pronunciation may be confused with the proprietary name or established name of a different drug or ingredient." 21 C.F.R. §§ 201.10(c)(5), 202.1(a)(5); *see also Pharmacia Corp, et. al. v. Alcon Labs, Inc.*, 201

2003P-0366

C4

F.Supp.2d 335, 345 (D.N.J. 2002). Here, the Prilosec OTC (omeprazole magnesium) and prescription Prilosec (omeprazole sodium) unquestionably are different drugs with different active ingredients, yet the names being used are not just confusingly similar, they are the same: "Prilosec." It is beyond any reasonable dispute that consumers would believe drugs whose names share the same core word (in this case "Prilosec") contain the same active ingredient and thus would perceive both such drugs to be the same. It is also beyond any reasonable dispute that the drugs are not the same, and the maker of the products, AstraZeneca, has gone on record with its PTO submission stating that the products contain different active ingredients. FDA's drug naming regulations cannot possibly be interpreted as allowing different drug substances that are approved for different indications, and which admittedly contain different active ingredients, and are not even bioequivalent, to be sold under the *same* trade name. P&G's continued sale of OTC omeprazole magnesium under the trade name "Prilosec" violates FDA regulations, and FDA has violated its own regulations by approving the OTC product with this name and by permitting it to be marketed under that name.

The Mattingly Petition has been pending for more than one year. Our comments in support of the Mattingly Petition and P&G's comment in opposition to it have been before FDA for many months. During that time, FDA's inaction on the Mattingly Petition has unfortunately allowed consumers to continue to be misled by P&G's use of the "Prilosec" name, with a concomitant and ever growing danger of confusion and misuse of the OTC omeprazole magnesium product. FDA should immediately require P&G's OTC omeprazole magnesium product to be sold under a trade name other than "Prilosec OTC." We are prepared to seek the assistance of the courts to compel FDA action on this matter, and we will consider the Mattingly Petition to have been denied if FDA does not take the requested action by November 15, 2004.

Sincerely,

A handwritten signature in black ink, appearing to read "Stuart Williams", with a long horizontal flourish extending to the right.

Stuart A. Williams,
Chief Legal Officer

cc: w/encl. Janet Woodcock, MD, Center Director
Charles Ganley, MD, Division of OTC Drug Products
Daniel E. Troy, Chief Counsel

**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:

Leslie Morioka
Patent Department
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787
Tel.: (212) 819-8200
Fax: (212) 354-8113

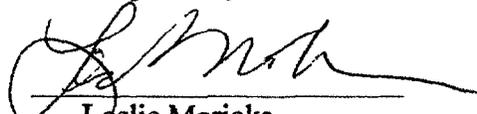
Anna Brodowsky, Esq.
AstraZeneca AB
R&D Headquarters
Global Intellectual Property
S-151 85 Södertälje
Sweden
Tel: 011-46-8-553-260-00
Fax: 011-46-8-553-288-20

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



Leslie Morioka
Reg. No. 40,304

Attorney for Applicant

WHITE & CASE
1155 Avenue of the Americas
New York, New York 10036
Tel.: (212) 819-8200
Fax: (212) 354-8113