IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	**US 5,817,338**
Issued:	**October 6, 1998**
To:	**Pontus J.A. Bergstrand** **Kurt I. Lövgren**
For:	**Multiple Unit Tableted Dosage Form of Omeprazole**

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that this paper is being transmitted via the Electronic Filing System to the U.S. Patent and Trademark Office on the date indicated below.

/John M. Genova/	32,224
Signature	Reg. No.
John M. Genova	December 16, 2008
Signer's Name	Date

MAIL STOP HATCH-WAXMAN PTE
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

PTE APPLICANT'S REPLY TO FDA

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December 15, 2008

Jane A. Axelrad
Director of the Office of Regulatory Policy
Center for Drug Evaluation and Research
Department of Health & Human Services
Food and Drug Administration
Rockville, MD 20857

Re: Patent Term Extension Application for US 5,817,338
Prilosec OTC
Your Docket No. FDA 2004E-0463
Our File: 1103326-0945

Dear Ms. Axelrad:

We are in receipt of a copy of the FDA's letter of October 21, 2008, (attached hereto as Exhibit A), to The Honorable Jon Dudas, Director of the United States Patent and Trademark Office ("PTO"), in connection with the referenced application for patent term extension ("PTE"). This letter is a retraction of FDA's opinion of four years' standing, as set forth in the FDA's letter October 19, 2004, (Exhibit B), that the subject patent is eligible for PTE and that the PTE application was timely filed.

This 2008 FDA letter was evidently in response to a request from the PTO dated April 1, 2008, which did not mention the correspondence in 2004 between the two agencies in which both agencies agreed on the timeliness of the filing. The 2008 FDA letter was also silent as to the earlier correspondence.

I write to inform you that in view of the abrupt and arbitrary change in the PTO position regarding timeliness, a Petition to the Director under 37 C.F.R. §1.181, and supporting Declaration, were filed with the PTO on May 30, 2008, in the name of AstraZeneca AB, the PTE applicant. The Petition is pending and available in the image file wrapper of the Patent Application Information Retrieval ("PAIR") system of the PTO website (uspto.gov).

In brief, the Petition requests that the Director invoke his supervisory authority to prevent the PTO from retroactively applying a new method of determining timeliness to an already filed PTE application. In filing its PTE application when it did, Applicant relied on its prior experience in

filing for PTE, from a successful filing in 1991 for which PTE was granted to its filing in 2004 of the instant PTE application.

Furthermore, the Petition identifies twelve (12) third-party patents that were granted PTE between 1986 and October 2007 on applications filed within 60 days of FDA approval, ***"excluding"*** the day of FDA approval: US 3,721,687; US 3,732,340; US 4,407,288; US 4,513,006; US 4,702,253; US 4,830,010; US 4,836,217; US 4,941,093; US 5,441,745; US 5,532,221; US 5,639,639; and US 5,827,937.

In addition, there is legal precedent for determining the filing period as AstraZeneca AB did in filing its PTE application, *In re Alcon Laboratories Inc.*, 13 USPQ2d 1115 (Comm'r Pat. & Trademarks 1989). In *Alcon Labs*, Tobradex was approved for commercial market or use by the FDA on August 18, 1998, and the Tobradex PTE application was filed with the PTO on October 17, 1998. Commissioner Quigg found the Tobradex PTE application, which was filed within 60 days of FDA approval, ***"excluding"*** the day of FDA of approval, "to comply with the requirements of [35 U.S.C.] §156(d) and the provisions of 37 C.F.R. §§1.740 and 1.741." *In re Alcon Labs. Inc.*, 13 USPQ2d at 1116.

With respect to the Prilosec OTC PTE application, in FDA's 2004 opinion letter, FDA stated that its official records indicated that the product Prilosec OTC was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. §156(a)(4), and that it represented the first permitted commercial marketing or use the product, as defined by 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). In the same 2004 opinion letter, FDA stated that the NDA was approved on June 20, 2003, which makes the submission of the PTE application on August 19, 2003, timely within the meaning of 35 U.S.C. §156(d)(1).

Yet after four years of silence, the FDA now retracts its previous opinion and states that the product Prilosec OTC does not represent the first permitted commercial marketing or use of that product, as defined by 35 U.S.C. §156(f)(1) and interpreted by *Glaxo*, and that the PTE application was not timely within the meaning of 35 U.S.C. §156(d)(1). Other than pronouncing its contrary opinion regarding eligibility and timeliness, FDA's 2008 letter is noteworthy for its failure to provide any rationale for its abrupt reversal other than its previous determinations were in error.

With specific regard to the determination of timeliness, there has been no substantive change during the four years following the 2004 FDA letter, as demonstrated by the interagency agreement of understanding, entitled *Memorandum of Understanding Between The Patent and Trademark Office and The Food and Drug Administration* (the "*1987 Memorandum of Understanding*"), MOU 225-86-8251, 52 Fed. Reg. 17830 (May 12, 1987), and the FDA's "Frequently Asked Questions on the Patent Term Restoration Program" (hereinafter "2008 FDA Guidelines"), last updated May 12, 2008, which is still posted and available on the FDA's website at http://www.fda.gov/cder/about/smallbiz/patent_term.htm. In response to a PTO request for assistance in making a PTE determination, the *1987 Memorandum of Understanding* provides that the FDA will provide a written reply, "[i]nform[ing] the PTO whether the patent

term restoration application was [inter alia] submitted **within 60 days *after* the product was approved**." (emphasis added.) Similarly, the answer to Question 5 of the 2008 FDA Guidelines provides:

> **5. When is a patent extension application submitted and where is it submitted?**
>
> Application for patent extension must be filed ***within 60 days of FDA approval*** of the drug product even if the product cannot be commercially marketed at that time.... The patent extension application is filed with the PTO.

(emphasis added.) In its 2008 opinion letter, FDA states that it incorrectly ***"excluded"*** the day of approval from the 60-day time period for determining whether the PTE application was timely. Such an interpretation is not only untimely and hence unduly prejudicial as to the instant application, but contradicts these two public guidances for the public and the legal precedent provided by *Alcon Labs* regarding the timeliness of a PTE application in view of the governing statute and the implementing regulations.

FDA's 2008 letter ends with an expression of regret for the inconvenience that its errors may have caused. Surely, however, inconvenience to the agencies commissioned to apply the PTE statute for the public benefit is outweighed by the public's detrimental reliance on the agencies' long-standing policy and procedures and legal precedent. Furthermore, the agencies' abrupt and unexplained change in their conclusions regarding an already pending PTE application after four years of silence cannot be permitted as a matter of public policy or the notice and due process requirements under the U.S. Constitution.

Respectfully submitted,

Leslie Morioka

cc: Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research Center, FDA (by Fax and E-mail)
Gerald F. Masoudi, Esq., Chief Counsel, FDA (by E-mail)
Mary Till, Esq., Legal Advisor, Office of Patent Administration (by Fax and PAIR)

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 21 2008

Re: Prilosec OTC
Formerly Docket No. 2004E-0397
Current Docket No. FDA-2004-E-0463

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension (PTE) for U.S. Patent No. 5,817,338 filed by AstraZeneca AB, under 35 U.S.C. § 156. The human drug product claimed by the patent is Prilosec OTC (omeprazole magnesium), which was assigned new drug application (NDA) No. 21-229. On October 19, 2004, the Food and Drug Administration (FDA) forwarded a letter to your attention stating that (1) Prilosec OTC was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4); (2) Prilosec OTC represented 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); and (3) the submission of the patent term extension application on August 19, 2003, was timely within the meaning of 35 U.S.C. § 156(d)(1).

In your April 1, 2008, letter requesting determination of the applicable regulatory review period, you request that FDA first respond to two inquiries with respect to the eligibility of the patent for Prilosec OTC before determining the regulatory review period. First, you ask that FDA reevaluate whether the submission of the PTE application on August 19, 2003, was timely within the meaning of 35 U.S.C. § 156(d)(1). Second, you ask that FDA reevaluate whether the product 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).

In response to your inquiries, we have reexamined our records and have concluded that our October 19, 2004, determinations were in error. Consequently, the regulatory review period for this product has not been determined.

First, the NDA 21-229 for Prilosec OTC was approved on June 20, 2003. FDA incorrectly excluded the day of approval from the 60-day time period for determining whether the PTE application was timely. Consequently, the closing date for submission of a timely PTE application was Monday, August 18, 2003, which makes the submission

of the PTE application on August 19, 2003, not timely within the meaning of 35 U.S.C. § 156(d)(1).

Second, a review of FDA's official records indicates that NDA 21-229 for Prilosec OTC was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that Prilosec OTC (omeprazole magnesium) does not represent 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). The active ingredient in Prilosec OTC (omeprazole magnesium) is a magnesium salt of an active ingredient (omeprazole) that has been previously approved for commercial marketing or use in Astra Zeneca's NDA 19-810 for Prilosec. NDA 19-810 was approved September 14, 1989.

We regret the inconvenience these errors may have caused. Should you conclude that the subject patent remains 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: Leslie Morioka
White & Case
Patent Department
1155 Avenue of the Americas
New York, NY 10036-2787

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 19 2004

Re: Prilosec OTC
Docket No. 04E-0397

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,817,338 filed by AstraZeneca AB under 35 U.S.C. § 156. The human drug product claimed by the patent is Prilosec OTC (omeprazole magnesium), which was assigned NDA No. 21-229.

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).

The NDA was approved on June 20, 2003, which makes the submission of the patent term extension application on August 19, 2003, 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: Leslie Morioka
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