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.

/Andrew Fessak/	48,528
Signature	Reg. No.
Andrew Fessak	April 15, 2009
Signer's Name	Date

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

REQUEST FOR RECONSIDERATION OF FINAL AGENCY DECISION

REQUEST FOR RECONSIDERATION
OF FINAL AGENCY DECISION

Sir:

In its Denial of Patent Term Extension Application for U.S. Patent No. 5,817,338 ("Denial") on December 16, 2008, the United States Patent and Trademark Office ("PTO") maintained its position regarding eligibility for patent term extension that has been rejected by the U.S. Court of Appeals for the Federal Circuit and again most recently by a U.S. District Court following Federal Circuit precedent in PhotoCure ASA v. Dudas, No. 1:08-cv-718, 2009 WL 855807 (E.D. Va. Mar. 31, 2009).

Secondly, the PTO admitted that it changed in 2008 its methodology regarding the determination of timeliness after having deemed as timely Applicant's filing of its application in 2003. Applicant AstraZeneca AB does not dispute, as a general principle, that the PTO has the authority to change its methodology with sufficient notice to the public. However, when the PTO changes its methodology regarding timeliness retroactively during the pendency of the subject application so as to deem it untimely filed, such a change should be impermissible.[1]

The patent term extension application for U.S. Patent No. 5,817,338 (the "'338 patent") (the "PTE application") was filed on August 19, 2003, by AstraZeneca AB in connection with the drug Prilosec OTC®, which received approval from the Food and Drug Administration ("FDA") on June 20, 2003. The PTO alleges that the '338 patent is not eligible for patent term extension under 35 U.S.C. § 156 because Prilosec OTC is not "the first permitted commercial marketing" of the active ingredient. In view of that determination, the PTO denied as moot Applicant's two related Petitions to the Director under 37 C.F.R. § 1.181, filed May 30, 2008, and June 10, 2008 (the "Petition"). Applicant filed the Petitions to demonstrate that the PTO had granted patent term extensions on applications that had been filed in the same way that Applicant had filed the instant PTE application. In fact, Applicant itself had previously been granted a patent term extension on an application that had been filed in the same way as the instant PTE application.

I. Request for Reconsideration - 37 C.F.R. § 1.750

The PTO refers to the December 16, 2008 Denial as a Final Agency Decision (the "Decision"). (Decision at 11.) Because the PTO did not expressly provide for the Applicant to submit a request for reconsideration, Applicant relies on 37 C.F.R. § 1.750, which also references 37 C.F.R. § 1.136. The mail date of the Decision is December 16, 2008. Five (5) one-month extensions of time are available under § 1.136, thus making June 16, 2009, the last possible date for submitting a request for reconsideration. Authorization is hereby given to the

[1] Applicant AstraZeneca AB also had a second PTE application pending when the PTO changed it methodology, further exacerbating the prejudice and harm to which Applicant is subjected. (See Patent Term Extension Application for U.S. Patent No. 5,674,860, filed September 19, 2006, in connection with Symbicort® (budesonide/formoterol fumarate dihydrate)).

Commissioner to charge any extension fee, and any other required fee, in connection with this Request to Deposit Account 23-1703.

II. Prilosec OTC Satisfies "the Product" Requirement of 35 U.S.C. § 156(a)(5)(A)

The PTE application presents the issue of whether the approval of Prilosec OTC represents "the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred," 35 U.S.C. § 156(a)(5)(A).

Under the PTO's construction of "active ingredient" and "product" as used in 35 U.S.C. § 156(f), Prilosec OTC (omeprazole magnesium) is the same "product" as Prilosec® (omeprazole) because both are formulations of the same underlying molecule – omeprazole. The PTO asserts that its definition of "active ingredient" as the "non-salified and non-esterified form of the active ingredient" – a definition not found in the statute – comports with the Federal Circuit's determination in Pfizer Inc. v. Dr. Reddy's Labs. Ltd., 359 F.3d 1361 (Fed. Cir. 2004), that "active ingredient" means active moiety. (Decision at 5.) Therefore, according to the PTO, the approval of Prilosec OTC is not the first commercial marketing of the product in view of the prior approval and commercial marketing of Prilosec. (Decision at 6.) The fundamental error of the Decision is made manifestly clear by the recent PhotoCure decision.

Similarly at issue in PhotoCure was whether the drug product Metvixia (methyl aminolevulinate hydrochloride) ("MAL hydrochloride") satisfied "the product" requirement of 35 U.S.C. § 156(a)(5)(A) in view of a commercial drug product predating Metvixia called Levulan® (aminolevulinic acid hydrochloride) ("ALA hydrochloride"). Relying on Pfizer, the PTO had concluded that since the active ingredients of both Metvixia and Levulan share the same common moiety – aminolevulinic acid ("ALA") – the prior approval and marketing of Levulan rendered Metvixia ineligible as the first permitted commercial marketing or use of the "product" under Section 156(a)(5)(A). PhotoCure, 2009 WL 855807, at *2. Accordingly, the PTO denied PhotoCure's request for patent term extension.

PhotoCure unequivocally rejects the active moiety approach adopted by the PTO for determining PTE eligibility under Section 156(a)(5)(A) in view of Federal Circuit precedent. PhotoCure, 2009 WL 855807, at *8. Noting that the Federal Circuit denied an *en banc* hearing in Pfizer and that Pfizer is in direct conflict with the earlier decision, Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392 (Fed. Cir. 1990) ("Glaxo II"), the PhotoCure Court stated that it was bound by Glaxo II. PhotoCure, 2009 WL 855807, at *7 (citations omitted).

The PhotoCure Court's analysis includes a review of Glaxo II and the underlying decision by the district court in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989) ("Glaxo I"). PhotoCure, 2009 WL 855807, at *5-6. As noted by the PhotoCure Court, Glaxo II affirmed the Glaxo I district court's interpretation of Sections 156(a)(5)(A) and 156(f)(2). PhotoCure, 2009 WL 855807, at *6. Specifically, the PhotoCure Court observed that the Federal Circuit agreed that the statutory language of 35 U.S.C. § 156(f)(2) was unambiguous; the terms "active ingredient," "salt," and "ester" all had well-defined, ordinary plain meanings at the time the statute was enacted. Id. (citation omitted). The Federal Circuit rejected the PTO's proposed definition of "product" as being a "new chemical entity," i.e., "new active moiety," because it was contrary to the plain meaning of the statute. Id. Moreover, nothing in the

legislative history of 35 U.S.C. § 156 suggested a clearly expressed legislative intent contrary to the plain meaning of "active ingredient . . . including any salt or ester of the active ingredient." Photocure, 2009 WL 855807, at *4 (citation omitted).

Therefore, applying Glaxo II and the plain meaning of the statute, the PhotoCure Court concluded that "the active ingredient in Metvixia is MAL hydrochloride and not the active moiety ALA because MAL hydrochloride is the ingredient physically present in Metvixia that permits the drug to work effectively." PhotoCure, 2009 WL 855807, at *8. Therefore, under Section 156, "the product" is MAL hydrochloride, which was not previously approved by the FDA.

In view of PhotoCure, the active ingredient of Prilosec OTC is omeprazole magnesium salt and not the active moiety omeprazole. Because omeprazole magnesium has not been previously approved by the FDA, Prilosec OTC is a new product under the statute and satisfies 35 U.S.C. § 156(a)(5)(A), as well as the other criteria for patent term extension. Accordingly, under Glaxo II on which the PhotoCure Court relied, the '338 patent is entitled to PTE.

III. Applicant's Petitions Regarding Timeliness Are Not Moot

The PTO deemed Applicant's Petitions regarding timeliness as moot because the PTE application failed to satisfy Section 156(a)(5)(A). However, in view of PhotoCure, the PTE application must be considered eligible on substantive grounds. Accordingly, the PTO needs to address the timeliness of the filing of the PTE application.

In reaching the determination that the PTE application is untimely, the PTO relied upon Unimed, Inc. v. Quigg, 888 F.2d 826, 828 (Fed. Cir. 1989), where the Federal Circuit is said to have articulated that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date." (Decision at 7-8.) If the method for determining the timeliness of a PTE application is unambiguous as the PTO contends, then the PTO is not entitled to agency deference in its inconsistent analysis and application of Section 156(d)(1).

As noted by the PhotoCure Court, "[t]he amount of deference that an agency interpretation of a statute warrants under Skidmore varies with the circumstances." PhotoCure, 2009 WL 855807, at *10 (citing United States v. Mead Corp., 533 U.S. 218, 228 (2001); Cathedral Candle Co. v. United States Int'l Trade Comm'n, 400 F.3d 1352, 1365-66 (Fed. Cir. 2005)); see Skidmore v. Swift & Co., 323 U.S. 134 (1944). Skidmore deference may be applicable to agency interpretations not having the force of law. Id. at *9 (citing Christensen v. Harris County, 529 U.S. 576, 587 (2000)). One important factor in determining the amount of deference is whether the "agency's position has been consistent." Id. at *10 (citing Cathedral Candle Co., 400 F.3d at 1366).

As evidenced by the following paragraphs, which are excerpted from the Petitions, incorporated herein by reference, the PTO's application of the statute has been consistently riddled with inconsistency.

a. **The PTE application – PTO and FDA: first timely, then untimely**

- **PTO letter dated July 19, 2004:** "Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156 of [sic] the active ingredient is omeprazole magnesium, not omeprazole." (Petition at ¶3) (emphasis added)

- **FDA response dated October 19, 2004:** "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)." (Petition at ¶4; 10/19/2004 FDA letter attached as Exhibit A to 12/15/2008 Letter to FDA attached hereto) (emphasis added)

- **PTO letter dated April 1, 2008:** The PTO stated that the subject PTE Application was not timely filed. This 2008 PTO Letter did not refer to the prior favorable PTO and FDA letters of July 19, 2004, and October 19, 2004. (Petition at ¶¶ 5 and 6) (emphasis added)

- **FDA response dated October 21, 2008:** The FDA retracted its favorable opinion regarding eligibility and timeliness as set forth in its letter of October 19, 2004, and stated that the PTE application was neither timely filed nor eligible for PTE extension. The FDA stated that it had previously incorrectly determined the timeliness of the PTE application by excluding the day of FDA approval from the 60-day period. (10/21/2008 FDA letter attached as Exhibit B to 12/15/2008 Letter to FDA attached hereto) (emphasis added)

b. **PTO and FDA published guidelines support instant PTE application**

Neither the PTO nor the FDA has changed its description from 1987 (at the latest) regarding how to timely file an application for patent term extension, as follows:

- ***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) - provides that the FDA will provide a written reply, "informing the [PTO] whether the patent term extension application was [inter alia] submitted **within 60 days *after* the product was approved**." (Petition at ¶8) (emphasis added)

- **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. 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.
>
> (Petition at ¶9) (emphasis added)

c. PTO's numerous grants of PTEs affirms timeliness of instant PTE application

As identified in the Petitions, the PTO has granted 12 patent term extensions, beginning in 1986, based on third-party PTE applications filed within 60 days after FDA approval. The US patents enjoying the benefits of these patent term extensions are US 3,721,687; 3,732,340; 4,407,288; 4,513,006; 4,702,253; 4,830,010; 4,836,217; 4,941,093; 5,441,745; 5,532,221; 5,639,639; and 5,827,937; this last patent term extension was granted on October 7, 2007. (Petition at ¶11)

d. Tobradex court decision affirms timeliness of instant PTE application

Although the Petitions identified only patents that were granted PTE, it should be noted that the PTE application for Tobradex® in connection with US 3,691,279, which was the subject of In re Alcon Labs. Inc., 13 USPQ 2d 1115 (Comm'r Pat. & Trademarks 1989), was also filed in the same way the instant PTE application was filed. Tobradex was approved for commercial marketing 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 [37 C.F.R.] § 156(d) and the provisions of 37 C.F.R. §§ 1.740 and 1.741." In re Alcon Labs. Inc., 13 USPQ 2d at 1116 (emphasis added). (12/15/08 Letter to FDA at 2.)

e. PTE applicant's own Foscavir® PTE

In 1993, Applicant itself was granted a patent term extension for its approved Foscavir® drug product, based on an application filed within 60 days of FDA approval, like the instant PTE application. (Petition at ¶10)

The PTO has acknowledged its inconsistency in administering the statute by admitting that "the USPTO has changed the way in which it makes the timeliness count between 2004 and 2008." (Decision at 9.) In view of this admission and the foregoing historical facts (as set forth in more detail in Applicant's Petitions incorporated herein by reference), the PTO's administration of the statute has been inconsistent, notwithstanding its alleged expertise in administering the statute, and, therefore, does not warrant Skidmore deference. Cathedral Candle Co., 400 F.3d at 1366; see also PhotoCure, 2009 WL 855807, at *10.

Even in the absence of agency deference, the PTO argues that it has the authority to correct its previous mistakes. (Decision at 9-10.) The PTO should, however, follow proper procedures a) to provide adequate notice to the public, including to any applicant *before* filing its application for patent term extension, and b) to avoid unduly prejudicing any pending applications by retroactively applying to them a material change in policy and procedures. Even if there had been adequate public notice in 2008 when the PTO changed its method of determining timeliness of filing a PTE application, it still would have been unduly prejudicial to the already-filed, instant PTE application. Accordingly, whatever interest the PTO may have to review timeliness according to a different standard as to pending applications is far outweighed by the interests of Applicant and its reliance on the methodology used by the PTO for more than 20 years until 2008.

Applicant respectfully requests that (1) the PTO consider Applicant's Petitions and return to its original determination made in 2004 that the instant PTE application was timely filed, as set forth in the PTO's letter of October 19, 2004; and (2) the PTO determine that the instant PTE application is eligible for a patent term extension in view of Glaxo II and PhotoCure.

Respectfully submitted,

Dated: April 15, 2009

/Leslie Morioka/
Leslie Morioka
Reg. No. 40,304

Attorney for Applicant

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New York, New York 10036
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Attachment: Copy of December 15, 2008 letter to Jane A. Axelrad of the FDA with Exhibits A and B

ATTACHMENT

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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

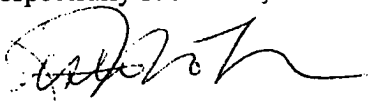
term restoration application was [inter alia] submitted **within 60 days *after* the product was approved**." (emphasis added.) Similarly, the answer to Question 5 of the 2008 FDA Guidelines provides:

> **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

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
White & Case
Patent Department
1155 Avenue of the Americas
New York, NY 10036

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 2 1 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
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