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Leslie Morioka
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036

In re: Patent Term Extension
Application for
U.S. Patent No. 5,817,338

DENIAL OF PATENT TERM EXTENSION APPLICATION FOR U.S. PATENT NO. 5,817,338

This is in response to the application for extension of the patent term of U.S. Patent No. 5,817,338 (the '338 patent) under 35 U.S.C. § 156, which was filed in the United States Patent and Trademark Office ("USPTO") on August 19, 2003. The patent term extension application ("PTE application") was filed by AstraZeneca AB ("Applicant"), the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of a human drug known by the tradename, Prilosec OTC®, which was approved for commercial marketing and use by the Food and Drug Administration ("FDA") on June 20, 2003.

This is also in response to two petitions filed by Applicant on May 30, 2008, and June 10, 2008, under 37 C.F.R. § 1.181, seeking to invoke the supervisory authority of the Director in order to "request that the PTO maintain its original position that Applicant's PTE Application was submitted timely. . . ."

A determination has been made that the '338 patent is **NOT** eligible for patent term extension based upon the regulatory review period of Prilosec OTC®. Therefore, Applicant's PTE application is **DENIED**. Because of the determination that the '338 patent is ineligible for patent term extension, Applicant's two petitions are in turn **denied as moot**.

FACTUAL BACKGROUND

1) On October 6, 1988, the USPTO issued the '338 patent to Pontus J.A. Bergstrand and Kurt I. Lövgren; it was originally assigned to Astra Aktiebelag, now AstraZeneca AB.

2) On June 20, 2003, the FDA approved New Drug Application ("NDA") No. 21-229, thereby granting permission for commercial marketing or use of Prilosec OTC® (omeprazole magnesium).

3) On August 19, 2003, Applicant filed a PTE application under section 156 to extend the term of the '338 patent based on the FDA regulatory review period of Prilosec OTC®.

4) On July 19, 2004, pursuant to the Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration, *see* 52 Fed. Reg. 17830, May 12, 1987, the USPTO requested assistance from FDA ("First USPTO Letter to FDA") in determining eligibility of the '338 patent for patent term extension based on the regulatory review period of Prilosec OTC®. The USPTO indicated in its letter that "the subject patent would be eligible for extension of the patent term."

5) On October 19, 2004, the FDA responded to the First USPTO Letter to FDA. The FDA indicated that Prilosec OTC® was subject to a regulatory review period within the meaning of § 156(g) as required by § 156(a)(4). The FDA further indicated that the permission for commercial marketing or use of Prilosec OTC® constituted the first permitted commercial marketing or use of the product, as defined under § 156(f)(1). Finally, the FDA indicated that the NDA was approved on June 20, 2003, and that the submission of the PTE Application on August 19, 2003, was timely within the meaning of § 156(d)(1).

6) On April 1, 2008, the USPTO sent a second letter to the FDA ("Second USPTO Letter to FDA") requesting that FDA determine the applicable regulatory review period pursuant to § 156(d)(2)(A). The USPTO letter nevertheless requested additional information regarding: (1) the timeliness of the PTE Application in light of the plain meaning of the statutory deadline for filing a patent term extension application as stated in § 156(d)(1) and as interpreted in *Unimed v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989); and (2) whether Prilosec OTC® constituted the first permitted commercial marketing or use based on the plain statutory language of § 156(f)(2), and related court decisions, in light of the previous FDA approval of NDA No. 19-810 for Prilosec® (omeprazole) on September 14, 1989. The USPTO indicated that it considered the PTE Application to be untimely filed and that Prilosec OTC® does not constitute the first permitted commercial marketing or use of the product under the provision of law under which regulatory review occurred.

7) On May 30, 2008, Applicant filed a petition pursuant to the provisions of 37 C.F.R. § 1.181 ("Original Petition") seeking to invoke the supervisory authority of the Director in order to "request that the PTO maintain its original position that Applicant's PTE Application was submitted timely. . . ." *See* Original Petition at 15.

8) On June 10, 2008, Applicant filed a revised petition correcting errors in the Original Petition without amending or changing the substance of that earlier petition ("Revised Petition").

9) On October 21, 2008, the FDA responded to the Second USPTO Letter to FDA, indicating that the PTE Application was not timely filed and that the approval of NDA 21-229 for Prilosec OTC® was not the first permitted commercial marketing or use as required by section 156(a)(5)(A). The FDA explained that it erred as to both of the USPTO's prior inquiries regarding Prilosec OTC®.

DECISION

This dismissal is a decision on the merits of the PTE application as well as a decision on the merits of the Original Petition and the Revised Petition.

I. Prilosec OTC® Is Not the First Permitted Commercial Marketing or Use of the Product under the Provision of Law under which Regulatory Review Occurred as Required by 35 U.S.C. § 156(a)(5)(A)

A. The USPTO Has Construed "Active Ingredient" as Used in the Definition of "Product" To Mean the Underlying Molecule or Ion (Excluding those Appended Portions of the Molecule that Cause It to be a Salt or Ester) Responsible for the Physiological or Pharmacological Action of the Drug

Section 156(a) sets forth several eligibility requirements for a patent term extension. *See* 35 U.S.C. § 156(a)(1) – (a)(5), (d)(1) & (e)(1). Under 35 U.S.C. § 156(a)(5)(A), "the permission for the commercial marketing or use of the product . . . [must be] the *first* permitted commercial marketing or use of the *product* under the provision of law under which such regulatory review period occurred." (Emphasis added). Based on that language, whether the '338 patent is eligible for patent term extension turns on whether the approval of Prilosec OTC® is the first permitted commercial marketing or use of the "product" under the provision of law under which the regulatory review period occurred.

The term "product" is expressly defined in § 156(f) as follows:

(f) For purposes of this section:
  (1) The term "product" means:
    (A) A drug product . . .
  (2) The term "drug product" means the *active ingredient* of -
    (A) A new drug, antibiotic drug, or human biological product . . . *.including any* salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

35 U.S.C. § 156(f) (emphases added). Thus, the definition for "product" can be expressed as:

Product = drug product = the active ingredient of [a] new drug . . . including any

salt or ester of the active ingredient

Section 156 does not expressly define the term "active ingredient." The USPTO has defined the term to mean the underlying molecule or ion (excluding those appended portions of the molecule that cause it to be a salt or ester) responsible for the physiological or pharmacological action of the drug. The USPTO arrived at this definition based on the plain language of section 156(f)(2), giving effect to each word in that provision. Specifically, in distinguishing "active ingredient" from a "salt or ester of the active ingredient," the statute suggests that the "active ingredient" cannot itself be a salt or an ester. It necessarily follows that the "active ingredient" therefore must be a distinct molecule or ion from either a salt or an ester; *i.e.*, an underlying molecule or ion (excluding those appended portions of the molecule that cause it to be a salt or ester) responsible for the physiological or pharmacological action of the drug.

Inserting the USPTO's definition of "active ingredient" back into the statute, section 156(f)'s "product" includes: (i) the non-salified and non-esterified form of the active ingredient (i.e., the underlying molecule or ion (excluding those appended portions of the molecule that cause it to be a salt or ester) responsible for the physiological or pharmacological action of the drug substance); (ii) salts of the underlying molecule or ion; and (iii) esters of the underlying molecule or ion. In other words, a "product" can be expressed as:

> Product = the non-salified and non-esterified form of the active ingredient (*i.e.*, the underlying molecule or ion responsible for the physiological or pharmacological action of the drug substance) = salts of the underlying molecule or ion = esters of the underlying molecule or ion

Because the term "product" covers three different types of chemical formulations, a salt of a molecule is statutorily the same "product" under § 156 as an ester of the molecule and as the underlying molecule itself. The same is true for an ester of a molecule as well as the underlying molecule itself. Accordingly, if any one of the three formulations has previously been granted permission for commercial marketing or use under the same provision of law, then any subsequent formulation granted permission for commercial marketing or use under the same provision of law will not meet the eligibility requirements in § 156(a)(5)(A); it will not be first.

B. The USPTO's Construction of "Active Ingredient" Matches the Federal Circuit's Construction

The Federal Circuit has construed the term "active ingredient" as used in § 156 like the USPTO. In *Pfizer v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004), the Federal Circuit addressed the meaning of the statutory phrase "active ingredient" as used in section 156(f)(2). The *Pfizer* Court accepted the FDA's definition of the term "active ingredient" as meaning "active moiety." *Id.* at 1366 (citing *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,358 (F.D.A. Oct. 3, 1994)). The Court, in turn, observed that "active moiety" means "the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or

pharmacological action of the drug substance," *id.* (quoting 21 C.F.R. § 314.108(a))(omission in original). Accordingly, the USPTO's definition of "active ingredient" matches the Federal Circuit's construction of that term as referring to an underlying molecule or ion (excluding those appended portions of the molecule that cause it to be a salt or ester) responsible for the physiological or pharmacological action of the drug.

The Federal Circuit has issued two other decisions that address the meaning of terms used in section 156, both of which pre-date *Pfizer*. Neither decision, however, specifically construes the proper scope and meaning of "active ingredient." First, in *Fisons plc v. Quigg,* 876 F.2d 99 (Fed. Cir. 1989), the Federal Circuit addressed the meaning of the phrase "the first permitted commercial marketing or use of the product." Fisons argued that "product" should not be interpreted to mean "active ingredient," but instead referred to the "particular drug product that the FDA approved." The Court disagreed, affirming the district court's finding that the term "'product' as used in Subsection (a)(5)(A) refers only to the patented drug's active ingredient." *Id.* at 102. Second, in *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990), the Federal Circuit addressed whether the USPTO was correct that Congress intended "product" to mean "any 'new chemical entity,' *i.e.*, 'new active moiety.'" *Id.* at 394. The Court concluded that USPTO's interpretation was incorrect because Congress "provid[ed] an explicit and precise definition of 'product' in § 156(f)(2), using well-established scientific terms." *Id.* at 399. Hence, both *Fisons* and *Glaxo* addressed the meaning of the term "product" as necessary for resolution of those cases, but in no way prescribed a definition for "active ingredient."

C. Public Policy Supports the USPTO's Construction of "Active Ingredient"

In *Fisons plc v. Quigg,* 1988 WL 150851 (D.D.C. 1988), the district court reviewed the legislative history of section 156 in detail and found that Congress intended for patent term extensions to be available only to pioneering new chemical entities and not to follow-on drugs. In the Court's words:

> Congress did not intend that every patented drug that experienced lengthy or delayed regulatory review receive the benefits of patent restoration. Under Section 156(a)(5)(A), only new, pioneer chemical entities were to have their effective lives legislatively restored.

Id. at *9. In making that finding, the Court walked through the various criticisms of § 156(a)(5)(A), noting that many commentators, particularly the pharmaceutical industry, attacked § 156(a)(5)(A) for not applying to "new uses for the drug, new dosage forms or innovative formulations, all of which require full new drug applications." *Id.* at *7. The Court found that Congress did not yield to the pressure: "By enacting and not amending Section 156 in this regard, Congress implicitly, but clearly, rejected industry's plea, like that articulated by Stafford, for loosened eligibility requirements." *Id.* at *8. Additionally, the Court observed that the House rejected a proposed amendment supported by thirteen Representatives that sought to make patent term extension available for patents protecting aspects beyond just the pioneer chemical entity like use, dosage, and formulation. *Id.*

By properly differentiating between (i) the non-salified and non-esterified form of the

active ingredient (*i.e.*, the underlying molecule or ion responsible for the physiological or pharmacological action of the drug substance); (ii) salts of the underlying molecule or ion; and (iii) esters of the underlying molecule or ion, the USPTO gives effect to Congress's intent to reward the patents protecting only pioneering new chemical entities with patent term extensions. Without such differentiation, a patent protecting the follow-on salt of an underlying molecule could qualify for patent term extension because the follow-on salt would be treated as a different "product" from the underlying pioneering molecule. The same would be true for a follow-on ester on an underlying pioneering molecule as well as the follow-on acid or base for a pioneering salt or ester.

D. The "Active Ingredient" in Prilosec OTC® is Omeprazole, the Same "Active Ingredient" as in Prilosec®

Prilosec OTC® is the brand name for omeprazole magnesium. Said differently, Prilosec OTC® is omeprazole formulated as a salt; in particular, a magnesium salt. Applicant admits as much in its PTE Application, stating that omeprazole magnesium "is the magnesium salt of omeprazole." PTE Application at 2, ¶1. Before the FDA approved Prilosec OTC®, it approved Prilosec®. Prilosec® is the brand name for omeprazole, a base molecule. Applicant acknowledges in its PTE Application that Prilosec® is omeprazole. *Id.* at 2, ¶4. The following chart summarizes the various nomenclatures for the drugs at issue here:

Brand Name	Chemical Name	Formulation Type	Underlying Molecule (aka Active Ingredient)
Prilosec®	Omeprazole	Base	Omeprazole
Prilosec OTC®	Omeprazole magnesium	Salt of base	Omeprazole

Under the USPTO's construction of "active ingredient" and in turn "product" as used in section 156(f), Prilosec OTC® is the same product as Prilosec®. Both are formulations of the same underlying molecule – omeprazole. Prilosec OTC ® is a salt formulation of omeprazole, while Prilosec® is the base. Because Prilosec® is considered to be the same product as Prilosec OTC® and because Prilosec ® was commercially marketed before Prilosec OTC®, the approval of Prilosec OTC® is not the first commercial marketing or use of the product under the provision of law under which the regulatory review period occurred.

Notably, the FDA has advised the USPTO that the approval of Prilosec OTC® fails to meet the patent term extension eligibility requirement set forth in section 156(a)(5)(A). Specifically, the FDA official records indicate that the approval of NDA No. 21-229 (omeprazole magnesium) does not constitute the first permitted commercial marketing or use of the product as required by section 156(a)(5)(A) in light of the approval of NDA No. 19-810 (omeprazole). Additionally, after

approving Prilosec OTC® for commercial marketing or use, the FDA published information about the drug on its website. That information supports the USPTO's determination that the approval of Prilosec OTC® does not constitute the first permitted commercial marketing or use of the product subject to the regulatory review period as required by § 156(a)(5)(A). On the FDA's webpage called Drug@FDA,[1] the FDA indicated that the "Chemical Type" for Prilosec OTC® is "2 New ester, new salt or other noncovalent derivative" and "3 New formulation." The FDA also created an online resource for questions and answers about Prilosec OTC®.[2] The FDA asked the question: "Will Prilosec OTC work as well as the prescription strength Prilosec?" *See* question 4. The FDA answered: "Both prescription Prilosec and Prilosec OTC contain the same active ingredient, omeprazole, which effectively stops acid production."

In sum, because the FDA's approval of Prilosec OTC® does not constitute the first permitted commercial marketing or use of the product under the provision of law under which the regulatory review period occurred in light of the earlier grant of permission for commercial marketing and use of Prilosec®, the eligibility requirement set forth in section 156(a)(5)(A) is not satisfied and the '338 patent is ineligible for patent term extension.

II. The Submission of the PTE Application for U.S. Patent No. 5,817,338 Is Untimely Within the Meaning of 35 U.S.C. § 156(d)(1)

As noted earlier, section 156(a) contains several eligibility requirements for a patent term extension. In addition to the requirement that the drug be the first commercial marketing or use of the product under the provision of law under which regulatory review occurred, discussed in the previous section, *see supra* § I, the PTE application must be timely filed. Section 156(d)(1) provides, in relevant part:

> To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period *beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred* for commercial marketing or use.

35 U.S.C. § 156(d)(1) (emphasis added). The "beginning on" language makes clear that the triggering date for filing a PTE application is the day of FDA approval, *i.e.*, the date of the NDA approval letter. The triggering date is not the day after FDA approval. In other words, the first day of the sixty-day period within which an applicant must submit a PTE application is the day of FDA approval. The day after FDA approval is considered to be the second day in the sixty-day application window.

In *Unimed, Inc. v. Quigg*, 888 F.2d 826, 828 (Fed. Cir. 1989), the Federal Circuit

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1 *See* Drugs@FDA found at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/, last visited on 12/3/2008, copy attached hereto as Appendix 1.

2 *See* http://www.fda.gov/cder/drug/infopage/prilosecOTC/prilosecotcQ&A.htm, last visited on 12/3/2008, copy attached hereto as Appendix 2.

articulated that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date." To be sure, the Federal Circuit explained the correct triggering date through the facts in that case by stating: "the sixty-day period specified in section 156(d)(1) commenced on May 31, 1985, the date the FDA's letter to Unimed giving notice of its final approval of Marinol. . . ." *Id.* at 829.

Here, Applicant received FDA approval on June 20, 2003, triggering the start of the sixty-day period for filing its PTE application and making its PTE application due on or before August 18, 2003. Applicant did not, however, file its PTE application until August 19, 2003, one day late. It is unclear how or why Applicant missed the sixty date deadline because Applicant correctly indicated in its PTE application that the first day of the sixty-day period "began on June 20, 2003." Specifically, Applicant stated: "This application is timely 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." PTE Application at 3, ¶5 (emphasis added). In any event, because Applicant filed its PTE application one day late, the eligibility requirement set forth in section 156(d)(1) is not satisfied and the '338 patent is ineligible for patent term extension for this independent reason.

III. Applicant's Original Petition and Revised Petition Fail on the Merits and Are Moot

Applicant filed a petition requesting that the supervisory authority of the Director be invoked "to prevent the USPTO from retroactively applying to the subject PTE application an apparently new method of determining timeliness that had not yet been announced to the public." Revised Petition at 1. In its Revised Petition, Applicant did not assert that the USPTO interprets the statute, or the Federal Circuit's construction of it in *Unimed*, incorrectly in its Second USPTO Letter to FDA. Nor does Applicant deny that it filed its PTE Application on day sixty-one of the period beginning on the date of approval by the FDA. Instead, Applicant argues that there has been a change in methodology by the USPTO and the FDA in applying the provisions of § 156(d)(1) from the First USPTO Letter to FDA in 2004 to the Second USPTO Letter to FDA in 2008. According to Applicant, that policy change cannot be retroactively applied to its PTE Application in light of *SEC v. Chenery*, 332 U.S. 194 (1947), and *Retail, Wholesale & Dep't Store Union v. NLRB*, 466 F.2d 380, 390 (D.C. Cir. 1972). Thus, Applicant argues that the USPTO should be bound to the timeliness statements made in the First USPTO Letter to FDA and that the USPTO should find that its PTE Application was timely filed under section 156(d)(1).

Applicant's arguments fail because the USPTO has the power to make a correction upon realizing a mistake. In any event, because the USPTO herein determines that Applicant's PTE Application fails to satisfy two of the statutory eligibility requirements, *see supra* §§ I & II, Applicant's Original Petition and Revised Petition are moot.

A. The USPTO Has Revised Its Methodology for Making Timeliness Determinations to Conform to the Plain Language of Section 156 and Case Law

Applicant is correct that the USPTO has changed the way in which it makes the timeliness count between 2004 and 2008. The agency has done so because it realized that it was erroneously beginning the sixty-day count on the wrong day. By not counting the date of FDA approval as one of the sixty days included in the time period for filing a PTE application, the USPTO was failing to comply with section 156 and case law. The FDA made the same error as the USPTO and also corrected itself. In its response to the USPTO Second Letter to FDA, the FDA indicated:

> We have reexamined our records and have concluded that our October 19, 2004, determinations were in error. . . . 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).

If the USPTO treated Applicant's late filed PTE application as timely filed, as Applicant requests, the agency would perpetuate an erroneous application of section 156(d)(1); the USPTO cannot do so. Moreover, the USPTO has no discretion under section 156 to waive any of the eligibility requirements.

B. Courts Have Consistently Held that Administrative Agencies Have the Authority to Correct Previous Mistakes

Here, until the instant dismissal of the PTE application, the USPTO has not issued any agency determination regarding the eligibility of Applicant's patent for a patent term extension; the agency released only preliminary views in the First and Second USPTO Letters to FDA. As a result, no rights to a patent term extension have vested. Because no rights have vested to Applicant, reconsideration of the preliminary agency position expressed in the First USPTO Letter to FDA is clearly proper, especially in light of the USPTO's initial erroneous application of the plain language of section 156(d)(1).

Moreover, even if the First USPTO Letter to FDA could be considered as an agency determination, inherent authority exists for a federal agency to remediate previous error and diverge from a past practice of incorrectly administrating a statute. *See The Last Best Beef v. Dudas*, 506 F.3d 333, 340 (4th Cir. 2007) ("[f]irst, federal agencies, including the USPTO, have broad authority to correct their prior errors."); *see also Trujillo v. General Electric Co.*, 621 F.2d 1084 (10th Cir. 1980) (("Administrative agencies have an inherent authority to reconsider their own decisions, since the power to decide in the first instance carries with it the power to reconsider") (citing *Albertson v. Fed. Commc'ns Comm'n*, 182 F.2d 397 (D.C. Cir. 1950)). Indeed, the Federal Circuit has explained that past erroneous construction of a statute should not be

perpetuated. *See In re Boulevard Entertainment, Inc.*, 334 F.3d 1336, 1343 (Fed. Cir. 2003) ("The fact that, whether because of administrative error or otherwise, some marks have been registered even though they may be in violation of the governing statutory standard does not mean that the agency must forgo applying that standard in all other cases.").

C. Applicant's Reliance on Case Law is Misplaced

Applicant relies on *Chenery* and *Retail, Wholesale and Dep't Store Union* to support its argument that a change in policy regarding the correct interpretation of section 156(d)(1) cannot be retroactively applied to its PTE Application. Applicant's argument is based on the flawed premise the USPTO has the discretion to accept Applicant's late-filed PTE Application. As noted earlier, precedent is clear: the USPTO's authority under section 156 is limited to the terms of the statute. *See Somerset v. Dudas*, 500 F.3d 1344, 1346 (Fed. Cir. 2007) (consulting the express language of section 156(e)(2) when determining the extent of the USPTO's authority to grant interim patent term extensions). In this case, the USPTO has no statutory authority to grant Applicant's PTE Application because it was not timely filed. If the USPTO's correction of past mistakes regarding the correct interpretation of section 156(d)(1) amounts to a change in policy, the problem is not the denial of PTE applications like Applicant's, the problem is with the existing patents that contain improvidently granted extensions. Congress provided the solution to that problem with the invalidity defense set forth in 35 U.S.C. § 282. It did not authorize the USPTO to accept a late-filed PTE application under any circumstances.

CONCLUSION

Applicant's PTE application is **DENIED**. In light of the dismissal of Applicant's PTE Application, Applicant's Original Petition and Revised Petition are **denied as moot**.

THIS IS CONSIDERED A FINAL AGENCY DECISION.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002
Attention: Beverly Friedman

RE: PRILOSEC OTC®
FDA Docket No.: FDA-2004-E-0463

APPENDIX 1

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DRUG EVALUATION AND RESEARCH

Drugs@FDA

FDA Approved Drug Products

Drug Details

Drug Name(s)	PRILOSEC OTC (Brand Name Drug)
FDA Application No.	(NDA) 021229
Active Ingredient(s)	OMEPRAZOLE MAGNESIUM
Company	ASTRAZENECA
Original Approval or Tentative Approval Date	June 20, 2003
Chemical Type	2 New ester, new salt, or other noncovalent derivative 3 New formulation
Review Classification	S Standard review drug

- There are no other OTC drugs with the same Active Ingredient, Strength and Dosage Form/Route
- Approval History, Letters, Reviews, and Related Documents
- Questions and Answers
- Label Information
- FDA Press Release
- Other Important Information from FDA

Products on Application (NDA) #021229

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing	RLD	TE

				Status		Code
PRILOSEC OTC	OMEPRAZOLE MAGNESIUM	EQ 20MG BASE	TABLET, DELAYED RELEASE; ORAL	Over-the-counter	Yes	None

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FDA/Center for Drug Evaluation and Research
Office of Training and Communications
Division of Information Services
Update Frequency: Daily

APPENDIX 2

Questions and Answers on Prilosec OTC (omeprazole)

1. What is FDA announcing today?

The FDA is announcing the approval of Prilosec OTC (omeprazole) as an over-the-counter (OTC) drug product. Until today, Prilosec was available only with a doctor's prescription. FDA originally approved prescription Prilosec in 1989.

2. What is Prilosec OTC used to treat?

Prilosec OTC is used to treat frequent heartburn. Heartburn occurs when the stomach contents back up and out of the stomach into the esophagus (the tube that connects the throat to the stomach). Frequer heartburn is when you have heartburn 2 or more days a week.

Prilosec OTC is not the right medicine for you if you have occasional heartburn, one episode of heartburn a week or less, or if you want immediate relief of heartburn.

It is very important that you carefully read and understand the Prilosec OTC label directions, warnings, and side effects. Most importantly, the label will tell you when you should seek medical attention instead of taking Prilosec OTC.

3. How does Prilosec OTC work?

Prilosec OTC stops the stomach from making acid. This causes less heartburn.

4. Will Prilosec OTC work as well as the prescription strength Prilosec?

Both prescription Prilosec and Prilosec OTC contain the same active ingredient, omeprazole, which effectively stops acid production. Prescription Prilosec treats diseases that require diagnosis and supervision by a doctor. Prilosec OTC treats only symptoms of frequer heartburn. Used as directed, Prilosec OTC will not treat the conditions that prescription Prilosec treats.

5. How is Prilosec OTC taken?

Prilosec OTC is a delayed-release 20mg tablet, taken once a day (every 24 hours) for 14 days before eating. You should not take it for more than 14 days or repeat a 14-day course more often than every 4 months unless directed by a doctor.

Do not crush, break, or chew the tablet. This decreases how well Prilosec OTC works in the body.

6. If Prilosec OTC takes a few days to take effect, can I take more each day to make it work faster?

No. Prilosec OTC is not intended for immediate relief of occasional heartburn. Prilosec OTC may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours.

7. Who should take prescription strength Prilosec rather than Prilosec OTC?

Although the two products contain omeprazole, prescription Prilosec is for treating conditions such as inflammation of the esophagus (esophagitis), ulcers, and other medical conditions for which a doctor's supervision is needed.

For this reason, stop taking Prilosec OTC and tell your doctor if you:

- are not feeling better and your heartburn continues to worsen
- need to take this product for more than 14 days
- need to take more than 1 course of treatment every 4 months

Prilosec OTC is not appropriate for adults who:

- have only occasional heartburn
- have one episode of heartburn a week or less
- want immediate relief of heartburn

8. Who should NOT take Prilosec OTC?

Do not take Prilosec OTC if you have:

- had an allergic reaction to Prilosec in the past
- trouble or pain swallowing food
- vomiting with blood
- bloody or black stools

9. Does Prilosec OTC interact with food or other drugs?

When you are taking Prilosec OTC, it is especially important that your health care provider know if you are taking any of the following:

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)

10. How is Prilosec OTC different from the other OTC treatments for heartburn?

There are other OTC drug products used to provide immediate relief fc heartburn. These include antacids and acid reducer drug products suc as Pepcid, Zantac, Tagamet, and Axid. Prilosec OTC should not be confused with these products because it works differently and is not intended for immediate relief.

11. What are some possible side effects of Prilosec OTC?

Although side effects from Prilosec OTC are not common, they can occur. Tell your doctor if any of these symptoms are severe or do not g away:

- headache
- diarrhea
- constipation
- upset stomach
- vomiting
- stomach pain
- cough
- cold symptoms
- dizziness
- rash

12. How can I report a side effect with Prilosec OTC to the FDA?

You can report a side effect the following ways:

- Visit www.fda.gov/medwatch and click on "How to Report"
- Call 1 - 800-FDA-1088
- Fax 1 - 800-FDA-0178

13. When will Prilosec OTC be available?

The company marketing Prilosec OTC makes the decision on availability. For further information, please contact the manufacturer, Procter and Gamble, directly.

14. What if I have other questions about Prilosec OTC?

If you have further questions regarding Prilosec OTC or any medications, please contact the Center for Drug's Division of Drug Information at: 888-INFOFDA (888-463-6332), or email us at: druginfo@fda.hhs.gov.

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