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Mailed: July 28, 2005

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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,143,771

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 6,143,771 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on May 25, 2005. The application was filed by AstaZeneca AB, the owner of U.S. Patent No. 6,143,771 by virtue of the Assignment to Astra AB by the inventors and by Assignment from Astra AB to AstraZeneca AB. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of NEXIUM® I.V. esomeprazole sodium for injection. NEXIUM® I.V. was approved for commercial use and sale by the Food and Drug Administration (FDA) on March 31, 2005.

A determination has been made that U.S. Patent No. 6,143,771 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of NEXIUM® I.V.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

According to Applicants, the product for which patent term extension is sought is NEXIUM® I.V. (esomeprazole sodium for injection). Applicants admit that a patent term extension for PRILOSEC® (omeprazole) was previously granted for U.S. Patent No. 4,255,431, now expired. Additionally, Applicants admit that patent term extension applications have been filed for NEXIUM® (esomeprazole magnesium) and PRILOSEC® OTC (omeprazole magnesium) for U.S. Patent Nos. 4,738,974 and 5,817,338, respectively. It is noted that an interim extension of 1 year has been granted for U.S. Patent No. 4,738,974.

The USPTO understands that esomeprazole sodium, the active ingredient of NEXIUM® I.V., is not the same active ingredient as PRILOSEC® (omeprazole), NEXIUM® (esomeprazole magnesium) or PRILOSEC® OTC (omeprazole magnesium). The difference between the active ingredient in NEXIUM I.V.® and NEXIUM® is a sodium salt and a magnesium salt of the active moiety, esomeprazole, respectively.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter*

alia, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 6,143,771 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (B) Any medical device, food additive or color additive subject to regulation under the Federal Food Drug and Cosmetic Act.
> (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. (Emphasis added.)

The terms are similarly defined in the Food Drug and Cosmetic Act (21 C.F.R. 60.3(b)(10)).

> 21 C.F.R. 60.3(b)(10) Human drug product means the active ingredient of a new drug or human biologic product (as those terms are used in the [FD&C] Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added).

In Pfizer, Inc. v. Dr. Reddy's Labs., 359 F.3d 1361, 69 USPQ2d (BNA) 2016 (Fed. Cir. 2004), the Federal Circuit provided guidance on what constitutes a "product" for purposes of FDA regulatory review. The court found that the approved product is the active ingredient of NORVASC®, amlodipine, not amlodipine besylate *per se*, because test data for both amlodipine besylate and amlodipine maleate had been submitted to the Food and Drug Administration, and also because, as stated by the court:

> We conclude that the active ingredient is amlodipine, and that it is the same whether administered as the besylate salt or the maleate salt. The statutory definition of "drug product" is met by amlodipine and its salts. Dr. Reddy's is proposing to market the "drug product," as defined in 35 U.S.C. §156(f), for the same approved uses. The statute foresaw variation in the *salt or ester* of an active ingredient, and guarded against the very loophole now urged. See 35 U.S.C. §156(f); 21 U.S.C. §355(j)(5)(D)(i) and (v). As

> several *amici curiae* point out, the Hatch-Waxman Act established a balance whereby the patent term extension is offset by facilitating generic entry when the extended term expires, yet preserving the innovation incentive. Whether or not this bargain achieved "perfect symmetry" -- Dr. Reddy's argues that it was not intended to do so, but was designed to favor the generics -- the text of the statute shows that it was not intended to be defeated by simply changing the salt. None of the aspects offered to the district court or on this appeal suggests a statutory intent to provide the generic producer with access to the pioneer's approved uses and data while barring extension of patent coverage of the drug product whose approvals and data are provided. To the contrary, as we have discussed, the Hatch-Waxman Act foresaw and averted the potential loophole of a change in the salt of the active ingredient. (Emphasis added.)

The court in Pfizer did not discuss Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224, 10 USPQ 2d 1100 (E.D. Va. 1989); aff'd., 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990), although the Pfizer district court acknowledged the law of the federal circuit articulated in Glaxo. In Glaxo, much like Pfizer, there was a new member (cefurozime axetil) of the same active moiety as two previously approved salts (two sodium salts of cefuroxime). In Glaxo, the court found that since the new member (cefurozime axetil) was neither a salt nor an ester of a previously approved product, the new ester could support a patent term extension. Eligibility for patent term extension must be consistent with the rights derived from a patent term extension. Accordingly, if the rights derived from the extension of a patent based upon the regulatory approval of a salt encompass other compounds within the same active moiety, then extension based upon subsequent approvals of other compounds within the same active moiety must be barred. As Pfizer suggests this result, Glaxo must be treated as overruled, and the application for patent term extension dismissed since the active moiety in NEXIUM I.V.® is esomeprazole, which was previously approved in NEXIUM® and hence does not constitute the first commercial marketing or use.

In view of the above, the term of U.S. Patent No. 6,143,771 is NOT eligible for extension under 35 U.S.C. § 156 based upon the approval of the product NEXIUM® I.V. and the application for patent term extension, filed May 25, 2005, is dismissed.

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

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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. E-mail inquiries should be directed to Mary.Till@uspto.gov.

/s/
_____
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RE: NEXIUM® I.V.