



OCT 25 2005

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

In re U.S. Patent No. 6,489,346

Application for Patent Term Extension for:

ZEGERID® (omeprazole)

A notice of final determination of ineligibility was mailed on August 30, 2004, stating that an application for patent term extension that was filed on August 12, 2004 was dismissed as ineligible.

Applicant filed a reply on February 28, 2005, arguing that the patent should be entitled to patent term extension because the enteric coated, delayed-release omeprazole of Prilosec® should be considered a different active ingredient than the omeprazole of Zegerid®¹. Moreover, applicant argues that reliance upon *Arnold Partnership v. Dudas*, 362 F.3d 1338 (Fed. Cir. 2004), is misplaced, because there was no issue of enteric coating therein. Applicant argues that the Office should instead look to *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990), wherein a different delivery mechanism was allowed to distinguish one approval from another, and allow for patent term extension for a second approval. Applicant argues that the different absorption of omeprazole via Zegerid®, and the synergistic amount of sodium bicarbonate merit patent term extension for U.S. Patent No. 6,489,346. Finally, applicants argue that the New Drug Application for Zegerid® was submitted under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, and that section 505(b)(1) and 505(j) are different provisions of law. Accordingly, applicant argues that the prior approvals, being under different provisions of law, should not preclude patent term extension for Zegerid®.

In *Pfizer, Inc. v. Dr. Reddy's Laboratories*, 359 F.3d 1361 (Fed. Cir. 2004), the Federal Circuit provided guidance on what constitutes a "product" for purposes of FDA regulatory review. The *Pfizer* court, in determining that amlodipine maleate was covered by the patent term extension granted to Pfizer for amlodipine besylate, stated:

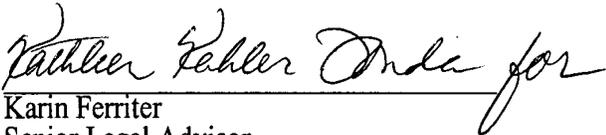
The FDA ruled that "the term 'active ingredient' as used in the phrase 'active ingredient including any salt or ester of the active ingredient' means active moiety." *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50358 (F.D.A. Oct. 3, 1994). The FDA has defined "active moiety" as "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." 21 C.F.R. § 314.108(a).

¹The trademark was registered on March 1, 2005.

Pfizer at 1366. *Glaxo*, like *Pfizer*, concerned different members of the same active moiety. However, in *Glaxo* the court had found that because the new member (cefurozime axetil) was neither a salt nor an ester of a previously approved product (two sodium salts of cefuroxime), 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 an active ingredient 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 reliance upon *Glaxo* appears inappropriate.

The assistance of your Office is requested in confirming that the approval of the product identified in the application, Zegerid® (omeprazole), was the first permitted commercial marketing or use of any active ingredient thereof under the provision of law under which regulatory review occurred. (35 U.S.C. 156(a)(5)(A)).

Telephone inquiries regarding this communication should be directed to the undersigned at (571)272-7744.



Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosures: Copy of application for patent term extension
Notice of Final Determination
Request for Reconsideration

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