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Washington, D.C. 20231

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,013,743

### NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 5,013,743 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on August 15, 1997. The application was filed by Takeda Chemical Industries, Ltd., 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 product known by the tradename PREVACID™ having the active ingredients lansoprazole and amoxicillin in delayed release capsules (NDA 20-877) and the active ingredients lansoprazole, amoxicillin and clarithromycin in delayed release capsules (NDA 20-876). PREVACID™ was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 17, 1997.

A determination has been made that U.S. Patent No. 5,013,743 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of PREVACID™.

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.

FDA's official records indicate that lansoprazole, amoxicillin and clarithromycin was previously approved for commercial marketing or use prior to the approval of PREVACID™. In a letter dated December 10, 1998, FDA stated:

A review of the Food and Drug Administration's official records indicates that these products were subject to a regulatory review period before their commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). In the patent term extension application, applicant acknowledges that all of the active ingredients in both products, i.e. lansoprazole, amoxicillin and clarithromycin, have previously been approved in other separate products. FDA records confirm that the approved products marketed under Prevacid™ do not represent the first permitted commercial marketing or use of the products, because other products containing the active ingredients lansoprazole, amoxicillin, and clarithromycin have previously been approved (see attached printouts listing those approved NDAs).

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. 5,013,743 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 . . .
  - (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.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredients in the approved product are lansoprazole, amoxicillin, and clarithromycin. As noted in the above FDA letter and shown in the attachment thereto (page AD 38 of the Patent and Exclusivity Data Appendix to Approved Drug Products with Therapeutic Equivalence Evaluations, 18th Edition, 1998) (Orange Book), and pages 3-26-28, 3-81, and 3-194 of the Prescription Drug Product List of the Orange Book, the active ingredients lansoprazole, amoxicillin, and clarithromycin were approved for commercial marketing and use prior to the approval of the applicant's product. Furthermore, the prior approval of the active ingredient lansoprazole in Prevacid (NDA 20-406) on May 10, 1995 by the Food and Drug Administration was under section 505 of the FDCA, the same provision of law under which regulatory review of the product PREVACID™ (NDA 20-877 and 20-876) occurred. The approval of the product clarithromycin in BIAXIN on October 31, 1991 and December 23, 1993 and the approval of the product amoxicillin, which was approved on December 1, 1982 (amoxicillin pediatric) and March 8, 1988 (TRIMOX) (see page 3-27 of the Prescription Product List) were also under section 505 of the FDCA. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's approval of lansoprazole, amoxicillin, and clarithromycin does not qualify as the first permitted marketing or use of any of the active ingredients. Since the approval of PREVACID™ (NDA 20-877 and 20-876) was not the first permitted marketing or use of any of the active ingredients thereof, the patent is not eligible for patent term extension based upon the regulatory review of PREVACID™ (NDA 20-877 and 20-876). See In re Fisons Pharmaceuticals Limited,

231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

In view of the above, the term of U.S. Patent No. 5,128,453 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product PREVACID™ (NDA 20-877 and 20-876) and the application for patent term extension, filed August 15, 1997, is dismissed.

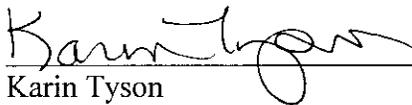
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
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Rockville, MD 20857

RE: PREVACID™  
FDA Docket No.: 97E-0047