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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,938,763

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,938,763, which claims the product ATRIDOX™, is ineligible for patent term extension under 35 U.S.C. § 156.

An application for extension of the patent term of U.S. Patent No. 4,938,763 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on October 23, 1998. The application was filed by Atrix Laboratories, 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 ATRIDOX™ having the active ingredient doxycycline hyclate. ATRIDOX™ was approved for commercial use and sale by the Food and Drug Administration (FDA) on September 3, 1998.

A determination has been made that U.S. Patent No. 4,938,763 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ATRIDOX™.

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.

The application for patent term extension states that the product ATRIGEL® Delivery System contains two active ingredients: doxycycline hyclate and polymeric formulation delivery system, both of which have been previously approved for commercial use or sale by the Food and Drug Administration. A review of the Prescription Drug Product List, of the text "Approved Drug Products with Therapeutic Equivalence Evaluations" (FDA's Orange Book), 18th Edition, 1998, page 3-125 and 3-125 (copy attached), reveals that many products containing the active ingredient doxycycline hyclate have been previously approved. For example, in oral capsule form, the products DOXY-LEMMON (50 mg) was approved on August 23, 1984, and DOXYCYCLINE HYCLATE (100 mg, Barr) was approved on January 28, 1983. Furthermore, doxycycline hyclate has also been approved in an injectable form with the products

DOXYCYCLINE (100 mg base/vial) on March 9, 1998. See also USPDI, Volume I, Drug Information for the Health Care Professional, Doxycycline Hyclate, pages 2828- 2829.

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. 4,938,763 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 ingredient in the approved product is doxycycline hyclate. The polymeric formulation delivery system included in syringe B of ATRIDOX™ is not an active ingredient since doxycycline hyclate, not the polymeric formulation system, provides the desired pharmacological activity for treatment of chronic adult periodontitis.¹ The prior approval under Section 510(k) of the Federal Food, Drug and Cosmetic Act of poly(DL-lactide) and N-methyl-2-pyrrolidone, ingredients of the polymeric formulation system, confirms that FDA does not consider these ingredients to be drugs and instead considers the polymeric formulation to be a medical device. As noted in the application for patent term extension and as shown in the Prescription Drug Product List of the Approved

¹The term "active ingredient" is defined in 21 CFR 60.3(b)(2) as "(2) any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

Drug Products with Therapeutic Equivalence Evaluations, for example), the active ingredient doxycycline hyclate had been approved for commercial marketing and use prior to the approval of the applicant's product. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's approval of doxycycline hyclate does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of ATRIDOX™ was not the first permitted marketing or use of the active ingredient thereof, the patent is not eligible for patent term extension based upon the regulatory review of ATRIDOX™. 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. 4,938,763 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product ATRIDOX™ and the application for patent term extension, filed October 23, 1998, is dismissed.

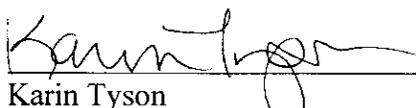
Any correspondence with respect to this matter should be addressed as follows:

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Washington, D.C. 20231

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

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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

Attachments