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Mailed: July 27, 2005

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,829,434

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 5,829,434 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on May 27, 2005. The application was filed by Schering Corporation, the owner of U.S. Patent No. 5,829,434 by virtue of the Assignment to Schering by the inventors. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a product which is a cap-activated inhalation-driven multi-dose dry powder inhaler containing mometasone furoate and anhydrous lactose. ASMANEX® TWISTHALER® was approved for commercial use and sale by the Food and Drug Administration (FDA) on March 30, 2005.

A determination has been made that U.S. Patent No. 5,829,434 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ASMANEX® TWISTHALER® .

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.

Applicants assert that ASMANEX® TWISTHALER® is the first permitted commercial marketing of the product following the regulatory review period. 35 U.S.C. § 156(f)(1) defines product as "(A) [a] drug product. (B) [a]ny medical device, food additive, or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act." In the present application, the product, the ASMANEX® TWISTHALER®, was subject to regulatory review under section 505(b) of the FFDCA, 21 U.S.C. § 355, not as a medical device under section 515 of the FFDCA, 21 U.S.C. § 360e.

Additionally, Applicants appear to have been granted a 3 year data exclusivity by the Food and Drug Administration under 21 C.F.R. § 314.108(b)(4) for a "new product." 21 C.F.R. § 314.108(b)(4)(iii) provides that the drug product contains an active moiety that was previously approved in another application under section 505(b) of the FFDCA. Regulatory review under section 505(b) of the FFDCA applies to new drugs. In the present application, the active ingredient, mometasone furoate is not a new drug, rather, mometasone furoate is the active ingredient in both ELOCON® and NASONEX®. Since the ASMANEX® TWISTHALER®

product is not the first permitted commercial marketing of mometasone furoate, U.S. Patent No. 5,829,434 does not appear to be eligible for patent term extension.

The FDA official records indicate that the active ingredient of ASMANEX® TWISTHALER®, mometasone furoate, was approved under § 505 of the FFDCA prior to the approval of ASMANEX® TWISTHALER®. As Applicants accurately represent, mometasone furoate was previously approved under 505 of the FFDCA for commercial use or sale as an ointment in ELOCON® and as a nasal spray in NASONEX® .

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. 5,829,434 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.)

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, ASMANEX® TWISTHALER® is mometasone furoate. As indicated in the Food and Drug Administration's "Orange Book," the active ingredient, mometasone furoate, had been approved for commercial marketing and use prior to the approval of the applicant’s product (enclosed report). Furthermore, the prior approval of the active ingredient, momeatsone furoate in ELOCON® by the Food and Drug Administration was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product ASMANEX® TWISTHALER® occurred. Applying the definition of “product” provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant’s product, ASMANEX® TWISTHALER®, does not qualify as the first permitted marketing or use of the active

ingredient. Since the approval of ASMANEX® TWISTHALER® was not the first permitted marketing or use of mometasone furoate, the patent is not eligible for patent term extension based upon the regulatory review of ASMANEX® TWISTHALER® which occurred under section 505(b) of the FFDCA, 21 U.S.C. 355. 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 USPQ2d 1628 (Fed. Cir. 1990).

In view of the above, the term of U.S. Patent No. 5,829,434 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product ASMANEX® TWISTHALER® and the application for patent term extension, filed May 27, 2005, is dismissed.

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

By mail: Mail Stop Patent Ext.
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. E-mail inquiries should be directed to Mary.Till@uspto.gov.

/s/

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
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Attention: Claudia Grillo

RE: ASMANEX® TWISTHALER®

Enclosure: Search Results from the Orange Book- Mometasone furoate