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Re: Patent Term Extension
Application for
U.S. Patent No. RE35,724

# FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156 FOR U.S. PATENT NO. RE35,724

This is in response to the application for extension of the term of U.S. Patent No. RE35,724 ("the '724 patent") filed under 35 U.S.C. § 156 ("the PTE Application) in the United States Patent and Trademark Office ("USPTO") on June 22, 1998, and the request for reconsideration filed on July 26, 1999 ("the Request"). The PTE Application was filed by Savient Pharmaceuticals, Inc. ("Applicant"), the current owner of the '724 patent, through the previous owner of record, Bio-Technology General Corp. Extension was sought based upon the premarket review of Mircette® under section 505 of the Federal Food Drug and Cosmetic Act ("FFDCA"). Because the Food and Drug Administration ("FDA") and the USPTO have determined that Applicant failed to comply with 35 U.S.C. § 156(a)(5)(A), Applicant's request for extension of the patent term of the '724 patent under 35 U.S.C. § 156(d)(1) is **DENIED** and its request for reconsideration is **DENIED**.

## A. Factual Background

On April 22, 1998, the FDA approved NDA No. 20-7134 for Mircette®, an oral contraceptive having as active ingredients desogestrel and ethinyl estradiol.

On June 22, 1998, Applicant timely filed a request for patent term extension in the USPTO (June 21, 1998 was a Sunday.) See 37 C.F.R. § 1.7.

On August 14, 1998, the USPTO requested FDA's assistance in determining the '724 patent's eligibility for patent term extension. The August 14, 1998, letter notes, in part:

> Our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156. The active ingredient of MIRCETTE™, desogestrel and ethinyl estradiol, have been previously approved in the products Ortho-Cept® and Desogen®.

In a letter dated October 7, 1998, FDA advised the USPTO that Mircette® was subject to a regulatory review period as required by 35 U.S.C. § 156(a)(4), but that their records indicated that the approval was not the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp 1224 (E.D. Va. 1989), aff'd, 894 f.2d. 392 (Fed. Cir. 1990).

On February 24, 1999, the USPTO issued a notice of final determination of ineligibility indicating that because Mircette® was not the first permitted commercial marketing or use of the product, as product is defined in 35 U.S.C. § 156(f), the request for patent term extension was dismissed as ineligible.

On August 2, 1999, Applicant submitted a request for reconsideration to the notice of final determination arguing that Mircette® was eligible because the product involved a novel sequence of administration of the previously approved ingredients, which results in an improvement in the activity of the contraceptive product. The improvement also allows a reduction in the dosage required to achieve contraception.

**B. Decision**

**1. 35 U.S.C. § 156(a)(5)(A) requires that the permission for the commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.**

35 U.S.C. § 156(a) provides (in part) that:
The term of a patent which claims a product ... shall be extended in accordance with this section ... if –

(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 the '724 patent, 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).

Applicant acknowledges that both active ingredients, desogestrel and ethinyl estradiol, were previously approved by the FDA, see page 2, second full paragraph. Additionally, both the USPTO (see USPTO's notice of final determination of February 24, 1999) and the FDA (see

FDA's letter of October 7, 1998) have concluded, and Applicant admits, that the prior approval of the active ingredients by the FDA were under section 505 of the FFDCA, the same provision of law under which regulatory review of the product Mircette® occurred.

In Arnold Partnership v. Dudas, 70 U.S.P.Q.2d 1311 (Fed. Cir. 2004), the Federal Circuit addressed the issue of a drug product with two active ingredients in the context of a patent term extension where each ingredient had been previously approved. There the court determined that the patent term restoration statute, 35 U.S.C. § 156, permits extension of the term for a drug product patent where applicant's permission to market the product is the "first permitted commercial marketing or use," with proper interpretation of the statute applying to an approval of a drug product with two active ingredients only if one of those active ingredients has not been previously approved for marketing, since the language of the statute requires examination of a patent's eligibility for extension on a component-by-component basis. The court cautioned that the statute was not susceptible to an alternate reading that would allow extension of a patent with two previously approved active ingredients if merely the combination thereof constitutes the "first permitted commercial marketing or use." In applying Arnold Partnership to the present application, extension is not proper here because Mircette® does not involve approval of a drug product where at least one of the active ingredients had not been previously reviewed and approved under section 505 of the FFDCA. Because the approval of Mircette® (desogestrel and ethinyl estradiol) was not the first permitted marketing or use of either active ingredient, Applicant fails to comply with the requirements of 35 U.S.C. 156(a)(5)(A) and therefore, the application for PTE must be **denied**.

**2. Applicant's arguments with respect to dosages of the active ingredients and administration protocol for Mircette® is unpersuasive**

As stated *supra*, Applicant acknowledges that both active ingredients have been previously reviewed and approved under the same section of the FFDCA as the review and approval of Mircette®. Applicant argues , however, that since a different dosage and administration protocol is employed, the Mircette® product "**will be** the first permitted commercial marketing or use of the product under Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355 (35 U.S.C. § 156(a)(5)(A))." See page 2 bridging page 3 of the Request. (Emphasis added). Arguments with respect to dosage and administration protocols have no bearing on determining compliance with 35 U.S.C. § 156(a)(5)(A). Although the benefit of decreasing the dosage of active ingredients desogestrel and ethinyl estradiol because of differences in administration protocols is interesting, such observations have no relevance in determining "first permitted commercial marketing or use of the product" as required by 35 U.S.C. 156(a)(5)(A). Because Applicant's arguments regarding dosage and administration protocol do not rebut the finding that the approval of Mircette® was not the first permitted commercial marketing or use of either active ingredient, Applicant fails to comply with the requirements of 35 U.S.C. 156(a)(5)(A) and therefore, the application for PTE must be **denied**.

## C. Conclusion

For the reasons stated above, Applicant's request for extension of the patent term of the '724 patent is **DENIED** and Applicant's request for reconsideration is **DENIED**.

This is considered a final agency action.

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

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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.

Brian E. Hanlon
Deputy Director
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for Patent Examination Policy

cc: Office of Regulatory Policy
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Attention: Beverly Friedman

Re: Mircette®
FDA Docket No.: 1998E-0795