Commissioner of Patents and Trademarks
Patent and Trademark Office (P.T.O.)

IN RE RECKITT & COLMAN PRODUCTS LIMITED
March 27, 1987

Richard E. Ficher, Esq.

***1** Bacon and Thomas

625 Slatens Lane - 4th Floor

Alexandria, VA 22314

Ronald L. Wilson

Health Assessment Policy Staff

Food and Drug Administration

5600 Fisher Lane

Rockville, MD 20857

Charles E. Van Horn

Director Patent Examining Group 120

Request for Patent Term Extension Under 35 U.S.C. § 156

ORDER VACATING INTERIM EXTENSION

Reckitt & Colman Products Limited (Reckitt), the owner of record in the Patent and Trademark Office (PTO), of U.S. Patent 3,433,791 (patent), in response to an order to show cause issued by the PTO on January 28, 1987, requests that a decision on the vacating of the interim extension granted on March 17, 1986 for U.S. Patent No. 3,433,791 as well as the final decision on the Reckitt application for extension of the term of the above patent be held in abeyance until a 'final' decision is rendered in Norwich Eaton Pharmaceuticals, Inc. v. Bowen, 808 F.2d 486 (6th Cir. 1987). Reckitt also requests that the patent term be extended until a final decision in the above litigation is rendered or until March 18, 1988, [FN1] whichever is earlier. For reasons hereinafter given, the above requests are denied and the interim extension granted on March 17, 1986 order is vacated ab initio.

FACTS

The PTO issued an order on March 17, 1986 granting an interim extension under 35 U.S.C. 156(e)(2) of the term of U.S. Patent 3,433,791 until 14 calendar days after the date a notice of appeal to the U.S. Court of Appeals for the Sixth Circuit was due in Norwich

Eaton Parmaceuticals, Inc. v. Bowen, supra, and in the event a notice of appeal was timely filed, until 14 calendar days after the entry of a decision by the U.S. Court of Appeals for the Sixth Circuit on any such appeal and, if no decision was rendered in such an appeal prior to March 17, 1987, the interim extension was set to expire on March 17, 1987. In re Reckitt, 230 USPQ 369 (Comm'r. Pats. 1986).

An appeal to the U.S. Court of Appeals for the Sixth Circuit from a judgment of the U.S. District Court for the Southern District of Ohio was timely filed on May 1, 1986. In a decision dated January 9, 1987, the Sixth Circuit reversed the district court and held that the Food and Drug Administration (FDA) determination that buprenorphine hydrochloride (BUPRENEX) had been approved on December 29, 1981 was a reasonable interpretation under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the regulations promulgated thereunder and was not in conflict with the expressed congressional intent. In so deciding the Sixth Court accepted the FDA interpretation of the language 'date of approval' to mean 'the date of [sic--on?] which the agency exercised its authority under the Federal Food, Drug, and Cosmetic Act to approve a new drug application' (Norwich, supra 808 F.2d at 492.). The FDA letter of December 29, 1981 approved the new drug application (NDA). It was the FDA position, accepted by the Sixth Circuit that 'Norwich could have marketed the drug at the time of the 1981 approval as a Schedule II drug. Its decision not to do so was a marketing decision, not a result compelled by law.' (Norwich, supra 808 F.2d at 492.). The Sixth Court thus found that the FDA determination that Buprenex had been approved in 1981 was proper.

***2** In a PTO order dated January 28, 1987, applicant was given thirty (30) days from the date of that order to show cause as to why the PTO should not issue an order vacating, ab initio, the interim extension granted on March 17, 1986 and further denying the application for extension of the patent term of U.S. Patent 3,433,791 as not being filed in accordance with the requirements of 35 U.S.C. 156(a)(3) as defined in 35 U.S.C. 156(d)(1).

In a response to the above order received in the PTO on February 27, 1987, applicant filed a request that:

1. A decision on whether the March 17, 1986 interim extension should be vacated ab initio and a final decision on Reckitt & Colman's application for extension of the buprenorphine patent term be held in abeyance until a final decision in the case of Norwich Eaton Pharmaceuticals, Inc., v. Bowen is rendered by the United States Supreme Court; and
2. The interim extension of the buprenorphine patent term be extended until a final decision in the Norwich litigation is rendered by the Supreme Court or until March 18, 1988, whichever is earlier.

DISCUSSION

The term of an appropriate patent may be extended if an application for extension is submitted by the owner of the patent in accordance with the requirements of 35 U.S.C. 156(d). See 35 U.S.C. 156(a)(3). Such an application must be submitted within the sixty day period beginning on the date the product received permission under the

provision of law under which the applicable regulatory review period occurred for commercial marketing or use. 35 U.S.C. 156(d)(1).

The PTO is responsible for determining eligibility of an application for patent term extension. The FDA is responsible under 35 U.S.C. 156 for the determination of the length of the applicable regulatory review period for the product which forms the basis for the application for patent term extension. 35 U.S.C. 156(d)(2)(A). A human drug product receives permission for commercial marketing and use under Section 505 of the FFDCA when a NDA is approved by the FDA. The regulatory review period for a human drug product is defined for the purposes of 35 USC 156 to end on the date the NDA was approved under section 505 of the FFDCA. 35 U.S.C. 156(g)(1)(B)(ii). The FDA has determined that the NDA for BUPRENEX was approved on December 29, 1981 and that Norwich could have marketed the drug at the time of the 1981 approval as a Schedule II drug. This determination was approved by the Sixth Circuit on January 9, 1987. Norwich Eaton Pharmaceuticals, Inc. v. Bowen, supra%u.

Since the application for extension of the term of U.S. Patent No. 3,433,791 was filed (August 26, 1985), more than sixty days after the product buprenorphine hydrochloride (BUPRENEX) was approved for commercial marketing or use (December 29, 1981), the terms of 35 U.S.C. 156(a)(3) have not been met. This patent is not eligible for patent term extension under 35 U.S.C. 156. An interim extension under 35 U.S.C. 156(e)(2) is not authorized unless the Commissioner determines that the subject patent is eligible for extension under 35 U.S.C. 156.

***3** In the response of February 27, 1987, applicant argues that the current legal and factual posture of this matter parallels in all relevant respects that in existence at the time of the PTO's March 17, 1986 Order. It is applicant's position that continuation of the relief afforded at that time is both necessary and appropriate.

Contrary to applicant's arguments, the legal and factual posture of the matter has changed significantly compared to that which existed at the time of the March 17, 1986 Order. In issuing the Order granting an interim extension the PTO was acting in harmony with a decision of a district court. To issue a new interim extension at this time would place the PTO in direct conflict with the decision of the Sixth Circuit discussed above. The order granting the interim extension clearly stated that the final determination in the Norwich litigation could render the interim extension invalid should it be determined that the FDA approved the NDA for BUPRENEX more than sixty days prior to the date Reckitt filed its patent term extension application. As noted, the above decision approved the FDA position that the NDA for the product BUPRENEX was approved more than sixty days prior to the date Reckitt filed its patent term extension application. Accordingly, the interim extension is invalid and any further interim extension would be contrary to the authorization granted to the Commissioner in 35 USC 156(e)(2).

While the March 17, 1986 Order did reflect concern on the part of the PTO as to the legal and practical ability to extend the term of the patent which might have expired in the event of a final judicial determination in favor of Norwich, the arguments related thereto have been rendered moot by the expiration of the now void ab initio interim extension previously granted. [FN2] In accordance with the March 17,

1982 Order and in the absence of any application for further interim extension pending a final decision in the Norwich litigation, the now void ab initio interim extension of the term of U.S. Patent No. 3,433,791 expired on January 23, 1987 or 14 calendar days following the decision of January 9, 1987 by the Sixth Circuit. Should it subsequently be necessary for the PTO to reconsider the adverse decision of eligibility for the subject application, the question of extending the term of previously expired patent can then be addressed.

While the ultimate outcome of the Norwich litigation may not be final, there appears to be no legitimate basis for delay on the part of the PTO from issuing a decision which is consistent with the Sixth Circuit decision and clarifies the status of the application for patent term extension. The PTO seeks to avoid confusion on the part of the public or interested third parties concerning whether the expiration of the now void ab initio interim extension and thus expiration of U.S. Patent No. 3,433,791 which could result from delay in acting in accordance with Sixth Circuit decision on the matters here involved.

***4** The requested stay in these proceedings as to the issues presented herein is not appropriate. Applicant's request does not meet the four factor test determinative as to whether a stay should be granted in this type of proceeding. First, applicant has not demonstrated that there is a likelihood of a grant of the petition for writ of certiorari or information which would indicate a likelihood of success on the merits if certiorari is granted. Second, applicant has not demonstrated the likelihood that applicant will be irreparably harmed absent a stay. Third, the prospect that others will be harmed if the stay is granted has not been addressed by applicant. Fourth, the public interest which would be served in granting the stay has not been discussed. Wisconsin GasCo. v. FERC, 758 F.2d 669, 673-674 (D.C. Cir. 1985).

The request that the interim extension be extended until a final decision is the Norwich litigation is rendered is inappropriate. An interim extension under 35 U.S.C. 156(e)(2) is not authorized unless the Commissioner determines that the subject patent is eligible for extension under 35 U.S.C. 156. For the reasons herein stated, it has been determined that the application is not eligible for extension. The issuance of an interim extension as requested would be contrary to the law. 35 U.S.C. 156(e)(2).

DECISION

The interim extension of the term of U.S. Patent 3,433,791 issued in the March 16, 1986 Order is hereby vacated ab initio.

The PTO concludes that U.S. Patent No. 3,433,791 is not eligible for extension of the patent term under 35 U.S.C. 156 since the application for extension was not filed in accordance with the requirement of 35 U.S.C. 156(a)(3) as defined in 35 U.S.C. 156(d)(1).

The request by applicant (Reckitt & Colman, Ltd) that the vacating of the interim extension and the final decision on eligibility on the application for patent term extension of U.S. Patent No. 3,433,791 be held in abeyance until a 'final' decision is rendered in the case of

Norwich Eaton Pharmaceuticals, Inc., v. Bowen is DENIED.

Similarly the request by applicant that the interim extension of the patent term be extended until a final decision in the Norwich litigation is rendered by the Supreme Court or until March 18, 1988, whichever is first, is DENIED.

The application for extension of the term of U.S. Patent No. 3,433,791 is DENIED.

FN1. An extension to March 18, 1988 would correspond to the maximum extension of the term of U.S. Patent 3,433,791, if the application is determined to be eligibile for patent term extension under 35 U.S.C. 156.

FN2. The March 17, 1986 Order stated in pertinent part:
'an interm extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent 3,433,791 is granted----- until 14 calendar days after entry of a decision by the U.S. Court Appeals for the Sixth Circuit on the appeal' . . . .'

2 U.S.P.Q.2d 1450

END OF DOCUMENT