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

IN RE ALCON LABORATORIES, INC.
Patent No. 3,691,279
September 1, 1989

Donald J. Quigg

Commissioner of Patents and Trademarks

Decision on Request for Interim Extension or Conditional Stay Order

***1** An application for patent term extension has been filed under 35 U.S.C. § 156. In a paper filed August 23, 1989, Alcon Laboratories, Inc. (Alcon), applicant for extension of the term of U.S. Patent No. 3,691,279, has made the following alternative requests:

(1) that the Commissioner grant an interim term extension of one year for Patent No. 3,691,279 from the expiration date of that patent (September 12, 1989) under 35 U.S.C. § 156(e)(2); or

(2) in the event that the Commissioner issues a decision denying Alcon's application for patent term extension, that the Commissioner issue an order staying the effect of any adverse decision, conditioned upon Alcon seeking judicial review within thirty days of the adverse decision. For the reasons noted below, these requests are denied.

## Facts

An application for patent term extension of U.S. Patent No. 3,691,279 was filed by Alcon on October 17, 1988. The term of that patent is set to expire on September 12, 1989. The patent is said to claim tobramycin, one of the two active ingredients in a human drug product known as Tobradex.

On June 16, 1989, an order to show cause was issued asking Alcon to show cause why the application for patent term extension should not be denied. The order provided a tentative analysis of the relevant statutory provisions as applied to the subject patent and the human drug product Tobradex, and gave Alcon one month to respond. Alcon filed responses to the order on August 11 and 21, 1989.

The application for patent term extension has been denied in a decision entered concurrently with this decision.

## Discussion

The Commissioner has authority to issue an interim extension of a patent term under the circumstances defined in § 156(e)(2) as follows:

If the term of a patent for which an application has been submitted under subsection (d) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the

Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension. [Emphasis supplied]
An interim extension is not authorized under the circumstances of this case since a decision to deny a certificate of extension has been made before the term of Patent No. 3,691,279 will expire, and an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent is eligible for extension. In this case, a determination is being made that the patent is not eligible for patent term extension. It is also noted that Alcon did not file the request for an interim extension of the subject patent at least three months prior to the expiration date of the patent. 37 CFR § 1.760.

***2** Alcon has requested, as an alternative to an interim extension of the patent term, that the operation and effect of a denial of the application for patent term extension be stayed contemporaneously with such a decision so as to allow Alcon adequate time within which to seek judicial review. Alcon asserts, without explanation or factual support, that such action would serve to avert the extreme and potentially irrevocable prejudice that Alcon would otherwise stand to suffer.

The Patent and Trademark Office (PTO) is aware that tobramycin has been available for medical use since the mid-1970s, [FN1] and approved for commercial marketing as an opthalmic product (Tobrex) in the United States since December 1980. [FN2] When the patent on tobramycin expires on September 12, 1989, no organization will be excluded from making, using or selling tobramycin by Patent No. 3,691,279.

Among the compromises embodied in the Drug Price Competition and Patent Term Restoration Act of 1984 were provisions to spur approval and availability of generic drugs (after the term of the relevant patent expired), while allowing patent term restoration for certain patented drugs. Fisons plc v. Quigg, 8 U.S.P.Q.2d 1491, 1500 (D.D.C.1988), aff'd 876 F.2d 99, 10 U.S.P.Q.2d 1869 (Fed.Cir.1989). Once the patent expires, interested parties are free to market FDA-approved generic versions of the drug product formerly protected by the patent. For these reasons, there is a public interest for not staying the effectiveness of a decision that denies an extension of the term of a patent which is not eligible for patent term extension under 35 U.S.C. § 156.

Alcon's request for a "stay" of the effect of the decision denying a patent term extension is analogous to a motion for TRO or preliminary injunction. There are generally four factors considered in evaluating whether a TRO or injunction should be entered. [FN3] Consideration of those factors in this case demonstrates that a stay should not be entered by PTO in this case.

First, the record demonstrates that Alcon is not entitled to any patent term extension and Alcon's application for patent term extension has been denied. If judicial review is sought, presumably the reviewing court will give some deference to the PTO's interpretation of § 156--a statute PTO is charged with administering. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984); Chula Vista City School District v. Bennett, 824 F.2d 1573, 1579-80 (Fed.Cir.1987), cert. denied, 108 S.Ct. 774 (1988). Accordingly, Alcon

has not made a showing that it is likely to succeed on the merits.

Second, Alcon will not suffer irreparable harm if a stay is not entered. Indeed, in this case, lack of irreparable harm may be dispositive. To lawfully market a drug in the United States, an entity or person must have a new drug application (NDA) or an abbreviated new drug application (ANDA) approved by FDA (21 U.S.C. § § 355, 357). The record before PTO does not establish that any entity, other than Alcon, has approval to market a product corresponding to tobramycin or Tobradex. Hence, on the record before PTO, no entity or person, other than Alcon may lawfully market tobramycin or Tobradex in the United States. It follows that failure to grant an interim extension will not result in irreparable harm to Alcon.

***3** Third, inasmuch as PTO does not make and sell drugs, issuance of a stay would not directly affect PTO. Instead, PTO represents, in this case, the public interest.

Fourth, as noted earlier, upon expiration of the subject patent, other entities and persons should be free to take the steps necessary to commercially market and use drugs corresponding to tobramycin and Tobradex. Granting an interim extension would preclude others from marketing these drugs, assuming an ANDA is approved, during the period of the interim extension. Accordingly, granting an interim extension could have an adverse effect upon competition with respect to drugs corresponding to tobramycin and Tobradex. An interim extension would be particularly harmful to other drug companies (generic or research intensive) who may be in the process of seeking an NDA or ANDA approval at this time and who might obtain that approval in the very near future. Assessment of this fourth factor is made somewhat difficult, because the pendency of NDA's and ANDA's is normally maintained in confidence by FDA unless the party seeking the NDA or ANDA makes its application known.

The "first" and "second" factors demonstrate, in this case, that a stay should not be entered.

## Decision

For the reasons given above, and for the reasons given in the decision denying patent term extension eligibility to the patent directed to tobramycin, the requests for an interim extension of the term of U.S. Patent No. 3,691,279 under 35 U.S.C. § 156(e)(2), and for an order staying the effect and operation of the decision denying the application for patent term extension of U.S. Patent No. 3,691,279 are DENIED.

FN1. Exhibit C of the application for patent term extension, page 2, under Pharmacology and Microbiology.

FN2. Letter from FDA to PTO dated November 30, 1988, indicating that the NDA 50-541 for the product Tobrex, containing tobramycin as the active ingredient, was approved on December 12, 1980.

FN3. The four factors are set out in numerous cases, including Virginia Petroleum Jobbers Ass'n v. Federal Power Commission, 259 F.2d 921 (D.C.Cir.1958); Washington Metropolitan Area Transit Commission v. Holiday Tours, Inc., 559 F.2d 841, 842-843 (D.C.Cir.1977); Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Bradley, 756 F.2d 1048, 1054-55 (4th Cir.1985); Wetzel v. Edwards, 635 F.2d 283 (4th Cir.1980); Telvest, Inc. v. Bradshaw, 618 F.2d 1029 (4th Cir.1980); Maryland Undercoating Co., Inc. v. Payne, 603 F.2d 477 (4th Cir.1979); and Blackwelder Furniture Co. of Statesville, Inc. v. Selig Mfg. Co., 550 F.2d 189 (4th Cir.1977).

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