

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re SmithKline Beecham Corporation :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 4,197,297 : INTERIM EXTENSION

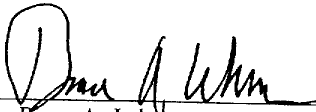
On March 21, 1997, Neurex Corporation, an agent of SmithKline Beecham Corporation, the owner of record of U.S. Patent No. 4,197,297, filed an application under 35 U.S.C. § 156(d)(5) for interim extension of the term of U.S. Patent No. 4,197,297. The patent claims the active ingredient, fenoldopam mesylate, in the human drug product "CORLOPAM®" and methods of use of said active ingredient. The application indicates, and the Food and Drug Administration (FDA) has confirmed, that the product is currently undergoing a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the FDA for permission to market or use the product commercially. The original term of the patent expires on April 8, 1997.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period may extend beyond the date of expiration of the patent, interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,197,297 is granted for a period of one year from the original expiration date of the patent.

APR - 7 1997

Date



Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks