UNITED STATES PATENT AND TRADEMARK OFFICE

In re University of Rochester Request for Patent Term Extension

U.S. Patent No. 5,360,897

ORDER GRANTING

INTERIM EXTENSION

On April 14, 2000, University of Rochester, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 5,360,897, through its appointed agent, American Home Products Corporation, filed an application under 35 U.S.C. § 156, requesting an extension of 1,086 days. The original expiration date of the patent is June 16, 2004. The patent claims the human drug product "PREVNAR®" vaccine, a pneumococcal 7-valent conjugate vaccine (Diphtheria CRM₁₉₇ Protein). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,360,897 is granted for a period of one year from the original expiration date of the patent, until June 16, 2005.

Date

Jon W. Dud**a**s

Acting Under Secretary of Commerce for Intellectual Property and

Acting Director of the United States Patent and Trademark Office