In re L’Oreal S.A.
Request for Patent Term Extension
U.S. Patent No. 4,585,597 : CERTIFICATE OF
: INTERIM EXTENSION

On April 30, 2004, patent owner, L’Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl™ SX (ecamsule) in the human drug product ANTHÉLIOS™ SP, a method of use of ecamsule, and a method of manufacturing ecamsule. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product ANTHÉLIOS™ SP (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The patent was previously extended for a term of one year.

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 will continue beyond the extended expiration date of the patent (June 16, 2004), an interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2005.

Date 6/24/04

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office