

SEP - 2 1999



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OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Ted K. Ringsred
3M/Office of Intellectual Property Counsel
P.O. Box 33427
St. Paul, MN 55133-3427

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,689,338

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,689,338, which claims the human drug product ALDARA™ (imiquimod) and the method of use of ALDARA™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods. In the absence of such request for reconsideration or election of U.S. Patent No. 5,238,944, the Commissioner will issue a certificate of extension of the above-identified patent, under seal, for a period of five years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of October 15, 1998 (63 Fed. Reg. 55398). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,254) + 217 \\ &= 1,844 \text{ days (5.05 years)}\end{aligned}$$

Since the regulatory review period began September 1, 1987, after the patent issue date (August 25, 1987), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Applicant has also filed an application for patent term extension of U.S. Patent No. 5,238,944 based upon the regulatory review of ALDARA™. No more than one patent may be extended for

a regulatory review period of a single product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different eligible patents based upon the same regulatory review period for a product, the certificate of extension is issued to the eligible patent having the earliest date of issuance unless applicant elects a different eligible patent. Therefore, only one of above-identified patent and U.S. Patent No. 5,238,944 can be extended based upon the regulatory review period of ALDARA™. Accordingly, applicant is required to elect a single patent upon which the extension will be based. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted and the application for U.S. Patent No. 5,238,944 will be dismissed.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.	4,689,338
Granted:	August 25, 1987
Original Expiration Date ¹ :	August 25, 2004
Applicant:	John F. Gerster
Owner of Record:	Riker Laboratories
Title:	1H-Imadazo[4,5-C]Quinolin-4-Amines and Antiviral Use
Classification:	514/293
Product Trade Name:	ALDARA™ (imiquimod)
Term Extended:	5 years
Expiration Date of Extension:	August 25, 2009

Any correspondence with respect to this matter should be addressed as follows:

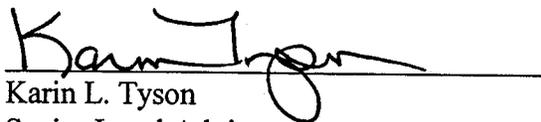
By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

¹Subject to the provisions of 35 U.S.C. § 41(b).

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: ALDARA™
FDA Docket No.: 97E-0270