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Amy E. Hamilton
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Patent Division/AEH
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Indianapolis, IN 46285

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,048,306

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,048,306, which claims the human drug product DYNABAC® (dirithromycin), is eligible for patent term extension under 35 U.S.C. § 156 for a period of 1,626 days from the original expiration date of the patent, September 13, 1994. See 35 U.S.C. § 156(d)(5)(E)(i).

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 9, 1996 (61 Fed. Reg. 41,636). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,687) + 782 \\ &= 1,626 \text{ days (4.45 years)}\end{aligned}$$

Since the regulatory review period began September 16, 1988 (the date the Investigational New Drug application was removed from clinical hold), after the patent issue date (September 13, 1977), 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.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

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. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,626 days.

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

U.S. Patent No.	:	4,048,306
Granted	:	September 13, 1977

Original Expiration Date : September 13, 1994
Applicant : Roland Maier et al.
Owner of Record : Boehringer Ingelheim GmbH
Title : Aldehyde-Erythromycyclamine
Condensation Products
Classification : 424/180
Product Trade Name : DYNABAC®
Term Extended : 1,626 days
Expiration Date of Extension : February 25, 1999

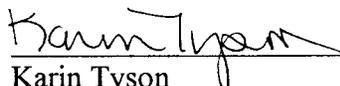
Any correspondence with respect to this matter should be addressed as follows:

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

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

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

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



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

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: DYNABAC®
FDA Docket No.: 96E-0154