

MAY - 6 1998



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Tom M. Moran
Cooley Godword Castro Huddleson & Tatum
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155

Re: Patent Term Extension
Application for
U.S. Patent No. 5,021,458

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,021,458, which claims the human drug product MENTAX® (butenafine hydrochloride) and a method of use of MENTAX® (butenafine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 866 days.

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 866 days.

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 April 21, 1997 (62 Fed. Reg. 19324). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (638) + 563 \\ &= 882 \text{ days} \end{aligned}$$

Since the regulatory review period began July 7, 1993, after the patent issue date (June 4, 1991), 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.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 882 days, would extend the patent from its original expiration date June 4, 2008 (35 U.S.C. § 154) to November 3, 2010, which is beyond the 14-year limit (the approval date is October 18, 1996, thus the 14 year limit is October 18, 2010). The period of extension is thus limited to October 18, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 4, 2008, to and including October 18, 2010, or 866 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

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

U.S. Patent No.:	5,021,458
Granted:	June 4, 1991
Original Expiration Date ¹ :	June 4, 2008
Applicant:	Tetsuya Maeda et al.
Owner of Record:	Kaken Pharmaceutical Co., Ltd.
Title:	Amine Derivatives and Fungicides Containing the Same
Classification:	514/655
Product Trade Name:	MENTAX® (butenafine hydrochloride)
Term Extended:	866 days
Expiration Date of Extension:	October 18, 2010

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

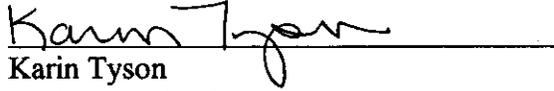
By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

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

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

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

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



Karin Tyson
Senior 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: MENTAX® (butenafine hydrochloride)
FDA Docket No.: 97E-0047