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MAY - 5 1998

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,639,436

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,639,436, which claims the human drug product GLYSET™ (Mitigol), 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. 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 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 July 18, 1997 (62 Fed. Reg. 38561). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (4,544 - 1,285) + 356 \\ &= 1,986 \text{ days (5.44 years)}\end{aligned}$$

Since the regulatory review period began July 22, 1983, before the patent issued (January 27, 1987), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 22, 1983 to January 27, 1987 is 1,285 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) 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 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.

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

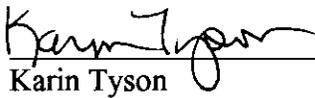
U.S. Patent No.: 4,639,436

Granted: January 27, 1987
Original Expiration Date¹: January 27, 2004
Applicant: Bodo Junge et al.
Owner of Record: Bayer AG
Title: Antidiabetic 3,4,5-Trihydroxypiperidines
Classification: 514/24
Product Trade Name: GLYSET™ (Mitigol)
Term Extended: Five years
Expiration Date: January 27, 2009

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

By mail: Assistant Commissioner for Patents By FAX: (703) 308-6916
 Box Patent Ext. Attn: Special Program Law Office
 Washington, D.C. 20231

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: GLYSET™ (Mitigol)
FDA Docket No.: 97E-0077