



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

MAR 20 1997

Barbara A. Shimei, Esq.
Bayer Corporation
400 Morgan Lane
West Haven, CT 06516

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,904,769

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,904,769, which claims the human drug product PRECOSE® (acarbose), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 922 days.

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 May 30, 1996 (61 Fed. Reg. 27085). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (161) + 1,858 \\ &= 1939 \text{ days (5.3 years)} \end{aligned}$$

Since the regulatory review period began March 23, 1980, before the patent issued (February 27, 1990), 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 March 23, 1980 to February 27, 1990 is 3,628 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 3,789 - 3,628 = 161 days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

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 (September 6, 1995) when added to the period of extension calculated above (1,939 days) cannot exceed fourteen years. The period of extension is thus limited to September 6, 2009, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of seventeen years (35 U.S.C. § 154) would expire on February 27, 2007, the period of extension is the number of days to extend the term of the patent from its expiration date to and including September 6, 2009, or 922 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further 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 922 days.

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

U.S. Patent No.	:	4,904,769
Granted	:	February 27, 1990
Original Expiration Date	:	February 27, 2007
Applicant	:	Erich Rauenbusch
Owner of Record	:	Bayer Aktiengesellschaft
Title	:	Highly Pure Acarbose
Classification	:	536/17.2
Product Trade Name	:	PRECOSE® (acarbose)
Term Extended	:	922 days
Expiration Date of Extension	:	September 6, 2009

Any correspondence from applicant 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 Karin Tyson at (703) 306-3159.



Hiram H. Bernstein
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: PRECOSE® (acarbose)
FDA Docket No.: 95E- 0385