



APR 25 1997

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,935,437

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,935,437, which claims the human drug product ARIMIDEX®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 565 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 August 27, 1996 (61 Fed. Reg. 44,069). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,062) + 274 \\ &= 805 \text{ days (2.2 years)} \end{aligned}$$

Since the regulatory review period began May 2, 1992, after the patent issue date (June 19, 1990), 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 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 plus the period of extension cannot extend beyond fourteen years after the date of approval of the approved product (December 27, 1995). The period of extension is thus limited to December 27, 2009, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of twenty years from the earliest applicable filing date (35 U.S.C. § 154) would expire on June 10, 2008, the period of extension is the number of days to extend the term of the patent from its expiration date to and including December 27, 2009, or 565 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 565 days.

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

U.S. Patent No.	:	4,935,437
Granted	:	June 19, 1990
Original Expiration Date	:	June 10, 2008
Applicant	:	Philip N. Edwards, et al.
Owner of Record	:	ZENECA Limited
Title	:	(Substituted Aralkyl) Heterocyclic Compounds
Classification	:	514/383
Product Trade Name	:	ARIMIDEX®
Term Extended	:	565 days
Expiration Date of Extension	:	December 27, 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

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: ARIMIDEX®
FDA Docket No.: 96E-0153