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

Chief IP Counsel, Pharmaceuticals  
Zeneca Corporation  
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Wilmington, DE 19850-15437

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,859,692

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,859,692, which claims the human drug product ACCOLATE® (zafirlukast) and a method of use of the human drug product ACCOLATE® (zafirlukast), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,496 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 1,496 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 April 4, 1997 (62 Fed. Reg. 16,164). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,651 - 516) + 459 \\ &= 1,527 \text{ days} \end{aligned}$$

Since the regulatory review period began March 24, 1988, before the patent issued (August 22, 1989), 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 24, 1988 to August 22, 1989 is 516 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.) 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 (September 26, 1996) plus any patent term extension under § 156 cannot exceed fourteen years. The period of extension calculated above, 1,527 days, would extend the patent to October 27, 2010, which is beyond the 14 year limit (14 years after the approval date is September 26, 2010) set forth in 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 expiration date, August 22, 2006, to and including September 26, 2010, or 1,496 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.	:	4,859,692
Granted	:	August 22, 1989
Original Expiration Date	:	August 22, 2006
Applicant	:	Peter R. Bernstein, et al.
Owner of Record	:	Zeneca, Inc.
Title	:	Heterocyclic Amide Derivatives and Pharmaceutical Use
Classification	:	514/381
Product Trade Name	:	ACCOLATE® (zafirlukast)
Term Extended	:	1,496 days
Expiration Date of Extension	:	September 26, 2010

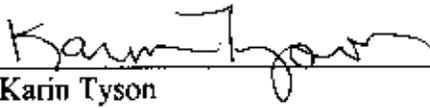
Any correspondence with respect to this matter should be addressed as follows:

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

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  
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RE: ACCOLATE® (zafirlukast)  
FDA Docket No.: 96E-0507