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Washington, D.C. 20231

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,861,584

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,861,584, which claims a method of using the human drug product IVY BLOCK® (bentoquatam), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,458 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 1,458 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 March 17, 1997 (62 Fed. Reg. 12652). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,946) + 698 \\ &= 1,671 \text{ days (4.58 years)} \end{aligned}$$

Since the regulatory review period began June 2, 1989, after the patent issue date (August 29, 1989), 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, 1,671 days, would extend the patent from August 29, 2006 (35 U.S.C. § 154) to March 27, 2011, which is beyond the 14-year limit (the approval date is August 26, 1996, thus the 14 year limit is August 26, 2010). The period of extension is thus limited to August 26, 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, August 29, 2006, to and including August 26, 2010, or 1,458 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.:	4,861,584
Granted:	August 29, 1989
Original Expiration Date ¹ :	August 29, 2006
Applicant:	Thomas W. Powell, Jr. et al.
Owner of Record:	United Catalysts, Inc.
Title:	Allergen Absorbent and Blocking Aerosol Composition
Classification:	424/79
Product Trade Name:	IVY BLOCK® (bentoquatam)
Term Extended:	1,458 days
Expiration Date of Extension:	August 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

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: IVY BLOCK® (bentoquatam)
FDA Docket No.: 96E-0465