

JUL 28 1998



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

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New York, NY 10036

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,599,353

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,599,353, which claims a method of use of the human drug product XALATAN Sterile Ophthalmic Solution™ and the human drug product XALATAN Sterile Ophthalmic Solution™ (latanoprost), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,116 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 1,116 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 4, 1997 (62 Fed. Reg. 16162). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,519) + 356 \\ &= 1,116 \text{ days} \end{aligned}$$

Since the regulatory review period began April 20, 1991, after the patent issue date (July 8, 1986), 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.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to 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.	:	4,599,353
Granted	:	July 8, 1986

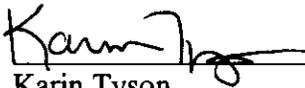
Original Expiration Date : July 8, 2003  
Applicant : Laszlo Z. Bito  
Owner of Record : The Trustees of Columbia University  
in the City of New York  
Title : Use of Eicosanoids and Their  
Derivatives for Treatment of Ocular  
Hypertension and Glaucoma  
Classification : 514/530  
Product Trade Name : XALATAN Sterile Ophthalmic  
Solution™ (latanoprost)  
Term Extended : 1,116 days  
Expiration Date of Extension : July 28, 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

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: XALATAN  
FDA Docket No.: 96E-0503