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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,019,369

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,019,369, which claims the method of use of the human drug product DaunoXome® (daunorubicin citrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 680 days. U.S. Patent No. 5,019,369 has an original expiration date of May 28, 2008, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 680 days will result in an extended expiration date of April 8, 2010.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to the requirement for an election 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 reply, the Commissioner will issue a certificate of extension, under seal, for a period of 680 days in the above-identified patent.

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 March 21, 1997 (62 Fed. Reg. 13,651). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,629 - 992) + 1,142 \\ &= 1,461 \text{ days} \end{aligned}$$

Since the regulatory review period began September 8, 1988, before the patent issued (May 28, 1991), 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 September 8, 1988 to May 28, 1991 is 992 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: $1,629 - 992 = 637$ days.) 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 (April 8, 1996) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above

1,461 days, would extend the patent to May 28, 2012, which is beyond the 14 year limit (14 years after the approval date is April 8, 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 original expiration date, May 28, 2008, to and including April 8, 2010, or 680 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

It is noted that applicant has also filed applications for patent term extension of U.S. Patent Nos. 5,435,989 and 5,441,745 based upon the regulatory review of the product DaunoXome®. No more than one patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted. Accordingly, unless another patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 680 days.

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

U.S. Patent No.	:	5,019,369
Granted	:	May 28, 1991
Original Expiration Date	:	May 28, 2008
Applicant	:	Cary A. Presant et al.
Owner of Record	:	NeXstar Pharmaceuticals, Inc.
Title	:	Method of Targeting Tumors in Humans
Classification	:	424/1.1
Product Trade Name	:	DaunoXome® (daunorubicin citrate)
Term Extended	:	680 days
Expiration Date of Extension	:	April 8, 2010

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 the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
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RE: DaunoXome®
FDA Docket No.: 96E-0288