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Charles E. Van Horn  
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.  
1300 I Street, N.W.  
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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,441,745

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,441,745, 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 238 days. U.S. Patent No. 5,441,745 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 238 days will result in an extended expiration date of January 21, 2009.

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 request for reconsideration and if the above-identified patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 238 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 March 21, 1997 (62 Fed. Reg. 13,651). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,629 - 1,629) + 1,142 - 904 \\ &= 238 \text{ days} \end{aligned}$$

Since the regulatory review period began September 8, 1988, before the patent issued, August 15, 1995, 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). The testing phase of an approved product is defined as the period beginning on the date that an exemption under subsection 505(i) of the Federal Food Drug and Cosmetic Act became effective for the approved product, September 8, 1988, and ending on the date an application for the approved product was initially submitted under section 507, February 22, 1993. Since both of these dates were before the issue date of the patent, none of the testing phase has been considered. The approval phase of a product begins on the date the application for the approved product was initially submitted. For DaunoXome®, this date was February 22, 1993, which was before the issue date of the patent, August 15, 1995. Accordingly, since from February 22, 1993 to August 15, 1995 is 904 days; this period is subtracted from the number of days occurring in the

approval phase according to the FDA determination of the length of the regulatory review period: 1,142 - 904 = 238 days. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year exception of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to 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. 5,019,369 and 5,435,989 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 dismissed. (The application for patent term extension for U.S. Patent No. 5,019,369 will be granted.) Accordingly, if the above-identified patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 238 days.

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

U.S. Patent No.	:	5,441,745
Granted	:	August 15, 1995
Original Expiration Date	:	May 28, 2008
Applicant	:	Cary A. Presant et al.
Owner of Record	:	NcXstar Pharmaceuticals, Inc.
Title	:	Method of Delivering Micellular Particles Encapsulating Chemotherapeutic Agents to Tumors in the Body
Classification	:	424/450
Product Trade Name	:	DaunoXome® (daunorubicin citrate)
Term Extended	:	238 days

Expiration Date of Extension : January 21, 2009

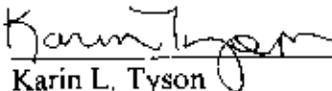
Any correspondence from applicant with respect to this matter should be addressed as follows:

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-0286