

SEP - 2 1999



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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,897,255

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,897,255, which claims the method of making the human drug product Verluma™ (Technetium Tc 99m Nofetumomab Merpentan), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,298 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 1,298 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 July 10, 1998 (63 Fed. Reg. 37597). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (925 - 925) + 2,435 - 41 \\ &= 2,394 \text{ days} \end{aligned}$$

Since the testing phase of the regulatory review period began June 11, 1987 and ended December 21, 1989, before the patent issued (January 30, 1990), none of the testing phase has been considered. Moreover, since the approval phase of the regulatory review period began December 21, 1989, before the patent issued, only that part of the approval phase 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 December 21, 1989 to January 30, 1990 is 41 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 plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 2,394 days, would extend the patent from January 30, 2007 (35 U.S.C. § 154) to August 20, 2013, which is beyond the 14-year limit (the approval date is August 20, 1996, thus the 14 year limit is

August 20, 2010). The period of extension is thus limited to August 20, 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, January 30, 2007, to and including August 20, 2010, or 1,298 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.	:	4,897,255
Granted	:	January 30, 1990
Original Expiration Date	:	January 30, 2007
Applicant	:	Alan R. Fritzberg et al.
Owner of Record	:	NeoRx Corporation
Title	:	Metal Radionuclide Labeled Proteins for Diagnosis and Therapy
Classification	:	424/1.1
Product Trade Name	:	Verluma™ (Technetium Tc 99m Nofetumomab Merpentan)
Term Extended	:	1,298 days
Expiration Date of Extension	:	August 20, 2010

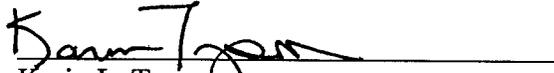
Any correspondence from applicant with respect to this matter should be addressed as follows:

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: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

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: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
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RE: Verluma™ (Technetium Tc 99m
Nofetumomab Merpentan)
FDA Docket No.: 96E-0452