



JAN 11 2001

Karen L. Kimble, Senior Counsel
Patent Department
The Dow Chemical Company
1790 Building, Washington St.
Midland, MI 48674

Re: Patent Term Extension
Application for
U.S. Patent No. 4,898,724

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,898,724, which claims the human drug product QUADRAMET® (samarium sm 153 EDTMP), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,511 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 Director will issue a certificate of extension, under seal, for a period of 1,511 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 July 17, 1998 (63 Fed. Reg.38657). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2189 - 235) + 655 \\ &= 1,632 \text{ days}\end{aligned}$$

Since the regulatory review period began June 16, 1989, before the patent issued (February 6, 1990), 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 June 16, 1989 to February 6, 1990 is 235 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, 1,632 days, would extend the patent from February 6, 2007 (35 U.S.C. § 154) to July 27, 2011, which is beyond the 14-year limit (the approval date is March 28, 1997, thus the 14 year limit is March 28, 2011). The period of extension is thus limited to March 28, 2011, 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, February 6, 2007, to and including March 28, 2011, or 1,511 days.

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

U.S. Patent No.:

4,898,724

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

U.S. Patent No.	4,898,724
Granted	February 6, 1990
Original Expiration Date ¹	February 6, 2007
Applicant:	Jaime Simon, et al
Owner of Record:	The Dow Chemical Company
Title	Organic Amine Phosphonic Acid Complexes for the Treatment of Calcific Tumors
Classification:	424/1.77
Product Trade Name:	QUADRAMET® (samarium sm 153 EDTMP)
Term Extended	,51 days
Expiration Date of Extension:	March 28, 2011

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

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Karin Tyson

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
Rockville, MD 20852

RE: QUADRAMET®
FDA Docket No.: 97E-0291

¹Subject to the provisions of 35 U.S.C. § 41(b).