



JUL 24 2000

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,246,925

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,246,925, which claims the method of use of the human drug product ZEMPLAR® (paricalcitol), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 574 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 574 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 (64 Fed. Reg. 10003). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (623) + 456 \\ &= 768 \text{ days} \end{aligned}$$

Since the regulatory review period began May 6, 1995, after the patent issue date (September 21, 1993), 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.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, 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, 768 days, would extend the patent from September 21, 2010 (35 U.S.C. § 154) to October 28, 2012, which is beyond the 14-year limit (the approval date is April 17, 1998, thus the 14 year limit is April 17, 2012). The period of extension is thus limited to April 17, 2012, 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, September 21, 2010, to and including April 17, 2012, or 574 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:

Patent No.: 5,246,925  
Granted: September 21, 1993

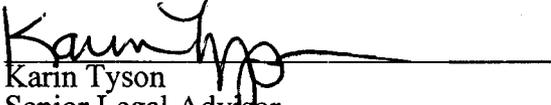
Original Expiration Date<sup>1</sup>: September 21, 2010  
 Applicant: Hector F. DeLuca, et al  
 Owner of Record: Wisconsin Alumni Research Foundation  
 Title: 19-NOR-Vitamin D Compounds for Use in Treating Hyperparathyroidism  
 Classification: 514/167  
 Product Trade Name: ZEMPLAR® (paricalcitol)  
 Term Extended: 574 days  
 Expiration Date of Extension: April 17, 2012

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: David T. Read  
 Acting Director Regulatory Policy Staff, CDER  
 Food and Drug Administration  
 1451 Rockville Pike, HFD-7  
 Rockville, MD 20852

RE: ZEMPLAR® (paricalcitol)  
 FDA Docket No.: 98E-0794

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