



JUL 10 2000

Edmund J. Sease
ZARLEY, McKEE, THOMTE, VOORHEES & SEASE
801 GRAND AVE.
SUITE 3200
DES MOINES IOWA 50309

Re: Patent Term Extension
Application for
U.S. Patent No. 5,192,808

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,192,808, which claims the method of use of the animal drug product Anipryl® (selegiline hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 272 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 272 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 August 4, 1998 (63 Fed. Reg. 41578). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2275 - 784) + 54 \\ &= 800 \text{ days} \end{aligned}$$

Since the regulatory review period began January 15, 1991, before the patent issued (March 9, 1993), 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 January 15, 1991 to March 9, 1993 is 784 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, 800 days, would extend the patent from August 31, 2010 (35 U.S.C. § 154) to November 8, 2012, which is beyond the 14-year limit (the approval date is May 30, 1997, thus the 14 year limit is May 30, 2011). The period of extension is thus limited to May 30, 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, May 30, 1997, to and including May 30, 2011, or 272 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. 5,192,808

Page 2

U.S. Patent No. 5,192,808
Granted: March 9, 1993
Original Expiration Date¹: August 31, 2010
Applicant: William W. Ruehl, et al.
Owner of Record: Deprenyl Animal Health, Inc.
Title: Therapeutic Effect of L-Deprenyl in the Management of Pituitary-Dependent Hyperadrenocorticism (Cushing's Disease)
Classification: 514/654
Product Trade Name: Anipryl® (selegiline hydrochloride)
Term Extended: 272 days
Expiration Date of Extension: May 30, 201

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: RE: Anipryl®
FDA Docket No.: 97E-0338

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