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SEP - 5 1997

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,816,456

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,816,456, which claims the human drug product COGNEX®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 343 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 December 8, 1994 (59 Fed. Reg. 63,368). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,095 - 660) + 1,194 \\ &= 1,412 \text{ days} \end{aligned}$$

Since the regulatory review period began June 6, 1987, before the patent issued (March 28, 1989), 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 6, 1987 to March 28, 1989 is 660 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 1,095 - 660 = 435 days.) 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 because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (September 9, 1993) when added to the period of extension calculated above (1,412 days) cannot exceed fourteen years. The period of extension is thus limited to September 9, 2007, by operation of 35 U.S.C. § 156(c)(3). Since the original patent term of twenty years from the earliest filing date relied upon under 35 U.S.C. § 120 (35 U.S.C. § 154) would expire on October 1, 2006, the period of extension is the number of days to extend the term of the patent from its expiration date to and including September 9, 2007, or 343 days.

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

determined above.

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 343 days.

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

| | |
|---------------------------|--|
| U.S. Patent No.: | 4,816,456 |
| Granted: | March 28, 1989 |
| Original Expiration Date: | October 1, 2006 |
| Applicant: | Dr. William K. Summers |
| Owner of Record: | Dr. William K. Summers |
| Title: | Administration of Monoamine Acridines in Cholinergic Neuronal Deficit States |
| Classification: | 514/255 |
| Product Trade Name: | COGNEX® |
| Term Extended: | 343 days |
| Extended Expiration Date: | September 9, 2007 |

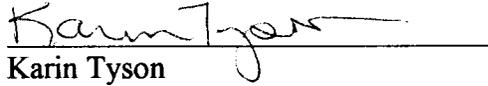
Further correspondence with respect to this matter should be addressed as follows:

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

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries regarding this order should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
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Rockville, MD 20857

Re.: COGNEX®
FDA Docket No. 93E-0447