

AUG 20 1998



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Washington, D.C. 20231

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,895,841

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,895,841, which claims the human drug product ARICEPT® (donepezil hydrochloride) and methods of use of ARICEPT®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 888 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 888 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 18, 1997 (62 Fed. Reg. 38564). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,900) + 235 \\ &= 1,185 \text{ days} \end{aligned}$$

Since the regulatory review period began January 23, 1991, after the patent issue date (January 23, 1990), 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.

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, 1,185 days, would extend the patent from June 20, 2008 (35 U.S.C. § 154) to September 22, 2011, which is beyond the 14-year limit (the approval date is November 25, 1996, thus the 14 year limit is November 25, 2010). The period of extension is thus limited to November 25, 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, June 20, 2008, to and including November 25, 2010, or 888 days.

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

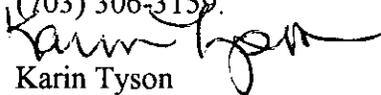
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,895,841
Granted:	January 23, 1990
Original Expiration Date:	June 20, 2008, subject to 35 U.S.C. § 41(b)
Applicant:	Hachiro Sugimoto et al.
Owner of Record:	Eisai Co., Ltd.
Title:	Cyclic Amine Compounds with Activity Against Acetylcholinesterase
Classification:	514/212
Product Trade Name:	ARICEPT™ (donepezil hydrochloride)
Term Extended:	888 days
Expiration Date of Extension:	November 25, 2010

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
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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: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: ARICEPT™ (donepezil hydrochloride)
FDA Docket No.: 97E-0066