

Mailed: March 19, 2002

Steven F. Weinstock
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500In Re: Patent Term Extension
Application for
U.S. Patent No. 5,010,090

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,010,090, which claims the human drug product Gabitril (tiagabine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156.

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 1,255 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 10, 2001 (66 Fed. Reg. 35988). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,651) + 695 \\ &= 1,521 \text{ days}\end{aligned}$$

Since the regulatory review period began May 1, 1991, after the patent issue date (April 23, 1991), 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.

Although the limitations of 35 U.S.C. § 156(g)(6) do not operate to reduce the period of patent term extension determined above, the fourteen year limitation of 35 U.S.C. § 156(c)(3) does. 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, 1,521 days, would extend the patent from April 23, 2008 (35 U.S.C. § 154) to June 22, 2012, which is beyond the 14-year limit (the approval date is September 30, 1997, thus the 14 year limit is September 30, 2011). The period of extension is thus limited to September 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, April 23, 2008, to and including September 30, 2011, or 1,255 days.

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

U.S. Patent No.	:	5,010,090
Granted	:	April 23, 1991
Original Expiration Date	:	April 23, 2008

Applicant : Frederik C. Gronvald, et al.
Owner of Record : Novo Nordisk A/S
Title : N-(Butenyl Substituted) Azaheterocyclic Carboxylic
Acids
Classification : 514/326
Product Trade Name : Gabitril (tiagabine hydrochloride)
Term Extended : 1,255 days
Expiration Date of Extension : September 30, 2011

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

By mail: Commissioner for Patents
Mail Stop Patent Extension
PO Box 2327
Arlington VA 22202

By FAX: (703) 872-9411

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

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read RE: Gabitril (tiagabine hydrochloride)
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 00N-1254
Food and Drug Administration
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