

AUG 14 1997



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Washington, D.C. 20005-3315

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,544,664

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,544,664, which claims the animal drug product DOMITOR® (medetomidine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156, unless U.S. Patent No. 4,670,455 is elected for extension. The period of extension has been determined to be three years.

A single request for reconsideration of this final determination as to the length of the term of the patent and statement of election 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.

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 November 29, 1996 (61 Fed. Reg. 60,708). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,294 - 176) + 1,706 \\ &= 2,853 \text{ days (7.8 years)} \end{aligned}$$

Since the regulatory review period began April 8, 1985, before the patent issued (October 1, 1985), 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 April 8, 1985 to October 1, 1985 is 176 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: $2,294 - 176 = 2,118$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The three year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued (October 1, 1985) and an action described in 35 U.S.C. § 156(g)(6)(B) was taken (April 8, 1985) before the date of enactment of 35 U.S.C. § 156 (November 16, 1988, see 35 U.S.C. § 156(f)(8)). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed three years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for three years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Applicant has also filed an application for patent term extension of U.S. Patent No. 4,670,455 based upon the regulatory review of the product DOMITOR® (medetomidine hydrochloride). No more than one patent may be extended for a single regulatory review period of a product. 35 U.S.C. 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted. In the absence of an election of U.S. Patent No. 4,670,455, the Commissioner will issue a certificate of extension, under seal, for a period of three years for the above-identified patent.

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

U.S. Patent No.:	4,544,664
Granted:	October 1, 1985
Original Expiration Date:	February 11, 2001
Applicant:	Arto J. Karjalainen et al.
Owner of Record:	Orzon-Yhtymä Oy
Title:	Antihypertensive Substituted Imidazole Derivatives
Classification:	514/396
Product Trade Name:	DOMITOR® (medetomidine hydrochloride)
Term Extended:	Three years
Expiration Date of Extension:	February 11, 2004

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

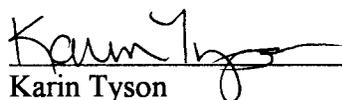
By mail: Assistant Commissioner for Patents

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Attn: Special Program Law Office

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

Telephone inquiries related to this determination 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
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: DOMITOR®
FDA Docket No.: 96E-0196