



FEB 5 2001

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,867,164

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,867,164, which claims the medical device Neuro Cybernetic Prosthesis (NCP®) System, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,761 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 Director will issue a certificate of extension, under seal, for a period of 1,761 days.

The period of extension has been calculated using the Food and Drug Administration's amended determination of the length of the regulatory review period published in the Federal Register of May 15, 2000 (65 Fed. Reg. 31010). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,730 - 378) + 1,507 \\ &= 2,183 \text{ days} \end{aligned}$$

Since the regulatory review period began September 6, 1988, before the patent issued (September 19, 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 September 6, 1988 to September 19, 1989 is 378 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.

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, 2,183 days, would extend the patent from September 19, 2006 (35 U.S.C. § 154) to September 10, 2012, which is beyond the 14-year limit (the approval date is July 16, 1997, thus the 14 year limit is July 16, 2011). The period of extension is thus limited to July 16, 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, September 19, 2006, to and including July 16, 2011, or 1,761 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	4,867,164
Granted	September 19, 1989
Original Expiration Date ¹	September 19, 2006
Applicant	Jacob Zabara
Owner of Record	Jacob Zabara
Title	Neurocybernetic Prosthesis
Classification	607/45
Product Trade Name	Neuro Cybernetic Prosthesis (NCP®) System
Term Extended	,761 days
Expiration Date of Extension	July 16, 201

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

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

By FAX (703) 872-941

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



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

cc David T. Read
 Acting Director Regulatory Policy Staff, CDER
 Food and Drug Administration
 1451 Rockville Pike, HFD-7
 Rockville, MD 20852

Re: NCP®

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