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Washington, D.C. 20231

SEP - 2 1999

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United States Surgical Corporation
150 Glover Ave.
Norwalk, Connecticut 06850

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,961,740

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,961,740, which claims the medical device Ray Threaded Fusion Cage™ and the method of use of the medical device Ray Threaded Fusion Cage™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 742 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 742 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 October 13, 1998 (63 Fed. Reg. 54719). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,357) + 504 \\ &= 1,183 \text{ days} \end{aligned}$$

Since the regulatory review period began September 27, 1991, after the patent issue date (October 9, 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, 1,183 days, would extend the patent from October 17, 2008 to January 13, 2012, which is beyond the 14-year limit (the approval date is October 29, 1996, 14 years after the approval date is October 29, 2010). The period of extension is thus limited to October 29, 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 October 17, 2008, to and including October 29, 2010, or 742 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.:	4,961,740
Granted:	October 9, 1990
Original Expiration Date:	October 17, 2008
Applicant:	Charles D. Ray, et al.
Owner of Record:	Surgical Dynamics, Inc.
Title:	V-Tread Fusion Cage and Method of Fusing a Bone Joint
Classification:	606/61
Product Trade Name:	Ray Threaded Fusion Cage
Term Extended:	742 days
Extended Expiration Date:	October 29, 2010

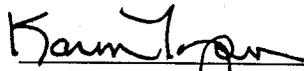
Any correspondence with respect to this matter should be addressed as follows:

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

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

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

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



Karin L. Tyson

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

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

RE: Ray Threaded Fusion Cage
FDA Docket No.: 97E-0087