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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,947,840

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,947,840, which claims a method of use of the medical device INTEGRA® Artificial Skin, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 923 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 923 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 August 21, 1997 (62 Fed. Reg. 44477). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,173 - 2,449) + 1,304 \\ &= 1,666 \text{ days}\end{aligned}$$

Since the regulatory review period began November 30, 1983, before the patent issued (August 14, 1990), 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 November 30, 1983 to August 14, 1990 is 2,449 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.

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 (March 1, 1996) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above 1,666, would extend the patent to March 13, 2012, which is beyond the 14 year limit (14 years after the approval date is March 1, 2010) set forth in 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 expiration date, March 13, 2012, to and including March 1, 2010, or 923 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.	:	4,947,840
Granted	:	August 14, 1990
Original Expiration Date	:	March 13, 2012
Applicant	:	Ioannis V. Yannas et al.
Owner of Record	:	Massachusetts Institute of Technology
Title	:	Biodegradable Templates for the Regeneration of Tissues
Classification	:	128/156
Product Trade Name	:	INTEGRA® Artificial Skin
Term Extended	:	923 days
Expiration Date of Extension	:	March 1, 2010

Any correspondence from applicant 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: 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 L. 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: INTEGRA Artificial Skin®  
FDA Docket No.: 96E-0272