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F. Dominic Cerrito, Esq.
JONES DAY
222 East 41st Street
New York, New York 10017

FEB 19 2008

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,994,078

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156(d)(5) FOR U.S. PATENT NO. 4,994,078

This is in response to the application for interim extension of the term of U.S. Patent No. 4,994,078 ("the '078 patent") filed under 35 U.S.C. § 156(d)(5) in the United States Patent and Trademark Office ("USPTO") on February 1, 2008 ("the PTE Application"). The PTE Application was filed by Jarvik Heart Inc. ("Applicant"). Interim extension is sought based upon the continuing premarket review of the Jarvik 2000 Heart under section 515 of the Federal Food Drug and Cosmetic Act ("FFDCA"). Because the USPTO has determined that no application under section 515 of the FFDCA was submitted for the Jarvik 2000 Heart, Applicant's request for interim extension of the patent term of the '078 patent under 35 U.S.C. § 156(d)(5) is **DENIED.**

A. Factual Background

A pre-Investigational Device Exemption ("IDE") application was submitted to the FDA on November 16, 1998.

An IDE application was submitted to the FDA on March 2, 2000, and received by the FDA on March 3, 2000.

The IDE application was approved on March 31, 2000, and was assigned IDE No. G000058.

A Pre-Market Approval ("PMA") Shell was submitted to the FDA on November 20, 2007.

The PMA Shell was accepted on January 14, 2008, by FDA and assigned PMA Shell No. M070017.

On February 1, 2008, an application for interim patent term extension under 35 U.S.C. § 156(d)(5) was filed. The application for patent term extension seeks to extend U.S. Patent No. 4,994,078 under the statutory provisions of 35 U.S.C. § 156(d)(5) which govern interim extensions where a product claimed in a patent has not yet received approval for commercial marketing or use from the regulating agency.

On February 15, 2008, pursuant to 37 C.F.R. § 1.740(a)(13), Applicant filed a

Submission ("Submission") with the USPTO copies of correspondence to FDA in relation to the submission of PMA Module 1.

B. Decision

For a medical device, 35 U.S.C. § 156(d)(5) requires a regulatory review period under 35 U.S.C. § 156(g)(3)(B)(ii) to have begun

According to 35 U.S.C. § 156(g), the term "regulatory review period" includes a testing phase and an approval phase, see 21 C.F.R. § 60.22. Depending upon the type of product subject to regulatory review, the "testing phase" is defined in (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156. Similarly, depending upon the type of product subject to regulatory review, the "approval phase" is defined in (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) of subsection (g) of 35 U.S.C. § 156.

One of the requirements for an interim extension under 35 U.S.C. § 156(d)(5) is that the owner of record or his agent reasonably expects that the "approval phase" (recited in 156(d)(5)(A) as "the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii) and (5)(B)(ii) of subsection (g) of 35 U.S.C. § 156"), which must have **begun** for a product would continue beyond the original expiration of the patent term. In other words, in order to be eligible for an interim extension under 35 U.S.C. § 156(d)(5) for the subject medical device, a Pre-Market Approval application (PMA) must have been filed under section 515 of the FFDCA for Jarvik 2000 Heart. Specifically, section 156(d)(5)(A) provides (in part):

> If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration date of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire.

35 U.S.C. § 156(d)(5)(A).

Although page 2 of the initial application materials states that "[t]he product is subject to regulatory review under section 515 of the [FFDCA]," no PMA application under section 515 of the FFDCA for Jarvik 2000 Heart has been filed. In this regard, page 11 of the initial application materials states that a PMA Shell (M070017) was submitted on November 20, 2007. Further, page 1 of the Submission states that a Module 1: System Engineering for PMA Shell M070017 was submitted on January 30, 2008. However, neither the PMA Shell nor the PMA Module 1 constitutes "an application . . . initially submitted with respect to the device under section 515." Therefore, the applicable regulatory review period described in paragraph (3)(B)(ii) of subsection (g) of 35 U.S.C. § 156 has not begun.

In particular, the FDA does not consider the submission of a PMA shell or a first PMA module to trigger the beginning of the period described in paragraph (3)(B)(ii) of subsection (g). For example, with respect to the medical device Genesis Neurostimulation System, for which patent term extension was sought for U.S. Patent No. 4,793,353, the Applicant for extension proffered that the submission of a PMA Module 1 on April 3, 2001, started the regulatory review period of 156(g)(3)(B)(ii). FDA concluded that April 3, 2001 was not the date the premarket approval application for Genesis Neurostimulation System (PMA P010032) was initially submitted. Rather, FDA concluded that the date the application was initially submitted was the date that the PMA application was completed, i.e., May 29, 2001 (copies of FDA's letter of February 24, 2003, in relation to the patent term extension of U.S. Patent No. 4,793,353, and the Applicant's Exhibit E indicating submission of Modules 1 and 2 are attached hereto).

Since 35 U.S.C. § 156(d)(5) requires that, in the case of medical devices, a regulatory review under 35 U.S.C. § 156 (g)(3)(B)(ii) have begun, and a PMA under section 515 of the FFDCA triggering the regulatory review period under 156(g)(3)(B)(ii) has not been filed, the USPTO must deny Applicant's application for an interim extension under 35 U.S.C. § 156(d)(5) for U.S. Patent No. 4,994,078.

C. Conclusion

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,994,078 is not eligible for interim extension of the patent term under 35 U.S.C. § 156. A regulatory review period under 35 U.S.C. § 156(g)(3)(B)(ii) has not begun for the Jarvik 2000 Heart. Accordingly, the application for extension of the patent term is **DENIED**.

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

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7728

Telephone inquiries related to this determination should be directed to the Raul Tamayo at (571) 272-7728.

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Building 51, Room 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: Jarvik 2000 Heart
FDA Docket No.:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Genesis Neurostimulation System
Docket No.: 02E-0149

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

FEB 24 2003

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,793,353, filed by Advanced Neuromodulation Systems, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Genesis Neurostimulation System, the medical device claimed by the patent.

The total length of the regulatory review period for Genesis Neurostimulation System is 469 days. Of this time, 292 days occurred during the testing phase and 177 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: August 11, 2000.

   The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on June 16, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 11, 2000, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: May 29, 2001.

   The applicant claims April 3, 2001, as the date the premarket approval application (PMA) for Genesis Neurostimulation System (PMA P010032) was initially submitted. However, FDA records indicate that PMA P010032 was submitted on May 29, 2001.

3. The date the application was approved: November 21, 2001.

FDA has verified the applicant's claim that PMA P010032 was approved on November 21, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Peter Lando
Hughes & Luce, L.L.P.
Patent Docketing
1717 Main Street, Suite 2800
Dallas, TX 75201

EXHIBIT E

STATEMENT OF RELEVANT DATES AND INFORMATION PURUSANT TO 35 U.S.C. 156(g) AS SET FORTH IN 37 CFR § 1.740(a)(10)

1. The § 515(a)(2) Review was submitted on June 16, 1999. The § 515(a)(2) Review was determined on February 23, 2001. The FDA administrative record for the § 515(a)(2) Review is referenced and documented at the FDA under Docket # 00P-0788.

2. The Class III Review was submitted on April 3, 2001. The first section of the application concerned Module 1, whereby the manufacturing facility and design control information was reviewed. The application for Module 2 of the Class III Review was submitted on May 25, 2001 and approved on November 21, 2001. The PMA filing number for the Class III Review is P010032.