UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
www.USPTO.gov

Aaron L. Parker
Finnegan, Henderson, Farabow, Garrett & Dunner LLP
901 New York Ave. NW
Washington, DC 20001

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,762,599

MAR 24 2015

NOTICE OF DETERMINATION OF INELIGIBILITY

An application for extension of the patent term of U.S. Patent No. 5,762,599 (the '599 patent) under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office (USPTO) on December 12, 2014. The application was filed by Vesiflo Inc. (Applicant), a licensee of the owner of record of the '599 patent, Personal Medical Corp. Extension was sought based upon the order under section 513(f)(2) of the Federal Food Drug and Cosmetic Act (FFDCA) granting permission to market inFlow Intraurethral Valve-Pump and Activator dated October 14, 2014. A determination has been made that the '599 patent is not eligible for extension because (1) the application for extension was untimely filed and (2) the regulatory review under section 513(f)(2) of the FFDCA is not a regulatory review period within the meaning of 35 U.S.C. 156(g)(3)(B)(i) and (ii). Therefore, Applicant's request for extension of the patent term of the '599 patent under 35 U.S.C. 156(d)(1) is **dismissed**.

Additionally, since the USPTO has determined that the patent for which patent term extension has been sought is ineligible for extension, no interim extension under 35 U.S.C. 156(e)(2) can be granted. Therefore, in order to obtain any interim extension under 35 U.S.C. 156(e)(2), the USPTO must find the present patent eligible for extension not later than the expiry of the patent term of the '599 patent.

A single request for reconsideration of this DETERMINATION OF INELIGIBILITY may be made if filed by Applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. § 1.136. *See* 37 C.F.R. § 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the PTE Application.

A. U.S. Patent No. 5,762,599 Is Not Eligible for Patent Term Extension

A determination has been made that the '599 patent is **NOT** eligible for patent term extension under § 156 based upon the FDA review under section 513(f)(2) of the FFDCA of the inFlow Intraurethral Valve-Pump and Activator.

1. 35 U.S.C. 156(d)(1) requires that an application for patent term extension be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use

The timing provision in § 156(d)(1) for submission of an application for patent term extension is triggered by FDA granting permission for commercial marketing or use of a "product" under the "provision of law" under which the applicable "regulatory review period" occurred.

Specifically, the statute states:

> (d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period **beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred** for commercial marketing or use. (Emphasis added)

The term "product" is defined in the statute at section 156(f)(1)(B) and includes medical devices. The permission for commercial marketing or use of the product (medical device) ties the review of the product to a particular "provision of law under which the applicable regulatory review period occurred." The language defining a "regulatory review period" is expressly set forth in 35 U.S.C. 156(g), with § 156(g)(1)-156(g)(5) delineating the regulatory review period based on the type of product reviewed. For medical devices, the relevant provision is 35 U.S.C. 156(g)(3)(B). Subsections (i) and (ii) of § 156(g)(3)(B) identify section 515 of the FFDCA as the relevant provision of law and require that an application have been initially submitted under section 515 in order for the first time period defined in §156(g)(3)(B)(i) to be complete. Since no application under section 515 of the FFDCA was filed with FDA, the time period in §156(g)(3)(B)(i) has not ended. Turning to the §156(g)(3)(B)(ii) period, since no application was filed under either 515 or 515(f)(5), the regulatory review specified in §156(g)(3)(B)(ii) did not begin nor did it end. Instead, an order under 513(f)(2) of the FFDCA for applicant's medical device was issued October 14, 2014. This means that the triggering event in §156(d)(1) has not occurred since the product was not reviewed under "the provision of law"—section 515 of the FFDCA —under which the applicable "regulatory review period" occurred —the regulatory review period as defined in 35 U.S.C. 156(g)(3)(B)(i) and (ii).

It is not enough that a Pre-PMA application for the InFlow Intraurethral Valve-Pump and Activator was submitted under section 515 of the FFDCA, since the application was refused by FDA. See application at page 12. The definition of "regulatory review period" in § 156(g)(3)(B) requires that an application for a medical device be submitted under section 515 and also that the application submitted under section 515 be approved. An application under section 515 of the FFDCA was not approved for the inFlow Intraurethral Valve-Pump and Activator. Because an application under section 515 of the FFDCA was not approved for the InFlow Intraurethral Valve-Pump and Activator, Applicant's time period to file an application has not been triggered. Thus, any application seeking to extend a patent based on the review under section 513(f)(2) of the FFDCA is untimely and hence the application is **dismissed**.

2. 35 U.S.C. § 156 Requires a Medical Device to Have Been Subject to a Regulatory Review Period Before its Commercial Marketing or Use, Defines the Regulatory Review Period for the Medical Device, and Requires that an Application for the Medical Device Submitted Under Section 515 of the FFDCA be Approved

35 U.S.C. § 156(a) provides (in part) that:

> The term of a patent which claims a product ... shall be extended in accordance with this section ... if –
>
> ... (4) the product has been subject to a regulatory review period before its commercial marketing or use.

For medical devices, the term "regulatory review period" is defined in § 156(g)(3)(B) as follows:

> (B) The regulatory review period for a medical device is the sum of –
>
> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date **such application was approved** under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added).

The phrase "such application" in 35 U.S.C. § 156(g)(3)(B)(ii) is clear and unambiguous. It refers to the prior recitation in § 156(g)(3)(B)(ii) of the "application [that] was initially submitted with respect to the device under section 515" of the FFDCA. The definition of "regulatory review period" in § 156(g)(3)(B) thus requires that an application for a medical device be submitted under section 515 of the FFDCA and also that the application under section 515 be approved.

Here, an application under section 515 of the FFDCA was not approved for the inFlow Intraurethral Valve-Pump and Activator. As admitted by applicant at page 12 of their application, the pre-PMA application submitted under section 515 of the FFDCA for review by FDA for the inFlow Intraurethral Valve-Pump and Activator was refused. Because an application under section 515 of the FFDCA was not approved for the inFlow Intraurethral Valve-Pump and Activator, Applicant fails to comply with 35 U.S.C. § 156(a)(4). Therefore, the '599 patent is **ineligible** for

patent term extension under 35 U.S.C. § 156.

B. Original Expiration of U.S. Patent No. 5,762,599

On June 9, 2015, according to the application for patent term extension on page 4, U.S. Patent No. 5,762,599 will expire. Because the '599 patent is not eligible for patent term extension, an interim extension pursuant to the provisions of 35 U.S.C. 156(e)(2) cannot be granted.

If a patent will expire before the Director has made a determination to issue or deny an application for patent term extension, § 156(e)(2) provides for an interim patent term extension of up to one year:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

§ 156(e)(2) (emphasis added).

Based on the express language of §156(e)(2), certain conditions must be satisfied in order to permit the Director to issue an interim extension. Specifically, the language "before a certificate of extension is issued or denied" in § 156(e)(2) indicates that an interim extension may be granted only during the period of time prior to the Director's determination either to issue the certificate or deny the applicant's request. Furthermore, the language "if he determines that the patent is eligible for extension," which follows the aforementioned language, instructs the Director to grant an interim extension only if the patent is eligible for patent term extension. If the patent is not eligible, then § 156(e)(2) explicitly prohibits the Director from granting an interim extension.

The legislative history of the Hatch-Waxman Act is consistent with this interpretation. There are two committee reports that address § 156. The Committee on Energy and Commerce prepared a report for the House version of the Act (H.R. 3605), giving a general explanation for how the provision would operate in practice:

> It is possible that the original term of the patent for which extension is sought could expire before a final decision by the Commissioner to issue a certificate of extension. This might occur, for instance, because the determination of due diligence by the Secretary of HHS or Agriculture has not been completed.

> In such circumstances, the Commissioner is required to determine whether the patent is eligible for extension under section 156(a), and if it is, to issue a certificate of extension for a period of up to one year. The length of this interim extension is discretionary with the Commissioner, but is intended to provide time for the completion of any outstanding requirements. If the Commissioner determined that subsequent interim extensions were necessary, and consistent with the objectives of section 156(e)(2), they could be granted as well. In no event could these interim extensions be longer than the maximum period of extension to which the application is thought to be eligible.

H.R. Rep. No. 857(I), 98th Cong., 2d Sess. (June 21, 1981), reprinted in 1984 U.S.C.C.A.N. 2647 at 29.

The Committee on the Judiciary likewise prepared a separate report on H.R. 3605 and explained even less about § 156(e)(2):

> Proposed section 156(e) provides that the Commissioner's determination that a patent is eligible for extension is to be made solely on the basis of information contained in the application. If it is determined that the patent is eligible for an extension, the Commissioner shall issue a certificate of extension, under seal, for the period determined, in accordance with procedures authorized by subsection (c). The certificate shall be recorded in official patent files and becomes a part of the original patent.
>
> In the event that the original term of the patent for which extension is sought will expire before a final decision by the Commissioner on that extension, the Commissioner may issue an interim extension certificate for a period of up to one year.

H.R. Rep. No. 857(II), 98th Cong., 2d Sess. (Aug. 1, 1984) (emphasis added).

The Committee on Energy and Commerce's discussion supports reading § 156(e)(2) as permitting an interim extension only if the Director determines that the patent is eligible for a patent term extension. In particular, the portion that states "and if it is" implies that an interim extension should not be granted if a patent is not eligible for extension under § 156(a). While the Committee on the Judiciary did not specifically state that eligibility is a prerequisite for an interim extension, such an interpretation is not inconsistent with this report.

Furthermore, the Federal Circuit has squarely addressed the issue of granting an interim extension when the underlying application for extension has been denied and found that the USPTO is without authority to grant an interim extension when the underlying application is denied. Somerset Pharms., Inc. v. Dudas, 500 F.3d 1344, 1346 (Fed. Cir. 2007) (explaining that when the Director denies a patent term extension, "the Director has no statutory authority to issue the interim extension" under § 156(e)(2)).

Thus, because the '599 patent is not eligible for patent term extension, an interim extension under § 156(e)(2) cannot be granted.

C. Conclusion

For the reasons stated above, Applicant's request for extension of the patent term of the '599 patent is **dismissed** Additionally, since the underlying application is not eligible for extension, the USPTO is without authority to grant an interim extension, thus, no interim extension under 35 U.S.C. 156(e)(2) can be granted.

Any correspondence with respect to this matter should be submitted via the EFS-Web System and should be addressed as follows:

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

Telephone inquiries related to this determination should be directed to Mary C. Till, Senior Legal Advisor, at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration

cc: Office of Management
Food and Drug Administration
10001 New Hampshire Avenue,
Hillandale Campus RM 3180
Silver Spring, MD 20993

Attention: Beverly Friedman

Re: inFlow Intraurethral Valve-Pump and Activator
Docket No. :