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Intuitive Surgical, Inc.
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In re: Patent Term Extension
Application for
U.S. Patent No. 5,808,665

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156 FOR U.S. PATENT NO. 5,808,665

This is in response to the application for extension of the term of U.S. Patent No. 5,808,665 ("the '665 patent") filed under 35 U.S.C. § 156 in the United States Patent and Trademark Office ("USPTO") on September 11, 2000 ("the PTE Application), the Request for reconsideration filed on January 9, 2002 ("the Request"), and the Petition to the director for questions not specifically provided for under 37 CFR 1.182 filed on April 19, 2004. The PTE Application was filed by Intuitive Surgical ("Applicant"), the exclusive licensee of the '665 patent and marketing applicant of the da Vinci™ System. Extension was sought based upon the premarket review of the da Vinci™ System under sections 515 and 510(k) of the Federal Food Drug and Cosmetic Act ("FFDCA"). Because the Food and Drug Administration ("FDA") and the USPTO have determined that no application under 515 of the FFDCA was approved for the da Vinci™ System (endoscopic instrument control system and endoscopic instruments), Applicant's request for extension of the patent term of the '665 patent under 35 U.S.C. 156(d)(1) is **DENIED** and its request for reconsideration is **DENIED**. Additionally, the petition to the director under 37 C.F.R. § 1.182 is **MOOT** in view of this decision.

A. Factual Background

On January 17, 1999, as stated at page 5 of the PTE Application, Applicant submitted to the Food and Drug Administration ("FDA") an application (#K990144) under section 510(k) of the FFDCA (21 U.S.C. § 360(k)) seeking clearance of its da Vinci™ System.

During the course of the FDA's review of the 510(k) application submitted January 17, 1999, it was decided that a pre-market approval application ("PMA") under section 515 of the FFDCA would be required. See, page 2 of a letter dated July 23, 2007, sent by the FDA to the USPTO.

On November 18, 1999, as stated at page 5 of the PTE Application, Applicant submitted to the FDA a complete PMA application (#P990079) under section 515 of the FFDCA for review of the da Vinci™ System. The FDA accepted the PMA application for filing on November 29, 1999.

During the course of the FDA's review of the PMA, the FDA "decided that the appropriate path to market for [the da Vinci™ System] should be through a 510(k) application

rather than a PMA." See, page 2 of the July 23, 2007, letter. The FDA consequently closed the PMA application on June 20, 2000, and reopened the 510(k) application. See, id.

On July 11, 2000, as stated at page 2 of the July 23, 2007, letter, the da Vinci™ System was cleared for marketing under section 510(k) of the FFDCA.

On September 11, 2000, Applicant filed the PTE Application with the USPTO to extend the term of the '665 patent. In the PTE Application, Applicant states:

> within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials, and ends on approval under the "Act," i.e. the FD&C Act, which includes both sections 515 and 510(k) of Chapter 5. While the calculation of the regulatory review period requires that an application be submitted under section 515, the statute thus clearly encompasses situations (such as the present case) where approval is eventually granted under another section of the FD&C Act.

On November 27, 2000, the USPTO requested FDA's assistance in determining the '665 patent's eligibility for patent term extension. The November 27, 2000, letter notes:

> [t]he application for patent term extension raises the issue of whether the application was subject to a regulatory review period under 35 U.S.C. § 156(g) because the approval for commercial marketing or use is said to have been under § 510(k) of the [FFDCA], which is not the same as an approval under § 515 of said Act.

In a letter dated October 2, 2001, the FDA advises the USPTO that the da Vinci™ System was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

On November 14, 2001, the USPTO mailed a Notice of Final Determination of Ineligibility in which the USPTO states that the '665 patent is ineligible for patent term extension under 35 U.S.C. § 156. In particular, the Notice states:

> The medical device da VINCI™ system underwent regulatory review under Section 510(k) of the [FFDCA]. For regulatory review of a medical device claimed by a patent to give rise to eligibility for patent term extension, the regulatory review must have been under Section 515 of the FFDCA. See 35 U.S.C. § 156(g)(3)(A). Since the regulatory review of VINCI™ system was under Section 510(k), not Section 515, the patent is not eligible for patent term extension. See Manual of Patent Examining Procedure, Section 2751, page 2700-14, Eighth edition (August 2001), citing In re Nitinol Medical Technologies Inc., 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also Baxter Diagnostics v. AVL Scientific Corp., 798 F.Supp. 612, 619-620, 25 USPQ2d

1428, 1434 (1992) (Congress intended only Class III medical devices to be eligible for patent term extension).

On January 9, 2002, Applicant filed a Request for Reconsideration for Patent Term Extension Under 35 U.S.C. § 156. The Request states at page 2 that "[t]he regulatory review of the da Vinci™ System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k)." (Emphasis in the original.) The Request further states at page 2 that, "[a]s the da Vinci™ System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension." The Request also states at page 2 that "within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the 'Act,' i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5."

In a letter dated April 9, 2002, the USPTO requests that the FDA comment on the Request for Reconsideration. The April 9, 2002, letter makes note of Applicant's argument that the regulatory review period of the product was as required by 35 U.S.C. § 156(g)(3)(B), because regulatory review was conducted under Section 515 of the FFDCA, and the subsequent approval under the Act, albeit under section 510(k) of the Act, did not diminish the patent's eligibility for patent term extension.

On April 19, 2004, Applicant filed a Petition to Director for Questions Not Specifically Provided for Under 37 CFR 1.182. Applicant states in the Petition that they have not received any further official correspondence from the USPTO or FDA regarding the Request, subsequent to the USPTO's letter of April 9, 2002, to the FDA.

In the July 23, 2007, letter sent by the FDA to the USPTO, the FDA responds to the USPTO's April 9, 2002, letter. The July 23, 2007, letter states at page 2 that the determination in the FDA's October 2, 2001, letter that the da Vinci™ System was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4), "was in error." The July 23, 2007, letter further states at page 2 that, "[a]lthough the da VINCI system was reviewed for a time under § 515 of the FFDCA, it was not approved under § 515." Also at page 2, the July 23, 2007, letter concludes that, "[b]ecause [the da Vinci™ System] was not approved under § 515 of the FFDCA, it was not subject to a regulatory review period as defined under 35 U.S.C. § 156(g)(3)(B)(ii), and it is ineligible for patent term extension."

B. Decision

1. 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 da Vinci™ System. As stated in the FDA's July 23, 2007, letter, the PMA application submitted under section 515 of the FFDCA for review of the da Vinci™ System was closed on June 20, 2000. Because an application under section 515 of the FFDCA was not approved for the da Vinci™ System, Applicant fails to comply with 35 U.S.C. § 156(a)(4). Therefore, the '665 patent is **ineligible** for patent term extension under 35 U.S.C. § 156.

2. Applicant's Argument that the Da Vinci™ System is Eligible for Patent Term Extension Because "Regulatory Review ... was Conducted under both Sections 515 and 510(k) of Chapter 5 of the FFDCA" is Unpersuasive

At page 2 of the PTE Application, Applicant states that "[t]he regulatory review of the da Vinci™ System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k)." (Emphasis in the original). Applicant thereafter concludes on page 2 of the PTE Application that, "[a]s the da Vinci™ System was subjected to regulatory review under section 515 of the FFDCA, Applicants are entitled to a patent term extension."

However, for the reasons stated earlier herein, it is not enough that a PMA application for the da Vinci™ System was submitted and reviewed under section 515 of the FFDCA for the '665 patent to be eligible for patent term extension pursuant to 35 U.S.C. § 156. 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 da Vinci™ System. The PMA application submitted under section 515 of the FFDCA for review of the da Vinci™ System was closed on June 20, 2000. Because an application under section 515 of the FFDCA was not approved for the da Vinci™ System, Applicant fails to comply with 35 U.S.C. § 156(a)(4). Therefore, the '665 patent is **ineligible** for patent term extension under 35 U.S.C. § 156.

3. Applicant's Argument that, "Within the Plain Language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a Regulatory Review Period begins at the Initiation of Human Clinical Trials and ends on Approval Under the 'Act'" is Unpersuasive

At page 2 of the PTE Application, Applicant reproduces 35 U.S.C. § 156(g)(3)(B)(i) and (ii) and emphasizes the phrase "ending on the date such application was approved under such Act" recited in § 156(g)(3)(B)(ii). In view of the emphasized phrase, Applicant states at page 2 of the PTE Application that, "[t]herefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the 'Act,' i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5."

However, as stated earlier herein, the phrase "such application" in section 156(g)(3)(B)(ii) of Title 35 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. Because an application under section 515 was not approved for the da Vinci™ System, the '665 patent is ineligible for patent term extension under 35 U.S.C. § 156.

Further, even if, as Applicant states, a regulatory review period begins at the initiation of human clinical trials and ends on approval under the Act, i.e., the FFDCA, which includes both sections 515 and 510(k) of Chapter 5, there was no approval under the FFDCA of the da Vinci™ System. First, as stated at page 2 of the FDA's July 23, 2007, letter, the PMA application submitted under section 515 of the FFDCA for review of the da Vinci™ System was closed on June 20, 2000. Second, the FDA did not "approve" the 510(k) application #K990144. As stated at page 3 of the July 23, 2007, letter, "[p]remarket submissions under § 510(k) of the FFDCA are not *approved* by FDA (See 21 CFR 807.97)." (Emphasis in the original). As the FDA explains at page 2 of the July 23, 2007, letter:

> An FDA finding of substantial equivalence of the device to a legally marketed predicate device results in a classification for the device and clears it for commercial distribution. It does not mean that FDA approves the device.

Thus, contrary to the statement by Applicant at page 3 of the Request that "[o]n July 11, 2000, the FDA approved the 510(k) application #K990144," the FDA on July 11, 2000, "determined [the da Vinci™ System] to be substantially equivalent (for the indications for use stated in the labeling) to legally marketed predicate devices and cleared [it] for marketing under § 510(k) of the FFDCA." See, page 2 of the FDA's July 23, 2007, letter.

Therefore, there was no approval of the da Vinci™ System within the meaning of 35 U.S.C. § 156(g)(3)(B)(ii). Because Applicants have not complied with 35 U.S.C. 156(a)(4), the '665 patent is **ineligible** for patent term extension under 35 U.S.C. § 156.

4. Conclusion

For the reasons stated above, Applicant's request for extension of the patent term of the '665 patent is **DENIED**; Applicant's Request is **DENIED** and Applicant's Petition to the director for questions not specifically provided for under 37 CFR 1.182 is **MOOT**.

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

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Robert A. Clarke
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Re: da Vinci™ System
FDA Docket No.: 2001E-0095

Attention: Beverly Friedman