UNITED STATES PATENT AND TRADEMARK OFFICE

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DEC 31 2007

Michael A. Gollin
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In re: Patent Term Extension
Application for
U.S. Patent No. 5,716,981

DECISION DENYING REQUEST FOR RECONSIDERATION IN APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5,716,981

Dear Mr. Gollin:

This is in response to the Request for Reconsideration of Final Determination filed on May 3, 2007 ("the Request"), in the application for extension of the term of U.S. Patent No. 5,716,981 ("the '981 patent") under 35 U.S.C. § 156 ("the PTE Application"). The Request asks the United States Patent and Trademark Office ("USPTO") to reconsider, in conjunction with the Food and Drug Administration ("FDA"), the FDA's determination of the length of the regulatory review period, which was used to calculate the period of extension set forth in the Notice of Final Determination mailed by the USPTO on April 3, 2007. Because the USPTO has no authority to change or redetermine the regulatory review period determined by the FDA, Applicant's Request is DENIED.

A. Factual Background

On March 4, 2004, the FDA approved the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System, which is the subject of Pre-Market Approval Application (PMA) P030025.

On May 3, 2004, Angiotech Pharmaceuticals, Inc. ("Applicant"), the owner of the '981 patent, filed the PTE Application with the USPTO in compliance with 37 CFR § 1.740 to extend the term of the '981 patent. In the PTE Application, Applicant identifies October 12, 2000, which is the initiation date of the clinical trial (TAXUS I) in Germany for the Paclitaxel-Eluting Coronary Stent

System, as the date a clinical investigation on humans involving the device began according to 37 CFR § 1.777(c)(1). Based on the October 12, 2000, first human clinical trial date, Applicant calculates in the PTE Application a testing period of 866 total days. Applicant also calculates in the PTE Application an approval period of 374 total days, resulting in an eligible extension of 807 days for the '981 patent.

On May 24, 2004, the USPTO requested FDA's assistance in determining the '981 patent's eligibility for patent term extension.

In a letter dated February 24, 2006, the FDA advises the USPTO that the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System has undergone a regulatory review period and that the approval of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System represents the first permitted commercial marketing or use of the product.

On April 4, 2006, the USPTO requested that FDA determine the product's regulatory review period.

In a letter dated June 14, 2006, the FDA advises the USPTO that it has determined the total length of the regulatory review period for the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System to be 716 days. The FDA states in the June 2006 letter that of the 716 days, 456 days occurred during the testing phase and 260 days occurred during the approval phase. The FDA did not use the October 12, 2000, date, which was identified by Applicant as the initiation date of the clinical trial (TAXUS I) in Germany for the Paclitaxel-Eluting Coronary Stent System, in determining the length of the testing phase. Instead, the FDA determined the length of the testing phase from the date of March 21, 2002, which is when FDA records indicate that the investigational device exemption (IDE) was substantially complete for permitting clinical studies to have begun.

The FDA's determination of the regulatory review period for the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System was published in the Federal Register of July 5, 2006 (71 Fed. Reg. 38170). Pursuant to 35 U.S.C. § 156(d)(2)(B)(i) and (ii), the July 5, 2006, publication states that any interested person may file (i) within 180 days, a due diligence petition or (ii) within 60 days, a request for an informal hearing on the determination.

In a letter dated January 10, 2007, the FDA confirms that (i) the 180-day period for filing a due diligence petition has expired, (ii) the FDA has received no such petition, and (iii) the FDA considers the regulatory review period determination to be final.

On April 3, 2007, the USPTO mailed a Notice of Final Determination in which the USPTO states that the period of extension for the '981 patent was determined to be 488 days. The Notice also states that the 488 day period of extension was calculated using the FDA's determination of the length of the regulatory review period published in the July 5, 2006, Federal Register. In the Notice, the USPTO gives Applicant the opportunity to file within one month a request for reconsideration "of this final determination as to the length of extension of the term of the patent."

On May 3, 2007, Applicant filed a Request for Reconsideration of Final Determination. The Request asks the USPTO to reconsider, in conjunction with the FDA, the FDA's determination of the length of the regulatory review period, which was used by the USPTO to calculate the period of extension set forth in the April 3, 2007, Notice of Final Determination.

B. Decision

1. The Plain Language of 35 U.S.C. § 156(d) Shows That the Determination of the Regulatory Review Period Is Committed by Statute to the FDA

The terms of 35 U.S.C. § 156(d) are clear and unambiguous. After a copy of the extension application is forwarded by the USPTO to the appropriate Secretary, the Secretary receiving the application shall review the dates contained in the application and determine the applicable regulatory review period. Specifically, 35 U.S.C. § 156(d)(2)(A) states:

> (A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), The Commissioner shall notify –
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> * * *
>
> (ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,
>
> of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, *the Secretary* receiving the application *shall review the dates* contained in the application pursuant to paragraph (1)(C) *and determine the applicable regulatory review period*, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination. (emphasis added).

The statute thus plainly mandates the FDA to determine the regulatory review period. The statute does not authorize the USPTO to change or redetermine the regulatory review period determined by the FDA.

Here, the USPTO requested that the FDA determine the regulatory review period for the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System by letter dated April 4, 2006. The

FDA advised the USPTO that it had determined the total length of the regulatory review period for the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System by letter dated June 14, 2006. Subsequent to the publication of the FDA-determined regulatory review period in the Federal Register of July 5, 2006 (71 Fed. Reg. 38170), the FDA sent the USPTO a letter dated January 10, 2007, confirming that the FDA's regulatory review period determination is final. In accordance with 35 U.S.C. § 156(d), the USPTO has no authority to change or redetermine the regulatory review period determined by the FDA.

2. Judicial Precedent Confirms That the USPTO Has No Authority to Change or Redetermine the Regulatory Review Period Determined by the FDA

Judicial precedent confirms that the FDA alone, and not the USPTO, is directed by statute to determine the regulatory review period. In Astra v. Lehman, 71 F.3d 1578 (Fed. Cir. 1995), the Federal Circuit affirmed a judgment by the United States District Court for the District of Columbia that the USPTO is not authorized to redetermine or set aside the regulatory review period determined by the FDA.

Appellant Aktiebolaget Astra ("Astra") had a patent for a method of combating viral infections, and applied to the USPTO pursuant to 35 U.S.C. § 156 to extend the term of its patent. The USPTO requested the FDA to make a determination of the review period as required by 35 U.S.C. § 156(d). Astra did not contest the FDA's determination of the regulatory review period by requesting either a revision or a hearing pursuant to 21 CFR §§ 60.24, 60.26. Instead, Astra brought a declaratory judgment action against the USPTO claiming that the calculated period of extension was too short due to the FDA's determination of the regulatory review period. The district court affirmed summary judgment for the USPTO, holding that the plain meaning of the statute had been followed, and that the USPTO did not have the authority to change the FDA's determination of the review period made under the statute.

In affirming the decision of the district court, the Federal Circuit focused on the issue of "whether the Commissioner [of Patents and Trademarks] has authority to review and set aside a final determination of a regulatory review period made by the Secretary [of Health and Human Services]." Astra, 71 F.3d at 1580. The Federal Circuit analyzed both the language and legislative history of 35 U.S.C. § 156. See id. at 1580-81. It concluded that "the language of section 156(d)(2)(A) is unambiguous and uncontroverted" and mandates that the FDA alone, not the USPTO, determines the regulatory review period. Id. at 1581. The Federal Circuit further concluded that the legislative history provides "a contemporaneous and clear confirmation of [its] reading of the statute." Id.

Therefore, in accordance with judicial precedent, the USPTO has no authority to change or redetermine the regulatory review period determined by the FDA.

3. Applicant's Argument That It Is Appropriate for the USPTO to Consider And to Determine - With FDA - Whether the Regulatory Review Period Was Correctly Calculated is Unpersuasive

At page 1 and elsewhere within the PTE Application, Applicant acknowledges that the FDA, as the delegate of the Secretary of Health and Human Services, is given the statutory duty to determine the regulatory review period. However, Applicant repeatedly states in the PTE Application that it is appropriate for the USPTO to consider and to determine – with FDA – whether the regulatory review period was correctly calculated. For example, at page 3 of the PTE Application, Applicant states that "it is appropriate for the PTO to consider with FDA whether criteria used in determining the testing phase of the regulatory review period, and relied upon by the PTO in issuing the PTE, were contrary to the governing patent law."

The same argument was squarely addressed and rejected by the Federal Circuit in Astra. See 71 F.3d at 1580-81. Specifically, Astra argued "that section 156(d)(1) requires both the Commissioner and the Secretary to make the determination" of the regulatory review period. Id. at 1581. The Federal Circuit disagreed. In particular, the court stated that "[a]lthough the statute provides that the Commissioner and the Secretary are jointly to determine the 'period of the extension,' the statute, in section 156(d)(2)(A)(ii) . . ., is clear that the length of the 'regulatory review period,' shall be determined by the Secretary." Id. The court further states that "[s]ection 156(d)(1) does not contradict that interpretation." Id. Thus, it is clear that determination of the regulatory review period is outside the duties of the USPTO in their role in administration of 35 U.S.C. § 156.

In light of the Federal Circuit's decision in Astra, Applicant's argument that it is appropriate for the USPTO to consider and to determine - with FDA - whether the regulatory review period was correctly calculated is unpersuasive.

4. Conclusion

For the reasons stated above, the USPTO has no authority to change or redetermine the regulatory review period determined by the FDA, and Applicant's Request for Reconsideration is **DENIED**. This is a final agency decision.

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

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Mary C. Till
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for Patent Examination Policy

cc: Office of Regulatory Policy
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Attention: Beverly Friedman

Re: TAXUS® EXPRESS2™
(Paclitaxel-Eluting Coronary Stent System)
FDA Docket No.: 2004E-0396