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The AIA Technical Corrections Act Changes How Patent Term Adjustment is Calculated and Challenged

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On April 1, 2013, the USPTO published an interim final rule¹ implementing various provisions of the AIA Technical Corrections Act ("AIA TCA").² This new legislation and its implementing regulations significantly alter how patent term adjustment ("PTA") is calculated and challenged.³

STREAMLINED PTA DETERMINATION TO REDUCE THE COMPLEXITY AND COST OF CORRECTING PTA ERRORS

One of the most significant changes brought about by the AIA TCA is the streamlining of PTA calculations by the USPTO.

Prior to the enactment of the AIA TCA, there were two points in time at which the USPTO notified an applicant of its PTA calculation. The first occurred with a Notice of Allowance.⁴ In this instance, the PTA calculation was based on the USPTO's assumption that the allowed patent would issue on a certain predicted date. An applicant that disagreed with the USPTO's PTA determination had to file a request for PTA reconsideration on or before the payment of the issue fee.⁵ However, as it could not be known on what day the patent would issue and whether additional PTA would accrue, a second PTA notification would be provided when the patent actually issued.⁶ If the PTA printed on the issued patent was still in error, an applicant had to file a second request for reconsideration no

¹ Revisions to Patent Term Adjustment. Fed. Reg. Vol. 78, No. 62: 19416-19421 (published on April 1, 2013).

² AIA Technical Corrections Act, Pub. Law No. 112-274 (enacted January 14, 2013), 126 Stat. 2457.

³ The American Inventors Protection Act of 1999 (§§ 4401-4402, Pub. Law. No. 106-113, 113 Stat. 1356) amended 35 U.S.C. § 154 to create "guarantees" against three different types of USPTO delays: (1) "Part A" delay, which accrues when the USPTO fails to take an action within a certain period of time, such as issuing a first office action within 14 months, issuing a second office action or allowance within four months of a response, or issuing a patent within four months of the issue fee payment; (2) "Part B" delay, which accrues when the USPTO fails to issue a patent within three years from the filing date of the patent application; and (3) "Part C" delay, which accrues when an application is involved in an interference or appeal, or is subject to a secrecy order. To determine the total amount of patent term adjustment an applicant is entitled to, the USPTO used (and still uses today) a computer program that combines Part A, Part B, and Part C delays, subtracts any overlapping days, and then subtracts any Applicant-caused delays to arrive at the final patent term adjustment figure. See Manual of Patent Examination and Procedure § 2733 (8th ed., August 2012).

⁴ Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, Fed. Reg. Vol. 65, No. 181: 56365 – 56394 (published September 18, 2000). Because a Notice of Allowance is sent well before a patent is actually granted, the PTA determination that accompanies the Notice of Allowance is known as a pre-issuance PTA determination.

⁵ See 35 U.S.C. 154(b)(3)(B)(ii) and 37 C.F.R. 1.705(b) (prior to their amendment by the AIA Technical Corrections Act).

⁶ Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. Vol. 65, No. 181: 56365-56394, at page 56374 (explaining that a two-part process is required because the USPTO was obliged under 35 USC 154(b)(3) to provide a patent term adjustment determination before the issue date, and thus before the final patent term adjustment determination could be known).

later than two months from the date the patent issued. However, this second request for reconsideration could not raise any PTA issues that could have been raised in the first, pre-issuance PTA determination.⁷

Under the AIA TCA, the USPTO is no longer required to provide a PTA determination when issuing the Notice of Allowance and is instead only required to provide a single PTA determination on or before the patent issuance date.⁸ The USPTO has indicated it will continue to provide (as it has in the past)⁹ an indication of the PTA with a patent's Issue Notification, but the PTA indicated on the patent itself will now serve as the USPTO's "official" PTA determination.¹⁰ A request for reconsideration of this official PTA determination may now be filed up to seven months after the patent grant date.¹¹

The changes discussed above reduce the complexity and thus the costs associated with challenging a PTA. These changes also provide applicants with a longer period of time to decide whether or not to challenge any USPTO errors in calculating PTA.

NEW START DATE FOR USPTO 14-MONTH DEADLINE FOR U.S. NATIONAL STAGE APPLICATIONS

Another significant change brought about by the AIA TCA is that Part A delay for the USPTO's failure to issue a first office action within 14 months now begins to accrue upon commencement of the U.S. national stage. This occurs when an applicant pays the fee for entry into the U.S. national stage and submits a copy of the international application (and its English translation, if the application was initially filed in a language other than English).¹²

Prior to the enactment of the AIA TCA, Part A delay for the USPTO's failure to issue a first office action within the prescribed 14-month period began to accrue on "the date on which an international application fulfilled the requirements of section 371." This required the submission of: (1) the fee for entry into the U.S. national stage; (2) a copy of the international application and its English translation (if such a translation was necessary)¹³;

⁷ See 37 C.F.R. 1.705(d) (prior to its amendment by the AIA Technical Corrections Act).

⁸ AIA Technical Corrections Act § 1(h)(2) (amending 35 U.S.C. § 154(b)(3)(i) to state that the USPTO's PTA determination shall be provided "no later than the date of issuance of the patent").

⁹ See K.L. Tyson and R.W. Bahr, *Patent Term Guarantee Overview*, <u>http://www.uspto.gov/patents/law/aipa/pta/patent_term_guarantee.jsp</u>, accessed on April 8, 2013.

¹⁰ Revisions to Patent Term Adjustment. Fed. Reg., Vol. 78, No. 62: 19416-19421, at page 19418 (published on April 1, 2013).

¹¹ AIA Technical Corrections Act, § 1(h)(3)(A) and *Revisions to Patent Term Adjustment*. Fed. Reg. Vol. 78, No. 62: 19416-19421, at page 19418. 37 C.F.R. § 1.705(b) as amended now states: "Any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted. This two month time period may be extended under the provisions of § 1.136(a)." The provisions of 37 C.F.R. § 1.136(a) provide for an additional feebased extension of up to five months, bringing the total time period in which to challenge the USPTO's patent term adjustment determination to seven months from the patent grant date.

¹² Prior to the America Invents Act, the USPTO defined when an international application entered the national stage as the date when the international applicant submitted all the documents and fees required by 35 U.S.C. 371(c) within the period set forth in 37 C.F.R. 1.495, which meant that an international application would not enter the U.S. national stage until the applicant filed the inventor's oath or declaration, which was required under 35 U.S.C. 371(c)(4). See *Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act*, Fed. Reg. Vol. 77, No. 157: 48776-48826, at page 48795. After September 16, 2012 (the effective date of the America Invents Act), 37 C.F.R. 1.491(b) was amended to state that an international application enters the national stage when the applicant has filed "the documents and fees required by 35 U.S.C. 271(c)(1) and (c)(2) within the period set in 1.495."

¹³ 35 U.S.C. § 371(c)(2) further specifies that the copy of the international application need not be submitted if it was already sent to the USPTO from the International Bureau.

(3) amendments to the claims, if any, and their English translation (if necessary); (4) the inventor's oath or inventor's declaration; and (5) an English translation of any annexes to the International Preliminary Examination Report, if any such annexes were initially filed in a language other than English.¹⁴

This change permits U.S. national stage applicants to delay submission of an executed inventor oath/declaration without risking a loss of potential PTA.

NEW LIMITS ON THE TIMING AND SCOPE OF PTA CHALLENGES

Another significant change brought about by the AIA TCA is the imposition of new limits on the timing and scope of PTA challenges. Patent applicants dissatisfied with the USPTO's official PTA determination must first file a request for reconsideration with the USPTO Director within seven months of the patent grant date. Applicants then wait for the Director's decision on this request before filing a civil action in district court under 35 U.S.C. § 154(b)(4). Additionally, the AIA TCA declares that a civil action under 35 U.S.C. § 154(b)(4) is the "exclusive" judicial remedy for a dissatisfied patentee, and it also specifies that such a civil action must be brought in the District Court for the Eastern District of Virginia within 180 days of the date of the Director's decision on the applicant's request for PTA reconsideration.¹⁵

Prior to the AIA TCA, 35 U.S.C. § 154(b)(4)A) permitted applicants dissatisfied with a PTA determination to bring an action directly in district court within 180 days of the patent grant date. Thus, if the USPTO did not act on a request for PTA reconsideration in a timely fashion, an applicant could still bring an action in district court within 180 days of the patent grant date to address the issue.

However, under the AIA TCA, if the USPTO fails to timely respond to a request for PTA reconsideration, an applicant will have to wait for the Director's decision prior to filing a civil action in district court under 35 U.S.C. § 154(b)(4). Furthermore, with the insertion of the word "exclusive" into 154(b)(4)(A), it may now be more difficult for an applicant to invoke alternative theories of recovery, such as challenging a PTA determination as an unconstitutional taking, in order to circumvent the timing and administrative exhaustion requirements set forth in the AIA TCA.¹⁶

CONCLUSION

Given the important changes brought about by the AIA TCA, clients with patent applications pending before the USPTO or patents that have been granted on or after January 14, 2013 should review any PTA calculations they have received from the USPTO with great care to ensure that the changes brought about by the AIA TCA have been taken into consideration.

¹⁴ See 35 U.S.C. § 371(c) and the Manual of Patent Examination and Procedure § 1893.03(b).

¹⁵ AIA Technical Corrections Act, § 1(h)(3)(A) and (B) (inserting the phrase "shall have exclusive remedy" into 35 U.S.C. § 154 (b)(3)(B)(ii) and also replacing the phrase "the grant of the patent" with "the date of the Director's decision on the applicant's request for reconsideration"). See also Leahy-Smith America Invents Act § 9, Pub. L. No. 112-29, 125 Stat. 284 (2011) (enacted September 16, 2011) and *Revisions to Patent Term Adjustment*. Fed. Reg. Vol. 78, No. 62: 19418-19421, at pages 19418 and 19420.

¹⁶ See, e.g., Novartis A.G. v. Kappos, No. 10-cv-1138 (ESH) (D.D.C. Nov. 15, 2012) (pre AIA Technical Corrections Act case challenging USPTO's interpretation of 35 U.S.C. 154(b)(1)(B) as a violation of the Takings Clause of the Fifth Amendment on the ground that the USPTO's erroneous PTA determination deprived Novartis of its property interest in its patent term without compensation).

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