U.S. Patent and Trademark Office Miscalculates Patent Term Adjustment for Patents Issued from 35 U.S.C. § 371 National Stage Filings

Fish & Richardson and our pharmaceutical client Japan Tobacco Inc. (JT) have discovered a significant error in the manner by which the U.S. Patent and Trademark Office (PTO) calculates the amount of patent term adjustment (PTA) to which a patent is entitled under 35 U.S.C. § 154(b). This error is independent of the error at issue in the highly publicized case Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008), which concerned the PTO's method of calculating overlap between "A Delay" (resulting from the PTO's failure to issue actions within specified time frames) and "B Delay"(resulting from application pendency that exceeds three years).

Distinct from the Wyeth v. Dudas issue, the error identified by Fish & Richardson and JT concerns how the PTO calculates the length of B Delay for patents granted from most 35 U.S.C. § 371 national stage filings. The PTO's practice has been to award B Delay beginning three years after completion of the requirements under § 371(c) (e.g., submission of inventor's oath or declaration). However, the statute and regulations require that this period begin three years after the national stage has "commenced" under 35 U.S.C. § 371(b) or § 371(f). This commencement is often, though not always, prior to completion of the requirements under § 371(c). As a result, PTA resulting from B Delay is often longer than that provided by the PTO's practice. This difference can be many months or even more than a year. For biotech and pharma patents in particular, these additional days of patent term can be of significant value.

Fish & Richardson challenged the PTO's practice on behalf of JT's U.S. Patent No. 7,465,444 and received a favorable Decision from the Office of Petitions on June 16, 2009. On September 9, 2009, the PTO issued a formal Notice (copy enclosed) acknowledging that they calculate incorrectly three year pendency for § 371 filings and they are "in the process" of correcting the problem. The PTO's Notice instructs patentees to file a request for correction of this error within two months after patent issuance. Because this systemic error has not yet been corrected by the PTO, we recommend that this issue be reviewed independently for all patents derived from § 371 national stage filings and for which maximizing patent term is important. Fish & Richardson monitors this and all other aspects of PTA determination as part of a comprehensive PTA review available to all of our clients.

Legal Basis for Calculating "B Delay" for 35 U.S.C. § 371 National Stage Filings

When calculating "B Delay" for a national stage filing under 35 U.S.C. § 371(b), application pendency must be measured from the date that is 30 months from the priority date of the international application (i.e., not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371, which is the PTO's current practice).

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States … the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued. 35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. 371(b) or (f)."[1]

> (b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including… 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences."

> (b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

> (f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

[1] Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that "[i]n the case of an international application, the phrase 'actual filing date of the application in the United States' [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f)."

35 U.S.C. § 371(f) applies where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. § 371(b) are reproduced below.

Article 22

Copy, Translation, and Fee, to Designated Offices

(1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)

(2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39
Copy, Translation, and Fee, to Elected Offices

(1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from the priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

> Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01. (emphasis added)

In view of the foregoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.[2]

[2] In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "B Delay," the beginning of the relevant period for purposes of calculating "A Delay" is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II) and 37 C.F.R. § 1.702(a)(1).

Hypothetical Applications of the Correct Method for Measuring "B Delay" for § 371 National Stage Applications

The time at which the three year "B Delay" clock starts for a § 371 national stage filing depends upon whether the national stage commences under 35 U.S.C. § 371(b) or 35 U.S.C. § 371(f).

35 U.S.C. § 371(b)

The U.S. national stage commences under 35 U.S.C. § 371(b) on the date that is 30 months from the priority date of a PCT application *unless* the applicant files an express request for early processing and completes the requirements of § 371(c) prior to the 30 month date.

(a) Example of PTO practice awarding too little PTA

> A U.S. national stage application is filed with the PTO on or before January 1, 2004, the date that is 30 months from the priority date of a PCT application. The application is filed at the PTO without one or more of the items required by § 371(c) (e.g., an inventor's oath or declaration). The PTO issues a Notification of Missing Requirements and the applicant submits all missing parts on September 1, 2004. The PTO practice has been to start the B Delay clock three years after completion of the 371(c) requirements, on September 2, 2007. However, the B Delay clock should have started on January 2, 2007 (i.e., three years after commencement). In this example, eight months of potential PTA is lost by misapplication of the rule. This scenario is most common for U.S. national stage filings that are made without inclusion of an inventor's oath or declaration at the time of filing.

(b) Example of PTO practice awarding too much PTA

> In some instances, correct application of the rule can result in *less* PTA than is provided by current PTO practice. Consider again a PCT application that has a 30 month date of January 1, 2004. In this example, a complete U.S. national stage application is filed with the PTO on October 1, 2003, such that § 371(c) is complied with on the day of filing. However, the applicant does not file an express request for early processing in compliance with 35 U.S.C. § 371(f). In this instance,

current PTO practice would be to start the B Delay clock three years after completion of the § 371(c) requirements, on October 2, 2006. However, the B Delay clock should have started on January 2, 2007 (i.e., three years after commencement). In this example, three months of PTA is incorrectly awarded by misapplication of the rule.

35 U.S.C. § 371(f)

The B Delay clock can be started three years after a date that is *before* the 30 month date if the national stage is commenced under § 371(f). This requires that that the applicant file an express request for early processing *and* complete the requirements of § 371(c) prior to the 30 month date. If either one of these requirements is not met, then the national stage (and the reference date the B Delay clock) will commence on the date that is 30 months from the priority date of the PCT application.

Jack Brennan, Ph.D.
Principal
Fish & Richardson P.C.
601 Lexington Avenue - 52nd Floor
New York, NY 10022-4611
(212) 765-5070
brennan@fr.com

Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371

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Summary: The computer program that the United States Patent and Trademark Office (USPTO) uses to calculate patent term adjustment incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications if the requirements of 35 U.S.C. § 371 are not fulfilled on the date that the national stage commenced under 35 U.S.C. § 371(b) or (f). The USPTO is in the process of correcting this computer program. Applicants seeking a revised patent term adjustment determination based on this calculation must submit a timely request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d).

Background: Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional patent term adjustment if the issue of an original patent is delayed due to the failure of the USPTO to issue a patent within three years after the actual filing date of the application. The USPTO implemented the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) in 37 CFR 1.702(b) and 37 CFR 1.703(b). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56365, 56391-92 (Sept. 18, 2000) (final rule). The USPTO indicated the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) is measured from the date that the national stage commences under 35 U.S C. § 371(b) or (f) in an international application. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56382-84.

The USPTO makes patent term adjustment determinations by a computer program that uses the information recorded in the USPTO's automated patent application information system (the Patent Application Locating and Monitoring system or PALM system), except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56370, 56380-81.

Discussion: The USPTO is in the process of correcting an error in the computer program that it uses to calculate the patent term adjustment that affects patents issuing from international applications entering the national stage as to the United States pursuant to 35 U.S.C. § 371. The USPTO's computer program incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications as being measured from the date that the requirements of 35 U.S.C. § 371 were fulfilled rather than the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application. The USPTO is correcting the computer program to reflect that the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications is measured from the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application.

An applicant seeking a revised patent term adjustment determination based upon the three-year pendency provision must submit a timely request for reconsideration of the patent term adjustment indicated in the patent. The USPTO does not calculate and inform the applicant of the patent term adjustment based upon the three-year pendency

provision of 35 U.S.C. § 154(b)(1)(B) in the notice of allowance because the USPTO must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Thus, reconsideration of the patent term adjustment indicated in the patent as it relates to the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) is **not** considered a matter that could have been raised in an application for patent term adjustment under 37 CFR 1.705(b) (provides for reconsideration of the patent term adjustment indicated in the notice of allowance). Therefore, a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued.

For Further Information Contact: The Office of Patent Legal Administration by telephone at (571) 272-7702, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office