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Case Spotlight

Obstacles to Correcting Patent Term Adjustments

With the much anticipated opinion of *Wyeth v. Kappos*, No. 2009-1120, 2010 WL 27184 (Fed. Cir. Jan. 7, 2010), the Federal Circuit overturned one aspect of the PTO's methodology of calculating the amount of a patent term adjustment (PTA) an applicant is due under the Patent Term Guarantees of 35 U.S.C. § 154(b). While *Wyeth* will apply to calculating PTAs going forward, procedural obstacles may foreclose patentees from obtaining a correction of prior PTA determinations for issued patents or patent applications in which the issue fee has already been paid.

As part of switching to a patent system where the term of a utility patent is measured twenty years from the patent's earliest effective filing date, rather than seventeen years from its issue date, Congress enacted certain "Patent Term Guarantees" to ensure that delays by the PTO in processing a patent application would not unfairly deprive a patentee from enjoying the full term of its patent. *See generally*, Robert A. Matthews, Jr., *Annotated Patent Digest* § 9:24 Extensions for PTO Delays. The Patent Term Guarantees address three periods of possible delays in processing a patent application; denoted herein as Period A, B, and C. "Period A" delays occur when the PTO fails to meet certain examination deadlines, such as issuing a first office action within fourteen months after the application had been filed. 35 U.S.C. § 154(b)(1)(A)(i)-(iv). A "Period B" delay arises where the PTO fails to issue a patent within three years from the actual filing date, subject to several caveats. 35 U.S.C. § 154(b)(1)(B)(i)-(iii). "Period C" delays account for delays due to interference proceedings, secrecy orders, or an appeal to the Board of Patent Appeals. 35 U.S.C. § 154(b)(1)(C).

In general, for each day of PTO delay, the applicant is entitled to one day of a PTA. The total number of days of a PTA must be reduced by the number of days that the applicant "failed to engage in reasonable efforts to conclude prosecution." 35 U.S.C. § 154(b)(2)(C). Additionally, to prevent a double counting of delays, the statute further provides that "[t]o the extent that *periods of delay* attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A) (emphasis added).

The main legal question in *Wyeth* concerned the proper construction of the "overlap" provision of § 154(b)(2)(A), and specifically how the PTA should be calculated where the patent had Period A delays during the first three years of its prosecution and a Period B delay for being issued more than three years from the actual application filing date. Viewing Period A delays as necessarily contributing to any Period B delay, the PTO had taken the position that for patents subject to a Period B delay *all* Period A delays "overlapped" with the Period B delays, even if

those Period A delays happened during the first three years of the application's pendency. Under this view of the statute, an applicant was entitled to a PTA equal to the greater of the total number of days of Period A delays or the number of days of Period B delay; but never a combination of the two periods.

In *Wyeth* two pharmaceutical companies challenged the PTO's methodology of calculating the PTA where Period A delays overlapped with a Period B delay for two different patents. For the first patent, the PTO had calculated that the application was subject to 610 days of Period A delays, 345 days of B delay, and 148 days of applicant delay. Further, only 51 days of Period A delays had occurred more than three years after the actual filing date of the application. Applying its view that an applicant was only entitled to a PTA of the greater of the Period A delays or the days of Period B delay, the PTO gave the patentee 610 days of PTA less the 148 days of delay caused by the applicant for a total PTA of 462 days. The applicant objected and argued that Period A delays occurring before the Period B delay began did not "overlap" under the statute. Accordingly, since there were only 51 days of Period A delays that happened during the Period B delay, the applicant argued that it was entitled to a PTA equal to 610 (the total Period A delays) plus 345 (the total days of Period B delay) minus 51 (the number of days of Period A delays that overlapped with the Period B delay) minus 148 (the applicant's delay), which would have resulted in a PTA of 756 days.

After the PTO denied the applicants' request for reconsideration of the PTA determination, the applicant brought suit against the PTO under 35 U.S.C. § 154(b)(4). In that suit, the applicants argued that "'A period' and 'B period' [delays] overlap only if they occur on the same calendar day or days." *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 140 (D.D.C. Sept. 30, 2008). In granting the applicants summary judgment, the district court agreed with the applicant's construction of the statute and specifically that "overlap" requires the delays to occur on the same calendar day. *Id.* at 140-42. On appeal, the Federal Circuit affirmed.

Considering the statute's text, the Federal Circuit stated that it "detect[ed] no ambiguity in the terms 'periods of delay' and 'overlap.'" 2010 WL 27184 at *4. It found that a Period A delay "runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action." *Id.* In contrast, a Period B delay "under the express language of the B clause … runs from the three-year mark after filing until the application issues." Based on this understanding of the two periods, the Federal Circuit held that it was "clear that no 'overlap' happens unless the violations occur at the same time. … If an A delay occurs on one day and a B delay occurs on a different day, those two days do not 'overlap' under section 154(b)(2)." *Id.* at *5. The Federal Circuit concluded that "[t]he PTO's position cannot be reconciled with the language of the statute. … The problem with the PTO's interpretation is that it considers the application *delayed* under the B guarantee during the period *before it has delayed.*" *Id.*

The PTO argued that since Period A delays often lead to Period B delays, there would be an inequity in not treating all Period A delays as overlapping with a Period B delay. Although giving some acknowledgement to this observation, the Federal Circuit noted that the PTO's solution produced its own "potential perverse results." *Id.* at 5. It therefore instructed that "[r]egardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities, even if it could. In the end, the law has put a policy in effect that this court must enforce, not criticize or correct." *Id.* at *6. Hence, at the end of the day, the Federal Circuit overruled the PTO's methodology of treating all Period A delays as overlapping any Period B delay.

With a clear (even if potentially debatable) ruling from the Federal Circuit overturning the methodology the PTO has followed for the last several years in calculating PTAs, many who feel they were the victim of an incorrect PTA calculation by the PTO may wonder if they have any recourse to obtain a correction of a prior PTA determination. While nothing in *Wyeth* on its face prevents a retroactive application of the ruling, other procedural requirements to obtaining a PTA may preclude patentees from obtaining a correction of a prior PTA determination.

First, 35 U.S.C. § 154(b)(4), which permits a district court action to challenge the PTO's PTA determination, expressly states that the action must be "filed … within 180 days after the grant of the patent." The statute provides for no exceptions to the six-month deadline. This *statutorily imposed* deadline will likely preclude most, if not all, suits where the patent issued more than six months before the applicant filed the suit. Given that the Federal Circuit

affirmed a ruling handed down on September 30, 2008, its seems unlikely that courts will give weight to an argument that Federal Circuit's opinion represents an intervening change in the law justifying an exception to the statute's six-month deadline.

Second, even in situations where the six-month deadline has not passed, some patentees may face another procedural obstacle. The PTA statutory provision expressly states that the PTO has to provide an applicant "one opportunity to request reconsideration of any patent term adjustment determination made by the Director." 35 U.S.C. § 154(b)(3)(B)(ii). A patentee who failed to file a request for reconsideration of the PTA in the PTO before filing a lawsuit may face an argument that its suit should be dismissed because the patentee failed to exhaust its administrative remedies. *Cf. Wyeth*, 2010 WL 27184 at *3 (noting patentee had filed in the PTO petitions for reconsideration of the PTA determinations). (Whether a futility-type argument can overcome a failure-to-exhaust defense for a PTA challenge raises an interesting issue beyond the scope of this summary.) Additionally, for those holding issued patents, it seems unlikely that, under the current regulations, they can file in the PTO a post-issuance request to correct a prior PTA determination since under the applicable PTO regulation *all* requests for reconsidering the PTO's determination of a term adjustment "*must* be filed no later than the payment of the issue fee." 37 C.F.R. 1.705(b) ("*Any* request for reconsideration of the patent term adjustment indicated in the notice of allowance … *must* be by way of an application for patent term adjustment. An application for patent term adjustment under this section *must* be filed no later than the payment of the issue fee …."); *see also* 37 C.F.R. 1.705(e) ("The periods set forth in this section are *not extendable*.").

There may be some creative solutions to the above-identified obstacles. But whether the costs to develop and support such solutions make pursuing a PTA correction worthwhile is something each patent holder will have to determine for itself.

ABOUT THE AUTHOR

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