

INTELLECTUAL PROPERTY & *Life Sciences*

Federal Circuit Affirms Ruling of USPTO Error In Calculating Patent Term Adjustment

By Robert J. Paradiso and Lisa K. Schroeder

Under 35 U.S.C. Section 154, patentees are entitled to patent term adjustment (“PTA”) to remedy certain delays attributable to the United States Patent and Trademark Office (“USPTO”) that occurred during the prosecution of the patent. Specifically, Section 154 contains three guarantees to patent applicants regarding the expediency with which their patent applications will be handled: the “A guarantee” under Section 154(b)(1)(A) of prompt USPTO examination and response time; the “B guarantee” under Section 154(b)(1)(B) of no more than a three-year application pendency; and the “C guarantee” under Section 154(b)(1)(C) of adjustments for delays due to interferences, secrecy orders, and appeals. In the event of any delays by the USPTO under these guarantees (each, an “A delay,” “B delay,”

and “C delay,” respectively), a patentee is entitled to an additional day of patent term for each day by which prosecution of the patent application was delayed. Patent term adjustments are important because under the American Inventors Protection Act of 1999, the term of a U.S. patent was changed from 17 years from the grant date to 20 years from the earliest effective filing date. Accordingly, any delay in the prosecution of a patent application effectively reduces the term of the issued patent under this statute.

Any patent term adjustments made pursuant to Section 154 are reduced by certain applicant-attributable delays during the patent application process. The adjustments are also subject to an overlap reduction: “To the extent that periods of delay attributable to grounds specified in [Section 154(b)(1)] overlap, the period of adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.”

In *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the Federal Circuit affirmed the D.C. District Court’s ruling that the USPTO had been incorrectly implementing the overlap reduction.

At issue in *Wyeth* was the interpretation and application of the mandate under §154(b)(2)(A), *supra*, that the period of PTA shall not exceed the actual number of days the issuance of the patent was delayed in the event of an overlap between an A delay and a B delay. A clear example of such an overlap is when there is USPTO-attributable delay in issuing an action (A delay) that occurs after an application has been pending more than three years (B delay). Although this period of delay can be categorized as both A and B delay, the period should only be counted once when calculating PTA — otherwise the patentee would receive a windfall of having one day of delay count towards two days of additional patent term.

However, prior to *Wyeth*, under the USPTO’s interpretation of this section, B delay could occur at any time during an application’s pendency, not just during the period beginning three years after the filing date of the application. See 69 Fed. Reg. 21706 (2004). Therefore, under this interpretation, the period of A delay would always overlap with the period of B delay. Accordingly, the USPTO used the greater of A delay or B delay to determine

Paradiso is a member of the tech group at Lowenstein Sandler in Roseland and leads the firm’s life sciences patent practice. Schroeder is an associate in the tech group and counsels clients on all aspects of intellectual property law.

the appropriate PTA for a patent, but never combined the two because under its interpretation such a combination would result in a period of adjustment that exceeded the actual number of days the issuance of the patent was delayed. In essence, the USPTO was taking the strict stance that any delay in examination or response that occurred prior to the three-year mark (an A delay) was directly attributable to any subsequent delay of issuance beyond three years (a B delay), thus resulting in an “overlap” under Section 154(b)(2)(A).

The USPTO’s approach to PTA calculation was challenged during its determination of PTA for two patents owned by Wyeth and Elan Pharma, U.S. Patent Nos. 7,179,892 and 7,189,819, which cover inventions directed to the treatment of Alzheimer’s disease. During the prosecution of each patent, the USPTO undisputedly caused both A delays and B delays, which entitled the applicants to PTA. However, Wyeth disagreed with the USPTO’s above-described “greater-of-A-or-B” approach to its calculation of PTA for each of these patents. Instead, Wyeth argued that with regard to reductions for overlap of A delay and B delay, only those A delays occurring after the three-year mark should have been deducted from the PTA as “overlaps,” yielding an additional 294 days of PTA for the ‘892 patent and an additional 230 days of PTA for the ‘819 patent.

After unsuccessfully filing petitions for reconsideration of these PTA determinations with the USPTO, Wyeth filed an action with the District Court for the District of Columbia seeking an order directing the USPTO to grant an adjustment as per Wyeth’s interpretation of Section 154. The district court ultimately sided with Wyeth, finding that periods of A delay occurring prior to the three-year mark *do not* overlap with B delay, and therefore should not be deducted from the PTA calculation. *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 142 (D.D.C. 2008). The USPTO subsequently appealed to the Federal Circuit.

In the context of Section 154(b), the Federal Circuit found that the “period of

delay” under the express language of the B guarantee “runs from the three-year mark after filing until the application issues.” Accordingly, the Federal Circuit affirmed the lower court’s ruling that “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.”

Next Steps

The USPTO has indicated that neither it nor the Department of Justice will seek further review of the Federal Circuit’s *Wyeth* decision. The USPTO also issued a notice on February 1, stating that it expects to complete modification of its PTA calculation software by March 2. The notice sets forth interim procedures by which owners of patents granted prior to March 2 may request reconsideration of PTA at no fee, so long as such request is filed with the USPTO within 180 days of the patent’s grant date, the time period allowed for seeking a civil remedy under Section 154(b)(4)(A) (“An applicant dissatisfied with a determination made by the Director . . . shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.”). Undoubtedly, at least part of the reasoning behind the USPTO’s willingness to reconsider PTA within the 180-day window is to provide an avenue for applicants to receive post-*Wyeth* PTA review other than bringing a civil action in district court. This alternative to civil litigation will be expected to reduce the time and resources necessary for the USPTO to address applicants’ rights under *Wyeth*. However, patentees are cautioned that filing a petition under the interim procedures will not preserve the right to take action against the USPTO in district court under Section 154(b)(4)(A).

Given that the USPTO has been miscalculating PTA since at least 2004, the interim procedures beg the question of whether there is any recourse for patentees with miscalculated PTA who are outside

of the 180-day window. Cases have been filed in the wake of *Wyeth* arguing that the doctrine of equitable tolling should be invoked so that patentees that would normally be outside of this window can challenge their miscalculated PTA. In one case, The General Hospital Corporation filed a complaint on January 16, 2009 (after the district court case *Wyeth v. Dudas*), seeking a judgment that the PTA for its U.S. Patent No. 7,367,341 be corrected from 214 days to 515 days. The ‘341 patent issued on May 6, 2008, outside of the 180-day period set forth in the statute. However, in its complaint The General Hospital Corporation alleges that the *Wyeth v. Dudas* decision “constitutes a change in law sufficient to invoke the doctrine of equitable tolling to allow for the filing of this complaint at this time.” This case was stayed pursuant to an order entered March 30, 2009, pending the final disposition of the appeal from *Wyeth v. Dudas*, and proceedings do not appear to have resumed as of the time of submission of this article.

It is questionable whether the doctrine of equitable tolling will offer patentees any recourse outside the 180-day window. Arguably, the *Wyeth* decision is not new law, as the decision only clarified the interpretation of an existing statute. The USPTO will most likely take the position that patentees outside the 180-day window were in the same position as *Wyeth* and Elan Pharma, and should have brought a district court action within the statutory time frame if they wanted to preserve their rights. By the time the equitable tolling line of cases is decided, it will likely be too late for patentees to protest miscalculated PTA without some intervening act of Congress. However, in the event that the D.C. District Court is receptive to the equitable tolling arguments and *Wyeth v. Kappos* is ultimately construed as re-starting the statutory 180-day time frame, patentees should file a complaint prior to July 6 (180 days after the issuance of the Federal Circuit’s *Wyeth* decision) in order to preserve any right they may have to protest miscalculated PTA. ■