BRACEWELL

INSIGHTS

Re-Calculating Patent Term Adjustments Once Again

January 24, 2014

By: ***Keith R. Derrington***

The Federal Circuit has adjusted the way we calculate Patent Term Adjustments (PTA) once again with its holdings in *Novartis* and *Exelixis*.[1] The Federal Circuit held that the United States Patent and Trademark Office (USPTO) has been incorrectly calculating PTA for patents that issue as a result of continued examination.[2] Until now, the PTO has not adjusted patent terms to compensate for the time occurring after allowance and before issuance for patents that issue as a result of requests for continued examination. The Federal Circuit has indicated that this time period is to be included in the PTA calculation, thus potentially extending the life of many patents.

Historical Treatment of Time Spent in Continued Examination

Before 1994, a patent term in the United States ran seventeen years from the date of issuance of a patent. When the law changed in 1994 to set the term at twenty years from the filing date of the patent, the life of some patents was shortened due to USPTO delays in processing of the application. PTA was created to compensate a patentee for delays caused by the USPTO, such that the term of the patent was increased one day for each day of USPTO delay.[3]

The current regulations for PTA from the USPTO do not allow for term adjustments for any time consumed by continued examination of the application, irrespective of when the continued examination was initiated by the patent applicant.[4] Additionally, the regulations have been applied such that the PTA does not include the number of days from the date of request for continued examination to the date the patent was *issued*. Thus, the time from allowance to issuance of a patent subject to continued examination is not included in PTA, even though such a time period would be included for a patent not subject to continued examination.

Review of PTA Determinations

A patent applicant who disagrees with the USPTO's determination of PTA can request reconsideration of the calculation within two months of issuance.[5] An applicant who is still dissatisfied after reconsideration may file suit in U. S. District Court in the District of Columbia within 180 days after grant of the patent. Using this review process, Novartis filed suit regarding a number of its patents, arguing that the USPTO had improperly calculated the PTA of patents that issued as a result of continued examination. Novartis argued: (1) if a request for continued examination is filed after an application has been pending for three years, the time spent in continued examination should not reduce PTA; and (2) continued examination ends once the application is allowed, thus the time period from allowance to issuance should be added to any

relevant PTA.

The Federal Circuit rejected the first argument and agreed with the USPTO regulations that no adjustment of time is available for any time in continued examination, even if continued examination commenced after the application had been pending three years.

On the second argument, however, the Federal Circuit agreed with Novartis and held that the time consumed by continued examination should be limited to the time up to the date of allowance, assuming no further examination of the matter at the USPTO.[6] In finding that such time period should be assessed in the PTA calculation, the Court noted that examination ends at allowance. Including a calculation for the time from allowance to issuance in the PTA can cause an addition of several weeks to several months to the term, thus extending the life of these patents.

Statute of Limitations Timing for Reconsideration of PTA Calculations

Novartis further argued that its claims for adjustments of PTA for fifteen of its patents were not time barred under the statute of limitations, even though it filed suit more than 180 days after issuance of these patents.[7] Novartis unsuccessfully argued that the 180 day period did not apply to its challenges based on statutory construction principles. The Federal Circuit found Novartis's argument "unreasonable" citing a "flaw in drafting" that did not reasonably support Novartis's position.[8]

Conclusion

Based on the Federal Circuit's decision, it is clear that patentees need to be mindful of the clock and timely file requests for reconsideration of PTA, and timely file suit if unsatisfied with the decision of the USPTO regarding the individual PTA assigned to each patent. Time is of the essence and caused Novartis to lose valuable adjustments to terms of a number of its patents. Additionally, patentees should be mindful of the new PTA rules, double check PTA calculations of newly granted patents, and timely seek reconsideration for those patents affected by recent Federal Circuit decisions.

---

[1] ***Novartis AG v. Lee*** , No. 2013-1160,-1179 (Fed. Cir. Jan. 15, 2014); ***Exelixis v. Lee***, No. 2013-1175 (Fed. Cir. Jan.15, 2014) (vacating judgments and remanding for redetermination of the patent term adjustments consistent with the *Novartis* decision).

[2] The *Novartis* decision is limited to patents issuing as a result of continued examination. The calculation of PTA for other types of applications, such as continuations and continuations-in-part, is not subject to the same exclusion as continued examination applications. 35 U.S.C. § 154(b)(1)(B).

[3] 35 U.S.C. § 154(b)(1)(A).

[4] 37 C.F.R. § 1.702(b)(1).

[5] 37 C.F.R. § 1.705(b).

[6] The Federal Circuit noted that there are instances in which prosecution on the merits is reopened after an allowance. In such cases, examination of the application is not yet complete.

[7] Novartis also proffered an equitable tolling argument based on its delay in filing suit while waiting on a decision in *Wyeth* v. *Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Federal Circuit made clear that no such tolling was available, as the legal theory for alternative PTA calculations was clear to Novartis even while *Wyeth* was pending and that delay based on waiting for another party to secure a favorable ruling was not excusable.

[8] Novartis also argued that its Fifth Amendment rights had been violated because it had been unable to secure extra time on its patents. The Federal Circuit made clear that there is no constitutional violation where one's own neglect causes a loss of PTA.