Keywords: patent term extension; patent term adjustment

General: Patent term adjustment time should be calculated by determining the length of time between application filing and patent issuance, subtracting any continued examination time (and another other time identified in 35 U.S.C. § 154(b)(1)(B)), and determining the extent to which the result exceeds three years.

Novartis AG v. Lee
2013-1160, -1179 (Fed. Cir. 2014).

I. Background and Facts

In 1994, the method of measuring the effective term of a patent was changed by Congress. The original law provided that a patent's term began at issuance and ended after a measured amount of time (typically 17 years). Under the 1994 law, a patent's term begins at issuance and generally ends 20 years after the filing date of the patent application. As a result, delays during prosecution will reduce the term of a patent.

In 1999, Congress provided for extensions of patent terms to compensate for certain application-processing delays caused by the PTO. Specifically, 35 U.S.C. § 154(b)(1) makes three "patent guarantees." The three guarantees are: (A) prompt patent and trademark office responses, (B) no more than three years of application pendency, and (C) adjustments for delays to due derivation proceedings, secrecy orders, and appeals. Failure by the PTO to satisfy these guarantees can result in the extension of a patent's term. However, certain exclusions to these guarantees apply. For example, regarding the guarantee of no more than three years of application pendency, if the issuance of a patent is delayed due to continued examination of the application (e.g., by an RCE), such time will not count against the three year timeline.

Novartis AG ("Novartis") filed suits that challenged the determinations by the Patent and Trademark Office of how much time to add, under 35 U.S.C. § 154(b), to the otherwise-applicable term of various Novartis patents. In particular, Novartis challenged the PTO's interpretation of 35 U.S.C. § 154(b)(1)(B), which guarantees patent application pendency of no more than three years, not including any time consumed by continued examination requested by the application, among other factors.

The PTO regulations for implementing 35 U.S.C. § 154(b)(1)(B) in cases including a request for continued examination consists of two steps. First, the term of a patent should be adjusted if the issuance of the patent was delayed by the PTO beyond three years from filing, not including any time consumed by a request for continued examination by the applicant. Second, if the applicant is entitled to an extension, the period of adjustment is equal to the number of days from the first day after the expiration of three years from filing to the date the patent issued, not including the number of days in the period beginning on the date of the filing of an RCE and ending on the date the patent was issued. In other words, the PTO argued that time consumed by continued examination, no matter when initiated, did not count towards the depletion of the three year time allotment, and that, when an RCE is filed, time consumed between allowance and issuance is considered "continued examination." Novartis argued that, after the expiration of the three year time allotment, further time spent in the PTO must be added to the patent term, even if it is time spent on continued examination requested after that date. Additionally, Novartis argued that time consumed by continued examination should be limited to the time spent up to allowance (i.e., including the time from allowance to issuance).

The district court ruled that the PTO's interpretation of 35 U.S.C. § 154(b)(1)(B) was incorrect.

II. Issue

A. Did the district court err in rejecting the PTO's interpretation of 35 U.S.C. § 154(b)(1)(B) in cases where a request for continued examination is filed?

III. Discussion

Yes and no. The Federal Circuit agreed with the PTO's position that no adjustment time is available for any time related to continued examinations, even if the continued examination was initiated more than three years after the filing of a patent application. While the Federal Circuit noted that the statutory provision did allow for some ambiguity, the Federal Circuit held that the PTO's interpretation best accorded with the full text and purpose of the statute. "Patent term adjustment time should be calculated by determining the length of the time between application filing and patent issuance, then subtracting any continued examination time (and any other time identified in 35 U.S.C. § 154(b)(1)(B)) and determining the extent to which the result exceeds three years." This approach ensures that applicants recover for any delays due to the failure of the PTO without allowing the applicant to recover for any time consumed by continued examination, as the statue requires. Indeed, delays that are not due to the failure of the PTO, no matter when initiated, should not account against three years allotted to for examination.

However, the Federal Circuit disagreed with the PTO's position that any time up until patent issuance, even after allowance, is considered "continued examination" when, for example, an RCE had been in the case and should be excluded from the patent term adjustment calculation. In a case without continued examination, the time from allowance to issuance would certainly count towards the PTO's three year allotment. There is no reason to distinguish the time from allowance to issuance in a continued-examination case. As with the first point discussed above, the distinction to be made is whether certain delays are attributable to the PTO. On that basis, continued examinations are not distinguished according to when they are initiated. Similarly, allowance-to-issue time should not be distinguished according to whether there is a continued examination during prosecution. Furthermore, the common-sense understanding of "examination" is time up to allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening.

IV. Conclusion

Patent term adjustment time should be calculated by determining the length of time between application filing and patent issuance, then subtracting any continued examination time (and another other time identified in 35 U.S.C. § 154(b)(1)(B)) and determining the extent to which the result exceeds three years.