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# Federal Circuit Clarifies Calculation of Patent Term Adjustment for Applications with Continued Examination Requests


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In a **recent ruling**, the Federal Circuit clarified the scope of available Patent Term Adjustment (PTA) resulting from the U.S. Patent and Trademark Office's (PTO) failure to issue a patent within three years from the date the application was filed, for applications in which a request for continued examination (RCE) was made. *Novartis AG v. Lee*, 2013-1160, 2013-1179 (Fed. Cir. Jan. 15, 2014). Under the decision, PTA is not available for the period of prosecuting the RCE to allowance, but is available for the period from allowance to issuance.

**Background on PTA and Recent Challenges to the PTO's Interpretation of B Delay**

The term of a U.S. utility patent is 20 years measured from the filing date of the application. However, in practical terms, the patent application provides no benefit to the patentee until the day it issues as a patent from the PTO. Consequently, excessive delays at the PTO would significantly reduce the "effective" term of the patent. To avoid this result, Congress established a system of patent term adjustment that adds time to the end of a patent's life to offset certain kinds of delays encountered at the PTO.

Under this system, a patent is entitled to PTA based on delays attributable to the PTO. Specifically, the **patent statute** provides for PTA for three categories of patent office delays:

. "A delays" for failure of the PTO to act promptly, including its failure to issue a first Office Action within fourteen months from the filing date, or to respond to any applicant action within four months;
. "B delays" for failure of the PTO to issue a patent within three years of the filing date of the application (or entry of an international application into the National Stage); and
. "C delays" which accrue when an application is delayed due to a secrecy order, interference, derivation proceeding or appeal.

Notably, the statute provides certain exceptions to what would otherwise fall within B delay. For example, B delay does not include "any time consumed by continued examination of the application requested by the applicant." According to the **PTO's rules**, "time consumed by continued examination" is the period beginning when an RCE is filed and ending on the issue date of the patent.

Many patent owners have challenged the PTO's interpretation of what constitutes B delay in the situation where an RCE was filed more than three years after the application filing date. *Exelixis, Inc. v. Kappos*, 906 F. Supp. 2d 474 (E.D. Va. 2012) (*Exelixis I*) was the first case to address how to calculate B delay in such a situation. In *Exelixis I*, the court interpreted the statute's disallowance of RCE prosecution time to hinge upon the timing of when the RCE was filed. Specifically, the court held that the time spent prosecuting an RCE was only disallowed in calculating B delay when the RCE was filed within three years of the application filing date. If the RCE was filed after the three-year date, time spent prosecuting it was eligible for PTA on a day-for-day basis. Similarly, in *Novartis A.G. v. Kappos*, 904 F. Supp. 2d 58 (D. D.C. 2012), the District Court for the District of Columbia sided with the reasoning in *Exelixis I* and held that an RCE filed after the three-year date did not diminish B delay-related PTA.

However, in a subsequent case brought by Exelixis on the issue, (*Exelixis, Inc. v. Kappos*, 2013 WL 314754 (E.D. Va. Jan. 28, 2013) (*Exelixis II*)), the court took a contrary position and held that an RCE, no matter when it is filed, serves to toll B delay. Thus, under *Exelixis II*, time consumed by continued examination is always excludable from a PTA calculation. This decision created a split of authority within the Eastern District of Virginia on this issue. Since *Exelixis I* was decided, more than one hundred new PTA cases have been filed in the Eastern District of Virginia.

The *Exelixis* cases were consolidated on appeal, and the *Novartis* case was separately appealed. On

November 5, 2013, the Federal Circuit heard oral arguments for all three cases. The Court subsequently issued a precedential opinion in *Novartis* and remanded the *Exelixis* cases in light of its *Novartis* decision.

**The Federal Circuit Interprets B Delay to Exclude Time Spent Prosecuting RCE to Allowance Regardless of When RCE is Filed**

The main issue in *Novartis* was the statutory interpretation of the B delay carve-out for "time consumed by continued examination." In addressing the issue, the Federal Circuit disposed of the *Exelixis I* interpretation of the statute, noting that such an interpretation "runs counter to the textual fact that there is no time-of-initiation restriction on the processes identified in the exclusions, including continued examination." Rather, the Court concluded that B delay "should be calculated by determining the length of time between application and patent issuance, then subtracting any continued examination time (and any other [exceptions]…) and determining the extent to which the result exceeds three years." Thus, "time spent in continued examination does not deplete the PTO's allotment of three years for application processing before a resulting patent has its term extended, no matter when continued examination begins."

As for the amount of time to be subtracted in determining B delay, the Federal Circuit further clarified that "time consumed by continued examination" does not include the time from allowance to issuance, as "such time is plainly attributable to the PTO." The Court reasoned that "examination" ends at allowance after prosecution on the merits has closed and no further examination on the merits occurs. Noting that the time from allowance to issuance undisputedly would count toward the PTO's three-year allotment in a case not involving a continued examination, the court found no basis for distinguishing a continued examination case. Thus, '"time consumed by continued examination,' 35 U.S.C. §154(b)(1)(B)(i), is the time up to allowance but not later, unless examination on the merits resumes."

**Considerations for Patent Owners**

First, since the period of time from allowance to issuance, if after three years from filing, is now eligible for PTA even when an RCE was filed, it may now be advantageous in some cases to delay paying the issue fee until close to the deadline in order to maximize the PTA.

Second, the Patent Office has not yet issued any internal guidance or revised its rules to account for the *Novartis* decision. Until the Office revises its procedures, it is unlikely that the PTA reported on the face of any patents that were prosecuted for more than three years and that included an RCE will be calculated correctly. However, since challenges to a PTA determination have to be filed within two months of the patent issuance (extendable by payment of fees for a total of seven months), correction of the mistake is only available for patents issued less than seven months ago. Accordingly, any patents issuing in the past seven months, as well as those that issue henceforth, should be reviewed for applicability of the change to the RCE exclusion mandated by the Novartis decision.

If you have any questions regarding PTA calculations, do not hesitate to contact our patent practitioners.