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Federal Circuit Rules in the Exelixis / Novartis Cases that the USPTO Has Been Partially Miscalculating Patent Term Adjustment

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In 1994, Congress changed the way that a patent's term is calculated. At that time, the term of a patent was changed from 17 years after the patent's issue date to 20 years after its filing date. Because delays in the Patent Office threaten to automatically shorten any term that depends on a filing date, Congress acted in 1999 to provide a patent term adjustment (PTA) for patents that suffered from such delays. The statute enacted by Congress provides PTA for three types of delays, referred to as A-Delays, B-Delays, and C-Delays (in reference to the lettering of the subparagraphs in the statute that define them). A-Delays are delays in issuing a first office action more than 14 months after filing and in issuing the patent more than 4 months after the issue fee has been paid, for example, regardless of how long the time between filing and issuance has been. 35 U.S.C. § 154(b)(1)(A). B-Delays are delays that cause an application to be pending overall for more than 3 years, causing the 20-years-from-filing term to be less than the 17-years-from-issuance term. 35 U.S.C. § 154(b)(1)(B). C-Delays are unusual delays caused by derivation

proceedings, interference proceedings, secrecy orders, and appeals. 35 U.S.C. §154(b)(1)(C). The statute also explains that there is no double dipping. If A-Delays overlap with B-Delays, for example, the PTA is calculated so that "the period of any adjustment…shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A).

In both the *Exelixis* and *Novartis* cases, B-Delay was at issue. Subparagraph B of the statute reads as follows:

(B) Guarantee of no more than 3-year application pendency— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—

(i) *any time consumed by continued examination of the application requested by the applicant under section 132(b) [an RCE]*;

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

35 U.S.C. § 154(b)(1)(B). As can be seen, clause (i) provides an "RCE Exception" when calculating B-Delay. An RCE is a "request for continued examination" initiated by an applicant after the PTO has finally rejected an application. An RCE is a common mechanism used by applicants to continue prosecution of a rejected patent application. The issue here is when and how the RCE Exception for B-Delay PTA operates.

In *Exelixis, Inc. v. Kappos*, 906 F.Supp.2d 474 (E.D. Va. 2012) ("*Exelixis I*"), the PTO did not issue a final rejection until more than 3 years after filing. In response to the final rejection, Exelixis filed an RCE. The PTO then allowed the case, and the patent issued. The patent issued 199 days after the 3-years-from-filing date. In computing so-called "B Delay" PTA, however, the PTO did not count any time after the RCE was filed and therefore awarded only 85 days of PTA (the time between 3-years-from-filing date and

the RCE filing date). Exelixis argued that the "B Delay" PTA should be 199 days. Exelixis sued the PTO to get more PTA than the PTO had calculated for it. Here is a timeline from the district court's opinion illustrating the relevant dates and the parties' positions:



The district court held that the PTO's calculation was contrary to the statute and that the PTA should include all 199 days from the 3-years-from-filing date until issuance, regardless of the fact that the RCE had been filed. Significantly, the district court construed the statute to mean that if the RCE had been filed *before* the 3-years-from-filing date, then an RCE *would* act to preclude PTA. Two weeks later, in *Novartis v. Kappos*, 904 F.Supp.2d 58 (D.D.C. 2012), a judge in the U.S. District Court for the District of Columbia adopted the same holding to resolve a similar dispute.

However, just a few weeks after that, another judge in the Eastern District of Virginia concluded that the decision in*Exelixis I* was incorrect and that the PTO's reading of the law was proper. *Exelixis, Inc. v. Kappos*, 919 F.Supp.2d 689 (E.D. Va. 2013) ("*Exelixis* II"). And just over a week ago, another district judge in the U.S. District Court for the District of Columbia also concluded that the PTO's method of calculation was correct and that *Exelixis I* had been wrongly decided. *Abraxis science, LLC v. Kappos* (D.D.C. No. 1:11-CV-730, Jan. 8, 2014). This resulted in a 2-2 split among district court judges on the issue.

On January 15, 2014, the U.S. Court of Appeals for the Federal Circuit resolved appeals in the *Exelixis* and *Novartis*cases. The Federal Circuit concluded that "the PTO was partly correct and partly incorrect in its interpretation of § 154(b)(1)(B)." Novartis and Exelixis had argued that "once three calendar years from the application filing date have come and gone, time spent in the PTO after that date must be added to the patent term even if it is time spent on a continued examination requested after that date." In contrast, the PTO had argued that "any time consumed by continued examination," no matter when initiated, "does not count toward depleting the allotment of three years the PTO has before any adjustment time begins to accrue." In the PTO's view, "no adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application's filing."

On this point, the Federal Circuit agreed with the PTO. The court conceded that the text of the statute "might be read" both ways, but concluded that the PTO's reading was "the better reading." The court relied on the text of the statute as well as the reason for having the RCE Exception in the first place. The reason for the RCE Exception is that "certain delays are not attributable to the PTO—delays not 'due to the failure of' the PTO to move the process along"—and so "should not count against the three years before adjustments begin." As the court observed, that rationale is applicable regardless of whether the RCE was initiated before or after the three-years-from-filing date.

However, the Federal Circuit concluded that the PTO was incorrect to include *all* of the time after the filing of an RCE in the RCE Exception. Specifically, the time between allowance and issuance should not be considered to be "time consumed by continued examination" under an RCE. In the case of *Exelixis I*, this was the 97-day period between April 27, 2011 and August 2, 2011. According to the court, "an 'examination' presumptively ends at allowance." The statute is "best understood as making distinctions based on whether certain delays are attributable to the PTO," and "allowance-to-issuance time is…plainly attributable to the PTO." In other words, "[s]uch time from allowance to issuance undisputedly would count toward the PTO's three-year allotment in a case not involving a continued examination. There is no basis for distinguishing a continued examination case."

The bottom line, therefore, is that the PTO has been partially miscalculating PTA in cases involving B-Delay and the RCE Exception. Under new regulations recently promulgated by the PTO, any request for reconsideration of such a miscalculation must be filed within two months after the patent is granted, although this time may be extended under certain circumstances. 37 CFR § 1.705(b). In the event of an adverse decision by the Director, the applicant may file a civil action within 180 days from the Director's decision. 35 U.S.C. §154(b)(4)(A).