Client Alert

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Preserving Your Right to Patent Term Adjustment: The *Exelixis* Decision and Lessons From *Wyeth*

The U.S. District Court for the Eastern District of Virginia recently overturned the United States Patent & Trademark Office ("USPTO") interpretation of the patent term adjustment ("PTA") statute in *Exelixis, Inc. v. Kappos*. Similar to *Wyeth v. Kappos*, where a previous USPTO interpretation of the PTA statute was overturned, the *Exelixis* decision promises to add months and even years to the patent term of many patents. The *Wyeth* experience, however, teaches us that *Exelixis* will not apply retroactively, and specific actions must be taken now to preserve a patentee's rights should the Federal Circuit affirm the *Exelixis* decision.

Section 154(b)(1)(B) provides a guarantee of PTA of a one-day term extension for every day it takes the patent to issue after three years from the filing date, subject to certain conditions. *See* 35 U.S.C. § 154(b)(1)(B); *see also* 37 C.F.R. § 1.702(b). The period that begins after the three-year window is referred to as the "B period," which, if awarded, adds day-for-day term extension to the PTA calculation for USPTO delay.

The statutory scheme exempts certain applicant-initiated activities from the calculation of the B-period delay, including (i) filing of an RCE, (ii) notice of appeal or (iii) applicant request for a delay of processing.[1] The USPTO interpreted this statutory provision such that if any of the (i)-(iii) events occurred at any time during prosecution, the further accrual of B period delay would stop. Practically, this means that if the applicant filed an RCE even after the case had been pending for three years, the accrual of B period delay would stop at the moment the RCE was filed.

Exelixis is a patentee caught in this interpretation. The USPTO granted Exelixis 368 days of PTA for U.S. Patent No. 7,989,622, tolling the B period at April 11, 2011, due to the filing of an RCE, instead of August 2, 2011, at the grant of the patent. In *Exelixis v. Kappos,*[2] the patentee challenged the USPTO's interpretation of § 154(b)(1)(B) after the USPTO dismissed a petition requesting the award of B period adjustment beyond the date the RCE was filed, because the RCE was filed after the three-year pendency guarantee period. The question considered by the court was "whether [35 U.S.C.] § 154(b)(1)(B) requires that … any PTA be reduced by time attributable to an RCE, where … the RCE is filed after the expiration of the three-year guarantee period specified in that statute." 2012 U.S. Dist. LEXIS 157762, at *7. Under

[1] (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) [RCE];

(ii) any time consumed by a proceeding under section 135(a) [interference], any time consumed by the imposition of an order under section 181 [secrecy order], or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court [appeal]; 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).

[2] *Exelixis, Inc. v. Kappos*, No.1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012).

the USPTO's interpretation, once an RCE is filed, the patent application no longer accrues B period delays (e.g., the RCE "tolls" the applicability of the B period). The court did not agree with the USPTO.

The district court held that the filing of an RCE after the three-year time period does not toll the calculation of the PTA. *Id*. at *26. The court's interpretation was guided by the language of the statute, which provides a guarantee of patent term if the USPTO takes more than three years to issue a patent, unless the enumerated applicant-initiated activities occur within the three-year period. Therefore, if an RCE is filed *after* the three-year time period, the patent application continues to accrue PTA under a B period. *Id*.

The logical extension of the holding in *Exelixis* is that any of the three conditions listed — RCE, appellate review and/or delay in processing at applicant's request — do not toll the B period if they occur *after* the three-year time period. The USPTO routinely tolls the B period if a notice of appeal is filed at any time during prosecution, even if this does not lead to an actual appeal to the Patent Trial and Appeal Board. Under the interpretation of 35 U.S.C. § 154(b)(1)(B) outlined in the *Exelixis* decision, the B period would not be tolled by the filing of an RCE, notice of appeal or applicant's request for delay of processing, if these events occur outside the three-year period. 2012 U.S. Dist. LEXIS 157762, at *11–12. Applicants should be aware of the effect of taking one of the actions enumerated in the statute within the three-year period and should avoid taking such actions until the application has been pending for more than three years, whenever possible.

Past experience tells us that the USPTO will not begin implementing the *Exelixis* decision unless and until the Federal Circuit affirms the district court. For example, after the *Wyeth* district court decision,[3] where patent owners filed the petition for reconsideration of PTA within the permitted two-month window, the USPTO continued to deny those petitions until after it lost the Federal Circuit appeal.[4] The USPTO refused to correct the "*Wyeth* error" until the district court's decision was upheld by the Federal Circuit. Although the USPTO accepted requests for reconsideration of PTA decisions for patents having issued within 180 days of the *Wyeth* decision, requests for reconsideration outside this window were not accepted. *See Novartis AG v. Kappos,* 2012 WL 5564736 (D.D.C. November 15, 2012).

For patent owners interested in preserving their PTA rights under *Exelixis*:

- A request for reconsideration of PTA must be filed with the USPTO within two months of the patent grant; or
- A district court challenge to the PTA determination must be filed with the U.S. District Court for the Eastern District of Virginia within 180 days of the patent grant.[5]

As observed with *Wyeth*, we expect that the USPTO may not begin to correct PTA determinations in view of the *Exelixis* decision until after the Federal Circuit decides the issue. It is recommended that patent owners file a request for reconsideration with the USPTO within two months of the patent grant. This has the advantage that, under *Novartis* and *Bristol-Myers Squibb*, patent owners may then file a district court action within 180 days of the petition decision to challenge any PTA determination by the USPTO. *See, e.g., Bristol-Myers Squibb Co. v. Kappos,* 841 F. Supp. 2d 238 (D.D.C. 2012); *Novartis AG v. Kappos,* 2012 WL 5564736 (D.D.C. November 15, 2012). If a district court complaint is filed, a patent owner may consolidate the challenges for each of its patents into a single district court action, as was done in *Novartis.*

[3] *Wyeth v. Dudas*, 580 F.Supp.2d 138, 141 (D.D.C. 2008).
[4] *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010).
[5] Section 9 of the AIA has moved venue from the District Court for the District of Columbia to the Eastern District of Virginia, ending possible uncertainty about the proper forum for bringing these actions.

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