Important New Patent Term Adjustment Decision Allowing Post-RCE B Delay

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A recent decision calls into question the US Patent and Trademark Office (PTO) regulation providing that B delay stops accruing as soon as a Request for Continued Examination (RCE) is filed. In March 2018, the PTO declined to appeal a district court decision rejecting the PTO's application of the provision excluding "time consumed by continued examination" from "B delay" under the patent term adjustment (PTA) statute. *See ARIAD Pharms. Inc. v. Matal*, No. 1:17–cv–733, 2018 WL 339141 (Jan. 5, 2018). Although the circumstances of the *ARIAD* case were unusual, the implications of the decision could be broader, potentially entitling patentees to additional days of PTA for most applications involving continued examination.

Background

Under 35 U.S.C. § 154(b), a patent holder is entitled to PTA to compensate for certain delays by the PTO in issuing the patent, including "B delay," which accrues if the PTO fails to issue a patent within three years. Under the statute, "time consumed by continued examination" of the patent is excluded from B delay. . § 154(b)(1)(B)(i). The *ARIAD* case addressed whether the period of time consumed by continued examination necessarily begins on the day an RCE is filed, as the PTO argued.

The dispute in this case arose because the PTO lost an RCE filed by ARIAD and so, before even considering whether to commence the requested continued examination, erroneously concluded that ARIAD had abandoned its patent application. 2018 WL 339141, at *2. Four months elapsed before the PTO corrected its error and forwarded the application to the examiner to begin continued examination. Applying 37 C.F.R. § 1.703(b)(1), the PTO held that this four-month period was time consumed by continued examination because it was part of the period beginning on the date the RCE was filed. ARIAD challenged that view before the PTO but lost and, as a result, received no patent term adjustment.

In June 2017 ARIAD, represented by WilmerHale, filed an Administrative Procedure Act (APA) challenge to the PTO's decision in the US District Court for the Eastern District of Virginia. In litigation, the PTO adhered to its position that any time following an RCE is time consumed by

continued examination, even if the PTO is not actually engaged in continued examination. The PTO invoked *Chevron* deference and argued that ARIAD's view threatened to disrupt the PTA regime. ARIAD argued that under the plain language of the statute, the time when the PTO thought ARIAD's application had been abandoned could not have been time consumed by continued examination, and that the PTO was not entitled to *Chevron* deference because its rulemaking authority under the statute is limited to promulgating procedural rules. ARIAD also explained that the Federal Circuit's decision in the *Novartis* case, the PTO's interpretation of parallel provisions of the statute, and the PTO's regulations and procedures governing RCE practice all supported its position.

The District Court's Opinion

On January 5, 2018, Judge Ellis of the Eastern District of Virginia issued an opinion granting ARIAD's motion for summary judgment and rejecting the PTO's application of the statute. The court first relied on the plain language of the statute. It explained that Congress did not use the phrase "time after the applicant filed a request for continued examination" or "time attributable to a request for continued examination" in the statute. 2018 WL 339141, at *3. "Instead, Congress chose to draft the provision as 'any time consumed by continued examination of the application requested by the applicant.'" . The court concluded that "[t]ime cannot possibly be used in the course of continued examination where, as here, the PTO erroneously determines the application is abandoned." *Id*.

The court then explained that the structure of the statute also supports ARIAD's interpretation. It noted that "Section 154(b)(1)(B) uses the same phrase, 'time consumed by,' in other provisions, namely the statute also excludes from 'B Delay' 'time consumed by' secrecy orders, appellate review, and proceedings pursuant to § 135(a)." 2018 WL 339141, at *4. The court further observed that the PTO's "regulations interpreting these provisions have made clear that the calculation of the 'time consumed by' begins when the event at issue actually occurs—i.e., the imposition of the order, the beginning of the § 135(a) proceeding, or when the appellate court gains jurisdiction." . Applying the "same principle" to the continued examination exclusion "suggests that the clock for 'time consumed by continued examination' should start when the continued examination requested actually begins." *Id*.

The court also concluded that the Federal Circuit's decision in *Novartis v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), and the purpose of the PTA statute both supported ARIAD's interpretation. 2018 WL 339141, at *4-*5. Relying on the Federal Circuit's decision in *Wyeth v. Kappos*, 591 F.3d 1364, 1370 (Fed. Cir. 2010), the court rejected the PTO's contention that "the statute's 'A Delay' provisions serve the purpose ARIAD seeks to read into the 'B Delay' provisions." 2018 WL 339141, at *5. The court also concluded that "the plain language of the statute successfully avoids th[e] parade of horribles the PTO predicts." . Specifically, the court noted that "[i]f, as the statute suggests, 'time consumed by continued examination' begins when the RCE is forwarded to the patent examiner, the PTO would not need to determine which days the patent examiner actually engaged in continued examination because the clock would begin to run as soon as the request was forwarded." *Id*.

Finally, the court rejected the PTO's attempt to invoke *Chevron* deference for the interpretation set forth in its regulation. The court first explained that "it is well-settled that where, as here, an agency's interpretation is contrary to the plain language of an unambiguous statute, no deference is afforded

to that interpretation." 2018 WL 339141, at *6. The court then went on to affirm the long-standing principle that the PTO is not entitled to *Chevron* deference for substantive interpretations where it has authority to promulgate regulations governing only procedural issues. *See id*. ("[B]ecause the grant of [rulemaking] authority [in 35 U.S.C. § 154(3)(A)] was procedural, not substantive, the PTO's regulations are inconsistent with that rulemaking authority to the extent the regulations make substantive adjustments to the PTA and the patent term."). The court specifically rejected the PTO's reliance on *Cuozzo Speed Technologies LLC v. Lee*, 136 S. Ct. 2131 (2016), since in this case the PTO's rulemaking authority was "expressly limited to developing 'procedures' for the determination of patent term adjustments." 2018 WL 339141, at *6.

Implications for Other Cases Involving Continued Examination

On its face, the court's decision was narrow. The court held that "the PTO's construction of 35 U.S.C. § 154(b)(1)(B)(i), *as applied to these facts*, is not faithful to the plain meaning and purpose of the statute." 2018 WL 339141, at *6 (emphasis added). But the court's decision potentially has broader implications for the PTO's administration of the PTA statute. Rather than agree with the PTO that the exclusion from B delay necessarily begins upon the filing of an RCE, as set forth in 37 C.F.R. § 1.703(b)(1), the court suggested that the exclusion may begin more appropriately when the application is forwarded to the examiner.

As noted above, the court rejected the PTO's arguments about administrability under such an interpretation, stating that "[i]f, as the statute suggests, 'time consumed by continued examination' begins when the RCE is forwarded to the patent examiner, the PTO would not need to determine which days the patent examiner actually engaged in continued examination because the clock would begin to run as soon as the request was forwarded." 2018 WL 339141, at *5. Looking to the parallel exclusions in the statute, the court also indicated that the continued examination exclusion begins "when the continued examination requested actually begins." . at *4. The court recognized that continued examination is not automatic upon the filing of an RCE. Citing the *Manual of Patent Examining Procedure*, the court observed that "[w]hen an RCE is filed, the 'Technology Center' assigned to the application initially processes the request and verifies that all the threshold requirements for continued examination are satisfied." . at *1. Only once the requirements for continued examination are found to be satisfied will the PTO "withdraw the finality of the preceding rejection and forward the RCE to the patent examiner for review." *Id*.

In light of the decision in *ARIAD*, applicants who requested continued examination should consider whether to seek additional PTA for the period between the filing of the RCE and the date the application was forwarded to the examiner. And for those patents where every day of protection matters, patentees should strongly consider filing suit to contest any decision by the PTO adhering to 37 C.F.R. § 1.703(b)(1) and excluding PTA from the date of filing of an RCE.

WilmerHale has significant experience handling PTA requests in the PTO and challenging adverse PTA determinations in court under the APA. For more information, contact Brian Boynton and Emily Whelan.

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