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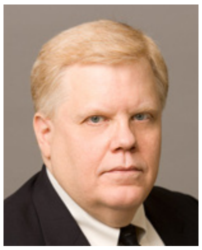

IP: Value in the backwaters of patent law

THE COURTS HAVE RECENTLY ISSUED SIGNIFICANT DECISIONS INTERPRETING THE STATUTE PROVIDING FOR PATENT TERM ADJUSTMENT

In a nod to patent harmonization, the U.S. acceded to the dominant world view when it adjusted the definition of patent term by passing into law the 1994 Uruguay Round Agreements Act (URAA). Under the URAA, patent term extends from patent issuance to 20 years from the filing date of the underlying patent application, thus providing a variable patent term dependent on issuance date. Previously, the U.S. had simply defined patent term as 17 years from patent issuance. The effective term of a U.S. patent under the current definition will equal the old term of 17 years from issuance when the application spends three years in U.S. Patent and Trademark Office (USPTO) examination. It is the rare U.S. patent application that is under examination for exactly three years, and those in the business and patenting communities are aware that the typical application is examined for longer, and often significantly longer, than three years. To mitigate the potential loss of term due to examination delay, Congress in 1994, and again in 1999, provided for patent term adjustment. Despite the time that has passed, the courts have recently issued some significant decisions interpreting the statute providing for term adjustment, as highlighted below.

- Patent term adjustment determinations are complicated
- Compensations for distinct delays are added
- After three years of examination, it's mostly gravy

The statutory scheme for term adjustment created by Congress, codified at 35 USC § 154, is not a model of clarity. Implementation of that scheme by the USPTO exercising its rulemaking authority did little to clarify the situation. That lack of clarity, coupled to the starchy bookkeeping nature of determining proper adjustments, has undoubtedly contributed to the decade-long delay in resolving the finer points of the law. Two recent federal district court decisions, *Exelixis, Inc. v. Kappos* and *Novartis AG v. Kappos*, along with the *Wyeth v. Kappos* decision a couple of years ago, have opened eyes to the value of ensuring that a patent receives its full term adjustment, particularly in fields such as pharmaceuticals and biotechnology that can reap significant rewards at the end of patent terms. Appreciating the import of these decisions will be aided by a brief look at the governing statute.

The definition of patent term as extending from patent issuance to 20 years from the application filing date is laid out in straightforward fashion in § 154(a). Things begin to get a little fuzzy, however, in subsection (b). Section 154(b)(1) provides the government's adjustment guarantees, and § 154(b)(2) enumerates limitations on those guarantees. There are several specific guarantees in § 154(b)(1), each compensable on a day-for-day basis for any delay by the USPTO, but the recent court cases and this article focus on five. Section 154(b)(1)(A) provides four guarantees for particular USPTO delays. Time beyond 14 months taken by the USPTO to initially communicate regarding a filed application is compensable delay, as is any time beyond four months for the USPTO to respond to action by the applicant, the Patent Trial and Appeal Board, or a court. These specific delays are often referred to as "A" delays. Section 154(b)(1)(B) provides a remedy for any application pendency beyond three years, referred to as a "B" delay. Before turning to the limitations in § 154(b)(2), it's worth noting § 154(b)(1)(B) itself defines a limitation in establishing that compensable "B" delays are tolled by filing a request for continued examination (RCE) within the three-year examination window. Section 154(b)(2)provides the remaining limitations on compensable delays by the USPTO, including the lack of compensation for lack of effort by the applicant to reasonably conclude the examination process, for overlaps in delay periods (i.e., no double-counting), and for any time beyond the actual number of days of delay. Finally, the statute provides for a 180-day period in which to bring a civil action in the Eastern District of Virginia challenging the adjustment determination. The recent cases have provided significant pro-patentee interpretations of the statutory scheme.

In the 2010 *Wyeth* case, the court considered possible overlap between "A" delays and the "B" delay. The USPTO took the position that any "A" delay necessarily pushed back the date of patent issuance, and this push-back period should not be double-counted by inclusion in the "B" delay. According to the USPTO, then, any compensation for "B" delay should be net of any "A" delay. The contrary position, adopted by the court, was that "A" delays occurring within the first three years of examination, as found in *Wyeth*, could not overlap with any "B" delay because the period for "B" delay didn't even begin until three years into examination. As a consequence, the "A" and "B" delays in Wyeth were added, resulting in a gain of 294 and 486 days of term for the two patents-in-issue, during which Wyeth could continue to enjoy its position of advantage in an Alzheimer's disease market estimated at $160 billion annually in 2010.

In November, the Eastern District of Virginia in *Exelixis v. Kappos* addressed the issue of whether delays beyond the three-year examination term would be tolled by filing an RCE after the three-year anniversary. The statute expressly provides that compensable delay is tolled by filing an RCE within the three-year period of examination, but the USPTO had promulgated a rule (37 CFR § 1.703(b)) cutting off compensable delay whenever an RCE is filed. The court held that the statute limited the tolling effect of RCEs to those RCEs filed within the first three years of examination, meaning that the filing of an RCE more than three years after filing the application would not stop the clock on compensable delay. For Exelixis and its anti-cancer therapeutic, the proper determination adds 114 days of exclusivity for its therapeutic in the $157 billion dollar annual cancer treatment market.

The district court for Washington, D.C., followed *Exelixis* in deciding *Novartis AG v. Kappos*. Going beyond affirming that RCEs filed three or more years into examination would not halt compensation for USPTO delays, the *Novartis AG* court held that requests for reconsideration of patent term adjustment timely filed in the USPTO would toll the 180-day period for seeking redress by civil action. Some commentators have urged caution regarding this aspect of the *Novartis AG* decision, noting that the statute expressly provides for appeal of patent term adjustment by civil action in the Eastern District of Virginia. The important point here is that the 180-day clock begins ticking upon patent issuance, and there may be issued patents of sufficient value to justify court action to obtain the full measure of compensable delay.

Court interpretations of patent term adjustment have revealed that "A" delays within the first three years of examination are added to any "B" delays and RCEs filed after those first three years will not cut off adjustments for USPTO delays, both benefitting the patentee. Even without raising the specter of renewed Lemelson-style submarine patents, the corrected adjustments to patent term could prove valuable enough to pay close heed to adjustment calculations. With Wyeth's patent drawn to an Alzheimer's disease treatment and Exelixis' patent protecting an anti-cancer treatment, each day of adjusted term promises to add significant value.

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