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Who Is Your Money On?

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Wyeth. Elan. Genentech. Amgen. GlaxoSmithKline. Novartis. AstraZeneca.

These and scores of other life science companies are suing the U.S. Patent and Trademark Office over "patent term adjustment," challenging the Patent Office's implementation of the statute that governs when new patents will expire. They are betting that Wyeth will win a test case currently pending in the U.S. Court of Appeals for the D.C. Circuit, *Wyeth v. Kappos*, no. 2009-1120. If they are right, these bets could be worth billions of dollars for the biotech and pharmaceutical companies.

Other industries, accustomed to product life cycles far shorter than the typical patent term—such as the telecommunications, software, and computer industries—have placed few wagers. But the stakes are high for all patentees.

WHAT IS 'PATENT TERM ADJUSTMENT?'

Patent term adjustment compensates patent owners for the Patent Office's delay in issuing many patents.

Before 1995, U.S. patents expired 17 years from the date of issuance. Patent Office delays shifted a patent's term (the period between a patent's issuance and expiry), but did not reduce its length. That year, however, as a consequence of congressional implementation of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), patent terms were changed. For all applications filed on or after June 8, 1995, the term begins on the issue date and ends 20 years from the date on which the application for patent was filed.

Under this "post-GATT" statutory regime, if the Patent Office takes exactly three years to issue a patent (the 2009

average was 34.6 months), then the term of the patent remains 17 years. But it is not uncommon for the Patent Office to take far longer to examine a patent. When that happens, every day that the Patent Office delays issuance also reduces the length of the term by one day. If the Patent Office takes six years to issue a patent, then the period between issuance and expiry will be only 14 years.

Acknowledging the potential adverse effects of the newly enacted patent term, Congress included in the 1995 legislation a limited form of patent term extension to compensate for Patent Office delays. A far more expansive form of patent term adjustment was included in the American Inventors Protection Act of 1999 (the "AIPA"). It is the Patent Office's regulatory implementation of these 1999 statutory changes that *Wyeth* has challenged.

The AIPA guarantees against two common types of Patent Office delay. The so-called "A" guarantee provides several explicit deadlines by which the Patent Office must respond to applicants' various submissions. For each failure of the Patent Office to meet its respective "A" deadlines, the applicant is awarded a day-for-day adjustment (lengthening) of the patent term. The "B" guarantee is a no-fault backstop provision: If a patent takes longer than three years to issue, then the applicant is awarded a patent term adjustment equal to that delay, thus ensuring that Patent Office delays cannot reduce patent terms to below the pre-GATT 17-year term.

The 1999 legislation limited the patent term adjustment calculation in two major ways. First, delay by the applicant is subtracted from any adjustment. Second, overlapping adjustments are limited to "the actual number of days the issuance of the patent was delayed." It is this overlap



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provision, codified at 35 U.S.C. § 154(b) (2)(A), and more particularly the Patent Office's implementing regulation, that is at issue in the *Wyeth* case currently on appeal.

WYETH V. KAPPOS: IS THE PATENT OFFICE CORRECTLY CALCULATING PTA?

The AIPA provides for judicial review of Patent Office term adjustment decisions by way of civil action in the U.S. district court in Washington, D.C., followed by appeal to the Court of Appeals for the Federal Circuit.

In accordance with these provisions, *Wyeth* sued the director of the Patent Office (currently David Kappos) over the

amount of adjustment awarded two patents relating to the treatment of Alzheimer's disease. The Patent Office had missed deadlines during the examination of both applications (violating the "A" guarantee), and the patents each took more than three years to issue (violating the "B" guarantee). Many of the "A" guarantee violations took place within the first three years after the applications were filed, i.e., before the "B" guarantee took effect. Thus, most of the "A" delays and the "B" delay did not actually occur on the same days.

Wyeth reasoned that when the "A" delay and the "B" delay did not occur on the same days, those delays did not overlap, and thus Wyeth was entitled to a patent term adjustment for the "A" guarantee *and* the "B" guarantee. The Patent Office, in its implementation of the "overlap" provision, reasoned that every day for which it missed an "A" guarantee would necessarily contribute to missing the "B" guarantee, regardless of whether the two occurred on the same day or not. Thus, the Patent Office gave Wyeth the greater of the "A" delay or the "B" delay, but not both.

The district court, while expressing sympathy for the Patent Office's rationale, nonetheless accorded no *Chevron* deference to the Patent Office's statutory interpretation, finding that the statutory language referring to the "actual number of days" of overlap clearly and unambiguously mandated *Wyeth's* interpretation. 580 F. Supp. 2d 138. The Patent Office appealed, and the Court of Appeals is expected to rule soon.

IS THE PATENT OFFICE MAKING OTHER MISTAKES?

The calculation of "A" and "B" overlap is not the only error that the Patent Office may be making.

Recently, the Patent Office admitted shortchanging some international applicants by miscalculating their effective filing date for patent term adjustment purposes. In addition, genuine issues exist, but have not yet been tested, regarding the Patent Office's calculation of applicant delays, which shorten patent term adjustment, as well as its limitation of the "B" guarantee when a request for continued examination is made.

The *Wyeth* decision will be important not only for the actual holding as to the calculation of "A"/"B" delay overlap, but also for what it says about the level of deference that the Federal Circuit may accord later challenges to other term adjustment calculations.

HOW SHOULD YOU PRESERVE YOUR RIGHTS?

Despite losing the *Wyeth* case at the district court level, the Patent Office is refusing to change its method of calculating overlap pending decision on appeal.

Accordingly, to preserve your rights to additional patent term, you must follow the challenge procedures laid out in the statute, *see* 35 U.S.C. § 154(b)(3) & (4), and the regulations, *see* 37 C.F.R. § 1.704(b) & (d). Generally speaking, the process includes the filing of an application for term adjustment when paying the issue fee, followed by a renewed application two months after the patent issues, followed by the filing of a civil lawsuit in the U.S. district court in Washington, D.C., within 180 days after the patent is issued.

Currently, the Patent Office is routinely denying both the initial and renewed applications for patent term adjustment that are based on the *Wyeth* district court decision, which obligates a patentee to file a civil lawsuit to preserve its rights. Nearly 100 such lawsuits have been filed since the District Court's *Wyeth* decision; currently, all these lawsuits are being stayed pending the outcome of the *Wyeth* appeal.

Patentees who miss these deadlines are not likely to preserve their rights, even if *Wyeth* later wins in the Federal Circuit.

WHO ELSE SHOULD BE CONCERNED ABOUT THE OUTCOME OF WYETH?

The roster of plaintiffs in the patent term adjustment lawsuits that are currently pending (and stayed) against the Patent Office demonstrates that the life science industry clearly understands the stakes in the patent term adjustment lottery. In an industry with decades'-long product development and regulatory approval timelines, the last day of a patent term is often the most lucrative, and every

additional day of patent exclusivity protects a hard-won market.

But statistics from the Patent Office show that patent applications in other technologies are subject to far greater average delay in the Patent Office than are applications drawn up for biotechnology and small molecule therapeutics.

Network, multiplexing, cable and security patents (tech center 2400 in the Patent Office) average four years to issue.

Communications patents (tech center 2600) average more than three-and-a-half years, while computer architecture, software, and information security patents take nearly that long. While the terminal days of a patent term are well understood to be crucial for blockbuster drugs, they can also matter to licensors in the telecommunications, software, and computer industries.

It is odd that high tech companies with business models dependent upon patent license revenues have not yet joined the rush to sue the Patent Office and protect these rights.

CONCLUSION: IS YOUR COMPANY 'ON BOARD'?

To be sure, the economic effects of *Wyeth* will take years to manifest fully. The additional patent term at issue in *Wyeth* gets tacked onto the end of a patent's life—in 2023 and 2025-26, respectively, for *Wyeth's* patents. But the potential is great, and the cost of preserving your rights is relatively small.

All patentees, not just life science companies, should be paying attention to the Federal Circuit's upcoming decision in *Wyeth*.

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