

Legal Updates & News

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Federal Circuit's *Wyeth* Decision a Likely Boon for Patent Holders

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Last week, the Federal Circuit handed down a much anticipated decision that is likely to extend the effective term of many recently issued patents and patents that will issue from currently pending applications. In *Wyeth*, the Federal Circuit affirmed the decision of the U.S. District Court for the District of Columbia rejecting the U.S. Patent and Trademark Office's ("PTO") conservative interpretation of the patent term adjustment statute as inconsistent with the clear and unambiguous language of the statute. *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010), *aff'g Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008). The decision is certain to have profound implications for patent holders as well as their licensees and competitors.

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Statutory Background

Before 1995, U.S. patents had a term of 17 years from the date of issuance. In an effort to harmonize the U.S. patent system with the international consensus, the patent term was changed to 20 years from the filing date for applications filed on or after June 8, 1995.^[1] One advantage of the old 17-year regime was that procedural delays did not reduce the effective patent term because the term did not commence until a patent issued. In contrast, under the current 20-year regime, the useful life of a patent is reduced by the amount of time that elapses between the filing date and the issue date of the patent.

Recognizing this problem, Congress passed the American Inventors Protection Act of 1999 ("AIPA"), promising to compensate patent applicants for any delay during prosecution caused by the Patent Office.^[2] This promise was codified in 35 U.S.C. § 154(b)(1) in the form of three "guarantees": (A) guarantee of prompt PTO responses (e.g., a first office action within 14 months of filing); (B) guarantee of no more than 3-year application pendency; and (C) guarantee against delays due to interferences, secrecy orders, and appeals. Delays caused by the PTO can be offset by applicant-caused delays.^[3] Importantly, the AIPA imposed the following limitation on clauses (A) and (B): "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not extend the actual number of days the issuance of the patent was delayed."^[4] Proper interpretation of this limitation became the central issue in *Wyeth*.

Legal Claims and Holding

The PTO has long taken the position that delays caused by the B guarantee (“B delays”) start with the filing of the application, and not three years later.^[5] Under this interpretation, delays caused by the A guarantee (“A delays”) necessarily overlap with the B delays regardless of whether the A delays occurred before or after the three-year mark from filing. Accordingly, the PTO has been calculating patent term adjustments based on the greater of the A delay or B delay. The PTO rationalized its position by saying that combining the A and B delays to determine a patent term adjustment would amount to double counting because the A delays during the first three years of prosecution ultimately lead to the B delays after the three-year mark.

Wyeth and Elan Pharma challenged the PTO’s interpretation, arguing that it was contrary to the plain language of the statute. The pharmaceutical manufacturers contended that because the B delays do not commence until three years after filing, only those A delays that occur after the three-year mark should be used to determine the overlap under § 154(b)(2)(A). Accordingly, Wyeth and Elan proposed the following formula for calculating patent term adjustment (“PTA”): $PTA = (A \text{ delay}) + (B \text{ delay}) - (A/B \text{ overlap after 3 years from filing}) - (\text{Applicant-caused delay})$.

The district court sided with the plaintiffs, and the Federal Circuit affirmed. The Federal Circuit stated that “a violation of the B guarantee – the one at the heart of the issue in this case – begins when the PTO fails ‘to issue a patent within 3 years of the actual filing date of the application in the United States’ [and] ends when ‘the patent is issued.’”^[6] Because the period of delay under the B clause runs from the three-year mark after filing until the patent issues, the Federal Circuit held that “no ‘overlap’ can transpire between the A delay and the B delay” before the three-year mark.^[7] The Federal Circuit criticized the PTO’s “greater of A or B” interpretation as “strained,” endorsing the district court’s position that “[t]he problem with the PTO’s interpretation is that it considers the application delayed under [the B guarantee] during the period before it has [sic] delayed.”^[8] Regarding the PTO’s double counting argument, the Federal Circuit acknowledged that there could be situations where inequities might result under the statute, but held that the plain language of the statute must prevail nonetheless.^[9] Finally, the Federal Circuit agreed with the district court’s conclusion that the PTO’s interpretation was not entitled to *Chevron* deference because it was contrary to the clear and unambiguous language of the statute.^[10]

Immediate Implications

So far the PTO has not provided any indication whether it is planning to request an *en banc* rehearing by the Federal Circuit or appeal to the U.S. Supreme Court. However, regardless of what it decides to do in the future, the PTO must now revise its PTA calculations according to the *Wyeth* decision. Patentees should keep in mind that they have limited opportunities to seek PTA correction. For applications that have received a Notice of Allowance, a petition to correct PTA must be filed before the issue fee is paid.^[11] For recently issued patents, a petition to correct PTA must be filed within two months of issue.^[12] Alternatively, the patentee may file a civil action against the Director of the PTO in the District Court for the District of Columbia within 180 days of issue.^[13] For patents that issued over 180 days ago, the remedy is currently uncertain. Since the *Wyeth* decision does not state whether its holding applies retroactively, it is not clear whether a petition for a certificate of correction will be effective to obtain the benefit of the revised PTA formula under *Wyeth*. Patentees should stay tuned for further developments. Applicants who have not paid the issue fee for a recently allowed application and patentees who hold patents issued within the last three months are strongly advised to contact their counsel as soon as possible to determine if they are entitled to a greater patent term adjustment than was initially calculated by the PTO.

Footnotes

^[1] See Pub. L. No. 103-465, § 532 (1994).

^[2] See Pub. L. No. 106-113, § 4402 (1999).

^[3] 35 U.S.C. § 154(b)(2)(C).

[4] 35 U.S.C. § 154(b)(2)(A).

[5] See 69 Fed. Reg. 21706 (2004) (“If an application is entitled to a [B-]adjustment... the entire period during which the application was pending before the [PTO]..., and not just the period beginning three years after the actual filing date of the application; is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).”).

[6] Slip op. at 8 (citation omitted).

[7] *Id.*

[8] *Id.*, quoting *Wyeth*, 580 F. Supp. 2d at 142 (emphasis in original).

[9] See Slip op. at 9-10 (“Regardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities, even if it could. In the end, the law has put a policy in effect that this court must enforce, not criticize or correct.”).

[10] See *id.* at 5 and 13.

[11] 37 C.F.R. § 1.705(b).

[12] 37 C.F.R. § 1.705(d).

[13] 35 U.S.C. § 154(b)(4)(A).