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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@portfolioimedia.com

Patent Term Adjustment After Wyeth V. Kappos

Law360, New York (January 28, 2010) -- Earlier this month, the Federal Circuit affirmed the decision of the U.S. District Court for the District of Columbia that the U.S. Patent and Trademark Office has been under-calculating the amount of patent term adjustment (PTA) due under certain provisions of the American Inventors Protection Act (AIPA) of 1999.

On Jan. 21, the PTO announced that it will not challenge the Federal Circuit's interpretation.

As a result of the decision in *Wyeth v. Kappos*, No. 2009-1120, 2010 U.S. App. LEXIS 300, 2010 WL 27184 (Fed. Cir. Jan. 7, 2010), applicants who are still engaged in substantive prosecution and who fit the Wyeth fact pattern should soon begin to receive the benefit of the decision without further action.

However, those whose applications have been allowed or recently issued must follow certain procedures and meet specific time limits to preserve their rights to additional PTA under Wyeth, as discussed below. In addition, the Federal Circuit's refusal to defer to the PTO's rulemaking authority implies that patentees may also be able to challenge other aspects of PTA calculations.

The Wyeth Issue

The PTA provisions of the AIPA provide three categories of term guarantee.

The so-called "A" guarantee assures that the PTO will promptly respond to applicant submissions, including an initial office action within 14 months of the application filing date and subsequent office actions within four months of the applicant's last response. For every day of PTO delay beyond these deadlines, the patentee receives one day of term adjustment. See 35 U.S.C. § 154(b)(1)(A); 37 C.F.R. §§ 1.702(a), 1.703(a).

The "B" guarantee is a no-fault backstop assurance of at least a 17-year term from issuance, i.e., no less than the pre-GATT term. If an application has not issued as a patent after three years, then the patentee receives a day of term adjustment for every day of delay thereafter. See 35 U.S.C. § 154(b)(1)(B); 37 C.F.R. §§ 1.702(b), 1.703(b).

"C" delays deal with extraordinary situations, such as interferences, secrecy orders and administrative appeals. See 35 U.S.C. § 154(b)(1)(C); 37 C.F.R. §§ 1.702(c)-(e), 1.703(c)-(e).

The AIPA limited PTA in two major ways. First, if the applicant fails to act diligently in prosecuting an application, then the applicant's delay is subtracted from any term adjustment.

The second limitation was at issue in Wyeth: where “periods of [“A”, “B” or “C”] delay ... overlap,” the net adjustment is limited to “the actual number of days the issuance of the patent was delayed,” to prevent double counting. 35 U.S.C. § 154(b)(2)(A).

The “overlap” regulation first promulgated by the PTO merely reiterated the statutory language, but did not explain how “overlap” was to be calculated. See 37 C.F.R. § 1.703(f) (2002).

Later, the PTO amended the regulation to recite overlapping periods of “adjustment,” rather than “delay,” and explained its interpretation in a Federal Register notice. 69 Fed. Reg. 21706, 34283-84 (2004).

According to the PTO, a patentee was due only the greater of any “A” or “B” adjustment, but not both. For example, if the PTO were to take 18 months to issue a first office action instead of 14 months (resulting in four months of “A” delay), and if the same application issued three years and four months after filing (resulting in four months of “B” delay), the PTO would award only four months of PTA, not eight months.

The PTO reasoned that the “A” delay necessarily contributed to the “B” delay, and the PTO’s approach prevented such constructive double-counting of PTA.

Wyeth challenged the PTO’s interpretation of “overlap,” arguing that the statute clearly limited “overlap” to any “A” and “B” delays falling on the same calendar day; i.e., that “overlap” could only occur when the “A” delays occurred more than three years after the initial filing date. Under Wyeth’s interpretation, patentees should often receive adjustments under both the “A” and “B” guarantees.

After unsuccessfully petitioning the PTO, Wyeth sued and won summary judgment in district court.

On appeal, the Federal Circuit sympathized with the PTO’s desire to prevent double-counting and consequent PTA windfalls, but affirmed the district court decision in Wyeth’s favor, holding that the language of the statute was unambiguous that both the “A” and “B” delays must be counted unless they fall on the same calendar day.

As the court noted, “this court does not take upon itself the role of correcting all statutory inequities, even if it could.” Slip op. at 10.

The Effects of Wyeth in the PTO

On Jan. 21, the PTO announced that it would not seek further review of the Wyeth decision, and that it is preparing guidance for expediting requests for recalculation of PTA in light of Wyeth. In the meantime, the PTO explicitly reminded applicants and patentees that they must seek review of PTA determinations pursuant to the statutory and regulatory scheme.

The statute and the regulations spell out a three-stage procedure for challenging the PTO’s determination of PTA. After receiving the PTO’s initial calculation with a notice of allowance, an applicant must first file an application (petition) under 37 C.F.R. § 1.705(b) with or before paying the issue fee.

The PTO will routinely reject any Wyeth arguments in a 705(b) petition as premature, because the exact issue date, and thus the length of any “B” delay, is not yet known.

However, “B” delay can be calculated before a patent issues in one instance: when the applicant has previously filed a request for continued examination (RCE).

As detailed below, under the current regulations any “B” delay stops accruing immediately upon the filing of an RCE, which makes the issue date immaterial to the amount of “B” delay.

In this case, the literal language of 37 C.F.R. § 1.705(b) appears to require an applicant to raise any Wyeth overlap issue, or else forfeit the issue. The PTO has not been enforcing the literal language of the rule, although that policy could change when the PTO begins implementing the Wyeth decision.

The PTO’s decision on a 1.705(b) petition, and its PTA calculation using “B” delay, will appear on the face of the issued patent. To challenge that result, the patentee must file a 1.705(d) petition within two months after the issue date. (The PTO has given no indication that it will now waive that deadline under 37 C.F.R. § 1.183.)

A 1.705(d) petition is typically the first time that a patentee can raise the Wyeth issue. If a patentee is not satisfied with the PTO’s decision on its 1.705(d) petition, the final stage is a civil lawsuit which must be filed in the U.S. District Court for the District of Columbia within 180 days after issuance. See 35 U.S.C. § 154(b)(4)(A).

Pending release of the promised guidance from the PTO, applicants and patentees who are entitled to additional PTA under Wyeth must still use the petition and civil suit procedures. Adherence to the statutory and regulatory deadlines is critical.

For the patentees who have already filed complaints (there have been about 100), the PTO seems likely to stipulate to judgments implementing the Wyeth adjustment and to issue certificates of correction under 37 C.F.R. § 1.322.

However, for the million and a half patentees over the past decade who missed the 180-day deadline for filing suit, the adjustment printed on the face of the patent is likely final. See 35 U.S.C. § 154(b)(4)(A) (“An applicant dissatisfied with [the PTO’s PTA calculation] shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent”).

At least one patentee is currently challenging the 180-day deadline on equitable tolling grounds. See Gen. Hosp Corp. v. Dudas (D.D.C. no. 09-cv-109). However, General Hospital’s chance of success seems low in light of Henderson v. Shinseki, 589 F.3d 1201 (Fed. Cir. 2009) (en banc).

In Henderson, the Federal Circuit contrasted the applicability of equitable tolling to (1) statutes of limitations (time limits on the first opportunity for review of a government action, which can be equitably tolled) and (2) time-of-review statutes (time limits for subsequent appeals, which cannot be equitably tolled).

Although not a patent case, Henderson implies that 35 U.S.C. § 154(b)(4) (which is titled, “Appeal of [PTA] Determination”) is a time-of-review statute to which equitable tolling does not apply.

Is the PTO Making Other Errors?

Both the district court and the Federal Circuit gave short shrift to the PTO’s argument that its rulemaking should have been accorded Chevron deference.

The Federal Circuit disposed of that argument in two sentences, see slip op. at 13, after reaching the same conclusion in another case just two days earlier. See Koninklijke Philips Elecs. NV v. Cardiac Sci. Operating Co., 93 U.S.P.Q.2d 1227 (Fed. Cir. 2010). This standard of review may embolden others to challenge different aspects of the PTA regulations.

In particular, Congress explicitly limited the PTO's authority to "establishing procedures" for determining PTA. 35 U.S.C. § 154(b)(3)(A). The PTO may well have exceeded that limited authority in its regulations governing the effects of requests for continued examination (RCE) upon "B" delay.

The implementing regulation, 37 C.F.R. § 1.703(b)(1), establishes an unequivocal bright-line rule: Although "A" delay can accrue after an RCE is filed, not a single day of "B" delay is permitted after the filing of an RCE. The statute, however, is not so absolute, excluding only "time consumed by continued examination" following the filing of an RCE. 35 U.S.C. § 154(b)(1)(B)(i).

It is by no means certain that the PTO has correctly construed the "consumed by ... examination" language; the statute arguably excludes from "B" delay only the time, or perhaps some portion of the time, consumed by "examination" (actions of the PTO itself) during the course of continued prosecution. It is also uncertain whether Congress intended a unitary, bright-line rule or case-by-case determinations.

Moreover, the plain language of the statute suggests a radically different interpretation of the statutory requirement from that currently presumed by the PTO.

As written, the statute defines a "trigger" for accrual of the "B" guarantee, then separately states how much compensatory PTA is due if the "B" guarantee is triggered. Under this interpretation, the filing of an "RCE" is relevant only to the trigger, not to the remedy. Consider the literal statutory language:

"if the issue of an original patent is delayed due to the failure of the [PTO] 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);

...,

[then] 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).

Under this interpretation, the filing of an RCE after three years, i.e. after the "B" guarantee is already triggered, can have no effect on the amount of amount of PTA awarded. Even if the PTO's interpretation reflected the intent of Congress, Wyeth teaches that the plain language of the statute nonetheless governs.

Conclusion

Applicants with allowed applications and recent patentees must not count on automatically receiving additional patent term they may be due under the Wyeth decision. Instead, they must follow the procedures for filing 1.705(b) and 705(d) petitions and a civil lawsuit under 35 U.S.C. § 1.154(b)(4)(A). Given the deadlines for these filings, applicants and patentees must act quickly to preserve their rights under Wyeth.

Although the net present value of additional Wyeth patent term adjustment may not be precisely calculable, the investment is small. Applicants who are more venturesome will likely invest in novel challenges to PTA calculations with confidence that the Federal Circuit will view such challenges without deference to the PTO's current interpretations.

--By Robert W. Ashbrook and Daniel M. Becker (pictured), Dechert LLP

Robert Ashbrook is an associate with Dechert in the firm's Philadelphia office. Daniel Becker is a partner with the firm in the Silicon Valley, Calif., office.

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