

Additional Patent Term Adjustment Under Wyeth

Law360, New York (December 15, 2008) -- On Sept. 30, 2008, the U.S. District Court for the District of Columbia issued a decision changing how the U.S. Patent and Trademark Office (PTO) must calculate patent term adjustment under 35 U.S.C. § 154. *Wyeth v. Dudas*, No. 07-1492, 88 U.S.P.Q.2d 1538 (D.D.C. 2008).

This decision particularly affects patents stemming from applications that were pending at the PTO for more than three years. Recalculating patent term adjustment under *Wyeth* may result in significantly longer patent term, which can be of considerable value to patent holders.

Section 154 establishes that a patent's term is 20 years from its earliest effective U.S. non-provisional filing date. Because patentees do not benefit from patent term while the application is being prosecuted, § 154(b)(1) provides for patent term adjustment ("PTA") to account for PTO delays under certain circumstances.

For example, the statute extends a patent's term one day for each day the PTO fails to meet particular deadlines, such as issuing a first Office Action within 14 months, responding to a reply within four months, and so forth. (This type of delay is called an "A delay" because it appears in § 154(b)(1)(A)).

In addition, the statute provides a one-day extension of term for each day that the application is pending beyond three years from the filing date. (This type of delay is called a "B delay"). The three-year clock stops upon the occurrence of certain events, such as patent issuance or the filing of a request for continued examination (RCE).

To prevent double-counting of delay periods, § 154 dictates that, to the extent that "A delays" and a "B delay" overlap, the patent term adjustment "shall not exceed the actual number of days the issuance of the patent was delayed." § 154(b)(2)(A).

The PTO historically interpreted this language to mean that a patentee may obtain credit for "A delay" or "B delay," whichever is larger, but not for both A delay and B delay.

According to the PTO, the entire time of prosecution corresponds to a "B period" for the purposes of identifying overlap, not just the period starting three years after the filing date.

Thus, in the PTO's view, any "A delay" necessarily overlaps with "B delay," regardless of whether the "A delay" occurs before or after the three year mark.

In *Wyeth*, the D.C. District Court overruled the PTO's interpretation, concluding that periods of delay only "overlap" if they actually occur on the same calendar day.

Thus, if an "A delay" occurs on one day, and a "B delay" occurs on another day, a patentee may obtain a patent term adjustment of $A + B$ days. As such, any "A delay" occurring before the three year mark will not overlap with any "B delay." These "A delays" must be counted in addition to all "B delay" when calculating PTA.

The *Wyeth* decision will provide greater patent term for many U.S. patents that have undergone prosecution lasting more than three years. This benefit is likely to be significant for patents in fields such as biotechnology, pharmaceuticals and chemistry, where prosecution often lasts much longer than three years.

Most likely because of its importance and implications from an administrative standpoint, the PTO filed a Notice of Appeal regarding the district court decision on Nov. 28, 2008. Notably, the PTO appealed the case to the U.S. Court of Appeals for the District of Columbia Circuit.

Because this case addresses part of the U.S. Patent Statute, however, expect the D.C. Circuit to transfer to case to the Federal Circuit. Obviously, one cannot know in advance exactly how the Federal Circuit will ultimately resolve the appeal.

The *Wyeth* opinion, however, persuasively points out that the PTO's construction cannot be squared with the clear language of § 154(b)(1)(B). As stated by the district court, if Congress had intended § 154(b)(1)(B) to merely guarantee a 17-year patent term (as measured from grant, under prior law) and no more, it could have easily drafted the statute accordingly.

In addition, even assuming the statute on its face creates an unintended "windfall" of patent term adjustment in some cases, any flaw in statutory language is something for Congress to remedy, not the PTO, given the PTO's lack of substantive rule-making authority.

Unless and until *Wyeth* is reversed, patentees should consider taking immediate action to determine whether their patents might benefit from a recalculation of PTA under *Wyeth's* methodology.

Notably, 37 C.F.R. § 1.705 indicates that any request for reconsideration of a final PTA determination by the PTO must be filed within two months after the grant of a patent.

Thus, patentees may wish to review the PTA awarded in all recently granted patents, and consider immediately filing such requests for any patents that may benefit from *Wyeth* ruling.

It is unclear whether any administrative (PTO) avenue exists to recalculate PTA in patents that issued

more than two months before the Wyeth decision.

Section 154 itself, however, provides that an applicant dissatisfied with a PTO determination regarding PTA may file a civil action in the D.C. District Court within 180 days after a patent issues. § 154(b)(4).

Thus, even if the PTO fails to provide a means to recalculate PTA for patents that issued more than two months ago, patentees may want to explore filing a civil action in the District of Columbia within 180 days of grant to pursue possible additional term adjustment.

Since the Wyeth decision last September, a number of other pharmaceutical companies have already filed complaints against the PTO in the D.C. District Court regarding recently issued patents. Such companies include Purac Biochem BV, Molecular Insight Pharms. Inc., Solvay Pharms GmbH and Biogen Idec Inc.

If a patentee decides to pursue a civil action, the patentee may ask the district court to stay the proceeding pending resolution of the appeal of the Wyeth decision.

Such a stay would likely keep litigation costs down while the matter is resolved, while complying with the 180-day filing requirement. A stay also could give the patentee an opportunity to pursue any administrative remedies that may be offered by the PTO.

For patents that have issued more than 180 days previously, a patentee may be able to obtain a recalculation of PTA by requesting from the PTO a Certificate of Correction under 35 U.S.C. § 254 and 27 C.F.R. § 1.322.

A pending request for a Certificate of Correction also could provide additional grounds for staying a civil action (as discussed above), pending the outcome of any appeal. It is not clear, however, that the PTO will grant a Certificate of Correction to recalculate PTA.

For patents that have not yet issued, applicants should consider carefully reviewing any notification of estimated PTA provided by the PTO with a Notice of Allowance.

As stated in § 154(b)(3)(B), an applicant has "one opportunity to request reconsideration of any patent term adjustment made by the Director." 37 C.F.R. § 1.705 provides that an applicant must file a request for a PTA after the PTO mails a Notice of Allowance but no later than when the applicant pays the issue fee.

Rule 1.705(d) further provides that any request for reconsideration after a patent has issued "that raises issues that were raised or could have been raised" in a previous request "will be dismissed as untimely."

Thus, applicants are advised to consider requesting recalculations of PTA based on the Wyeth decision soon after the PTO mails a Notice of Allowance, such as by submitting a request with the issue fee

payment.

In sum, owners of patents that have issued in the last six months and undergone more than three years of prosecution (before filing an RCE, if applicable) may want to take action quickly.

Depending on the issue date, patentees may want to consider filing a Request for Reconsideration of PTA with the PTO (within 2 months of issue) and/or filing a civil action with the D.C. District Court (within 180 days of issue).

Patentees also may wish to explore whether a request for a Certificate of Correction might be used to obtain a recalculation of PTA.

Because even one day of additional patent term can result in considerable economic, commercial and competitive advantage, this is one situation where taking the time to “check the math” may have significant payoff.

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