

CLIENT ALERT

FEDERAL CIRCUIT AFFIRMS DECISION FINDING USPTO MISCALCULATES PATENT TERM ADJUSTMENT

January 13, 2010

Executive Summary

On January 7, 2010, in the case of *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. January 7, 2010), the Court of Appeals for the Federal Circuit (Federal Circuit) issued a decision that will likely require the United States Patent and Trademark Office (USPTO) to change its method of calculating Patent Term Adjustments, resulting in longer term for many patents (in some cases lengthening term by months or even years). The increased term is particularly valuable for patents that benefit from additional term at the end of their patent life, such as those in the biotechnology, pharmaceutical, and medical device industries. The Federal Circuit's decision confirms the 2008 ruling of the district court in *Wyeth v. Dudas*, which held that the USPTO's methodology for determining Patent Term Adjustment was erroneous.

Background

In 1995, the United States Congress changed the calculation of the term of a U.S. patent from 17 years from the date of patent issue to 20 years from the date of patent filing. With the change, the term of an issued patent was expected to be at least 17 years, or more if prosecution took less than three years. In practice, many patents took longer than three years to issue, meaning the effective life span of the patent was less than it would have been under the prior law.

To address the concern over truncated patent terms, and to compensate for prosecution delays attributed to the USPTO, Congress enacted the 1999 American Inventors Protection Act (AIPA). The AIPA, in part, provided a means to adjust patent terms shortened due to USPTO delays, a mechanism known as Patent Term Adjustment (PTA). PTA is now determined for each allowed application using a complex set of rules that, in general, involves adding up delays caused by the USPTO and subtracting delays caused by the patent applicant. If the result is greater than zero, the difference is added to the term of the issued patent.

In the AIPA legislation, Congress mandated that the USPTO and the applicant should be diligent in prosecution to avoid delay, and that the USPTO should issue a patent within three years of its filing date. PTA is calculated based on several categories of delay, including "A" delays, which result from the USPTO missing deadlines for actions during prosecution, and "B" delays, which

include days in excess of three years from the filing date of the application to the date the patent issues. The AIPA legislation mandates that each day of delay by the USPTO be counted only once, with no double counting of overlapping USPTO delays.

Although the rules for PTA calculation were set forth by Congress, it was left to the USPTO to interpret and implement the rules. The USPTO interprets the requirement to avoid double counting of overlap of "A" and "B" delays to mean that a patent receives PTA credit for either "A" delays or "B" delays -- whichever is longer -- but does not receive credit for both.

The *Wyeth* case centers on the USPTO's interpretation of the term "overlap" and the manner of calculating PTA from "A" and "B" delays. The PTO considers the "B" delay as beginning at the filing date of the application so that any "A" delay necessarily overlaps a "B" delay and only one type of delay is counted toward adjusting a patent's term.

The court in *Wyeth* disagreed with the USPTO's interpretation and held that a "B" delay does not start until the three-year date has passed, so an "A" delay that falls in the first three years would not overlap the "B" delay period, and the patent term should be credited for the sum of the "A" and "B" delays that do not overlap. The USPTO's adjustment calculation methodology was held to be improper by the district court in *Wyeth*, and the USPTO appealed the decision to the Federal Circuit.

Federal Circuit's Decision

In its ruling of January 7, 2010, the Federal Circuit struck down the USPTO's methodology for determining Patent Term Adjustment. The USPTO argued that the AIPA statute was ambiguous with respect to the terms "delay" and "overlap" and sought deference for its interpretation of the statutory language.

The Federal Circuit disagreed with the USPTO's position and held that the statutory language "sets an unambiguous rule for overlapping extensions." The ruling stated that it was clear from the statute that "no 'overlap' happens unless the violations occur at the same time" and that "each 'period of delay' has its own discrete time span whose boundaries are defined" in the statute. The Court held that "the PTO's position cannot be reconciled with the language of the statute" and because the statutory language for determining overlap of extensions is unambiguous, the USPTO is not entitled to deference for its interpretation.

In affirming the judgment of the district court, the Federal Circuit held that the statutory language did not support the PTO's "A" or "B" delay methodology for calculating PTA.

Effect on Current Practice

Despite the Federal Circuit's decision, unless and until the USPTO amends its PTA calculation methodology, specific steps must be taken by a patent owner to secure the correct PTA. One can challenge the USPTO's current "A" or "B" methodology by filing a request for reconsideration

with the USPTO no later than when paying the issue fee or within two months of patent issuance. If the USPTO does not grant such a request within 180 days of patent issuance, a patentee must file a civil suit against the USPTO to preserve its rights. Numerous suits were filed after the district court's decision in *Wyeth*, and the Federal Circuit's affirmance will make such suits even more attractive.

Regardless of whether the USPTO accepts the court's ruling and revises its PTA calculation methodology, or decides to pursue additional judicial review, the *Wyeth* case highlights the importance of monitoring PTA determinations by the USPTO and taking actions to ensure maximum patent term. The USPTO used the incorrect calculation methodology regarding the "overlap" issue for years before applicants successfully challenged that methodology. Also, after years of challenges from applicants, the USPTO recently admitted it had been incorrectly calculating PTA for US National Stage PCT applications.

Besides these systemic errors, surveys have reported that the USPTO quite often makes simple computational errors in determining PTA, even when using the correct methodology. Patentees who maintain patents for their full term should seriously consider reviewing PTA calculations and, if there are errors, challenging those calculations in the USPTO and, if necessary, the district court.

For Further Information

Wolf Greenfield has extensive experience challenging PTA calculations both with the USPTO and the district court. Please contact your Wolf Greenfield attorney if you would like more information.