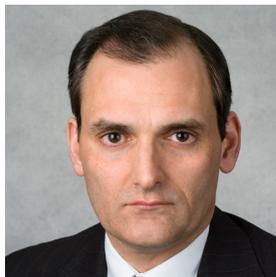


Client Advisory | *January 2010*

Federal Circuit Upholds Decision Granting Additional Patent Term Adjustment to Compensate for Examination Delays

Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008), *aff'd sub nom. Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010).



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On January 7, 2010 the U.S. Court of Appeals for Federal Circuit affirmed a district court decision holding that the interpretation of the patent term adjustment statute that the U.S. Patent Office follows is incorrect as a matter of law. This decision is significant for patent owners because the Federal Circuit opened the door to major revisions of patent term adjustment calculations. These revisions may extend the lives of some patents by significant amounts, thereby giving patent owners more time to accrue the benefits of their patents. Indeed, extending the lives of patents can significantly increase the revenue derived from those patents.

Patent Term Adjustment Background

In 1994, the United States changed the effective patent term from seventeen years from patent issuance to twenty years from the filing of the patent application. Under the original seventeen-years-from-issuance patent rule, any delay in patent examination did not diminish the resulting term of the patent because the term would not begin until issue, i.e., after the delay. A twenty-years-from-filing patent term, however, can be reduced by prolonged patent prosecution because the patent term runs during prosecution.

The American Inventors Protection Act (“AIPA”) of 1999 (codified at 35 U.S.C. § 154) addresses this problem by compensating patent applicants for three types of patent examination delays:

- “A Delays” arising from the failure of the Patent Office to comply with various statutory deadlines (e.g., failing to

mail a first office action within fourteen months of the patent application filing date under 35 U.S.C. § 111(a));

- “B Delays” arising from the failure of the Patent Office to grant a patent within three years of the patent application filing date; and
- “C Delays” arising from certain administrative actions, e.g., interferences, secrecy orders, and appeals.

The relationship between A Delays and B Delays is governed by 35 U.S.C. § 154(b)(2)(A), which states that “[t]o 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 exceed the actual number of days the issuance of the patent was delayed.”

Previously, the Patent Office interpreted the “double-counting” provision of 35 U.S.C. § 154(b)(2)(A) by concluding that the A and B Delays started at the same time and, therefore, patentees were only eligible for patent term adjustment for the larger of the two delays. For example, if a patent subject to twenty days of A Delay issued twenty days after the three-year anniversary of filing, the patent would be eligible for twenty days of patent term adjustment under the interpretation that the Patent Office followed.

The District Court Decision

Wyeth (now owned by Pfizer) and Elan Pharma (collectively referred to as “Wyeth”) own U.S. Patent Nos. 7,179,892 (“the ‘892 Patent”) and 7,189,819 (“the ‘819 Patent”) that relate to treatments for Alzheimer’s disease.

The '892 Patent was entitled to 610 days of A Delay (fifty-one days of which occurred more than three years after the filing date) and 345 days of B Delay. The Patent Office awarded 610 days of patent term adjustment (the larger of the A or B Delays) less 148 days of applicant delay, for a total of 462 days.

The '819 Patent was entitled to 336 days of A Delay (106 days of which occurred more than three years after the filing date) and 827 days of B Delay. The Patent Office awarded 827 days of patent term adjustment (the larger of the A or B delays) less 335 days of applicant delay, for a total of 492 days.

After petitioning the Patent Office for correction of its patent term adjustment calculations, Wyeth filed suit in the U.S. District Court for the District of Columbia (the required venue under 35 U.S.C. § 154) and moved for summary judgment. On September 30, 2008 the district court granted summary judgment in favor of Wyeth concluding (i) the Patent Office does not have substantive-rulemaking authority, and (ii) the interpretation of the double-counting provision by the Patent Office was contrary to the plain language of the statute.

The district court further held that the proper formula for patent term adjustment under 35 U.S.C. § 154 is:

- the number of days of A Delay, plus
- the number of days of B Delay, less
- the number of days of overlap between the A Delay and the B Delay, and less
- the number of days of applicant delay.

The district court held that the period(s) of A Delay and B Delay do not overlap unless the delays occur on the same day.

The Patent Office appealed to the U.S. Court of Appeals for the Federal Circuit and oral argument was heard before Judges Rader, Plager, and Moore on October 7, 2009.

The Federal Circuit Decision

In a unanimous decision affirming the district court's grant of summary judgment, the Federal Circuit held that the language of 35 U.S.C. § 154(b)(2)(A) is unambiguous because each period of delay "has its own discrete time span whose boundaries are defined [by statute]." The Federal Circuit approvingly quoted the district court decision noting 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 [been] delayed."

The Federal Circuit rejected the Patent Office's arguments that (i) A Delays during the first three years of prosecution ultimately lead to B Delays after the three-year anniversary of filing, and (ii) patentees may receive disparate treatment of patent term adjustment under Wyeth's proposed approach. The Federal Circuit noted that its role is to enforce the law and not to second-guess the wisdom of statutes enacted by Congress.

Finally, the Federal Circuit rejected the Patent Office's argument that Wyeth's interpretation runs counter to the statutory history of the ALPA. The Federal Circuit noted House Report No. 106-464 stated that "no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard; in fact most will receive considerably more."

In view of the decision by the Federal Circuit, Wyeth's '892 Patent was properly entitled to 756 days of patent term adjustment, which is 294 days more than what the Patent Office calculated. The '819 Patent was properly entitled to 722 days of patent term adjustment, which is 230 days more than what the Patent Office calculated.

The Impact of Wyeth v. Kappos

On January 11, 2010, the Patent Office posted a notice on its website indicating that the Solicitor General would determine whether to seek further review of the *Wyeth* decision. Any petition for rehearing before the Federal Circuit must be filed within forty-five days after entry of judgment. Any petition for a writ of certiorari to the U.S. Supreme Court must be filed within ninety days after entry of judgment.

The Patent Office also indicated that pending a determination by the Solicitor General, the Patent Office is in the process of changing how it calculates patent term adjustment to conform to the *Wyeth* decision.

Finally, the Patent Office reminded patentees of the deadlines for challenging patent term adjustment under the statute and Patent Office rules. If a patentee believes that there is an error in the Patent Office's calculations of patent term adjustment, the patentee must, depending on the type of error, challenge those calculations when paying the issue fee or file a petition to request

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reconsideration within two months of the issuance of the patent.

The Patent Office's response to such petitions will, of course, vary depending on whether the Patent Office challenges the *Wyeth* decision. If the Patent Office chooses to challenge *Wyeth*, it is advisable to file a civil action in the U.S. District Court for the District of Columbia within 180 days of the issuance of the patent to preserve the patentee's rights. In our experience from filing several such suits, the government frequently seeks to stay these suits until final resolution of *Wyeth*.

A more complicated question concerns what recourse patentees have, if any, for patents that issued more than 180 days before the district court's September 30, 2008 decision. Patentees could petition the Director of the Patent Office to suspend the rules that require a request to reconsider the patent term adjustment be filed within two months of patent issuance. It is unclear,

however, whether the 180-day period to file suit would prohibit the Patent Office from taking any action after the 180-day period.

Conclusion

The law of patent term adjustment has been fluid since the original *Wyeth* decision in 2008 and will remain so in the short term. While awaiting further actions from the Patent Office in the case, we recommend that patent owners remain diligent in reviewing the patent term adjustment calculations performed by the Patent Office and take appropriate action (e.g., request reconsideration and/or file a civil action) to preserve their rights to additional patent term.

Our firm is experienced in counseling clients on prosecution strategies to maximize patent term adjustment as well as administrative and judicial challenges to patent term adjustment calculations. We would be happy to assist with any patent term adjustment questions that you may have.

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