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Patent Term After *Wyeth v. Kappos*

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Prior to 1995, the term of a U.S. patent was 17 years from the date of issue. In 1995, the patent laws were amended to change the term of an issued patent to 20 years from the original filing date in an effort to harmonize U.S. laws with patent laws in other countries.

One consequence of the change was the potential for an unfairly shortened patent life due to U.S. Patent and Trademark Office delays that would prevent the patent from being issued within three years.

To address the issue, the American Inventors Protection Act (AIPA) of 1999 provided for "Patent Term Adjustment," or PTA, a mechanism by which patentees can be awarded additional patent term to offset PTO delays.

Under the AIPA, a patentee is to receive one additional day of patent term, or PTA, for two types of PTO delay: (1) each day that the PTO caused a delay during prosecution (A Delay) and (2) any day that an application is pending beyond three years from filing date (B Delay) as long as the delay from the two periods does not overlap.

The adjustment is then reduced by any delay caused by the patentee; for example, by extending the deadline for complying with filing formalities or responding to an office action.

The PTO then published rules regarding how PTA would be calculated. In particular, the PTO interpreted the "no overlap" language of the AIPA to mean that any A Delay would necessarily result in B Delay, so a patentee was entitled a PTA equal to the greater of the two types of delay, but not both. The PTO has applied that formula for calculating PTA since 1999.

Initially, the PTO calculates PTA for each issued patent. If the patentee disagrees with the calculation, it must request correction within two months of issuance. If the patentee continues to disagree with the PTO's calculation, it may file a lawsuit in the U.S. District Court for the District of Columbia. The lawsuit must be filed within 180 days from the patent issue date.

Challenge of 'no overlap' language

In January, the Federal Circuit upheld a District Court decision regarding the proper calculation of patent term adjustment for issued patents. *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010).

Wyeth challenged the PTO's interpretation of the "no overlap" language in calculating PTA, arguing that a patentee is entitled to PTA for both A Delay and B Delay and that the correct interpretation of the statutory requirement that the two types of delay have "no overlap" means that they must not occur on exactly the same date.

Wyeth's interpretation was that a patentee is entitled to all A Delay term extension accrued prior to the date that is three years from the filing date of the application; then, if the application is still pending, the patentee is entitled to all the A Delay and all the B Delay that accrues after that three-year date.

Both the District Court and the Federal Circuit agreed. As a result, the PTO has agreed to comply with the decision when calculating PTA for patents issued after March 2, 2010, and has issued interim procedures for requesting recalculation of PTA in recently issued patents.

Under the interim procedures, the PTO will accept requests for recalculation of patent term for patents issued before March 2, 2010, and less than 180 days prior to filing the request - if they are made solely on the basis of the Wyeth decision.

Any request not based solely on Wyeth must be made within the normal two-month period. According to the PTO, requests for recalculation that were pending at the time of the Wyeth decision will be recalculated as required by that decision.

However, because the interim procedures are not binding and no patentee is guaranteed that its request will be granted, many lawsuits are still being filed against the PTO for commercially important patents that have reached the 180-day limit for appealing administrative rulings.

Retroactive?

One significant question that has not been addressed at all in the interim guidelines is whether the Wyeth decision will be applied retroactively to extend the term of patents that issued more than 180 days before the PTO interim procedures were published.

Because recalculation of PTA under Wyeth is very complicated and can result in very substantial increases in patent term, the administrative and political issues surrounding the issue are sure to be hotly contested.

Administrative concerns include, for example, the sheer number of patents that fall into this category. It is estimated that approximately 200,000 patents issued during the period of time that the PTO was applying the wrong formula for

calculating PTA. If requests for recalculation of PTA were made for even half of those patents, the requests would quickly outstrip the PTO's administrative resources.

Although the PTO is in the process of developing a new computer program that uses the information recorded in the PTO's Patent Application Locating and Monitoring (PALM) system to recalculate patent term, it has warned that many recalculations are complex because there are numerous types of communications exchanged between applicants and the PTO that impact the calculation.

Politically, a decision to recalculate PTA in older patents would create even more problems.

On one hand, there is a fundamental unfairness involved in depriving a patentee of patent term and potentially causing substantial financial loss as the result of PTO error. Sales on patented drug products can, in some cases, amount to billions of dollars a year. PTA of even a single additional day can equate to millions of dollars of income to the patentee.

On the other hand, extending the term of a patent that is expected to expire on a certain date could cause financial ruin for a company that has planned a product launch around that expiration date, only to find that at the last minute the patent term has been extended, potentially, by years.

In a recent public appearance in Cambridge, the under secretary of commerce for intellectual property and director of the U.S. Patent and Trademark Office, David Kappos, indicated that the PTO currently feels that it has no legal mechanism for allowing requests for recalculation of patents filed more than 180 days after a patent has issued. 35 U.S.C. §154(b)(4)(A) provides for appeal of PTA determinations as follows:

"(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) 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. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change."

The statutory provision for appeal of a PTO decision on PTA does not clearly state that the PTO loses jurisdiction over these cases after 180 days. It merely provides a time frame for which a patentee can take action in federal court to challenge the decision.

Although Kappos indicated that the PTO would consider some of the proposals for rule changes to address older patents that were suggested by the audience, there is no evidence that the PTO actually intends to move in that direction.

Moreover, unless the PTO makes a decision to allow requests in older patents, any petition to the commissioner for relief is unlikely to be successful. It is possible that only significant political pressure from patentees interested in obtaining Wyeth-based PTA for a patent issued more than 180 days before the filing of a request for recalculation will cause the PTO to reconsider its current rules.

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