

VALUATION OF EARLY-STAGE TECHNOLOGIES



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More Organizations Ask PTO to Recalculate Term Adjustments

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by: [Wolf, Greenfield & Sacks, P.C.](#)

More than one-fourth of the US Patent and Trademark Office's (USPTO) patent term adjustment (PTA) calculations may be wrong, estimates MaryDilys Anderson, an attorney specializing in biotech and pharmaceutical patents with Wolf, Greenfield & Sacks, P.C., a Boston intellectual property law firm.

Errors can be procedural or substantive. The USPTO draws information from its database in order to calculate PTA. If such information is incorrect, then the PTA will likely be incorrect. Examples include miscoded or mislabeled documents and incorrect dates.

Substantive errors arise from the USPTO's flawed interpretation of federal laws and its own rules relating to PTA. These results may result in days, months, or even years of lost patent term.

Patents last 20 years from their filing date, so delays in getting a patent granted can cut into actual patent life. If a patent is granted more than three years after filing date because of USPTO delays, lost patent life can be regained through PTA.

USPTO uses a complex set of rules to calculate PTA. Essentially, these rules amount to adding up delays 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 form of PTA.

A proactive approach can increase your PTA and also help reduce the chance of PTA errors, Anderson says.

First, your patent attorney should make sure all documents and dates relating to your patent application are correctly entered and identified in the USPTO database. "Reviewing entries and requesting correct during prosecution can avoid miscalculations later," Anderson says.

Second, minimizing applicant delays will reduce any time that might ultimately be deducted from your PTA.

Third, document examiners' requests in writing, Anderson adds. If the patent examiner asks for a replacement document or other filing, reference the examiner's request in the filing papers. That way, the submission should not be categorized as contributing to applicant delay.

And it's not just corporations that need to be vigilant—universities and hospitals should scrutinize PTA to maximize the value that potential licensees place on a patent. "There can be significant value added by getting as much PTA as you're entitled to," says Anderson.

After PTA has been granted, make sure it's correct, especially if a covered product or technology will



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have a long commercial lifespan. With products like pharmaceuticals and some medical devices, additional PTA can mean millions of additional value.

If the PTA calculated by the USPTO is incorrect, the error can be challenged. A request for reconsideration can be filed with the USPTO only during two specific time periods. If you miss the deadline, you can file suit in the United States District Court for the District of Columbia within 180 days after the issue date of the patent.

Numerous such suits challenging the PTO's method of calculating PTA are pending, including the Wyeth v. Dudas case. Currently, the USPTO does not count certain delay time periods it interprets as double-dipping. The Wyeth court disagreed with the USPTO interpretation, and the USPTO has appealed to the Federal Circuit.

"If the appeals court upholds the district court's ruling in favor of Wyeth, some patent holders would be entitled to over a year of additional PTA," Anderson says.

Patent applicants should be vigilant now in order to preserve their rights to additional PTA should Wyeth prevail.

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