

Adjusting the life of a US patent due to Patent Office delay

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In the case of biotechnology and pharmaceutical inventions, the term of a patent is of particular importance because commercialization often occurs long after the patent application is filed. Ordinarily, in exchange for the full disclosure of one's invention to the public, a patentee is entitled patent protection extending 20 years from the filing date of the patent application. The patent laws, however, require the US Patent and Trademark Office (PTO) to compensate a patentee—in the form of patent term adjustment—for delays that are caused by the agency.

In January 2010, the US Court of Appeals for the Federal Circuit issued an important decision in the case of *Wyeth v. Kappos*, in which it confirmed that the PTO had been systematically miscalculating patent term adjustments by misapplying a portion of the relevant statute and depriving some patentees of the full term of their patents.¹ Moreover, separate and apart from the error revealed in *Wyeth*, Japan Tobacco, Inc., recently discovered a second error relating to the PTO's method of calculating patent term adjustment for certain US national stage applications.² In September 2009, the PTO acknowledged this error and agreed that one of Japan Tobacco's pharmaceutical patents was entitled to a larger term of adjustment.³

The discovery of the *Wyeth* and *Japan Tobacco* errors are critical reminders that patent applicants must be diligent in checking adjustment calculations as well as the PTO's methodology for applying the relevant statute and rules, to ensure that they are granted the full amount of patent protection allowed under the law.

New laws and guarantees

In 1995, Congress enacted a law that changed the term of a patent in the United States from seventeen years from *issuance of the patent* to twenty years from *filing of the patent application*.⁴ Under the old law, any delay that was caused by the PTO while the application was pending would not impact the life of a patent because the patent term did not begin until the day the patent issued. Under the new regime, however, those delays would have the potential to consume a portion

of a patent's shelf life, given that the term began to run on the day the patent application was filed. In 1999, the patent laws were further amended to provide certain "guarantees" that would compensate patentees for lost time caused by PTO delay. Two of those guarantees were at the heart of the *Wyeth* case.

The first guarantee, set forth in 35 USC §154(b)(1)(A), allows for a patent term adjustment if the PTO fails to meet certain deadlines during the prosecution of the patent application. For example, the PTO has fourteen months to issue a first office action. If it fails to meet that deadline, the statute provides that a patentee can receive a one-day extension for each day the PTO fails to respond after the fourteen-month period ends. These types of extensions are referred to as "A delays."

The second guarantee declares that the total pendency of the application should be no longer than three years from the date the application was filed (the "three-year mark"). Section 154(b)(1)(B) guarantees that for each day that the PTO delays issuing a patent beyond the three-year mark, a patentee is entitled to a one-day extension. Such delays are referred to as "B delays."

Notably, the statute further included a provision that serves to limit the term of an adjustment in the event that the periods of delay under A or B overlap. Specifically, 35 USC §154(b)(1)(C) provides: "To the extent *periods of delay* attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted . . . shall not exceed the actual number of days the issuance of the patent was delayed"⁵ (emphasis added). The error asserted in *Wyeth* centered on the proper interpretation of this particular provision.

Wyeth v. Kappos — The end of an "error"

In *Wyeth*, plaintiffs Wyeth and Elan Pharma International, Ltd. (collectively "Wyeth") brought suit against the PTO in the US District Court for the District of Columbia. Wyeth argued that the PTO misapplied the statutory provisions governing patent term adjustment. It was undisputed that the PTO caused delays during the prosecution of two of Wyeth's patent applications, which resulted in both A delays and B delays and entitled Wyeth to adjustments under §154(b). With regard to the first patent, Wyeth argued that it was entitled to an

adjustment of 756 days, rather than the 462 days it was initially granted. For the second patent, Wyeth argued that it was entitled to 722 extra days, as opposed to the 492 days initially granted. The explanation for the discrepancy in the calculation focused on the proper interpretation of the statutory language in §154(b)(1)(C). Specifically, the parties disagreed on the circumstances under which “*periods of delay . . . overlap.*” The district court agreed with Wyeth’s interpretation and granted summary judgment in its favor.

On appeal, the Federal Circuit affirmed the district court’s decision. The reviewing court began its analysis, as it always does in cases concerning statutory interpretation, by looking at the plain language of the statute. In particular, the court focused on the terms “periods of delay” and “overlap.” According to the court, there was no ambiguity in the statute with regard to the meaning of “periods of delay,” as those periods were “expressly designate[d]” in the statute.⁶ More specifically, the court found that the starting and end points of the periods of delay were clearly defined. As to A delays, the period begins when the PTO fails to meet a deadline to take a certain action and ends when “the action described...is taken.”⁷ In other words, the period of delay for an A delay “runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action.”⁸ As for B delays, the plain language of the

statute dictates that the period begins at the three-year mark and ends when the patent issues.

Upon turning to the PTO’s manner of calculating patent term adjustment, it became clear that the method could not be reconciled with the court’s interpretation of “periods of delay.” Under the PTO’s method, when faced with periods of A delay and B delay, the PTO would simply take the greater of the two delays and subtract any delay caused by the applicant in order to determine the total patent term adjustment. The PTO argued that such a method was justifiable because it avoided double counting any time during periods of B delay (after the three-year mark) that may have been caused by a delay that occurred during the period of A delay. In the PTO’s view, this method (referred to as the “greater-of-A-or-B rubric”) prevented patentees from receiving “some type of windfall adjustment under the statute.”⁹

Writing for a unanimous panel, Judge Rader swiftly rejected the PTO’s approach upon examining the language of the statute. Affirming with approval the decision of the district court, Judge Rader highlighted the error of the agency’s ways by stating 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 delayed.*”¹⁰ The court agreed with Wyeth’s proposed construction that it found consistent with the statutory language. Under that

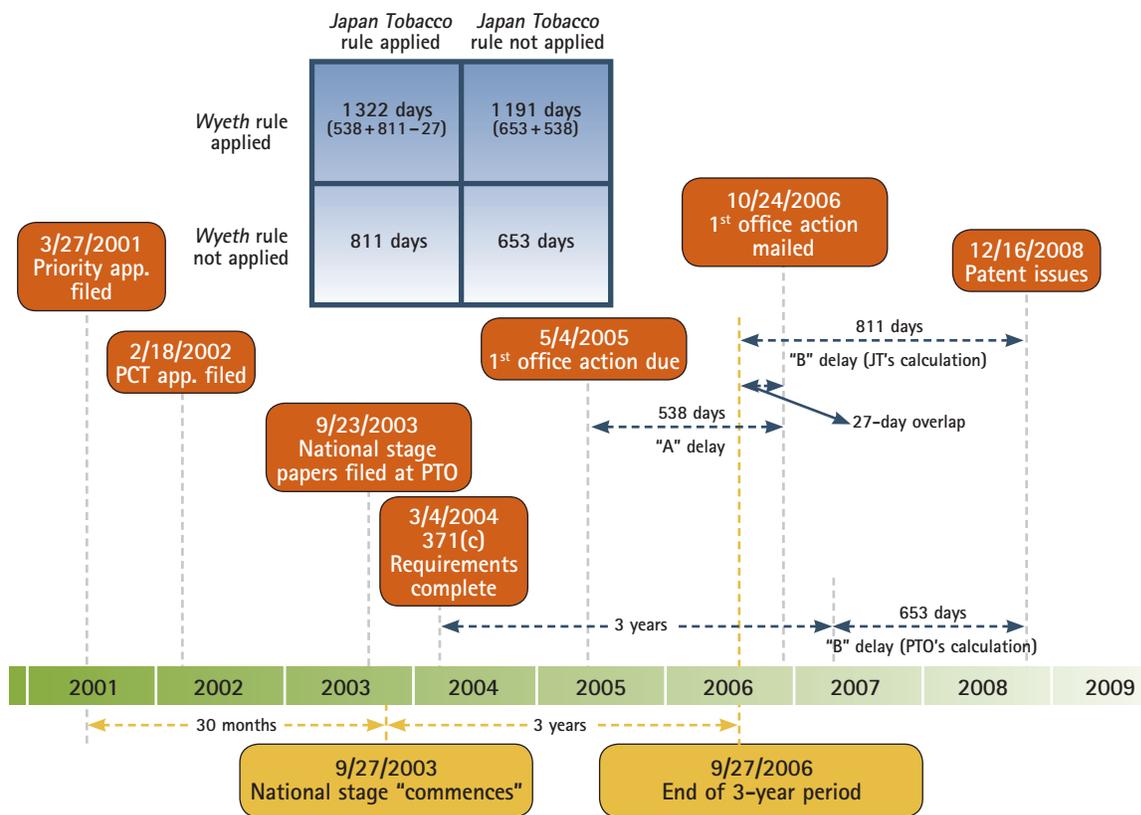


Figure 1. PTA calculation for US Patent No. 7,465,444

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interpretation, any possibility of overlap between the two types of delay can only occur at some point after the three-year mark, because it is only at that point that a B delay could even exist. As such, the court determined that patentees are entitled to patent term adjustment that includes the addition of A delays and B delays, except for those periods where they occur on the same calendar day(s). That method can be referred to as the “A-plus-B-minus-overlap” method.

A modified example of the facts of the *Wyeth* case highlights the significant difference between the two methods. Assume the following facts: 1) an A delay of 600 days; 2) a B delay of 400 days; 3) an overlap of 50 days (i.e., a period of A delay occurring after the three-year mark); and 4) an applicant delay of 100 days. Under the PTO’s greater-of-A-or-B rubric, the total patent term adjustment would amount to 600 days (the greater of A delay and B delay) minus 100 days (applicant delay) for a total of 500 days of patent term adjustment. Under the “A-plus-B-minus-overlap” method, the total patent term adjustment would equal 600 days plus 400 days (A+B delay) minus 50 days (overlap) minus 100 days (applicant delay) for a total of 850 days. Thus, in this example, the calculation under the PTO method would deprive a patentee of 350 days of additional patent life or, in more practical terms, nearly an entire year of valuable IP protection.

The *Japan Tobacco* error

In addition to the PTO’s historical mistake uncovered in *Wyeth*, Japan Tobacco discovered yet another significant error relating to patent term adjustment calculations in the context of US national stage filings under 35 USC §371. The error concerned the proper standard for determining the period of B delay under §154(b)(1)(B), which, as discussed above, guarantees a one-day extension for each day after the three-year mark that the PTO delays in issuing the patent. For purposes of determining when the B delay clock begins to run in a national stage filing, the regulations provide that the actual filing date of the application is when the “national stage commenced under 35 USC 371(b) or (f).”¹¹

Section 371(b) provides that “[s]ubject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty,” with the time limit being thirty months from the priority date.¹² Moreover, §371(f) provides that “[a]t the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order...and the applicable requirements of subsection (c)” have been satisfied.¹³ Reading those provisions in conjunction, the governing statute dictates that the national stage commences thirty months from the priority date of a Patent Cooperation Treaty application, unless an applicant satisfies the requirements of §371(c) and expressly requests early processing prior to the thirty-month date.

Japan Tobacco sought recalculation of the patent term adjustment it was awarded for US Patent No. 7,465,444 upon realizing that the PTO had been systematically counting the period of B delay from the date the requirements of §371(c) were met, rather than from the commencement date (which in this case was thirty months from the prior-

ity date). Based on the PTO’s improper application of the governing provisions, Japan Tobacco asserted that it was entitled to additional patent term adjustment. In June 2009, the PTO acknowledged the miscalculation and agreed with Japan Tobacco that it was entitled to an adjustment of 811 days for B delay, as opposed to the original adjustment of 653 days. Thus, by exercising diligence in assessing and challenging the PTO’s application of the provisions governing patent term adjustment, Japan Tobacco was able to breathe at least an additional 158 days of life into its patent. In September 2009, the PTO published a Notice stating that the error identified by Japan Tobacco was a systemic error and advised affected patentees on the procedure and timing to have the error corrected.¹⁴

Real-world impact of the *Wyeth* and *Japan Tobacco* rules

The *Japan Tobacco* rule often increases the total period of B delay, whereas the *Wyeth* rule allows for the addition of periods of A delay and B delay. The facts of the *Japan Tobacco* case provide an excellent example of the interplay of the *Wyeth* and *Japan Tobacco* rules and the significant impact those rules can have on patent term adjustment calculations. *Japan Tobacco* involved the following facts: 1) 538 days of A delay; 2) 653 days of B delay (under the PTO’s incorrect interpretation in *Japan Tobacco*); 3) 811 days of B delay (under the correct interpretation in *Japan Tobacco*); 4) 27 days of overlap (occurring only if the *Japan Tobacco* rule is applied); and 5) zero days of applicant delay. The total patent term adjustment when neither rule is applied is 653 days, which was the original patent term adjustment granted by the PTO. Applying the *Wyeth* rule alone, the patentee is entitled to 538 days (A delay) plus 653 days (B delay) for a total of 1191 days. Under the *Japan Tobacco* rule alone, the patent term adjustment amounts to 811 days. When both the *Wyeth* and *Japan Tobacco* rules are applied, the allowable patent term adjustment is 538 days (A delay) plus 811 days (B delay under the *Japan Tobacco* rule)¹⁵ minus 27 days (overlap), yielding a total patent term adjustment of 1322 days. *Figure 1* provides an illustration of the patent term adjustment calculation.

The errors revealed in *Wyeth* and *Japan Tobacco* represent just two examples of the undefined number of instances in which a patentee has been deprived of its full statutory patent term adjustment as a result of miscalculations committed by the PTO. In the *Japan Tobacco* example, the patentee should be able to more than double its patent term adjustment and claim a total of more than 3.5 years of total adjustment upon proper application of the statute and rules. For pharmaceutical and biotech companies, where a single day of market exclusivity can translate into enormous profits and considerable competitive advantage, the importance of seeking extended patent protection in the form of patent term adjustment is indisputable.

Conclusion

The Federal Circuit’s decision in *Wyeth* and the PTO’s decision in *Japan Tobacco* shine a light on the fallible nature of the PTO. The agency’s systematic miscalculation of patent term adjustment

has precluded many patentees from realizing the full value of their patents. Because the agency has yet to implement a reliable system for calculating patent term adjustment in a manner that is consistent with the rulings of *Wyeth* and *Japan Tobacco*, a greater burden is placed on patentees to practice vigilance in confirming that they are receiving the full patent term adjustment allowed under the law and to preserve their rights in the process.¹⁶

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3. See <http://www.fr.com/news/article/detail.cfm?articleid=984>.
4. See Pub. L. No. 103-465, §532, 108 Stat. 4809, 4984 (1994).
5. 35 USC §154(b)(1)(C) (emphasis added).
6. *Wyeth*, slip op. at 7.
7. *Id.* at 7-8 (citing 35 USC §154(b)(1)(A)).
8. *Wyeth*, slip op. at 8.
9. *Id.* at 9.
10. *Id.* at 8 (emphases in original).
11. 37 CFR §1.702(b); see also MPEP §2730 (emphasis added).
12. 35 USC 371(b) (emphasis added).
13. 35 USC 371(f) (emphasis added).
14. http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/20090909_pta_calc_in_pct.pdf.
15. For more information on calculating B delay, see <http://www.fr.com/practice/bdelay.cfm>.
16. On January 28, 2010, the PTO announced the implementation of an interim procedure that would allow patentees to request recalculation of patent term adjustment without a fee or petition while the agency updates its computer system in accordance with the *Wyeth* decision. See http://www.uspto.gov/news/pr/2010/10_06.jsp.