

LexisNexis® Emerging Issues Analysis

Brian S. Sun and Laurie A. Axford on

Wyeth v. Kappos and the ABCs of Patent Term Adjustment

2010 Emerging Issues 4907

[Click here for more Emerging Issues Analyses related to this Area of Law.](#)

Introduction

On January 7, 2010, the Court of Appeals for the Federal Circuit handed down a significant decision affecting patent term adjustment in favor of patentees (*Wyeth v. Kappos*, 2009 [591 F.3d 1364](#) (Fed. Cir. 2009)). In affirming the U.S. District Court for the District of Columbia, the Federal Circuit dismissed the U.S. Patent and Trademark Office's ("PTO") arguments relating to its interpretation of [35 U.S.C. 154\(b\)](#), which governs Patent Term Adjustment ("PTA"). Specifically, the Federal Circuit affirmed the District Court's grant of summary judgment in favor of Plaintiffs-Appellees Wyeth and Elan Pharma International Ltd. ("Wyeth"), finding that the PTO's calculation of PTA for two of Wyeth's patents was improper, and that Wyeth had thus been denied a portion of the patent term to which it was entitled under [35 U.S.C. 154\(b\)](#). Ultimately, as a result of the Federal Circuit's decision, the post-*Wyeth* landscape will lead not only to an increase in PTA filings, but also to a flurry of additional PTAs for patents that issued previously.

History

The Patent Term Guarantee Act, part of the American Inventors Protection Act, was enacted in 1999, largely in response to the General Agreement on Tariffs and Trade ("GATT"), which had been signed into law in 1994. The GATT legislation went into effect on January 1, 1996, its biggest effect directly impacting the measurement of patent term protection going forward. Under the new law, patent term protection would extend twenty years from the filing date, in contrast to the prior measurement of seventeen years from issuance. As a consequence, new calculations for patent term protection became heavily dependent on how quickly a patent application could be prosecuted to issuance. Accordingly, due to major concerns regarding the potential reduction in patent life as a result of PTO-caused delays during prosecution, [35 U.S.C. 154\(b\)](#) was subsequently amended to provide specific "guarantees" for patent term adjustment based on delays in prosecution.

TOTAL SOLUTIONS

[Legal](#) [Academic](#) [Risk & Information](#) [Analytics](#) [Corporate & Professional](#) [Government](#)



LexisNexis® Emerging Issues Analysis

Brian S. Sun and Laurie A. Axford on

Wyeth v. Kappos and the ABCs of Patent Term Adjustment**The “A” - “B” - “C”s of PTAs**

[35 U.S.C. 154](#)(b) lays out three separate “guarantees” to ensure proper patent term adjustments for applicants who experience delays in prosecution due to the PTO or extreme circumstances. Specifically, the statute enumerates “A”, “B” and “C” periods, of which “A” and “B” periods are attributed to PTO-caused delays ([35 U.S.C. 154](#)(b)(1)). The “C” period relates to delays due to interferences, secrecy orders and appeals, and was not at issue in *Wyeth*.

The “A” period, or “Guarantee of Prompt Patent and Trademark Office Responses,” provides applicants with a one day term adjustment for each day that the PTO exceeds a prescribed time allocation depending on the particular stage of prosecution. For example, the PTO is allotted fourteen months commencing from the application filing date to issue an initial Office Action. Therefore, for each day over the fourteen month deadline, a prospective patentee will be entitled to an extra day of PTA.

Likewise, the “B” period, or “Guarantee of No More than 3-Year Application Pendency,” comes into effect when a patent application has been pending for at least three years, and provides patentees with a single day term adjustment for every day of delay thereafter. Thus, the “B” period offers assurance to applicants that their patent protection will extend at least seventeen years from issuance, which is no less than what patentees were entitled to pre-GATT.

As a counterbalance to the enumerated “guarantees,” applicants are also subject to two limitations that affect the calculation of any potential PTA. First, applicants are required to act diligently in prosecuting their applications ([35 U.S.C. 154](#)(b)(2)(C)). Similar to the timing requirements imposed on the PTO under the “A” period, applicants must also comply with prescribed deadlines as set forth, where each day of delay is ultimately subtracted from the total PTA.

The second limitation applies to restrict PTA when any “periods of delay” “overlap.” Specifically, [35 U.S.C. 154](#)(b)(2)(A) states that to the extent the “A”, “B” and “C” periods 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.” The dispositive issue in the *Wyeth* case centers on the correct interpretation of the statutory language directed to when “periods of delay” “overlap.”

The Federal Circuit’s Interpretation

Relying on the language of [35 U.S.C. 154](#)(b)(3), which directs the PTO to “prescribe regulations establishing procedures for the application for and determination of patent

TOTAL SOLUTIONS

Legal Academic Risk & Information Analytics Corporate & Professional Government



LexisNexis® Emerging Issues Analysis

Brian S. Sun and Laurie A. Axford on

Wyeth v. Kappos and the ABCs of Patent Term Adjustment

term adjustments,” the PTO’s interpretation permitted “B” delay to occur at any time after an application was filed. As such, under the PTO’s interpretation, “A” and “B” periods could therefore begin overlapping each other from the very moment an application was filed. Accordingly, the PTO argued that PTA calculations should be measured on a greater of “A” or “B” rubric, thereby making it impossible for “A” and “B” periods to ever be combined.

In defending its interpretation, the PTO argued that “A” delays during the first three years of prosecution ultimately led to “B” delays after the three-year mark from filing, thereby necessitating the greater of “A” or “B” approach in order to prevent double-counting of PTA. Wyeth disagreed with the PTO’s interpretation, arguing that the statute clearly limited “overlap” to cover only situations where “A” delays occurred more than three years from the filing date.

The Federal Circuit agreed with Wyeth, holding that the language of the statute was clear and unambiguous, and therefore not subject to interpretation by the PTO. In construing the provisions of [35 U.S.C. 154\(b\)](#), the Federal Circuit found no ambiguity in the terms “periods of delay” and “overlap,” stating, “each ‘period of delay’ has its own discrete time span whose boundaries are defined in section 154(b)(1).” (*Wyeth*, [591 F.3d 1364, 1369](#)). As discussed further by the court, “before the three-year mark, no ‘overlap’ can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect. If an A delay occurs on one day and a B delay occurs on a different day, those two days do not ‘overlap’ under section 154(b)(2).” (*Id.*, [at 1370](#)). Accordingly, the court affirmed the district court’s ruling for summary judgment in favor of Wyeth, holding that “Section 154(b)’s language is clear, unambiguous, and intolerant of the PTO’s suggested interpretation.” (*Id.*, [at 1372](#)).

Shortly after the Federal Circuit issued its ruling, the PTO announced on January 21, 2010 that it would not appeal the Wyeth decision, instead stating that it was already in the process of preparing procedures for expediting requests for recalculation of PTA that were in line with the Federal Circuit’s interpretation.

The Fallout

The USPTO’s Interim Procedures. After announcing that it would not challenge the Federal Circuit’s decision, the PTO instituted an interim procedure for requesting recalculation of patent term based on the Wyeth decision. (See [75 Fed. Reg. 5043](#), (Feb. 1, 2010)). The interim procedure, which is provided free of charge, may be utilized for any

TOTAL SOLUTIONS

[Legal](#) [Academic](#) [Risk & Information Analytics](#) [Corporate & Professional](#) [Government](#)



LexisNexis® Emerging Issues Analysis

Brian S. Sun and Laurie A. Axford on

Wyeth v. Kappos and the ABCs of Patent Term Adjustment

patent issued prior to March 2, 2010 so long as the request for reconsideration is submitted within 180 days of the day the patent was granted. Further, the request for reconsideration may only be filed if the sole basis for requesting the recalculation is premised on the USPTO's pre-Wyeth interpretation of [35 U.S.C. 154\(b\)](#).

Accordingly, this alternative procedure provides many patentees with a "second bite of the apple" by waiving the statutory requirement that any request for reconsideration of patent term adjustment must be filed within two months of the date the patent issued.

The PTO's Authority to Recalculate PTA. Although the majority of patentees will likely have no issue with the PTO's demonstrated compliance with the Federal Circuit holding, there remain concerns as to whether the PTO even possesses the authority to institute interim procedures to reconsider PTA calculations. As pointed out by the Wyeth court, "Section 154(b)(3) of the statute directs the PTO to 'prescribe regulations establishing procedures for the application for and determination of patent term adjustments.'" (*Wyeth*, [591 F.3d 1364, 1367](#)).

Further, [35 U.S.C. 154\(b\)\(3\)\(B\)\(ii\)](#) authorizes the Director of the PTO to provide applicants with only *one* opportunity to request reconsideration of any PTA determination. As discussed above, the PTO's interim procedures waive the requirement that any request for reconsideration must be filed within two months of the date the patent issued.

Lastly, in its decision, the Federal Circuit dismissed the PTO's argument for *Chevron* deference with regard to the PTO's authority to interpret when "A" and "B" delays may occur, but the court was silent on what, if any, measures the PTO could take to correct past miscalculations of PTA. (See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* [467 U.S. 837](#) (1984)). Thus, the PTO's institution of interim procedures, which waive certain statutory provisions in order to recalculate PTA, could be construed as an improper exercise of authority that falls outside the scope granted to it by Congress.

The Post-Wyeth Landscape

Although the interim procedures instituted by the PTO have generated a great deal of interest, the number of patents that actually meet the eligibility requirements make up only a small fraction of the patents which may or may not have been accorded incorrect PTA. As such, for any patent that issues on or after March 2, 2010, patentees may not rely on the PTO's interim procedures, but must file a request for reconsideration under

TOTAL SOLUTIONS

[Legal](#) [Academic](#) [Risk & Information Analytics](#) [Corporate & Professional](#) [Government](#)

LexisNexis® Emerging Issues Analysis

Brian S. Sun and Laurie A. Axford on

Wyeth v. Kappos and the ABCs of Patent Term Adjustment

[37 C.F.R. 1.705](#)(d) that complies with the requirements of [37 C.F.R. 1.705](#)(b)(1) and (b)(2) within *two months* of the issue date.

Further, while the *Wyeth* case should be regarded as a victory for patentees, the Federal Circuit's decision should not dramatically change the manner in which the majority of patent practitioners handle the determination of PTA for their clients. Specifically, practitioners should continue to monitor for any PTO or applicant caused delays while still under prosecution, or at a minimum, they should calculate the correct PTA upon receipt of a Notice of Allowance. Additionally, although the PTO has promised an updated compute algorithm by March 2, 2010, based upon the previous high error rate of the PTO's computer software, prospective patentees should still consider asking their patent counsel to perform an independent PTA calculation to confirm an accurate determination.

It is also worth noting that the PTO plans to revise their Patent Application Information Retrieval ("PAIR") PTA calculation screen to show the number of days of "A", "B" and "C" delay separately, as well as the number of days of overlap for each period of delay, followed by the number of days of non-overlapping USPTO delay, applicant delay and total PTA. Unlike the March 2, 2010 deadline however, the PTO does not expect to implement the revised PAIR screen until sometime in July 2010.

Relief for "Old" Patents

Unfortunately, for patentees whose patents were issued more than 180 days ago, the likelihood that any additional PTA can still be recouped is uncertain at best. [35 U.S.C. 154](#)(b)(4) provides a civil remedy to applicants that are dissatisfied with a determination made by the Director under [35 U.S.C. 154](#)(b)(3) so long as the civil action is filed in D.C. District Court within 180 days from the issue date of the patent. In light of the statutory language provided in [35 U.S.C. 154](#)(b)(4), there may be only a few options available to patentees who still wish to capitalize on the impact of the *Wyeth* decision.

One potential avenue for patentees to recover PTA beyond the 180 day window is to petition the PTO Director under [37 C.F.R. § 1.181](#)(a)(2) for a Certificate of Correction based on the statutory language of [35 U.S.C. § 254](#), which states, "Whenever a mistake in a patent, incurred through the fault of the Patent and Trademark Office, is clearly disclosed by the records of the Office, the Director may issue a certificate of correction stating the fact and nature of such mistake, under seal, without charge, to be recorded in the records of patents." Section 254 goes on further to state that any patent which receives a Certificate of Correction shall have the same effect for causes of action arising

TOTAL SOLUTIONS

Legal Academic Risk & Information Analytics Corporate & Professional Government



LexisNexis® Emerging Issues Analysis

Brian S. Sun and Laurie A. Axford on

Wyeth v. Kappos and the ABCs of Patent Term Adjustment

thereafter as if the patent had been originally issued with the correction. Thus, based simply on the plain language of the statute, it seems possible that the PTO Director could issue a Certificate of Correction upon petition.

Further, several patentees of patents that issued more than 180 days before their respective statutory periods ended have already filed suit against the PTO Director to reclaim portions of PTA that were miscalculated pre-Wyeth, under the doctrine of equitable tolling.

In brief, the doctrine of equitable tolling preserves a plaintiff's claims when strict application of a statute of limitations would be inequitable. (See *Serdarevic v. Advanced Medical Optics Inc.*, [532 F.3d 1352, 1363](#) (Fed. Cir. 2008)). More specifically, if equitable tolling is found to apply, a statute of limitations will not bar a plaintiff's cause of action so long as the plaintiff acted with due diligence. The doctrine of equitable tolling is generally reserved only for extreme circumstances.

One of the patentees, The General Hospital Corporation, filed its complaint on January 16, 2009 arguing that the *Wyeth* decision constituted a change in the law sufficient to invoke the doctrine of equitable tolling to permit the filing of its complaint after the expiration of the 180 day period. In a similar case filed on January 29, 2010, Idera Pharmaceuticals also argued that the court should apply the doctrine of equitable tolling on the premise that Idera's cause of action did not arise until the *Wyeth* case was decided.

Because plaintiffs must demonstrate not only that they had acted with due diligence but also that the circumstances are "rare and exceptional," the likelihood of success for an argument relying on the doctrine of equitable tolling will likely depend on several factors. Specifically, it is possible that the court will not consider patentees to have acted with due diligence if they did not at least pursue all of their opportunities for requesting reconsideration and filing for appeal under [35 U.S.C. 154](#)(b)(3) and (b)(4).

Conclusion

Although several questions still remain as to just how many patentees will recover additional patent term adjustment following *Wyeth*, it is almost assuredly certain that future patentees will be entitled to a greater patent term based on the Federal Circuit's interpretation of the statutory language in [35 U.S.C. 154](#)(b). Further, even though the PTO has promised that it will reconfigure its software to correctly calculate PTA post-*Wyeth*, patentees should be encouraged to consult with their respective patent counsel to con-

TOTAL SOLUTIONS

Legal Academic Risk & Information Analytics Corporate & Professional Government



LexisNexis® Emerging Issues Analysis

*Brian S. Sun and Laurie A. Axford on***Wyeth v. Kappos and the ABCs of Patent Term Adjustment**

firm that they have been awarded the correct amount of PTA. Lastly, for patentees whose patents have already exceeded the 180 day statutory window to file a civil action as set forth under [35 U.S.C. 154\(b\)\(4\)](#), it is very likely that the Federal Circuit will soon weigh in on whether the *Wyeth* PTA calculation can be applied retroactively.

[Click here for more Emerging Issues Analyses related to this Area of Law.](#)

About the Authors. Brian S. Sun is an Associate Patent Attorney in the Chemical, Pharmaceutical and Biotechnology Department of The Nath Law Group. Mr. Sun's practice areas include the preparation and prosecution of patent applications in the United States, conducting due diligence analyses and providing opinion and litigation support.

Laurie A. Axford is a Partner in the Chemical, Pharmaceutical and Biotechnology Department of The Nath Law Group. She is resident in the San Diego area office. Ms. Axford's practice focuses on complex IP portfolio management and strategies. She is experienced in the preparation, prosecution, and acquisition of U.S. and foreign patents; the preparation of patentability, freedom to operate, non-infringement, and validity opinions; and all aspects of client counseling.

Ms. Axford's areas of expertise involve inventions relating to biotechnology, nanotechnology, biochemistry, polymers, textiles, small molecules, assay devices, and therapeutic drug delivery systems. She is highly experienced in the prosecution and management of IP portfolios for a vast array of domestic and global clients – corporations, universities, research institutions, small companies, start-ups and individual inventors.

Emerging Issues Analysis is the title of this LexisNexis® publication. All information provided in this publication is provided for educational purposes. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.

TOTAL SOLUTIONS

[Legal](#) [Academic](#) [Risk & Information Analytics](#) [Corporate & Professional](#) [Government](#)

LexisNexis, Lexis and the Knowledge Burst logo are registered trademarks of Reed Elsevier Properties Inc., used under license. Matthew Bender is a registered trademark of Matthew Bender Properties Inc.