



# Does Patent Term Adjustment Need Adjustment?

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Does Patent Term Adjustment Need Adjustment?

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## Abstract

This paper examines the patent term adjustment (PTA) system enacted in the American Inventors Protection Act of 1999 and its implementation by the U.S. Patent and Trademark Office (PTO). First, the mechanics of the PTA statute are described. Next, the provision governing the manner in which overlapping periods of delay are treated is considered in connection with the recent D.C. District Court decision in Wyeth v. Dudas, which rejected the longstanding PTO interpretation of this provision. In addition, the disparate treatment in the PTA statute of delay caused by the applicant and delay caused by the PTO is examined. With this preliminary analysis in hand, this paper outlines the effects of three proposals to modify the present PTA system: 1) The position adopted by the plaintiffs in the Wyeth litigation; 2) a proposal by the PTO to eliminate certain types of PTO delay from the PTA calculation; and 3) a proposal by the author to address several inconsistencies in the present statute. To shed further light on these three proposals, empirical data from recently issued patents are considered.

## 1. Introduction

U.S. patents issuing today are generally entitled to a patent term of 20 years from the earliest effective U.S. filing date.<sup>1</sup> This duration reflects a tradeoff between the desire to incentivize and reward invention on the one hand, and the need to make successful technologies available to the public on the other.<sup>2</sup>

While some industries change rapidly and are therefore relatively insensitive to patent term, other industries can be highly sensitive to patent expiration dates. For example, in the biotechnology and pharmaceutical industries, patent applicants often spend years conducting clinical trials, obtaining approval from the Food and Drug Administration (FDA), and preparing to market the approved drug or other product. This lengthy process can cost upward of \$1 billion for a single drug approval,<sup>3</sup> making post-issuance patent term a critical factor in recouping costs. In addition, patent applications that feature complex subject matter, or that are assigned to art units within the U.S. Patent and Trademark Office (PTO) with significant backlogs, frequently experience administrative delays during prosecution, pushing back the date of issuance and thereby shrinking enforceable patent term within the 20-year time frame.

In view of these concerns, two principal mechanisms<sup>4</sup> have been made available to patentees to extend patent term, under certain circumstances, beyond the 20-year date. The Drug

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<sup>1</sup> 35 U.S.C. § 154(a)(2). The 20-year patent term was adopted by the U.S. when it passed the Uruguay Round Agreements Act (URAA) in 1994 in order to harmonize its patent law with international treaty obligations. Pub. L. No. 103-465, §532, 108 Stat. 4983 (1994). Prior to the URAA, patent term was 17 years from the date of issue. Under the URAA, patents in force on June 8, 1995, or patents that issued from applications filed prior to June 8, 1995, have a term that is the greater of 20 years from filing or 17 years from issue. 35 U.S.C. § 154(c)(1).

<sup>2</sup> In general terms, this tradeoff is rooted in Art. I, § 8, cl. 8 of the U.S. Constitution, which gives Congress the power “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries” (emphasis added).

<sup>3</sup> See, e.g., Christopher P. Adams & Van V. Brantner, Spending on New Drug Development, 18 Health Economics (Epub ahead of print, Feb. 26, 2009), which estimates that bringing a new drug to market can take 6 to 12 years and cost \$1.2 billion.

<sup>4</sup> An additional mechanism, rarely utilized, is private legislation. The PTO lists eight patents whose terms have been extended in this manner at <http://www.uspto.gov/web/offices/pac/dapp/opla/term/law.html>.

Price Competition and Patent Term Restoration Act of 1984,<sup>5</sup> also known as the “Hatch-Waxman Act,” addresses regulatory delay at the FDA by allowing applicants to restore half of the period between the investigational new drug (IND) application and the filing of a new drug application (NDA), and the entire period between NDA filing and NDA approval,<sup>6</sup> less any period in which the patentee did not exercise due diligence.<sup>7</sup> The maximum Hatch-Waxman extension is five years,<sup>8</sup> and the total patent term following FDA approval may not exceed 14 years.<sup>9</sup> Of course, Hatch-Waxman extension is only available to the subset of patentees who obtain FDA approval for a patented invention.

Of much wider applicability is patent term adjustment (PTA), which is designed to offset PTO delay during patent prosecution. The current form of PTA was enacted in the American Inventors Protection Act of 1999<sup>10</sup> (AIPA) (and amended by the Intellectual Property and High Technology Technical Amendments Act of 2002<sup>11</sup>).<sup>12</sup> In general terms, the patent expiration date is extended one day for each day of PTO delay, and shortened one day for each day of applicant delay,<sup>13</sup> based on a set of rules prescribed in the governing statute<sup>14</sup> and in PTO regulations.<sup>15</sup> The standardized nature of the PTA determination allows it to be carried out by a

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<sup>5</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>6</sup> 35 U.S.C. § 156(c)(2).

<sup>7</sup> 35 U.S.C. § 156(c)(1).

<sup>8</sup> 35 U.S.C. § 156(g)(6)(A).

<sup>9</sup> 35 U.S.C. § 156(c)(3).

<sup>10</sup> Pub. L. No. 106-113, 113 Stat. 1501A-557 (1999).

<sup>11</sup> Pub. L. No. 107-273, 116 Stat. 1901 (2002).

<sup>12</sup> A simplified form of patent term extension was enacted in the URAA and is still applicable to applications filed between June 8, 1995 and May 28, 2000. See 37 C.F.R. § 1.701 and Manual of Patent Examining Procedure (M.P.E.P.) § 2720.

<sup>13</sup> PTA can never be less than zero; that is, the minimum patent term, assuming no terminal disclaimer, is 20 years from the earliest effective filing date.

<sup>14</sup> 35 U.S.C. § 154(b).

<sup>15</sup> 37 C.F.R. §§ 1.702-1.705.

computer algorithm based on the PTO's Patent Application Locating and Monitoring (PALM) system records for that application.<sup>16</sup>

As the backlog of applications at the PTO grows, an increasing number of patent applicants are experiencing significant delays during prosecution, resulting in additional patent term. Indeed, a recent analysis estimates that 72% of recently issued patents receive some PTA.<sup>17</sup>

Further underscoring the growing recognition of the importance of PTA, Wyeth and Elan Pharma International Ltd. (collectively "Wyeth") recently prevailed in a lawsuit against the PTO<sup>18</sup> in which they asserted that the PTO had misinterpreted the PTA statute and had denied them the full extent of patent term that they deserved under the statute. Wyeth's victory in district court has spawned numerous similar lawsuits by other companies or institutions in the pharmaceutical industry.<sup>19</sup> It is no surprise that this effort to increase PTA by challenging the PTO's interpretation of the statute has emerged from the pharmaceutical industry, in which each additional day of patent term could mean millions of dollars of revenue for the patentee.<sup>20</sup>

This paper examines the PTA statute and its implementation by the PTO. After describing the mechanics of the PTA calculation and the legislative history behind the statute's enactment, a number of alternatives to the current system are considered, including the

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<sup>16</sup> M.P.E.P. § 2733. The PALM system is an electronic database that tracks the prosecution histories of patent applications.

<sup>17</sup> Dennis Crouch, Extending the Patent Term: Most Patents Are Extended Due to PTO Delay (2008), <http://www.patentlyo.com/patent/2008/03/extending-the-p.html>.

<sup>18</sup> Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008). The PTO has appealed the case, and it is currently pending before the U.S. Court of Appeals for the Federal Circuit.

<sup>19</sup> To date, at least the following companies or institutions, aside from Wyeth and Elan, have filed similar suits in D.C. District Court: Alexion Pharmaceuticals, Inc.; Bayer Bioscience GmbH; Biogen Idec Inc.; Eurand, Inc.; General Hospital Corporation; Ironwood Pharmaceuticals, Inc.; Max-Planck-Gesellschaft zur Forderung der Wissenschaften eV; Medarex, Inc.; Molecular Insight Pharmaceuticals, Inc.; Napo Pharmaceuticals, Inc.; Purac Biochem B.V.; Solvay Pharmaceuticals GmbH; and Syntonix Pharmaceuticals. For comment, see Donald Zuhn, More § 154(b)(4)(A) Actions Filed against Director (2009), <http://www.patentdocs.org/2009/02/more-154b4a-actions-filed-against-director.html>. Notably, all patents at issue are directed to pharmaceutical subject matter.

<sup>20</sup> See, e.g., John A. Pearce II, How Companies can Preserve Market Dominance after Patents Expire, 39 Long Range Planning 71, 73 (2006).

interpretation of the current rules proposed by Wyeth; a proposal by the PTO to simplify the PTA calculation; and a proposal of the author for correcting the current unequal treatment of the PTO and the applicant. Each proposal is examined from a theoretical point of view as well as in the context of empirical data obtained from recently issued patents.

## 2. Description and purpose of PTA

### 2.1 Types of delay

PTA is governed by 35 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702-1.705. The starting point for the calculation is the ordinary 20-year term, which is measured from the earliest effective U.S. filing date.<sup>21</sup> The total PTA is then calculated and added to the initial 20-year expiration date to obtain an adjusted expiration date.

The statute provides day-for-day extension of the patent term for each of three types of PTO delay, which will be referred to as “A delay,” “B delay,” and “C delay” after the corresponding subsections of the statute.<sup>22</sup> Applicant delay is then subtracted from PTO delay to determine the total PTA. Each type of delay is described in further detail below.

In the first type of delay, “A delay,” specific deadlines are set for various PTO actions: the first Office Action must be mailed within 14 months from filing, and subsequently the PTO must reply within four months to various actions taken by the applicant, the Board of Patent Appeals and Interferences, or a federal court.<sup>23</sup> Any delay in meeting these deadlines is added together day-for-day to compute the A delay.

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<sup>21</sup> The earliest effective filing date is the filing date of the earliest non-provisional U.S. filing or Patent Cooperation Treaty filing to which the application claims priority. Note also that no PTA is available if the adjustment would extend the patent term past the date of a terminal disclaimer. 35 U.S.C. §§ 154(a)(2) and 154(b)(1)(B).

<sup>22</sup> The corresponding sections of the statute are 35 U.S.C. §§ 154(b)(1)(A), 154(b)(1)(B), and 154(b)(1)(C), respectively.

<sup>23</sup> Specifically, the PTO must respond within four months to an applicant reply or appeal; it must respond within four months to an appeal decision of the Board of Patent Appeals and Interferences or of a federal court; and it must

“B delay” measures delay beyond three years from the filing date or date of completion of U.S. national stage filing requirements. This delay partially compensates for the loss in patent term, in prolonged cases, that would otherwise result from the shift from a 17-years-from-issue system to the current 20-years-from-filing system. Under the previous system, no matter how long prosecution took, the resulting enforceable patent term was fixed at 17 years; under the present system, the patent term for a patent issuing more than three years after the earliest effective filing date will still be 17 years provided that there is no offsetting applicant delay, because the period between the three-year mark and the issue date is counted as B delay and added to the original expiration date.<sup>24</sup> However, it should be noted that if the applicant files a Request for Continued Examination (“RCE”), no further B delay is available from the date of filing of the RCE.<sup>25</sup> Thus, in practice, many patents issuing more than three years from filing may not receive a full 17 additional years of patent term.

“C delay” measures delay due to interferences, secrecy orders, and appeals of adverse determinations of patentability to the Board of Patent Appeals and Interferences. This period compensates day-for-day for less-frequent PTO proceedings that either the PTO initiated on its own or that the applicant requested out of necessity, such as an appeal to reverse examiner error.<sup>26</sup>

Applicant delay is incurred by failure on the part of applicants to engage in “reasonable efforts to conclude processing or examination of applications.”<sup>27</sup> For example, if the applicant takes more than three months to respond to any Office Action, the period in excess of three

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issue a patent within four months from payment of the issue fee (assuming all other PTO requirements have been met). This is sometimes called the “14-4-4-4 Rule.”

<sup>24</sup> Patent terms longer than 17 years are also possible, even for patents taking longer than three years to issue, if A or C delay exceed B delay. This will be discussed in more detail below.

<sup>25</sup> 35 U.S.C. § 154(b)(1)(B)(i).

<sup>26</sup> Of course, the appeal period only counts as C delay if the Board reverses the examiner’s adverse determination of patentability. 35 U.S.C. § 154(b)(1)(C)(iii).

<sup>27</sup> 35 U.S.C. § 154(b)(2)(C)(i).



months is counted as applicant delay.<sup>28</sup> In addition, the statute specifies that the PTO will prescribe regulations establishing circumstances that constitute failure to engage in reasonable efforts to conclude processing or examination;<sup>29</sup> for example, the PTO specifies numerous such circumstances in 37 C.F.R. § 1.704(c) and M.P.E.P. § 2732. As noted above, applicant delay is subtracted from total PTO delay to determine the total PTA, which may not be negative.

## 2.2 Overlap provision

To address the problem of overlapping periods of PTO delay, Congress provided that, “To the extent that periods of [A delay, B delay, and C delay] 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.”<sup>30</sup> As an example, if the PTO takes more than four months to issue a new Office Action following a paper filed by the applicant, and this occurs more than three years from the date of filing, the delay would count as both A delay and B delay. Under the overlap provision of § 154(b)(2)(A), such delay is only counted once, not twice.

The overlap provision gives rise to an interpretive question: What is meant by “the actual number of days the issuance of the patent was delayed”? The simplest interpretation is that the statute is referring to the type of double-counting illustrated above: If particular calendar days count, for example, as both A delay and B delay, then they are only to be counted once, not twice. This interpretation is referred to below as the “Wyeth interpretation” in view of the plaintiff’s argument in Wyeth.<sup>31</sup>

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<sup>28</sup> 35 U.S.C. § 154(b)(2)(C)(ii).

<sup>29</sup> 35 U.S.C. § 154(b)(2)(C)(iii).

<sup>30</sup> 35 U.S.C. § 154(b)(2)(A).

<sup>31</sup> Wyeth at 140.

However, the PTO has adopted a different and more expansive interpretation of the overlap provision, in particular as it relates to B delay. In an interpretive statement published in the Federal Register, the PTO stated (emphasis added): “[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154 (b)(1)(B) in determining whether periods of delay ‘overlap’ under 35 U.S.C. 154(b)(2)(A).”<sup>32</sup> This interpretation is referred to below as the “standard interpretation.” A consequence of the standard interpretation is that the applicant receives the greater of A delay and B delay, but not both delays.

The Wyeth court rejected the standard interpretation in its recent decision, stating (emphasis added): “The only way that periods of time can ‘overlap’ is if they occur on the same day. If an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day...The problem with the PTO’s construction is that it considers the application delayed under § 154(b)(1)(B) during the period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies ‘if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.’ ‘B delay’ begins when the PTO has failed to issue a patent within three years, not before.”<sup>33</sup>

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<sup>32</sup> Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004).

<sup>33</sup> Wyeth at 141-142.

If Wyeth is affirmed on appeal,<sup>34</sup> the result for many applicants will be a “windfall” of patent term. In particular, A delay in the first three years will be added back into the overall PTA calculation, to the extent that it was eliminated under the standard interpretation of the overlap provision.<sup>35</sup> In cases having significant periods of both A delay and B delay, the gain will be substantial. In certain sectors such as the pharmaceutical industry, the additional patent term could translate into hundreds of millions of dollars of additional revenue for a single patentee.<sup>36</sup> Thus, at least for certain patentees, a great deal is at stake in determining the correct interpretation of § 154(b)(2)(A).

### 3. Clues from the legislative history

The PTA statute was enacted as part of the 1999 AIPA. According to the House of Representatives Conference Report,<sup>37</sup> the statute “amends the provisions in the Patent Act that

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<sup>34</sup> A key question on appeal will likely be whether the district court’s Chevron deference analysis is correct. Specifically, the district court ruled that “the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules,” *Id.* at 141. The court relied in part on Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), which stated: “Because Congress has not vested the Commissioner [of Patents] with any general substantive rulemaking power, the ‘Final Determination’ at issue in this case cannot possibly have the ‘force and effect of law.’” However, in a recent ruling, the Federal Circuit held that “the USPTO’s interpretations of statutes that pertain to the USPTO’s delegated authority are entitled to Chevron deference.” Tafas v. Doll, 2009 U.S. App. LEXIS 5806, \*15 (Fed. Cir. Mar. 20, 2009). The Tafas ruling may diminish the likelihood that the Wyeth district court will be affirmed with respect to its Chevron analysis, although the cases are arguably distinguishable: the PTO’s position in Wyeth is based on an interpretive statement rather than a rule enacted after a notice-and-comment period, as in Tafas. Notably, the Wyeth district court ultimately relies on “step 1” of the Chevron two-step analysis, stating that “Chevron would not save the PTO’s interpretation...because it cannot be reconciled with the plain text of the statute.” Wyeth at 141. If the Federal Circuit agrees with the district court’s Chevron step 1 analysis, then it will be unnecessary to determine the requisite degree of deference to the PTO in evaluating its interpretation of § 154(b)(2)(A).

<sup>35</sup> Currently, a patentee has two months from the issue date to request reconsideration of PTA by the PTO, 37 C.F.R. § 1.705(d), and 180 days from the issue date to appeal the PTO’s PTA calculation to the D.C. district court. 35 U.S.C. § 154(b)(4)(A). It is unclear whether, if Wyeth is affirmed, the PTA for patents issued before these deadlines will be eligible for retroactive modification.

<sup>36</sup> As a rough estimate, using Pearce’s average figure of \$2.6 million of revenue per day for best-selling drugs at the end of their patent term, *supra* note 20, and assuming an average of 100 days of PTA increase under Wyeth, the result would be an additional \$260 million in revenue for a single drug. A one-year increase in PTA would result in nearly \$1 billion in additional revenue. See discussion below for empirical data on the average increase in PTA under Wyeth (and other alternative proposals).

<sup>37</sup> The Conference Report provides a section-by-section analysis of the relevant provisions of the AIPA and is thus considered to be the most useful source of legislative history for present purposes. For further details on the politics

compensate patent applicants for certain reductions in patent term that are not the fault of the applicant.”<sup>38</sup> The Conference Report goes on to note the deficiencies of the patent bills pending in the previous Congress, observing that a 10-year cap on secrecy orders, interferences, and successful appeals is too short in some cases, and further that no adjustments had been provided for PTO delays that were beyond the control of the applicant. The Conference Report then states (emphasis added): “Accordingly, subtitle D removes the 10–year caps from the existing provisions, adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, includes a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, 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.”<sup>39</sup>

As this excerpt suggests, the general tenor of the Conference Report seems to be sympathetic to the applicant, who had been, until the enactment of the new statute, unduly penalized for PTO delays beyond his or her control. Indeed, Congress appears willing to give a substantial new benefit to the applicant, noting that most applicants will now receive considerably more than 17 years of patent term. It is not entirely clear, however, whether Congress’s underlying assumption is that most applications will grant before the three-year mark, thereby automatically receiving more than 17 years of patent term by virtue of the 20-year total from the time of filing, or whether Congress believes that most applicants having patents granted after the three-year mark will receive considerably more than 17 years. This point is

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behind the enactment of the AIPA, see Edward R. Ergenzinger Jr., The American Inventor’s Protection Act: A Legislative History, 7 Wake Forest Intell. Prop. L.J. 142 (2006).

<sup>38</sup> H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.).

<sup>39</sup> Id.

important: if the second interpretation is the correct one, then the legislative history may be suggesting that, in most cases having B delay, there will also be A or C delay, and that this delay is to be added to the B delay to result in a term greater than 17 years. Under this assumption, the Wyeth interpretation becomes more plausible. However, it is difficult to determine which interpretation of the legislative history is correct.

Bolstering the view that Congress intended to err on the side of the applicant is the inclusion of the words “for good measure” in the above excerpt from the Conference Report. This phrase suggests that, by adding the three-year provision to the PTA statute, Congress was providing an additional layer of protection for the applicant, above and beyond the A and C delay provisions. Again, this language is suggestive but is insufficient to determine unambiguous Congressional intent.

Intriguingly, the Conference Report includes a calculation of PTA that would produce different results depending on whether the standard interpretation or the Wyeth interpretation were followed. In considering U.S. national stage applications filed under the Patent Cooperation Treaty (PCT),<sup>40</sup> the Conference Report states (emphasis added): “[D]ay-for-day restoration of term is granted if the USPTO has not issued a patent within three years after ‘the actual date of the application in the United States.’ This language was intentionally selected to exclude the filing date of an application under the Patent Cooperation Treaty (PCT). Otherwise, an applicant could obtain up to a 30-month extension of a U.S. patent merely by filing under

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<sup>40</sup> The PCT is a multilateral treaty among more than 125 countries that allows for the filing of a single international application, which may later be filed in the national patent offices of any of the signatory countries. A national stage application filed under the PCT may be filed up to 30 months from the priority date, which could correspond to the date of filing of the PCT application. “Protecting Your Inventions Abroad,” World Intellectual Property Organization, April 2006.

PCT, rather than directly in the USPTO, gaining an unfair advantage in contrast to strictly domestic applicants.”<sup>41</sup>

The stated period of extension – 30 months – provides an opportunity to test which interpretation is being followed. For purposes of simplicity, assume that the U.S. national stage application is filed exactly 30 months after the PCT application is filed; prosecution of the U.S. application takes exactly three years; and issuance of the first Office Action occurs exactly 14 months from filing in the U.S.<sup>42</sup>

Under the standard interpretation, the calculation is simple: An applicant who was able to use the PCT filing date as the base date for PTA purposes would experience a 30-month “delay” in prosecution, resulting in issuance of the patent 30 months past the three-year mark. The B delay would thus be 30 months. The A delay would also be 30 months, since the first Office Action would issue 44 months (30 months + 14 months) after the filing date of the PCT. Since the standard interpretation of “delay” selects the greater of A delay and B delay, but not both, the total PTO delay would be 30 months – as indicated in the Conference Report.

In contrast, under the Wyeth interpretation, the total PTO delay would be 52 months. This is because the sum of A delay and B delay is 60 months, and only 8 of these months overlap directly (since the first Office Action issues 44 months after the date of filing of the PCT, which is 8 months past the three-year mark).

This result would seem to be dispositive: Congress intended the standard interpretation, not the Wyeth interpretation.<sup>43</sup> Nevertheless, as is often the case, it is difficult to be certain of

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<sup>41</sup> H.R. Rep. No. 106-464, at 126 (1999) (Conf. Rep.).

<sup>42</sup> These assumptions correspond to the statutory benchmark time periods in each case.

<sup>43</sup> Notably, the PTO has not raised this argument either before the Wyeth district court or in its appellate brief to the Federal Circuit.

Congressional intent,<sup>44</sup> given that this Congressional “calculation” is likely not intended as an illustration of the overlap provision in action, but rather simply illustrates the necessity of keying the language of the statute to the U.S. filing date. Indeed, it may be that Congress never carefully considered the issue of what constitutes “overlap” at all; otherwise, perhaps it would have recognized the potential ambiguity in the statutory language and provided a number of clarifying examples.

In short, the legislative history generally seems sympathetic to the applicant, and even seems willing to err in favor of the applicant over the PTO; but the sole concrete, if perhaps inadvertent, calculation provided by Congress is consistent with the PTO, not the Wyeth, interpretation.

#### 4. Flaws with the current PTA statute

Assuming, for the moment, that the PTO has correctly interpreted the overlap provision, it is worth asking a broader question: Does the overall statutory scheme make sense? That is, does it satisfy principles of consistency and fairness? While many details of the statute and its implementation by the PTO could be examined,<sup>45</sup> this paper focuses on two in particular: The overlap provision for PTO delay, and the offsetting provision for applicant delay.

The standard interpretation of the overlap provision is consistent with the assumption that earlier delay in prosecution always causes later delay. For example, consider an application filed

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<sup>44</sup> For commentary on the difficulties of analyzing legislative intent, see, e.g., Bank One Chicago v. Midwest Bank & Trust Co., 516 U.S. 264, 279 (1996) (Scalia J., concurring) (“The law *is* what the law *says*, and we should content ourselves with reading it rather than psychoanalyzing those who enacted it.”)

<sup>45</sup> As one example, fairness concerns have been raised over the PTO’s regulations regarding what constitutes applicant delay. See, e.g., Letter from Michael K. Kirk, Executive Director, American Intellectual Property Law Association, to Q. Todd Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (June 1, 2000). See also Letter from Chuck Ludlam, Vice President, Government Relations, BIO, to The Honorable Nick Godici, Commissioner for Patents (May 18, 2000). These and numerous related comments are posted at <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/pta>.

on January 1, 2009 that, absent PTO delay, would have required three years of prosecution time, issuing on January 1, 2012. Now assume that the examiner takes an unduly long time issuing a particular Office Action early in prosecution, resulting in a six-month delay entirely before the three-year mark. As a result, under the assumption that earlier delay causes later delay, the patent issues on July 1, 2012. In this case, the A delay is six months, and the B delay is also six months. The sum of the two periods of delay is 12 months, but there has only been a six-month, not a 12-month, delay in prosecution. By starting the “overlap” period for B delay as of the filing date, not just the three-year mark, the PTO factors in its assumption that A delay effectively causes B delay, and that simply adding these periods of delay together would amount to double-counting.

Of course, it is possible to take a contrary view, namely, that PTO A delay (in the first three years) should not be viewed as the cause of PTO B delay. Under this theory, once PTO A delay occurs, the PTO could make up for lost time by speeding up subsequent prosecution. However, the PTO freely acknowledges that examiners are not expected to make any such efforts, stating: “Patent examiner performance plans...do not hold examiners responsible for the patent term adjustment that may result in their applications. Thus, an examiner should not be overly mindful of the patent term adjustment implications of their actions.”<sup>46</sup> Furthermore, changing the statute to explicitly reflect the Wyeth interpretation, while surely resulting in longer patent terms, would not necessarily result in an examiner incentive system that rewarded reduced PTO delay. As for applicant delay, there is even less justification for expecting the PTO to offset it by speeding up subsequent prosecution, and thus it is even more sensible to assume that applicant delay should be considered to cause an equal amount of PTO B delay. Thus, a baseline

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<sup>46</sup> Changes To Implement Patent Term Adjustment Under Twenty-Year Patent Term, Part II, 65 Fed. Reg. 56,366, 56,385 (Sep. 18, 2000).



assumption of a causal relationship between PTO A and B delay, or between applicant delay and PTO B delay, seems reasonable, and in any event appears to reflect the reality of examination at the PTO.<sup>47</sup>

Turning to the offsetting provision for applicant delay, as a preliminary matter, it is helpful to consider how patent term changed with the enactment of the Uruguay Round Agreements Act (URAA) in 1994 (see Footnote 1). As discussed above, prior to the URAA, patent term was 17 years from the date of issue, regardless of the duration of pendency. Following the URAA, patent term was 20 years from the earliest effective filing date.<sup>48</sup> One of the key accomplishments of this change, aside from international harmonization, was to largely eliminate the problem of so-called “submarine patents.”<sup>49</sup> For example, under the old system, an applicant could file a series of continuations, and then a patent could “surface” without warning, years or even decades later, with issued claims covering a competitor’s product and a full 17 years to enforce the claims. In contrast, following the URAA, a patent would expire 20 years from filing, regardless of how long it took to issue.<sup>50</sup> Thus, from a patent term perspective, the fairness problem associated with submarine patents was largely solved: an applicant was still entitled to file a series of continuations, but the patent term clock would continue to run.

Put another way, under the post-URAA regime, applicant delay penalized the applicant in a way that did not previously occur: Whereas the old patent term was unaffected by applicant delay, the new patent term would decrease, day-for-day, as applicant delay increased. Thus, an

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<sup>47</sup> Of course, this is a separate issue from the intent of Congress, or from the plain meaning of the statute.

<sup>48</sup> As noted in Footnote 1, there was a transitional provision in the URAA: patents in force on June 8, 1995, or patents that issued from applications filed prior to June 8, 1995, have a term that is the greater of twenty years from filing or seventeen years from issue. 35 U.S.C. § 154(c)(1).

<sup>49</sup> See, e.g., Steve Blount, The Use of Delaying Tactics to Obtain Submarine Patents and Amend Around A Patent that A Competitor has Designed Around, 81 J. Pat. & Trademark Off. Soc’y 11 (1999).

<sup>50</sup> In addition, the AIPA required that applications be published 18 months from their earliest filing date, largely eliminating the surprise factor associated with submarine patents. 35 U.S.C. § 122(b)(1)(A).

incentive to expedite prosecution, and a penalty for not doing so, were effectively provided by the URAA change in patent term.

As discussed above, the legislative history of the AIPA suggests that the goal of Congress was to compensate applicants for delays caused by the PTO, not to increase the effective penalty for delay instituted by the URAA. Yet the AIPA approach to PTA requires that applicant delay be subtracted from PTO delay, which amounts to penalizing the applicant twice. A further example will illustrate this.

Assume an application is filed on January 1, 2009, and claims no earlier priority. Assume further that prosecution takes three years, and the resulting patent issues on January 1, 2012. In the absence of PTA, the patent would expire on January 1, 2029, resulting in 17 years of patent term. Next, assume that there is a PTO A delay of one month. This causes the patent to issue on February 1, 2012 and to expire on February 1, 2029, resulting in an unchanged 17 years of patent term. This is a fair outcome: Because the delay was entirely due to the PTO, the patent term should be unaffected.

Now assume that there is also an applicant delay of one month. This causes the patent to issue on March 1, 2012; furthermore, the PTA calculation offsets the PTO delay with the applicant delay, resulting in a PTA of zero, an expiration date of January 1, 2029, and a total patent term of 16 years, 10 months. By delaying one month, the applicant has lost two months of patent term. This is a surprising result, particularly in view of the generally favorable attitude of Congress toward patentees in the AIPA.<sup>51</sup>

One of the leading proponents of the notion of offsetting PTO and applicant delays, the Biotechnology Industry Organization (BIO), analogized the offsetting calculation to a chess clock. As a BIO official testified in 1999 before the House Subcommittee on Courts and

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<sup>51</sup> Consider the Act's very name: The "American Inventors Protection Act."

Intellectual Property, which was considering the AIPA legislation: “Chess clocks have two clocks, one for each player...The clock which is running is the clock for the player who must make the next move. When he or she makes the move, he or she taps the mechanism to stop his or her own clock and start the other player’s clock. The importance of this analogy is simple – It is only fair for the PTO to be under some pressure to complete action on an application. It should not be only the applicant who feels the pressure.”<sup>52</sup>

However, there is a marked flaw in this analogy: Following the URAA, the clock is always running against the applicant.<sup>53</sup> That is, every day that passes in which the application is not issued as a patent decreases the remaining patent term available to the applicant. Therefore, applicant delay penalizes the applicant even without an offsetting provision in the PTA calculation. Absent the PTA statute, no such clock is running against the PTO. The offsetting

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<sup>52</sup> Testimony Regarding the Patent Term for Biotechnology Inventions, Testimony of Charles Ludlam, Vice President for Government Relations, Biotechnology Industry Organization (BIO) before the House Subcommittee on Courts and Intellectual Property Regarding the Patent Term for Biotechnology Inventions: Protecting Diligent Patent Applications (March 25, 1999).

<sup>53</sup> One could argue that, at least in the pharmaceutical context, the chess-clock model of PTA properly places its focus on the expiration date of the patent rather than the total post-issuance term, given that drug patents often realize their real value years after issuance. For example, if a drug takes eight years to be approved by the FDA, and the associated patent issues only five years after filing, then there are three years during which the patent is effectively worthless (since no product is on the market yet, and there are no generic competitors to sue). However, this argument misses the fact that, under current law, patent term is extended both for FDA delay and PTO delay. 35 U.S.C. § 156(a). Thus, in the above example, the patent may be eligible for patent term extension of up to the full three years of FDA delay after issuance, and it may be eligible for PTA of a further two years for B delay. Given this additive effect, delayed issuance of a drug patent, even well before FDA approval, may be of great economic significance to the patentee. Thus, it is sensible to consider questions of consistency and fairness in the PTA statute with respect to the entire period of enforceable patent term.

provision proposed by BIO<sup>54</sup> and adopted by Congress provides such a clock to penalize PTO delay, but also doubles the penalty for applicant delay in some circumstances.<sup>55</sup>

To provide a better picture of the PTA provisions of the AIPA under the standard interpretation, Table 1 presents a summary of the effects of each type of delay:

Table 1<sup>56</sup>

Type of Delay	< 3-year pendency		> 3-year pendency		
	App < PTO <sub>Total</sub>	App > PTO <sub>Total</sub>	App < PTO <sub>Total</sub>		App > PTO <sub>Total</sub>
			PTO <sub>A</sub> > PTO <sub>B</sub>	PTO <sub>B</sub> > PTO <sub>A</sub>	
App	← = <b>-2</b> →	— = <b>-1</b> →	← = <b>-2</b> →	— = <b>-1</b> →	— = <b>-1</b> →
PTO <sub>A</sub>	→ = <b>0</b> →	— = <b>-1</b> →	→ = <b>0</b> →	→ = <b>0</b> →	— = <b>-1</b> →
PTO <sub>B</sub>	N/A	N/A	— = <b>-1</b> →	→ = <b>0</b> →	— = <b>-1</b> →
PTO <sub>C</sub>	N/A	N/A	→ = <b>0</b> →	→ = <b>0</b> →	— = <b>-1</b> →

Each cell of Table 1 shows the number of days that total patent term is changed for each day of additional applicant delay, PTO A delay, PTO B delay, or PTO C delay<sup>57</sup> under various

<sup>54</sup> In the words of Mr. Ludlam (emphasis added): “BIO was...intimately involved with the drafting and enactment of the term restoration provisions of the legislation. It is safe to say that no organization had more involvement with the drafting and enactment of these provisions than BIO and the provisions would not have been included in the legislation...but for BIO’s involvement. The whole “chess clock” approach was proposed and drafted by BIO. We were also involved with the drafting of the committee reports and other legislative history regarding these provisions.” Letter from Charles Ludlam, BIO Vice President for Government Relations, to the Commissioner for Patents (May 18, 2000).

<sup>55</sup> The reduction in patent term is not always twice the applicant delay. For example, if the applicant delay exceeds the PTO delay, then the excess applicant delay is ignored in the PTA calculation, and in effect only counts once against the applicant.

<sup>56</sup> Applicant delay is designated “App”; each type of PTO delay is designated with a corresponding subscript; and total PTO delay is designated “PTO<sub>Total</sub>.”

<sup>57</sup> Four main assumptions are made in order to simplify Table 1: 1) Applicant delay is assumed to occur either in the first three years or simultaneous with B delay; 2) A delay is assumed to occur within the first three years; 3) C delay (the rarest type of PTO delay) is assumed to occur after the three-year mark; and 4) no RCE is filed by the applicant. These assumptions are not as limiting as they may appear, as it is straightforward to use Table 1 to understand what would happen under other scenarios. In particular, applicant delay occurring subsequent to the termination of B

circumstances. The bottom arrow in each cell indicates the effect of delay on the issue date: In every case, the issue date is delayed a day, so all cells have bottom arrows pointing to the right. The top arrow, or line, in each cell indicates the effect of delay on the expiration date: A right arrow means one additional day of delay, a left arrow means expiration occurs a day earlier, and a line means no change in expiration date. The table is calculated based on the assumption that a day of any type of delay causes the issue date to be delayed a day. Of course, this is not necessarily true in all circumstances, but it is a reasonable simplifying assumption, and as noted above, it is the basis of current PTO practice.

An examination of Table 1 reveals a number of distortions that are not obviously consistent with the underlying motivations behind the AIPA. For example, in principle, delay caused by the PTO should never reduce patent term;<sup>58</sup> however, as Table 1 shows, when applicant delay exceeds total PTO delay, each additional day of PTO A, B, or C delay results in a one-day reduction in patent term.<sup>59</sup> In addition, as already noted above, applicant delay is doubly penalized under some circumstances but singly penalized under others. Even if the policy choice is made to punish applicants two-fold for applicant delay, it is difficult to see the logic behind doing so only when the applicant has delayed less than the PTO, but not when the applicant has

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delay (e.g., subsequent to the filing of an RCE) would function just like applicant delay for applications pending less than three years. A delay occurring after the three-year mark and simultaneously with B delay may be ignored because of the literal overlap of the A and B periods. Meanwhile, A delay occurring subsequent to the termination of B delay would function much the same as C delay occurring after the three-year mark, since C delay is confined to occurrences which are not counted within B delay. See 35 U.S.C. §§ 154(b)(1)(B) and 154(b)(1)(C). Likewise, C delay in the first three years would function just like A delay during this time period, as it would trigger the overlap provision with B delay under the PTO interpretation. As for an RCE filing, its consequences are conceptually clear: Filing an RCE stops B delay from accumulating further, and thus it would no longer be true that each additional day of applicant delay generates an additional day of B delay. This would result in a double penalty for the applicant under more circumstances than presently indicated in Table 1.

<sup>58</sup> The Conference Report states (emphasis added): “[The statute] adds a new provision to compensate applicants fully for USPTO-caused administrative delays.” H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.).

<sup>59</sup> This is a consequence of the fact that PTA cannot be negative.

delayed more than the PTO.<sup>60</sup>

There is a further inconsistency in the treatment of applicant delay. Consider applications pending more than three years and for which the applicant delay is less than the total PTO delay. If PTO B delay exceeds PTO A delay, then such an applicant is only penalized one day for each day of applicant delay; this is because applicant delay is treated as causing PTO B delay, and the increases in applicant and PTO delay offset one another in the final calculation. However, if PTO A delay exceeds PTO B delay, then each day of applicant delay is doubly penalized, because there is no offsetting increase in total PTO delay under the standard interpretation of the overlap provision. This inconsistency reflects the awkward fit between A delay, which is measured in the context of a specific event in prosecution, and B delay, which is essentially a measure of the duration of prosecution as a whole.

To return to the overall question asked at the beginning of this section, namely, whether the overall statutory scheme satisfies principles of consistency and fairness: With respect to the overlap provision, the PTO's interpretation achieves consistent and fair results if one accepts the existence of a causal relationship between early delay in prosecution and later delay in issuance. A requirement that the PTO redouble its efforts when it has already caused delay early in prosecution, while it would be favorable to applicants, does not reflect the reality of a backlogged PTO that does not track PTA as a basis of examiner evaluation.

On the other hand, with respect to the applicant delay offsetting provision, Table 1 demonstrates its inconsistency in various circumstances, and thus its essential unfairness. A system in which an applicant delay of one additional day always gave rise to a patent term reduction of one day, and in which PTO delay that was not a result of applicant delay always left

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<sup>60</sup> According to the Conference Report, it is “[o]nly those who purposely manipulate the system to delay the issuance of their patents” who should be penalized. Id.

the patent term unchanged, would arguably achieve a more equitable outcome. Such a proposed modification to the current scheme is described further below, in addition to two other modifications that have been proposed by others.

## 5. Three approaches to modify PTA

In this section, three modifications to the current PTA regime are considered: 1. The Wyeth court's view of the current statute, in which A delay in the first three years is not viewed as overlapping with B delay (the "Wyeth proposal"); 2. A PTO proposal for a modified statute in which only B delay counts as PTO delay (the "PTO proposal"); and 3. An approach which offsets only applicant delay that is causally linked to PTO B delay (the "applicant delay proposal").

### 5.1 The Wyeth proposal

The Wyeth proposal differs from the standard approach in its interpretation of the overlap provision of 35 U.S.C. § 154(b)(2)(A). As noted above, the Wyeth court held that B delay begins as of the three-year mark, not before, and thus A delay occurring in the first three years cannot overlap with B delay.<sup>61</sup> This is not based on policy considerations but rather a strict reading of the language of the statute. Indeed, the court readily acknowledges that its holding may be contrary to Congressional intent.<sup>62</sup> Nevertheless, if this is indeed what the current statute means, it is important to understand its ramifications.

Table 2 presents a summary of the effects of each type of delay under this proposal:

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<sup>61</sup> Wyeth at 142.

<sup>62</sup> "The PTO's efforts to prevent windfall extensions may be reasonable – they may even be consistent with Congress's intent – but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency." Id.

Table 2<sup>63</sup>

Type of Delay	< 3-year pendency		> 3-year pendency	
	App < PTO <sub>Total</sub>	App > PTO <sub>Total</sub>	App < PTO <sub>Total</sub>	App > PTO <sub>Total</sub>
App	← = <b>-2</b> →	— = <b>-1</b> →	— = <b>-1</b> →	— = <b>-1</b> →
PTO <sub>A</sub>	→ = <b>0</b> →	— = <b>-1</b> →	→ <sup>2</sup> = <b>+1</b> →	— = <b>-1</b> →
PTO <sub>B</sub>	N/A	N/A	→ = <b>0</b> →	— = <b>-1</b> →
PTO <sub>C</sub>	N/A	N/A	→ = <b>0</b> →	— = <b>-1</b> →

As Table 2 shows, one of the distortions associated with the standard interpretation is gone:

When an application has been pending for over three years and applicant delay is less than total PTO delay, each additional day of applicant delay reduces the PTA by one day, not two (as occurs under the standard interpretation when  $PTO_A > PTO_B$ ). However, a new distortion has been introduced: Under the same conditions identified above, each additional day of A delay increases PTA by one day, benefiting the applicant. This is because the additional day of A delay results in an additional day of B delay, and since A and B delays are added together under the Wyeth interpretation, the date of expiration is pushed back a total of two additional days. This scenario most plainly reveals the incongruity of construing the overlap provision according to the Wyeth interpretation, even if this interpretation may best reflect the literal meaning of the statutory language.

Meanwhile, the Wyeth interpretation leaves undisturbed a number of other distortions seen in Table 1 – for example, the distortions that occur when applicant delay exceeds total PTO

<sup>63</sup> Because A delay and B delay are simply added under the Wyeth proposal, and are not compared as in the standard interpretation, there is no need for separate columns in Table 2 in which  $PTO_A > PTO_B$  and  $PTO_B > PTO_A$ .



delay, or when applicant delay is less than total PTO delay for applications pending less than three years.

What is clear is that applicants would tend to receive more PTA under the Wyeth interpretation than under the standard interpretation. This is achieved by removing at least one PTO-favoring distortion while introducing a new applicant-favoring distortion. On first principles, there is no obvious basis for arguing that the set of distortions reflected in Table 2 is superior to those shown in Table 1. Because the applicant is systematically over-penalized under the standard interpretation, the Wyeth interpretation does have the virtue of shifting the balance in the direction of the applicant, though one cannot tell from Table 2 whether applicants will, in practice, be systematically overcompensated as a result.

## 5.2 The PTO proposal

The PTO has made the following proposal: “The USPTO would limit the grounds for receiving patent term adjustment to the USPTO’s failure to issue the application within three years from the actual filing date...The term of the patent would be adjusted one day for each day after the end of the three-year period until the patent is issued. The period of adjustment under 35 U.S.C. § 154(b) would be reduced by any period of further examination pursuant to 35 U.S.C. § 132(b) (request for continued examination (RCE) filing) and any period of appellate review by the BPAI or by a Federal court, except if the patent was issued under a decision reversing an adverse determination of patentability.”<sup>64</sup> Essentially, the PTO has proposed abolishing PTO A delay, and C delay occurring in the first three years (or after the filing of an RCE), as appropriate

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<sup>64</sup> “Simplification of Patent Term Adjustment,” PTO Action Paper, last modified September 20, 2007; see [http://www.uspto.gov/web/offices/com/strat21/action/lr1ap11\\_12.htm](http://www.uspto.gov/web/offices/com/strat21/action/lr1ap11_12.htm). The PTO made two additional proposals in the same document, which are not discussed further here: either eliminating PTA altogether and allowing for issuance of the claims at the three-year mark, subject to further examination; or simply making determination of PTA a post-grant activity. Of course, all of the PTO’s proposals would require Congressional action.

bases for PTA. Rather, under the PTO’s proposal, only PTO delay that resulted in an issue date more than three years after filing would be an appropriate basis for PTA.

Table 3 presents a summary of the effects of each type of delay under this proposal.

Table 3<sup>65</sup>

Type of Delay	< 3-year pendency	> 3-year pendency	
		App < PTO <sub>Total</sub>	App > PTO <sub>Total</sub>
App	— → = <b>-1</b>	— → = <b>-1</b>	— → = <b>-1</b>
PTO <sub>A</sub>	— → = <b>-1</b>	→ → = <b>0</b>	— → = <b>-1</b>
PTO <sub>B</sub>	N/A	→ → = <b>0</b>	— → = <b>-1</b>

The PTO’s approach has the virtue of simplicity, as the streamlined Table 3 makes evident. This would make calculation of the PTA slightly easier for applicants and the PTO.<sup>66</sup> In addition, some of the inconsistency seen in Table 1 has been eliminated: For example, each additional day of applicant delay always results in one day less of patent term (under the assumptions of Footnote 57).<sup>67</sup> However, the distortion would remain that the applicant would be penalized for PTO delay when applicant delay exceeded PTO delay in an application past the

<sup>65</sup> Table 3 has been simplified even more than Table 2 by removing the column in which applicant delay is less than total PTO delay for less than three-year pendency. Note that the “PTO<sub>A</sub>” row is retained in order to consider the effects of this category of delay, even though it is not directly counted in the PTA calculation under the PTO proposal. However, the “PTO<sub>C</sub>” row is eliminated, as the PTO proposal effectively incorporates C delay into B delay.

<sup>66</sup> It should be noted that most of the complexity of the calculation would likely remain, because of the large number of distinct bases of applicant delay that the PTO has specified, none of which would disappear under the PTO proposal. See 37 C.F.R. § 1.704(c) and M.P.E.P. § 2732. Thus, the PTO’s argument in its Action Paper, *supra* note 64, that its proposal would simplify the PTA calculation, does not have much force.

<sup>67</sup> Note, however, that if the applicant files an RCE, and B delay has already accrued, additional applicant delay will reduce the PTA and result in the double penalty discussed above.

three-year mark. In addition, the distortion for A delay in applications pending less than three years would remain, precisely because the PTO proposal ignores A delay.

Interestingly, one of the rationales the PTO cites is an effort to “remain consistent with Congressional intent to guarantee diligent applicants a seventeen-year term (from grant).”<sup>68</sup> In fact, the PTO proposal would seem to diverge considerably from Congressional intent; as noted above, Congress indicated that “most [applicants] will receive considerably more [than 17 years.]”<sup>69</sup> By including fairly elaborate provisions for counting A delay and C delay in the PTA calculation, the current statute goes well beyond preserving the pre-GATT 17-year term for diligent applicants; it also holds the PTO to specific timetables for each event in prosecution. It is these timetables that the PTO proposes to eliminate.

In effect, the PTO is suggesting that, as long as the applicant receives a patent within three years, no harm has been done. This would even hold true if the PTO took nearly three years before examining a straightforward application and issuing a first-action allowance. However, an applicant may argue that it is unfair to be penalized for internal delays within the PTO, and that if not for these delays, the issued patent would be in force for more than 17 years, until the 20-year expiration date. The structure of the current statute suggests that Congress sided with the applicant in this context, and it provided specific timetables within 35 U.S.C. § 154(b)(1)(A) in order to provide benchmarks that the PTO is expected to meet in all cases.

Thus, while the PTO proposal has some desirable simplifying features, these come at the expense of apparent Congressional intent and would result in a significant decrease in patent term for many applicants.

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<sup>68</sup> PTO Action Paper, *supra* note 64.

<sup>69</sup> H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.).

### 5.3 The applicant delay proposal

To address the fairness and consistency problems with the applicant delay offsetting provision, as discussed above, I propose that only applicant delay that is causally linked to PTO B delay should be used to offset total PTO delay. This change would fit the Congressional intent of “compensat[ing] applicants fully for USPTO-caused administrative delays,”<sup>70</sup> while recognizing that B delay caused by earlier or concurrent applicant delay should not be counted as “USPTO-caused administrative delay.”

The logic of the proposal is as follows. PTO A delay is strictly a function of the time it takes the PTO to complete a specific event in prosecution: To act on the application within 14 months from filing, to respond to an applicant reply or a Board of Patent Appeals and Interferences decision within four months, or to issue a patent within four months of payment of the issue fee. The applicant does not have any role in this purely internal type of PTO delay and therefore should not be penalized for it. Likewise, C delay relating to an interference, a secrecy order, or appellate review favorable to the applicant, also is not the “fault” of the applicant.<sup>71</sup> In contrast, B delay is a measure of the duration of prosecution as a whole; thus, when applicant delay precedes or runs in parallel with B delay, it is logical to hold the applicant accountable and reduce the overall PTA by the amount of applicant delay that is causally linked to the B delay.<sup>72</sup>

Likewise, consistent with the notion developed above that early delay causes later delay, any A delay that is causally linked to B delay – namely, A delay that precedes or runs parallel to B delay – should also be discounted. This feature is consistent with the standard interpretation of the overlap provision.

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<sup>70</sup> H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.).

<sup>71</sup> It is true that an applicant voluntarily initiates an appeal, but if it is successful, it makes considerably more sense to hold the PTO accountable for the delay than it does to penalize the applicant.

<sup>72</sup> That is, any applicant delay preceding or running parallel to B delay should be subtracted from the PTO B delay, to the extent that B delay is present.

Table 4 presents a summary of the effects of each type of delay under this proposal.

Table 4

Type of delay	< 3-year pendency		> 3-year pendency		
	App < PTO <sub>A</sub>	App > PTO <sub>A</sub>	App < PTO <sub>B</sub>		App > PTO <sub>B</sub>
			PTO <sub>A</sub> > (PTO <sub>B</sub> - App)	(PTO <sub>B</sub> - App) > PTO <sub>A</sub>	
App	— → = <b>-1</b>	— → = <b>-1</b>	— → = <b>-1</b>	— → = <b>-1</b>	— → = <b>-1</b>
PTO <sub>A</sub>	→ = <b>0</b> →	→ = <b>0</b> →	→ = <b>0</b> →	→ = <b>0</b> →	→ = <b>0</b> →
PTO <sub>B</sub>	N/A	N/A	— → = <b>-1</b>	→ = <b>0</b> →	— → = <b>-1</b>
PTO <sub>C</sub>	N/A	N/A	→ = <b>0</b> →	→ = <b>0</b> →	→ = <b>0</b> →

As Table 4 shows, the key distortions seen in Tables 1, 2, and 3 are gone. Applicant delay of one additional day now results in the loss of one day of patent term in all cases. An increase in PTO A or C delay no longer penalizes the applicant under any circumstances. An increase in B delay only penalizes the applicant in two cases, as shown in Table 4, and these are based on the principle that the “blame” for the additional B delay is attributable to either PTO A delay or applicant delay. Thus, the applicant delay proposal addresses the inequities associated with the current scheme and arguably produces a considerably fairer system.

## 6. Empirical data

In order to better evaluate each of the three proposed PTA models described above, a cross-section of all utility patents issued in January 2009 was examined (the “general” sample).

In particular, the image file wrappers for 118 patents<sup>73</sup> were individually analyzed to determine the types and amounts of delay present,<sup>74</sup> if any, and to calculate the delay under the standard (PTO) interpretation as well as the three proposals. Of the 118 patents (all of which were filed after the AIPA went into effect), 94, or 80%, had some PTO delay during prosecution. The average delays and PTA calculations, including standard deviations, for these 94 patents are shown in Table 5.

Table 5

Days of delay (st. dev.)				PTA <sup>75</sup> (st. dev.)			
PTO <sub>A</sub>	PTO <sub>A</sub> and PTO <sub>B</sub> overlap	PTO <sub>B</sub> (excluding PTO <sub>A</sub> )	App	Standard interpret- ation	Wyeth proposal	PTO proposal	App delay proposal
403 (271)	31 (83)	138 (169)	48 (82)	388 (277)	517 (401)	147 (205)	422 (282)
Number of patents having PTA [% of 114]				87 [74%]	87 [74%]	52 [44%]	94 [80%]
Number of days changed relative to standard interpretation (st. dev.)					+129 (157)	-241 (171)	+34 (55)

As Table 5 indicates, among patents with PTO delay, the average PTA under the standard interpretation is 388 days. This corresponds to an average PTA of 359 days, or approximately one year, for those patents having PTA under the standard interpretation.<sup>76</sup> The table suggests that the single biggest contributor to PTA is A delay, which averages 403 days. Indeed, by far the most frequent pattern observed in the analysis was a single, sizeable period of A delay due to

<sup>73</sup> One out of every hundred utility patents in this group was analyzed. While the total number of patents reviewed was necessarily somewhat small due to the need for inspection and analysis of each individual image file wrapper, and the dispersion of the data is substantial (see the large standard deviations in Table 5 and the histograms in Figs. 1a-1f), it is nevertheless possible to observe qualitative trends. A more rigorous quantitative analysis must await data collection using larger sample sizes.

<sup>74</sup> Only two of the patents analyzed in the general sample had C delay (in the amounts of 605 and 693 days). Accordingly, for simplicity, C delay is not included in Table 5.

<sup>75</sup> Terminal disclaimers were not reviewed to determine their potential effect on patent term.

<sup>76</sup> The percentage of patents having PTA (74%) and the average duration (359 days) are both in fairly good agreement with an analysis of over 6,000 utility patents issued in March 2008, which calculated a 72% rate of patents having PTA and an average PTA among these extended patents of 392 days. Crouch, *supra* note 17.

a late first Office Action. In contrast, average B delay is only about one-third as long. Average applicant delay was quite modest in comparison to either type of PTO delay, averaging only 48 days (though with a standard deviation of nearly twice this duration).

Under the Wyeth proposal, an average increase in PTA of 129 days, or 33%, is observed. This corresponds closely to the average period of B delay (excluding overlapping A delay) of 138 days. This is because, in most cases, the period of A delay is larger than the period of B delay;<sup>77</sup> thus, under the standard interpretation, only the A delay is taken into account,<sup>78</sup> whereas under the Wyeth proposal, A and B delay are added together. The most common effect of changing from the standard interpretation of PTA to the Wyeth proposal, then, is to add the period of B delay to the standard PTA.<sup>79</sup>

Turning to the PTO proposal, the data provide some insight into the PTO's motivation for proposing to eliminate A delay. Based on the results shown in Table 5, the PTO proposal would achieve an instant drop in the number of patents having PTA, from 74% to 44%, and it would decrease the amount of PTA by 62%. The result would be that the long A delays commonly associated with first Office Actions would no longer count as delays. In essence, the PTO seeks to remove from the PTA calculation the single variable responsible for the majority of PTA. While the PTO's motivation for its proposal may indeed be, as it states, to simplify PTA, it is notable that the proposed "simplification" would have the self-serving effect of making the PTO appear to operate in a considerably more timely and efficient manner.

Interestingly, the applicant delay proposal, on average, has relatively little effect on the PTA, increasing it by only 35 days, or 8.9%. This is because the average applicant delay is only

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<sup>77</sup> In only five of the patents analyzed in Table 5 does B delay (non-overlapping) exceed A delay.

<sup>78</sup> Note that, as to applicant delay, this situation corresponds to one of the "-2" cells of Table 1. That is, for every additional day of applicant delay, the applicant is doubly penalized under the standard interpretation. This inequity is removed in the Wyeth proposal, as shown in Table 2.

<sup>79</sup> This is not true in every instance; for example, it fails when applicant delay exceeds PTO delay.

48 days, and the applicant delay proposal generally results in an increase over the standard PTA commensurate with the amount of applicant delay. Thus, in applications with relatively little applicant delay, this proposal makes a correspondingly small difference in calculating the PTA.

To evaluate whether sector-specific effects are observed, a similar analysis was conducted for 117 patents issued in January 2009 in the biotechnology/pharmaceutical sector (referred to as the “pharma” sample).<sup>80</sup> Of the 114 of these patents that were filed after the AIPA went into effect, 84, or 74%, had some PTO delay during prosecution. The average delays and PTA calculations, including standard deviations, for these 84 patents are shown in Table 6.

Table 6

Days of delay (st. dev.)				PTA (st. dev.)			
PTO <sub>A</sub>	PTO <sub>A</sub> and PTO <sub>B</sub> overlap	PTO <sub>B</sub> (excluding PTO <sub>A</sub> )	App	Standard interpret- ation	Wyeth proposal	PTO proposal	App delay proposal
344 (243)	22 (75)	196 (216)	108 (140)	277 (235)	445 (404)	148 (216)	353 (245)
Number of patents having PTA [% of 114]				72 [63%]	73 [64%]	42 [37%]	84 [74%]
Number of days changed relative to standard interpretation (st. dev.)					+168 (197)	-129 (129)	+76 (90)

Several differences between Tables 5 and 6 are apparent. First, average A delay is somewhat shorter in Table 6 than in Table 5, though this difference does not rise to the  $p=0.05$  level of statistical significance.<sup>81</sup> Second, average B delay is substantially longer in the pharma

<sup>80</sup> Patents issued in January 2009 and classified under classes 424 or 514 (drugs) or 435 or 800 (biotechnology) were identified, resulting in 587 hits. (Regarding the patent classifications used herein, see, e.g., Bronwyn H. Hall et al., *The NBER Patent Citation Data File: Lessons, Insights and Methodological Tools*, 41 (Nat'l Bureau of Econ. Research, Working Paper No. 8498, 2001), <http://www.nber.org/papers/w8498>). One out of every five, or 117, of these patents were analyzed to generate Table 6. Note that no patent in this sample had C delay.

<sup>81</sup> Two-sample  $t(176)=1.53$ ,  $p=0.13$ . Throughout this analysis, two-tailed independent t-tests assuming unequal variances were computed using Microsoft Excel's Data Analysis package. The null hypothesis for each t-test posited that the statistic being measured had the same mean in the general and pharma samples.



sample, and this difference is at the threshold of statistical significance.<sup>82</sup> Third, average applicant delay is dramatically longer for pharma patents, and this difference is statistically significant.<sup>83</sup>

Histograms of these distributions are shown in Figs. 1a-1f. As Fig. 1a shows, A delay in the general sample is quite broadly dispersed and ranges from 0 to over 1,000 days. This likely reflects the substantial variability in backlogs among different art groups at the PTO: Some art groups have no difficulty meeting the 14-month benchmark for a first Office Action, while others miss by months or even years. For pharma patents, the A delay histogram (Fig. 1b) is shifted somewhat to the left, meaning slightly shorter delays, though as noted above this difference is not statistically significant given the small sample sizes analyzed here. Figs. 1c and 1d show the opposite trend for B delay: While B delay in the general sample tends to be shifted to the left in Fig. 1c, B delay in the pharma sample is more broadly dispersed, and is, on average, longer. Likewise, Figs. 1e and 1f show a similar pattern for applicant delay.

What effect do these observed differences have on PTA under the standard interpretation and the three proposals? Standard PTA is reduced significantly in the pharma sample, with the reduction roughly corresponding to the combination of the decrease in average A delay and the increase in applicant delay. Notably, the increase in B delay does not have much effect on the average standard PTA, since the A delay still dominates in most cases and thus is the only PTO delay counted. This means that, of the three main effects observed<sup>84</sup> – decreased A delay, increased B delay, and increased applicant delay – only the first and third appear to contribute to the calculation in most cases, resulting in an average PTA that is reduced by 111 days.

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<sup>82</sup>  $t(157)=1.96$ ,  $p=0.051$ .

<sup>83</sup>  $t(130)=3.44$ ,  $p=0.00078$ .

<sup>84</sup> That is to say, the effects observed in comparing the two samples. Even without the change in average A delay reaching the level of statistical significance, the comparison is still instructive in helping to understand how changes in the inputs to the PTA formula – namely, applicant delay and the various PTO delays – affect the PTA calculation.