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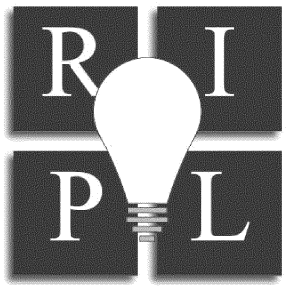

STATISTICAL ANALYSIS OF FEDERAL DISTRICT COURT CASES SEEKING LONGER PATENT TERM ADJUSTMENTS IN THE WAKE OF *WYETH V. KAPPOS*

VERNE A. LUCKOW & STEVEN C. BALSAROTTI

ABSTRACT

Over 175 Federal District Court cases filed from September 2008 through July 2010 were analyzed to determine common features noted by applicants seeking longer patent term adjustments ("PTAs") in view of a Federal District Court ruling, later affirmed by the U.S. Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, which held that the United States Patent and Trademark Office ("PTO") misinterpreted a statute relating to the calculation of PTAs involving overlapping periods of delay attributable to the PTO or to the applicant. Applicant and PTO errors in calculating PTAs were common, often relating to counting errors due to the mischaracterization of events that occur at the beginning or end of specific delay periods. Asymmetries were also noted in the treatment of delay periods encountered in the prosecution of national phase applications based on earlier-filed international applications, compared to applications which take priority only to earlier-filed U.S. applications. Common patterns of delay were noted, and practices that minimize Applicant Delay, maximizing effective PTA, are highlighted. Despite the intent of Congress to compensate applicants for delays in prosecution in an industry-independent manner, applicants seeking reconsideration of a patent term adjustment in Federal District Court are highly-biased toward institutions seeking patents on pharmaceutical and related biotechnology inventions. Unlike patent term extensions, which are sought in a six-month period prior to regulatory approval and sale of a pharmaceutical product, and often long after a patent has issued claiming the product, court cases identifying patents needing longer PTAs provide early notice to the public, including investors and competitors, of technologies considered to have particular value to the applicant. Understanding the complex calculations behind PTAs, patent term extensions, and expiration dates, is key to the development of successful scientific, legal, and business strategies involving licensing and ownership of patented technologies.

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INTRODUCTION

The economic life of a patented product or process can vary widely. Many patents have little or no value, some provide maximum value in the early years of a patent term, and others provide maximum value in the middle or later years of a patent term.[1] In the computer hardware and software industries, where low barriers to market entry and intense competition fuel rapid innovation and frequent copying of popular products and services, the legal life of a patented product or process is often longer than its economic life.[2] In highly-regulated areas, such as the pharmaceutical and biotechnology industries, where projects are often characterized as involving high risk and long development times, the economic life of a commercially-successful product or process is often longer than the legal protection offered by a patent.[3] Patent term adjustments ("PTAs") and patent term extensions ("PTEs"), which lengthen a 20 year patent term, are highly-desired by regulated industries, to ensure that the costs of research and development of patented products are adequately accounted for, and that profit margins are high enough to ensure investment in new products and processes.[4]

The term of a patent can be lengthened under several statutes to compensate patent owners for long delays relating to periods of review by the agencies such as the United States Patent and Trademark Office ("PTO") or the Federal Drug Administration ("FDA").[5] PTAs authorized under 35 U.S.C. § 154(b) were designed by Congress to compensate patent owners for delays from the date a patent

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[1] *See* Genelink Biosciences, Inc. v. Colby, No. 09-5573, 2010 WL 2681915, at *7, n.10 (D.N.J. July 1, 2010); R. Hoe & Co. v. Comm'r of Internal Revenue, 7 B.T.A. 1277, 1279 (B.T.A. 1927); Brian M. Daniel, Scott D. Phillips & David Tenenbaum, *Financial Aspects of Licensing Agreements: Valuation and Auditing*, *in* ADVANCED LICENSING AGREEMENTS FOR THE NEW ECONOMY 2001, at 85, 89–91 (PLI Pat., Copyright, Trademark, & Literary Property Course Handbook Series, 2001), *available at* WL, 644 PLI/Pat 85.

[2] *See, e.g.*, Sandvik, Inc. v. Comm'r, 52 T.C.M (CCH) 1181 (T.C. 1986).

[3] *See* Ann M. Thayer, *Blockbuster Model Breaking Down: Pharma Industry Reaches New Sales Peak, Despite Rising Costs and Bigger Challenges for Drug R&D*, MODERN DRUG DISCOVERY, June 2004, at 23–24.

[4] *See* Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); OFFICE OF TECHNOLOGY ASSESSMENT, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY 3–4 (1981).

[5] 35 U.S.C. §§ 154, 155, 156 (2006); 37 C.F.R. §§ 1.702(a), 1.703(a) (2010).

application is filed through the date a patent is granted, taking into account delays attributable to the PTO and the applicant.[6] The length of prosecution can vary considerably, depending on the complexity of the subject matter being examined, and the actions of the PTO or the applicant. PTEs authorized under 35 U.S.C. § 156 compensate patent owners for delays during periods when a drug product is being reviewed by the FDA, including review periods which extend beyond the issue date of a patent granted by the PTO.[7] The relevant statutes, and the rules interpreting and implementing the statutes relating to the expiration date of a patent and periods of data or marketing exclusivity put forth by these agencies, are remarkably complex. Changes affecting the interpretation of a statute or regulation directed to one agency, through legislative action, court rulings, or agency procedures, invariably affect procedures and policies of other agencies, and business strategies for many patent applicants and owners, their licensees, and their competitors.[8]

I. BACKGROUND

A. Patent Term Adjustments under 35 U.S.C. § 154(b)

In part to compensate applicants for delays related to prosecution after the PTO implemented policies set forth in the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS") in 1995,[9] Congress implemented 35 U.S.C. § 154(b) as part of the American Inventors Protection Act of 1999 ("AIPA") to provide three guarantees of patent term in view of several types of delay recognized under this statute:

- A delays provide day-for-day extensions for every day that issuance of a patent is delayed by a failure of the PTO to comply with various statutory deadlines (14 months for a first office action ("OA"), 4 months to respond to a reply, 4 months to issue a patent after the fee is paid, and 4 months to act on an application after the date of a decision by the Board of Patent Appeals and Interferences ("BPAI") or a federal court).

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[6] 35 U.S.C. § 154(b); 37 C.F.R. § 1.703(a). PTA rules were first proposed by the PTO in March of 2000. Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 17,215 (Mar. 31, 2000). The PTA provisions apply to utility and plant applications filed on or after May 29, 2000. American Inventors Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1536. The provisions of the Uruguay Round Agreements Act apply to utility and plant applications filed on or after June 8, 1995 and before May 29, 2000. Uruguay Round Agreements Act, Pub. L. No. 103-465, §§ 531–34, 108 Stat. 4809, 4982–91 (1994).

[7] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b, 68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282).

[8] *See, e.g.*, Ortho-McNeil Pharm., Inc. v. Lupin Pharm., 603 F.3d 1377, 1379 (Fed. Cir. 2010).

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, 1869 U.N.T.S. 299 (1994); Wyeth v. Kappos, 591 F.3d 1364, 1366 (Fed. Cir. 2010).

- B delays relate to the guarantee of no more than a three-year application pendency. A day-for-day extension is granted for every day greater than three years and one day after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO. Periods attributable to the applicants own delay, including suspended prosecution, requests for continued examination ("RCE"), plus time consumed by secrecy orders, interferences, and appeals that exceed the three-year pendency period, are excluded.

- C delays relate to typically rare delays resulting from interferences, secrecy orders, and appeals.[10]

Congress also wanted to prevent windfall extensions due to periods of double counting by providing a limitation that specified that to the extent that periods of A, B, or C delay overlap, the period of any adjustment under 35 U.S.C. § 154(b) shall not exceed the actual number of days the issuance was delayed.[11] The three types of guaranteed adjustments must also be offset by periods of delay attributable to the applicant's failure (by act or failure to act) to engage in reasonable efforts to conclude prosecution of the application, designated here as D delays.[12] Tables A1 and A2 provide detailed lists of actions that contribute to PTO and Applicant Delays, and provide examples of submissions that do not trigger Applicant Delays (e.g., change of entity status, power of attorney) as interpreted by the PTO in 37 C.F.R. §§ 1.701–1.705 and Manual of Patent Examining Procedure ("MPEP") §§ 2701–2764.[13] Regulations 37 C.F.R. §§ 1.703 and 1.704, directly relating to the calculation of PTO and Applicant Delays, are provided as a convenience for the reader in Tables A3 and A4, below.

Wyeth challenged the PTO interpretation of 35 U.S.C. § 154(b), specifically when B delays (the 3 year pendency guarantee) overlap A delays. In a theoretical scenario described in the Federal District Court decision illustrated in Figure 1, there were two A delays, one during the first three years of prosecution, and the second during the period from years 4–6, before the patent issued.[14] Wyeth argued that the 3 year pendency guarantee for B delays overlapped only with the second A delay period, and that the proper PTA was the sum of the periods for the first A delay (1 year), plus the B delay (3 years), to give a PTA of 4 years.[15] The PTO interpreted the rule as meaning that the B delay overlapped both A delays for years 1–6, and the applicant

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[10] 35 U.S.C. § 154(b)(1).

[11] *Id.* § 154(b)(2)(A).

[12] *Id.* § 154(b)(2)(C); 37 C.F.R. § 1.702(a) (2010).

[13] 37 C.F.R. § 1.703; U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2701–64 (8th ed. 8th Rev., July 2010) [hereinafter MPEP]. In 37 C.F.R. § 1.703, the period of adjustment due to examination delay is the calculated as the sum of five periods: § 1.703(a) relating to all A delays with respect to the 14, 4, 4 and 4 month examination delay rules; § 1.703(b) relating to B delays with respect to the three-year pendency guarantee; § 1.703(c) relating to C delays, for interferences, to the extent that the interference and prosecution periods involved are not overlapping; § 1.703(d) relating to C delays, for secrecy orders, to the extent that four types of secrecy periods are not overlapping; and § 1.703(e) relating to C delays, for appeals, to the BPAI or to a federal court.

[14] Wyeth v. Kappos, 591 F.3d at 1368.

[15] *Id.*

was entitled only to *the longer of the B delay* (with a credit only for periods where the application is pending beyond three years) *and the A delay, but not both*, resulting in a PTA of only 3 years.[16] The District Court Judge ruled against the PTO in *Wyeth v. Dudas*, noting that interpretation of a statute must square with the words of Congress, and that if "the outcome is an unintended result, the problem is for Congress to remedy, not the agency."[17] The PTO appealed the ruling on November 28, 2008.[18] Intrigued by these events, we evaluated nine weeks of patent grant data for November and December, 2008, and determined that over 70% of the 4,000 utility patents which issue each week should be eligible for longer PTAs, if the ruling in *Wyeth v. Dudas* would prevail upon appeal.[19]

The U.S. Court of Appeals for Federal Circuit ("CAFC") affirmed the lower court ruling on January 7, 2010, noting that the language of 35 U.S.C. § 154(b) "is clear, unambiguous, and intolerant of the PTO's suggested interpretation" of the meaning of the word "overlapping."[20] On January 26, 2010, the PTO posted a notice on its website indicating that it was not going to challenge the decision of the CAFC, but needed time to redesign internal databases and external web pages available on their Patent Application Information Retrieval ("PAIR") website relating to the calculation and display of PTAs.[21] A formal notice regarding interim procedures to request a recalculation of a PTA to comply with *Wyeth v. Kappos* was published in the Federal

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[16] *Id.* On April 22, 2004, the Patent Office published its final rules with respect to calculation of patent term adjustments under 35 U.S.C. § 154(b) in 69 Fed. Reg. 21,704. The PTO later issued an explanation. Explanation of 37 C.F.R. 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. 34,283 (June 21, 2004). In its explanation, the PTO took the view that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(2)(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 entire 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). *Id.* Under this interpretation, for any administrative delay under 35 U.S.C. § 154(b)(1)(A), the applicant gets credit for the *longer* of A delay or B delay, but *never* A delay *plus* B delay. *Id.*

[17] Wyeth v. Dudas, 580 F. Supp. 2d at 142.

[18] Wyeth v. Kappos, 591 F.3d at 1364; Brief for Defendant-Appellant at 6, Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008) (No. 2009–1120), 2009 WL 789065.

[19] We also noted that about eight percent of all patents that were pending greater than three years, and were not terminally disclaimed to another patent, had a PTA recorded on the face of the patent as being zero. This group was labeled as having "hidden eligibility" for larger PTAs in view of the judges' decision in *Wyeth v. Dudas*. *See* NEAL, GERBER & EISENBERG LLP, OPPORTUNITIES FOR LONGER PATENT TERM ADJUSTMENTS (2009) (internal publication, on file with The John Marshall Review of Intellectual Property Law). The actual number of affected patents is slightly lower, as patents having an RCE, or in some cases a notice of appeal in a case also having an RCE, filed before the start of the three year B delay period, would not be eligible for larger PTAs. Information about RCEs and appeals, however, are not available on the face of a patent. *See* discussion *infra* Part II.A.

[20] Wyeth v. Kappos, 591 F.3d at 1372.

[21] Interim Procedure for Patentees to Request a Recalculation of the Patent Term Adjustment to Comply with the Federal Circuit Decision in Wyeth v. Kappos Regarding the Overlapping Delay Provision of 35 U.S.C. § 154(b)(2)(A), 75 Fed. Reg. 5043 (Feb. 1, 2010) [hereinafter PTO Interim Procedure] (signed by David Kappos on Jan. 26, 2010), *available at* http://www.uspto.gov/patents/announce/pta_wyeth.pdf. On February 15, 2010, the PTO removed the total amount of examination and Applicant Delay from its PTA tab under public and private PAIR, but left numbers in the adjusted PTA field unaltered.

Register on February 1, 2010.[22] Patents issuing on or after March 2, 2010 would have a PTA calculated according to the ruling in *Wyeth v. Kappos*.[23] Newly-designed web pages displaying PTA information were scheduled to be available as early as July, 2010.[24]

B. Statistical Analysis of PTAs Requested by Applicants

To better understand the economic and legal implications of the Federal District and Appellate Court decisions concerning the calculation of PTAs, we began collecting and analyzing over 175 Federal District Court cases which have been filed against the Director or Acting Director of the PTO from September, 2008 through July, 2010, where the plaintiffs were seeking to have the District Court reconsider the PTA calculated by the PTO of their recently-issued patents. We examined all cases filed in Federal District Court in the District of Columbia where Dudas, Doll, or Kappos were listed as defendants for matters that related only to PTAs. Usually, plaintiffs were seeking recalculation of the PTA for a single patent, but several involved requests for recalculations concerning two or more patents.

Initially, we were interested in determining common patterns of delay noted in all court complaints requesting larger PTAs. Better knowledge of the factors affecting the length of delay periods would simplify our formulas for the calculation of PTAs, and facilitate the development of business strategies that minimize Applicant Delays and maximize terms of patents held by our clients. The task became more challenging when the pace of filing accelerated in 2009, and when we observed repeated patterns of errors by applicants, *and the PTO*, particularly in the calculation of PTAs for patents involving RCEs, and applications entering the U.S. for examination under 35 U.S.C. § 371 based on earlier-filed international applications.

Our analysis, described in detail below, illustrates the extraordinary complexity of these statutes and regulations, unexpected asymmetries in the treatment of different delay periods, and a strong bias towards lawsuits involving patents relating to pharmaceutical products and processes. We do not believe the bias, asymmetries, or high error rates we observed were anticipated by Congress when the statues concerning PTAs were prepared and when the PTO implemented its regulations interpreting the statues. Careful parsing of both is key to the development of strategies to maximize the terms of patents owned by clients and their licensees, and required for a better understanding of portfolios held by their competitors around the world.

Table 1 summarizes our analysis, showing that the median amount of additional PTA requested by all applicants in the cases we analyzed was 301 days. Figure 2 shows a scatter chart displaying the differences between the *PTA* initially calculated by the PTO (PTA_{PTO}) and those requested by the plaintiffs ($PTA_{Requested}$) for each patent listed in the complaints.

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[22] *Id.*

[23] *Id.*

[24] *Id.* Newly-designed web pages became available in mid-September, 2010, which, unfortunately, omit many of the key data values required to calculate a PTA.

Table 1
Statistical Analysis of PTAs Calculated by the PTO
Compared to Those Requested by Applicants (n=225)

	PTA_{PTO}	$PTA_{Requested}$	$\Delta PTA_{Requested\text{-}PTO}$
Min	0	57	–75
Max	1497	2128	**1754**
Mean	449.4	779.2	**330.0**
Median	**423**	**775**	**301**

We discovered many complex issues during our analysis that are best described using a common set of terms and formulas that convey the meaning of words set forth in the relevant statutes and regulations. Understanding the terms and formulas described in the following sections will greatly facilitate an understanding of the patterns of delays that we observed in these cases and the practice tips we provide to maximize the term of a patent, and its value, in a portfolio of related patents.

C. General Formulas for Calculating the Term of a Patent Having a Patent Term Adjustment

Currently, the *adjusted term* of a utility *patent*, *f*(APT), is 20 years from the filing date of the earliest non-provisional application to which priority is claimed,[25] designated here as the *normal term*, *f*(NT), plus the *PTA*, *f*(PTA), taking into account the total period for guaranteed adjustments (for A, B, or C delays), minus the total period for required reductions (D delays), *but only if the sum of the period for guaranteed adjustments minus the period for required reductions is positive or zero.*[26] The terms and delay periods can be expressed as parameters in simple Formulas 1 and 2, as shown below:

Formula 1

$$f(APT) = f(NT) + f(PTA)$$

Formula 1 omits several variables, and assumes that the patent does not expire sooner than 20 years due to failure to pay maintenance fees,[27] is invalidated in proceedings before the PTO or in a federal court, or is subject to statutory or terminal disclaimers[28] that truncate the term of some or all of the claims in a patent to a period less than the normal 20 year term.

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[25] 35 U.S.C. § 154 (a)(2) (2006).

[26] 35 U.S.C. § 154 (b)(2)(C); 37 C.F.R. §§ 1.702, 1.704(b) (2010); MPEP, *supra* note 13, § 2732. Tables A1 and A2, located at the end of this document, provide a detailed summary of the various types of guaranteed adjustments and required reductions.

[27] 35 U.S.C. § 41; MPEP, *supra* note 13, § 2501.

[28] MPEP, *supra* note 13, §§ 1701, 2701.

Formula 2

$f(PTA)$ = (Guaranteed Adjustments due to A, B, or C Delays) – (Required Reductions for Applicant Delays)

Formula 2 is also very general, as the regulations outlined in 37 C.F.R. §§ 1.701–1.705 require a detailed analysis of all of the correspondence to and from the PTO, which are not always recorded properly or recognized by the PTO computer program that calculates the PTA, when a Notice of Allowance ("NOA") is prepared, when a patent is granted, or when the calculation by the PTO is challenged by the applicant.[29]

Complicating PTA analysis, is the assumption that most, if not all, of correspondence which triggers and terminates an A delay period never overlaps (e.g., OA issued, followed by a response filed by the applicant), while some events which trigger or terminate C delays, relating to interferences, secrecy orders, and appeals to the BPAI or to a federal court, may overlap other prosecution activities.[30] It is also important to recognize that there are activities in some delay categories that may take place more than once during prosecution (e.g., an applicant taking longer than 3 months to respond to an OA or the PTO taking longer than 4 months to mail a reply to a response), that need to be recognized throughout the equations. In other cases, however, the formulas reflect events that take place only once during prosecution (e.g., issuing a first office action on the merits ("FOAM") of the application or payment of an issue fee), and many which rarely occur (i.e., secrecy orders, interference proceedings, and appeals).

Teasing apart the requirements listed in 35 U.S.C. § 154(b) as implemented by the PTO in 37 C.F.R. §§ 1.703 and 1.704 reveals *a far more complex set of formulas*, as shown in the following sections:

Formula 3

$$f(A) = f(1.703(\text{a})) = \sum_{\text{i=4}}^{\text{i=6}} f(1.703(\text{a})(i))$$

Formula 3 indicates that the total amount of A period delay is expressed as the sum of six possible delays outlined in 37 C.F.R. §§ 1.703(a)(1) through 1.703(a)(6) (*not shown here as formulas*, but see Table A3 for the text of the regulations). The most important of these is 1.703(a)(1), which relates to examination delays that occur when the PTO mails its FOAM more than 14 months after the filing date of the application. Other important A delays include those described in 1.703(a)(2) and 1.703(a)(6), which relate to mailing of OAs more than 4 months from the filing of a response, and failure to issue a patent more than 4 months after receiving the issue fee, respectively.

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[29] 37 C.F.R. §§ 1.701–1.705; U.S. PAT. & TRADEMARK OFFICE, DEP'T OF COMMERCE, *Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371*, 1347 OFF. GAZ. PAT. & TRADEMARK OFFICE 49, 49 (2009) [hereinafter *PTO Calculation Notice*].

[30] 37 C.F.R. § 1.703(a)(1)–(6).

Formula 4

$$f(B) = f(1.703(\text{b})) = \left[\begin{array}{c} IssDt - \\ \{f(APD) + 3Y + 1D\} \end{array} \right] - \sum_{i=1}^{i=4} f(1.703(\text{b})(i))$$

Formula 4 expresses the relationship between factors considered in the calculation of the three-year pendency guarantee, or B delay.[31] B delay is expressed as the time beginning 3 years *plus 1 day* after the application date ("APD") of a U.S. application or the national stage entry of an international application through the issue date (IssDt) of a patent, minus the sum of four possible periods of delay outlined in 37 C.F.R. § 1.703(b)(1)–(4).[32] The most important of these is when an applicant files an RCE. In this case, the total B period is the time beginning 3 years plus 1 day after filing, through the issue date, minus the period beginning on the date the RCE was filed, through the issue date. Many applicants in the court cases noted below fail to account for one or both of the starting and ending (flanking) dates in their calculations. This leads to counting errors which are off by +1 or −1 days. When calculating the total amount of B period delay, the amount an A period delay overlaps with a B period delay is designated here as "AB overlap".[33]

Formula 4 is actually more complex than shown above, as the application date for U.S. applications under 35 U.S.C. § 111(a) is much easier to determine, compared to the application date for an international application entering the United States according to procedures outlined in 35 U.S.C. § 371(b) or (f).[34] The PTO did not acknowledge errors in its own procedures for calculating the filing date of international applications until recently, which requires consideration of priority, commencement, pre-examination completion, and express demand dates that are not always available by viewing information published on the first page of an issued patent, or viewing information shown on the PTA tab in the online version of the PTO PAIR database.[35] Errors noted in applications filed under 35 U.S.C. § 371 are discussed in detail in several sections below.

Formulas 5–12, shown below, illustrate the need to obtain and consider multiple dates to calculate the *starting clock date* for many PTA events, particularly the A Clock Start ("ACS") and the B Clock Start ("BCS"), described in more detail below. Note that the *actual filing date ("AFD")* of an international application is *not used* in the formulas below, although it is often tied to the priority date of such an application. The *actual filing date* of an international application, however, is used to determine the start of a normal 20 year patent term, $f(\text{NT})$, to which the PTA, if any, is appended (formula not shown).

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[31] 35 U.S.C. § 154(b).

[32] 37 C.F.R. § 1.703(b)(1)–(4).

[33] Date counting errors, particularly for patents involving RCEs, are surprisingly common. *Nearly 70% of all cases involving RCEs appear to have one- or two-day counting errors.* When the A delay overlaps the B delay, date counting errors may offset each other, making it appear as if the calculated PTA is the same as that calculated properly. Nearly all applicants specified how they calculated B delays, but very few provided details describing calculations involving overlaps between A and B delays.

[34] 35 U.S.C. §§ 111(a), 371.

[35] Wyeth v. Kappos, 591 F.3d 1364, 1364 (Fed. Cir. 2010); *PTO Calculation Notice*, *supra* note 29, at 49.

Formula 5

$$f(APD) = f(APD_{US}) \quad or \quad f(APD_{Intl})$$

Formula 5 specifies that the functions for determining the Application Date ("APD") of a U.S. or an international application entering the United States are mutually exclusive.

Formula 6

$$f(APD_{US}) = f(111(a)Dt)$$

Formula 7

$$f(111(a)Dt) = \text{filing of specification with claims, and drawing, if required}$$

Formulas 6 and 7 specify that the application date of a U.S. application is the date specified under 35 U.S.C. § 111(a).

Formula 8

$$f(APD_{Intl}) = \min[f(371(b)Dt), f(371(f)Dt)]$$

Formula 9

$$f(371(b)Dt) = \text{Priority Date} + 30 \text{ Months}$$

Formula 10

$$f(371(c)Dt) = [\text{filing of international application with translation, if required, amendments, international pre-examination report, with translations, if required, national fee and oath or declaration (with late fee surcharges, if needed)}]$$

Formula 11

$$f(371(f)Dt) = \max[\text{Written Early National Stage Commencement Dt}, f(371(c)Dt)]$$

Formulas 8–11 specify that the APD of an application entering the United States under 35 U.S.C. § 371 requires consideration of events specified in 35 U.S.C. § 371(b), (c), and (f) as noted in extensive detail in MPEP § 1893.03(b).[36] The § 371(b) date is the priority date plus 30 months, the § 371(c) date occurs when the events relating to filing of a specification, amendments, preliminary exam report are complied with, along with payment of fees, and submission of an oath or declaration.[37] The § 371(f) date is the later of the written (express) request for early

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[36] 35 U.S.C. §§ 102(e), 132, 154(b)(1)(A)–(B), 363, 371(b)–(c), 371(f); 37 C.F.R. §§ 1.475, 1.496, 1.497(c), 1.702(a)(1), 1.704(b); MPEP, *supra* note 13, § 1893.03(b), *available at* http://www.uspto.gov/web/offices/pac/mpep/documents/1800_1893_03_b.htm#sect1893.03b.

[37] 35 U.S.C. § 371(b)–(c).

national stage commencement date and the § 371(c) date.[38] The application filing date of an international application, then, is the earlier of the § 371(b) date and the § 371(f) date. Note that an early written request can shift the effective application date earlier, and that failure of an applicant to comply with the requirements of § 371(c), such as having missing parts, can shift the effective application date later.

It is important to note that the starting dates, designated here as A Clock Start ("ACS") and B Clock Start ("BCS") dates, from which A and B delays are measured, *can be different* for applications entering the United States under 35 U.S.C. § 371, compared to the A and B clock start dates for normal U.S. applications, which are always the same.

- For normal U.S. applications, the ACS date and the BCS date are both measured from the filing date of a non-provisional U.S. application, specified above as $f(111(a)Dt)$, or just the App date. The A Period Start ("APS") date is the App date + 14 months + 0 days. The BCS date is the App date, and the B Period Start ("BPS") date is the App date + 3 years + 1 day.

- For applications entering the United States under 35 U.S.C. § 371, the ACS is the later of the § 371(b), (c), or (f) dates, and the APS is the ACS date + 14 months + 0 days. For 35 U.S.C. § 371 applications, the BCS date is the earlier of the § 371(b) and the § 371(f) dates. The BPS date is the earlier of the § 371(b) or the § 371(f) dates + 3 years + 1 day.

This asymmetry in A and B Clock Start dates is not obvious when you read the relevant the statutes, regulations, and explanations for the first time, or even the tenth time. In a notice published in the Official Gazette on October 6, 2009, the PTO stated that their algorithms for calculating A and B Clock Start dates and Period Start dates for § 371 applications were incorrect, and that measures were being taken to correct the program.[39] Careful analysis is required to ensure that all of the proper dates are accounted for when calculating A and B delays for § 371 applications. These issues are described in more detail in several sections, below.

Formula 12

$$f(\mathrm{C}_1) = f(1.703(\mathrm{c})) = \sum_{i=1}^{i=2} f(1.703(\mathrm{c})(i)) - f(\mathrm{OP}_{\mathrm{C}_1})$$

Formula 13

$$f(\mathrm{C}_2) = f(1.703(\mathrm{d})) = \sum_{i=1}^{i=4} f(1.703(\mathrm{d})(i)) - f(\mathrm{OP}_{\mathrm{C}_2})$$

Formula 14

$$f(\mathrm{C}_3) = f(1.703(\mathrm{e})) = \left[\min(141Dt, 145Dt) - 134 \mathit{and} 41.31Dt + 1\right]$$

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[38] *Id.* § 371(c), (f).

[39] *PTO Calculation Notice*, *supra* note 29, at 49.

Formulas 12–14 express the relationship between factors considered in the calculation of C delays (designated here as C_1, C_2, and C_3 delays) relating to interferences, secrecy orders, and appeals described in 37 C.F.R. § 1.703(c), (d), and (e). Complicating this analysis are the provisions of 37 C.F.R. § 1.703(c) relating to the declaration and termination of interference proceedings, which require that the period of adjustment under § 1.703(c) is the sum of two periods, to the extent that the periods are not overlapping, $f(OP_{C1})$.[40] Similarly, the period of adjustment under § 1.703(d), relating to secrecy orders and interference proceedings, is the sum of four periods, to the extent that the periods are not overlapping, $f(OP_{C2})$.[41] $f(OP_{C1})$, and $f(OP_{C2})$ are designated here as C_1- and C_2-specific *(or local)* overlapping delay amounts, respectively, to distinguish them from the *global* A, B, and C overlapping delay amounts, noted below.

The complexity of reducing overlapping intervals under 37 C.F.R. § 1.704(c), (d), and (e) for secrecy orders and interferences during C delay periods, is amplified once again, by a provision in 37 C.F.R. § 1.704(f) which reduces the PTA for all overlapping A, B, and C delay periods, as specified below (emphasis added).

> The adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. § 154(a)(2). To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed. The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, *to the extent that such periods are not overlapping*, less the sum of the periods calculated under § 1.704. The date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.[42]

This means that the five types of delay periods, designated as A under § 1.702(a), B under § 1.702(b), and C under § 1.702(c)–(e), need to be compared, accounting for any overlapping intervals. Once this number is determined, it is reduced by the delays attributable to action or inaction by the applicant under § 1.704 that impede the timely prosecution of the application. Taking into account periods of overlap in the A, B, and C periods, the PTA, $f(\text{PTA})$, is calculated as shown in Formulas 15 and 16.

Formula 15

$$f(PTA) = \left[\left\{\sum(\text{A, B, and C Delays}) - \sum(\text{Global Overlapping Delays})\right\} - \text{Applicant Delays}\right]$$

Formula 16

$$f(PTA) = f(A + B + C_1 + C_2 + C_3) - f(OP_{ABC}) - f(AD)$$

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[40] 37 C.F.R. § 1.703(c).
[41] *Id.* § 1.703(d).
[42] *Id.* § 1.703(f).

Many of these formulas can be implemented in computer programs, or in spreadsheets, but it is important to note that (1) recognition of the appropriate trigger events often requires examination of a variety of documents that are not always recorded properly in PTO or applicant databases (and may occur only once, many times, or rarely, if ever), and (2) the calculation of offsets, due to overlapping date ranges, *are remarkably challenging tasks*.

Fortunately, complex methods to calculate offsets for multiple overlapping periods involving local or global overlapping delay periods are not needed for the general formulas noted above to solve equations involving scenarios such as those presented in *Wyeth v. Dudas*, where parameters relating to the length and overlap of only A and B delay periods are in dispute, as shown in below.

Formula 17

$$f(PTA_{Wyeth}) = f(A) + f(B) - f(OP_{AB}) - f(AD)$$

Formula 18

$$f(PTA_{PTO}) = \max\left[f(A), f(B)\right] - f(OP_{AB}) - f(AD)$$

Formula 17 indicates that the PTA is the sum of the A and B period delays, which are offset by the overlap between the A and B periods, and the total amount of Applicant Delay. Formula 18 reflects the original PTO interpretation of 35 U.S.C. § 154(b), as noted above, when the B delay period overlapped A delay periods that occurred before and after three years from the filing date of an application, and the applicant was entitled only to *the longer of the B delay* (with a credit only for periods where the application is pending beyond three years) *and the A delay, but not both*.

In nearly all cases, however, when a patent application was pending for more than three years, Formula 17 provides a larger PTA than that calculated using Formula 18.[43] The difference between the two amounts, as shown in Formula 19, may be substantial, easily adding months, *and sometimes years*, to the term of a utility patent.

Formula 19

$$f(\Delta PTA_{Wyeth-PTO}) = f(PTA_{Wyeth}) - f(PTA_{PTO})$$

It is also important to note that *adding A or B delays (whichever was omitted by the PTO), can dramatically increase the PTA* using Formula 17, even in simple cases, where there is no overlap between the A and B periods (AB overlap), or there is no Applicant Delay, and when both amounts are zero.

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[43] Cases having an RCE are one exception. A detailed discussion is provided in subsequent sections.

D. Required Deductions for Applicant Delays under 35 U.S.C. § 154(b)

A very important factor in determining the value of a PTA reflected in the formulas noted above is the total amount of delay charged to the applicant, designated here as *f*(AD) or D delays, that the applicant (by act or failure to act) did not engage in reasonable efforts to conclude prosecution of the application. Dozens of events can trigger Applicant Delays as noted in Table A2. The most significant of these are failure to respond to an OA in a timely fashion, such as responding 3–6 months after a substantive OA was mailed to the applicant, which will typically count as 1–92 days of Applicant Delay.[44] Longer delays, due to mailing, instead of filing a response electronically, or failing to provide missing parts of applications within prescribed time limits, are also possible. Another common Applicant Delay reflects submission of a supplemental reply after a response was filed, but before the examiner has prepared and mailed a new OA.[45] These types of delay can occur several times during prosecution, unlike many of the activities that trigger and terminate events counted in A, B, or C delays. Strategies that minimize Applicant Delay, contributing to larger PTAs, are discussed in greater detail below.

E. Time Limits for Challenging PTA Determinations Before the PTO and in the Courts

Current regulations set time limits for filing petitions to request reconsideration of the PTA listed on an NOA and after a patent has issued.[46] Two types of petitions are available:

- Under 37 C.F.R. § 1.705(b), requests for reconsideration of the PTA in the NOA must be filed no later than the payment of the issue fee, and no earlier than the date of mailing of the NOA.

- Under 37 C.F.R. § 1.705(d), if the PTA is indicated in a notice of allowance is revised, the patent will indicate the revised PTA. Any request for reconsideration of the PTA indicated in the patent must be filed within two months of the date the patent issued.

Both types of petitions must be accompanied by a fee and a statement of facts setting forth the correct PTA and relevant remarks supporting the new adjustments.[47] Challenges under 1.705(b) typically relate to disputes over the characterization of A, C, or Applicant Delays prior to the NOA. Those raised under 1.705(d) can include those raised under 1.705(b) plus B delays, and any new A, C, or Applicant Delays between the NOA and the issue date. Under 1.705(d), however,

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[44] 35 U.S.C. § 154(b)(2)(C) (2006).

[45] *Id.* § 154(b)(1)(A).

[46] *Id.* § 154(b)(3); 37 C.F.R. § 1.705(b), (d). The statutes 35 U.S.C. § 154(b)(3) and 37 C.F.R. § 1.705(b) provide one opportunity to request reconsideration of any PTA listed on the notice of allowance, and 37 C.F.R. § 1.705(d) provides an opportunity to request reconsideration of any PTA listed on a patent. 35 U.S.C. § 154(b)(3); 37 C.F.R. § 1.705(b), (d).

[47] 37 C.F.R. § 1.705(b), (d).

"any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for PTA under paragraph (b) of this section shall be dismissed as untimely as to those issues."[48] The periods for reconsideration set forth in 37 C.F.R. § 1.705 are not extendible.[49]

If the patent issued more than two months and less than 180 days ago, the applicant can appeal a determination by the Director of the PTO by means of a civil action against the Director filed in the U.S. District Court for the District of Columbia.[50] Bypassing the PTO petition process before filing a civil action does not appear to be an option, because 35 U.S.C. § 154(b)(4)(A) specifically refers to 35 U.S.C. § 154(b)(3) relating to procedures for PTA determination.[51] Civil actions requesting reconsideration of a PTA for a patent that issued more than 180 days ago are prohibited.[52]

When major changes to the PTA regulations were made in April 22, 2004, the PTO offered applicants until July 21, 2004 to seek reconsideration of an adjustment or an extension for a patent having a NOA mailed before May 24, 2004.[53] Immediately after the decisions in *Wyeth v. Dudas* and *Wyeth v. Kappos*, the PTO took a firm stance on time limits, and insisted that petitions for reconsideration of PTA after a patent has issued be filed no later than two months from the issue date.[54] On February 1, 2010, however, a simplified Interim Request for Recalculation procedure became available to request recalculations of PTA to comply with the ruling in *Wyeth v. Kappos*, which waived the requirements of 37 C.F.R. § 1.705(b)(2) and the fee required under 37 C.F.R. § 1.18(e).[55] An applicant may use the simplified procedure by filing form PTO/SB/131, provided that:

(1) the patent issued before March 2, 2010;
(2) the form is filed within 180 days of the grant of a patent or within two months of a decision under 1.705(d);

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[48] *Id.* § 1.705(d).

[49] *Id.* § 1.705(e).

[50] 35 U.S.C. § 154(b)(4)(A).

> An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

Id.

[51] *Id.*

[52] *Id.*

[53] Revision of Patent Term Extension and Patent Term Adjustment Provisions, 69 Fed. Reg. 21,704 (Apr. 22, 2004). The final PTA rules stated that:

> [a]ny request for reconsideration of the patent term extension or adjustment indicated on a patent resulting from an application in which the notice of allowance was mailed before May 24, 2004 on the basis of changes to 37 C.F.R. §§ 1.701 or 1.702 in this final rule must be filed no later than July 21, 2004.

Id.

[54] PTO Interim Procedure, *supra* note 21.

[55] *Id.*

(3) the sole reason for reconsideration is the PTO's pre-*Wyeth* interpretation of B delays under 35 U.S.C. § 154(b)(2)(A);
(4) an utility or plant application filed under 35 U.S.C. § 111(a) was filed on or after May 29, 2000, or an application filed under 35 U.S.C. § 371 must have an international filing date on or after May 29, 2000; and
(5) the patentee must not have filed a civil action under 35 U.S.C. § 154(b)(4)(A).[56]

The PTO will provide decisions on a timely-filed interim request or a request for reconsideration under 1.705(d), even if more than 180 days have elapsed since the patent issued.[57] But, the filing of these requests *will not toll* the statutory time limits which require that a civil action be filed "within 180 days after the grant of the patent."[58] In a presentation made to the American Intellectual Property Lawyers Association ("AIPLA") in March, 2010, a representative of the Office of Patent Legal Administration stated that the PTO will not entertain any other request for reconsideration under 37 C.F.R. § 1.705, or under §§ 1.181 (Petition to the Director), 1.183 (Suspension of rules), 1.322 (Certificate of correction of Office mistake), or 1.323 (Certificate of correction of applicant's mistake) filed more than 180 days after the grant of a patent.[59]

The Interim Request for Recalculation procedure does not apply for patents that issue on or after March 2, 2010, as they will reflect a PTA calculation performed according to the ruling in *Wyeth v. Kappos*.[60] A request for reconsideration filed under 37 C.F.R. § 1.705(d) can still be filed to challenge errors in the determination of other delay periods.[61] If a patentee notices that a PTA should be *less* than what the PTO calculated, the patentee must file a request for reconsideration within 30 days or one month, whichever is longer, to dispute the recalculated amount of PTA.[62] MPEP § 2733 describes specific procedures to follow when the expected PTA is shorter, or longer, than expected.[63]

It should be noted, however, that the PTO revised its procedures on July 20, 2010, when it published a notice in the Federal Register stating that the PTO will place letters asserting that the PTA is greater than what the applicant or patentee believes is appropriate in the file of the application or patent without further review.[64] It is not quite clear what effect this will have, if such a patent is later litigated or subject to regulatory review over issues relating its expiration date.

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[56] *Id.*; *Questions and Answers Related to Wyeth v. Kappos*, U.S. PAT. & TRADEMARK OFFICE 1, http://www.uspto.gov/patents/law/aipa/pta/wyeth_faqs_20100422.pdf (last updated April 22, 2010).

[57] *Questions and Answers Related to Wyeth v. Kappos*, *supra* note 56, at 1.

[58] *Id.*

[59] Kery A. Fries, U.S. Pat. & Trademark Office, Address at American Intellectual Property Law Association (Mar. 20, 2010), http://www.aipla.org/Content/Microsites101/Biotechnology/USPTO_Partnership_Meetings/March_2010/BCP_Fries.ppt.

[60] *Questions and Answers Related to Wyeth v. Kappos*, *supra* note 56, at 1.

[61] *Id.*

[62] *Id.*

[63] MPEP, *supra* note 13, § 2733, *available at* http://www.uspto.gov/web/offices/pac/mpep/documents/2700_2733.htm#sect2733.

[64] Treatment of Letters Stating that the USPTO's Patent Term Adjustment Determination is Greater than What the Applicant or Patentee Believes is Appropriate, 75 Fed. Reg. 42,079 (July 20, 2010).

The PTO deployed an automated system for recalculating PTAs in response to requests for reconsideration on April 16, 2010. A patentee or assignee will have 30 days or one month, whichever is longer, after the mailing of a recalculation determination to file a reply under 1.705(d), accompanied by a fee, to contest the recalculation determination.[65] If the patentee or assignee does not reply within that period, the PTO will issue a certificate of correction within two months reflecting the new determination.[66] If the new determination is contested, the PTO will consider the reply and either issue the certificate of correction, or revise its determination, as appropriate.[67]

On April 22, 2010, the PTO published answers to 24 frequently asked questions related to the ruling in *Wyeth v. Kappos*.[68] A key point noted in the Q&A is that the PTO *will not* recalculate the PTA of any patent voluntarily.[69] A timely request for reconsideration under 37 C.F.R. § 1.705(d), or a timely submission of an Interim Request for Recalculation form, is required before the PTO will recalculate a PTA, mail a recalculation determination, and issue a certificate of correction, if needed.[70]

The Q&A also states that an Interim Request for Recalculation procedure should not be used for patents that have no B delay:

- These include patents that issue in less than three years from the application date of an application filed under 35 U.S.C. § 111(a) or the date of national stage commencement of an international application filed under 35 U.S.C. § 371(b) or (f).

- This also includes applications of both types, where the time period is *longer than three years*, but the *filing of a first RCE is less than three years*, truncating any B delay after that date.[71]

Post-grant verification or audit procedures may need to be altered to reflect these observations, because RCEs are recorded in PAIR, but *not* on the face of a published patent.[72]

We are aware of several petition decisions where patentees in the lawsuits noted below have attempted to use the interim procedure to request recalculation of a PTA. The PTO dismissed their requests in formal decisions, noting that the requests were ineligible for any of seven reasons, including the five noted above.[73] The two new reasons are (1) that design and reissue patents or patents in a reexamination are not eligible, and (2) that a continuing prosecution application ("CPA") of a utility or plant application filed under 35 U.S.C. § 111(a) or an international application be filed on

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[65] *Questions and Answers Related to Wyeth v. Kappos*, *supra* note 56, at 2.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] PTO Interim Procedure, *supra* note 21.
[73] *See, e.g.*, U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION NO. 10/925,873, DECISION ON REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF WYETH (Apr. 21, 2010).

or after May 29, 2000, where the parent application was filed before May 29, 2000, is ineligible.

The PTO's position on time limits would seem to leave many applicants that did not challenge their PTA determinations for patents issuing in 2008 through late 2009 without recourse for correction through the petition process within the PTO, although at least three patentees, including General Hospital Corp.,[74] Idera Pharmaceuticals,[75] and Novartis[76] asserted that the change in law after *Wyeth v. Kappos* was sufficient to invoke the common law doctrine of equitable tolling to not bar a claim where the plaintiff, despite its due diligence, could not or did not discover its injury until after the expiration of the time limit for seeking reconsideration of PTAs for its patents.[77] The Novartis complaint states that it lacked knowledge and adequate notice of its claim that the PTO had been improperly interpreting the provisions of 35 U.S.C. § 154(b)(2)(A) relating to the calculation between A delays and B delays, until the PTO announced that it would not appeal the Wyeth v. Kappos decision on January 21, 2010, or at the earliest, January 7, 2010.[78] Novartis also asserted that the miscalculations deprived it of patent term under a related doctrine, called the discovery rule, where a cause of action accrues when the plaintiff has or should have had knowledge of the existence of the injury, its cause in fact, and some evidence of wrongdoing.[79] Violations of the Fifth Amendment under the takings clause, and the Administrative Procedures Act under 5 U.S.C. §§ 701–706, were also asserted by Novartis.[80] It is too early to tell whether Novartis will prevail in its case against the PTO based on these or other doctrines, but patentees, assignees, and licensees, in similar positions with "old" patents, would be wise to monitor the progress of this case to determine the strategies involved in challenging the PTA determinations for patents that issued before the interim rules for reconsideration were implemented on February 1, 2010.

It is also not clear that failure by a patent practitioner to notify a client of ways to challenge the determination through the PTO petition process or in court challenges amounts to malpractice, given the apparent need to establish value of a patent, that must be fully-paid up and enforceable, before it expires 15 or more years from now. Sophisticated clients, in particular, would have a difficult time asserting

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[74] Complaint, General Hosp. Corp. v. Dudas, No. 09-CV-00109 (D.D.C. Jan. 16, 2009) (regarding U.S. Patent No. 7,367,341).

[75] Complaint, Idera Pharm. Inc. v. Kappos, No. 10-CV-00166 (D.D.C. Jan. 29, 2010) (regarding U.S. Patent No. 7,569,554 and U.S. Patent No. 7,517,862).

[76] Complaint, Novartis AG v. Kappos, No. 10-CV-01138 (D.D.C. July 6, 2010) (regarding eleven U.S. Patents that issued in the years 2003 to 2009).

[77] Plaintiff's Amended Complaint at 1, Idera Pharm. Inc. v. Kappos, No. 10-CV-0166 (D.D.C. Jan. 29, 2010). Idera Pharmaceuticals, however, challenged the 180 period for filing a complaint in Federal court for U.S. Patent No. 7,517,862 (filed Aug. 25, 2004) (issued Apr. 14, 2009), asserting the decision in *Wyeth v. Dudas*, as affirmed by the CAFC in *Wyeth v. Kappos*, constitutes "a change in law sufficient to invoke the doctrine of equitable tolling," as the '862 patent issued 290 days before Idera's complaint was filed on January 29, 2010. *Id.* In the same complaint, a PTA was requested for U.S. Patent No. 7,569,554 (filed May 14, 2004) (issued Aug. 4, 2009), which issued within the 180 day window, which is terminally disclaimed to the '862 patent. *See* discussion *infra* Part II.I.

[78] Complaint at 8, Novartis AG v. Kappos, No. 10-CV-01138 (D.D.C. July 6, 2010).

[79] *Id.*

[80] *Id.* at 2-3.

malpractice, we imagine, as many would have been expected to be aware of the controversy relating to the calculation of patent term adjustments.

It is interesting to note that the PTO provides only a high level view of statistics relating to petitions to the Director of the PTO.[81] The number of petitions relating to PTAs and patent term extensions are available for fiscal years (October 1-September 30, each year) for 2005–2009.[82] In 2005–2007, the number of petitions ranged from 608 to 687, but dipped to 476 in 2008, and rose to 1613 in 2009.[83] When these numbers are compared to the numbers of utility patents granted in calendar years 2008 (158,424) and 2009 (167,801), it is clear that the actual frequency of petitions filed each year relating to PTAs or extensions is very low (approx. 0.3% – 1%).[84] There is no easy way to identify patents having these types of petitions using any of the publicly-accessible or commercially-available databases, so the ability to identify specific patents in court cases challenging PTA determinations provides interested practitioners with the first opportunity to examine common issues and patterns of delay in a large sample of patents.

II. ANALYSIS

A. Detailed Statistical Analysis of PTA Progeny Cases

We analyzed 179 Federal District Court cases filed against the Director or Acting Director of the PTO from September, 2008 through July, 2010, where the plaintiffs were seeking to have the court reconsider the PTA of one or more of their recently-issued patents calculated by the PTO. Table A5 provides a brief summary of the cases, listing the party names, case identification information, and the filing date of each case. Table A6 lists key information about the parties and the patents listed in each case.[85]

We attempted to characterize many of various types of delay attributable to the PTO or to the applicant to get a better understanding of common factors and patterns behind requests for larger PTAs. While a detailed analysis of every PTA case and its final disposition is beyond the scope of this paper, it is possible to determine the scope of the problem by reviewing the types of arguments made in the initial complaints filed by the applicants, which point out errors made by the PTO or the

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[81] U. S. PAT. & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2009 137 (2009), *available at* http://www.uspto.gov/about/stratplan/ar/2009/2009annualreport.pdf.

[82] *Id.*

[83] *Id.*

[84] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, PATENT COUNTS BY CLASS BY YEAR tbl.A1-1, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.htm#PartA1-1 (last updated Apr. 20, 2010).

[85] We included all PTA cases filed between September 2008 and July 2010, including the original Wyeth case filed in 2007 concerning two related patents, even though 38 of the 225 patents analyzed issued more than 183 days (taking into account weekends and holidays) prior to the filing of the complaint. Eighteen of these cases were filed by Bristol-Myers Squibb in two consolidated cases, and one, filed by Tepha, Inc., concerns a patent that issued in April, 2006, four years prior to the filing of their complaint. Many of the complaints filed in June and July 2010, notably by Novartis, involve "old" patents.

applicant in determining the PTA calculated at the time a patent issues.[86] Better knowledge of common types of delay would simplify our formulas for the calculation of PTAs, and facilitate the development of business strategies that minimize Applicant Delays, and maximize terms, of patents held by our clients or their competitors.

B. Subject Matter Bias Towards Pharmaceutical and Biotechnology Inventions

It is clear by glancing at the party names and titles in Table A5, that many of the PTA progeny cases were filed by companies and universities with recent patents relating to drug products. Subject matter bias is illustrated in Table A6, which shows a pivot table, segregating all of the patents by broad technology categories, and their primary U.S. patent class.[87] About 89% of the patents relate to technologies of interest to the biotechnology and pharmaceutical industries, generally classified as chemical (26%) or drugs and medical (64%), with about 7% relating to computers and communications, and about 3% relating to electrical, mechanical, or other technologies.

The bias is striking if you compare the actual frequency to the expected frequency of patents in these classes for all patents that issued in 2009.[88] In our sample, 39 of 225 patents (17%) were in primary class 424, and 76 (34%) were in class 514. In 2009, patents designated as belonging to primary class 424 occurred at a frequency of 1.09%, while those in class 514 occurred at a frequency of 2.08%. The ratio of actual/expected frequencies, representing bias, were 15.1 for class 424 and 17.9 for class 514.

A detailed analysis of products or processes disclosed or claimed in the patents listed in Table A6 may be warranted by competitors, licensees, and investors having a strong interest in a particular technology area cited in these cases. The limited timeframe for challenging PTA calculations under *Wyeth*, opened a unique window into business strategies for these industries, forcing institutions to identify key technologies to the public, long before they might otherwise be recognized.[89]

Before filing a complaint in federal court, a potential plaintiff must consider the amount of PTA to be gained, the cost of legal services, the potential likelihood that the patent will be in force through its normal expiration date, and the value of the adjusted patent and related patents to the institution or its licensees at that time.[90] Financial considerations may not be the dominating factor here, as Bristol-Meyers Squibb filed several consolidated complaints, listing 25 patents in this period, while

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[86] *See* Table A7 *infra* and accompanying text.

[87] *See* Bronwyn H. Hall, Adam B. Jaffe & Manuel Trajtenberg, *The NBER Patent Citation Data File: Lessons, Insights and Methodological Tools* (Nat'l Bureau of Econ. Research, Working Paper No. 8498, 2001). The high-level technological categories and subcategories listed in Table A7 are adapted from the National Beuro of Economic Research. More information is available at http://www.nber.org/patents.

[88] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, PATENT COUNTS BY CLASS BY YEAR tbl.A1-1, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.htm#PartA1-1 (last updated Apr. 20, 2010).

[89] 35 U.S.C. § 154(b) (2006); Wyeth v. Kappos, 591 F.3d 1364, 1366 (Fed. Cir. 2010).

[90] *See* discussion *infra* Part II.

Pfizer filed complaints listing only three patents.[91] A detailed evaluation of the products and processes claimed in these patents and their economic impact on the pharmaceutical industry is ongoing.

C. Comparison of Simple and Complex Cases

We classified the PTA cases into two general groups: simple and complex. Over 50%, characterized as simple, involved scenarios where the total PTO and Applicant Delays could be determined from the PAIR database, and we could easily characterize and independently verify the type and amount of delays assigned to particular categories listed in 37 C.F.R. §§ 1.703 and 1.704.[92] The remainder, which we characterized as complex, include those having one or more RCEs,[93] applications taking priority to international applications entering the United States for examination under 35 U.S.C. § 371, notices of appeal,[94] missing parts before examination,[95] or those involving filing of documents after a NOA.[96] Cases where there appear to be mistakes made by applicants in their complaints, or by the PTO in their calculations, with respect to date range arithmetic were also characterized as complex to facilitate our analysis. Nearly all of the cases having RCEs were categorized as complex, for example, as many of these appear to have mistakes with respect to date range calculations affecting the amount of B delay and AB overlaps used in the formulas noted above.[97]

Table A7, summarizes our statistical analysis of A, B, C, and Applicant Delays noted in all 225 of the PTA progeny cases, providing minimum, maximum, mean, median, mode, standard deviation, and fractional distribution for various types of delays. A detailed analysis of specific types of delays is provided in subsequent sections.

D. Common Sources of A Delay

Large A delays, where the PTO took longer than 14 months to issue a FOAM, were found in nearly all of the 225 cases we examined, with the median being 492 days, and average, minimum, and maximum being 496.9, 27, and 1287 days,

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[91] *See* Hall, Jaffe & Trajtenberg, *supra* note 87; U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, PATENT COUNTS BY CLASS BY YEAR tbl.A1-1, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.htm#PartA1-1 (last updated Apr. 20, 2010). Note, however, that 18 of the 25 patents listed in consolidated cases filed by Bristol-Meyers Squibb appear to be for patents that issued more than 180 days prior to the filing of complaints in the Federal District Court.

[92] 37 C.F.R. §§ 1.703–1.704 (2010).

[93] 35 U.S.C. § 132(b).

[94] 37 C.F.R. § 41.31 (explaining a patent owner can appeal by filing notice of appeal with the PTO and pay the requisite fee).

[95] *Id.* § 1.53(f) (explaining that a patent applicant will be issued notice and time to cure the defect of missing materials in its patent application in order to prevent the application's abandonment).

[96] *Id.* § 1.312.

[97] *See* discussion *infra* Part II.F.

respectively. A histogram illustrating the distribution of 14 Month ("Mo") A delays under 1.703(a)(1) is shown in Figure 4 (n=225).

Generally, when a 14 Mo A delay is longer than 22 months (3 years minus 14 months), it begins to overlap with the start of the B delay period. At that point, the cumulative PTA is offset by the amount of overlap between the A and B periods. We found that 32 of 225 (15%) patents analyzed had 14 Mo A delays which were greater than or equal to than 669 days (22 months x approx. 30.44 days/month).[98] These long A delays directly contribute to the accumulation of large B delays, noted in the complaints and appeal briefs debated by the parties and judges as policy considerations not met by the "plain language" of the statute in the *Wyeth v. Dudas* and *Wyeth v. Kappos* decisions. Minimizing this initial examination delay will go a long way towards accelerating prosecution, which was a primary goal of Congress in drafting the American Inventors Protection Act of 1999.[99]

Another common A delay is failure to issue a second or subsequent OA within four months from the filing of a response to the previous OA. We found that 67/225 (30%) of all cases examined had at least one 4 Mo A delay under 1.703(a)(2) or (3), and seven had two or more.[100] The median amount of the first 4 Mo examination delay was 28 days, and the second was 36 days.

A delays compensating the applicant for failure to issue a patent within 4 months from receiving payment of the issue fee under 1.704(a)(6) were less common. These occurred in 43 (19%) of the cases, and the median amount of delay was 52 days. A delays under 1.704(a)(4), relating to a favorable decision after appeal to the BPAI or an OA after a notice of appeal, occurred in at least 14 cases (discussed in more detail below).

E. Common Sources of Three Year Pendency B Delay

Nearly all of the PTA progeny cases we analyzed involved disputes with the PTO over calculations of PTA involving B delay (222 of 225 cases), measured from a date beginning 3 years plus 1 day after the application filing date. As noted above, the application filing date for these purposes can differ depending on whether the application is a U.S. national application being examined under 35 U.S.C. § 111(a) or

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[98] The difference between BPS and APS over the four year span from 1/1/2005 to 1/1/2009, which includes one leap year, ranges from 669 days to 673 days, with median and average being 671 and 670.7 days, respectively. Slightly different results are obtained when the Microsoft Excel DATE, YEAR, MONTH, and DAY functions are used to perform date calculations, compared to the EDATE function, which provides the expected results, noted above.

[99] Q. Todd Dickinson, Acting Comm'r, U.S. Pat. & Trademark Office, Presentation at the Washington Law School's Symposium on Reducing Patent Prosecution Costs Through an International Patent System: Reducing Patent Prosecution Costs: United States Legislative Developments (1999) (transcript available at http://www.law.washington.edu/casrip/symposium/Number5/pub5atcl19.pdf).

[100] 37 C.F.R. § 1.703(a)(2)–(3). Given the amount of data, we did not distinguish between responses which were replies to non-final office actions or similar requests under 1.704(a)(2) and replies to final office actions under 1.704(a)(3). The delays reported in the data fields available under the PTA tab in PAIR are not specified with sufficient detail, and we generally did not note whether a reply was in response to a final or non-final office action, since the starting and ending events for both were similar, with identical offsets of four months.

an international application entering the United States for examination under 35 U.S.C. § 371.[101] The full B delay period ends on the date the application issues as a patent, which may be shortened by any of the four types of truncating or intervening events specified in 37 C.F.R. § 1.703(b)(1)–(4).[102] Truncating events prevent further accumulation of B delays through the issue date, while intervening events permit resumption of B delay after an intervening A or C delay period (shifting the period type from a B period to an A or a C period and back to a B period of delay).[103] The B delay may also be interrupted by a period where no delay is assessed.

Further complicating B delay analysis is the requirement to offset A and C delays by the amount that a B delay overlaps an A or a C delay under 37 C.F.R. § 1.703(f).[104] Table 2 shows the frequency of cases where a single 14 month A delay, or a 14 Month A delay in combination with other A delays was observed, and whether any of the A delays overlap with any portion of the B delay.

Table 2
Analysis of A and B Delay Overlaps (n=225)*

Class	A does not overlap B	A overlaps B
14 Mo A (125 total)	104 (46.2%)	21 (9.3%)
14 Mo A + other A (100 total)	36 (16.0%)	64 (28.4%)

*Percentages do not add up to 100% due to rounding.

The most common event which truncates the B delay is the filing of an RCE, which occurred in 97 of 225 (43%) cases. When an RCE is involved, the B delay period is the length of the full B delay period, noted above, minus the period from the filing date of the RCE through the Issue Date.

Unfortunately, many applicants appear to miscalculate the proper B delay when an RCE is involved, by using a B period starting date that is 3 years, instead of 3 years and 1 day, after the application filing date. If there is a 14 month A delay that overlaps with the B delay, and the applicant has the wrong B period start date, the overlap between the A and B delays is also off by 1 day, but in the opposite direction, and the two errors offset each other. If there is no overlap, the 1 day B delay counting error propagates throughout the remaining calculations.

To better understand the source of B delay counting errors, we evaluated each of the cases having one or more RCEs during prosecution. Our preliminary analysis suggests that at least 75 of 97 (70%) RCE cases had date counting errors, if we

[101] 35 U.S.C. §§ 111(a), 371 (2006).
[102] 37 C.F.R. § 1.703(b)(1)–(4).
[103] 35 U.S.C. § 154
[104] 37 C.F.R. § 1.703(f).

assumed that 14 month A delays were properly calculated by the PTO.[105] When we reviewed the complaints for those cases in detail, we noted that many applicants incorrectly describe and misapply, or correctly describe but misapply, the rules for B delay specified in 37 C.F.R. § 1.703(b). The PTO is not without fault here either, as several RCEs can be filed during the course of prosecution. When this occurs, the first RCE is used to determine when a B delay is truncated. In several cases, the PTO or the patentee missed the first RCE, leading to an improper calculation of the total B delay.[106]

Filing appeals complicates matters further by invoking provisions which relate to multiple overlapping periods.[107] Unlike RCEs, which truncate only B delay, appeals may affect A, B, and C delays, and permit resumption of B delay after a subsequent event which terminates the appeal. The relevant regulations with type of delay, and net effect (±), are shown below *[emphasis added]*:

> A(+) 1.703(a)(3) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with § 1.113(c) [*reply to a final rejection or action with cancellation of, or appeal from the rejection of, each rejected claim*] was filed and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.
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> A(+) 1.703(a)(4) The number of days, if any, in the period beginning on the day after the date that is four months after the date an appeal brief in compliance with § 41.37 of this title was filed and ending on the date of mailing of any of an examiner's answer under § 41.39 [*reply to appeal brief*] of this title, an action under 35 U.S.C. § 132 [*rejection, objection, requirement*], or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.
>
> A(+) 1.703(a)(5) The number of days, if any, in the period beginning on the day after the date that is four months after the date of a final decision by the Board of Patent Appeals and Interferences or by a federal court in an appeal under 35 U.S.C. § 141 or a civil action under 35 U.S.C. §§ 145 or 146 where at least one allowable claim remains in the application and ending on the date of mailing of either an

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[105] Data on file with author.

[106] *See, e.g.*, Complaint, Celldex Research Corp. v. Kappos, No. 10-00035 (D.D.C. Jan. 8, 2010; Complaint, The Kitasato Inst. v. Kappos, No. 10-00333 (D.D.C. Jan. 8, 2010); U.S. PAT. & TRADEMARK OFFICE, DEP'T OF COMMERCE, APPLICATION NO. 09/851,614, PATENT TERM ADJUSTMENT PETITION (July 28, 2009); U.S. PAT. & TRADEMARK OFFICE, DEP'T OF COMMERCE, APPLICATION NO. 10/363,484, PATENT TERM ADJUSTMENT PETITION (Sept. 8, 2009); U.S. PAT. & TRADEMARK OFFICE, DEP'T OF COMMERCE, APPLICATION NO. 11/101,593, PATENT TERM ADJUSTMENT PETITION (Feb. 15, 2010).

[107] 35 U.S.C. § 154 (b)(1)(C).

action under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.

B(-) 1.703(b)(4) The number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. § 134 and § 41.31 of this title and ending on the date of the last decision by the Board of Patent Appeals and Interferences or by a federal court in an appeal under 35 U.S.C. § 141 or a civil action under 35 U.S.C. § 145, or on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first, if the appeal did not result in a decision by the Board of Patent Appeals and Interferences.

C_3(+) 1.703(e) The period of adjustment under § 1.702(e) is the sum of the number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. § 134 and § 41.31 of this title and ending on the date of a final decision in favor of the applicant by the Board of Patent Appeals and Interferences or by a federal court in an appeal under 35 U.S.C. § 141 or a civil action under 35 U.S.C. § 145.

Careful examination of these regulations reveals that A delays under 1.703(a)(3), (4), or (5) may overlap each other. For example, in 1.703(a)(3), "a reply in compliance with § 1.113(c) [*reply to a final rejection or action with cancellation of, or appeal from the rejection of, each rejected claim*]" is usually filed at the same time as a notice of appeal specified under 35 U.S.C. § 134 and 37 C.F.R. § 41.31.[108] The terminating event under 1.703(a)(3) is an action under 35 U.S.C. § 132, or a NOA under 35 U.S.C. § 151, whichever occurs first.[109] If an applicant then goes on to file a compliant appeal brief, and the examiner takes longer than four months to prepare a reply or a NOA, additional A delay will be awarded under 1.703(a)(4). Note that the two regulations are different, with 1.703(a)(4) referring to a compliant appeal brief, and 1.703(a)(3) referring to a reply to a final rejection or action involving appeal of each rejected claim. If the case is appealed to the BPAI or a federal court and at least one allowable claim remains after review, more A delay will be awarded under 1.703(a)(5), if the PTO takes longer than four months after the BPAI or a federal court issues a final decision. In 1.703(e), C_3 delay can accumulate for the period beginning with the notice of appeal to the BPAI through the date of a final decision in favor of the applicant by the BPAI or a federal court. If the BPAI or a federal court issues a final decision in favor of the applicant, the 1.703(e) delay will overlap any 1.703(a)(3-5) delay that may have occurred.

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[108] 35 U.S.C. § 134; 37 C.F.R. §§ 1.703(a)(3), 41.31.
[109] 35 U.S.C. §§ 132, 151; 37 C.F.R. § 1.703(a)(3).

In 1.703(b)(4), B delay is interrupted, or split, from the time a notice of appeal is filed, through the date of the last decision by the BPAI or by a federal court, or on the date of mailing of reply, or a NOA, "whichever occurs first, if the appeal did not result in a decision" by the BPAI or a federal court.[110] In any event, B delay can accumulate after termination of the appeal, as it was interrupted from the filing of the notice of appeal through the terminating event, and not truncated, as is the case for RCEs.

Note the difference between the A and the C delays under these regulations. Under 1.703(a)(3), (4), or (5), A delay is awarded if an examiner takes longer than four months to act following a notice of appeal, a compliant-appeal brief, or decision by the BPAI or a federal court, where at least one allowable claim remains.[111] C delay for the entire period is awarded if a decision by the BPAI or a federal court in favor of the applicant is final, and the examiner is not in control of the appeal.

To maximize PTA, an appeal should be filed rather than an RCE. The appeal delay period can be characterized as a C delay, and failing that, an A delay, so that patterns of delay starting 3 years and 1 day after the application file date could be B-A-B, B-A-A-B, or B-C-B. Filing an RCE instead of an appeal, perhaps for economic or time considerations, will provide a truncated B delay, but may result in a patent that issues much earlier by comparison, due to the backlog of cases before the BPAI.

Applicants who consider days at the end of the term to be more valuable than those at the beginning of the term, such as in the pharmaceutical and biotechnology industries, may benefit from filing an appeal rather than an RCE because an appeal preserves PTO delay, maximizing the PTA granted when a patent issues. The lower cost of filing an RCE compared to an appeal, taking into account attorney time, will be insignificant to many drug companies, compared to the reward of longer patent term at the peak of economic value for many drug products. Delaying prosecution through the appeals process may also benefit an applicant, where regulatory delays prevent sales of a product until approval, which are factored into patent term extensions under 35 U.S.C. § 156 that are appended to the normal 20 year term and the PTA. We found fourteen cases involving appeals as noted in Table 3.

Table 3
Patents Involving Appeals

Filing Date Docket No. Parties	U.S. Patent	Summary
2009-01-16 2009cv00112 Syntonix Pharmaceuticals	7,404,956	Four entries in PTA PAIR description relating to appeals: Notice of Appeal filed 7/25/2007; Request for Pre-Appeal Conference filed 7/25/2007; Preappeals Conference Decision - Reopen Prosecution on 8/27/2007; and Mail Appeals Conference Reopen Prosec. on 8/28/2007. Complaint does not mention 38 day A delay for appeal or a 66 day A delay relating to payment of

[110] 37 C.F.R. § 1.703(b)(4).
[111] *Id.* § 1.703(a)(3)–(5).

Filing Date Docket No. Parties	U.S. Patent	Summary
		the issue fee. The 38 day delay appears to be calculated by the PTO as four months from the date of an amendment after final rejection filed by the applicant (from 5/22/2007 to 9/22/2007) through the date of the NOA on 10/30/2007. The 38 day delay appears to be an A delay under 1.703(a)(3) measured from the day the amendment after final rejection was filed, with an intervening advisory action mailed on 7/12/2007 before a notice of appeal was filed on 7/25/2007. The overall pattern of delays would appear to be A-B-A-B, with the 38 day A delay for the appeal interrupting the B delay and only the 66 day issue fee A delay overlapping the B delay.
2009-03-13 2009cv00487 Geron	7,425,448	Complex case with 14 entries in PTA PAIR description relating to appeals. First entry is a Notice of Appeal, filed 10/10/2006, and the last entry is Mail BPAI Decision on Appeal-Reversed, on 4/28/2008. The entire period recorded in PAIR as a PTO delay of 567 days. The complaint does not characterize the appeal delay, but the applicants included it in their calculations as A delay, which when added to a 523 day 14 Mo A delay totaled 1090 days that was offset by a 567 day overlap between A and B delay and 153 days of Applicant Delay. Entire period appears to qualify as C delay under 1.703(e), because the appeal was successful, and not as A delay, so the pattern of delays would be A-B-C-B, with the B delay interrupted by the C delay, instead of having the appeal delay characterized as A delay which overlaps the B delay.
2009-07-17 Squibb 2009cv01330 Bristol-Meyers Squibb	7,455,835	Complex case involving two RCEs and a terminal disclaimer to an application which was expressly abandoned at a later date. A notice of appeal was filed on 5/2/2005, more than 7 months before the first RCE was filed on 12/5/2005. No other events in PAIR relating to appeals. Complaint does not acknowledge the notice of appeal, but the amount of B delay requested appears to be calculated using the first of the two RCEs as a terminating event. PAIR also indicates a 77 day Applicant Delay for late filling of a miscellaneous paper,

Filing Date Docket No. Parties	U.S. Patent	Summary
		which was not mentioned in the complaint.
2009-12-28 2009cv02425 Paratek Pharmaceuticals	7,553,828	Complex case where applicants filed a notice of appeal on 2/5/2008, 21 days before filing an RCE on 2/26/2008. Complaint characterized the 21 day period as part of a 511 day period (including a 490 day period from the RCE date through the issue date) as time to be subtracted from the maximum possible B delay period, none of which are listed in PAIR. None of the A delay provisions of 1.702(a)(3)–(5) appear to apply, but under the B delay provisions of 1.703(b)(4) and with the provisions of 1.703(b)(1) relating to RCEs, the entire period of time from the filing of the notice of appeal through the issue date would be excluded from time contributing to B delays.
2010-03-12 2010cv00416 Mount Sinai School of Medicine of NY University	7,588,768	Complex case where applicants filed a notice of appeal on 11/14/2007, nearly 5 months before filing an RCE on 4/11/2008. No other events are found in PAIR that relate to appeals. The notice of appeal was mentioned in complaint, but the requested B delay period was calculated using the RCE date as a terminating event. Applicants also disputed the PTO's characterization and calculation of Applicant Delay under 1.704(c)(10) for one of two papers filed after the notice of allowance.
2010-04-09 2010cv00575 Human Genome Sciences	7,601,351	Complex case involving dispute over characterization of Applicant Delays and a 45 day delay under 1.703(b)(4) for filing a notice of appeal before the notice of allowance.
2010-04-12 2010cv00580 Tepha	7,025,980	Complex case attempting to claim PTA where complaint was filed 4 years after the patent issued, involving small A delay of 29 days with maximum B delay of 940 days (net 198 days), interrupted by C3 delay of 742 days for successful appeal. The Plaintiffs did not assert equitable tolling, takings, or due process as reasons for the PTO's decision to not calculate PTA for patents that issued more than 180 days before March 2, 2010.
2010-05-26 2010cv00892	7,323,495	Complex, terminally disclaimed to 11/129,338, and Notice of Appeal not mentioned in complaint

Filing Date Docket No. Parties	U.S. Patent	Summary
Magnachem		(See Table 8)
2010-06-17 2010cv01023 Japan Tobacco	7,635,704	Complex § 371 case, involving a dispute over the period from filing of a Notice of Appeal to the NOA.
2010-06-21 2010cv01041 Logitech Europe	7,636,805	Complex case involving a dispute over the characterization of an Applicant Delay, two RCEs, plus a Notice of Appeal.
2010-07-06 2010cv01138 Novartis	7,112,673	Complex case involving an "old" § 371 application, where it appears that a Notice of Appeal was filed on 5/8/2006, but not used in B delay calculations by the applicants; that would shorten the B delay from 415 days to 278 days.
2010-07-06 2010cv01138 Novartis	7,265,089	Complex case involving an "old" patent, where it appears the Notice of Appeal was filed before an RCE, but not used in B delay calculations by the applicants.
2010-07-09 2010cv01173 Kuros Biosurgery	7,247,609	Complex case involving an "old" patent having a Notice of Appeal and disputes over the characterization of B delay and Applicant Delay.

F. Asymmetries in the Treatment of 14 Month A and Three Years Plus One Day B delays for Applications Processed under 35 U.S.C. § 371

As noted in Formulas 5–11, international applications entering the U.S. national stage under 35 U.S.C. § 371 are treated differently than U.S. applications filed under 35 U.S.C. § 111(a). In many cases, the A and B Clock Start dates for § 371 applications are the same, but there may be times when the B Clock Start ("BCS") date is before the A Clock Start ("ACS") date. Table 4, summarizes our analysis, which shows that the ACS and BCS are the same for all 111(a) patents and 18 (8%) 35 U.S.C. § 371 patents, and that the BCS is earlier than the ACS for 25 (11%) 35 U.S.C. § 371 patents.

Table 4
Analysis of Patents Comparing A and B Clock Start Dates (n=225)

Class	ACS = BCS	BCS < ACS
35 U.S.C. § 111(a)	182 (84%)	0 (0%)
35 U.S.C. § 371	18 (8%)	25 (11%)

The effect of a later ACS is to shorten the time between the A period start ("APS") date and the B period start ("BPS") date. What is not clear, however, is whether a § 371 application, which is delayed for some reason, is put into the queue for examination at the same point, or at a later point, compared to an application that was fully compliant upon filing. If it loses position in the queue, then it is more likely that a long 14 month A delay will overlap the start of the B delay period, because the gap between the APS and BPS is less than 22 months plus 1 day (36 months plus 1 day minus 14 months) when the ACS and the BCS start on the same date, as is the case for all 35 U.S.C. § 111(a), and half of the 35 U.S.C. § 371 applications as noted in Table 4. This gap ranges from 669–673 days, with the median amount 671 days.[112] Table 5 provides a list of the 23 patents where the BCS date was before the ACS date, and the difference between the BPS and APS was less than 671±2 days.

Table 5
Difference Between BPS and APS Dates for § 371 Applications Processed Having a BCS Date Before the ACS Date Where ΔBPS–APS Is Less than 671±2 Days

U.S. Patent	ΔBPS-APS (Days)
7,635,704	122
7,635,701	300
7,576,221	304
7,531,174	311
7,576,135	326
7,517,965	414
7,446,175	435
7,419,999	439
7,514,437	448
7,578,874	463
7,470,792	499
7,560,484	505
7,541,493	518
7,348,353	526
7,629,341	529
7,521,212	534
7,531,326	550
7,438,901	634
6,878,721	638
7,094,781	648
7,569,337	666
7,112,673	666
7,205,302	667

[112] *See supra* note 100 and accompanying text.

One interesting case occurred in U.S. Patent No. 7,560,484 (filed Aug. 28, 2001) (assigned to The Kitsasato Inst.) where the BCS (2/28/2003), was over five months (165 days) before the ACS (8/12/2003).[113] Over this period the applicants filed an Information Disclosure Statement ("IDS") and supporting documents, plus an oath or declaration, which were accepted by the PTO on 8/12/2003 as being fully-compliant with the requirements of § 371, particularly § 371(c)(1), (2), and (4).[114] The difference between the BPS and the APS in this case, was 505 days, which is much shorter than the normal situation where 671 (±2) days are needed for a 14 month A delay to begin to overlap the start of the B period when the ACS and BCS start on the same date. The 14 Mo A delay was 610 days, as a result of waiting for papers to cure the non-compliant status, when the restriction requirement was mailed on 6/14/2006, and the overlap between the end of the 14 Mo A delay and the start of the B delay was 106 days.[115] This case was also complicated by the PTO's initial use of the § 371(c) date instead of the§ 371(b)/(f) date for the BCS date, the filing of two RCEs, the first of which the PTO missed in its initial calculation, and a dispute over the characterization of an Applicant Delay period.

An applicant filing a specification under 35 U.S.C. § 371 which does not comply with all of the requirements of § 371(c) (filing of international application with translation, if required, filing of any amendments, international pre-examination report, with translations, if required, payment of national fees, and filing of oath or declaration (with late fee surcharges, if needed)), appears to be put at a disadvantage compared to an applicant filing the same documents under 35 U.S.C. § 111(a).[116] If an oath was missing, for example, the § 371 applicant would find that the start of the A clock start ("ACS") was delayed after the B clock start ("BCS") full compliance date. The PTO or Designated/Examination Office ("DO/EO") would send a notice of missing parts, usually with a deadline for responding of two months after the mailing date of the notice.[117] When all papers are received, with appropriate fees for late filing, the applicant would receive a notice of acceptance by the PTO as the designated/elected office, specifying the dates for compliance with all the requirements of § 371 and § 371(c).

If the same application is filed under 35 U.S.C. § 111(a), the PTO will mail a notice of missing parts, with the same deadline for responding within two months after the mailing date of the notice. If the 111(a) applicant complies in the same timely fashion as the § 371 applicant, the 111(a) applicant will not be penalized by having the ACS shifted after the BCS. The net effect is that the § 371 applicant may lose 14 Month A delay compared to the 111(a) applicant. If a non-compliant 111(a) application and a non-compliant § 371 application were both filed on the same date and issued on the same date, with similar delays, the PTA awarded to the patent

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[113] Note also that use of the Excel EDATE function is required to properly do date calculations involving addition or subtraction of months, such as adding thirty months to the priority date of 8/31/2000, which is 2/28/2003, compared to the incorrect result of 3/3/2003 obtained using a combination of DATE, YEAR, MONTH, and DAY functions.

[114] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION No. 10/363,484, NOTICE OF ACCEPTANCE OF APPLICATION (Aug. 29, 2003).

[115] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION NO. 10/363,484, OFFICE ACTION COMMUNICATION, (June 14, 2006).

[116] 35 U.S.C. §§ 111(a), 371(c) (2006).

[117] MPEP, *supra* note 13, § 506.02.

based on the 111(a) application will be longer than that awarded to patent based on the § 371 application. The period of non-compliance for the § 371 application is lost compared to the 111(a) application, which would accumulate 14 Month A delay during the same period.

It is not clear whether the asymmetrical treatment of applications filed under 35 U.S.C. § 111(a) and 35 U.S.C. § 371 was intended by Congress when it drafted 35 U.S.C. § 154(b).[118] A fairer approach would be to require full compliance with application formalities before examination could proceed, so that the ACS and the BCS would always begin on the same date, and that the difference between the A Period Start and the B Period Start would never be less than 671±2 days.

G. Common Sources of Applicant Delay

Applicant Delays under 1.704(b) for failure to respond within 3 months of the mailing date of a notice or action issued by the PTO are quite common. We found 165 (73%) cases having at least one delay under 1.704(b) (designated here as 1.704(b)[1st]), with a median delay of 58 days, and a minimum, maximum, and mean delays of 1, 278, and 53.5 days, respectively. Unlike other delays which occur once or rarely, Applicant Delays under 1.704(b) can occur several times during prosecution. We also found 97 cases with at least two occurrences of Applicant Delay under this rule, and 48, 22, 13, and 5 cases with at least 3, 4, 5, or 6 occurrences, respectively, of Applicant Delay. Table 6 summarizes features of ten cases having notably large Applicant Delays.

Table 6
Top 10 Patents Having Large Applicant Delays

Filing Date Docket No. Parties	U.S. Patent	Total Applicant Delay	Summary
2008-12-23 2008cv02225 Alexion Pharmaceuticals	7,435,412	612 Days (1.68 years)	Four periods of Applicant Delay for replies in excess of three months under 1.704(b) including a large delay of 278 days for missing parts before examination, and four characterized as supplemental replies or other papers filed under 1.704(c) after a reply was filed.

[118] *See generally* H.R. REP. No. 103-826, pt. 1, at 8–9, *reprinted in* 1994 U.S.C.C.A.N. 3773, 3777–78. (reporting on the reasons for patent term adjustments); S. REP. NO. 103-412, at 228–31 (reporting on the reasons for patent term adjustments).

Filing Date Docket No. Parties	U.S. Patent	Total Applicant Delay	Summary
2008-09-05 2008cv01542 Napo Pharmaceuticals	7,341,744	595 Days (1.63 years)	Four periods of Applicant Delay for replies in excess of three months, one characterized as a supplemental reply or other paper, and a 350 day delay for revival of an abandoned application.
2009-12-04 2009cv02306 Neuralstem	7,544,511	556 Days (1.52 years)	Four periods of Applicant Delay for replies in excess of three months, and three characterized as a supplemental replies or other papers, including two, for 176, and 315 days.
2010-01-13 2010cv00064 Celldex Research	7,560,534	552 Days (1.51 years)	Five periods of Applicant Delay for replies in excess of three months, and two characterized as a supplemental replies or other papers.
2009-04-23 2009cv00754 Biogen Idec Ma	7,442,370	532 Days (1.46 years)	Two periods of Applicant Delay for replies in excess of three months, and two characterized as a supplemental reply or other papers, and a 329 day delay for abandonment and revival during pre-examination processing.
2009-07-17 2009cv01330 Bristol-Meyers Squibb	7,455,835	523 Days (1.43 years)	Five periods of Applicant Delay for replies in excess of three months, and one characterized as a miscellaneous paper filed after the mailing of a notice of allowance.
2009-12-11 2009cv02354 Thrombogenics	7,547,435	443 Days (1.21 years)	Six periods of Applicant Delay for replies in excess of three months, and two characterized as a supplemental reply or other papers.
2009-03-12 2009cv00480 Medarex	7,425,541	413 Days (1.13 years)	Six periods of Applicant Delay for replies in excess of three months, including a 14 day period for filing a late response to a notice to file missing parts, which the PTO missed.

Filing Date Docket No. Parties	U.S. Patent	Total Applicant Delay	Summary
2010-01-08 2010cv00035 Celldex Research	7,563,876	392 Days (1.07 years)	Six periods of Applicant Delay for replies in excess of three months. The PTO acknowledged four errors in the calculation of Applicant Delay, including mischaracterization of two periods relating to sequence listings as untimely, and overlooking a reply in excess of three months, plus a supplemental reply.
2009-03-20 2009cv00540 Biogen Idec	7,429,644	384 Days (1.05 years)	Three periods of Applicant Delay for replies in excess of three months, and two characterized as supplemental replies or other papers.

Without knowing the reason for any of the delay periods noted in Table 6, it is clear that the cumulative effect of the Applicant Delays would contribute to a *great economic loss for the patent owner and any licensee*. If any of these patents provide a right to exclude others from making, using, selling, offering to sell, or importing[119] an FDA-approved drug product, the loss of term could be substantial. If the product brought in $1 million/day, the loss of term would range from just under $400 million to over $600 million for the patents listed above. Multiplying those amounts by 10 for a blockbuster product, or even dividing these amounts by 1,000, provides dollar amounts that are substantial by any measure.

The "mailbox" or "safe-harbor" provisions provided in the last sentence of 37 C.F.R. § 1.703(f) provide both incentives and penalties that must be considered when filing a response.[120] Applicants taking a full six months to respond within the statutory deadline for responding to an OA will be assessed for a delay that is 3 months from the original deadline, plus the time between the response was filed and the time it was received by the PTO. In many cases, this will be 90–92 days, if a response is filed electronically by the applicant. In U.S. Patent No. 7,544,362 (filed Feb. 22, 20006), however, the applicant mailed a response with a certificate of mailing, that was received by the PTO a week later, which was considered timely-filed, but resulting in a 97 day Applicant Delay penalty.[121] Payment of a fee for the three month extension to reply was also required in this case.[122]

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[119] *See* 35 U.S.C. § 271(a).

[120] 37 C.F.R. § 1.703(f) (2010) ("[t]he date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.").

[121] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION No. 11/359,334, PATENT TERM ADJUSTMENT PETITION (July 20, 2009). Applicant Delay can be larger than three months (approx. ninety days) if it was filed on the six month statutory deadline for filing a response due to the provision in 1.704(f). 37 C.F.R. § 1.704(f). If a response is timely submitted electronically or by fax, and received on the last day of a response period the Applicant Delay will be three months. *Id.* If it was mailed using a certificate of mailing and received on a later date, the response will be

Applicants are not assessed a PTA reduction for responding to requests which are due less than 3 months from the mailing date of a request, even though they may be required to pay an extension fee to do so. For example, an applicant responding to a restriction requirement with a one month deadline that files a response after the deadline, but before the end of the third month, will be required to pay for a two month extension fee, but is not assessed for a PTA delay within this period. A response to a restriction requirement at the 6 month statutory deadline, for example, will be assessed for a PTA reduction for days beyond the third month (approx. 90–92 days), plus a five month extension fee.

Another common reduction occurs when an applicant files a supplementary response after a response to a PTO notice or action is filed. In many cases, these are IDSs, listing patents and other published documents that may be relevant and worthy of consideration by the examiner.[123] These delays are assessed a day-for-day reduction starting from the time the original response was filed, to the date the supplementary response is received.[124]

Applicants are not assessed this reduction under 37 C.F.R. § 1.704(d), however, if the applicant files a certified statement, that all the documents cited in the IDS were first cited in a communication from a foreign patent office in a related application, and that the communication was received by an individual designated in 1.56(c) less than 30 days before the IDS was filed.[125]

It is also important to note that the PTO currently requires IDSs filed through EFS-Web to be submitted on PTO Form SB/08a (01-10).[126] This form includes the statements under 37 C.F.R. § 1.97(e) and a checkbox to indicate which statements an applicant wishes to make, but omits the required statement under 37 C.F.R. § 1.704(d).[127] To take advantage of the 30 day safe harbor created by C.F.R. § 1.704(d), an applicant must check the box labeled "See attached certification statement" on PTO Form SB/08a (01-10) and attach a separate paper including a certified statement pursuant to 37 C.F.R. § 1.704(d) that all the documents cited in the IDS were first cited in a communication from a foreign patent office in a related

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timely, but the applicant will be penalized for the extra time it took to for the letter to be sent to and be processed by the PTO, not counting weekends and holidays. *Id.*

[122] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION No. 11/359,334, PATENT TERM ADJUSTMENT PETITION (July 20, 2009).

[123] 37 C.F.R. § 1.704(d).

[124] *Id.*

[125] *Id.* 37 C.F.R. § 1.704(d) relates to the thirty day "safe harbor" provision to avoid PTA reductions, which is distinguishable from that provided under 37 C.F.R. § 1.97(e)(1), which provides a certification that the items listed in the IDS were cited in a communication from a foreign patent office in a counterpart application no more than three months prior to the filing of the IDS. 37 C.F.R. § 1.704(d); 37 C.F.R. § 1.97(e)(1). The latter rule is used to avoid paying a fee when an IDS is filed after a first OA, or to force consideration of an IDS after a final OA or NOA with payment of a fee; *see* 37 C.F.R. § 1.97(e)(1).

[126] MPEP, *supra* note 13, § 609.07 ("As of May of 2002 IDSs may be submitted to the Office via the EFS."); U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, FORM PTO/SB/08A, INFORMATION DISCLOSURE STATEMENT BY APPLICANT (2010), http://www.uspto.gov/patents/process/file/efs/guidance/updated_IDS.pdf. Additional information on the PTO's EFS-Web can be found at http://www.uspto.gov/patents/process/file/efs/index.jsp.

[127] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, FORM PTO/SB/08A, INFORMATION DISCLOSURE STATEMENT BY APPLICANT (2010), http://www.uspto.gov/patents/process/file/efs/guidance/updated_IDS.pdf.

application and the communication was received by an individual designated in 1.56(c) less than 30 days before the IDS was filed.[128] Note also, that the 30 day period under 37 C.F.R. § 1.704(d) is not extendable.[129]

A statement under 37 C.F.R. § 1.704(e) must state either: (1) that each item of information contained in the IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (2) that no item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in § 1.56(c) more than three months prior to the filing of the IDS.

H. Applicant Delays Assessed for Missing Parts Before Formal Examination

Large reductions can be assessed before formal examination, if an applicant is slow in responding to a request to supply or correct missing parts of an application, as noted in Table 7. Missing signatures on oaths and non-compliant sequence listings are common. Notable examples include U.S. 7,341,744 where the applicants were assessed a 350 day Applicant Delay for abandonment and revival of an application, and U.S. 7,435,412, where the applicant was assessed a 278 day Applicant Delay for missing parts for failure to supply a signed oath, compliant sequence listings, and compliant drawings.[130] An 821 day period for missing parts was assessed against the applicant in U.S. 7,442,381, until it was determined that a sheet of drawings was misplaced in the PTO after the application was filed.[131] The net effect of relabeling the Applicant Delay, in this case, however, may not fully compensate the applicant under current PTA statutes and regulations. It is clear from these examples, that regular monitoring of PAIR is required to ensure that the PTO has received all documents in response to a notice to file missing parts, and prompt filing of compliant documents are both required to avoid large assessments for Applicant Delays that occur before formal examination.

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[128] *Id.*

[129] 37 C.F.R. § 1.704(d).

[130] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION No. 09/712,033, PATENT TERM ADJUSTMENT HISTORY (entry of July 3, 2003), http://portal.uspto.gov/external/portal/pair/ (search for application no. 09/712,033; click tab labeled "Patent Term Adjustments"); U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION No. 10/379,151, PATENT TERM ADJUSTMENT HISTORY (entry of May 20, 2004), http://portal.uspto.gov/external/portal/pair/ (search for application no. 10/379,151; click tab labeled "Patent Term Adjustments").

[131] U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, APPLICATION NO. 10/804,331, PATENT TERM ADJUSTMENT HISTORY (entry of Mar. 28, 2007), http://portal.uspto.gov/external/portal/pair/ (search for application no. 10/804,331; click tab labeled "Patent Term Adjustments").

Table 7
Patents Assessed Applicant Delays for Missing Parts Before Formal Examination

Filing Date Docket No. Parties	U.S. Patent	Total Applicant Delay	Summary
2007-08-17 2007cv01492 Wyeth	7,189,819	335 Days	Dispute over characterization of a 107 day Applicant Delay for missing parts under 1.704(b),(c)(7); later reassessed as two delays of 38 and 69 days.
2008-09-05 2008cv01542 Napo Pharmaceuticals	7,341,744	595 Days	Applicants assessed with a 350 day Applicant Delay for abandonment and revival of application before application noted as complete on 3/27/2003, but filing/371(c) date set as 11/14/2000.
2008-12-12 2008cv02174 Medarex	7,387,776	261 Days	Applicants assessed with a 53 day Applicant Delay for missing oath or declaration.
2008-12-23 2008cv02225 Alexion Pharmaceuticals	7,435,412	612 Days	Applicants charged with a 278 day delay for missing parts before examination specified in three pre-exam formalities notices, including non-compliant oath or declaration, sequence listing, and drawings.
2009-04-21 2009cv00730 Alphavax	7,442,381	102 Days	Dispute over characterization of Applicant Delay, originally calculated to be 923 days, which included 821 day period for missing parts, (from mailing date of a Notice of Incomplete Non-Provisional Application to the date the filing fee was allegedly paid by the Plaintiff). Petition decision of 8/1/2006 however, indicated a sheet of drawings was subsequently misplaced in the PTO after filing of the application on 3/19/2004, even though PTA tab in PAIR still shows the 821 day period of Applicant Delay.
2009-11-25 2009cv02238 Bayhill Therapeutics	7,544,669	238 Days	Applicants assessed a 1 day Applicant Delay for missing part for an oath or declaration.

Filing Date Docket No. Parties	U.S. Patent	Total Applicant Delay	Summary
2010-02-12 2010cv00213 Andromeda Biotech	7,576,177	178 Days	Applicants assessed 90 day Applicant Delay for missing parts, relating to missing oath or declaration, sequence listing not provided in computer readable form, and statement indicating printed content in sequence listing identical to that provided on computer readable form, application complete on 4/21/2005, filing date 7/30/2004.
2010-03-12 2010cv00412 Enzon Pharmaceuticals	7,589,190	262 Days	Applicants assessed 90 day delay for missing parts, including missing oath or declaration, and non-compliant drawings.
2010-03-26 2010cv00504 Pfizer	7,595,325	115 Days	Applicants assessed 31 day delay for missing a signature on an oath or declaration.
2010-05-07 2010cv00743 Georgetown University	7,615,355	33 Days	Complex case involving dispute over 35 U.S.C. § 371 start dates and Notification of Missing Requirements relating to a declaration by the inventors.
2010-05-28 2010cv00894 University of Massachusetts	7,625,559	61 Days	Complex case where applicants assert multiple PTO errors including a 61 day Applicant Delay overlooked for missing parts, contend that a 43 day delay assessed for supplemental reply was in error because it was expressly requested by the examiner, and that the 14 Mo A delay was 688, not 465, days, because the PTO vacated the first restriction requirement.

I. The Effect of Terminal Disclaimers

Table 8 summarizes features of eight patents which had notices in their file history indicating that the patent would be terminally disclaimed to the expiration date of an issued patent, or to the expiration date of a patent issuing from a disclaimed application. Under 37 C.F.R. § 1.703(g), no patent "the term of which has been disclaimed beyond a specified date, shall be adjusted under § 1.702 and this

section beyond the expiration date specified in the disclaimer."[132] If the expiration date of the related patent (including any PTA and patent term extension under 35 U.S.C. § 156 of the related patent) is before the expiration date of the disclaimed patent without the PTA, then there is no benefit from the PTA awarded to the disclaimed patent. If the expiration date of the disclaimed patent with its PTA would be after that of the related patent, then the expiration date should be equal to that of the related patent, in effect truncating the PTA awarded to the disclaimed patent.

Table 8
Patents Having Terminal Disclaimers to Other Applications or Patents

Filing Date Docket No. Parties	U.S. Patent	Disclaimed to Application or Patent	Summary
2007-08-17 2007cv01492 Wyeth	7,179,892	7,189,819	Terminal disclaimer filed to an application which later issued as the '819 patent.
2009-02-17 2009cv00309 Purdue Pharma	7,413,748	7,270,830	Terminal disclaimer filed to the '830 patent, which was adjusted by 678 days. Expiration date without disclaimer would be the normal term plus 970 days, so the applicants assert the terminal disclaimer limits expiration date to the normal term plus 678 days, which is longer than the 537 days calculated by the PTO using its pre-*Wyeth* formulas.
2009-07-17 2009cv01330 Bristol-Meyers Squibb	7,455,835	09/877,987 10/419,008	Two terminal disclaimers filed, one to the '987 application, which was later expressly abandoned, and one to the '008 application, which has not issued. The two disclaimers were not mentioned in the District Court complaint.

[132] 37 C.F.R. § 1.703(g).

Filing Date Docket No. Parties	U.S. Patent	Disclaimed to Application or Patent	Summary
2010-01-13 2010cv00064 Celldex Research	7,560,534	10/903,191	Terminal disclaimer filed to the '191 application, which has not issued. Plaintiffs assert the terminal disclaimer is irrelevant, because the projected expiration date of a patent issuing from '191 application is longer than the expected term of the '534 patent of 5/8/2021 + 582 days, or 12/11/2022.
2010-01-25 2010cv00141 International MultiMedia	7,567,779	11/211,041	Terminal disclaimer filed to the '041 application, which has not issued. The terminal disclaimer was not mentioned in the District Court complaint.
2010-01-29 2010cv00166 Idera Pharmaceuticals	7,569,554	7,517,862	Terminal disclaimer disclaims the term of the '554 patent, which would extend beyond the expiration date of the '862 patent, listed in the same court complaint. Idera asserts expiration date of '862 patent is 1/25/2024 + 1,174 days, or 1/10/2026, and the adjustment requested for the '554 patent is 1275 days, which would extend beyond the expiration date of the '862 patent. Idera seeks a PTA of 606 days, which is the time between the unextended expiration date of the '554 patent, and the adjusted expiration date of the '862 patent. Idera also asserts that the decision in *Wyeth v. Kappos* constitutes "a change of law sufficient to invoke the doctrine of equitable tolling" to bring suit regarding the PTA recalculation request for the '862 patent, even though it issued more than 180 days before the complaint was filed on 1/29/2010.

Filing Date Docket No. Parties	U.S. Patent	Disclaimed to Application or Patent	Summary
2010-02-26 2010cv00312 Biogen Idec Ma	7,582,299	7,531,174	Terminal disclaimer disclaims the term which would extend beyond the expiration date of the '174 patent, which is subject to separate court action seeking review of the PTO's determination of PTA.
2010-03-03 2010cv00348 Merck Serono	7,585,840	7,638,480	Terminal disclaimer disclaims the term which would extend beyond the expiration date of the '480 patent, which issued on 12/19/2009. The application which lead to the '840 patent was a continuation-in-part of the application which lead to the '480 patent, so the unadjusted patent terms of both would expire on 3/26/2023. Petition for reconsideration filed for the '480 patent, which if granted would provide an additional 1062 days of adjustment. Petition for '840 patent requested 923 additional days of adjustment, so the terminal disclaimer has no net effect, because the adjusted expiration date of the '840 patent, if granted, expires before the adjusted expiration date of the disclaimed '480 patent.

Filing Date Docket No. Parties	U.S. Patent	Disclaimed to Application or Patent	Summary
2010-04-30 2010cv00673 Schering	7,612,058	11/158,429	Complex case involving terminal disclaimer filed to the '429 application, which was abandoned, although the complaint states the '058 patent is not subject to a disclaimer of term. Dispute over two potential Applicant Delays, including a request for refund, filed before the notice of allowance, and a comment responding to the examiner's reasons for allowance, filed after the notice of allowance.
2010-05-26 2010cv00892 Magnachem	7,323,495	11/129,338	Complex case involving an "old" patent which issued more than 180 days before the complaint was filed, which was terminally disclaimed to the '338 application. It appears as if 115 days of B delay was subtracted from Notice of Appeal (not mentioned in the complaint) through the NOA.

Our analysis of these and unrelated cases suggests that the current PTO practice is to not limit the PTA to a value which would set the expiration date to a value equal to the adjusted expiration date on the disclaimed patent as requested in U.S. Patent No. 7,413,748 or U.S. Patent No. 7,569,554. Instead, it appears as if certificate of corrections and issued patents are being processed so that the value of the PTA on the face of a patent having a terminal disclaimer is the value expected using the post-*Wyeth v. Kappos* formulas. This practice would require the public to inspect not only the PTA printed on the face of a patent and all certificates of correction, but also require an analysis of the front page and file history of all related patents to determine all of their expiration dates. Chronological analysis, from the earliest patent to issue, to the last to issue, would be required.

J. Tacking Rules, When Patent Term Provisions Under 35 U.S.C. §§ 154 and 156 Overlap

Complicating the determination of an expiration date are statutes, rules, and court decisions which provide term modifications when different statutes overlap. The "tacking rules" are spread throughout various laws and decisions, making it difficult to understand and apply them all to a given patent.

- A patent having a terminal disclaimer, linking expiration of a patent to the expiration of an earlier, related, commonly-owned patent filed under 35 U.S.C. § 253 to overcome an obvious-type double patenting rejection during prosecution, is not eligible for a PTA *which extends beyond the term of the disclaimed patent*, as provided under 35 U.S.C. § 154.[133]

- Pharmaceutical patents having terminal disclaimers, however, can be extended under 35 U.S.C. § 156 to reflect delays due to periods of regulatory review before and after a patent is granted.[134]

- Pharmaceutical patents eligible for PTAs under 35 U.S.C. § 154 are also eligible for patent term extensions under 35 U.S.C. § 156.[135]

Complicating the application of these three rules, are cases when the expiration date of a parent patent is incorrectly determined, affecting the expiration date of related patents that issue at a later date. The incorrect determination can be due to errors by the applicant, or by misinterpretation of rules by the PTO, regulatory agencies, or the courts, as noted above. Expiration date errors become amplified then, *affecting the perceived value* of a family of related patents. Billions of dollars may be at stake, for example, when deadlines to request patent term extensions, or patent term adjustments, are missed, or their values are incorrectly determined.[136] It's no wonder then, that expiration dates are prime targets for discussion in board rooms, court proceedings, policy-making bodies, and the media.

K. Shortfalls of the Analysis

We recognize several deficiencies in our statistical analysis of these cases. First, there is a substantial cost for the legal services needed to prepare and file petitions with the PTO and papers in Federal District Courts, so only applicants with a strong willingness to commit resources to secure larger PTAs, where there is a strong belief they will add value to a portfolio of patents, will endure the current process to seek reconsideration of the factors used to calculate a PTA. The bias towards patents relating to chemical and pharmaceutical inventions is strong evidence of this, where development and regulatory delays pressure drug companies to recover expenses incurred before a patent is filed, and in the years before a product is approved for sale by the FDA.

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[133] 37 C.F.R. § 1.703(g).

[134] *See, e.g.*, King Pharm., Inc. v. Teva Pharm. USA, Inc., 409 F. Supp. 2d 609, 611 (D.N.J. 2006); Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 1318 (Fed. Cir. 2007).

[135] 35 U.S.C. § 156 (2006).

[136] *See generally* Diana Goldenson, *A Day Late and a Few Million Dollars Short*, 27 NATURE BIOTECH. 538 (2009) (analyzing the last 100 applications filed that have been granted patent term extensions and noting that applicants, the PTO, and the FDA often made errors in calculating the deadlines for filing patent term extension requests). Of the last 100 filed applications that have been granted PTE, 78 had a miscalculated deadline, and at least 13 patents were improperly extended based on late-filed PTE requests. *Id.*

The scenarios described in PTA cases filed in a Federal District court may not reflect situations where applicants filed petitions seeking recalculation of a PTA with PTO, but did not proceed to the next step to file a court case, if they were dissatisfied with the petition decision provided by the PTO, or if there is no decision within 180 days of issuance. There is no easy way to identify and determine the number of patents having petitions filed during prosecution where the applicant requested recalculation of a PTA. Searching the PTO PAIR database one patent at a time to find enough examples to build a representative dataset would be tedious. The magnitude of timely-filed requests to recalculate a PTA, however, could be estimated by determining the increase in Certificates of Correction issued in 2009 and 2010, compared to the median value of Certificates issued in the years before 2009.

Many of the large pool of applicants that could benefit from the decision in *Wyeth v. Kappos*, who did not file petitions with the PTO, may not have been aware of the decision, or, if they were, could not justify the time or cost of filing additional petitions or court cases after their patent issued would waive their right to receive additional PTA. Applicants or their attorneys, who were not diligent in monitoring the progress of applications in view of these developments, may be out of time to request reconsideration of a PTA due to strict enforcement of deadlines set forth in 35 U.S.C. § 154(b)(4)(A) and 37 C.F.R. § 1.705(b),(d).[137]

To accelerate our analysis, IDSs were considered as supplemental replies categorized as entries under 1.704(c)(8) in our tables, even though 1.704(d) states that an IDS could be categorized under 1.704(c)(6), (8), (9), or (10) depending on the state of examination (before or after the FOAM, after a NOA). A similar approach was used to facilitate the characterization of A delays. Situations where the PTO took more than 4 months to respond to a reply to a final OA under 1.703(a)(3) were categorized as A delays under 1.703(a)(2) for responding to a reply to a rejection, objection, requirement, or a NOA. The specific nature of a supplemental reply or a response to a reply is not disclosed on the PTA tab under PAIR, and we did not record the starting or ending dates of events categorized as these types of delays in our database. In five cases, we could not easily assign an Applicant Delay to a specific category. These were classified, instead, as delays reported as 1.704(other) in the statistical summary provided in Table A8. The PTO, however, should have data on all types of examination and Applicant Delays, and we hope they will be able to provide a more detailed analysis of the types of delays *and error rates* used in PTA calculations for all of the affected patents that issued from 2008 to 2010.

III. PRACTICE TIPS TO MAXIMIZE PATENT TERMS

Applicants need to take several steps to maximize the terms of patents in their portfolio in view of the decision concerning the calculation of PTAs after *Wyeth v. Kappos*. These include: (1) evaluate applications about to issue to see if they would benefit from a recalculation of a PTA; (2) evaluate portfolios for recently-issued

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[137] 35 U.S.C. § 154(b)(4)(A); 37 C.F.R. § 1.705(b),(d). Following the CAFC's decision in *Wyeth v. Kappos*, the PTO temporarily rescinded the 37 C.F.R. § 1.705(d) period for patents that had issued within the period beginning 180 days before and ending prior to March 2, 2010 for filing a request for recalculation. PTO Interim Procedure, *supra* note 21.

patents that would benefit from PTA recalculations; (3) evaluate license agreements and patent portfolios to determine the impact of an altered expiration date on the expiration date and perceived value of related patents cited in an agreement, particularly provisions relating to payment of up-front fees and royalties; and (4) modify procedures to accelerate prosecution of pending applications. A convenient summary of the recommended actions discussed below is provided in Table 9 at the end of this section.

A. Evaluate the Prosecution History of Applications About to Issue

Applicants and their representatives should timely challenge the determination of a PTA printed on an NOA or issue notification, seeking clarification of events that contribute to delay periods which award too much or not enough PTA. Examining the electronic file history, and in some cases hard copy records, will be required, noting key dates which trigger and terminate events considered in various A, B, C, and Applicant Delay periods.

We noted several examples where the PTO mischaracterized, overlooked, or lost documents filed by an applicant. PTO document transmission and receipt records need to be compared to those maintained by the applicant to ensure that they agree, taking into account the different mailbox rules for (1) timely filing a response, and (2) receiving a response by the PTO for the purposes of determining a PTA. Special attention should also be paid to applications filed under 35 U.S.C. § 371 and those involving RCEs or notices of appeal.

Applicants should also notify the PTO when too much PTA has been awarded, as difficulties may arise later, if a third party seeks to challenge a patent, or otherwise limit its term, during litigation or other proceedings. We noted earlier, however, that in a policy change implemented on July 20, 2010, that if an applicant or patentee mails the PTO a letter asserting that too much PTA was awarded, the PTO will place the letter in the file of the application or patent without further review.[138] 35 U.S.C. § 154(b)(4)(B) states that "[t]he determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent," but the statute and regulations do not address issues relating to a post-issue challenge by a third party, although Certificates of Correction requested by a third party have been suggested as one possibility.[139] Under 37 C.F.R. § 1.705(f), however, the PTO will not consider submissions or petitions by a third party concerning PTAs under 35 U.S.C. § 154(b).[140] One good example, might be a licensee seeking to lengthen a term of a patent overlooked by a licensor. 35 U.S.C. § 154(b)(4)(B) is silent with respect to a time limit for challenges by a third party,

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[138] *See* Treatment of Letters Stating that the USPTO's Patent Term Adjustment Determination is Greater than What the Applicant or Patentee Believes is Appropriate, 75 Fed. Reg. 42,079 (July 20, 2010).

[139] *See Third-Party Oppositions to PTA Calculations?*, PATENTLYO (Feb. 4, 2010, 6:06 AM), http://www.patentlyo.com/patent/2010/02/opposing-pta-calculations.html.

[140] 37 C.F.R. § 1.705(f) ("No submission or petition on behalf of a third party concerning patent term adjustment under *35 U.S.C. §. 154(b)* will be considered by the Office. Any such submission or petition will be returned to the third party, or otherwise disposed of, at the convenience of the Office.").

unlike 35 U.S.C. § 154(b)(4)(A), which places a 180 day limit on a dissatisfied applicant to appeal a determination of PTA in court. A third party, then, might be able to challenge a PTA determination, including statements made by the applicant or the PTO to support a recalculation or to assert related violations of the duty of candor and good faith, at any point during the term of a patent. We note that a duty of disclosure, candor, and good faith is required in patent term extension proceedings under 37 C.F.R. § 1.765, and a similar duty, although unstated, might also apply to proceedings relating to PTAs.[141]

B. Evaluate Portfolios for Recently Issued Patents That Would Benefit from PTA Recalculations

The procedures noted above should also be used to review the prosecution history for patents which issued less than two months ago. A patent may be eligible for review under the expedited no-fee review for simple *Wyeth*-type B delay errors, if it issued in the six month period prior to March 2, 2010.[142] Reconsideration of all other types of errors require the filing of a petition and payment of fees under 37 C.F.R. § 1.705(d).

For patents which issued between two months and 180 days ago, consider filing a case in Federal District Court (D.D.C.) to request reconsideration of the calculation of a PTA.[143] If necessary, challenge provisions of the statute and the regulations in court which unfairly award too much or not enough PTA for a patent. Owners of patents which issued over 180 days ago may be out-of-luck, as the PTA on those patents may no longer be challenged.[144] It is not clear whether plaintiffs asserting doctrines of equitable tolling, unjust taking, or due process violations will prevail in their lawsuits against the PTO to obtain larger PTAs for "old" patents where the complaint was filed outside the 180 day window specified in the statues and the regulations. If any of them succeed, however, the PTAs of hundreds of thousands of patents may need to be recalculated, dwarfing the effort put forth by clients, their attorneys, and the PTO to address PTA issues for patents deemed to be eligible for reconsideration so far, under the interim post-*Wyeth* recalculation rules.

C. Evaluate License Agreements and Patent Portfolios to Determine the Impact of an Altered Expiration Date on the Expiration Date of Related Patents

A variety of provisions in licensing agreements may be linked to the expiration date of one or more patents in a portfolio. The termination of financial obligations, for example, may be tied to the expiration date of the last patent to expire in a licensed portfolio, even though confidentiality provisions remain in force to a later

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[141] 37 C.F.R. § 1.765; *see also* MPEP, *supra* note 13, § 2762 (providing more details on the "Duty of Disclosure in Patent Term Extension Proceedings").

[142] *See* PTO Interim Procedure, *supra* note 21.

[143] *See, e.g.*, Plaintiff's Amended Complaint, Idera Pharm. Inc. v. Kappos, No. 10-0166 (D.D.C. Jan. 29, 2010).

[144] *See Questions and Answers Related to Wyeth v. Kappos*, *supra* note 56, at 4.

date.[145] Upfront payments, milestone payments, and royalty rates are usually tied to the *perceived value* of one or more patents, which is linked to their *expiration date.*[146]

Licensors, licensees, and investors all tie value to the expiration date of a patent in their agreements. Knowledge of the expiration date is critical for allocating resources by patent owners, and their competitors, to meet business goals. If the expiration date of one patent in a portfolio is incorrect, the expiration date and perceived value of related patents may also be incorrect. Business plans that rely on the expiration date of patent owned by an institution or its competitors may need to be altered to properly allocate resources for research and development using funds obtained from product sales, investors, banks, or government sources.

D. Modify Procedures to Accelerate Prosecution of Pending Applications Which Will Lead to Longer Periods of Legal Protection After a Patent Issues

If an invention is in an area typically subject to long pendency times, applicants and their attorneys should pay close attention to deadlines to respond to requests for information or preparing a response to a formal OA. Inventors and their legal representatives should be timely informed of deadlines for responding to PTO notices, and the impact of failure to meet deadlines on the potential term and value of a patent.

Documents which are likely to be characterized by the PTO as supplemental replies should be avoided whenever possible, because they directly impact the assessment of Applicant Delays. Delays assessed for submission of IDS documents can be avoided by careful planning, by filing an IDS when a response to an OA is filed, whenever possible.

Formal requirements should be completed before the NOA is mailed. Communications after the NOA is mailed should be minimized, whenever possible, to avoid triggering delay periods requiring review and assessment of Applicant Delays.

Table 9
Top Practice Tips for Maximizing Patent Terms After *Wyeth v. Kappos*

Period	Tip	Description
Before Filing	Inform Client	Communicate with client providing clear notice that delays can be assessed against the applicant reducing any potential PTA assessed to the PTO. Reductions in PTA affect not only the term, but also the perceived value of a patent to its owners, investors, licensees, and their competitors.

[145] *See* Georgia-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970).
[146] *Id.*

Period	Tip	Description
During Prosecution	Missing Parts	Whenever possible, try to avoid filing incomplete applications, which result in delayed application filing dates or in assessments of Applicant Delay for failure to file missing parts within prescribed time limits.
		Monitor progress of pre-examination processing on the PAIR website to ensure documents are received and properly characterized in a timely fashion.
	Filing Responses to Office Actions	File responses within three months from the mailing date of an OA to avoid a reduction for Applicant Delays.
	Supplemental Replies	Avoid filing supplemental replies to minimize day-for-day reductions after a response is filed.
	Consider Appeals over RCEs	Consider Filing Appeals (which interrupt B Delays) instead of RCEs (which truncate B delays), balancing the cost and time needed for appeals with the need for expedient prosecution using RCEs.
Notice of Allowance	Post-Allowance Audit	Perform post-allowance audit confirming that internal data records (dates, numbers, strings) match data recorded in PTO and third party databases.
		Independently review the basis for the expected PTA calculated by the PTO, comparing data from internal physical records and electronic records with electronic records (continuity, file history, PTA records) available on the PTO PAIR system. Challenge any A or C delays that don't depend on the issue date, and any Applicant Delays that occur before the NOA, before paying the issue fee.
After Issuance	Post-Grant Audit	Perform post-grant audit using criteria noted above. Independently review the basis for the PTA calculated by the PTO. Timely-challenge any unresolved PTA issues raised at NOA, plus any new delays that occurred after the NOA within 2 months from the issue date of the patent.

Period	Tip	Description
	After an Adverse Decision on PTA Reconsideration	Timely-challenge issues that are unresolved in post-grant reconsideration requests in Federal District Court within 180 days from the issue date of the patent.

IV. PROPOSALS AND CONCLUSION

The complexity associated with calculating the term of a utility patent is quite clear. Filing dates and issue dates, with offsets for delays outside the permitted scope of time to respond to a rejection or request for information, periods for appeals to the PTO or a federal court, and accounting for overlapping periods of delay, make the process remarkably challenging. Analysis of a wide variety of documents, including the printed image and text versions of a patent, documents included or referenced in a file history, earlier-filed related applications, and documents sent to and from other agencies and federal courts, is required to ensure that all of the relevant dates are accounted for, and consistent, before calculating the expiration date of a patent modified by a statutory or terminal disclaimer, PTA, or patent term extension.

Careful reading and parsing of the statutes, regulations, petitions, complaints filed in Federal District Court, and court decisions relating to patent term adjustments, extensions, and terminal disclaimers dozens of times, lead us to conclude that these rules are confusing not only to applicants and their attorneys, but also to PTO officials. The high error rate resulting from the misinterpretation of starting and ending events for a variety of delay periods, the mischaracterization of documents filed by applicants, the improper calculation of application dates for applications entering the United States under 35 U.S.C. § 371, and far-too-common mistakes made in calculating the length of a delay period, have all contributed to unnecessary expenses and time lost by applicants and the PTO to apply the current rules for calculating a PTA. In the interest of simplicity and certainty, we would like to propose several actions to increase the clarity of PTA-related statutes and regulations and increase the transparency of factors considered and reported in PTA databases:

> The PTO should prepare and distribute illustrated fact sheets showing how to determine a PTA and how to challenge the PTA determined by the PTO at the time a NOA is made and when a patent issues, particularly for patents involving appeals. The program used to calculate PTA should be modified so that PAIR PTA reports (1) show every data field needed to calculate a PTA on a single page, particularly for international applications entering the United States under 35 U.S.C. § 371; (2) show when PTA date fields and calculation fields were created and last modified; and (3) characterize all PTO and Applicant Delays with references to the regulations and showing arrows, bars, or other indicators properly annotating the starting and ending dates for all A, B, C, and Applicant Delay periods. Use of dynamic waterfall charts and timelines of key events,

such as those shown in Figures 5 and 6, to illustrate the cumulative effect of different delay periods for a given patent, and to facilitate the comparison of PTA events for a group of patents, is highly recommended.

Congress should consider revisions that would eliminate asymmetry in the treatment of A and B delays, by having different start clocks (e.g., ACS, BCS) for applications entering the United States under 35 U.S.C. § 371 compared to U.S. applications being examined under 35 U.S.C. § 111(a), by making the ACS and BCS for 35 U.S.C. § 371 applications the same. Congress should also consider revisions that would eliminate the 3 month "mailbox" or "safe harbor" rule for PTA calculations, so that it is consistent with the "mailbox" rule used for timely filing replies to office rejections, objections, and requests. Applicant Delays for late replies would be assessed for all periods in which payment of an extension fee is required. Responses that are timely-filed and stamped with a certificate of mailing should not be assessed an Applicant Delay while they are in transit through the postal system. Revisions to 35 U.S.C. § 154(b) which would hold the PTO accountable for long delays in pre-examination processing similar to the adjustment provided for failure to respond within 4 months of a reply to an office action, should also be considered. These proposals, we believe, will stimulate both applicants, and the PTO, to pay attention to deadlines, causing office actions to issue sooner, and more responses to be timely-filed, accelerating prosecution and reducing overall pendency, from filing to issuance, by a great amount of time.

It is important to note that the multi-track examination initiative recently proposed by the PTO would require a modification of the regulations relating to PTAs.[147] In hearings held at the PTO on July 20, 2010, the AIPLA and the Intellectual Property Owners Association ("IPO") both questioned the proposed PTA provisions, particularly the determination of "aggregate average time" to the first office action, which is used in calculations to offset the PTA of applications in the delayed examination queue and some applications claiming priority to foreign

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[147] *See* Enhanced Examination Timing Control Initiative; Notice of Public Meeting, 75 Fed. Reg. 31,763–68 (June 4, 2010). Applications filed using a new Track 3 deferred examination process (an applicant-controlled, up to 30 month, queue prior to examination) would be more affected by these changes than applications filed using the Track 1 (accelerated examination) or Track 2 (default examination) queues. If a Track 3 applicant requests examination at month 30 and the aggregate average time to issue a first Office Action is 20 months, the proposed PTA reduction would be 10 months beginning on the expiration of the 20-month period and ending on the date on which the applicant requested examination to begin. *Id.* Applications in any of the three tracks that claim foreign priority would also be subject to offsetting reductions in PTA equal to the difference between the time an applicant submits all required documents up to 30 months after the filing of the application minus the aggregate average time to issue a first Office Action. *Id.* In Tracks 1 and 2, if a U.S. application claims priority to a prior-filed foreign application, which is abandoned prior to an action on the merits, the applicant must notify the PTO and request that the application be treated for examination queuing purposes as if the foreign priority had not been made. *Id.* Failure to notify the PTO within 3 months of the abandonment of the foreign application would an offset against a PTA as the PTO would not appreciate the need to treat the application as if first-filed in the PTO until such notice is given. *Id.*

applications in all examination queues.[148] It is not clear whether this refers to aggregate time across the entire examination corps, or whether this would be assessed across Technical Centers or Group Art Units. The IPO also stated that these rules could have unintended consequences, with a potential for gaming, and difficulties in distinguishing Applicant Delays from foreign office delays, and wondering if applicants would be able to contest the baseline PTA determined using an aggregate average time of a predetermined group.[149] We generally agree with these assertions, but strongly believe that proposals that lengthen or reduce patent terms should be vigorously debated and passed as statutes by Congress, first, giving the PTO more authority to set fees and establish regulations that reflect the true cost of accelerated, normal, and delayed examination procedures, while providing incentives to complete prosecution in a timely and efficient manner.

The public benefits when the expiration date of a patent is clear and certain. Competitors may introduce similar, if not identical, products or processes, and the patent owner, anticipating a decrease in revenue associated with its invention, can focus on improvements, adding features or reducing cost, that ultimately benefit the public. Understanding these complex rules is key to the development of scientific, legal, and business strategies that reward inventors, patent owners, and the public. Amending overly-complex statutes and regulations that are prone to misinterpretation, subject to disputes over the characterization of triggering and termination events, and frequent date calculation errors, may be required to reduce the substantial burden on technology innovators, and regulatory agencies that review and approve intellectual property rights limited in scope and term that benefit society in exchange for early public disclosure.

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[148] Public Meeting on Enhanced Examination Timing Control Initiative at the United States Patent and Trademark Office (July 20, 2010), http://www.uspto.gov/patents/announce/3-track_meeting_transcript.pdf.

[149] *Id.* at 75. It is also not clear whether the aggregate average time to the first office action would be determined as a monthly or yearly rolling average within a group, or determined on an artificial discontinuous basis (e.g., a preceding calendar or fiscal year), and how the aggregate average time to first office action would change over long periods of time.

APPENDIX

Table A1
Guaranteed Adjustments Under 35 U.S.C. § 154

Description	Examples of Delay	Statute or Regulation
A Delays (14-4-4-4 rule) Slow prosecution by the PTO provides a day-for-day adjustment for every day of delay throughout the slow periods.	• 14 months for a first office action. • 4 months to respond to a reply. • 4 months to issue a patent after the fee is paid. • 4 months to act on an application after the date of a decision by the Board of Patent Appeals and Interferences under § 134 *[relating to appeals by the patent applicant, patent owner or third party] or 135 [relating to interferences]* or a decision by a Federal court under § 141 [appeals from a BPAI decision], 145 *[civil action to obtain a patent]*, or 146 *[civil action in case of interferences]* in a case in which allowable claims remain in the application.	35 U.S.C. § 154(b)(1)(A)
B Delays (3-year pendency guarantee) Even if the PTO or the applicant is slow, an application must issue within a maximum of 3 years after filing, or a day-for-day adjustment is made to the term under a 20 years from filing rule.	Excluded from the 3-year maximum are several types of delay: • (i) any delay consumed by continued examination of the application requested by the applicant under § 132(b) (*RCE*); • (ii) any time consumed by a proceeding under § 135(a) *[interferences]*; any time consumed by the imposition of an order under § 181 *[secrecy orders]*, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or • (iii) any delay in the processing of the application by the PTO requested by the applicant except as permitted by paragraph (3)(C) *[delayed prosecution]*.	35 U.S.C. § 154(b)(1)(B)(i) 35 U.S.C. § 154(b)(1)(B)(ii) 35 U.S.C. § 154(b)(1)(B)(iii)
C Delays (Unavoidable delays) Unavoidable delays by the PTO or by the Applicant result in a day-for-day adjustment for each of the three types of fault-free delay.	Delays due to: • Any time due a proceeding under § 135(a) *[Interference proceeding]*; • The imposition of an order under § 181 [Review under government secrecy order delaying issuance of a patent]; or • Appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability *[Successful appeal of a rejected claim]*.	35 U.S.C. § 154(b)(1)(C) 37 C.F.R. § 1.702(c) 37 C.F.R. § 1.702(d) 37 C.F.R. § 1.702(e)

Table A2
Required Reductions in Calculating Adjustments Under 35 U.S.C. § 154

Detailed Description	Examples of Delay	Statute or Regulation
Required Reduction (Inaction Offsets for Applicant Delay) The period of adjustment of the term shall be reduced by a period equal to the time during which the applicant (by act or failure to act) failed to engage in reasonable efforts to conclude prosecution of the application.	Reduction bases listed in the statute and MPEP: The cumulative total of any periods in excess of 3 months that are taken to respond to a *notice* from the PTO making any rejection, objection, argument or other request, including: • Notice of incomplete nonprovisional application • Notice to file missing parts of an application • Notice of informal application • Notice to file corrected application papers, with filing date granted • Notice to comply with requirements for patent applications containing nucleotide sequences or amino acid sequence disclosures	35 U.S.C. § 154(b)(2)(C) 35 C.F.R. § 1.704(b) MPEP § 2732
	Reduction bases listed in the regulations: • Suspension of Action at the Applicant's request • Deferral of issuance of a patent at the Applicant's request • Abandonment of the application or late payment of the issue fee • Conversion of a provisional application to a nonprovisional application • Submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office Action or Notice of Allowance if the submission requires the PTO to mail a supplemental OA or NOA • Submission of a substantially complete reply having an inadvertent omission • Submission of an amendment or other paper (i) after a decision (by the Board of Patent Appeals and Interferences or a federal court, except for some decisions), but (ii) less than one month before the PTO mails an OA or NOA, if as a consequence, (iii) the PTO is required to mail a supplemental OA or NOA • Submission of 37 C.F.R. § 1.312 amendment or other paper after an NOA is mailed or given	35 C.F.R. § 1.704(c)(1)–(11)
	Papers submitted after an NOA that <u>do</u> trigger a reduction include: • Request for a refund • Status letter • Amendments under 37 C.F.R. § 1.312 • Late priority claims • Certified copy of a priority document • Drawings	1247 Off. Gaz. Pat. Office 111, 112 (June 26, 2001) 69 Fed. Reg. 21,707 (April 22, 2004)

Table A2
Required Reductions in Calculating Adjustments Under 35 U.S.C. § 154

Detailed Description	Examples of Delay	Statute or Regulation
	• Letters related to biological deposits • Oaths and declarations	
	Non-specific reduction bases recognized as conduct or inaction that interferes with the of the PTO to process or examine an application, even if it is not specifically addressed in the regulation or statute: • Applicant persists reconsideration in meritless petition under § 1.10 relating to date entitlement for paper filed by Express Mail • Parties to an interference obtain an extension for purposes of settlement negotiations which do not result in settlement, when scope of broadest claim in the application in condition for allowance is substantially the same as suggested or allowed by the examiner more than six months earlier • Late submission (after final rejection) by an applicant or practitioner of a statement to overcome rejection under § 103(a) if prior art reference is based on § 102(e), (f), or (g) under the § 103(c)(1) rule when the application and the § 103(a) prior art are commonly owned at the time the invention was made (or subject to an obligation of assignment to the same person).	MPEP § 2732
	Papers submitted after an NOA that do not trigger a reduction include: • Issue fee transmittal • Power of Attorney • Power to Inspect • Change of Address • Change of Entity Status • Response to Examiner's reasons for allowance or request to correct error or omission in NOA or notice of allowability • Letter relating to government interests	1247 Off. Gaz. Pat. & Trademark Office 111,112 (June 26, 2001)

Table A3
Determination of PTAs Under 35 U.S.C. § 154(b) Due to Examination Delay

§ 1.703 Period of adjustment of patent term due to examination delay.
(a) The period of adjustment under § 1.702(a) is the sum of the following periods:
(1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;
(2) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;
(3) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with § 1.113(c) was filed and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;
(4) The number of days, if any, in the period beginning on the day after the date that is four months after the date an appeal brief in compliance with § 41.37 of this title was filed and ending on the date of mailing of any of an examiner's answer under § 41.39 of this title, an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;
(5) The number of days, if any, in the period beginning on the day after the date that is four months after the date of a final decision by the Board of Patent Appeals and Interferences or by a federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145 or 146 where at least one allowable claim remains in the application and ending on the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first; and
(6) The number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued.
(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:
(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued;
(2)
(i) The number of days, if any, in the period beginning on the date an interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and
(ii) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension;
(3)
(i) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;
(ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 41.39 of this title in the application under secrecy order and ending on the date the secrecy order was removed;
(iii) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order was removed; and
(iv) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) of this chapter and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151;

Table A3
Determination of PTAs Under 35 U.S.C. § 154(b) Due to Examination Delay

and,
(4) The number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 41.31 of this title and ending on the date of the last decision by the Board of Patent Appeals and Interferences or by a federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145, or on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first, if the appeal did not result in a decision by the Board of Patent Appeals and Interferences.
(c) The period of adjustment under § 1.702(c) is the sum of the following periods, **to the extent that the periods are not overlapping**:
(1) The number of days, if any, in the period beginning on the date an interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and
(2) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension.
(d) The period of adjustment under § 1.702(d) is the sum of the following periods, **to the extent that the periods are not overlapping**:
(1) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;
(2) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 41.39 of this title in the application under secrecy order and ending on the date the secrecy order was removed;
(3) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order was removed; and
(4) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) of this chapter and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151.
(e) The period of adjustment under § 1.702(e) is the sum of the number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 41.31 of this title and ending on the date of a final decision in favor of the applicant by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.
(f) The adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. 154(a)(2). To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed. The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. The date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.
(g) No patent, the term of which has been disclaimed beyond a specified date, shall be adjusted under § 1.702 and this section beyond the expiration date specified in the disclaimer.

Table A4
Determination of PTAs Under 35 U.S.C. § 154(b) Due to Applicant Delay

§ 1.704 Period of adjustment of patent term due to applicant delay.
(b) With respect to the grounds for adjustment set forth in §§ 1.702(a) through (e), and in particular the ground of adjustment set forth in § 1.702(b), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph.
[Often occurs multiple times, e.g., 1st, 2nd, 3rd, etc.]
(1) Suspension of action under § 1.103 at the applicant's request, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date a request for suspension of action under § 1.103 was filed and ending on the date of the termination of the suspension;
(2) Deferral of issuance of a patent under § 1.314, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date a request for deferral of issuance of a patent under § 1.314 was filed and ending on the date the patent was issued;
(3) Abandonment of the application or late payment of the issue fee, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date of abandonment or the date after the date the issue fee was due and ending on the earlier of: (i) The date of mailing of the decision reviving the application or accepting late payment of the issue fee; or (ii) The date that is four months after the date the grantable petition to revive the application [manual adjustment required] or accept late payment of the issue fee was filed;
(4) Failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the mailing date of a notice of abandonment, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date two months from the mailing date of a notice of abandonment and ending on the date a petition to withdraw the holding of abandonment or to revive the application was filed;
(5) Conversion of a provisional application under 35 U.S.C. 111(b) to a nonprovisional application under 35 U.S.C. 111(a) pursuant to 35 U.S.C. 111(b)(5), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date the application was filed under 35 U.S.C. 111(b) and ending on the date a request in compliance with § 1.53(c)(3) to convert the provisional application into a nonprovisional application was filed;
(6) Submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or notice of allowance, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:(i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the date of mailing of the supplemental Office action or notice of allowance; or (ii) Four months [Manual adjustment required];
(7) Submission of a reply having an omission (§ 1.135(c)), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed;
(8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;
[Often occurs multiple times, e.g., 1st, 2nd, 3rd, etc.]

Table A4
Determination of PTAs Under 35 U.S.C. § 154(b) Due to Applicant Delay

(9) Submission of an amendment or other paper after a decision by the Board of Patent Appeals and Interferences, other than a decision designated as containing a new ground of rejection under § 41.50 (b) of this title or statement under § 41.50(c) of this title, or a decision by a Federal court, less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or supplemental notice of allowance, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of: (i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the mailing date of the supplemental Office action or notice of allowance; or (ii) Four months [manual adjustment required];
(10) Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of: (i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (ii) Four months [manual adjustment required]; ***[Can occur multiple times, e.g., 1st, 2nd, 3rd, etc.]*** and
(11) Further prosecution via a continuing application, in which case the period of adjustment set forth in § 1.703 shall not include any period that is prior to the actual filing date of the application that resulted in the patent [manual adjustment required].
(d) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable.
(e) Submission of an application for patent term adjustment under § 1.705(b) (with or without request under § 1.705(c) for reinstatement of reduced patent term adjustment) will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(10) of this section.

Table A5
Patents in Federal District Court PTA Cases Filed September, 2008–July, 2010

Plaintiff	Defendant	Docket No.	Filing Date	U.S. Patent	Issue Date
Wyeth, Elan Pharma Int'l, Ltd.	Dudas	1:2007cv01492	2007-08-17	7,179,892	2007-02-20
				7,189,819	2007-03-13
Napo Pharm., Inc.	Dudas	1:2008cv01542	2008-09-05	7,341,744	2008-03-11
Ironwood Pharm., Inc.	Dudas	1:2008cv01932	2008-11-07	7,371,727	2008-05-13
Solvay Pharm. GmbH	Dudas	1:2008cv02053	2008-11-28	7,381,729	2008-06-03
Biogen Idec, Inc.	Dudas	1:2008cv02061	2008-12-01	7,381,560	2008-06-03
Molecular Insight Pharm., Inc., Georgetown Univ.	Dudas	1:2008cv02065	2008-12-01	7,381,745	2008-06-03
Purac Biochem B.V.	Dudas	1:2008cv02067	2008-12-01	7,410,556	2008-08-12
Molecular Insight Pharm., Inc.	Dudas	1:2008cv02068	2008-12-01	7,381,399	2008-06-03
Eurand, Inc.	Dudas	1:2008cv02170	2008-12-12	7,387,793	2008-06-17
Medarex, Inc.	Dudas	1:2008cv02174	2008-12-12	7,387,776	2008-06-17
Alexion Pharm., Inc.	Dudas	1:2008cv02225	2008-12-23	7,393,648	2008-07-01
				7,396,917	2008-07-08
				7,399,594	2008-07-15
				7,408,041	2008-08-05
				7,414,111	2008-08-19
				7,427,665	2008-09-23
				7,435,412	2008-10-14
Bayer Bioscience GmbH, Max-Planck-Gesellschaft Zur Foderung der Wissenschaften EV	Dudas	1:2009cv00113	2009-01-15	7,402,420	2008-07-22
General Hospital Corp.	Dudas	1:2009cv00109	2009-01-16	7,367,341	2008-05-06
Syntonix Pharm., Inc.	Dudas	1:2009cv00112	2009-01-16	7,404,956	2008-07-29
Dyax Corp.	Doll	1:2009cv00243	2009-02-06	7,413,537	2008-08-19
Kabushiki Kaisha Hayashibara Seibutsu Kaguku Kenkyujo	Doll	1:2009cv00308	2009-02-17	7,414,038	2008-08-19
Purdue Pharma L.P.	Doll	1:2009cv00309	2009-02-17	7,413,748	2008-08-19
Alphavax, Inc.	Doll	1:2009cv00378	2009-02-25	7,419,674	2008-09-02
Glaxosmithkline Biologicals, S.A.	Doll	1:2009cv00398	2009-02-27	7,419,824	2008-09-02
Laboratoires Serono Sa	Doll	1:2009cv00407	2009-03-02	7,419,999	2008-09-02
Inotek Pharm. Corp.	Doll	1:2009cv00435	2009-03-05	7,423,144	2008-09-09
Medarex, Inc.	Doll	1:2009cv00480	2009-03-12	7,425,541	2008-09-16
Geron Corp.	Dudas	1:2009cv00487	2009-03-13	7,425,448	2008-09-16
Array Biopharma, Inc.	Doll	1:2009cv00502	2009-03-13	7,425,637	2008-09-16
Biogen Idec, Inc.	Dudas	1:2009cv00539	2009-03-20	7,427,403	2008-09-23
Biogen Idec, Inc.	Dudas	1:2009cv00540	2009-03-20	7,429,644	2008-09-30
Memory Pharm. Corp.	Doll	1:2009cv00575	2009-03-26	7,429,664	2008-09-30
Daido Metal Company, Ltd.	Doll	1:2009cv00628	2009-04-06	7,431,507	2008-10-07
Mason Ricardo Storm	Doll	1:2009cv00629	2009-04-06	7,432,978	2008-10-07
Institut National Des Sciences Appliquees (INSA)	Doll	1:2009cv00630	2009-04-06	7,439,049	2008-10-21
Novozymes Biopharma UK, Ltd.	Doll	1:2009cv00676	2009-04-10	7,435,410	2008-10-14
Gedeon Richter Vegyeszeti Gyar Rt	Doll	1:2009cv00684	2009-04-10	7,435,744	2008-10-14
Genmab A/S	Doll	1:2009cv00709	2009-04-17	7,438,907	2008-10-21
Accenture Global Services GmbH	Doll	1:2009cv00715	2009-04-20	7,440,906	2008-10-21
				7,457,762	2008-11-25
				7,457,763	2008-11-25
				7,461,008	2008-12-02
				7,469,219	2008-12-23
				7,502,744	2009-03-10
EBI Food Safety B.V.	Doll	1:2009cv00726	2009-04-20	7,438,901	2008-10-21
Alphavax, Inc.	Doll	1:2009cv00730	2009-04-21	7,442,381	2008-10-28

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Patents in Federal District Court PTA Cases Filed September, 2008–July, 2010

Plaintiff	Defendant	Docket No.	Filing Date	U.S. Patent	Issue Date
Biogen Idec Ma, Inc	Doll	1:2009cv00754	2009-04-23	7,442,370	2008-10-28
Hoffmann-La Roche, Inc.	Doll	1:2009cv00760	2009-04-24	7,442,776	2008-10-28
Biogen Idec Ma, Inc.	Doll	1:2009cv00792	2009-04-30	7,446,173	2008-11-04
Novartis AG	Doll	1:2009cv00804	2009-04-30	7,446,175	2008-11-04
Yeda Research & Development Co.	Doll	1:2009cv00820	2009-05-04	7,445,802	2008-11-04
Genentech, Inc.	Doll	1:2009cv00838	2009-05-06	7,449,184	2008-11-11
Medarex, Inc.	Doll	1:2009cv00902	2009-05-14	7,452,535	2008-11-18
Genentech, Inc.	Doll	1:2009cv00907	2009-05-15	7,452,539	2008-11-18
Glaxo Group, Ltd.	Doll	1:2009cv00908	2009-05-15	7,452,888	2008-11-18
Ohio State Univ. Research Found.	Doll	1:2009cv00960	2009-05-22	7,455,995	2008-11-25
Univ. of Massachusetts	Doll	1:2009cv01021	2009-06-01	7,459,547	2008-12-02
Astrazeneca AB	Doll	1:2009cv01037	2009-06-04	7,462,623	2008-12-09
Celgene Corp.	Doll	1:2009cv01080	2009-06-11	7,465,800	2008-12-16
Medarex, Inc.	Doll	1:2009cv01082	2009-06-11	7,465,446	2008-12-16
Palau Pharma, S.A.	Doll	1:2009cv01141	2009-06-22	7,468,376	2008-12-23
Arena Pharm., Inc.	Doll	1:2009cv01166	2009-06-26	7,470,699	2008-12-30
Human Genome Sciences, Inc.	Doll	1:2009cv01195	2009-06-29	7,470,510	2008-12-30
Novartis Vaccines & Diagnostics, Inc.	Doll	1:2009cv01201	2009-06-30	7,470,709	2008-12-30
Novartis AG	Doll	1:2009cv01202	2009-06-30	7,473,761	2009-01-06
Novartis AG	Doll	1:2009cv01203	2009-06-30	7,470,792	2008-12-30
Alnylam Europe AG	Doll	1:2009cv01227	2009-07-02	7,473,525	2009-01-06
Genentech, Inc.	Doll	1:2009cv01265	2009-07-08	7,476,724	2009-01-13
Nova Measuring Instruments, Ltd.	Doll	1:2009cv01305	2009-07-13	7,477,405	2009-01-13
Bristol-Meyers Squibb Co., Kosan Biosciences, Inc.	Doll	1:2009cv01330	2009-07-17	7,417,040	2008-08-26
				7,417,063	2008-08-26
				7,427,493	2008-09-23
				7,429,604	2008-09-30
				7,429,611	2008-09-30
				7,432,267	2008-10-07
				7,432,271	2008-10-07
				7,432,373	2008-10-07
				7,435,808	2008-10-14
				7,446,196	2008-11-04
				7,452,678	2008-11-18
				7,453,002	2008-11-18
				7,455,835	2008-11-25
				7,459,562	2008-12-02
				7,470,712	2008-12-30
				7,470,713	2008-12-30
				7,479,496	2009-01-20
				7,482,372	2009-01-27
				7,504,211	2009-03-17
				7,517,991	2009-04-14
Mosaid Technologies, Inc.	Doll	1:2009cv01345	2009-07-20	7,480,233	2009-01-20
P.N.A.Construction Tech., Inc.	Doll	1:2009cv01372	2009-07-24	7,481,031	2009-01-27
X-Ceptor Therapeutics, Inc.	Doll	1:2009cv01373	2009-07-24	7,482,366	2009-01-27
Juridical Foundation The Chemo-Sero-Therapeutic Research Inst.	Doll	1:2009cv01383	2009-07-27	7,482,436	2009-01-27
Exelixis, Inc.	Doll	1:2009cv01431	2009-07-31	7,485,634	2009-02-03
Dyax Corp.	Doll	1:2009cv01434	2009-07-31	7,485,297	2009-02-03
Intermune, Inc.	Kappos	1:2009cv01510	2009-08-11	7,491,794	2009-02-17
Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Int'l GmbH	Kappos	1:2009cv01542	2009-08-14	7,491,824	2009-02-17

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Plaintiff	Defendant	Docket No.	Filing Date	U.S. Patent	Issue Date
Geron Corp.	Kappos	1:2009cv01553	2009-08-17	7,494,982	2009-02-24
Human Genome Sciences, Inc.	Kappos	1:2009cv01585	2009-08-20	7,504,105	2009-03-17
Vertex Pharm., Inc.	Kappos	1:2009cv01599	2009-08-21	7,495,103	2009-02-24
Lifenet Health	Kappos	1:2009cv01645	2009-08-28	7,498,040	2009-03-03
				7,498,041	2009-03-03
Genetech, Inc.	Kappos	1:2009cv01646	2009-08-28	7,498,030	2009-03-03
Seattle Genetics, Inc.	Kappos	1:2009cv01647	2009-08-28	7,498,298	2009-03-03
Unilever Patent Holdings B.V.	Kappos	1:2009cv01673	2009-09-02	7,501,556	2009-03-10
Glaxo Group, Ltd.	Kappos	1:2009cv01714	2009-09-09	7,500,444	2009-03-10
Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Int'l GmbH	Kappos	1:2009cv01729	2009-09-11	7,504,378	2009-03-17
Vertex Pharm., Inc.	Kappos	1:2009cv01771	2009-09-18	7,507,826	2009-03-24
Amgen, Inc., Cytokinetics, Inc.	Kappos	1:2009cv01773	2009-09-18	7,507,735	2009-03-24
Iterative Therapeutics, Inc.	Kappos	1:2009cv01822	2009-09-24	7,511,121	2009-03-31
Amgen, Inc.	Kappos	1:2009cv01829	2009-09-25	7,511,012	2009-03-31
Therm Med LLC	Kappos	1:2009cv01863	2009-09-25	7,510,555	2009-03-31
Wellstat Therapeutics Corp.	Kappos	1:2009cv01866	2009-09-30	7,514,555	2009-04-07
Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Int'l GmbH	Kappos	1:2009cv01885	2009-10-02	7,514,557	2009-04-07
Smithkline Beecham Corp.	Kappos	1:2009cv01893	2009-10-05	7,514,437	2009-04-07
Rigel Pharm., Inc.	Kappos	1:2009cv01914	2009-10-08	7,517,886	2009-04-14
Chugai Seiyaku Kabushiki Kaisha	Kappos	1:2009cv01928	2009-10-09	7,517,965	2009-04-14
Banyu Pharmaceutical Co., Merck Sharp & Dohme Research, Ltd., Merck & Co.	Kappos	1:2009cv01955	2009-10-15	7,521,455	2009-04-21
Theravance, Inc.	Kappos	1:2009cv01956	2009-10-16	7,521,558	2009-04-21
Rockefeller Univ.	Kappos	1:2009cv01959	2009-10-16	7,521,258	2009-04-21
Commonwealth Scientific & Industrial Research Organisation	Kappos	1:2009cv01964	2009-10-19	7,521,593	2009-04-21
Mosaid Technologies, Inc.	Kappos	1:2009cv01965	2009-10-19	7,521,943	2009-04-21
Mosaid Technologies, Inc.	Kappos	1:2009cv01966	2009-10-19	7,522,615	2009-04-21
Mosaid Technologies, Inc.	Kappos	1:2009cv01968	2009-10-19	7,522,714	2009-04-21
Centre National de la Recherche Scientifique	Kappos	1:2009cv01969	2009-10-19	7,521,212	2009-04-21
Solvay Pharm., B.V.	Kappos	1:2009cv02007	2009-10-23	7,524,867	2009-04-28
Theravance, Inc.	Kappos	1:2009cv02078	2009-11-04	7,531,623	2009-05-12
Biogen Idec Ma, Inc.	Kappos	1:2009cv02097	2009-11-06	7,531,174	2009-05-12
Intrexon Corp.	Kappos	1:2009cv02106	2009-11-09	7,531,326	2009-05-12
Idenix Pharm., Inc.	Kappos	1:2009cv02127	2009-11-12	7,534,809	2009-05-19
Bayhill Therapeutics, Inc., Board of Trustees of the Leland Stanford Junior Univ.	Kappos	1:2009cv02238	2009-11-25	7,544,669	2009-06-09
Tolerx, Inc., Isis Innovation, Ltd., Cambridge Enterprises, Ltd.	Kappos	1:2009cv02255	2009-11-27	7,541,443	2009-06-02
Cephalon France	Kappos	1:2009cv02256	2009-11-27	7,541,493	2009-06-02
Trustees of Columbia Univ. in the City of New York	Kappos	1:2009cv02281	2009-12-02	7,544,678	2009-06-09
Memorial Sloan-Kettering Cancer Center	Kappos	1:2009cv02282	2009-12-02	7,541,179	2009-06-02
Pfizer, Inc., Pfizer Products, Inc.	Kappos	1:2009cv02283	2009-12-02	7,544,362	2009-06-09

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Plaintiff	Defendant	Docket No.	Filing Date	U.S. Patent	Issue Date
Conforma Therapeutics Corp.	Kappos	1:2009cv02292	2009-12-03	7,544,672	2009-06-09
Glaxosmithkline LLC	Kappos	1:2009cv02298	2009-12-04	7,547,719	2009-06-16
Transtech Pharma, Inc.	Kappos	1:2009cv02305	2009-12-04	7,544,699	2009-06-09
Neuralstem, Inc.	Kappos	1:2009cv02306	2009-12-04	7,544,511	2009-06-09
Thrombogenics NV	Kappos	1:2009cv02354	2009-12-11	7,547,435	2009-06-16
Mass. Institute of Tech.	Kappos	1:2009cv02355	2009-12-11	7,547,556	2009-06-16
Hoffman-La Roche, Inc.	Kappos	1:2009cv02373	2009-12-16	7,557,114	2009-07-07
Alantos Pharm. Holding, Inc.	Kappos	1:2009cv02418	2009-12-23	7,553,861	2009-06-30
Bristol-Myers Squibb Co.,	Kappos	1:2009cv02420	2009-12-23	7,589,193	2009-09-15
Bristol-Myers Squibb Pharma Co.				7,589,088	2009-09-15
				7,557,143	2009-07-07
				7,514,430	2009-04-07
				7,491,725	2009-02-17
Paratek Pharm., Inc.	Kappos	1:2009cv02425	2009-12-28	7,553,828	2009-06-30
Hoffmann-La Roche, Inc.	Kappos	1:2010cv00029	2010-01-08	7,563,441	2009-07-21
Kitasato Institute	Kappos	1:2010cv00033	2010-01-08	7,560,484	2009-07-14
Celldex Research Corp.	Kappos	1:2010cv00035	2010-01-08	7,563,876	2009-07-21
Celldex Research Corp.	Kappos	1:2010cv00064	2010-01-13	7,560,534	2009-07-14
Domantis, Ltd.	Kappos	1:2010cv00068	2010-01-14	7,563,443	2009-07-21
Eisai R&D Management Co.	Kappos	1:2010cv00082	2010-01-15	7,563,811	2009-07-21
Prochon Biotech, Ltd.	Kappos	1:2010cv00094	2010-01-19	7,563,769	2009-07-21
Mitsubishi Tanabe Pharma Corp.	Kappos	1:2010cv00129	2010-01-22	7,566,728	2009-07-28
Cephalon, Inc.	Kappos	1:2010cv00131	2010-01-22	7,566,805	2009-07-28
Int'l Multi-Media Corp.	Kappos	1:2010cv00141	2010-01-25	7,567,779	2009-07-28
Novartis AG	Kappos	1:2010cv00164	2010-01-29	7,569,337	2009-08-04
Idera Pharm., Inc.	Kappos	1:2010cv00166	2010-01-29	7,569,554	2009-08-04
				7,517,862	2009-04-14
Oncotherapy Science, Inc.	Kappos	1:2010cv00183	2010-02-01	7,569,351	2009-08-04
Andromeda Biotech, Ltd.	Kappos	1:2010cv00213	2010-02-12	7,576,177	2009-08-18
Daiichi Sankyo Co., Ltd.	Kappos	1:2010cv00215	2010-02-12	7,576,135	2009-08-18
Arius Two, Inc.	Kappos	1:2010cv00225	2010-02-16	7,579,019	2009-08-25
Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Int'l GmbH	Kappos	1:2010cv00253	2010-02-18	7,579,449	2009-08-25
Amgen, Inc., Millennium Pharm., Inc.	Kappos	1:2010cv00264	2010-02-19	7,579,168	2009-08-25
Markem-Imaje Corp.	Kappos	1:2010cv00269	2010-02-19	7,578,874	2009-08-25
Galderma Research & Dev.	Kappos	1:2010cv00271	2010-02-19	7,579,377	2009-08-25
Biogen Idec Ma, Inc.	Kappos	1:2010cv00312	2010-02-26	7,582,299	2009-09-01
Bullion Direct, Inc.	Kappos	1:2010cv00313	2010-02-26	7,584,135	2009-09-01
Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Int'l GmbH	Kappos	1:2010cv00318	2010-02-26	7,582,770	2009-09-01
Oxagen, Ltd.	Kappos	1:2010cv00325	2010-03-01	7,582,672	2009-09-01
Merck Serono S.A.	Kappos	1:2010cv00348	2010-03-03	7,585,840	2009-09-08
Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Int'l GmbH	Kappos	1:2010cv00370	2010-03-05	7,585,845	2009-09-08
Astrazeneca AB	Kappos	1:2010cv00372	2010-03-05	7,585,881	2009-09-08
Enzon Pharm., Inc., Santaris Pharma A/S	Kappos	1:2010cv00412	2010-03-12	7,589,190	2009-09-15
Mount Sinai School of Medicine of New York Univ.	Kappos	1:2010cv00416	2010-03-12	7,588,768	2009-09-15
Schering Corp.	Kappos	1:2010cv00424	2010-03-15	7,592,348	2009-09-22
Sylentis, S.A.U.	Kappos	1:2010cv00458	2010-03-19	7,592,325	2009-09-22

Table A5
Patents in Federal District Court PTA Cases Filed September, 2008–July, 2010

Plaintiff	Defendant	Docket No.	Filing Date	U.S. Patent	Issue Date
Children's Hospital & Research Center at Oakland	Kappos	1:2010cv00488	2010-03-24	7,595,307	2009-09-29
Genentech, Inc.	Kappos	1:2010cv00496	2010-03-26	7,595,046	2009-09-29
Pfizer, Inc.	Kappos	1:2010cv00504	2010-03-26	7,595,325	2009-09-29
Cummins-Allison Corp.	Kappos	1:2010cv00542	2010-04-02	7,599,543	2009-10-06
Amgen, Inc.& Medarex, Inc.	Kappos	1:2010cv00564	2010-04-07	7,601,818	2009-10-13
Cummins-Allison Corp.	Kappos	1:2010cv00567	2010-04-08	7,602,956	2009-10-13
Human Genome Sciences, Inc.	Kappos	1:2010cv00575	2010-04-09	7,601,351	2009-10-13
				7,605,236	2009-10-20
Tepha, Inc.	Kappos	1:2010cv00580	2010-04-12	7,025,980	2006-04-11
Kinaxis Holdings, Inc.	Kappos	1:2010cv00620	2010-04-21	7,610,212	2009-10-27
Schering Corp., Merck & Co.	Kappos	1:2010cv00673	2010-04-30	7,612,058	2009-11-03
Biogen Idec Ma, Inc.	Kappos	1:2010cv00674	2010-04-30	7,612,178	2009-11-03
Georgetown Univ.	Kappos	1:2010cv00743	2010-05-07	7,615,355	2009-11-10
Pfizer, Inc.	Kappos	1:2010cv00781	2010-05-13	7,618,626	2009-11-17
Magnachem Int'l Laboratories, Inc.	Kappos	1:2010cv00892	2010-05-26	7,323,495	2008-01-29
Univ. of Mass., Medarex, Inc.	Kappos	1:2010cv00894	2010-05-28	7,625,559	2009-12-01
Symphony Evolution, Inc.	Kappos	1:2010cv00938	2010-06-07	7,629,341	2009-12-08
UCB Pharma GmbH	Kappos	1:2010cv00972	2010-06-10	7,632,859	2009-12-15
Logitech Europe S.A.	Kappos	1:2010cv00987	2010-06-14	7,634,146	2009-12-15
Japan Tobacco, Inc.	Kappos	1:2010cv01023	2010-06-17	7,635,704	2009-12-22
Glaxo Group, Ltd.	Kappos	1:2010cv01032	2010-06-18	7,635,701	2009-12-22
Logitech Europe S.A.	Kappos	1:2010cv01041	2010-06-21	7,636,805	2009-12-22
Simply Thick, LLC.	Kappos	1:2010cv01076	2010-06-25	7,638,150	2009-12-29
Merck Sharp & Dohme Corp.	Kappos	1:2010cv01110	2010-06-30	7,326,708	2008-02-05
Novartis AG, Novartis Vaccines & Diagnostics, Inc.	Kappos	1:2010cv01138	2010-07-06	7,470,709	2008-12-30
				7,470,792	2008-12-30
				6,656,957	2003-12-02
				6,878,721	2005-04-12
				7,098,325	2006-08-29
				7,112,673	2006-09-26
				7,265,089	2007-09-04
				7,348,353	2008-03-25
				7,423,148	2008-09-09
				7,534,890	2009-05-19
				7,576,221	2009-08-18
Nippon Shinyaku Co., Ltd.	Kappos	1:2010cv01142	2010-07-06	7,205,302	2007-04-17
				7,494,997	2009-02-24
Actelion Pharm., Ltd.	Kappos	1:2010cv01145	2010-07-06	7,094,781	2006-08-22
Anaphore, Inc.	Kappos	1:2010cv01146	2010-07-06	7,642,044	2010-01-05
Kuros Biosurgery AG	Kappos	1:2010cv01173	2010-07-09	7,247,609	2007-07-24
Argentum Medical, LLC	Kappos	1:2010cv01177	2010-07-09	7,291,762	2007-11-06
Kuros Biosurgery AG	Kappos	1:2010cv01178	2010-07-09	7,575,740	2009-08-18
Classen Immunotherapies, Inc.	Kappos	1:2010cv01232	2010-07-21	7,653,639	2010-01-26

Table A6.1
Chemical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
Coating	106	Compositions: Coating or Plastic	Markem Corporation (Keene, NH)	7,578,874	Hot melt inks
Miscellaneous-chemical	203	Distillation: Processes, Separatory	Purac Biochem B.V. (Gorinchem, Neth.)	7,410,556	Purification of aqueous solutions of organic acids
	506	Combinatorial, Chemistry Technology: Method, Library, Apparatus	Dyax Corp. (Cambridge, MA)	7,413,537	Directed evolution of disulfide-bonded micro-proteins
	436	Chemistry: Analytical and Immunological Testing	Massachusetts Institute of Technology (Cambridge, MA)	7,547,556	Methods for filing a sample array by droplet dragging
			The Rockefeller University (New York, NY)	7,521,258	Methods of detecting, measuring, and evaluating modulators of body weight in biological samples, and diagnostic, monitoring, and therapeutic uses thereof
Organic Compounds	536	Organic Compounds -- Part of the Class 532-570 Series	Boehringer Ingelheim Int'l GmbH (Ingelheim, Ger.)	7,579,449	Glucopyranosyl-substituted phenyl derivatives, medicaments containing such compounds, their use and process for their manufacture
			Bristol-Myers Squibb Company (Princeton, NJ)	7,435,808	Polynucleotides encoding novel adiponectin receptor variant, AdipoR2v2
				7,589,193	C-aryl glucoside SGLT2 inhibitors and method
			Enzon Pharmaceuticals, Inc. (Santaris Pharma A/S (Den.)	7,589,190	Potent LNA oligonucleotides for the inhibition of HIF-1A expression
			Inotek Pharmaceuticals Corporation (Beverly, MA)	7,423,144	Purine Derivatives as adenosine A.sub.1 receptor agonists and methods of use thereof
			No Assignee	7,098,325	Process for the sulfurization of a phosphorus-containing compound
			University of Massachusetts (Boston, MA)	7,459,547	Methods and compositions for controlling efficacy of RNA silencing
	544	Organic Compounds -- Part of the Class 532-570 Series	Bristol-Meyers Squibb Company (Princeton, NJ)	7,432,373	Processes and intermediates useful for preparing fused heterocyclic kinase inhibitors

Table A6.1
Chemical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Kosan Biosciences, Incorporated (Hayward, CA)	7,446,196	Leptomycin compounds
			Chiron Corporation (Emeryville, CA)	7,423,148	Small molecule PI 3-kinase inhibitors and methods of their use
	546	Organic Compounds -- Part of the Class 532-570 Series	Boehringer Ingelheim Int'l GmbH (Ingelheim, Ger.)	7,514,557	Process for preparing acyclic HCV protease inhibitors
			Boehringer Ingelheim Pharma GmbH & Co., KG (Ingelheim, Ger.)	7,491,824	Method for preparing tiotropium salts
			Bristol-Myers Squibb Company (Princeton, NJ)	7,459,562	Monocyclic heterocycles as kinase inhibitors
				7,517,991	N-sulfonylpiperidine cannabinoid receptor 1 antagonists
			Celgene Corporation (Summit, NJ)	7,465,800	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione
			Memory Pharmaceuticals Corporation (Montvale, NJ)	7,429,664	Indazoles, benzothiazoles, and benzoisothiazoles, and preparation and uses thereof
			Novartis AG (Basel, Switz.)	7,534,890	Process for preparing 5-[(R)-2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-(1H)-quinolin-2-one salt, useful as an andrenoceptor agonist
			Theravance, Inc. (South San Francisco, CA)	7,521,558	Crystalline form of a biphenyl compound
			Vertex Pharmaceuticals Incorporated (Cambridge, MA)	7,495,103	Modulators of ATP-binding cassette transporters
				7,507,826	Azaindoles useful as inhibitors of JAK and other protein kinases
			Wellstat Therapeutics Corporation (Gaithersburg, MD)	7,514,555	Compounds for the treatment of metabolic disorders
	548	Organic Compounds -- Part of the Class 532-570 Series	Array BioPharma Inc. (Boulder, CO)	7,425,637	N3 alkylated benzimidazole derivatives as MEK inhibitors
			Boehringer Ingelheim Int'l GmbH (Ingelheim, Ger.)	7,582,770	Viral polymerase inhibitors

Table A6.1
Chemical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Bristol-Myers Squibb Company (Princeton, NJ)	7,453,002	Five-membered heterocycles useful as serine protease inhibitors
			Novartis AG (Basel, Switz.)	7,470,792	Process for the preparation of epothilone derivatives, new epothilone derivatives as well as new intermediate products for the process and the methods of preparing same
			Novartis Vaccines and Diagnostics, Inc. (Emeryville, CA)	7,576,221	Substituted imidazole derivatives
	564	Organic Compounds -- Part of the Class 532-570 Series	Cephalon France (Maisons Alfort, Fr.)	7,541,493	Modafinil synthesis process
			Cephalon, Inc. (Frazer, PA)	7,566,805	Modafinil compositions
	540	Organic Compounds -- Part of the Class 532-570 Series	Novartis AG (Basel, Switz.)	7,112,673	Dibenzo [b,f]azepine intermediates
Resins	530	Chemistry: Natural Resins or Derivatives; Peptides or Proteins; Lignins or Reaction Products Thereof	Alexion Pharmaceuticals, Inc. (Cheshire, CT)	7,396,917	Rationally designed antibodies
				7,408,041	Polypeptides and antibodies derived from chronic lymphocytic leukemia cells and uses thereof
				7,414,111	Engineered templates and their use in single primer amplification
				7,427,665	Chronic lymphocytic leukemia cell line
			Amgen, Inc. (Thousand Oaks, CA) Medarex, Inc. (Princeton, NJ)	7,601,818	Human anti-NGF neutralizing antibodies as selective NGF pathway inhibitors
			Andromeda Biotech Ltd. (Rehovot, Isr.)	7,576,177	Hsp peptides and analogs for modulation of immune responses via antigen presenting cells
			Biogen Idec MA Inc (Cambridge, MA)	7,612,178	Anti-IGF-1R antibodies and uses thereof
			Biogen Idec MA Inc. (Cambridge, MA)	7,429,644	Humanized anti-LT-.beta.-R antibodies
				7,446,173	Polymer conjugates of interferon beta-1A and uses

Table A6.1
Chemical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Celldex Research Corporation (Phillipsburg, NJ)	7,560,534	Molecular conjugates comprising human monoclonal antibodies to dendritic cells
			CellDex Therapeutics, Inc. (Phillipsburg, NJ)	7,563,876	Human monoclonal antibodies to dendritic cells
			Chugai Seiyaku Kabushiki Kaisha (Tokyo, Japan)	7,517,965	Non-neutralizing anti-aPC antibodies
			Genentech, Inc. (South San Francisco, CA)	7,476,724	Humanized anti-cmet antibodies
			Human Genome Sciences, Inc. (Rockville, MD)	7,605,236	Antibodies that immunospecifically bind to B lymphocyte stimulator protein
			Intermune, Inc. (Brisbane, CA)	7,491,794	Macrocyclic compounds as inhibitors of viral replication
			Juridical Foundation The Chemo-Sero-Therapeutic Research Institute (Kumamoto-Ken, Japan)	7,482,436	Human antihuman interleukin-6 antibody and fragment of antibody
			Neuralab Limited (Flatts, BM) Wyeth (Madison, NJ)	7,179,892	Humanized antibodies that recognize beta amyloid peptide
			No Assignee	7,442,776	Cancerous disease modifying antibodies
				7,511,121	Polymeric immunoglobulin fusion proteins that target low-affinity Fc.gamma.receptors
			Novartis AG (Basel, Switz.)	7,446,175	Antibodies to human IL-1.beta.
				7,473,761	Somatostatin analogues
			Theravance, Inc. (South San Francisco, CA)	7,531,623	Hydrochloride salts of a glycopeptide phosphonate derivative
			Tolerrx, Inc. (Cambridge, MA) Isis Innovation, Ltd. (Oxford, Gr. Brit.) Cambridge University Technical Services, Ltd. (Cambridge, Gr. Brit.)	7,541,443	Anti-CD4 antibodies
			Wyeth (Madison, NJ) Neuralab Limited (Smiths, BM)	7,189,819	Humanized antibodies that recognize beta amyloid peptide

Table A6.2
Computers & Communications Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
Communications	370	Multiplex Communications	Serconet Ltd. (Ra'Anana, Isr.)	7,480,233	Telephone communication system and method over local area network wiring
				7,522,615	Addressable outlet, and a network using same
	379	Telephonic Communications	Serconet Ltd. (Ra'Anana, Isr.)	7,522,714	Telephone outlet for implementing a local area network over telephone lines and a local area network using such outlets
	455	Telecommunications	Int'l Multi-Media Corporation (Narbeth, PA)	7,567,779	Sub-orbital, high altitude communications system
Computer Hardware & Software	705	Data Processing: Financial, Business Practice, Management, or Cost/Price Determination	Accenture Global Services GmbH (Switz.)	7,457,763	Predictive maintenance system
			Accenture Global Services GmbH (Schaffhausen, Switz.)	7,457,762	Optimization of management of maintenance, repair and overhaul of equipment in a specified time window
				7,469,219	Order management system
			Accenture Global Services GmbH (Schauffhausen, Switz.)	7,440,906	Identification, categorization, and integration of unplanned maintenance, repair and overhaul work on mechanical equipment
				7,461,008	Planning and scheduling modification of a configuration
			Accenture LLP (Palo Alto, CA)	7,502,744	Performing predictive maintenance based on a predictive maintenance target
			Bullion Direct, Inc. (Austin, TX)	7,584,135	System and method for electronic trading and delivery of a commoditized product
			Kinaxis Holdings Inc. (Ottawa, Can.)	7,610,212	System and method for determining a demand promise date based on a supply available date
	382	Image Analysis	Cummins-Allison Corp. (Mt. Prospect, IL)	7,599,543	Document processing system using full image scanning
				7,602,956	Document processing system using full image scanning

Table A6.2
Computers & Communications Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Logitech Europe S.A. (Switz.)	7,634,146	Methods and apparatus for encoding and decoding video data
	710	Electrical Computers and Digital Data Processing Systems: Input/Output	Logitech Europe S.A. (Switz.)	7,636,805	Method and apparatus for communicating data between two hosts
	707	Data Processing: Database and File Management, Data Structures, or Document Processing	Classen Immunotherapies, Inc. (Baltimore, MD)	7,653,639	Computer algorithms and methods for product safety

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
Biotechnology	435	Chemistry: Molecular Biology and Microbiology	Alexion Pharmaceuticals, Inc. (Cheshire, CT)	7,393,648	Hybrid antibodies
				7,399,594	Hybrid antibodies
			Alnylam Europe AG (Cambridge, MA)	7,473,525	Compositions and methods for inhibiting expression of anti-apoptotic genes
			Bayer Bioscience GmbH (Potsdam, Ger.)	7,402,420	Nucleic acid molecules encoding alternansucrase
			Biogen Idec Inc. (Cambridge, MA)	7,381,560	Expression and use of anti-CD20 antibodies
			Bristol-Myers Squibb Company (Princeton, NJ)	7,452,678	Identification of biomarkers for liver toxicity
			Bristol-Myers Squibb Company (Princeton, NY)	7,504,211	Methods of using EPHA2 for predicting activity of compounds that interact with and/or modulate protein tyrosine kinases and/or protein tyrosine kinase pathways in breast cells
			Centre National de la Recherche Scientifique (CNRS) (Paris, Fr.)	7,521,212	Method for producing oligopolysaccharides
			Georgetown University (Washington, DC)	7,615,355	Peripheral-type benzodiazepine receptor expression level as an index of organ damage and regeneration

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Geron Corporation (Menlo Park, CA)	7,425,448	Cardiomyocyte precursors from human embryonic stem cells
			GlaxoSmithKline Biologicals, S.A,. (Rixensart, Belg.)	7,419,824	BASB006 polypeptides from Neisseria meningitidis and immunogenic compositions thereof
			Human Genome Sciences, Inc. (Rockville, MD)	7,470,510	Methods for diagnosing cancer and determining a susceptibility for developing cancer
			Institut National des Sciences Appliquees (INSA) (Toulouse, Fr.)	7,439,049	Nucleic acid molecules coding for a dextran-saccharase catalysing the synthesis of dextran with .alpha. 1,2 osidic sidechains
			Intrexon Corporation (Blacksburg, VA)	7,531,326	Chimeric retinoid X receptors and their use in a novel ecdysone receptor-based inducible gene expression system
			Kosan Biosciences Incorporated (Hayward, CA)	7,427,493	Recombinant genes for polyketide modifying enzymes
			Memorial Sloan-Kettering Cancer Center (New York, NY)	7,541,179	Vector encoding human globin gene and use thereof in treatment of hemoglobinopathies
			Millennium Pharmaceuticals, Inc. (Cambridge, MA)	7,579,168	Human Dickkopf-related nucleic acid molecules
			Neuralstem Biopharmaceuticals Ltd. (College Park, MD)	7,544,511	Stable neural stem cell line methods
			Novartis AG (Basel, Switz.)	7,569,337	Coumarines useful as biomarkers
			Oncotherapy Science, Inc. (Kanagawa, Japan)	7,569,351	P53 dependent apoptosis-associated gene and protein
			The Ohio State University Research Foundation (Columbus, OH)	7,455,995	BAALC expression as a diagnostic marker for acute leukemia
			Anaphore, Inc. (La Jolla, CA) Hoffman-La Roche, Inc. (Nutley, NJ)	7,642,044	Trimerising module

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
	800	Multicellular Living Organisms and Unmodified Parts Thereof and Related Processes	Commonwealth Scientific and Industrial Research Organisation (Campbell, Austl.)	7,521,593	Barley with altered branching enzyme activity and starch and starch containing products with an increased amylose content
			Unilever Patent Holdings B.V. (Vlaardingen, Neth.)	7,501,556	Nutritionally enhanced plants
Drugs	424	Drug, Bio-Affecting and Body Treating Compositions	Alexion Pharmaceuticals, Inc. (Chesire, CT)	7,435,412	Chronic lymphocytic leukemia cell line
			Alpha Vax, Inc. (Research Triangle Park, NC)	7,419,674	Alpha virus-based cytomegalovirus vaccines
			AlphaVax, Inc. (Research Triangle Park, NC)	7,442,381	Alphavirus replicons and helper constructs
			Arius Two, Inc. (Raleigh, NC)	7,579,019	Pharmaceutical carrier device suitable for delivery of pharmaceutical compounds to mucosal surfaces
			Biogen Idec MA Inc. (Cambridge, MA)	7,427,403	Methods for inhibiting lymphotoxin .beta. receptor signalling
				7,442,370	Polymer conjugates of mutated neublastin
				7,531,174	Cripto blocking antibodies and uses thereof
				7,582,299	Cripto-specific antibodies
			Bristol-Myers Squibb Company (Princeton, NJ)	7,455,835	Methods for treating immune system diseases using a soluble CTLA4 molecule
			Domantis Limited (Cambridge, Gr. Brit.)	7,563,443	Monovalent anti-CD40L antibody polypeptides and compositions thereof
			Dyax Corp. (Cambridge, MA)	7,485,297	Method of inhibition of vascular development using an antibody
			Eurand, Inc. (Vandalia, OH)	7,387,793	Modified release dosage forms of skeletal muscle relaxants
			Exponential Biotherapies, Inc. (Port Washington, NY)	7,438,901	Virulent phages to control Listeria monocytogenes in foodstuffs and in food processing plants
			Genentech, Inc. (South San Francisco, CA)	7,449,184	Fixed dosing of HER antibodies

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
				7,452,539	Stabilizing polypeptides which have been exposed to urea
				7,595,046	Treatment of cancer using anti-Apo-2 antibodies
			Genetech, Inc. (South San Francisco, CA)	7,498,030	Treatment with anti-ErbB2 antibodies and anti-hormonal compounds
			Genmab A/S (Copenhagen, Den.)	7,438,907	Human monoclonal antibodies against CD25
			Hoffman-La Roche Inc. (Nutley, NJ)	7,563,441	Anti-P-selectin antibodies
			Human Genome Sciences, Inc. (Rockville, MD)	7,504,105	Treatment using antibodies to cytokine receptor common gamma chain like
				7,601,351	Antibodies against protective antigen
			LifeNet Health (Virginia Beach, VA)	7,498,040	Compositions for repair of defects in osseous tissues, and methods of making the same
				7,498,041	Composition for repair of defects in osseous tissues
			Medarex, Inc. (Princeton, NJ)	7,387,776	Human monoclonal antibodies against CD30
				7,452,535	Methods of treatment using CTLA-4 antibodies
				7,465,446	Surrogate therapeutic endpoint for anti-CTLA4-based immunotherapy of disease
			Molecular Insight Pharmaceuticals, Inc. (Cambridge, MA)	7,381,399	Technetium-dipyridine complexes, and methods of use thereof
			Mount Sinai School of Medicine of New York University (New York, NY)	7,588,768	Attenuated negative strand viruses with altered interferon antagonist activity for use as vaccines and pharmaceuticals
			Napo Pharmaceuticals, Inc. (South San Francisco, CA)	7,341,744	Method of treating secretory diarrhea with enteric formulations of proanthocyanidin polymer
			Novozymes Biopharma UK Limited (Nottingham, Gr. Brit.)	7,435,410	Methods of treatment with interferson and albumin fusion protein
			Pfizer Inc (New York, NY)	7,618,626	Combination treatment for non-hematologic malignancies

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
				7,544,362	N protein mutants of porcine reproductive and respiratory syndrome virus
			Purdue Pharma L.P. (Stamford, CT)	7,413,748	Transdermal buprenorphine to treat pain in sickle cell crisis
			Syntonix Pharmaceuticals, Inc. (Waltham, MA)	7,404,956	Immunoglobulin chimeric monomer-dimer hybrids
			Tepha, Inc. (Cambridge, MA)	7,025,980	Polyhydroxyalkanoate compositions for soft tissue repair, augmentation, and viscosupplementation
			ThromboGenics NV (Leuven, Belg.)	7,547,435	Pharmacological vitreolysis
			University of Massachusetts (Boston, MA) Medarex, Inc. (Princeton, NJ)	7,625,559	Antibodies against Clostridium difficile toxins and uses thereof
			Yeda Research and Development Co. Ltd (Rehovot, Isr.)	7,445,802	Site-specific in situ generation of allicin using a targeted alliinase delivery system for the treatment of cancers, tumors, infectious diseases and other allicin-sensitive diseases
			Kuros Biosurgery AG (Zurich, Switz.)	7,575,740	Compositions for tissue augmentation
	514	Drug, Bio-Affecting and Body Treating Compositions	Alantos Pharmaceuticals Holding, Inc. (Cambridge, MA)	7,553,861	Dipeptidyl peptidase-IV inhibitors
			Amgen Inc. (Thousand Oaks, CA)	7,511,012	Myostatin binding agents
			Applied Research Systems ARS Holding N.V. (Curacao, Neth.)	7,419,999	Gamma lactams as prostaglandin agonists and use thereof
			Arena Pharmaceuticals, Inc. (San Diego, CA)	7,470,699	Trisubstituted aryl and heteroaryl derivatives as modulators of metabolism and the prophylaxis and treatment of disorders related thereto
			AstraZeneca AB (Södertälje, Swed.)	7,462,623	Quinazoline derivatives as Src tyrosine kinase inhibitors

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
				7,585,881	Additional heteropolycyclic compounds and their use as metabotropic glutamate receptor antagonists
			Banyu Pharmaceutical Co. Ltd. (Chuo-ku Tokyo, Japan)	7,521,455	Fused ring 4-oxopyrimidine derivative
			Boehringer Ingelheim Int'l GmbH (Ingelheim, Ger.)	7,504,378	Macrocyclic peptides active against the hepatitis C virus
				7,585,845	Hepatitis C inhibitor compounds
			Bristol Myers Squibb Company (Princeton, NJ)	7,429,604	Six-membered heterocycles useful as serine protease inhibitors
				7,432,267	Fused cyclic modulators of nuclear hormone receptor function
				7,417,040	Fused tricyclic compounds as inhibitors of 17.beta.-hydroxysteroid dehydrogenase 3
				7,417,063	Bicyclic heterocycles useful as serine protease inhibitors
				7,429,611	Indole inhibitors of 15-lipoxygenase
				7,432,271	Pyrazolyl inhibitors of 15-lipoxygenase
				7,470,712	Amino-benzazoles as P2Y.sub.1 receptor inhibitors
				7,470,713	Imidazole based kinase inhibitors
				7,479,496	Substituted spiro azabicyclics as modulators of chemokine receptor activity
				7,482,372	Hydantoins and related heterocycles as inhibitors of matrix metalloproteinases and/or TNF-.alpha. converting enzyme (TACE)
				7,491,725	Process for preparing 2-aminothiazole-5-aromatic carboxamides as kinase inhibitors
				7,557,143	Thyroid receptor ligands

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
				7,589,088	Pyrimidine-based inhibitors of dipeptidyl peptidase IV and methods
				7,514,430	Piperizinones as modulators of chemokine receptor activity
			Children's Hospital and Research Center at Oakland (Oakland, CA)	7,595,307	Polysaccharide derivatives and uses in induction of an immune response
			Conforma Therapeutics Corporation (San Diego, CA)	7,544,672	Alkynyl pyrrolo[2,3-d]pyrimidines and related analogs as HSP90-inhibitors
			Cytokinetics, Inc. (South San Francisco, CA)	7,507,735	Compounds, compositions and methods
			Daiichi Pharmaceutical Co., Ltd. (Tokyo, Japan)	7,576,135	Diamine derivatives
			Eisai R&D Management Co., Ltd. (Bunkyo-ku, Japan)	7,563,811	1,2-dihydropyridine compounds, manufacturing method thereof and use thereof
			Exelixis, Inc. (South San Francisco, CA)	7,485,634	Azepinoindole and pyridoindole derivatives as pharmaceutical agents
			Galderma Research & Development (Biot, Fr.)	7,579,377	Administration of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders
			Gedeon Richter Vegyeszeti Gyar RT (Hung.)	7,435,744	Piperidine derivatives as NMDA receptor antagonists
			Georgetown University (Washington, DC)	7,381,745	Ligands for metabotropic glutamate receptors and inhibitors of NAALADase
			Geron Corporation (Menlo Park, CA)	7,494,982	Modified oligonucleotides for telomerase inhibition
			Glaxo Group Limited (Greenford, Gr. Brit.)	7,452,888	Quinoline derivatives and their use as 5-ht6 ligands
				7,635,701	Pyrimidine derivatives and their use as CB2 modulators
			Hoffman-La Roche Inc. (Nutley, NJ)	7,557,114	Heterocyclic-substituted phenyl methanones
			Idenix Pharmaceuticals, Inc. (Cambridge, MA)	7,534,809	Phospho-indoles as HIV inhibitors

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Idera Pharmaceuticals, Inc. (Cambridge, MA)	7,517,862	Modulation of immunostimulatory properties of oligonucleotide-based compounds by optimal presentation of 5' ends
				7,569,554	Synergistic treatment of cancer using immunomers in conjunction with therapeutic agents
			Kabushiki Kaisha Hayashibara Seibutsu Kagaku Kenkyujo (Okayama, Japan)	7,414,038	Embolic materials
			Medarex, Inc. (Princeton, NJ)	7,425,541	Enzyme-cleavable prodrug compounds
			Merck Serono S.A. (Geneva, Switz.)	7,585,840	Use of osteoprotegerin for the treatment and/or prevention of fibrotic disease
			Microbia, Inc. (Cambridge, MA)	7,371,727	Methods and compositions for the treatment of gastrointestinal disorders
			Mitsubishi Tanabe Pharma Corporation (Osaka, Japan)	7,566,728	Remedy for sleep disturbance
			Novartis AG (Basel, Switz.)	6,878,721	Beta2-adrenoceptor agonists
				7,348,353	Acetylene derivatives having mGluR 5 antagonistic activity
			Novartis Vaccines and Diagnostics, Inc. (Emeryville, CA)	7,470,709	Benzimidazole quinolinones and uses thereof
			Oxagen Limited (Abingdon, Gr. Brit.)	7,582,672	Compounds for the treatment of CRTH2-mediated diseases and conditions
			Palau Pharma, S.A. (Palau-solita i Plegamans, Spain)	7,468,376	Pyrazolopyridine derivates
			Paratek Pharmaceuticals, Inc. (Boston, MA)	7,553,828	9-aminomethyl substituted minocycline compounds
			Pfizer Inc. (New York, NY)	7,595,325	Substituted pyrrolo[2,3-d]pyrimidine derivatives useful in cancer treatment
			ProChon Biotech, Ltd. (Rehovot, Isr.)	7,563,769	FGF variants and methods for use thereof

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Rigel Pharmaceuticals, Inc. (South San Francisco, CA)	7,517,886	Methods of treating or preventing autoimmune diseases with 2,4-pyrimidinediamine compounds
			Schering Corporation (Kenilworth, NJ)	7,592,348	Heterocyclic aspartyl protease inhibitors
				7,612,058	Methods for inhibiting sterol absorption
			Seattle Genetics, Inc. (Bothell, WA)	7,498,298	Monomethylvaline compounds capable of conjugation to ligands
			SmithKline Beecham Corp. (Philadelphia, PA)	7,514,437	Substituted diketopiperazines as oxytocin antagonists
				7,547,719	3'-[(2z)-[1-(3,4-Dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4h-pyrazol-4-y- lidene]hydrazino]-2'-hydroxy-[1,1'-piphenyl]-acid bis-(monoethanolamine)
			Solvay Pharmaceuticals B.V. (Weesp, Neth.)	7,381,729	4-(4-trans-hydroxycyclohexyl)amino-2-phenyl-7H-pyrrolo [2,3D] pyrimidine hydrogen mesylate, its polymorphic forms, and methods for making same
				7,524,867	Tetrasubstituted imidazole derivatives as cannabinoid CB.sub.1 receptor modulators with a high CB.sub.1/CB.sub.2 receptor subtype selectivity
			Sylentis S.A.U. (Madrid, Spain)	7,592,325	Methods and compositions for the treatment of eye disorders with increased intraocular pressure
			The Board of Trustees of the Leland Stanford Junior University (Palo Alto, CA)	7,544,669	Polynucleotide therapy
			The Kitasato Institute (Tokyo, Japan)	7,560,484	Vaccine preparation containing fatty acid as a constituent
			The Trustees of Columbia University In the City of New York (New York, NY)	7,544,678	Anti-arrythmic and heart failure drugs that target the leak in the ryanodine receptor (RyR2)

Table A6.3
Drugs & Medical Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
			Transtech Pharma, Inc. (High Point, NC)	7,544,699	Aryl and heteroaryl compounds, compositions, and methods of use
			X-Ceptor Therapeutics, Inc. (San Diego, CA)	7,482,366	Modulators of LXR
			Magnachem Int'l Laboratories, Inc. (Boca Raton, FL)	7,323,495	Synthetic lactone formulations and method of use
			Symphony Evolution, Inc. (Rockville, MD)	7,629,341	Human ADAM-10 inhibitors
			Schwarz Pharma AG (Monheim, Ger.)	7,632,859	Iontophoretic delivery of rotigotine for the treatment of Parkinson's disease
			Japan Tobacco Inc. (Tokyo, Japan)	7,635,704	Stable crystal of 4-oxoquinoline compound
			Merck & Co., Inc. (Rahway, NJ)	7,326,708	Phosphoric acid salt of a dipeptidyl peptidase-IV inhibitor
			Novartis AG (Basel, Switz.) Sibia Neurosciences Inc. (La Jolla, CA)	6,656,957	Pyridine derivatives
			Chiron Corporation (Emeryville, CA)	7,265,089	KGF polypeptide compositions
			Nippon Shinyaku Co., Ltd. (Kyoto, Japan)	7,205,302	Heterocyclic compound derivatives and medicines
				7,494,997	Amide derivative
			Actelion Pharmaceuticals Ltd. (Switz.)	7,094,781	Sulfamides and their use as endothelin receptor antagonists
			Universitat Zurich (Zurich, Switz.) Eidgenossische Technische Hochschule Zurich (Zurich, Switz.)	7,247,609	Growth factor modified protein matrices for tissue engineering
Surgery & Med Inst.	128	Surgery	The General Hospital Corporation (Boston, MA)	7,367,341	Methods and devices for selective disruption of fatty tissue by controlled cooling
	606	Surgery	Therm Med, LLC (Erie, PA)	7,510,555	Enhanced systems and methods for RF-induced hyperthermia
	602	Surgery: Splint, Brace, or Bandage	Argentum Int'l, LLC (Lakemont, GA)	7,291,762	Multilayer conductive appliance having wound healing and analgesic properties

Table A6.4
Electrical & Electronic, Mechanical, and Other Patents Analyzed

Subcategory	Class	Major Class Name	Assignee	Patent	Title
Measuring & Testing	356	Optics: Measuring and Testing	Nova Measuring Instruments Ltd. (Rehovot, Isr.)	7,477,405	Method and system for measuring patterned structures
	324	Electricity: Measuring and Testing	Serconet, Ltd. (Ra'Anana, Isr.)	7,521,943	Device, method and system for estimating the termination to a wired transmission-line based on determination of characteristic impedance
Miscellaneous-Elec	348	Television	No Assignee	7,432,978	Portable device having a torch and a camera located between the bulb and the front face
Miscellaneous-Mechanical	384	Bearings	Daido Metal Company Ltd (Nagoya, Japan)	7,431,507	Sliding member
Miscellaneous-Others	116	Signals and Indicators	Glaxo Group Limited (Greenford, Gr. Brit.)	7,500,444	Actuation indicator for a dispensing device
	52	Static Structures (e.g., Buildings)	No Assignee	7,481,031	Load transfer plate for in situ concrete slabs
Agriculture,Husbandry,Food	426	Food or Edible Material: Processes, Compositions, and Products	Simply Thick LLP (Clayton, MO)	7,638,150	Process for preparing concentrate thickener compositions

Table A7*
Characterization of A, B, and Applicant Delays in PTA Cases (n=225)

Filing Date	Docket No.	Party Name	Patent	Delays				PTA_{Req}	PTA_{PTO}	$\Delta PTA_{(Req-PTO)}$	US?	RCE?	TD/Appeal	Simple/ Complex	Filed > 183 Days
				A & C	B	-AB	-Applicant								
2007-08-17	2007cv01492	Wyeth	7,179,892	610	345	-51	-148	756	462	294	+		TD	C	
2007-08-17	2007cv01492	Wyeth	7,189,819	336	827	-106	-335	722	492	230	+			C	
2008-09-05	2008cv01542	Napo Pharm.	7,341,744	1602	1048	-19	-595	2036	453	554	-	+		S	
2008-11-07	2008cv01932	Ironwood Pharm.	7,371,727	472	291	0	-61	702	411	291	+			S	
2008-11-28	2008cv02053	Solvay Pharm.	7,381,729	534	99	0	0	633	534	99	+	+		S	
2008-12-01	2008cv02061	Biogen Idec	7,381,560	1371	1389	-702	0	2058	1409	649	+			S	
2008-12-01	2008cv02065	Molecular Insight Pharm.	7,381,745	557	356	0	-267	646	377	269	+	+		S	
2008-12-01	2008cv02067	Purac Biochem	7,410,556	654	563	0	-268	949	386	563	-	+		S	
2008-12-01	2008cv02068	Molecular Insight Pharm.	7,381,399	682	815	-13	-181	1303	634	669	+			S	
2008-12-12	2008cv02170	Eurand	7,387,793	185	581	0	-111	655	470	185	+			S	
2008-12-12	2008cv02174	Medarex	7,387,776	492	290	0	-261	521	231	290	+	+		C	
2008-12-23	2008cv02225	Alexion Pharm.	7,393,648	538	296	0	-76	758	482	276	+	+		S	
2008-12-23	2008cv02225	Alexion Pharm.	7,396,917	575	241	0	-162	654	413	241	+	+		S	

* The dynamic nature of events following the filing of a court case, also preclude an analysis of the final disposition of every case, including events taking place at the PTO. Our analysis, supported by a database of key events, is primarily based on information provided in the court complaints, and public information available in the PAIR database, including the PTA entries, the electronic file wrapper, and the transaction history. Data reflected in tables describing A&C and B delays, AB overlaps, and Applicant delays generally reflect values asserted by the patentees, updated to reflect petition decisions noted in the file history, or the most likely values in our view if alternate scenarios were presented in the complaints. Cases which were assessed as being "Simple" were generally not reevaluated, while those involving disputes over the characterization of documents or delay periods, or had obvious date calculation errors, were designated "Complex." Complex cases were evaluated several times to ascertain issues, stimulating modifications to our database to record new fields in a few cases. The analysis was challenging when applicants did not provide direct support for their calculations for the sum of different delay periods noted above for each of the patents cited in their complaints. In a few cases, the requested PTAs differed from the calculated PTAs for reasons we could not ascertain, or they sought equitable relief for long delays that may be outside the scope of the PTA statutes and regulations. Patents noted with a "+" in the last column, for example, were listed in complaints that were filed more than 183 days after the patent issued. Please consult PACER and PAIR to obtain the most recent information concerning disposition of specific court complaints and petitions to the PTO relating to PTA recalculation requests.

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				A & C	B	-AB	-Applicant								
2008-12-23	2008cv02225	Alexion Pharm.	7,399,594	645	478	0	-133	990	512	478	+	+		S	
2008-12-23	2008cv02225	Alexion Pharm.	7,408,041	394	48	0	-136	306	258	48	+	+		S	
2008-12-23	2008cv02225	Alexion Pharm.	7,414,111	613	321	0	-64	870	549	321	+	+		C	
2008-12-23	2008cv02225	Alexion Pharm.	7,427,665	607	433	0	-228	812	379	433	-	+		S	
2008-12-23	2008cv02225	Alexion Pharm.	7,435,412	692	955	-23	-612	1012	343	669	+			S	
2009-01-15	2009cv00113	Bayer Bioscience	7,402,420	496	408	0	-237	667	259	408	+	+	App	C	
2009-01-16	2009cv00109	General Hospital	7,367,341	362	301	0	-148	515	214	301	+	+		S	+
2009-01-16	2009cv00112	Syntonix Pharm.	7,404,956	433	450	-104	-27	752	423	329	+		App	C	
2009-02-06	2009cv00243	Dyax	7,413,537	1925	1115	-140	-171	2729	639	975	+			S	
2009-02-17	2009cv00308	Kabushiki	7,414,038	758	640	-88	-1	1309	757	552	-	+		S	
2009-02-17	2009cv00309	Purdue Pharma	7,413,748	682	447	-14	-145	970	537	141	+	+	TD	C	
2009-02-25	2009cv00378	Alphavax	7,419,674	222	52	0	-202	72	20	52	+	+		C	
2009-02-27	2009cv00398	GlaxoSmithKline Biologicals	7,419,824	506	623	0	-165	964	458	506	+			C	
2009-03-02	2009cv00407	Laboratoires Serono	7,419,999	77	267	0	-53	291	214	77	-			S	
2009-03-05	2009cv00435	Iinotek Pharm.	7,423,144	182	107	-15	-32	242	150	92	+			S	
2009-03-12	2009cv00480	Medarex	7,425,541	654	1101	0	-413	1342	703	639	+	+		C	
2009-03-13	2009cv00487	Geron	7,425,448	1090	1162	-567	-153	1532	1009	523	+		App	C	
2009-03-13	2009cv00502	Array Biopharma	7,425,637	447	13	0	-65	395	382	13	+	+		C	
2009-03-20	2009cv00539	Biogen Idec	7,427,403	881	1316	-209	-767	1221	1009	212	+			C	
2009-03-20	2009cv00540	Biogen Idec	7,429,644	1454	384	0	-384	1454	520	550	+			S	
2009-03-26	2009cv00575	Memory Pharm.	7,429,664	777	736	-167	-5	1341	652	680	+			C	
2009-04-06	2009cv00628	Daido Metal	7,431,507	755	487	-86	-61	1095	694	401	+			S	
2009-04-06	2009cv00629	Storm	7,432,978	568	466	0	-28	1006	540	466	-			S	
2009-04-06	2009cv00630	Institut National Des Sciences Appliquees	7,439,049	429	390	-18	-46	755	301	454	-			C	
2009-04-10	2009cv00676	Novozymes Biopharma	7,435,410	270	129	-57	-148	194	122	72	+			C	
2009-04-10	2009cv00684	Gedeon	7,435,744	678	257	0	-98	837	580	257	+	+		C	
2009-04-17	2009cv00709	Genmab	7,438,907	473	470	0	-89	854	384	470	+	+		C	

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				A & C	B	-AB	-Applicant								
2009-04-20	2009cv00715	Accenture Global Services	7,440,906	1081	998	-411	-336	1332	745	587	+	+		S	
2009-04-20	2009cv00715	Accenture Global Services	7,457,762	1047	1138	-468	-68	1649	1070	579	+	+		C	
2009-04-20	2009cv00715	Accenture Global Services	7,457,763	1219	1119	-413	-187	1738	1032	706	+	+		C	
2009-04-20	2009cv00715	Accenture Global Services	7,461,008	1057	643	-376	-136	1188	921	267	+	+		S	
2009-04-20	2009cv00715	Accenture Global Services	7,469,219	567	215	0	-93	689	474	215	+	+		S	
2009-04-20	2009cv00715	Accenture Global Services	7,502,744	1120	709	-396	-194	1239	926	0	+	+		S	
2009-04-20	2009cv00726	Ebi Food Safety	7,438,901	468	325	0	-90	703	258	445	-			C	
2009-04-21	2009cv00730	Alphavax	7,442,381	745	589	-76	-102	1156	0	1156	+	+		S	
2009-04-23	2009cv00754	Biogen Idec	7,442,370	674	706	-11	-595	774	310	464	+	+		C	
2009-04-24	2009cv00760	Hoffman-LaRoche	7,442,776	580	445	0	-184	841	396	445	+	+		S	
2009-04-30	2009cv00792	Biogen Idec	7,446,173	590	305	0	-88	807	502	305	+	+		C	
2009-04-30	2009cv00804	Novartis	7,446,175	532	986	-98	-262	1158	489	642	-			C	
2009-05-04	2009cv00820	Yeda R&D	7,445,802	431	674	-1	-80	1024	594	430	+			S	
2009-05-06	2009cv00838	Genentech	7,449,184	331	149	0	-61	419	121	149	+			S	
2009-05-14	2009cv00902	Medarex	7,452,535	509	966	0	-318	1157	191	457	+	+		C	
2009-05-15	2009cv00907	Genentech	7,452,539	666	589	0	-92	1163	574	589	+	+		S	
2009-05-15	2009cv00908	Glaxo Group	7,452,888	498	175	0	-126	547	372	175	-	+		S	
2009-05-22	2009cv00960	Ohio State Research Foundation	7,455,995	629	884	-66	-179	1268	705	563	+	+		C	
2009-06-01	2009cv01021	Univ. of Mass.	7,459,547	231	267	0	-183	315	131	184	+	+		S	
2009-06-04	2009cv01037	Astrazeneca	7,462,623	553	219	-12	-2	758	551	207	-			C	
2009-06-11	2009cv01080	Cellgene	7,465,800	596	373	0	0	969	596	373	+	+		S	
2009-06-11	2009cv01082	Medarex	7,465,446	490	569	0	0	1059	569	490	+			S	
2009-06-22	2009cv01141	Palau Pharma	7,468,376	404	119	0	-56	467	348	119	+			S	
2009-06-26	2009cv01166	Arena Pharm.	7,470,699	397	540	0	-41	896	499	397	+			S	
2009-06-29	2009cv01195	Human Genome Sciences	7,470,510	557	561	0	-206	912	355	557	+	+		S	
2009-06-30	2009cv01201	Novartis Vaccines & Diagnostics	7,470,709	602	419	0	-210	811	392	419	+	+		C	
2009-06-30	2009cv01202	Novartis	7,473,761	953	1070	-490	-75	1458	878	580	+			S	

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				A & C	B	-AB	-Applicant								
2009-06-30	2009cv01203	Novartis	7,470,792	205	292	0	-74	423	218	205	-			C	
2009-07-02	2009cv01227	Alnylam Europe	7,473,525	805	1036	-248	-259	1334	768	566	+			C	
2009-07-08	2009cv01265	Genentech	7,476,724	515	162	-52	-84	541	431	110	+			C	
2009-07-13	2009cv01305	Nova Measuring Instruments	7,477,405	680	774	-175	-148	1131	472	659	+			C	
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,417,040	318	183	0	0	501	318	183	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,417,063	500	137	0	0	637	590	47	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,427,493	473	816	0	-126	1163	690	473	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,429,604	431	109	0	0	540	431	109	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,429,611	236	9	0	0	245	236	9	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,432,267	381	101	0	-11	471	370	101	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,432,271	523	402	-79	0	846	523	323	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,432,373	369	105	0	0	474	369	105	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,435,808	478	479	-45	-192	720	282	438	+			C	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,446,196	507	156	0	-28	635	479	156	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,452,678	571	515	-87	-115	884	456	428	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,453,002	302	158	0	-13	447	289	158	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,455,835	394	521	0	-523	392	0	392	+	+	Both	C	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,459,562	429	225	0	-38	616	391	225	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,470,712	509	346	0	-1	854	508	346	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,470,713	560	316	0	0	876	560	316	+			S	+
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,479,496	550	338	0	0	888	550	338	+			S	
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,482,372	590	303	0	0	893	590	303	+			S	
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,504,211	255	263	0	-313	205	0	205	+	+		S	
2009-07-17	2009cv01330	Bristol-Meyers Squibb	7,517,991	364	385	0	0	749	364	185	+			S	
2009-07-20	2009cv01345	Mosaid Technologies	7,480,233	802	255	-132	0	925	802	123	+			S	
2009-07-24	2009cv01372	PNA Construction Technologies	7,481,031	655	687	0	-335	1007	352	655	+			S	
2009-07-24	2009cv01373	X-Ceptor Therapeutics	7,482,366	692	553	-24	-5	1216	687	529	+			S	

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				A & C	B	-AB	-Applicant								
2009-07-27	2009cv01383	Judicial Foundation	7,482,436	427	334	0	0	761	427	334	-			S	
2009-07-31	2009cv01431	Exelixis	7,485,634	289	306	0	-265	330	41	289	+	+		C	
2009-07-31	2009cv01434	Dyax	7,485,297	259	178	0	-100	337	159	178	+			S	
2009-08-11	2009cv01510	Intermune	7,491,794	456	325	-57	0	724	399	325	+			C	
2009-08-14	2009cv01542	Boehringer Ingelheim Pharma	7,491,824	515	178	0	-37	656	478	178	+			S	
2009-08-17	2009cv01553	Geron	7,494,982	453	309	-25	-182	555	191	364	+	+		C	
2009-08-20	2009cv01585	Human Genome Sciences	7,504,105	410	265	0	-94	581	316	265	+	+		C	
2009-08-21	2009cv01599	Vertex Pharm.	7,495,103	509	244	0	-59	694	450	244	+			C	
2009-08-28	2009cv01645	Lifenet Health	7,498,040	261	142	-18	-154	231	107	124	+			S	
2009-08-28	2009cv01645	Lifenet Health	7,498,041	413	142	-19	-142	394	271	123	+			S	
2009-08-28	2009cv01646	Genentech	7,498,030	231	175	0	-103	303	128	175	+			S	
2009-08-28	2009cv01647	Seattle Genetics	7,498,298	321	483	-27	-199	578	274	304	+			S	
2009-09-02	2009cv01673	Unilever Patent Holdings	7,501,556	392	336	0	-95	633	392	241	-			S	
2009-09-09	2009cv01714	Glaxo Group	7,500,444	592	238	0	-27	803	565	238	-	+		S	
2009-09-11	2009cv01729	Boehringer Ingelheim Pharma	7,504,378	332	97	0	0	429	332	97	+			S	
2009-09-18	2009cv01771	Vertex Pharm.	7,507,826	369	73	0	-126	316	243	73	+	+		C	
2009-09-18	2009cv01773	Amgen	7,507,735	412	281	-88	0	605	412	193	+			S	
2009-09-24	2009cv01822	Iterative Therapeutics	7,511,121	472	530	0	-325	677	263	414	+	+		C	
2009-09-25	2009cv01829	Amgen	7,511,012	529	833	0	-252	1110	581	529	+			C	
2009-09-25	2009cv01863	Therm Med	7,510,555	549	422	-41	-282	648	267	381	+			S	
2009-09-30	2009cv01866	Wellstat Therapeutics	7,514,555	159	358	0	-276	241	82	159	-			S	
2009-10-02	2009cv01885	Boehringer Ingelheim Pharma	7,514,557	600	319	0	-30	889	570	319	+			S	
2009-10-05	2009cv01893	SmithKlineBeecham	7,514,437	408	449	-11	-33	813	375	438	-	+		C	
2009-10-08	2009cv01914	Rigel Pharm.	7,517,886	735	990	-371	-250	1104	740	364	+			S	
2009-10-09	2009cv01928	Chugai	7,517,965	360	448	0	-92	716	356	360	-			S	
2009-10-15	2009cv01955	Banyu Pharmaceutical	7,521,455	635	182	0	0	817	635	182	+	+		S	
2009-10-16	2009cv01956	Theravance	7,521,558	617	249	0	0	866	617	249	+			S	

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				A & C	B	-AB	-Applicant								
2009-10-16	2009cv01959	Rockefeller Univ.	7,521,258	441	255	0	-111	585	330	255	+	+		S	
2009-10-19	2009cv01964	CSIRO	7,521,593	585	615	0	-358	842	247	595	+	+		C	
2009-10-19	2009cv01965	Mosaid Technologies	7,521,943	751	388	-81	0	1058	751	307	+			S	
2009-10-19	2009cv01966	Mosaid Technologies	7,522,615	1287	745	-618	0	1414	1287	127	-			S	
2009-10-19	2009cv01968	Mosaid Technologies	7,522,714	593	86	0	0	679	593	86	+			S	
2009-10-19	2009cv01969	Centre National De La Recherche Scientifique	7,521,212	435	782	0	-378	839	264	575	-	+		C	
2009-10-23	2009cv02007	Solvay Pharm.	7,524,867	480	71	0	0	551	480	71	+	+		S	
2009-11-04	2009cv02078	Theravance	7,531,623	766	37	0	0	803	766	37	+	+		S	
2009-11-06	2009cv02097	Biogen Idec Ma	7,531,174	322	380	0	-171	531	233	298	-	+		S	
2009-11-09	2009cv02106	Intrexon	7,531,326	481	478	0	-288	671	193	478	-	+		C	
2009-11-12	2009cv02127	Idenix Pharm.	7,534,809	344	13	0	0	357	344	13	+	+		S	
2009-11-25	2009cv02238	Bayhill Therapeutics	7,544,669	719	561	0	-238	1042	481	561	+	+		S	
2009-11-27	2009cv02255	Tolerx	7,541,443	906	877	-235	-181	1367	605	762	+	+		C	
2009-11-27	2009cv02256	Cephalon France	7,541,493	422	198	-44	0	576	422	154	-			S	
2009-12-02	2009cv02281	Columbia Univ.	7,544,678	596	443	0	-97	942	499	443	+			S	
2009-12-02	2009cv02282	Memorial Sloan-Kettering Cancer Center	7,541,179	252	803	0	-372	683	431	252	+	+		S	
2009-12-02	2009cv02283	Pfizer	7,544,362	197	107	0	-97	207	100	107	+			S	
2009-12-03	2009cv02292	Conforma Therapeutics	7,544,672	43	72	0	0	115	72	43	+			C	
2009-12-04	2009cv02298	GlaxoSmithKline	7,547,719	290	573	-76	-2	785	288	497	-			C	
2009-12-04	2009cv02305	Transtech Pharma	7,544,699	530	226	0	-2	754	528	226	+	+		C	
2009-12-04	2009cv02306	Neuralstem	7,544,511	756	489	0	-556	689	200	489	+	+		C	
2009-12-11	2009cv02354	Thrombogenics	7,547,435	191	436	0	-443	184	0	184	+	+		C	
2009-12-11	2009cv02355	MIT	7,547,556	900	489	-231	-7	1151	893	258	+	+		S	
2009-12-16	2009cv02373	Hoffman-LaRoche	7,557,114	201	157	0	-122	236	79	157	+			S	
2009-12-23	2009cv02418	Alantos Pharm.	7,553,861	622	70	0	0	692	622	70	+			S	
2009-12-23	2009cv02420	Bristol-Meyers Squibb	7,491,725	251	203	0	-37	417	214	203	+			S	+
2009-12-23	2009cv02420	Bristol-Meyers Squibb	7,514,430	537	253	0	0	790	537	253	+			S	+

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				A & C	B	-AB	-Applicant								
2009-12-23	2009cv02420	Bristol-Meyers Squibb	7,557,143	682	354	-43	-29	964	653	311	+	+		S	
2009-12-23	2009cv02420	Bristol-Meyers Squibb	7,589,088	589	268	0	0	857	589	268	+			S	
2009-12-23	2009cv02420	Bristol-Meyers Squibb	7,589,193	433	357	0	0	790	433	357	+			S	
2009-12-28	2009cv02425	Paratek Pharm.	7,553,828	570	345	0	-212	703	358	345	+	+	App	C	
2010-01-08	2010cv00029	Hoffman-La Roche	7,563,441	471	216	0	-128	559	343	216	+	+		S	
2010-01-08	2010cv00033	Kitasato	7,560,484	610	673	-106	-189	988	779	209	-	+		C	
2010-01-08	2010cv00035	Celldex Research	7,563,876	1005	624	-67	-392	1170	613	557	+	+		S	
2010-01-13	2010cv00064	Celldex Research	7,560,534	657	507	-30	-552	582	171	411	+	+	TD	C	
2010-01-14	2010cv00068	Domantis	7,563,443	484	469	-23	-149	781	335	446	+			S	
2010-01-15	2010cv00082	Eisai R&D Management	7,563,811	309	380	0	-71	618	309	309	+			S	
2010-01-19	2010cv00094	Prochon	7,563,769	506	624	0	-266	864	358	506	+			S	
2010-01-22	2010cv00129	Mitsubishi	7,566,728	575	668	0	-98	1145	544	601	-			C	
2010-01-22	2010cv00131	Cephalon	7,566,805	256	146	-103	-150	149	107	42	-			C	
2010-01-25	2010cv00141	International MultiMedia	7,567,779	281	315	0	-187	409	128	281	+		TD	S	
2010-01-29	2010cv00164	Novartis	7,569,337	731	702	-89	-87	1257	640	617	-			C	
2010-01-29	2010cv00166	Idera Pharm.	7,517,862	687	598	-18	-93	1174	594	580	+			S	+
2010-01-29	2010cv00166	Idera Pharm.	7,569,554	668	812	-114	-91	1275	722	553	+		TD	C	
2010-02-01	2010cv00183	Oncotherapy Science	7,569,351	333	482	0	-352	463	129	334	-	+		C	
2010-02-12	2010cv00213	Andromeda Biotech	7,576,177	601	750	-132	-178	1041	572	469	+			S	
2010-02-12	2010cv00215	Daiichi Sankyo	7,576,135	144	419	0	-58	505	86	418	-			C	
2010-02-16	2010cv00225	Arius Two	7,579,019	856	542	-186	-21	1191	835	356	+			S	
2010-02-18	2010cv00253	Boehringer Ingelheim Pharma	7,579,449	302	29	0	-96	235	206	29	+	+		S	
2010-02-19	2010cv00264	Amgen	7,579,168	383	308	0	-121	570	262	308	+			S	
2010-02-19	2010cv00269	Markem-Imaje	7,578,874	449	316	0	-265	500	221	279	-	+		S	
2010-02-19	2010cv00271	Galderma R&D	7,579,377	820	715	-151	-106	1278	714	564	+			S	
2010-02-26	2010cv00312	Biogen Idec Ma	7,582,299	501	335	0	-335	501	166	335	+	+	TD	S	
2010-02-26	2010cv00313	Bullion Direct	7,584,135	1211	1115	-393	-139	1794	984	810	+	+		C	

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				A & C	B	-AB	-Applicant								
2010-02-26	2010cv00318	Boehringer Ingelheim Pharma	7,582,770	631	561	0	-67	1125	492	633	+			S	
2010-03-01	2010cv00325	Oxagen	7,582,672	546	329	0	-72	803	474	329	+	+		C	
2010-03-03	2010cv00348	Merck Serono	7,585,840	432	694	0	-203	923	491	432	+		TD	S	
2010-03-05	2010cv00370	Boehringer Ingelheim Pharma	7,585,845	457	132	0	0	589	518	71	+	+		S	
2010-03-05	2010cv00372	AstraZeneca	7,585,881	526	577	-65	-38	1000	553	512	+			S	
2010-03-12	2010cv00412	Enzon Pharm.	7,589,190	363	310	0	-262	411	101	310	+			S	
2010-03-12	2010cv00416	Mount Sinai School of Medicine of NY Univ.	7,588,768	600	514	0	-372	742	166	576	+	+	App	C	
2010-03-15	2010cv00424	Schering	7,592,348	596	649	0	-104	1141	551	590	+			C	
2010-03-19	2010cv00458	Sylentis	7,592,325	175	212	0	-116	271	96	175	+			S	
2010-03-24	2010cv00488	Children's Hospital	7,595,307	302	102	0	-63	341	239	102	+	+		C	
2010-03-26	2010cv00496	Genentech	7,595,046	551	294	0	-138	707	245	462	+			C	
2010-03-26	2010cv00504	Pfizer	7,595,325	391	490	-86	-115	680	375	391	+			C	
2010-04-02	2010cv00542	Cummins-Allison	7,599,543	780	424	-110	-60	1034	720	314	+			S	
2010-04-07	2010cv00564	Amgen	7,601,818	480	225	0	-63	642	417	227	+	+		S	
2010-04-08	2010cv00567	Cummins-Allison	7,602,956	690	266	-20	0	936	690	246	+	+		S	
2010-04-09	2010cv00575	Human Genome Sciences	7,601,351	722	1206	-163	-223	1542	1497	45	+	+	App	C	
2010-04-09	2010cv00575	Human Genome Sciences	7,605,236	207	350	0	-79	478	209	269	+			C	
2010-04-12	2010cv00580	Tepha	7,025,980	771	198	0	-143	826	797	29	+		App	C	+
2010-04-21	2010cv00620	Kinaxis	7,610,212	691	993	0	-82	1602	1233	369	+	+		C	
2010-04-30	2010cv00673	Schering	7,612,058	970	705	-301	0	1374	899	475	+		TD	C	
2010-04-30	2010cv00674	Biogen Idec MA	7,612,178	139	0	0	0	139	88	51	+			C	
2010-05-07	2010cv00743	Georgetown Univ.	7,615,355	838	751	-169	-33	1387	391	996	-			C	
2010-05-13	2010cv00781	Pfizer	7,618,626	104	0	0	-47	57	7	50	+	+		C	
2010-05-26	2010cv00892	Magnachem	7,323,495	387	335	-22	-41	659	409	250	+	+	Both	C	+
2010-05-28	2010cv00894	Univ. of Mass.	7,625,559	689	666	-18	-61	1276	623	653	+			C	
2010-06-07	2010cv00938	Symphony Evolution	7,629,341	604	550	-76	-138	940	506	434	-			C	
2010-06-10	2010cv00972	UCB Pharma	7,632,859	823	914	-154	-117	1466	1465	1	+	+		C	

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				A & C	B	-AB	-Applicant								
2010-06-14	2010cv00987	Logitech Europe	7,634,146	912	609	-239	-78	1204	834	370	+	+		C	
2010-06-17	2010cv01023	Japan Tobacco	7,635,704	44	581	-12	-93	520	237	283	-		App	C	
2010-06-18	2010cv01032	GlaxoSmithKline	7,635,701	527	669	-227	-119	850	550	300	-			C	
2010-06-21	2010cv01041	Logitech Europe	7,636,805	541	242	0	-269	514	277	237	+	+	App	C	
2010-06-25	2010cv01076	Simply Thick	7,638,150	699	463	0	-59	1103	889	214	-			C	
2010-06-30	2010cv01110	Merck Sharp & Dohme	7,326,708	657	226	0	0	883	657	226	+			C	+
2010-07-06	2010cv01138	Novartis	6,656,957	567	5	0	0	572	567	5	+			C	+
2010-07-06	2010cv01138	Novartis	6,878,721	81	129	0	0	210	130	80	-			C	+
2010-07-06	2010cv01138	Novartis	7,098,325	517	326	-153	-111	579	389	190	+			C	+
2010-07-06	2010cv01138	Novartis	7,112,673	364	415	-56	-185	538	235	359	-	+	App	C	+
2010-07-06	2010cv01138	Novartis	7,265,089	624	435	0	-97	962	527	435	+	+	App	C	+
2010-07-06	2010cv01138	Novartis	7,348,353	296	295	-63	-120	408	176	232	-			C	+
2010-07-06	2010cv01138	Novartis	7,423,148	333	16	0	-144	205	280	-75	+	+		C	+
2010-07-06	2010cv01138	Novartis	7,534,890	609	267	0	-89	787	520	267	-			C	+
2010-07-06	2010cv01138	Novartis	7,576,221	306	153	0	-222	237	141	96	+	+		C	+
2010-07-06	2010cv01142	Nippon Shinyaku	7,205,302	344	176	0	0	520	344	156	-			C	+
2010-07-06	2010cv01142	Nippon Shinyaku	7,494,997	220	271	0	-172	319	99	220	-	+		C	+
2010-07-06	2010cv01145	Actelion Pharm.	7,094,781	319	87	-38	-7	361	312	49	-			C	+
2010-07-06	2010cv01146	Anaphore	7,642,044	329	10	0	-125	214	94	120	+	+		C	
2010-07-09	2010cv01173	Kuros Biosurgery	7,247,609	593	375	-85	-188	695	492	290	+	+	App	C	+
2010-07-09	2010cv01177	Argentum Medical	7,291,762	533	132	-50	-361	254	172	82	+	+		S	+
2010-07-09	2010cv01178	Kuros Biosurgery	7,575,740	689	245	0	-188	746	501	245	+	+		C	+
2010-07-21	2010cv01232	Classen Immunotherapeutics	7,653,639	525	255	0	-61	719	374	1754	+	+		C	

Table A8
Statistical Analysis of A, B, and Applicant Delays in PTA Progeny Cases (n=225)

Count	Category	Code	Min	Max	Mean	Median	Mode	Std Dev	10%	25%	50%	75%	90%
223	14 M 1st OA	A(+)-1.703(a)(1)	29	1287	489.8	490	557	218.6	220.0	347.0	490.0	598.0	740.2
67	4M 1st Reply	A(+)-1.703(a)(2)[1st]	1	567	64.4	28	11	88.8	8.2	13.5	28.0	86.0	159.8
7	4M 2nd Reply	A(+)-1.703(a)(2)[2nd]	16	106	51.7	36	-	39.8	16.6	17.5	36.0	84.5	103.0
2	4M Final	A(+)-1.703(a)(3)	66	95	80.5	80.5	-	20.5	68.9	73.3	80.5	87.8	92.1
5	4M Appeal	A(+)-1.703(a)(4)	38	567	165.0	85	-	225.7	42.4	49.0	85.0	86.0	374.6
43	4M IssFee	A(+)-1.703(a)(6)	1	306	65.7	52	57	68.0	7.2	22.0	52.0	83.5	106.2
222	3Y minus	B(+)-1.703(b)	0	1933	620.5	557	424	409.1	156.1	311.3	557.0	832.0	1165.6
86	(RCE	B(-)-1.703(b)(1)	97	1276	469.6	453	309	256.8	202.0	268.0	453.0	548.8	807.0
6	BPAI/FC)	B(-)-1.703(b)(4)	21	742	288.2	161.5	-	306.2	33.0	62.5	161.5	500.5	670.0
2	C3	C3(+)-1.703(e)	598	742	670.0	670	-	101.8	612.4	634.0	670.0	706.0	727.6
165	D	D(-)-1.704(b)[1st]	1	278	53.5	58	92	37.4	4.0	28.0	58.0	89.0	92.0
97		D(-)-1.704(b)[2nd]	2	95	56.5	61	92	30.6	14.2	30.0	61.0	89.0	92.0
48		D(-)-1.704(b)[3rd]	1	122	60.9	75	91	36.6	2.7	30.0	75.0	91.0	94.0
22		D(-)-1.704(b)[4th]	1	95	60.5	81	92	36.4	5.2	27.0	81.0	91.8	92.9
13		D(-)-1.704(b)[5th]	2	91	50.1	52	61	26.5	29.2	30.0	52.0	62.0	87.2
5		D(-)-1.704(b)[6th]	62	92	82.2	90	-	13.0	67.6	76.0	90.0	91.0	91.6
4		D(-)-1.704(c)(1)	26	92	62.0	65	-	29.2	33.8	45.5	65.0	81.5	87.8
2		D(-)-1.704(c)(2)	61	91	76.0	76	-	21.2	64.0	68.5	76.0	83.5	88.0
2		D(-)-1.704(c)(3)	94	329	211.5	211.5	-	166.2	117.5	152.8	211.5	270.3	305.5
1		D(-)-1.704(c)(4)	350	350	350.0	350	-	-	350.0	350.0	350.0	350.0	350.0
7		D(-)-1.704(c)(7)	31	122	66.6	64	-	31.7	35.2	45.5	64.0	79.0	104.6
88		D(-)-1.704(c)(8)[1st]	1	271	43.9	31	31	39.6	7.0	18.0	31.0	67.0	86.3
32		D(-)-1.704(c)(8)[2nd]	5	176	51.8	45.5	5	40.4	9.1	22.0	45.5	73.3	90.3
9		D(-)-1.704(c)(8)[3rd]	8	215	61.7	31	-	65.8	11.2	21.0	31.0	92.0	117.4
4		D(-)-1.704(c)(8)[4th]	8	21	16.8	19	19	5.9	11.3	16.3	19.0	19.5	20.4
1		D(-)-1.704(c)(8)[5th]	31	31	31.0	31	-	-	31.0	31.0	31.0	31.0	31.0
32		D(-)-1.704(c)(10)	2	149	45.6	22	15	42.1	9.1	15.0	22.0	77.3	117.0
5		D(-)-1.704(other)[1st]	1	84	44.2	33	-	33.6	13.0	31.0	33.0	72.0	79.2
1		D(-)-1.704(other)[2nd]	4	4	4.0	4	-	-	4.0	4.0	4.0	4.0	4.0

" - " Not applicable, due to insufficient data.

Figure 1
Representative A and B Delays Illustrated in *Wyeth v. Dudas*

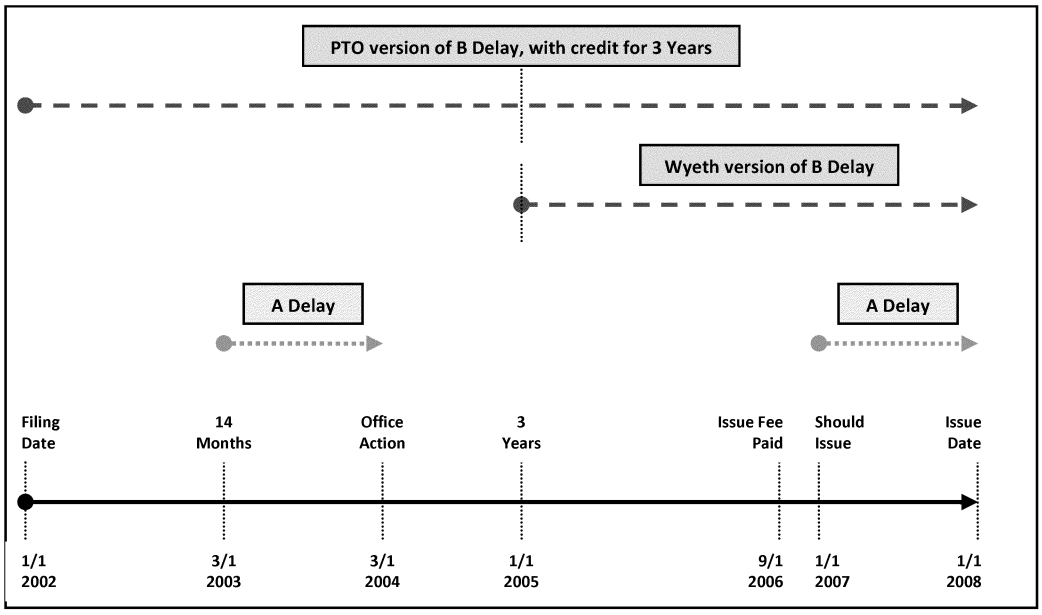

Figure 2
Scatter Chart of PTO PTAs Compared to PTAs Requested by Patentees (n=225)

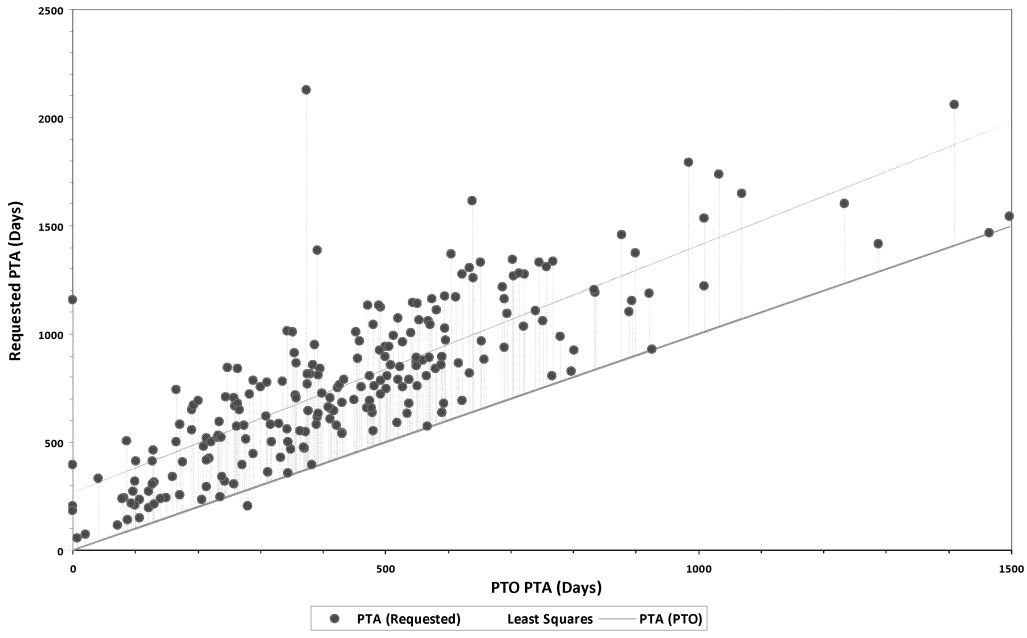

Figure 3
Frequency Distribution of Examination and Applicant Delays for All PTA Cases (n=225)

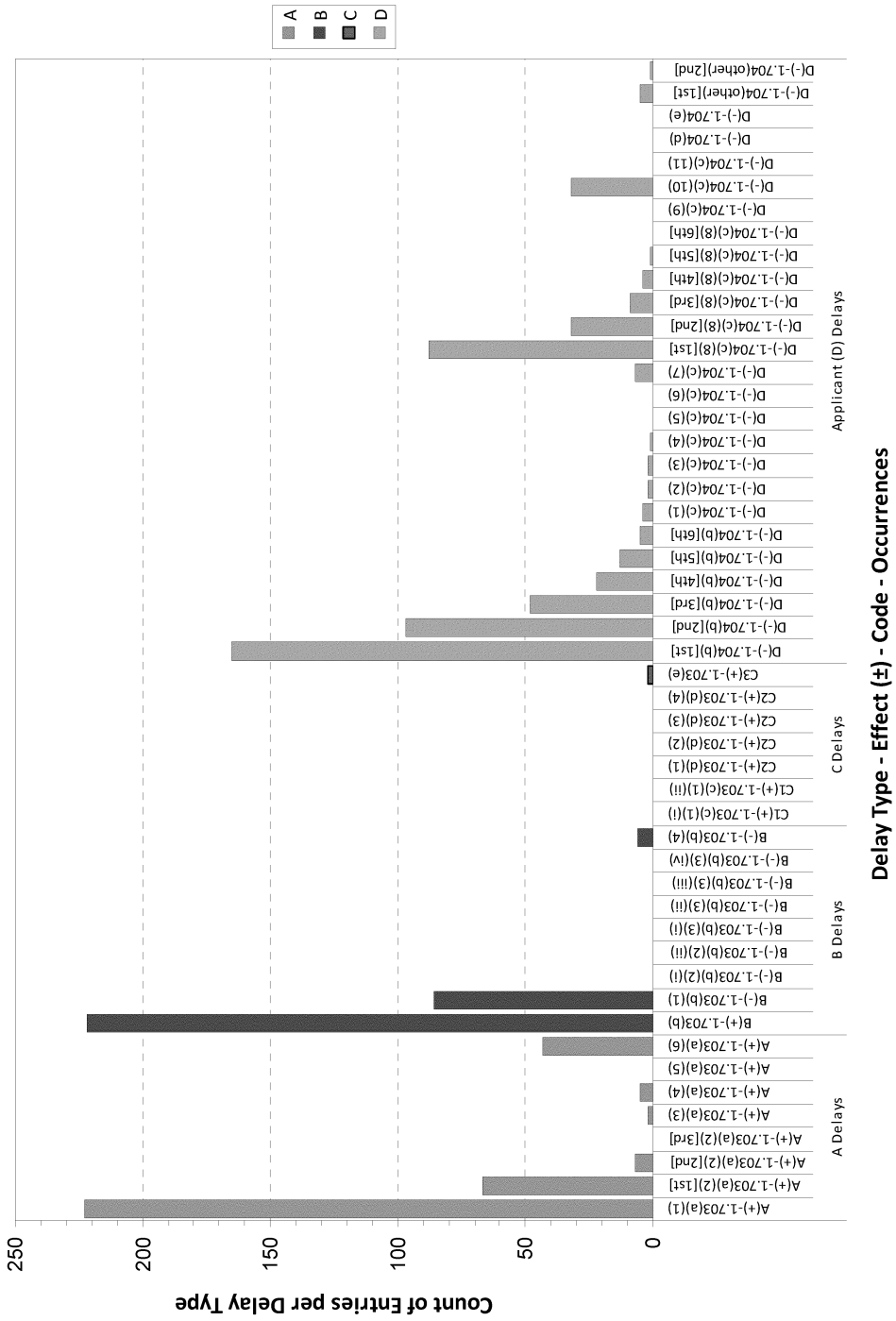

Figure 4
Frequency Distribution of 14 Month A Delays in PTA Progeny Cases (n=225)

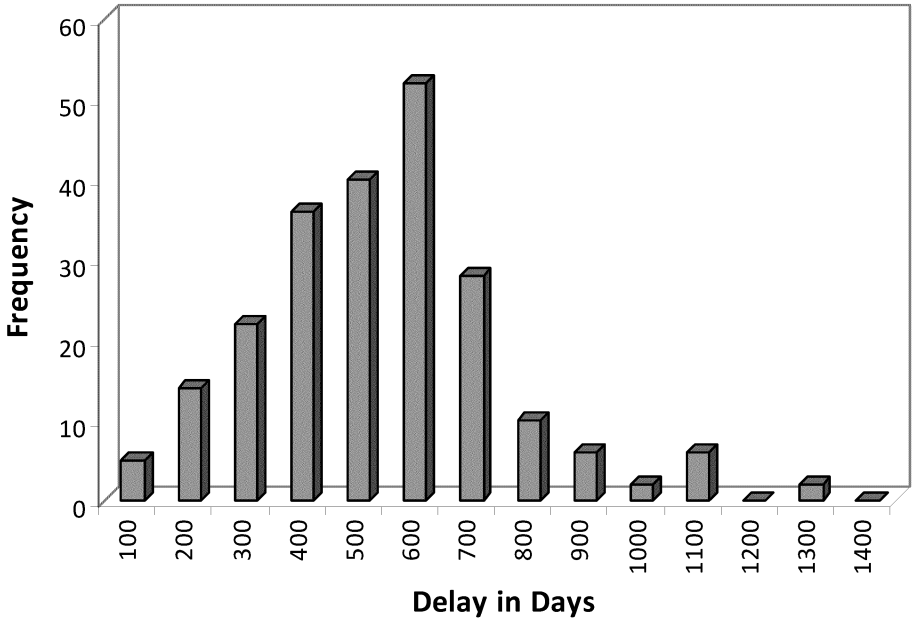

Figure 5
Waterfall Chart Illustrating Cumulative Delays for a Representative Patent

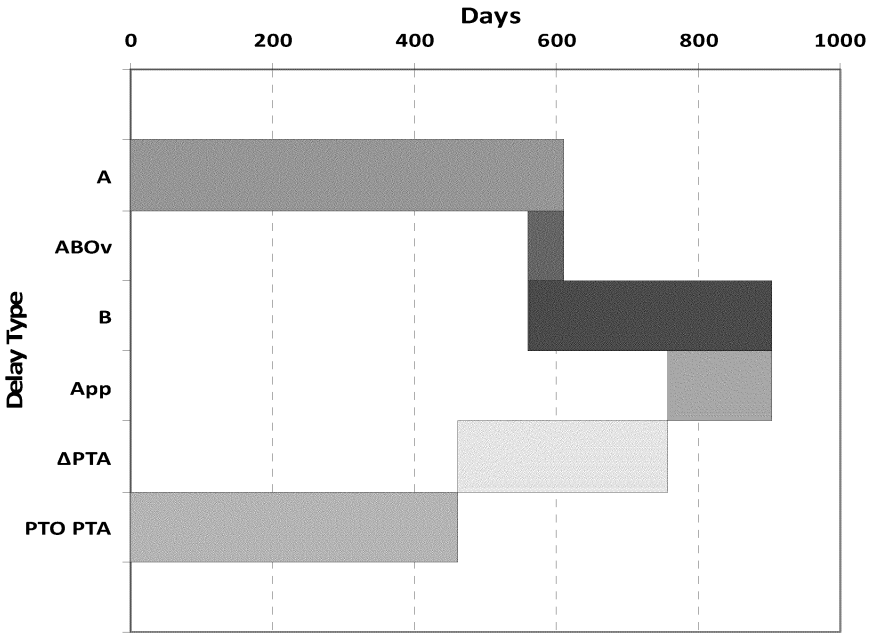

Figure 6
Timeline Illustrating Start of A Clock (ACS), B Clock (BCS), A Period (APS), B Period (BPS), and First RCE Dates Through Issue Date (ID) for a Representative Patent Where BCS<ACS