# Assessing the PTO System for Calculating AIPA Patent Term Adjustment

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The authors are Directors of PatentTerm Online, LLC, an online service to assist practitioners in independently calculating AIPA patent terms. The service is accessible at www.PatentTerm.com. Opinions expressed are solely those of the authors and are not legal advice.

## SUMMARY

o assess the effectiveness of the PTO system for calculating AIPA patent term adjustment (PTA), the authors carefully audited 50 recent patents, randomly selected subject to the criteria that each is assigned to a top 50 pharmaceutical firm and has a pendency of at least 36 months.

Our results indicate that practitioners should be extremely wary of relying exclusively on the PTO-calculated PTA. In 42% of the audited cases, the PTA was incorrectly calculated, with an error range of -319 days (too little PTA) to +177 days (too much PTA). In addition, another 46% of the cases had calculation errors, but those errors did not affect the final PTA (since the final PTA was zero). In only two cases did the applicant seek correction of an erroneous PTA.

# **OVERVIEW OF AIPA PTA CALCULATIONS**

On May 29, 2000, the Patent Term Guarantee provisions of the American Inventor's Protection Act of 1999 (AIPA) became effective<sup>2</sup>, correcting several perceived inequities in the twenty-year-fromfiling patent term provided under the Uruguay Round Agreements Act (URAA)<sup>3</sup>.

Specifically, AIPA provides patent term adjustment to compensate for certain term losses that are not the fault of the applicant such as various PTO prosecution delays, interference proceedings, and successful appeals<sup>4</sup>. Additionally, AIPA guarantees that diligent applicants will always receive at least the same 17-year term as provided under the pre-GATT patent law<sup>5</sup>. For nondiligent applicants, PTA is reduced in accordance with an intricate set of PTO regulations<sup>6</sup>.

Of course, all term guarantees provided by AIPA depend entirely on an accurate PTA determination. Since the laws and regulations implementing PTA are complex, both in substance and especially in application, this determination is not a straightforward proposition.

Primary responsibility for calculating PTA falls to the PTO, with oversight responsibility to the applicant. To fulfill its responsibility, the PTO relies on an automated computer program analyzing the prosecution history data stored in its Patent Application Location and Monitoring (PALM) system. Via this system, an initial PTA calculation is provided to the applicant with the notice of allowance. Thereafter, a final determination, including consideration of post-allowance activity, is provided with the issue notification<sup>7</sup>.

Upon receiving the initial PTA determination, the applicant typically has just one opportunity<sup>8</sup> to challenge the PTO-calculated PTA during the window from issuance of the notice of allowance to payment of the issue fee. Third parties cannot challenge PTA prior to issuance, but can raise the issue in an infringement or declaratory judgment action, or in conjunction with an Abbreviated New Drug Application (ANDA)<sup>9</sup>.

## **METHODOLOGY**

To assess the accuracy of the PTO system for calculating PTA, we randomly selected 50 U.S. national applications<sup>10</sup> subject to AIPA patent term adjustment, issuing from August to early November 2003, subject to the following criteria<sup>11</sup>:

- to increase the likelihood of prosecution activity affecting PTA, we selected applications having a longer than average pendency<sup>12</sup> of 36 to 40 months; and
- (2) to ensure potentially significant commercial value, we selected only applications assigned to a top 50 pharmaceutical company<sup>13</sup>.

For each application, we reviewed the publicly available File Contents and Patent Term Adjustment screens from the Patent Application Information Retrieval (PAIR) system, as well as the actual paper file wrapper for verification. Based on this information, we performed a complete independent PTA calculation, computing both the positive adjustment (for PTO delays and other no-fault delays) and reductions (for dilatory applicant behavior), as well as the final PTA.

# RESULTS

Of the 50 patents, we found that 88% had at least one PTA calculation error<sup>14</sup>, with one case having as many as 6 mistakes<sup>15</sup>. Somewhat analogous to death by a thousand paper cuts, numerous diverse and fact specific issues contributed, so a succinct and complete explanation of exactly what went wrong is difficult to present, but was precisely determined. To illustrate:

- In one case<sup>16</sup>, drawings filed after allowance did not generate a required PTA reduction. But in another case<sup>17</sup>, a phantom drawing (it wasn't actually filed) did generate a reduction.
- In one case<sup>18</sup>, the PTO required itself to respond within 4 months to a response to a notice to comply with sequence listing requirements, generating an improperly large PTA. In other cases<sup>19</sup>, however, the PTO did not require itself to respond within 4-months to an office action response, reducing the proper PTA.
- Information Disclosure Statements filed after office action responses did not typically generate proper reductions<sup>20</sup>, nor did various other papers (such as a request for refund) filed after allowance<sup>21</sup>.
- Rules requiring a 3-month applicant response to a final rejection, and a 4month PTO response thereto, were misapplied or missing in many cases<sup>22</sup>, as well as the rule for 3-year pendency guarantee<sup>23</sup>.
- And so on and so forth.

Generally, all PTA calculation errors stemmed from the rules being misapplied, rules not being applied where required, or PALM data errors where papers had the incorrect dates, improper classifications, or were missing altogether.

Error Category	No. Errors <sup>14</sup>	Typical PTA Effect	Exemplary US Patent Nos.		
PTO used incorrect applicant response event (or incorrect event date) in determining whether applicant took in excess of 3 months to reply to a PTO notice or action, or did not generate a PTA reduction where applicant took longer than 3 months to reply. See 37 CFR § 1.704(b).	30	Either	6,603,031; 6,605,666; 6,608,033; 6,610,204 (2 errors); 6,610,382; 6,610,708 <sup>25</sup> ; 6,613,761; 6,613,791 (2 errors); 6,627,196; 6,629,643; 6,630,175 (2 errors); 6,630,503 (2 errors); 6,630,572; 6,632,673; 6,632,675; 6,632,814; 6,632,838; 6,633,530; 6,634,747; 6,635,596 (2 errors); 6,635,655 (2 errors); 6,642,024; 6,642,038; 6,645,359		
PTO incorrectly calculcated PTA credit where patent issued more than 3 years (not including exclusionary periods) after its filing date. See 37 CFR §§ 1.702(b), 1.703(b).	29	Too Little PTA	6,605,623; 6,610,382; 6,610,708 <sup>25</sup> ; 6,610,905; 6,612,447; 6,613,761; 6,617,340 <sup>25</sup> ; 6,617,456; 6,620,866; 6,623,677; 6,627,106; 6,627,196; 6,627,199; 6,629,884; 6,630,283; 6,630,503; 6,630,572; 6,632,673; 6,632,675; 6,632,814; 6,632,872; 6,632,895; 6,633,530; 6,638,507; 6,641,820; 6,641,880; 6,641,942; 6,642,024; 6,642,038		
PTO failed to generate PTA reduction where applicant submitted a supplemental reply or other paper, not expressly requested by the examiner, after a reply had been filed. 37 CFR § 1.704(c)(8).	14	Too Much PTA	6,605,623 (2 errors); 6,607,570 (2 errors); 6,612,447; 6,630,175 (2 errors); 6,630,503; 6,632,673; 6,632,838; 6,635,655; 6,641,820; 6,642,038; 6,645,359		
PTO improperly applied, or failed to apply, rule requiring PTO to respond to a reply under 35 USC § 132 within 4 months. See 35 USC § $154(b)(1)(A)(ii)$ ; 37 CFR §§ $1.702(a)(2)$ , $1.703(a)(2)$ ,(3).	10	Either	6,605,666 (2 errors); 6,608,033; 6,610,905; 6,617,340 <sup>25</sup> ; 6,630,503; 6,630,572; 6,632,838; 6,634,747; 6,638,507		
PTO improperly applied, or failed to apply, rule requiring PTA reduction where applicant submitted a 37 CFR § 1.312 amendment or other paper after a notice of allowance. See 37 CFR § 1.704(c)(10).	9	Either	6,605,623; 6,609,888; 6,612,447; 6,632,673; 6,632,807; 6,633,530; 6,635,655; 6,642,024; 6,642,038		
PTO failed to generate a PTA reduction where applicant submitted a reply having an omission. 37 CFR § 1.704(c)(7).	7	Too Much PTA	6,605,666; 6,609,888; 6,617,456; 6,627,199; 6,630,572; 6,638,507; 6,641,820		
PTO failed to generate a PTA reduction where application was inadvertantly abandoned for failure to respond or late payment of issue fee. See 37 CFR § 1.704(c)(3).	3	Too Much PTA	6,612,447; 6,632,673; 6,634,747		
PTO failed to consider restart of response period in determining whether applicant took in excess of 3 months to reply to a PTO notice or action. See 37 CFR § $1.704(b)$ .	3	Too Little PTA	3,617,340 <sup>25</sup> ; 6,632,675; 6,641,820		
PTO improperly applied rule requiring PTO to issue the patent within 4 months after issue fee payment and all outstanding requirements are satisfied. See 35 USC § 154(b)(1)(A)(iv); 37 CFR §§ 1.702(a)(4), 1.703(a)(6).	2	Either	6,632,673; 6,632,807		
Total Errors in 50 Audited Cases	107				

A list of error categories as well as exemplary patent numbers is shown in Figure 1.

Not all errors caused the final PTA to be incorrect. In about half of the flawed calculations, the reductions were greater than the positive PTA, so the final PTA was zero despite the errors. In 42% of the 50 cases, however, the final PTO-calculated PTA was erroneous. A list of these cases along with the magnitude<sup>24</sup> of the errors is shown in Figure 2.

In only two of the audited cases<sup>25</sup> did the applicant seek correction of an erroneous PTO-calculated PTA. In the first case, the applicant disclosed to the PTO that too much PTA was granted at the time of allowance. The disclosure, however, delayed issuance which generated genuine PTA not recognized by the PTO, forcing the applicant to petition for correction. In the second case, the applicant petitioned for correction after allowance, but, again, the

# Figure 1. List of Error Categories.

petition delayed issuance which generated a few additional days of unrecognized PTA.

# CONCLUSION

Given the empirical data presented herein, practitioners should be extremely wary of relying exclusively on the PTO-calculated PTA, especially for cases having above average pendency, non-standard prosecution history, some probability of third party challenge, or significant commercial value.

A complete list of patents analyzed for this article, as well as an extensive article discussing PTA calculation, is available at www.PatentTerm.com. Practitioners interested in reviewing (or challenging) any of our calculations are invited to request our detailed analyses. E-mail your request to jlongfellow@patentterm.com. Please limit your request to two patents and provide specific patent numbers. Any corrections will be posted.

# **ENDNOTES**

- Professor of Law Emeritus, The George Mason University School of Law.
- Pub. L. 106-113, 113 Stat. 1501 (1999). AIPA PTA applies to applications filed on or after May 29, 2000. *Id.*
- 3. Pub. L. 103-465, 108 Stat. 4809 (1994).
- 35 USC § 154(b)(1)(A), (C). Under URAA, extensions for interferences and successful appeals were available, but limited to 5 years.
- 35 USC § 154(b)(1)(B); see also 145 Cong. Rec. S14708, S14718 (daily ed. Nov. 17, 1999).
- 6. See 37 CFR §§ 1.703-1.705.
- Some details of the initial and final PTO calculations are shown on the Patent Term Adjustment screen available via the PAIR system.
- See 37 CFR § 1.705. If a patent issues on other than its projected issue date and this change necessitates a PTA revision, the applicant may have a second opportunity to request reconsideration of some PTA issues within thirty days of issue. 37 CFR § 1.705(d).
- 35 USC § 154(b)(4)(B); see also Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56366, 56390 (Sept. 18, 2000).

Patent Number and Title		Audited PTA (days)	PTA Delta Too Much Granted	a <sup>24</sup> (days) Too Little Granted
6,610,708, Cyclic amino compounds	0	319		319 <sup>25</sup>
6,610,905, Transgenic mouse model for Kaposi's sarcoma	218	41	177	
6,641,880, Signage having films to reduce power consumption and improve luminance uniformity and method for using same	327	454		127
6,638,507, Mammalian proteases; related reagents	0	108		108
6,632,675, Multi-analyte reference solutions with stable pO2 in zero headspace containers	0	81		81
6,634,747, Sample indicator lens	72	0	72	
6,641,942, Solid-state energy storage module employing integrated interconnect board	217	262		45
6,617,340, N-(substituted glycyl)-pyrrolidines, pharmaceutical compositions containing them and their use in inhibiting dipeptidyl peptidase-IV	8	52		44 <sup>25</sup>
6,632,895, Functionalized alkoxyamine initiators	453	497		44
6,610,382, Friction control article for wet and dry applications	0	36		36
6,620,866, Rubber mixtures and vulcanizates containing agglomerated rubber gels	179	210		31
6,630,283, Photothermographic and photographic elements having a transparent support having antihalation properties and properties for reducing woodgrain	178	208		30
6,632,673, Directing the ratio of B2:B1 avermectins in Streptomyces avermitilis host cells	26	0	26	
6,632,872, Adhesive compositions including self-assembling molecules, adhesives, articles, and methods	319	344		25
6,633,530, Optical pickup apparatus with light source unit including first light source and common light receiving section	120	97	23	
6,627,199, Isolation, identification and characterization of tmst2, a novel member of the TNF-receptor supergene family	19	0	19	
6,623,677, Decorated article made by film insert molding	213	225		12
6,642,024, Guanylate-binding protein	54	66		12
6,627,106, Salt mixtures for storing thermal energy in the form of heat of phase transformation	268	279		11
6,632,807, (2R,4S)-(-)-[N-(4-diethoxyphosphorylmethyl)phenyl]-1,2,4,5- tetrahydro-4- methyl-7,8-methylenedioxy-5-oxo-3-benzothiepin-2-carboxamide	360	355	5	
6,642,038, GlcNAc phosphotransferase of the lysosomal targeting pathway	329	330		1

### Figure 2. List of Patents where PTO-Calculated final PTA was Incorrect.

#### 10. 35 USC § 111(a).

- 11. We omitted several applications where the prosecution history file was not readily available for public inspection from the PTO.
- 12. Since AIPA-based PTA generally deals with matters delaying prosecution in various forms, applications having shorter pendencies typically have less potential for PTA error. In fiscal 2003, the average application pendency was 26.7 months. See US Patent and Trademark Office Performance and Accountability Report: Fiscal Year 2003 <http://www.uspto.gov/web/offices/com/annual/2 003/index.html>.
- 13. Fourth Annual Pharm Exec 50, Pharmaceutical Executive (May 2003). Applications were located using a keyword search of company names in the PTO assignment data. Therefore, not all applications are pharmacological in nature.
- 14. The authors consider a calculation error to be the misapplication, or failure to apply, a PTA rule that demonstrably changes PTO-calculated positive adjustment (for PTO delays and other no-fault delays) or reductions (for dilatory applicant behavior) as shown on the Patent Term Adjustment

screen in the PAIR system. The authors believe the vast majority of errors are clear under the AIPA PTA statute, rules, and commentary. For the small percentage of errors where current authority is ambiguous, however, the authors used their judgment to predict the proper outcome.

- 15. US Patent No. 6,632,673. See Figure 1 for the error categories.
- US Patent No. 6,642,024. See 37 CFR § 1.704(c)(10).
- 17. US Patent No. 6,609,888.
- 18. US Patent No. 6,610,905.
- E.g., US Patent No. 6,638,507. See 35 USC § 154(b)(1)(A)(ii); 37 CFR §§ 1.702(a)(2), 1.703(a)(2),(3).
- 20. E.g., US Patent No. 6,612,447. See 37 CFR § 1.704(c)(8). An IDS after a reply which includes a statement under 37 CFR § 1.704(d), however, is not a reduction.
- E.g., US Patent No. 6,633,530. See 37 CFR § 1.704(c)(10); see also Clarification of 37 CFR 1.704(c)(10) - Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a

Notice of Allowance has been Mailed, 1247 Off. Gaz. Pat. Office 111 (June 26, 2001).

- 22. E.g., US Patent No. 6,632,838. See 37 CFR 1.704(b); 35 USC § 154(b)(1)(A)(ii); 37 CFR §§ 1.702(a)(2), 1.703(a)(3).
- 23. E.g., US Patent No. 6,617,340. See 35 USC § 154(b)(1)(B); 37 CFR §§ 1.702(b), 1.703(b). In applying the 3-year pendency guarantee, the authors did not count applicant-requested extensions as exclusionary periods, as is our understanding of the PTO interpretation. See 35 USC § 154(b)(1)(B)(iii); 37 CFR §§ 1.702(b)(5), 1.703(b).
- 24. In many cases, the error magnitude would have been greater but for offsetting errors.
- Applications for PTA correction were filed and granted in US Patent Nos. 6,617,340 and 6,610,708. See 37 CFR § 1.705.