

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH AND ELAN PHARMA
INTERNATIONAL LIMITED,

Plaintiffs,

v.

HON. JON W. DUDAS
Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office.

Defendant.

Civil Action No. 1:07-cv-01492 (JR)

**PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT TO CORRECT THE PATENT
TERM ADJUSTMENT FOR UNITED STATES PATENT NOS. 7,179,892 AND 7,189,819**

(Oral Argument Requested)

Plaintiffs, by their undersigned attorneys, move this Honorable Court for an Order pursuant to 35 U.S.C. § 154(b)(4) granting summary judgment against defendant, requiring defendant to change the adjustment of the patent term on United States patent 7,179,892 (the " '892 patent") from 462 days to 756 days and change the adjustment of the patent term on United States Patent 7,189,819 (the " '819 patent") from 492 days to 722 days.

The grounds for this motion are set forth in the accompanying declaration of Sapna W. Palla and memorandum of law.

Plaintiffs request oral argument on the motion

Dated: January 4, 2008

Respectfully submitted,



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**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION
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PRELIMINARY STATEMENT

Plaintiffs, Wyeth and Elan Pharma International Limited (collectively, “Wyeth/Elan”), submit this memorandum of law in support of their motion for summary judgment to correct the patent term adjustment for United States Patent 7,189,819 (the “819 patent”) from 492 days to 722 days, and United States Patent 7,179,892 (the “892 patent”) from 462 days to 756 days.

This Court “shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . [or] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A) & (C). Such are the circumstances here because the U.S. Patent and Trademark Office (“the PTO”) has grossly misapplied both the statute and its own regulations on patent term adjustments resulting in an unlawful and illogical patent term adjustment policy. The PTO’s position is indefensible, and leads to results that are inconsistent and unpredictable. A leading scholar in patent law has described this very practice by the PTO as “absurd under the statute and the law of common sense,” explaining:

[A]lthough the language of the statute seems quite clear and logical, and dictates a straightforward linear combination of [delays under (A) and delays under (B)]. . . the USPTO *interpretation* of its own Rules is in dramatic conflict with the clear wording of its own Rules. The author assures the readers that they will read in disbelief the illogic promulgated by the USPTO on this subject.

4 Irving Kayton, *Patent Practice* ch. 17, at 17:21 (8th ed. 2005) (attached as Palla Decl. Ex. K.) (emphasis in original).

While the terminology and time computations of this case may appear complex, the heart of this dispute is simple: must the PTO adjust patent terms for delays under (A) and (B) in a “straightforward linear combination,” as suggested by Professor Kayton, or simply for the longer of the delay under (A) and (B). The plain words of the statute and the clear Congressional intent that “most” patents will receive “considerably more” than the previous 17-year term demands

that the PTO adjust patent terms in that “straightforward linear combination” for PTO delays under both (A) and (B), with an exception that when both types of delay occur on a single day, that single day is not double counted. Summary judgment is now appropriate because no facts are in dispute. The Court need only rule on the proper construction of the statute governing patent term adjustments, 35 U.S.C. § 154(b). (the “Patent Act”).

The Patent Act recognizes two types of PTO delays which provide for extensions or “adjustments” of the term of a patent. The statute is explicit that a patentee is entitled to both of these adjustments for the PTO’s delay – *i.e.*, the adjustments are additive, and not alternatives as the PTO has improperly held here. Thus if one type of delay (A) is 30 months, and the other type of delay (B) is 20 months, then the patent term must be extended by 50 months, and not merely the longer of the two. One exception to this is where two types of delay occur on the same day, in which event the delays “overlap” and the patent term is extended by only one day. Hence, using the same hypothetical above, if delay period A and delay period B overlap by 10 months, then the life of the patent is extended by 40 months instead of 50.

Despite the explicit language of the statute, and its unambiguous legislative history, the PTO has misconstrued the law by effectively awarding applicants a patent adjustment based only on the longer of the delay under (A) or (B), and not the total (minus overlap) as the statute requires. As detailed below, the PTO’s error stems from an unreasonable and inconsistent interpretation of the terms “overlap” and “period of delay.”

BACKGROUND

Under the Patent Act, the ‘819 and ‘892 patents are entitled to a term of twenty years that is measured from the day on which their corresponding applications were filed.¹ Before a patent

¹ The ‘819 and ‘892 relate to a treatment of Alzheimer’s disease. (See Palla Decl. Ex. L.)

application issues as a patent, however, the PTO must examine the application to determine if the criteria for patentability of the claims are met. In the course of that process, the PTO typically will issue Office Actions that reject claims on various grounds. The applicant may then respond to those Office Actions with amendments or arguments that address the PTO's concerns. *See generally* USPTO, *Manual of Patent Examining Procedure* ch. 700 (2007 Rev.). This back and forth process takes time, and necessarily reduces the effective term of the issued patent which begins to run on the date the application was filed.

In order to protect the patent applicant from loss of patent term due to delays by the PTO, the Patent Act, 35 U.S.C. § 154(b), provides statutory guarantees that the PTO will take the required actions within certain time limits, and grants the patent applicant one day of additional patent term for each day the PTO exceeds the prescribed time limit.

Similarly, the statute provides for patent term to be reduced for one day for each day of delay that is attributable to the applicant. 35 U.S.C. § 154(b)(2)(C).

There are two categories of time limits at issue in this case. Subsection 154(b)(1)(A) [hereafter sometimes referred to as "(A)"] provides time limits for the PTO to take specified actions in the patent examination. For example, the PTO is required to issue a first office action or allowance within 14 months of the filing date. 35 U.S.C. § 154(b)(1)(A)(i). If the PTO exceeds the time limit, "the term of the patent shall be extended 1 day for each day after the end of the period specified . . . until the action . . . is taken." 35 U.S.C. § 154(b)(1)(A). A second time limit involved in this case appears in § 154(b)(1)(B) [hereafter sometimes referred to as (B)] and requires the PTO to issue a patent within three years of the filing date of the application. If the three-year deadline for issuing the patent is exceeded, "the term of the patent shall be

extended 1 day for each day after the end of that 3-year period until the patent is issued.”² Because two different kinds of PTO delay may overlap and occur on a single calendar day, Congress provided that only one day of adjustment to the patent term should be made for one day of delay when more than one type of delay occurs on a single day. 35 U.S.C. § 154(b)(2)(A).

Thus, plaintiffs are entitled to an adjustment of the patent term for the total of each day of delay under both (A) and (B), with the limitation that if both types of delay occur on a single day, the day should not be double counted, and only one day of adjustment is made for that single day on which the PTO missed two independent deadlines.

The PTO has refused to follow this simple statutory plan in calculating a patent term adjustment for the two patents in this case. The net effect of the PTO’s position is that plaintiffs received adjustment for either delays under (A) or delays under (B), rather than, as the statute requires, an adjustment for the total, non-overlapping PTO delays under both subsections. Plaintiffs were thus denied a full adjustment of the patent terms, and lost a portion of their patent term rights, solely because of the PTO’s failure to act within the statutory time limits.

The PTO’s error results from its use of two different and entirely inconsistent definitions of a “period of delay” under subsection (B), which requires the patent to be issued within three years of the application’s filing date. For the purposes of calculating patent term adjustment for its failure to meet the deadline under subsection (B) to issue the patent within three years of filing, the PTO logically defines period of delay as beginning three years after the filing date of the application. But in determining whether that period of delay under subsection (B) overlaps

² A third category, §154(b)(1)(C), provides a guarantee that patent term would not be lost for reasons of secrecy orders, interferences, or appeals and requires a day of adjustment for each day the patent issuance was delayed by reason of such events. That section is not in issue in this case.

with the delay under subsection (A), the PTO applies an entirely inconsistent definition. In that situation, the PTO defines period of delay under subsection (B) as the period from the filing date of the patent application to the date of issuance, not simply the period beginning three years after the filing date. As a practical matter, the PTO's shifting definition of the term period of delay allows it to excuse its failure to meet the statutory time limits under (A) when it fails also to meet the statutory guarantees under (B), whenever the delay under (B) is longer than (A).

The PTO's position has no support in the unambiguous language of § 154(b). It also frustrates Congress' clear intention that the twin guarantees of (A) and (B) would provide most applicants a patent term that is "considerably more" than the 17 year term that existed before the 1994 GATT amendments. (*See infra* pp. 20-21.) The PTO's position is unreasonable because it leads to two entirely different and inconsistent definitions of "periods of delay," and inconsistent treatment of similarly situated applicants. Further, the PTO's interpretation is not entitled to deference because the statute is not silent or ambiguous, nor did Congress authorize the PTO to determine what delays entitle the applicant to an adjustment.

STATEMENT OF FACTS

A. The Patents at Issue in This Case

Alzheimer's disease is a progressive and fatal brain disease, named for the German physician Alois Alzheimer, who first described it in 1906. Alzheimer's disease kills brain cells, causes severe memory loss, adversely affects thinking and behavior, and eventually causes death. More than five million Americans suffer from Alzheimer's for which today there is no known cure or effective treatment. A characteristic of Alzheimer's is the appearance in the brain of deposits or plaques composed of beta amyloid peptide. (*See* Palla Decl. Ex. A at col. 1, lines 16-44.)

Plaintiffs have discovered that certain antibodies against beta amyloid peptide are effective in preventing or clearing plaque deposits in animal models of Alzheimer's disease. The '819 and '892 patents claim "humanized" anti-beta amyloid antibodies that can be administered to patients to treat Alzheimer's; a potentially ground-breaking new treatment for Alzheimer's disease that has moved into Phase III trials. (*See* Palla Decl. Ex. L.)

B. The Patent Term Adjustment Provisions of 35 U.S.C. § 154(b)

Before the 1994 amendments to the Patent Act, the term of the patent began on the date of issuance. Although a delay by the PTO in the examination of the patent application delayed the start of the patent term, the delay did not shorten the effective term of the patent. The patent's term extended seventeen years from the date the patent ultimately issued.

In 1994 Congress amended the Patent Act to provide for a twenty-year patent term. That term, however, begins the date that the patent application is filed rather than the date the patent issued. Because no patent enforcement rights exist until the patent issues, any delay by the PTO in examining the patent application, or issuing the patent, erodes the patent's life by one day for every day of PTO delay. To assure inventors that PTO delays would not deprive them of patent life, the 1999 American Inventor's Protection Act ("AIPA")³ amended the patent term adjustment provisions of 35 U.S.C. § 154(b) to set time limits for various PTO actions and to provide an adjustment to the term of patents to restore each day of patent term lost when the PTO exceeded the time limits. *See* H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.).⁴

³ The AIPA is Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948). It was introduced in the 106th Congress on November 17, 1999 and was incorporated and enacted as law as part of Pub. L. No. 106-113. *See* Pub. L. No. 106-113, § 4402, 113 Stat. 1501, 1501A-557-1501A-560 (1999).

⁴ The bill to which H.R. Rep. No. 106-464 related, H.R. 1554, was incorporated as a whole into a later appropriations bill, H.R. 3194, which was enacted as Pub. L. No. 106-113. The

Section 154(b)(1) provides patent applicants with two distinct statutory “patent term guarantees” relevant here. The first of these appears in subsection (A), which is titled “Guarantee of prompt Patent and Trademark Office responses.” Under this guarantee, a patent applicant is entitled to a one-day restoration of the patent term for each day of delay during which the PTO has breached the guarantee by failing to meet a statutory timetable for taking certain specified actions on the patent application. 35 U.S.C. § 154(b)(1)(A). Subsection (1)(B) provides a distinct statutory “guarantee” that no application will remain pending more than three years, and it provides as a remedy for breach of this guarantee the restoration of one day of patent term for each day of delay during which the PTO has failed to issue the patent beyond the three-year time limit. 35 U.S.C. § 154(b)(1)(B).⁵

Conference Report on appropriation bill H.R. 3194, H.R. Rep. No. 106-479, does not contain a section-by-section analysis of S. 1948, but it purports to incorporate S. 1948, whose language is identical to that in H.R. 1554. H.R. Rep. No 106-464, submitted on November 9, 1999, does contain a section-by-section analysis of S.1948. On November 17, 1999, the same section-by-section analysis of S. 1948 from H.R. Rep. No. 106-464 was printed in the Congressional Record (145 Cong. Rec. S14696-03, S14718).

⁵ Sections § 154(b)(1)(A) and (B) state:

“(1) Patent Term Guarantees.

“(A) Guarantee of prompt Patent and Trademark Office responses. - Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to . . .

[(i) Act initially on an application within fourteen months of its filing date; (ii) Respond to a reply or appeal by applicant within four months of the reply or appeal; (iii) Act on an application within four months of a Board of Patent Appeals and Interferences (“BPAI”) or court decision in an application containing allowable claims; and (iv) Issue a patent within four months of the date the issue fee was paid.]

. . . the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.”

Because portions of these delay periods may sometimes overlap (*e.g.*, where the failure of the PTO to timely complete an action required under (A) occurs after the three-year limit of (B)), § 154(b)(2)(A) limits the statutory adjustment to one day for each day of “delay,” even though the PTO may have breached more than one statutory guarantee on a single day.

Section 154(b)(2)(A) therefore provides as follows:

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

This provision avoids double counting, so that an applicant may receive no more than a one-day adjustment for any single day of delay, regardless of the number of types of delay that may have occurred on that single day.

C. **The PTO’s Patent Term Adjustment Regulations**

The PTO’s promulgated regulations concerning patent term adjustments essentially repeat the terms of the statute.⁶ *See* 37 C.F.R. §§ 1.702-705. Section 1.702 (interpreting § 154(b)(1)) describes grounds for adjustment of patent term due to examination delay, and

“(B) Guarantee of no more than 3-year application pendency. - Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States [excluding certain periods not applicable here] the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.”

⁶ In March 2000, the PTO published a notice proposing changes to the rules of practice to implement the provisions of § 4402 of the AIPA. *See* Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 17,215 (proposed Mar. 31, 2000). In September 2000, the PTO issued a final rule to implement those provisions of the AIPA relating to the new PTA provisions. *See* Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56,366 (Sept. 18, 2000) (to be codified at 37 C.F.R. pt. 1).

§ 1.703 sets forth the method of calculating the period of adjustment of patent term due to examination delay.⁷

D. The PTO's Patent Term Adjustment For the Patents In Suit

The facts relating to the periods of delay for calculation of the patent term adjustments for the '819 and '892 patents are not in dispute. The detailed calculations of the correct patent term adjustment are set forth in the Palla Declaration.

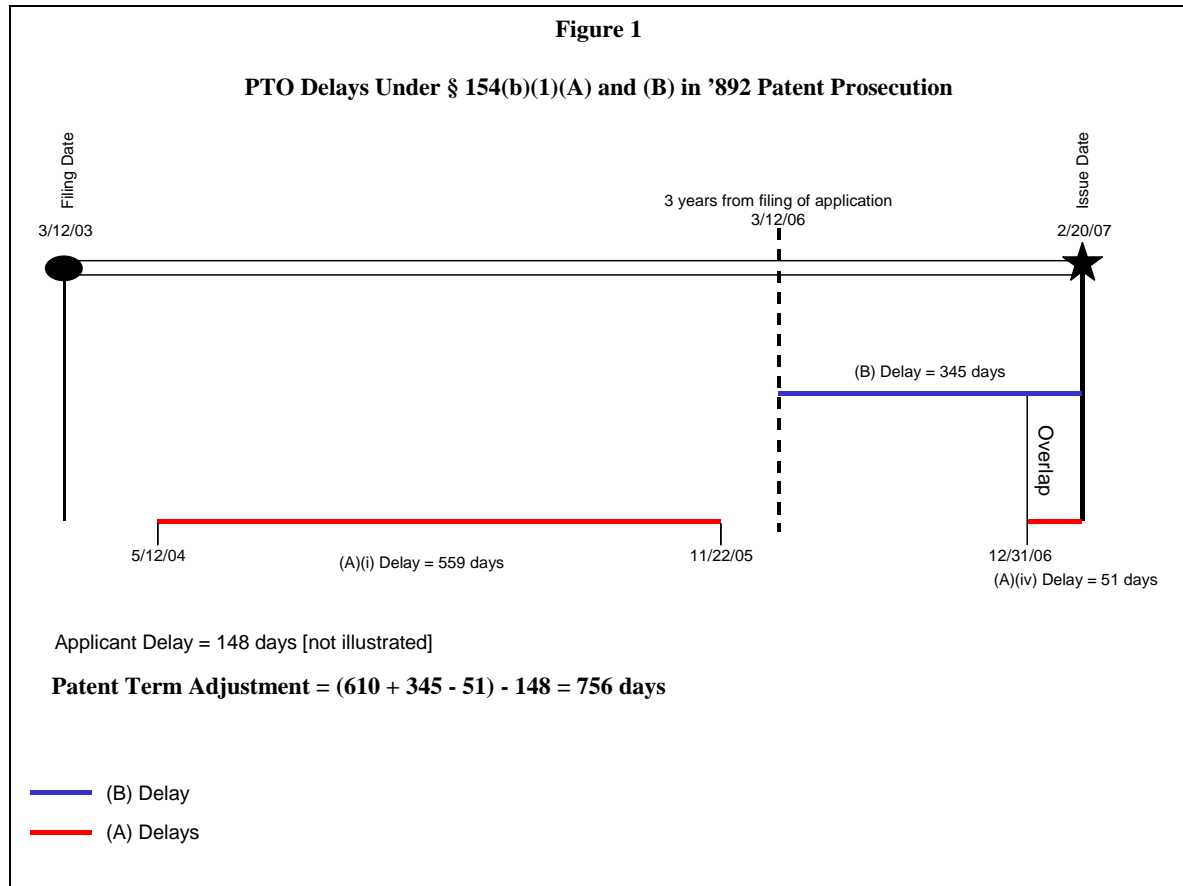
1. The Patent Term Adjustment to the '892 Patent

With regard to the '892 patent, there were 610 days of delay accruing under § 154(b)(1)(A), and 345 days of delay under § 154(b)(1)(B), because the patent did not issue until 345 days after the third anniversary of its filing. (Palla Decl. ¶¶ 6 (A)-(C).) Of the 610 days of delay accruing under (A), 559 days occurred during the first three years after the filing date of the patent application, and 51 days of that delay occurred after three years from the filing date of the application. Therefore, the 51 days of delay overlap with delay under (B) and should be counted only once. (*Id.* ¶ 6 (D).) After deducting the undisputed period of applicant delay

⁷ In an explanation of a revision issued on June 21, 2004, which modified 37 C.F.R. §1.703(f) to track literally the statute's reference to overlapping "delay," the PTO adopted an interpretation of the statute and its rules that was at odds with the language of both. It stated that the change in the language of §1.703(f) was made because, according to the PTO, the previous version of the regulation had "misled" applicants into believing that delays under 35 U.S.C. 154(b)(1)(A) and delays under 35 U.S.C. 154(b)(1)(B) were "overlapping" only if the period of delay under 35 U.S.C. 154(b)(1)(A) "occurred more than three years after the actual filing date of the application." *See* Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34,283, 34,283 (June 21, 2004). Instead, according to the PTO, "[i]f an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office . . . and not just the period beginning three years after the actual filing date of the application, is the period of delay 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.* This misinterpretation of the statute is at the heart of the dispute in this case.

(conceded to be 148 days under § 154(b)(2)(C)), the total adjustment due on the '892 patent is 756 days (*i.e.*, $(610 + 345 - 51) - 148 = 756$ days). (*Id.* ¶¶ 6 (A)-(G).)

The adjustment that should have applied to the '892 patent can be readily seen in graphic form:



The PTO ruled that all 610 days of delay under (A) -- both those occurring within three years from the application's filing date and those that occurred after the three-year period had elapsed -- overlapped with a period of delay under (B). (*Id.* Ex. F at 2.) The PTO made an adjustment based solely on the delay period of 610 days under (A), from which it deducted the 148 days of applicants' delay, resulting in 462 days. (*Id.*) It simply disregarded the period of delay under (B), including the 294 days of delay that did not overlap with any days of delay under (A) stating -- without any basis in either the statute or regulations -- that "[s]ince the

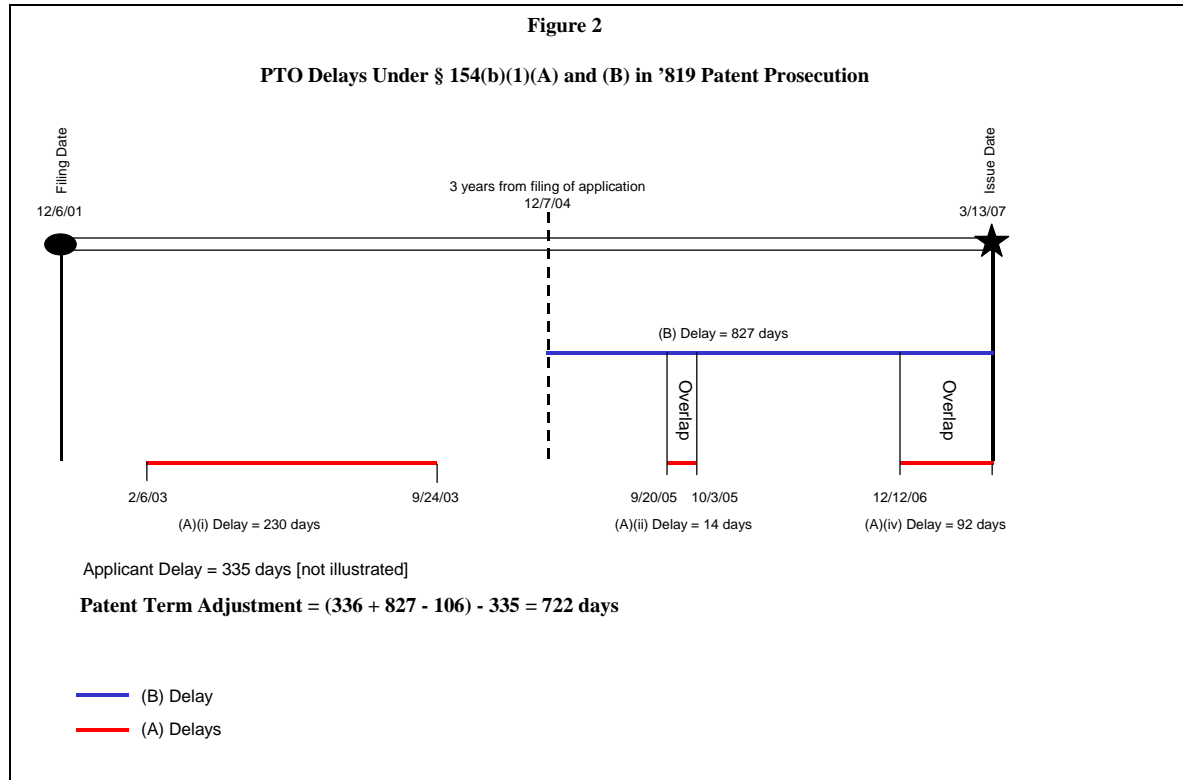
Office delays under [(A)] are greater than the delay for [(B)], applicants will receive no additional [patent term adjustment] time.” (*Id.*)

2. The Patent Term Adjustment to the ‘819 Patent

Regarding the ‘819 patent, the PTO agrees that there were 336 days of delay under § 154(b)(1)(A) for failure to timely take specified actions, and 827 days of delay under (B) consisting of the time after three years from the filing date before the patent issued. (Palla Decl. ¶¶ 9 (A)-(C); *id.* Ex. I at 10; Answer ¶ 30.) The 336 days of delay under (A) consist of 230 days of delay during the first three years of the patent prosecution, plus two separate periods of delay, one of 14 days and the other of 92 days, which occurred after three years from the application’s filing date. There is no dispute that 106 days of the delays accruing under (A) occurred more than three years after the filing date, so that those 106 days of delay under (A) thus overlap with delay under (B) and should only be counted once. (Palla Decl. ¶¶ 9 (D)-(E).) When applicants’ delays (which are conceded to total 335 days under § 154(b)(2)(C)) are deducted,⁸ there should be a 722-day adjustment (*i.e.*, $(336 + 827 - 106) - 335 = 722$ days.) (*Id.* at ¶¶ 9 (A)-(G); Ex. G.)

Again, the proper adjustment can be readily seen in graphic form:

⁸ There is no dispute concerning the applicants’ delay or its deduction from the adjustment. (*See* Palla Decl. ¶ 9 (F); Answer ¶ 34.)



The PTO allowed an adjustment of only 492 days for the ‘819 patent. The PTO again expressed the view that “in determining whether periods of delay ‘overlap’ under 35 U.S.C. 154(b)(2)(A)” the period of delay under § 154(b)(1)(B) “is the entire period during which the application was pending before the Office.” (*Id.* Ex. I at 12-13.) The PTO disregarded all 336 days of delay under (A) -- both the 230 days of delay that occurred within the first three-years after the filing date of the patent application, and the 106 days of delay that occurred after the three year time limit for patent issuance -- because it considered all of those days to “overlap” with the delay under subsection (B). (*Id.* Ex. I at 13.)

Further demonstrating that its ruling is entirely unmoored from the statutory scheme, the PTO could not even offer a coherent explanation for how it calculated the adjustment for the ‘819 patent. First, the PTO stated that it derived its adjustment by subtracting the entire period of 336 days of delay under (A), from the 827 days of delay under (B), yielding 491 days. (*Id.*)

In the next paragraph of the same decision, however, the PTO “maintain[ed]” without further explanation, “that the correct revised determination of patent term adjustment . . . is 492 [sic] days,” and not the 491 days it had just calculated. (*Id.*)

A 492-day adjustment would, however, be consistent with a policy of allowing an applicant an adjustment based on the longer of the delay under § 154(b)(1)(A) or under § 154(b)(1)(B), but not under both subsections. A 492 day adjustment equates to the 827 days of delay under (B), less the 335 days of applicant’s delay, which is the approach that the PTO followed with respect to the ‘892 patent, as discussed above. That may be what the PTO had intended to do, but in either case its approach was wrong.

The applicants’ petitions for reconsideration were denied by the PTO. (*See id.* Ex. F; Ex. I.) Applicants timely brought this action under 35 U.S.C. § 154(b)(4) which authorizes an applicant dissatisfied with the PTO’s patent term adjustment to bring a civil action against the Director of the PTO in the U.S. District Court for the District of Columbia, within 180 days after the grant of the patent, and requires the Director to alter the term of the patent to reflect any final judgment.

ARGUMENT

I. THE PTO’S DECISION IS CONTRARY TO THE UNAMBIGUOUS LANGUAGE OF THE PATENT TERM ADJUSTMENT STATUTE

A. The PTO’s Calculation of Periods of Delay That Overlap Under § 154(b)(2)(A) Cannot Be Reconciled With the Words of the Statute.

“A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.” *Perrin v. United States*, 444 U.S. 37, 42 (1979); *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426 (Fed. Cir. 1988)

(reversing PTO commissioner decision concerning his statutory power to stay a reexamination proceeding).

Furthermore, ordinary principles of statutory construction require examining the statutory text “in light of context, structure, and related statutory provisions.” *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 558 (2005). “[A]n agency’s interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear. . . .” *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 229 (1994).

The patent term adjustment statute is unambiguous. There are three types of PTO delays requiring adjustment under §§ 154(b)(1)(A), (B) and (C).⁹ Each section provides for a restoration of one day of patent term for each day of PTO delay, and the adjustments for delay are additive, and not alternatives.

The only statutory limitation of adjustments for delays under both (A) and (B) exist in § 154(b)(2). Here, only § 154(b)(2)(A) -- the limitation against double counting of delays that “overlap” -- is in contention. That provision states:

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

The correct application of the limitation of § 154(b)(2)(A) depends on the meaning of the statutory terms “overlap” and “periods of delay attributable to grounds specified in

⁹ Subsection (b)(1)(C), which is not at issue in this case, provides a separate “guarantee” that patent term will not be lost because of delay due to interference proceedings, secrecy orders, or successful appeals. 35 U.S.C. § 154(b)(1)(C). Subsection (b)(1)(C) also provides a one-day adjustment for every day of “delay” caused by such proceedings. However, unlike the delays against which § 154(b)(1)(A), provides a guarantee, the delays resulting from proceedings identified in § 154(b)(1)(C) are expressly excluded in determining whether the “Guarantee of no more than 3-year application pendency” has been breached. *See* 35 U.S.C. § 154(b)(1)(B).

paragraph (1).” If there is no “overlap” of a “period of delay,” then there is no limitation under § 154(b)(2)(A) on awarding one day of adjustment for each day of delay arising under both subsections 154(b)(1)(A) and (B).

Only the term, “periods of delay” in § 154(b)(2)(A) appears to be in dispute, but that term is susceptible to only one meaning for delays under § 154(b)(1)(A) and (B): it is the period of time that begins the day after the expiration of the allotted time for the PTO to act under each subsection of § 154(b)(1) and ends on the day when the required action occurs. The patent term adjustment for delay under § 154(b)(1)(A) is “1 day for each day *after the end of the period* specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.” (emphasis added). The patent term adjustment for delay under § 154(b)(1)(B) is similarly “1 day for each day *after the end* of that 3-year period until the patent issued.” (emphasis added). The delay (and the adjustment for delay) does not begin until *after* the time period allowed for the action has expired.¹⁰

Consequently, an “overlap” of “periods of delay” can occur only if there are grounds for an adjustment under two, or more, different subsections on the same day, for example, if the PTO is in default on two (or more) obligations on the same day. In such a case, the applicant receives only a one-day adjustment for that single day, and not two (or more) days of adjustment (*i.e.*, not one day of adjustment for each type of delay that occurs on a single day).

In applying the statute to the patent term adjustment in this case, the total adjustment is the sum of (A) delays and (B) delays. To prevent double counting of days where both (A) and (B) delays occur, the (A) delays that occurred after three years from the filing date of the

¹⁰ Section 154(b)(1)(C) does not prescribe a time period in which an action must be completed, but requires an adjustment for each day of delay due to interference proceedings, secrecy orders, or appeals that result in issuance of the patent.

application -- the point at which (B) delay starts -- are deducted from the total of (A) and (B) days of delay.

The period between the filing of the application, and the third anniversary of the filing, is not a “period of delay” under § 154(b)(1)(B) as the PTO contended when it determined that delays under (A) were overlapping with delays under (B) in the ‘892 and ‘819 patent prosecutions. Until the third anniversary of the application’s filing, there is *no* § 154(b)(1)(B) delay – the time for the action required by § 154(b)(1)(B) has not expired. It follows that a delay under § 154(b)(1)(A) that occurs within the first three years after the ‘892 and ‘819 patent applications had been filed has no delay under subsection 154(b)(1)(B) with which it could “overlap.”

The PTO’s clear error of law occurred when it denied an adjustment of the ‘819 patent for delays under § 154(b)(1)(A) in the first three years after the patent application was filed on the ground that those delays were overlapping with a delay under § 154(b)(1)(B). The PTO was also in error when it denied an adjustment of 294 days for the ‘892 patent for delays under § 154(b)(1)(B), even though that period of delay did not overlap with any period of delay under § 154(b)(1)(A).

Moreover, even if the PTO were correct that the entire period from the filing of the application to the issuance of the patent was a period of delay under § 154(b)(1)(B) -- and there is no basis in the statutory language for its position that the delay can begin on the day the application is filed -- its adjustment would still be incorrect. If delays under both (A) and (B) occur on a single day, the two types of delay “overlap.” That single day on which two delays occurred does not require two days of adjustment, but it is one day of delay, requiring one day of adjustment. Yet, while the PTO ruled in the case of the ‘819 patent that all of the (A) delays

occurring in the first three years overlapped with delay under (B), it did not count those days of delay as even one day of delay in calculating patent term adjustment, but instead excluded them from the adjustment entirely. No plausible meaning of the words of the statute could lead to this construction where multiple “overlapping delays” are no delay at all.

The PTO has denied the proper adjustment for the total PTO delay by applying arbitrary and inconsistent definitions of what constitutes a “period of delay” under § 154(b)(1)(B), contrary to the basic rule of statutory construction “that identical words and phrases within the same statute should normally be given the same meaning.” *Powerex Corp. v. Reliant Energy Servs., Inc.*, 127 S. Ct. 2411, 2417 (2007). When the PTO is determining whether a delay under (A) overlaps with a delay under (B), it defines the “period of delay” under (B) as beginning on the date the application was filed, and denies an adjustment for delays arising under § 154(b)(1)(A), including in the first three years of patent prosecution, because those delays “overlap” with delays under (B). When the PTO calculates the adjustment due to the applicant, however, the PTO redefines a period of delay under (B) to begin three years after the filing date of the application. It therefore does not award any adjustment for what it previously defined as a period of delay under (B) when it denied an adjustment for (A) because it overlapped with a delay under (B).

There is no basis in the statute for treating the first three years of patent prosecution as a “delay” under (B) for purposes of identifying an “overlap,” but then treating that same period of time as no “delay” for purposes of making the required term adjustment. Such a flip-flop on the meaning of “period of delay” has no basis in the statutory language.

The net result of the use of the inconsistent definitions of delay under (B) is that the PTO makes an adjustment of patent term for either the delay under (A) or the delay under (B), but not

both, even if the periods of delay under each subsection do not overlap. The PTO articulated this net result as an alternative statement of its position in the decisions at issue in this case. It stated:

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154 (b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154 (b)(1)(B).

(Palla Decl. Ex. I at 10;¹¹ *see also id.* Ex. F at 2.)

The PTO did not even attempt to justify this alternative statement of its position in these decisions with reference to any words in the statute. Subsections 154(b)(1)(A) and (b)(1)(B) are written in the form of two distinct and independent guarantees. Patent applicants are guaranteed both “prompt Patent and Trademark Office responses,” (A), and “No more than 3-year application pendency,” (B). There is not a word in the statute or the legislative history that implies that adjustments under (A) and (B) are only to be used as alternatives.

B. The Plain Meaning of § 154(b)(2)(A) Is Supported by the Legislative History.

A statute’s legislative history may be considered “to see if it calls the apparent clarity of the statutory language into question.” *Baker Hughes Inc. v. Kirk*, 921 F. Supp. 801, 810 (D.D.C. 1995). If it does not, the unambiguous language of the statute “must ordinarily be regarded as conclusive.” *United States v. Turquette*, 452 U.S. 576, 580 (1981).

¹¹ The cited Federal Register notice is not consistent with the PTO’s “either/or” approach. There, the PTO said, “[t]hus, the Office *does not* interpret 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B).” *See* *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34,283, 34,284 (June 21, 2004) (emphasis added). The PTO there allowed for one narrow exception where an adjustment under both sections might be possible. It was still incorrect and inconsistent with the statute.

The legislative history is clear that in providing the limitation regarding overlapping periods of delay under § 154(b)(2)(A), Congress intended only that one day of delay not count as two days of delay when the PTO was in default on two different obligations under § 154(b)(1) on the same day. The Conference Report explains:

To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (*e.g.*, delay due to a secrecy order under section 181 and administrative delay under section 154(b)(1)(A)), the term *should not be extended for each ground of delay but only for the actual number of days* that the issuance of a patent was delayed

H.R. Rep. No. 106-464, at 127 (1999) (Conf. Rep.) (emphasis added).

The legislative history concerning the treatment of overlapping delays is consistent with the plain language of the statute providing for separate guarantees and adjustments. Nothing in the legislative history suggests that Congress intended § 154(b)(2)(A) to preclude adjustments under both § 154(b)(1)(A) and (B) when the periods during which the PTO was in default under each section did not overlap. Each day in which the PTO fails to take one of the statutorily-required actions leading to patent issuance is a day on which the issuance of the original patent has been delayed, and for which extension is therefore required. *See* Revision of Patent Term Extension and Patent Term Adjustment Provisions, 69 Fed. Reg. 21,704, 21,711 (Apr. 22, 2004) (to be codified at 37 C.F.R. pt. 1).

Congress expressly contemplated that the statute would afford diligent applicants considerably more patent term when the guarantee of (A) was combined with the guarantee of (B) -- issuance within three years of filing -- stating:

Accordingly, subtitle D removes the 10-year caps from the existing provisions, adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, includes a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term

of less than the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more.

H.R. Rep. No. 106-464, at 125 (emphasis added).

This language confirms that Congress included adjustments under (B) to guarantee that at minimum, post-GATT applicants would receive the 17-year patent term that pre-GATT applicants enjoyed, while additionally providing for adjustment under (A) to compensate for PTO delays, fully intending that diligent applicants would not only receive the pre-GATT term but “considerably more.”¹²

II. THE PTO’S CONSTRUCTION OF § 154 IS UNREASONABLE BECAUSE IT LEADS TO INCONSISTENT TREATMENT OF SIMILAR APPLICANTS

The PTO’s approach to patent term adjustment suggests that the PTO would allow an adjustment under § 154(b)(1)(A) for a delay occurring in the first three years of patent prosecution, if the patent issued within three years of the application date and there were no adjustment due under § 154(b)(1)(B). This would follow from the PTO’s explanation in its decisions that it will make an adjustment under the longer of the (A) delay or (B) delay, but not both.¹³

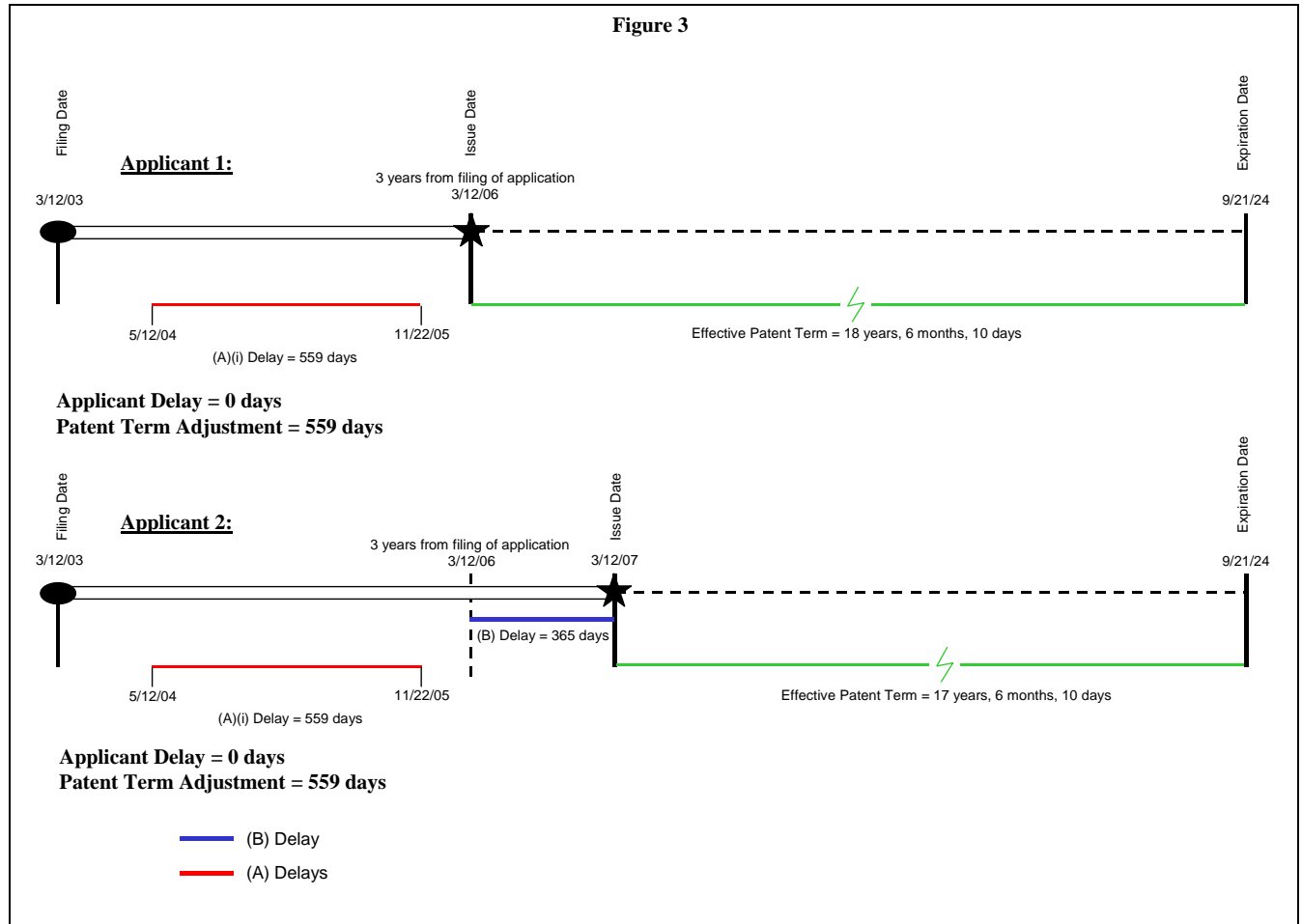
Nonetheless, if the PTO adheres to that interpretation, and allows adjustments under § 154(b)(1)(A) if there is no adjustment due under § 154(b)(1)(B), its construction is still

¹² On September 20, 2007, the PTO published a paper in which it advocates amending the current patent term adjustment law to achieve the result it currently seeks to impose by “construction.” (*See* Palla Decl. Ex. M.) In that paper, the PTO states that a patent term adjustment “should be limited to the situations in which the USPTO delayed processing or examination of the patent and this delay resulted in the application pending before the USPTO for more than three years.” (*Id.* at 1.) The PTO appears to be attempting to impose what it seeks as an amended statute by an untenable interpretation of the current, quite different, law.

¹³ One cannot reach the PTO’s explanation from the words of the statute if the term “period of delay” is given a consistent meaning.

unreasonable because it leads to inconsistent treatment of patent applicants, and deprives the applicant of patent term due to the PTO's failure to meet statutory deadlines.

For example, as illustrated in Figure 3 below, assume a first applicant filed a patent application on March 12, 2003, and the PTO failed to mail an action until November 22, 2005 (559 days longer than the 14 months permitted under § 154(b)(1)(A)(i)), but that application timely issued as a patent on March 12, 2006 -- exactly three years after the filing date. In that case, the PTO would apparently adjust the patent term by 559 days because there was a § 154(b)(1)(A) delay and no delay under § 154(b)(1)(B). The first applicant would thus have an effective patent term of 18 years, 6 months and 10 days. Now assume a second applicant filed a patent application also on March 12, 2003, and that the PTO also did not mail an office action until November 22, 2005 (producing the same 559 day delay). Assume that this second applicant's patent issued on March 12, 2007 -- four years after its filing, or one year beyond the time limit of (B). If the PTO used the approach it applied in this case to calculate the adjustment for the second applicant in this example, it would make an adjustment for the longer delay of (A) or (B). It thus would allow an adjustment for the 559 days of delay under (A), and allow no adjustment for the additional 365 days of delay under (B), because the delay under (A) was greater than the delay under (B). That adjustment would leave the second applicant in this example with a patent term of 17 years, 6 months and 10 days, one year shorter than the first applicant solely because of the unadjusted additional PTO delay that occurred under (B).



The PTO’s construction would thus severely penalize an applicant who suffered a delay under both (A) and (B), and would give him a substantially shorter patent term than the applicant who suffered a delay only under (A). The second applicant suffers a substantial loss of patent term due to the PTO’s additional delay under (B). That result would be contrary to the purpose of the statute of guaranteeing the applicant that the PTO’s failure to act within the statutory time limits will not result in a loss of patent term.

III. THE PTO’S CONSTRUCTION CANNOT BE JUSTIFIED BY DEFERENCE TO THE AGENCY

Challenges to the PTO’s determination of a period of patent term adjustment are governed by Chapter 7 of Title 5. *See* 35 U.S.C § 154(b)(4)(A). While an agency’s

interpretation of a statute it administers which is ambiguous or silent on the point of interpretation may be entitled to deference when it makes rules pursuant to a delegation of authority from Congress, *Chevron, U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-45 (1984), the “courts are the final authorities on issues of statutory construction. . . . [and] must reject administrative constructions of the statute, whether reached by adjudication or by rulemaking, that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.” *FEC v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981); *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1425 (Fed. Cir. 1988) (same).

The PTO’s construction of § 154(b) is not entitled to deference, because the statute is not ambiguous or silent on the issue of the adjustment for delays under multiple subsections, nor is it ambiguous or silent on the meaning of “periods of delay” that “overlap.”

Furthermore, even if the statute were ambiguous or silent on the issues, the PTO’s interpretation would not be entitled to *Chevron* deference because Congress did not delegate to the PTO the authority to determine what delays would entitle the patent applicant to an adjustment. The statute sets forth in detail the adjustments to which a patent applicant is entitled. The PTO was delegated only the authority to “prescribe regulations establishing procedures for the application for and determination of patent term adjustments,” 35 U.S.C. § 154(b)(3)(A), and was not delegated the substantive authority to determine what adjustments are appropriate. The PTO has not been granted the authority to make substantive rules of law even under its broadest rulemaking authority. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (“As we have previously held, the broadest of the PTO’s rulemaking powers - 35 U.S.C. § 6(a) - authorizes the Commissioner to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO];’ it does NOT grant the Commissioner the authority to issue

substantive rules.” (quoting *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)) (emphasis in original).

As the Supreme Court stated in *Gonzales v. Oregon*:

Deference in accordance with *Chevron*, however, is warranted only “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” (citation omitted) Otherwise, the interpretation is “entitled to respect” only to the extent it has the “power to persuade.”

546 U.S. 243, 255-56 (2006) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

The PTO’s interpretation of the AIPA patent term adjustment provisions was not included in the regulations it adopted, rather the regulations in 37 C.F.R. 1.702 merely parrot the words of the statute and do not provide any support for the PTO’s position. The PTO cannot bootstrap its interpretation of the statute by claiming that it is entitled to deference in interpreting its regulations that mirror the statute. The Supreme Court rejected such an approach in *Gonzales v. Oregon*:

Simply put, the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute. An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.

546 U.S. at 257.

An agency’s interpretation of even an ambiguous statute will not be accepted when, as here, the construction cannot be reconciled with the language. *See Rapanos v. United States*, 126 S. Ct. 2208, 2225 (2006) (rejecting the Army Corps of Engineers’ construction of the ambiguous statutory term “navigable waters” in favor of the only plausible construction). The statute in issue also does not implicate any special expertise of the Patent Office; rather, the issue is one of the meaning of plain English words in a statute where the Court has greater expertise. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

IV. THIS CASE PRESENTS SOLELY A LEGAL QUESTION OF STATUTORY CONSTRUCTION AND IS APPROPRIATE FOR SUMMARY JUDGMENT

Summary judgment is appropriate when the moving party has shown that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

Here, there are no disputed issues of material fact. All the facts related to calculating the patent term adjustment under § 154(b)(1) for both the '819 and '892 patents are undisputed. (*See supra* pp. 7-9; Answer ¶¶ 18, 22, 30, 34.) The only issue is the interpretation by the PTO of overlapping delays under § 154(b)(2)(A) and whether that interpretation is contrary to the requirements of the statute. Thus, since this case involves purely legal issues, it is appropriate for summary judgment.

CONCLUSION

For all the foregoing reasons, this Court should grant plaintiffs' motion for summary judgment that the patent term adjustment for the '892 patent be changed from 462 days to 756 days, and that the patent term adjustment for the '819 patent be changed from 492 days to 722 days.

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Respectfully submitted,



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