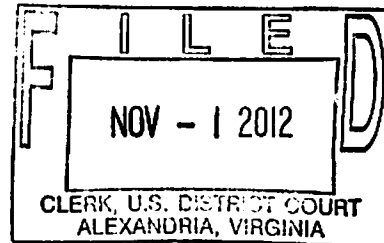


**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division**



EXELIXIS, INC.,)
Plaintiff,)

v.)

Case No. 1:12cv96

HON. DAVID J. KAPPOS, Under)
Secretary of Commerce for Intellectual)
Property and Director of the United)
States Patent and Trademark Office,)
Defendant.)

MEMORANDUM OPINION

In the 1990’s, Congress twice significantly altered the patent law landscape. First, in 1994, Congress enacted the Uruguay Round Agreements Act,¹ which (i) required the term of a patent to be measured from the date of application, (ii) extended a patent term from 17 to 20 years, and (iii) created patent term adjustment (“PTA”), extending the length of a patent term in the event that certain delays occurred in the processing of the application. Second, in 1999, Congress again altered the patent landscape by enacting the American Inventors Protection Act of 1999 (“AIPA”),² which significantly amended the PTA provisions and provided for a Request for Continued Examination (“RCE”), which permits an applicant to request additional examination of the patent application. Predictably, these alterations in the patent law landscape spawned substantial litigation, of which this case is a recent example.

¹ Pub. L. No. 103–465, Dec. 8, 1994, 108 Stat. 4809 (codified as amended in scattered sections of 35 U.S.C.).

² Pub. L. No. 106–113, 113 Stat. 1536 (codified as amended in scattered sections of 35 U.S.C.).

Presented here is the following, as yet unresolved, question concerning the application of AIPA's PTA provision:

Whether 35 § 154(b)(1)(B) requires that an applicant's PTA be reduced by the time attributable to an RCE, where, as here, the RCE is filed after the expiration of AIPA's guaranteed three year period.

For the reasons that follow, § 154's plain language neither addresses nor requires that an applicant's PTA be reduced by the time required to process an RCE that is filed after the expiration of the three year period.³

I.

Exelixis, Inc. ("Exelixis"), a Delaware corporation with its principal place of business in San Francisco, California, is the owner of United States Patent No. 7,989,622 ("the '622 patent"). This patent—entitled "Phosphatidylinositol 3-Kinase Inhibitors and Methods of their Use"—covers certain molecules that inhibit an enzyme associated with certain cancers that may be useful for the treatment and prevention of those cancers.

The administrative record reflects the various events that occurred in the course of the prosecution and examination of the application that led to the issuance of the patent. Only a few of these events—those pertinent to the PTA calculation and hence to the question presented—merit mention here.

First, the record reflects that the application for the '622 patent⁴ was filed on January 15, 2008. The record shows that the next event of PTA significance occurred on February 22, 2010,

³ Exelixis points out that if the question presented were decided to the contrary, it would be necessary to resolve a second question, namely whether the period of time between the date of the Notice of Allowance and the date of the patent issuance is properly included as "time consumed by continuing examination" under § 154(b)(1)(B)(i).

⁴ This application was a national stage application of a Patent Cooperation Treaty application. The Patent Cooperation Treaty is "an international agreement allowing inventors to streamline

when the United States Patent and Trademark Office (“PTO”) issued a “Restriction and/or Election Requirement,” its first notice pursuant to 35 U.S.C. § 132. This filing came approximately 25 months after the application was filed. The timing of this PTO filing is important to the PTA calculation inasmuch as § 154(b)(1)(A) requires the PTO to provide at least one § 132 notice (or alternatively, a notice of allowance) not later than 14 months after the application is filed, and to the extent the § 132 misses this 14 month deadline, the applicant receives a day for day credit toward the PTA.

The next event with PTA significance occurred, as the record reflects, on March 9, 2011, approximately 38 months after the application filing date, when the PTO issued a Final Rejection of the application. Barely a month later, Exelixis, on April 11, 2011, filed the RCE at issue here. This RCE modified and supplemented the application as follows: (i) claims 1–12, 14, 15, and 17–33 were cancelled, (ii) claims 13 and 16 were amended, (iii) claims 34–38 were added, and (iv) additional support was provided for the amended and added claims.

Thereafter, the PTO, with commendable, if, with respect to this application, uncharacteristic alacrity, responded less than three weeks later by mailing to Exelixis a “Notice of Allowance & Fees Due” with respect to the application. This Notice advised Exelixis (i) that “prosecution on the merits has closed,” (ii) that the application “is allowed for issuance as a patent,” and (iii) that the PTA for the ‘622 patent was calculated as 283 days, meaning that the ‘622 patent term would extend 20 years plus 283 days from the date of the patent application.

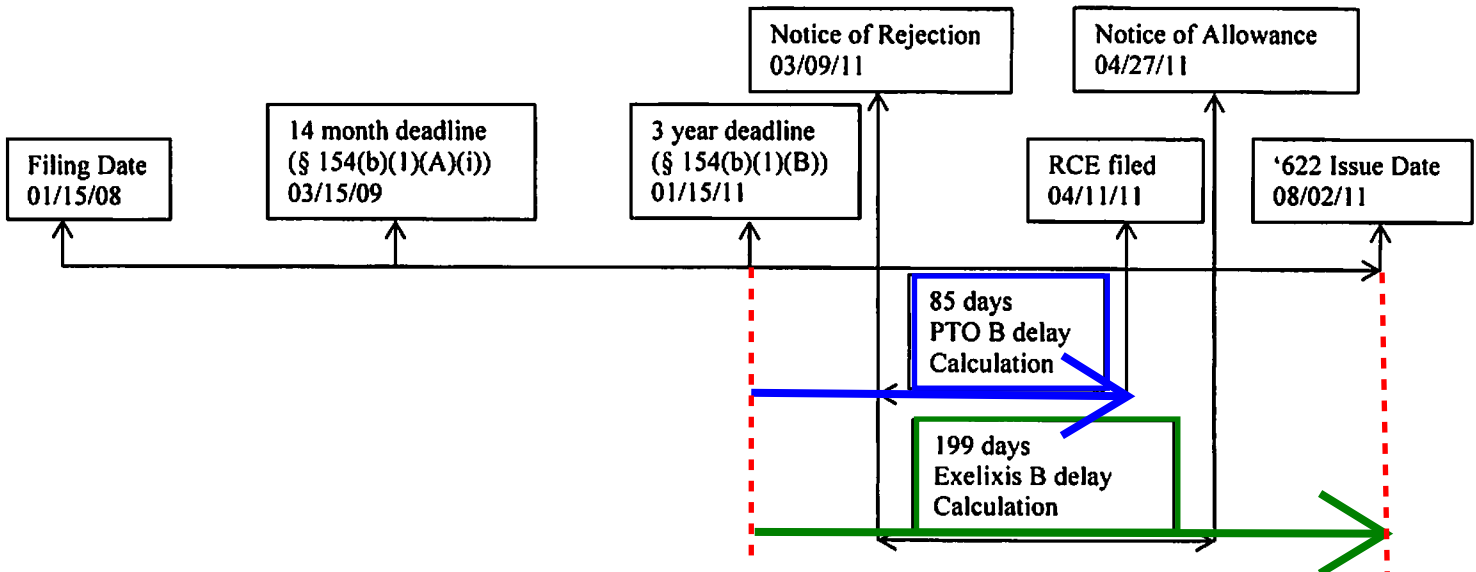
The record next shows that on April 28, 2011, Exelixis paid the issue fee, but then for reasons not disclosed in the record, the PTO did not mail the “Issue Notification” to Exelixis

the process of obtaining patent rights across multiple member nations.” *Helfgott & Karas, P.C. v. Dickenson*, 209 F.3d 1328, 1330 (Fed. Cir. 2000).

until July 17, 2011. The '622 patent issued thereafter on August 2, 2011. The Issue Notification included the PTO's final PTA calculation for the patent,⁵ totaling 368 days, consisting of (i) 344 days for PTA attributable to the PTO's failure to file a § 132 notification within 14 months of the patent application date, as required by § 154(b)(1)(A) ("A delay"), (ii) 85 days of PTA attributable to the PTO for the failure of a patent to issue within 3 years of the application date, as required by § 154(b)(1)(B) ("B delay"), (iii) 0 days of PTA pursuant to § 154(b)(1)(C) ("C delay"), and (iv) a 61 day PTA reduction attributable to Exelixis' delay pursuant to § 154(b)(2)(C) ("C reduction").

Exelixis does not dispute the PTO's calculation of A delay, C delay, or C reduction; instead, the parties' dispute focuses sharply on the PTO's B delay calculation. The PTO contends that the 85 days of B delay is arrived at by subtracting the number of days attributable to the RCE, 114 days (April 11, 2011 to August 2, 2011), from 199 days (the number of days from the expiration of the three year period—January 15, 2008 to January 15, 2011—to the issuance of the patent on August 2, 2011). Exelixis disagrees with the PTO's decision to reduce the PTA by the RCE and argues instead that the proper B delay calculation is 199 days, the number of days between the end of the § 154(b)(1)(B) guaranteed three year period (January 15, 2011) and the issuance of the patent (August 2, 2011). The following time line illustrates the '622 patent's path to issuance and the parties' competing B delay calculations:

⁵ The difference between the April 27, 2011 PTA calculation and the final PTA calculation reflects the addition of the B delay PTA.



As the timeline shows, the PTO’s notice of rejection, Exelixis’ RCE, the PTO’s notice of allowance, and the issuance of the patent all occurred after the expiration of the three year period that commenced on the application filing date. And as the timeline also makes clear, the question that divides the parties on these facts is whether § 154(b)(1)(B) requires that, or even addresses whether, any PTA be reduced by time attributable to an RCE where, as here, the RCE is filed after the expiration of the three year guarantee period specified in that statute.

II.

Resolution of this question is informed by a brief overview of AIPA’s PTA provisions. The starting point in this overview is to note that Congress, in 1994, in order to implement international agreements, amended the patent laws to extend the length of a patent term to 20 years, measured from the date of the patent application.⁶ Prior to this amendment, a patent term was 17 years, measured not from the application date, but from the date of the patent issuance. Recognizing that the examination and prosecution phase might result in delays in the issuance of

⁶ Uruguay Round Agreements Act, Pub. L. No. 103–465, Dec. 8, 1994, 108 Stat. 4809 (codified as amended in scattered sections of 35 U.S.C.).

a patent, Congress in the 1994 amendment provided for adjusting the patent term to account for delays that might occur owing to “interference delay,” “secrecy orders,” or “appellate review.”⁷ Then, in 1999, Congress again amended these provisions to add the PTA provisions now found in § 154(b).⁸ Taken as a whole, the clear goal and purpose of these provisions is to provide a successful applicant with a patent that can be enforced against putative infringers for approximately 17 years—20 years from the date of application less the three years for prosecution and examination—and to reach this goal by providing applicants with day for day patent term extensions for delays attributable to the PTO and day for day reductions of the patent term extension for delays attributable to an applicant’s failure to act with alacrity in certain circumstances.

A. The Patent Application Process

In order to patent an invention, a person must apply to the PTO for a patent. 35 U.S.C. § 111. A PTO patent examiner then determines whether the “applicant is entitled to a patent under the law,” and, if so, the PTO issues a patent. 35 U.S.C. § 131. If the patent examiner makes a contrary finding, then the PTO will issue a notice of rejection that puts forth “the reasons for such rejection.” 35 U.S.C. § 132(a). If the applicant receives a rejection notice, the applicant may continue to pursue the issuance of the patent as is, or may make an amendment to the patent application. On the second, or any subsequent, examination of the patent application, the patent examiner may determine that the rejection is final. 37 C.F.R. § 1.113. The applicant’s options

⁷ *Id.*

⁸ AIPA, Pub. L. No. 106–113, 113 Stat. 1536 (codified as amended in scattered sections of 35 U.S.C.). The portion of the AIPA that altered the PTA regime is sometimes referred to as the Patent Term Guarantee Act of 1999. *See, e.g., Wyeth v. Dudas*, 580 F.Supp.2d 138, 139 (D.D.C. 2008).

are then limited to an “appeal in the case of rejection of any claim” or “to [an] amendment” of the application. *Id.* The RCE is one such amendment. Once a final rejection has issued, the applicant generally has up to six months to file an RCE before the application is abandoned. *See* 37 C.F.R. § 1.135. An RCE, which may consist of (but is not limited to) “an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability,” functions to continue the examination of the current application by reopening the prosecution. 37 C.F.R. § 1.114(b).

Once the PTO determines that the application contains patentable claims, the PTO will issue a “Notice of Allowance” that informs the applicant that he “is entitled to a patent under the law[.]” 37 C.F.R. § 1.311(a). The applicant must then pay the requisite fees within three months, otherwise the application will be deemed abandoned. *Id.* Even after the fee has been paid, up until the patent actually issues, the application may be withdrawn by either the PTO or the applicant. 37 C.F.R. § 1.313.

B. Patent Term Adjustments

Subsection 154(b) of Title 35 governs the determination and measurement of PTA. Paragraph (1) of this subsection, entitled “Patent term guarantees,” sets forth three general guarantees designed to expedite the application, prosecution, and examination process. This paragraph also describes the various categories of events that generate PTA, i.e., events that result in the extension of the patent term.

First, subparagraph (A), entitled “Guarantee of prompt Patent and Trademark Office responses,”⁹ extends the patent term if the PTO fails to carry out certain acts during the

⁹ It is well settled that “‘the title of a statute and the heading of a section’ are ‘tools available for the resolution of a doubt’ about the meaning of a statute.” *Almendarez-Torres v. United States*,

prosecution and examination of the patent within prescribed timelines. For example, if the PTO takes more than four months to issue a patent once the “issue fee was paid” and “all outstanding requirements were satisfied,” then PTA is granted on a day for day basis for each day longer than four months until the patent is issued. § 154(b)(1)(A)(iv).

Next, subparagraph (B), entitled “Guarantee of no more than 3-year application pendency,” extends the patent term on a day for day basis “for each day after the end of that 3 year period until the patent is issued.” § 154(b)(1)(B). Subparagraph (B) ensures that the patent prosecution and examination process proceeds expeditiously to preserve an approximately 17 year patent term measured from the date of issuance. Certain events, such as time consumed by an RCE or by an applicant requested delay, are “not included” in the measurement, and here the parties disagree as to whether these events are “not included” in the measurement of the three year period (Exelixis’ position) or in the PTA calculation (the PTO’s position).

Finally, subparagraph (C), entitled “Guarantee of adjustments for delays due to interferences, secrecy orders, and appeals,” extends the patent term on a day for day basis for “each day of the pendency of the proceeding, order, or review[.]” § 154(b)(1)(C). Put simply, subparagraph (C) grants PTA for time consumed by certain special proceedings that may occur during the course of the prosecution and examination of the application.

The PTA awarded under paragraph (1) is subject to certain limitations set out in paragraph (2), entitled “Limitations.” Subparagraph (A) of paragraph (2) makes clear that “to

523 U.S. 224, 234 (1998) (quoting *Trainmen v. Baltimore & Ohio R. Co.*, 331 U.S. 519, 528–29 (1947)); see also *I.N.S. v. Nat’l Center for Immigrants’ Rights, Inc.*, 502 U.S. 183, 189 (1991) (“the title of a statute or section can aid in resolving an ambiguity in the legislation’s text”); *Reese v. United States*, 24 F.3d 228, 231 (Fed. Cir. 1994) (using the section title as an aid to resolving a statutory ambiguity); *United States v. Clawson*, 650 F.3d 530, 536 (4th Cir. 2011) (noting that the statute’s “heading further supports [the court’s] determination” of statutory meaning).

the extent that periods of delay . . . overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” § 154(b)(2)(A).¹⁰ In other words, the PTA calculation must not double count; the applicant may not receive more than one day of PTA for the same calendar day. Next, subparagraph (B) limits the granting of PTA for disclaimed patent terms. Finally, subparagraph (C), entitled “Reduction of period of adjustment,” reduces PTA for time consumed by delays attributable to the patent applicant. This includes the reduction of PTA by “a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” § 154(b)(2)(C)(i). The remaining paragraphs under subsection (b) set forth the procedures for the determination of PTA and for appeals of such determinations.

In this action, Exelixis contends that the PTO improperly calculated B delay by not providing a day for day PTA for time consumed by the RCE filed after the three year period had expired. In opposition, the PTO argues that the time consumed by an RCE is always excluded from the calculation of B delay because, in the PTO’s view, any time consumed by an RCE is subtracted from the PTA awarded under subparagraph (B), regardless of when the RCE is filed.

III.

A case is ripe for summary judgment where “there ‘is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.’” *Wyeth*, 591 F.3d at 1369 (quoting Fed.R.Civ.P. 56(c)). Because in the present case both parties “perceive no genuine issues of material fact,” there is only a legal determination to be made, namely whether the PTO’s method for calculating PTA under § 154(b)(1)(B) is contrary to law. *See id.* The PTO’s

¹⁰ *See Wyeth v. Kappos*, 591 F.3d 1364, 1368–72 (rejecting the PTO’s “greater-of-A-or-B rubric” and holding that § 154(b)(2)(A) applies only where there is overlap between A delay and B delay).

determination of PTA is subject to judicial review under the Administrative Procedure Act. 35 U.S.C. § 154(b)(4)(A). Thus, a district court may only set aside the PTO's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency abuses its discretion "where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold Partnership v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

IV.

Analysis of the question presented properly begins with the plain language of the statute. As the Supreme Court has noted, "it is axiomatic that '[t]he starting point in every case involving construction of a statute is the language itself.'" *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 685 (1985) (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 756 (1975) (Powell, J., concurring)).¹¹ Further, the Supreme Court has made clear that where "the statute's language is plain, 'the sole function of the courts is to enforce it according to its terms.'" *U.S. v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 241 (1989) (quoting *Caminettie v. United States*, 242 U.S. 470, 485 (1917)). The Supreme Court has warned, however, that there may be "rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters." *Ron Pair Enterprises*, 489 U.S. at 242 (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982)). It is only in those rare cases that "the intention of the drafters, rather than the strict language, controls." *Id.* And in the Federal Circuit, "only a 'most

¹¹ See also *Wyeth*, 591 F.3d at 1369 ("As always, the starting point in every case involving construction of a statute is the language itself.") (internal quotation marks omitted).

extraordinary showing of contrary intentions' by Congress justifies a departure from the plain language of a statute." *Wyeth*, 591 F.3d at 1371 (quoting *Garcia v. United States*, 469 U.S. 70, 75 (1984)). Thus, a court must give a statute its plain language meaning unless that meaning clearly contradicts the drafter's intent.

Here, the plain language meaning of subparagraph (B) is clear, unambiguous, and in accord with both the statute's structure and purpose. Subparagraph (B) provides in pertinent part,

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, not including:

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

...

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.

35 U.S.C. § 154(b)(1)(B). Simply put, the goal of this subparagraph, as its title indicates, is a "Guarantee of no more than 3-year application pendency." It accomplishes this goal by (i) starting a three year clock on the date the application is filed, (ii) tolling the running of this clock if, within the three year period, any of three events occur, including an RCE filing, and (iii) adding a day for day PTA to the patent term for any delay in the issuance of the patent after the three year clock, less any tolling, runs out. Thus, subparagraph (B) essentially describes two calculations. The first is a description of the calculation of the three year period: The three year clock begins to run on the date the application is filed and, except for three specific potential tolling events, including the filing of an RCE, the clock runs continuously until the three year period ends. In other words, the "not including" portion of subparagraph (B), followed by (i), (ii), and (iii), clearly and unambiguously modifies and pertains to the three year period and does not apply to, or refer to, the day for day PTA remedy. Subparagraph (B)'s second calculation is

simply a day for day addition to the PTA for every day beyond the end of the three year clock until the patent issues.

Especially notable about this reading of subparagraph (B), which is commanded by the provision's plain and unambiguous language, is that it does not address the filing of an RCE after the expiration of the three year clock. To be sure, the provision makes clear that the clock is tolled for the processing of an RCE filed before the three year clock runs out, but the provision does not refer to or mention RCE's filed after the three year clock has run. Instead, subparagraph (B) makes clear that once the three year clock has run, PTA is to be awarded on a day for day basis regardless of subsequent events.

Also notable of subparagraph (B) is that the reading compelled by its plain language is firmly supported by § 154(b)'s structure and purpose. The statute's purpose is to ensure that an applicant is provided with a PTA remedy for delays in examination and processing attributable to the PTO and to reduce any PTA by delays attributable to the applicant. Significantly, § 154(b) does not treat an RCE filing as applicant delay; instead applicant delay is treated in § 154(b)(2)(C), which is captioned "Reduction of period of adjustment"¹² and does not refer to RCE's. The RCE is treated only in subparagraph (B), which specifies that an RCE filed during the running of the three year clock tolls the running of that clock while the RCE is processed. In other words, the statute does not consider an applicant's submission of an RCE as "applicant delay" that warrants reduction under § 154(b)(2)(C); rather, the statute simply treats the time devoted to an RCE as time that should not be counted against the PTO in the running of the three year clock.

¹² Subsection (2)(C) addresses situations where applicants have "failed to engage in reasonable efforts to conclude prosecution of the application" and, as a result, the PTA that would otherwise be added to the patent term is reduced. § 154(b)(2)(C).

In summary, the plain and unambiguous language of subparagraph (B) requires that the time devoted to an RCE serves to toll the running of the three year clock, if the RCE is filed within the three year period; subparagraph (B) does not address RCE's filed after the running of the three year period nor does it require that the time consumed by an RCE filed after the running of the three year clock be deducted from the PTA. Put simply, RCE's have no impact on the PTA after the three year deadline has passed¹³ and subparagraph (B) clearly provides no basis for any RCE's to reduce PTA; instead, RCE's operate only to toll the three year guarantee deadline, if, and only if, they are filed within three years of the application filing date. Thus, the PTO erred in construing subparagraph (B) to the contrary. In doing so, the PTO, in essence, construed subparagraph (B) to punish the applicant for filing the RCE. Yet there is no basis for reading subparagraph (B) in this manner. Indeed, the PTO properly regards the RCE not as an occasion to punish the applicant, but as a "valuable tool in the patent prosecution process."¹⁴ Nor does the PTO list an RCE as one of 11 enumerated applicant delays.¹⁵ In sum, the PTO in this case incorrectly treats an RCE as a punitive measure, that is a measure aimed at punishing Exelixis by reducing PTA—rather than as a "valuable tool in the patent prosecution process"—where, as here, the RCE was filed after the expiration of the three year clock. Accordingly, the PTO's calculation of B delay must be set aside as "not in accordance with law" and "in excess of [its] statutory . . . authority" pursuant to 5 U.S.C. § 706(2)(A) and (C). *See also Wyeth*, 591 F.3d at 1372 (holding that because, in the context of § 154(b)(2)(C), § "154(b)'s language is clear,

¹³ A possible exception to this may occur where an RCE in particular circumstances not present here, is properly categorized as applicant delay under § 154(b)(2)(C).

¹⁴ Bob Stoll, *RCE Filings: The Facts*, Director's Forum: David Kappos' Public Blog, Jul. 26, 2010, http://www.uspto.gov/blog/director/entry/rce_filings_the_facts.

¹⁵ *See* 37 C.F.R. § 1.704

unambiguous, and intolerant of the PTO's suggested interpretation," the Federal Circuit "accords no deference to the PTO's [interpretation]").

The PTO offers several arguments in support of its interpretation, none of which is persuasive.¹⁶ First, the PTO argues that a proper reading of subparagraph (B) requires the insertion of the word "then" prior to the phrase "not including" that is followed by (i), (ii), and (iii). According to the PTO, inserting the word "then" at that point allows subparagraph (B) to be read so that time consumed by an RCE is deducted from the day for day remedy for the PTO's failure to meet the three year guarantee deadline. The short and dispositive answer to this argument is that the word "then" does not appear in the statute and the PTO's insertion of the word in its reading is not a construction of the provision but rather a re-writing of it. Neither courts nor agencies may change or alter the plain language and meaning of a statute because of a belief, however well founded, that the statute would be improved thereby.¹⁷ In any event, there is no persuasive reason to conclude that the statute would be improved by changing the language as the PTO proposes. This is so because the statute and the PTO¹⁸ do not regard RCE's as undesirable devices for which the applicant should be punished. Put differently, § 154(b) does not treat an RCE as an applicant's failure "to engage in reasonable efforts to conclude prosecution of the application" under § 154(b)(2)(C)(i). In effect, RCE's are something for

¹⁶ Although the plain language of subparagraph (B) may result in the PTO awarding C delay less often, this simply does not, as the PTO argues, render subparagraph (C) superfluous.

¹⁷ See *Badaracco v. Comm'r of Internal Revenue*, 464 U.S. 386, 398 (1984) ("Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvement."); see also *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1346 (Fed. Cir. 2003) ("it is the function of Congress, not the courts, to shape legislation in accordance with policy goals").

¹⁸ See *Stoll*, *supra* n. 14.

which the three year clock should be tolled, but not something that reduces the PTA. To avoid the problem presented in the present case—an RCE filed after the three year clock has expired—the PTO should aim to issue any notice of rejection before the expiration of the three year period and then, by regulation, require applicants to file RCE's in response to such notices within 30 days.

Next, the PTO argues that its construction of subparagraph (B) deserves *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), deference.¹⁹ To be sure, when statutes, as not the case here, are unclear or ambiguous, *Skidmore* deference to the PTO's interpretation might be appropriate.²⁰ Again, the short answer here is that *Skidmore* deference is unwarranted, when, as here, the statute is unambiguous.

Finally, the PTO argues that its reading of subparagraph (B) avoids absurd results. Under the PTO's view, the plain language of subparagraph (B) may lead to disparate treatment of some similarly situated applicants, depending on whether the applicant files the RCE before or after the expiration of the three year period. But such disparities arise only at the margins and the

¹⁹ For reasons the PTO did not make clear, the PTO explicitly declined to assert or claim *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), deference, notwithstanding the existence of a regulation—37 C.F.R. § 1.703—setting forth the very reading of subparagraph (B) that it advances here. In any event, *Chevron* deference is not appropriate because the statute is not ambiguous as written. Moreover, the regulation has the effect of altering the PTA and the patent term, which is a substantive alteration that the PTO is arguably unauthorized to make. See § 154(b)(3)(A) (“The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.”) (emphasis added).

²⁰ Indeed, it appears that in the Federal Circuit, *Skidmore* deference carries more force than in the other circuits. Compare *Cathedral Candle Co. v. U.S. Intern'l Trade Com'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005) (interpreting *Skidmore* and subsequent cases to require deference “even if we might not have adopted that construction without the benefit of the agency's analysis”) with *Shipbuilders Council of Am. V. U.S. Coast Guard*, 578 F.3d 234, 241 (4th Cir. 2009) (“Under the *Skidmore* standard, the court defers to an agency interpretation only if and to the extent that it is persuasive.”).

Federal Circuit rejected similar arguments in *Wyeth*, where it explained that “[r]egardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities.” *Wyeth*, 591 F.3d at 1370. Indeed, in subparagraph (B), Congress “has put a policy in effect that this court must enforce, not criticize or correct.” *See id.* It is also worth noting that the disparate treatment of applicants in these circumstances can be minimized by the PTO because the PTO controls the timing of a notice of rejection, which is a typical event that causes an applicant to file an RCE. Thus, if the PTO takes steps to issue notices of rejection well within the running of the three year clock and also requires RCE’s to be filed within a fixed number of days after receipt of such notice—also within the three year period, then the time devoted to RCE’s will generally count against the running of the clock and applicants will not be disparately treated.

v.

In sum, the plain and unambiguous language of subparagraph (B) requires that the time devoted to an RCE tolls the running of the three year clock if the RCE is filed within the three year period. And, put simply, RCE’s have no impact on PTA if filed after the three year deadline has passed. The PTO’s arguments to the contrary are not persuasive and, accordingly, the PTO’s interpretation of subparagraph (B) must be set aside as “not in accordance with law” and “in excess of [its] statutory . . . authority” pursuant to 5 U.S.C. § 706(2)(A) and (C). The proper measure of B delay in the present case is from January 15, 2011 (three years after the application filing date) to August 2, 2011 (the date the patent issued). Thus, the B delay PTA for the ‘622 patent is properly calculated as 199 days.

An appropriate Order will issue.

Alexandria, VA
November 1, 2012



T. S. Ellis, III
United States District Judge