

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABRAXIS BIOSCIENCE, LLC,

Plaintiff,

v.

HONORABLE DAVID KAPPOS, in his
official capacity as UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL
PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND
TRADEMARK OFFICE,

Defendant.

Civil Action No. 1:11-cv-00730
Judge Beryl A. Howell

MEMORANDUM OPINION

The plaintiff Abraxis Bioscience, LLC, brought this lawsuit against David Kappos, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“USPTO”), seeking a judgment that the patent term adjustment (“PTA”) for United States Patent No. 7,820,788 (“’788 patent”) be increased by at least 122 days from the 199 days awarded by USPTO, for a total PTA of at least 321 days or, alternatively, 323 days. Pending before the Court are the parties’ cross-motions for summary judgment. *See* Pl.’s Renewed Mot. Summ. J. Re PTA for Patent ‘788 (“Pl.’s Mot.”), ECF No. 20; Def.’s Cross-Mot. Summ. J. and Opp’n Pl.’s Renewed Mot. Summ. J. Re PTA for Patent ‘788 (“Def.’s Opp’n”), ECF No. 21.¹ For the reasons explained below, the USPTO’s Motion for

¹ Duplicate versions of the parties’ memoranda filed in support and opposition to these motions are docketed and, to simplify citation, the Court will reference only one of the duplicate memoranda. For example, the Defendant’s Memorandum and Points of Authority in Support of Director’s Cross- Motion for Summary Judgment and In Opposition to Plaintiff’s Motion for Summary Judgment is docketed in duplicate at both ECF Nos. 21 and 22; the Court will cite only to the memorandum at ECF No. 21. Similarly, the Plaintiff’s Reply on Its Renewed Motion for Summary Judgment and Opposition to the Defendant’s Cross-Motion for Summary Judgment is docketed in duplicate at both ECF Nos. 24 and 25; the Court will cite only to the memorandum docketed at ECF No. 24.

Summary Judgment is granted and the plaintiff's Renewed Motion for Summary Judgment Regarding the Calculation of Part B Delay for the United States Patent No. 7,820,788 is denied.²

I. BACKGROUND

A. Legal Framework

The plaintiff challenges the USPTO's interpretation of a statutory provision at 35 U.S.C. § 154(b)(1)(B)(i), which governs the determination of PTA when the patent applicant files a request for continued examination ("RCE"), as authorized by 35 U.S.C. § 132(b), more than three-years from the filing date of the patent application. Since a fundamental tenet of statutory construction is to examine the challenged text in context, an overview of the legal framework for determining a patent term is necessary. *See United States v. Ali*, 718 F.3d 929, 937 (D.C. Cir. 2013) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.") (internal quotation marks omitted)).

United States patent law originates from a constitutional grant of authority to the Congress "[t]o promote the Progress of Science and useful Arts, by securing for a limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8; *see also Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5 (1966) (references to "useful Arts" and "Discoveries" creates the right to patent protection). The brevity of this Patent Clause belies the complexity of defining the scope of the "exclusive Right" of inventors to their discoveries. At the outset, inventors do not automatically hold patent rights to their inventions. *See* 35 U.S.C. § 111. Inventors must submit applications to the USPTO for

² The plaintiff has requested oral argument on the pending motions. Pl.'s Counsel's Letter, dated June 8, 2012, ECF No. 26. This request is denied as unnecessary given the ample briefing of the issues in the parties' submissions. *See* LCvR 7(f) (allowance of oral hearing "within discretion of the court").

review and assessment whether a patent should issue. *See* 35 U.S.C. § 131. Upon issuance, the patent term in the United States was, until 1994, seventeen years, beginning from the date the patent was issued. *See* Act of March 2, 1861, ch. 88, § 16, 12 Stat. 246, 249 (codified as amended at 35 U.S.C. § 154). In order to harmonize the U.S. patent laws with those of America’s leading trading partners, Congress amended this regime in 1994 to adjust the term of a patent from seventeen to twenty years, beginning from the date the application was filed. *See* Uruguay Round Agreements Act (“URAA”), Pub. L. No. 103-465, 102 Stat. 4809 (codified as amended at 35 U.S.C. § 154(a)(2)); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (noting that the “purpose of URAA was not to extend patent terms, although it had that effect in some cases”).

Despite the addition of three years to the patent term in the URAA, measuring the patent term from the patent application filing date, rather than the date of patent issuance, could consume “some of the effective term of a patent . . . by the time it takes to prosecute the application.” *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 139–40 (D.D.C. 2008). To mitigate the effect of administrative delays on the patent term, Congress provided in the URAA for patent term extensions of no more than five years due to (1) “interference delay or secrecy orders,” under 35 U.S.C. §§ 135(a) and 181, respectively, or (2) appellate review. URAA § 532, 108 Stat. at 4984. These periods of patent extension were not only subject to a five year cap, but also to other limitations. For example, any period of extension was required to be reduced “by any time attributable to appellate review before the expiration of 3 years from the filing date of the application” and “for the period of time during which the applicant for patent did not act with due diligence.” *Id.* (originally codified at 35 U.S.C. § 154(b)(3)(B) & (C) (1994)). USPTO was authorized to determine when the applicant failed to act with due diligence. *Id.*

Both the bases for extensions of patent terms and the limitations on those extensions were further refined in 1999 with passage of American Inventors Protection Act of 1999 (“AIPA”). AIPA included, as Subtitle D of Title IV, the “Patent Term Guarantee Act of 1999,” which provided for the patent term adjustment that is at issue here. *See* AIPA, Pub. L. No. 106-113, §§ 4401–02, 113 Stat. 1501, 1501A-557 (1999) (codified, as amended, at 35 U.S.C. § 154(b)). While the five year cap on any PTA imposed by the URAA was eliminated, other limitations were retained in slightly different form. The key provisions of AIPA and implementing regulations implicated by the plaintiff’s challenge to the USPTO’s PTA calculation are summarized below.

1. *Patent Term Adjustments Under AIPA*

The AIPA amendments, *inter alia*, authorized “guarantee[d]” adjustments to the patent term in three circumstances set out in section 154(b)(1); imposed “limitations” on those adjustments in section 154(b)(2); and outlined the “procedures for patent term adjustment determination[s]” in section 154(b)(3). 35 U.S.C. § 154(b)(1),(2) & (3). The interplay among these guarantees, limitations and determination procedures provide significant interpretative fodder for the parties in this litigation.

a. *PTA “Guarantees” in Section 154(b)(1)*

The statute frames the three circumstances extending the patent term as “guarantees” designed to guard against diminution of a patent term due to enumerated administrative delays during consideration of the patent application. First, to “[g]uarantee [] prompt patent and trademark office responses,” a patent term is extended one day for each day that the USPTO fails to meet certain examination deadlines. 35 U.S.C. § 154(b)(1)(A) (“Part A”). For instance, most notably for purposes of the instant case, the patent term is extended under Part A for each day the

issuance of the patent is delayed “due to the failure of the [USPTO] to . . . issue a patent within 4 months after the date on which the issue fee was paid . . . and all outstanding requirements were satisfied.” *Id.* at § 154(b)(1)(A)(iv). This provision provides the USPTO with a 4-month “grace” period to issue a patent after issue fee payment before days begin to be counted as Part A delay.

Second, to “[g]uarantee [] no more than 3-year application pendency,” the patent term is extended one day for each day after the 3-year period after the application filing date “due to the failure of the [USPTO] to issue a patent within 3 years after the actual filing date of the application.” 35 U.S.C. § 154(b)(1)(B) (“Part B”). The extension of the patent term authorized under Part B does “not includ[e]” five enumerated time periods (set out in three clauses). These five time periods are described, in clauses (i) and (ii), as “any time consumed by” the applicant’s RCE under section 132(b), and proceedings under sections 135(a), 181, or appellate review, *id.* at § 154(b)(1)(B)(ii) and (ii); and, in clause (iii), as “any delay in” application processing requested by the applicant, “except as permitted by paragraph (3)(C),” *id.* at § 154(b)(1)(B)(iii).³

The USPTO’s interpretation of both subparagraph (B) and its clause (i) are the focus of the instant dispute. Section 154(b)(1)(B) provides in pertinent part:

- (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 [USPTO] 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);
 - (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any

³ Paragraph (3)(C) authorizes reinstatement to PTA of delay attributable to an applicant request when the applicant shows, prior to the patent issuance that “in spite of all due care,” it was unable to respond in a timely manner (*i.e.*, within 3 months of the date the notice was given or mailed to the applicant, 35 U.S.C. § 154(b)(2)(C)(ii)), but the reinstated time is capped at “three additional months for each such response.” 35 U.S.C. § 154(b)(3)(C).

- time consumed by appellate review by the Patent Trial and Appeal Board⁴ or by a Federal court; or
- (iii) any delay in the processing of the application by the [USPTO] requested by the applicant except as permitted by paragraph (3)(C), 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.

Id.

The Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), addressed the calculation of Part B delay within the framework of section 154(b), noting that each period of delay in Parts A, B and C “has its own discrete time span whose boundaries are defined in section 154(b)(1),” with “a start and an end.” *Id.* at 1369–70. “[A] violation of the ‘B guarantee . . . begins when the PTO fails ‘to issue a patent within 3 years after the actual filing date of the application in the United States’” and “[i]t ends when ‘the patent is issued.’” *Id.* at 1369 (quoting section 154(b)(1)(B)). The court rejected USPTO’s “strained interpretation” that “B delay can occur *anytime* after the application is filed,” and made clear that “[t]he ‘period of delay’ under the express language of the B clause therefore runs from the three-year mark after filing until the application issues.” *Id.* at 1370 (emphasis in original); *see also id.* (“the language of section 154(b) does not even permit B delay to start running until three years *after* the application is filed”) (emphasis in original).

Third, to “[g]uarantee [] adjustments for delays due to derivation proceedings, secrecy orders, and appeals,” the patent term is extended one day for each day that a “proceeding, order, or review, as the case may be,” under sections 135(a), 181 or an appeal, is pending. 35 U.S.C. § 154(b)(1)(C) (“Part C”). Thus, these specific periods of delay excluded from the PTA

⁴ Effective September 16, 2011, the Leahy-Smith America Invents Act changed the name of this entity from the “Board of Patent Appeals and Interferences” to the “Patent Trial and Appeal Board.” Pub. L. No. 112-29, 125 Stat. 284. The plaintiff filed its RCE and received a notice of allowance before the effective date of the name change.

determination under Part B when they occur three years after the filing of an application, are expressly restored to the patent term under Part C.⁵

b. PTA Limitations in Section 154(b)(2)

PTA is subject to several limitations laid out in section 154(b)(2). The limitation pertinent to the instant case is that any PTA set out in paragraph 1, which sets forth the three patent term “guarantees” under Parts A, B and C, is limited to the “extent [those] periods . . . overlap” but not to “exceed the actual number of days the issuance of the patent was delayed.” 35 U.S.C. § 154(b)(2)(A).⁶ In considering the proper construction of the limitation set out in section 154(b)(2)(A), the Federal Circuit in *Wyeth* rejected the USPTO’s practice, ostensibly to avoid “double-counting” when “A delays ‘cause’ B delays,” 591 F.3d at 1370, of computing the adjustment using “either the greater of the A delay or B delay . . . but never combin[ing] the two,” *id.* at 1368. Instead, the court made clear that the limitation in section 154(b)(2) operates to ensure that when overlapping periods occur, “no such day [is] counted twice,” *id.* at 1371.

c. PTA Determination Procedures in Section 154(b)(3)

In order to implement the patent term “guarantees,” Congress provided the USPTO with an express grant of authority to “prescribe regulations establishing procedures for the application for and determination of patent term adjustments.” 35 U.S.C. § 154(b)(3)(A). The determination of how much PTA has accrued is made by the USPTO and communicated to the patent applicant at the time the patent issues. 35 U.S.C. § 154(b)(3)(B).

⁵ By contrast to the URAA, which credited time for appellate review only when such review occurred three years after the filing of the application, the AIPA amendments operate to extend the patent term by the appellate review period whenever it occurs as Part C delay, so long as the applicant succeeds on review in obtaining reversal of an adverse determination of patentability.

⁶ Another limitation is that any PTA made under paragraph 1 must be reduced by any period of delay attributable to the applicant’s “fail[ure] to engage in reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). The USPTO is authorized to “proscribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(2)(C)(iii).

2. *RCE Proceedings*

The AIPA amendments permitted, for the first time, a patent applicant to request continued examination of an application after the USPTO had issued a final notice of rejection or notice of allowance of the claim by submitting an RCE. *See* 35 U.S.C. § 132(b); 37 C.F.R. § 1.114(b). As the USPTO explains, an “RCE is not a new patent application; it merely continues the examination of the same application” and, consequently, “retains (1) the filing date of the underlying application and (2) the amount of patent term adjustment that the underlying application accrued due to delays by the USPTO during the examination.” Def.’s Opp’n at 12–13 (citing *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR 56,366 (Sept. 18, 2000) (“Final Rule”) (discussing § 1.704(c)(11)). An RCE may include “an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability,” 37 C.F.R. § 1.114(c), but may not “introduce new matter into the disclosure of the invention,” 35 U.S.C. § 132(a). An RCE is initiated at the applicant’s request and, therefore, “any time consumed” by an RCE is excluded from Part B delay, which is designed to compensate for administrative delay attributable to the agency. *See* 35 U.S.C. § 154(b)(1)(B)(i).

3. *Challenged USPTO Regulations*

Following notice and comment, the USPTO promulgated two final rules interpreting the proper calculation of PTA under section 154(b)(1)(B). First, 37 C.F.R. § 1.702(b) describes the USPTO’s interpretation of the grounds for PTA due to the agency’s failure to take certain actions within specified time frames. Specifically, this regulation provides that “the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed . . . , but not

including: (1) [a]ny time consumed by continued examination of the application under 35 U.S.C. § 132(b).” 37 C.F.R. § 1.702(b)(1). This regulation also provides that “any time consumed by” proceedings under sections 135(a), 181 and appellate review are similarly “not included.” *Id.* at (b)(2)-(4).

The second regulation, 37 C.F.R. § 1.703(b), specifies the beginning and end dates of the periods for which there are grounds for PTA. Thus, while § 1.702(b)(1) provides that time consumed by an RCE is excluded in determining Part B delay, § 1.703(b) details how that excluded time is determined. Specifically, the time consumed by an RCE is described as “(1) the number of days, if any, in the period beginning on the date which a request for continued examination of the application . . . was filed and *ending on the date the patent was issued.*” 37 C.F.R. § 1.703(b)(1) (emphasis supplied). As reflected in § 1.703(b)(1), the USPTO considers the “time consumed by” RCE examination, whether filed before or after the three-year statutory deadline, to be the time period from the date the RCE is filed until the issuance of the patent. In other words, the USPTO construes section 154(b)(1)(B)(i) to command that if the applicant is successful in obtaining patent approval after an RCE, no matter whether the RCE is filed before or after the three-year statutory deadline, no Part B delay is accrued from the time the RCE is filed until the issuance of the patent. Def.’s Opp’n at 13 (“The USPTO has determined that the time consumed by examination of an RCE includes every day the RCE is pending before the USPTO from the filing date of the RCE until the date of issuance of the patent”); *see also Exelixis, Inc. v. Kappos*, 906 F. Supp. 2d 474, 480 (E.D. Va. 2012) (“*Exelixis I*”) (“[I]n 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”). By contrast to the patent issue end date for an RCE filing, regulation § 1.703(b) provides that the “time consumed by” proceedings under

sections 135(a), 181 and appellate review is measured from the date the proceeding is instituted until the date the proceeding is terminated, secrecy order is removed “or the date of the last decision” in an appeal.” 37 C.F.R. § 1.703(b)(2)-(4).

B. Patent Term Adjustment for the ’788 Patent

The plaintiff filed the application for the ’788 patent on October 26, 2006, as a continuation application of a prior application filed in 2003. Pl.’s Statement of Undisputed Facts in Supp. of its Mot. for Summ. J. Regarding Calculation of Part B Delay (“Pl.’s Facts”) ¶ 1, ECF No. 20-2; Pl.’s Mem. of P. & A. in Supp. of its Renewed Mot. for Summ. J. Regarding Calculation of Part B Delay (“Pl.’s Mem.”) at 8, ECF No. 20-1; Def.’s Statement of Material Facts Not in Genuine Dispute (“Def.’s Facts”) ¶ 1, ECF No. 21-1.⁷ Three years after the initial application, on October 26, 2009, the application was still pending. Over two months later, on December 31, 2009, the examiner issued a final rejection of the application, rejecting all pending claims as being unpatentable. Pl.’s Facts ¶ 14; Def.’s Facts ¶ 3. At this point, the plaintiff had several options, “including: abandon[ing] the application, request[ing] an interview with the [e]xaminer, fil[ing] a request for continued examination, fil[ing] a continuation or continuation-in-part application, or appeal[ing] the final rejection.” Def.’s Opp’n at 5. Any continuation or continuation-in-part application filed by the plaintiff at that point would have been treated as a newly-filed application, resulting in loss of all the PTA that had previously accrued. *Id.* (citing 37 C.F.R. § 1.704(c)(11)). Filing an RCE, however, would permit continued examination of the same application and the concomitant retention of all previously accrued PTA. *See id.*

The plaintiff met with the examiner and, subsequently, on April 14, 2010, filed an RCE that narrowed the scope of its claims. Pl.’s Facts ¶ 11; Def.’s Facts ¶¶ 4–5; *see also* Def.’s

⁷ The ’788 patent is entitled “Compositions and Methods of Delivery of Pharmacological Agents,” and was approved to treat metastatic breast cancer in 2005. Pl.’s Mem. at 3. “Within five years after its initial approval in 2005, Abraxane® became one of the leading drugs for treating metastatic breast cancer.” *Id.* at 4.

Opp'n at 6 (“[T]he Examiner suggested that ‘the broad claims be amended’ to overcome the prior art,” which advice the plaintiff followed when it “narrowed the scope of the claims as the Examiner ha[d] suggested.”) (internal citation and quotations omitted); *id.* at 18 (“Abraxis . . . substantially amended its claims during the pendency of the RCE to obtain a determination of patentability by the USPTO”). Indeed, the plaintiff’s RCE filing indicates that the plaintiff amended four claims (*i.e.*, Claims 2, 13, 24 and 25), added one new claim (*i.e.*, Claim 26) and withdrew twenty-one of the original twenty-five claims. Pl.’s Mot., Ex. 6 (“Pl.’s RCE Filing”), Part 1, at 2–3, ECF No. 20-8. On June 1, 2010, the examiner concluded that the plaintiff was legally entitled to a patent and sent a notice of allowance. Pl.’s Facts ¶ 10; Pl.’s Mot., Ex. 7 (“Notice of Allowance and Fee(s) Due”), ECF No. 20-10. On June 3, 2010, the plaintiff paid the requisite issue fee and filed a petition, pursuant to 37 C.F.R. §1.705(b), seeking a patent term adjustment under Part A and Part B. Pl.’s Mot., Ex. 8 (“Part B – Fee(s) Due”), ECF No. 20-11; Pl.’s Mot., Ex. 9 (“Application for Patent Term Adjustment under 37 C.F.R. 1.705”), ECF No. 20-12. Summarized below are the evolving patent term adjustments given to the ’788 patent leading up the instant litigation and pending cross-motions for summary judgment.

1. *Original Patent Term Adjustment*

On October 26, 2010, the USPTO issued the ’788 patent. Pl.’s Facts ¶ 14. At that time, the USPTO determined that the patent was eligible for a 23-day patent term adjustment under Part A⁸ and a 169-day patent term adjustment under Part B.⁹ Pl.’s Mot., Ex. 13 at 2 (“Patent Term Adjustments”), ECF No. 20-16.

⁸ As noted, under Part A, an applicant is entitled to a patent term adjustment for each day that the PTO fails to “issue a patent within 4 months after the date on which the issue fee was paid.” 35 U.S.C. § 154(b)(1)(A)(iv). The plaintiff paid the issue fee on June 3, 2010, and the USPTO issued the ’788 patent on October 26, 2010, which was four months and 23 days after the issue fee was paid. Pl.’s Mem. at 5. As a result, the USPTO determined that 23 days should be added to the patent term under Part A. Pl.’s Mot., Ex. 13 at 2.

⁹ To calculate Part B delay, the USPTO extended the patent term one day for each day after the end of the three-year statutory deadline, but excluded days after the plaintiff filed an RCE. The statutory deadline was October 26, 2009,

On April 15, 2011, the plaintiff filed the instant suit, alleging that the USPTO improperly calculated the patent term adjustment for the '788 patent under both Parts A and B. Compl. ¶ 20. In particular with respect to Part B, the plaintiff claimed entitlement to a 316-day PTA, contending that the “time consumed by” the RCE under § 154(b)(1)(B)(i) does not extend from the date on which an RCE is filed to the date that the patent is issued, as set forth in 37 C.F.R. § 1.703(b), but rather extends from the date on which an RCE is filed to the date that the USPTO issues a notice of allowance. *Id.* ¶¶ 31, 39. In the alternative, the plaintiff argued that “the time consumed by” the RCE extends from the date on which an RCE is filed to the date that the applicant pays the issue fee. Compl. ¶ 49.

2. Patent Term Adjustment After Remand to USPTO

On October 31, 2011, the parties jointly requested a remand to provide the USPTO with an opportunity to recalculate the PTA. *See* Order dated November 1, 2011, ECF No. 14. After reviewing its PTA determination, the USPTO granted the plaintiff the 135-day adjustment it sought under Part A.¹⁰ Pl.’s Mot., Ex. 15 (“Petition Decision”) at 3, ECF No. 20-18. With respect to Part B delay, however, the USPTO concluded that its prior determination of the patent adjustment period was correct given the periods of delay attributable to the USPTO and to the

and the plaintiff filed an RCE on April 14, 2010. Pl.’s Mem. at 5. As a result, the USPTO determined that 169 days, between October 26, 2009 and April 14, 2010, should be added to the patent term under Part B. Pl.’s Mot., Ex. 13 at 2.

¹⁰ The USPTO initially did not grant PTA under 35 U.S.C. § 154(b)(1)(A)(ii). Under that clause of Part A, an applicant is entitled to PTA if the USPTO fails to “respond to a reply under section 132 . . . within 4 months after the date on which the reply was filed.” The USPTO mailed a non-Final Office Action to the plaintiff on May 12, 2008. That action was subsequently withdrawn and replaced with a new non-Final Office Action mailed on October 10, 2008. The plaintiff successfully argued on remand that it was entitled to PTA for 112 days—from June 20, 2008 (four months after its reply under section 132) to October 10, 2008. On remand, the USPTO reversed its initial conclusion that the Office “responded to a reply” within the meaning of § 154(b)(1)(A)(ii) when it sent the first non-Final Office Action. Thus, the USPTO awarded 112 days of Part A delay as PTA for delays attributable to the USPTO before the three-year statutory deadline. Def.’s Opp’n at 30.

applicant. *Id.* at 4. The USPTO therefore granted the plaintiff a total of 199 days of adjustment.¹¹ Pl.’s Mot., Ex. 15 at 5; Def.’s Opp’n at 7.

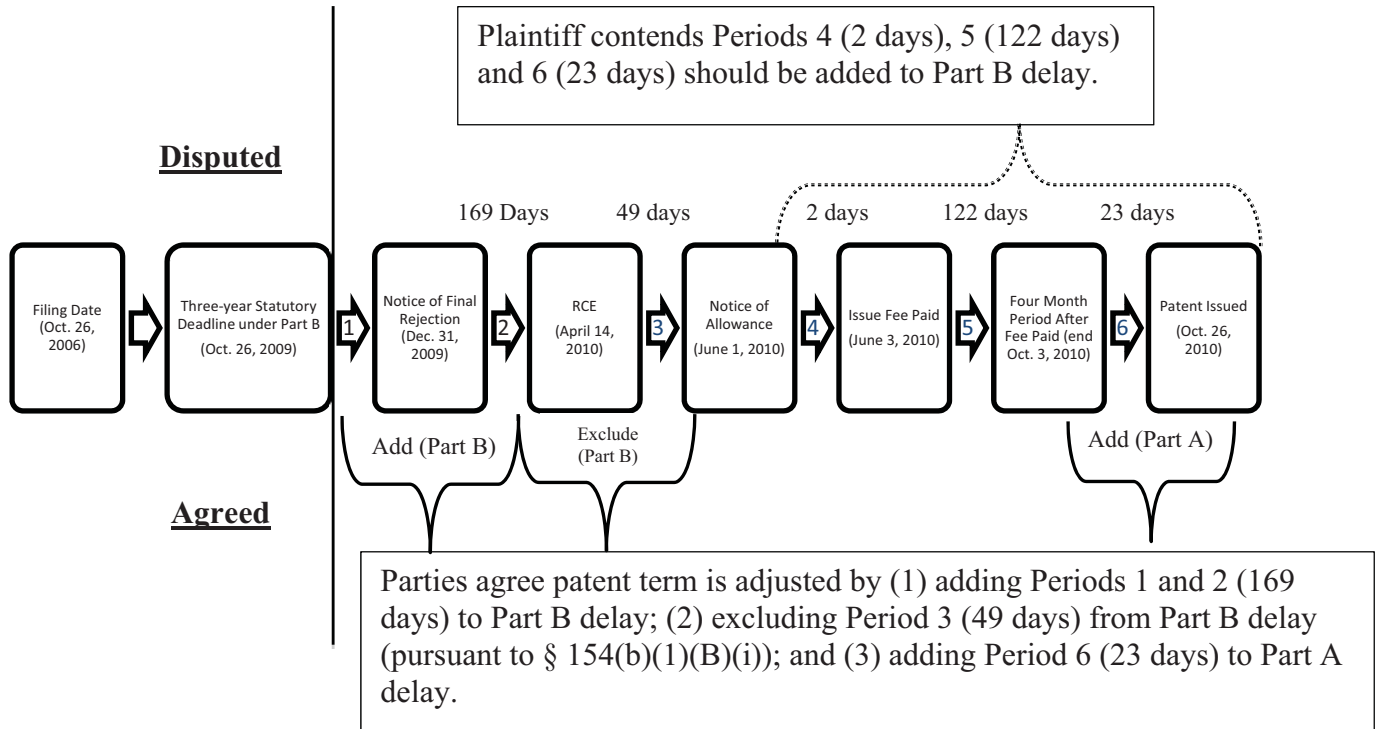
3. *Continued Dispute Over Part B Patent Term Adjustment*

Although the parties agree that the USPTO properly determined 135 days of Part A delay and 105 days of applicant delay, *see* Pl.’s Mem. at 18; Def.’s Opp’n at 30, they disagree about the amount of Part B delay to which the plaintiff is entitled. The parties agree on the counting of three time periods occurring after the 3-year statutory deadline: First, the parties agree that the 169 days beginning on the day after the three-year statutory deadline passed, on October 26, 2009, until April 13, 2010, which is the day before the plaintiff filed the RCE, should be added to the effective term of the ’788 patent. Pl.’s Mem. at 18, Def.’s Opp’n at 30. Second, the parties agree that the 49 days beginning on the date the RCE was filed, on April 14, 2010, until the date the USPTO sent the notice of allowance, on June 1, 2010, should be excluded from the Part B calculation. Compl. ¶ 49; Pl.’s Mem. at 18; Def.’s Opp’n at 30. Finally, the parties agree that the 23-days, which elapsed following the four-month period after the payment of the issue fee until the issuance of the patent, should be added to the PTA as Part A delay. The parties disagree about whether Part B delay should be added for the period from the notice of allowance, or alternatively, payment of the issue fee, until issuance of the patent, part of which period (*i.e.*, 23 days) has already been added to the PTA as Part A delay.

Figure 1, below, illustrates the ’788 patent’s path to issuance and the parties’ agreements and contested views about the calculation of the Part B delay for PTA.

¹¹ To determine the number of days of a patent term adjustment award, USPTO (1) adds the number of days of USPTO delay that accrued under Parts A, B, and C of Section 154(b)(1); (2) reduces that number by the number of overlapping days among Parts A, B, and C, to avoid double-counting, *see Wyeth*, 591 F.3d at 1370–71; and (3) reduces that number further by the number of days of applicant Part C delay that accrued under Section 154(b)(2)(C). In this case, the USPTO determined the total amount of PTA as follows: 135 [A delay] + 169 [B delay] + 0 [C delay] – 0 [overlap] – 105 [applicant delay] = 199 days. Def.’s Opp’n at 4.

Figure 1: '788 Patent Prosecution Timeline And Parties' Dispute Over Part B Patent Term Adjustment



To summarize with reference to Figure 1, the USPTO determined that Part B delay was 169 days [*i.e.* Periods 1 and 2], starting from the date that the application had been pending for more than three years (October 27, 2009) up to the date the plaintiff filed the RCE (April 14, 2010). Def.'s Opp'n at 30. The USPTO interprets § 154(b)(1)(B)(i) to exclude all time after the filing of an RCE until the issuance of the patent, as reflected in its regulation at 35 C.F.R. §1.703(b)(1). *Id.* Thus, under the USPTO's interpretation, the plaintiff would be entitled to a total of 199 days of delay computed as follows: 135 days of Part A delay (including 23 days that occurred after the 3-year deadline), plus 169 days of Part B delay [*i.e.* Periods 1 and 2], minus 105 days for applicant delay, for a total of 199 days of PTA. *Id.*

The plaintiff concurs with USPTO that Part B delay starts from October 27, 2009, the day after lapse of the 3-year statutory deadline, but disagrees that the end date is the filing of the RCE. Compl. ¶ 39(a). Instead, the plaintiff contends that the end date of the Part B delay period

is the issuance of the patent on October 26, 2010, for a total of 365 days. *Id.* The plaintiff initially argued, in its complaint and briefing in support of its pending summary judgment motion, that the only time period appropriate to deduct, under section 154(b)(1)(B)(i), from this total of 365 days is the 49 days between the filing of the RCE (April 14, 2010) until the issuance of the Notice of Allowance (June 1, 2010) [*i.e.* Period 3] (or, alternatively, 51 days to account for the 2 days until payment of the issue fee (June 3, 2010) [*i.e.* Period 4]), resulting in a Part B-delay of at least 316 days (or, alternatively, 314 days). Compl. ¶¶ 39(b), 49, 51(b); Pl.’s Mem. at 17; *see also* Figure 1.

After briefing was complete, however, the plaintiff asserted a new argument that because the RCE was filed more than three years from the application filing date, it is entitled to Part B adjustment for “every day from the end of the 3-year period after the filing of the patent application until issuance of its patent.” Pl.’s Notice of Recent Decisions (“Pl.’s Notice”), at 2–3, ECF No. 29. In other words, the plaintiff’s revised position is that Part B delay encompasses the entire 365-day period, with no deduction for any period “consumed by” the RCE filing. According to the plaintiff, “[a]t the very least, [plaintiff] is entitled to the subset of that period it has requested, not only for the reasons set forth in its pending summary judgment motion, but also for the reasons set forth” in two recent decisions, which will be discussed in more detail below. *Id.* at 3 (citing *Exelixis I* and *Novartis AG v. Kappos*, 904 F. Supp. 2d 58 (D.D.C. 2012) (“*Novartis*”).

The parties agree that, upon determination of the correct number of days attributable to Part B delay, the statute requires, under the limitations set out in paragraph (2), that overlapping periods of delay must be reduced to reflect an accurate number of days delayed. 35 U.S.C. § 154(B)(2)(A). The USPTO’s position is straightforward: after the 3-year deadline, Part B delay

accrued until, and ended upon, the filing the RCE and, since the 23 days of Part A-delay occurred thereafter, there is no overlap of Part A and B-delay periods. By contrast, predicated on its view that Part B delay continued until the patent issue date, the plaintiff argues that the 23-days following the four month period after the issue fee payment [*i.e.* Period 6] should be subtracted from the 314 days as overlapping Part A and B delay, resulting in 291 days of Part B delay. Pl.’s Mem. at 18; Figure 1. Thus, the plaintiff contends that it is entitled to at least a total PTA of 321 days derived from the following determinations: 135 days of Part A, plus 291 of non-overlapping days of Part B, minus 105 days of applicant delay.¹² In short, based on the briefing for the summary judgment motion, the parties’ dispute boils down to whether the four-month plus 2-day period after the notice of allowance was issued [*i.e.*, Periods 5 & 6] count as Part B delay.¹³

As the analysis that follows makes clear, the parties’ dispute about the correct interpretation of both section 154(b)(1)(B) and its clause (i) implicates the complex interplay among three provisions in the AIPA amendments: first, and most obviously, subparagraph (B), which guides the determination of Part B delay and excludes from a patent term extension, under clause (i), the specific time period “consumed by continued examination of the application requested by the applicant . . .;” second, section 154(b)(1)(A)(iv), which requires the USPTO to “issue a patent within four months after the date on which the issue fee was paid;” and, finally, the overlap provision in section 154(b)(2)(A), which requires that “the period of adjustment

¹² The plaintiff’s alternative positions are that the total PTA to which it is entitled is (1) 323 days, if the end date of the Part B delay is the issuance of the notice of allowance rather than the issue fee payment date, Pl.’s Mem. at 18; or (2) 372 days, which is derived from 135 days Part A, plus 365 days of Part B, minus 23 days overlap with Part A, minus 105 days applicant delay, *see* Pl.’s Notice, *generally*.

¹³ Period 5 is the four month period beginning the day after the date the issue fee was paid, June 3, 2010, and ending on October 3, 2010. Both June and September have 30 days and July and August have 31 days, resulting in a total of 122 days for Period 5.

granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.”

II. LEGAL STANDARDS

A. Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56, summary judgment may be granted when the Court finds, based upon the pleadings, depositions, and affidavits and other factual materials in the record, “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a), (c); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Wyeth Holdings Corp. v. Sebelius*, 603 F.3d 1291, 1296 (Fed. Cir. 2010); *Immunocept, L.L.C. v. Fulbright & Jaworski, L.L.P.*, 504 F.3d 1281, 1286 (Fed. Cir. 2007).¹⁴ To determine which facts are material, the Court looks to the substantive law on which each claim rests. *Anderson*, 477 U.S. at 248. The mere existence of a factual dispute does not bar summary judgment; instead, the dispute must be “genuine,” insofar as its resolution could establish an element of a claim or defense and, thereby, affect the outcome of the action. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson*, 477 U.S. at 248. Summary judgment is properly granted against a party who “fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp.*, 477 U.S. at 322.

In this case, the pending cross motions for summary judgment seek review of the plaintiff’s legal challenge to USPTO regulations and their application to the ’788 patent.

¹⁴ Appeals from decisions involving patent matters, even if brought under the APA, are made to the Federal Circuit and that appellate court therefore provides controlling precedent for this case. 28 U.S.C. §§1338(a), 1295(a)(1); *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1573 (Fed. Cir. 1984), *overruled on other grounds*, *Richardson-Merrell, Inc. v. Koller*, 472 U.S. 424 (1985) (“[A] district court exercising jurisdiction pursuant to 28 U.S.C. § 1338 is bound by the substantive patent law of this [Federal] circuit.”). *See also Gunn v. Minton*, 133 S. Ct. 1059, 1067 (2013) (“Congress ensured such uniformity [of patent law] by vesting exclusive jurisdiction over actual patent cases in the federal district courts and exclusive appellate jurisdiction in the Federal Circuit.”).

“[W]hen an agency action is challenged[] . . . [t]he entire case on review is a question of law, and only a question of law.” *Marshall Cnty. Healthcare Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). This Court need not and ought not engage in lengthy fact finding, since “[g]enerally speaking, district courts reviewing agency action under the APA’s arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions.” *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085 (D.C. Cir. 1996); *see also Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (“Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.”) (quotation marks and citation omitted); *McDonough v. Mabus*, 907 F. Supp. 2d 33, 42 (D.D.C. 2012); *Wilson v. McHugh*, 842 F. Supp. 2d 310, 315 (D.D.C. 2012); *Caez v. United States*, 815 F. Supp. 2d 184, 188 (D.D.C. 2011).

The parties agree on the material facts related to the calculation of the patent term adjustment for the ’788 patent. Each party maintains that it is entitled to judgment on the question of whether the USPTO’s method of calculating the PTA for the ’788 patent, under 35 U.S.C. § 154(b)(1)(B), is contrary to law. The Court concurs that no material facts are in dispute and that this case presents a purely legal issue, warranting the entry of summary judgment for the party entitled to prevail as a matter of law.

B. Administrative Procedure Act

A patent applicant “dissatisfied” with the USPTO’s patent term adjustment decision may seek judicial review under the Administrative Procedure Act (“APA”) to “change the period of the adjustment of the patent term.” 35 U.S.C. § 154(b)(4)(A) (“Chapter 7 of title 5 shall apply to

such action”).¹⁵ Under the APA, a district court shall set aside the agency’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). In explaining the factors that would warrant rejection of an agency rule, the Supreme Court has explained that, “[n]ormally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The scope of review of an agency rule is “narrow” to guard against the court substituting “its judgment for that of the agency.” *Burandt v. Dudas*, 528 F.3d 1329, 1332 (Fed. Cir. 2008) (quoting *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43)).

C. Chevron Framework

The familiar two-step process set out in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984), applies to judicial review of a challenge to an agency’s construction of a statute administered by the agency. The court must begin at *Chevron* Step One by “ask[ing] whether Congress has directly addressed the precise question at issue.” *Mayo Found. for Med. Educ. & Research v. United States*, 131 S.Ct. 704, 711 (2011) (internal citations omitted). “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013) (quoting *Chevron*, at 842–43). A statute that is unambiguous “means that there is ‘no gap for the agency to fill’ and thus ‘no room for agency

¹⁵ With passage of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, § 9, 125 Stat 284 (2011) (codified as amended at 35 U.S.C. § 154(b)(4)(A)), this statutory provision was changed to vest exclusive jurisdiction in the United States District Court for the Eastern District of Virginia for challenges to the USPTO’s PTA decisions. At the time of the filing of this lawsuit, however, such suits could be filed in the United States District Court for the District of Columbia, and consequently, this Court has jurisdiction.

discretion.” *United States v. Home Concrete & Supply, LLC*, 132 S. Ct. 1836, 1843-1844 (2012) (quoting *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005)).

To discern whether Congress has addressed the precise question, the court applies “the traditional tools of statutory construction.” *Id.* These tools include evaluation of the plain statutory text at issue, the purpose and structure of the statute as a whole, while giving effect, if possible, to every clause and word of a statute, and – where appropriate – the drafting history. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001); *Bell Atl. Tel. Co. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997); *Coal Employment Project v. Dole*, 889 F.2d 1127, 1131 (D.C. Cir. 1989).

If the statute is silent or ambiguous with respect to the specific issue under consideration, however, the analysis shifts to *Chevron* Step Two, where “the question for the court is whether the agency’s answer is based on a permissible construction of the statute.” *City of Arlington*, 133 S. Ct. at 1868. The job of the courts is not to engage in “their own interstitial lawmaking” and “mak[e] public policy by prescribing the meaning of ambiguous statutory commands.” *Id.* at 1873. Rather, the “archetypal *Chevron* questions, about how best to construe an ambiguous term in light of competing policy interests” belongs to the “agencies that administer the statutes.” *Id.* When Congress has delegated to the agency authority to make rules carrying the force of law, and the challenged agency interpretation was promulgated in the exercise of that authority, then the agency’s rule is entitled to deference “as long as it is a permissible construction of the statute, even if it differs from how the court would have interpreted the statute in the absence of an agency regulation.” *Sebelius v. Auburn Reg’l Med. Ctr.*, 133 S. Ct. 817, 826–27 (2013); *see also Nat’l Cable & Telecomms. Ass’n*, 545 U.S. at 980 (2005) (“If a statute is ambiguous, and if the implementing agency’s construction is reasonable, *Chevron* requires a federal court to accept the agency’s construction of the statute, even if the agency’s reading differs from what the court

believes is the best statutory interpretation.”)

Even when Congress has not provided the agency an express delegation of authority or responsibility “to implement a particular provision or fill a particular gap, [] it can still be apparent from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law, even one about which Congress did not actually have an intent as to a particular result.” *Home Concrete & Supply, LLC*, 132 S. Ct. at 1843–44 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001)). Thus, agency rules that do not qualify for the high level of deference required under *Chevron*, are not placed “outside the pale of any deference whatever” and “may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency, and given the value of uniformity in its administrative and judicial understandings of what a national law requires.” *Mead Corp.*, 533 U.S. at 234. Courts may defer to such agency rules “only to the extent that those [agency] interpretations have the ‘power to persuade.’” *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); see also *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). The “power to persuade” depends on “the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.” *Mead Corp.*, 533 U.S. at 227–28 (quoting *Skidmore*, 323 U.S. at 140).

D. *Skidmore* Deference Would Apply To the Challenged USPTO Regulations

If section 154(b)(1)(B) and its clause (i) are found to be ambiguous, the USPTO takes the position that its interpretation would be entitled to *Chevron* deference. Def.’s Opp’n at 19 n.10, ECF No. 21. *Chevron* deference to the agency’s interpretation “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.” *Gonzales v. Oregon*, 546 U.S. 243, 255–56 (2006) (quoting *Mead Corp.*, 533 U.S. at 226–27). The USPTO suggests that the Court need not reach the issue of whether *Chevron* deference is appropriate because the USPTO’s interpretation would satisfy the criteria for *Skidmore* deference. Def.’s Opp’n at 20 (citing *Brown v. United States*, 327 F.3d 1198, 1205 (D.C. Cir. 2003) (“Because we hold that [the agency’s] methodology satisfied the requirements for *Skidmore* deference, . . . we need not reach the question of *Chevron* deference.”)). Even if this suggestion were correct, however, this Court is bound by the precedent set in the Federal Circuit, which “has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency.” *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) *aff’d sub nom. Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) (citing *Merck*, 80 F.3d at 1549–50); *see also Exelixis II*, 919 F. Supp. 2d at 695 (“The Federal Circuit has decided that the PTO’s regulations are not entitled to *Chevron* deference, but may be entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134, (1944)”) (citing *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir.1996)); *Univ. of Massachusetts v. Kappos*, 903 F. Supp. 2d 77, 84 (D.D.C. 2012) (holding that the USPTO lacks the authority to issue substantive rules and construing 35 U.S.C. § 154(b)(3)(A) to limit the USPTO’s authority to promulgate “only procedural regulations regarding the conduct of proceedings before the agency”).

Indeed, the challenged USPTO regulations at issue in this case were issued pursuant to statutory authority to address procedural issues, not to determine substantive patent term rights. *See* 35 U.S.C. § 154(b)(3)(A) (USPTO “shall prescribe regulations establishing *procedures* for

the application for and determination of patent term adjustments under this section.”) (emphasis added); *see also* 35 U.S.C. § 2(b)(2)(A) (tasking USPTO with developing regulations governing the proceedings before the agency). Thus, if the statutory provision at issue is ambiguous, only *Skidmore* deference is appropriate, and the Court would review the challenged USPTO regulations under that standard.

III. DISCUSSION

The plaintiff argues that the USPTO’s regulations improperly deprived it of a patent term adjustment under Part B, which extends the patent term for delays that occur three years after the application is filed. According to the plaintiff, the patent term for the ‘788 patent should be adjusted by at least an additional 122 days between the payment of the issue fee and the issuance of the patent, *see* Figure 1 (Period 5), or, in the alternative, for the 124 days between the notice of allowance and the issuance of the patent, *see* Figure 1 (Periods 4 and 5). As noted, the parties focus their disagreement on the proper construction of section 154(b)(1)(B) and its clause (i), which excludes from Part B delay “any time consumed by continued examination of the application requested by the applicant under section 132(b).” While the USPTO, as reflected in 37 C.F.R. § 1.703(b), construes the term “examination” as continuing up until issuance of a patent, the plaintiff contends that this interpretation “cannot be squared with the text, purpose, or structure of the Patent Term Guarantee Act.” Pl.’s Reply on Renewed Mot. Summ. J. and Opp’n to Def.’s Cross-Mot. Summ. J. (“Pl.’s Reply”) at 8, ECF No. 24. Rather, the plaintiff argues that the “examination” of a patent in an RCE proceeding “concludes when a notice of allowance issues (or, at the latest, when the issue fee is paid)” and that “[a]ny subsequent delay is *not* time ‘consumed by continued examination’ and should not count against the applicant for purposes of calculating Part B delay.” *Id.* Notwithstanding the plaintiff’s position in the summary judgment

briefing regarding the amount of time required to be excluded from Part B delay under by clause (i), as noted, the plaintiff has more recently argued that after the 3-year statutory deadline, Part B delay accrues regardless of any RCE filing.

In evaluating the challenged USPTO regulations, the Court first examines section 154(b)(1)(B) to determine how plainly Congress articulated its intent in both subparagraph (B) and clause (i). For the reasons discussed below, the Court finds that this provision, generally, and clause (i), in particular, are ambiguous. Then, informed by the statutory analysis, the Court evaluates the reasonableness and persuasiveness of the challenged regulations.

A. 35 U.S.C. § 154(b)(1)(B) is Ambiguous

This Court has the benefit of the thoughtful opinions issued by three district court judges in evaluating any ambiguity in section 154(b)(1)(B) on the question of whether the filing of an RCE more than three years after the application filing stops the running of Part B delay. Two of these opinions concluded that subparagraph (B) was clear and unambiguous, and one opinion concluded the opposite. *Compare Exelixis I*, 906 F. Supp. 2d at 480 (“Here, the plain language meaning of subparagraph (B) is clear, unambiguous, and in accord with both the statute's structure and purpose.”); *and Novartis*, 904 F. Supp. 2d at 72 (“[T]he PTO’s interpretation is contrary to the plain and unambiguous language of § 154(b)(1)(B), and . . . contravenes the structure and purpose of the statute”); *with Exelixis, Inc. v. Kappos*, 919 F. Supp. 2d 689, 697 (E.D. Va. 2013) (“*Exelixis II*”) (“This Court parts ways with the reasoning in *Exelixis I* and declines to find that the statute's silence as to RCEs filed after the three-year period expresses “plain and unambiguous” congressional intent on the issue”). With respect to clause (i) in subparagraph (B), only the court in *Exelixis II* considered the proper interpretation of this

provision, implicitly finding that clause (i) was ambiguous by according *Skidmore* deference to the USPTO regulation interpreting it. 919 F. Supp. 2d at 702.¹⁶

The divergent conclusions in these opinions regarding whether section 154(b)(1)(B) is ambiguous suggests that Congress may not have spoken directly or plainly on the issue. “A statute is considered ambiguous if it can be read more than one way.” *Am. Fed’n of Labor & Cong. of Indus. Org. v. Fed. Election Comm’n*, 333 F.3d 168, 173 (D.C. Cir. 2003); *see also AFL-CIO*, 333 F.3d at 174 (“[T]he fact that [a] provision can support two plausible interpretations renders it ambiguous for purposes of *Chevron* analysis”); *United States v. Nofziger*, 878 F.2d 442, 446–47 (D.C. Cir. 1989). At the same time, a difference in judicial opinions about whether a statute’s meaning is plain is not dispositive of the issue. *See* Harry T. Edwards & Linda A. Elliott, *FEDERAL STANDARDS OF REVIEW*, at 148 (noting that, in some cases, “the search for a statute’s plain meaning is not so easy” and observing “the Supreme Court has issued many decisions resting on *Chevron* Step One that have been opposed by dissenting opinions”). The reasoning in the trilogy of opinions considering whether section 154(b)(1)(B) is ambiguous helps inform this determination.

In *Exelixis I*, the court examined the USPTO’s determination of Part B delay when, as in the instant case, an RCE is filed after the 3-year statutory deadline, posing the question as follows: “Whether 35 U.S.C. § 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.” 906 F. Supp. 2d at 475. The *Exelixis I* court found section 154(b)’s language “plain and unambiguous,” *id.* at 481, in supporting three conclusions: first,

¹⁶ Although the *Novartis* plaintiff also challenged the USPTO’s construction of the scope of “examination” under section 154(b)(1)(B)(i), the court did not reach that issue, explaining that “[b]ecause the Court concludes that the PTO erred in excluding from B Delay time consumed by an RCE filed after the three-year window has closed, the Court need not address *Novartis*’ alternative argument regarding the proper interpretation of “time consumed by” an RCE.” *Novartis*, 904 F. Supp. 2d at 70.

that the “not including” clause contained in section 154(b) “modifies and pertains to the three year period and does not apply to, or refer to, the day for day PTA remedy.” *Id.* at 481. In other words, the circumstances that are “not includ[ed]” in Part B delay, serve only to toll the “trigger,” or beginning date, for the 3-year deadline.

Second, the *Exelixis I* court concluded that if the “trigger” has already occurred (*i.e.*, the 3-year statutory deadline has already passed), the circumstances enumerated in the “not including” clause are simply irrelevant; only when the excluded circumstances, such as the filing of an RCE, occur before the 3-year deadline does this clause have any impact on the patent term adjustment for Part B delay. As the *Exelixis I* court explained, while “the clock is tolled for the processing of an RCE filed before the three year clock runs out, [] the provision does not refer to or mention RCE’s filed after the three year clock has run.” *Id.* at 481. From this legislative silence, the court found clarity, stating that “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.” *Id.* at 481.

Finally, the *Exelixis I* court concluded that section 154(b) “does not treat an RCE filing as applicant delay.” *Id.* (“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)”). This conclusion was significant in view of the provision’s “structure and purpose,” which “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.” *Id.* In reaching this conclusion, the court looked to the limitation provision captioned “Reduction of period of adjustment” in section 154(b)(2)(C), which the court noted does not expressly refer to RCE's but instead to periods of time when “the applicant failed to engage in reasonable efforts to conclude

prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). Since the filing of an RCE is not among the listed categories of “applicant delay” set out in section 154(b)(2)(C), the court determined that the USPTO erred in construing Part B in a manner that would “punish the applicant for filing the RCE.” *Id.* at 482. Further elaborating on this point, the *Exelixis I* court explained that “[p]ut differently, § 154(b) does not treat an RCE as an applicant’s failure ‘to engage in reasonable efforts to conclude prosecution of the application,’” and instead “RCE’s are something for which the three year clock should be tolled, but not something that reduces the PTA.” *Id.* at 483.

The *Exelixis I* court rejected the arguments advanced by the USPTO in favor of the agency’s interpretation. Specifically, the USPTO argued that the interpretation of section 154(b)(1)(B) adopted by the court renders the subsequent section— section 154(b)(1)(C)—superfluous. As noted, Part C provides for a PTA for delay caused by an interference proceeding, a secrecy order, or appellate review by the Board or a federal court. 35 U.S.C. § 154(b)(1)(C). The USPTO explained that, under the plaintiff’s interpretation of Part B, any interference proceeding, secrecy order, or appellate review occurring after the three-year statutory deadline would not be excluded from the patent term adjustment calculation. The PTO argued that this interpretation eliminated the need for Part C in many situations, thus rendering Part C superfluous. *Exelixis I*, 906 F. Supp. 2d at 482 n.16. The court disagreed, without extensive discussion. *Id.* (“Although the plain language of subparagraph (B) may result in the PTO awarding C delay less often, this simply does not, as the USPTO argues, render subparagraph (C) superfluous.”).¹⁷ In addition, the court was not persuaded by the USPTO’s argument that the

¹⁷ The *Exelixis I* court suggested that the cure for “the problem” of “an RCE filed after the three year clock has expired,” is for “the PTO to 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.” 906 F. Supp. 2d at 483.

plaintiff's proposed construction could lead to disparate treatment of some similarly-situated applicants, depending on which side of the three-year statutory line the applicant files an RCE, noting that "this court does not take upon itself the role of correcting all statutory inequities." *Id.* at 484 (quoting *Wyeth v. Kappos*, 591 F.3d at 1370).

A subsequent decision by a Judge on this Court described the rationale in *Exelixis I* as "well-reasoned" and "persuasive," and relied upon the case to reach the same conclusion that section 154(b)(1)(B) is "plain and unambiguous." *Novartis*, 904 F. Supp. 2d at 72. Like the *Exelixis I* court, the *Novartis* court rejected PTO's interpretation that the "not including" clause in subparagraph (B) is part of the remedy provision rather than the "trigger" provision, and concluded that Part B delay accrues and requires an award of PTA following the three-year statutory deadline, without regard to whether an RCE is filed during the post-deadline period. *Id.* at 71.

The *Novartis* court supplemented the reasons given in *Exelixis I* to bolster the rejection of USPTO's interpretation of subparagraph (B) by pointing to what it characterized as a conflict between USPTO's regulation at 37 C.F.R. § 1.703(b) and the immediately preceding regulation at §1.702(b). The court observed that section 1.703(b) provides, consistent with the USPTO's position, that "the 'remedy' consists of day-for-day PTA after [the three-year deadline], but does not include any time consumed by an RCE." According to the *Novartis* court, this provision is inconsistent with section 1.702(b),¹⁸ which "unambiguously provides that the three-year window will be tolled during the filing of an RCE, and says nothing about the remedy to be applied if and when that three-year mark is triggered." *Id.* at 72–73. In the court's view, "if both regulations

¹⁸ 37 C.F.R. § 1.702(b) provides: "[T]he term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) . . . , but not including: (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b)."

were to be applied as written, time consumed by an RCE would apply to both the trigger and the remedy provisions of the statute, and would effectively result in the double-counting of the ‘not including’ clause of § 154(b)(1)(B).” *Id.* at 73.

By contrast to the conclusions reached in *Exelixis I* and *Novartis*, the third court to consider the USPTO’s interpretation of Part B “declined to find that the statute’s silence as to RCEs filed after the three-year period expresses ‘plain and unambiguous’ congressional intent on the issue.” *Exelixis II*, 919 F. Supp. 2d at 697. The *Exelixis II* court observed that “treating RCEs filed before and after the three-year period in directly opposite ways, . . . will produce ‘absurd results,’” *id.* (quoting *Exelixis I* at 484), including the “paradox[ical]” situation where an “earlier-filed RCEs would indefinitely postpone B-delay PTA as if there were applicant-caused delay, but later-filed RCEs would suddenly be treated like PTO-caused delay and arbitrarily result in accruing PTA.” *Id.* at 699. As the court noted, “[t]his consequence would violate the canon that ‘a statutory construction that causes absurd results is to be avoided if at all possible.’” *Id.* (quoting *Timex V.I., Inc. v. United States*, 157 F.3d 879, 886 (Fed. Cir. 1998) (citing *Haggard Co. v. Helvering*, 308 U.S. 389, 394 (1940))).

Instead, the *Exelixis II* court concluded that “a reasonable interpretation of the statute and its legislative history support the conclusion that there is no reason to treat RCEs differently based upon when they were filed” *Id.* The court pointed out the obvious: section 154(b)(1)(B) “does not guarantee that a patent application will always be resolved within three years, as it specifically provides that certain events, such as the filing of an RCE by an applicant, will toll that three-year guarantee.” *Id.* at 697. The court explained that 37 C.F.R. §§ 1.702(b) and 1.703(b) are consistent with the overarching purpose of section 154(b) that an applicant should not be penalized by a delay attributable to the USPTO, but should also not benefit when

the delay was “requested by” or otherwise attributable to the applicant. *Exelixis II*, 919 F. Supp. 2d at 698; *see also Exelixis I*, 906 F. Supp. 2d at 481; *Novartis*, 904 F. Supp. 2d at 71. The *Exelixis II* court disputed the animating view in *Exelixis I*, adopted in *Novartis*, that an RCE is not counted as applicant delay, explaining that, to the contrary, “[t]he filing of an RCE is always done by the applicant to newly amend or enhance an application, and is therefore applicant-initiated delay whether filed before or after the three-year period has run.” *Exelixis II*, 919 F. Supp. 2d at 699.

Moreover, the *Exelixis II* court pointed out, based upon ample legislative history, that measuring the term of a patent from the date of filing instead of the date of issuance “was at least partly motivated by fear of so-called ‘submarine’ patents filed by applicants who had discovered that they could file ‘continuation prosecution applications’ (CPAs) to indefinitely delay the PTO’s completion of its examination, thereby keeping their applications ‘pending and secret until an industry with substantial investment in the technology can be targeted in an infringement suit.’” *Id* at 699 and n.13 (citing, *inter alia*, H.R. Rep. No. 106-464, at 125) (“Only those who purposely manipulate the system to delay the issuance of their patents will be penalized . . . , a result that the Conferees believe entirely appropriate.”); 140 Cong. Rec. 29,964 (1994) (statement of Sen. Hatch) (“[B]y focusing on the date of application rather than the date of issuance, the disruptive tactics of some who have sought to manipulate the patent system through the use of so-called “submarine” patents will come to an end.”); 140 Cong. Rec. 29,608 (statement of Rep. Ballenger) (“‘Submarine patents’ allow a patent applicant to delay issuing of a patent for years—shutting down or demanding royalties from businesses that independently develop that technology in question.”)). Since the RCE process permits applicants to retain their accrued PTA with unlimited opportunities to file RCEs after a final notice of rejection has been

issued, the potential exists “for the very abuses that spurred reform of the laws on patent terms in the first place.” *Id.* In short, the *Exelixis II* court determined that section 154(b) was ambiguous and that “the PTO’s regulation denying PTA from the time an RCE is filed comports with ‘a reasonable conclusion as to the proper construction of the statute’ under Skidmore.” *Id.* at 699.

Although this trilogy of opinions reaches different conclusions about whether section 154(b)(1)(B) is ambiguous, these cases uniformly construe this provision as silent about the effect of an RCE filing in the post-three year statutory deadline period. *See Exelixis I*, 906 F. Supp. 2d at 481; *Novartis*, 904 F. Supp. 2d at 72; *Exelixis II*, 919 F. Supp. 2d at 697. This Court agrees with the *Exelixis II* court that this silence makes section 154(b)(1)(B) susceptible to more than one plausible interpretation and, consequently, ambiguous. Close examination of the interaction of other subsections in this same statutory section further confirms this conclusion.

The ambiguity inherent in section 154(b)(1)(B) is highlighted upon review of the impact on Part A delay, Part C delay and the limitations in section 154(b)(2) if subparagraph B were construed to require tolling of the three-year deadline only when an RCE is filed within that three-year period, but to award Part B delay after the three year clock has run “regardless of subsequent events.” *Exelixis I*, 906 F. Supp. 2d at 481. This construction would render superfluous the operation of other adjustments provided in this section and, thereby, violate “one of the most basic interpretive canons, that ‘[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.’” *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (quoting 2A N. Singer, STATUTES AND STATUTORY CONSTRUCTION § 46.06, pp. 181–86 (rev. 6th ed. 2000)); *see also D. Ginsberg & Sons v. Popkin*, 285 U.S. 204, 208 (1932) (It is a “cardinal rule that, if possible, effect shall be given to every clause and part of a statute”); *Safari*

Club Int'l v. Jewell (In re Polar Bear Endangered Species Act Listing & Section 4(d) Rule Litig. - MDL No. 1993), 720 F.3d 354, 362 (D.C. Cir. 2013) (finding ambiguity since “provision cannot permit what [other] section [] expressly prohibits without rendering the latter superfluous”); *Davis County Solid Waste Management v. EPA*, 101 F.3d 1395, 1404 (D.C. Cir. 1996) (“[I]t is of course a well-established maxim of statutory construction that courts should avoid interpretations that render a statutory provision superfluous.”).

For example, if filing an RCE after the three-year statutory deadline has no effect on the accrual of Part B delay, the Part A adjustment under section 154(b)(1)(A)(iv) would not be given full effect. Specifically, section 154(b)(1)(A)(iv) only authorizes the accrual of Part A delay if the USPTO does not act “within 4 months after the issue fee was paid,” providing the agency a short four month “grace” period before the Part A delay begins. This “grace” period clause in section 154(b)(1)(A)(iv) is made superfluous and simply eliminated for Part A delay occurring after the three-year statutory deadline, if section 154(b)(1)(B) is interpreted to apply Part B delay for any and all time after the three-year statutory deadline. In other words, the *Exelixis I* and *Novartis* courts’ interpretation of the statute reads out a significant part of clause (iv) of section 154(b)(1)(A). While each delay period must be calculated according to its own beginning and end date, as the Federal Circuit instructed in *Wyeth*, 591 F.3d at 1370, the Court must evaluate the intended interplay of these calculations to assess consistency with the overall statutory purpose. Construing the statute to eliminate the Part A “grace” period when it occurs after the three-year deadline no matter the circumstance, would promote the perverse incentive for applicants to push review of their applications beyond three years in order to recoup four months of PTA under Part A that otherwise would not be attributed to agency delay.

This is the position urged by the plaintiff in this case. Notably, unlike in this case, neither of the patent applications reviewed by the courts in *Exelixis I* or *Novartis* received Part A delay after the three-year deadline based upon the PTO's delayed issuance of the patent beyond four months following the issue fee payment. *See Exelixis I*, 906 F. Supp. 2d at 476 ("The record [] shows that on April 28, 2011, Exelixis paid the issue fee . . . [and the] patent issued thereafter on August 2, 2011."); *Novartis*, 904 F. Supp. 2d at 70 (making no mention of Part A delay attributable to USPTO in issuance of "three of the four timely-challenged patents" that purportedly received improper Part B PTA). Those courts were, consequently, not squarely presented, as here, with nullification of a significant part of section 154(b)(1)(A)(iv) providing a "grace" period before Part A delay is triggered.

Similarly, reading the "not including" clause in section 154(b)(1)(B) as merely tolling the three-year deadline and without any operative effect after that deadline has passed, ignores how this provision interacts with Part C delay. For example, if the three "not including" clauses of subparagraph (B) are inoperative in the post-deadline period, then the three types of proceedings described in clause (ii) as excluded from Part B delay, would not have to be expressly added back to PTA as Part C delay. Instead, those three types of excluded proceedings would already be subsumed in the Part B delay when they occur three years after the application filing date.¹⁹

¹⁹ As noted, the time covered by three types of proceedings excluded from Part B delay under section 154(b)(1)(B)(ii) is restored under Part C. At best, this is consistent with the policy reflected in the limitation set out in section 154(b)(2)(A). This limitation provision directs that PTA "shall not exceed the actual number of days the issuance of the patent was delayed" and is designed to avoid double-counting of overlapping periods of delay attributable to any grounds set out in Parts A, B and C. The exclusion of proceedings in clause (ii) of subparagraph (B) reaches the same result but simply in a different manner than relying on the over-lapping limitation. Specifically, in the post-deadline period, the three types of proceedings enumerated in subparagraph (B) (ii) and in subparagraph (C) are counted only once as Part C delay. The Court is cognizant that an alternative interpretation to reconcile the guarantees and limitations in paragraphs (1) and (2) is possible: if the plaintiff's view is correct that Part B delay accrues after the three-year deadline, regardless of any of otherwise excludable event occurring, reliance on the over-lapping limitation to address double-counting would be even greater. This only underscores the ambiguity in section 154(b).

In short, based upon review of the structure and interplay among provisions in the statute, the Court cannot agree with the conclusion of the *Exelixis I* and *Novartis* courts that statutory silence about the effect of an RCE filing after the three-year statutory deadline unambiguously means that Part B delay accrues regardless of any other action taken in the post-deadline period.

Moreover, the underlying premise of that conclusion as expressed by the *Exelixis I* and *Novartis* courts — namely, that RCE filings are not treated as applicant delay in section 154(b)(1)(B) — is problematic. Contrary to this premise, RCE filings are given the same treatment within the “not including” part of subparagraph (B) as applicant requested delay: the “not including” part merely lists RCE filings first, in subparagraph (B)(i), and lists applicant requested delay last, in subparagraph (B)(iii). Notably, similar language is used in both these clauses: subparagraph (B)(iii) describes the applicant delay exclusion as “any delay in the processing of the application by the [USPTO] *requested by the applicant*,” while subparagraph (B)(i) describes the RCE processing exclusion as “any time consumed by continued examination of the application *requested by the applicant* under section 132(b).” (emphasis supplied). A plausible and, indeed, logical interpretation of this text is that subparagraph (B)(iii) serves as a catch-all provision for *general* applicant requested delay other than the *specific* type of applicant requested delay set out in subparagraph (B)(i) for RCE filings.

This construction is firmly supported by the fact that the general applicant requested delay at subparagraph (B)(iii) limits the delay attributable to the applicant “as permitted by paragraph (3)(C).” 35 U.S.C. § 154(b)(1)(B)(iii). Paragraph (3)(C) allows reinstatement of “an adjustment under paragraph (2)(C)” in certain circumstances. 35 U.S.C. § 154(b)(3)(C). The limitation set out in paragraph (2)(C), in turn, is titled “REDUCTION OF PERIOD OF ADJUSTMENT,” and sets out additional rules governing how applicant delay is accounted for in adjusting the term

of a patent. Notably, paragraph (2)(C) has three subparagraphs, the first of which makes clear that it applies to all of paragraph 1, which includes the subparagraphs describing Parts A, B, and C delays. 35 U.S.C. § 154(b)(3)(C)(i). Paragraph (2) (C) states that the PTA “under paragraph 1 shall be reduced” for any period “during which the applicant failed to engage in reasonable efforts to conclude prosecution of the patent.” 35 U.S.C. § 154(b)(2)(C)(i). The next subparagraph addresses adjustments for applicant delay “under the authority of paragraph (1)(B),” *id.* at (C)(ii), citing the Part B delay subparagraph as a whole and without limiting the reduction in PTA only to the type of applicant delay described in subparagraph (B)(iii). Instead, paragraph (2)(C) adjustments reducing PTA for applicant delay applies expressly to Part B delay generally. *Id.* at (2)(C)(ii) (“With respect to adjustments to patent term made under the authority of paragraph (1)(B)”).²⁰ In other words, if, as the *Exelixis I* and *Novartis* courts opined, RCE filings under subparagraph (B)(i) were not considered applicant delay, and applicant delay were restricted to subparagraph (B)(iii), then the limitations set out in paragraph (2)(C) reducing PTA for applicant delay should have been restricted in application to subparagraph (B)(iii), but they are not.

Finally, the last reason given by the *Novartis* court for its conclusion that section 154(b)(1)(B) was unambiguous rested on the perceived inconsistency between USPTO regulations 37 C.F.R. § 1.702(b) and § 1.703(b) in treating the circumstances enumerated in the “not including” clauses as related to both the “trigger” and the “remedy.” Regulation § 1.702(b) outlines the “Grounds for adjustment of patent term due to examination delay . . . ,” while §

²⁰ Paragraph (2) (C) also delegates to the USPTO authority to promulgate regulations establishing circumstances of applicant delay. 35 U.S.C. § 154(b)(2)(C)(iii). The *Exelixis II* court points out that the USPTO exercised this authority “to promulgate 37 C.F.R. § 1.703(b), the PTA regulation at issue in this litigation,” and to penalize applicants for RCE filings by excluding any time consumed by an RCE filing from Part B-delay. 919 F. Supp. 2d at 698. The court stated that this regulation is “consistent with abundant evidence of congressional intent,” citing “the conference report [which] unequivocally states, RCE-triggered time ‘consumed in the continued examination of the application . . . shall not be considered a delay by the USPTO.’” *Id.* (emphasis in opinion, not in original text).

1.703(b) describes the computation of the “Period of adjustment of patent term due to examination delay.” As the USPTO explained at the time these regulations were issued, § 1.702(b) “sets forth the bases for [PTA] under 35 U.S.C. 154(b)(1),” while § “1.703(b) specifies the period of adjustment” when one of those bases applies. Final Rule, 65 FR at 56,368. This Court finds no inconsistency in these two regulations, which have different purposes and, together, provide guidance on the effect of an applicant filing an RCE on the award of Part B-delay, whether filed before or after the three-year statutory deadline. These two USPTO regulations operate so that the circumstances described in the “not including” clauses effectively toll the “trigger,” when an RCE is filed before the three-year deadline, and reduce the PTA “remedy,” when an RCE is filed after the three-year deadline.

The Court concurs with the three other judges who have considered section 154(b)(1)(B) that this provision is silent on the effect of an RCE filing after the three-year statutory deadline, but finds, consistent with the *Exelixis II* court, that this silence produces plausible, alternative interpretations of how to determine Part B delay. Therefore, the Court finds that this provision is ambiguous.

B. Clause (i) of Section 154(b)(1)(B) Is Ambiguous

The determination that section 154(b)(1)(B) does not plainly render irrelevant any RCE filing after the 3-year statutory period, as the *Exelixis I* and *Novartis* courts found, leads next to the question of what effect clause (i) of subparagraph (B) actually has on Part B delay. Both parties assert that the meaning of clause (i) is unambiguous, even though they have different interpretations of this clause. Pl.’s Reply at 1 (“The ordinary meaning of ‘examination’ of a patent—whether continued or initial—is that it concludes when a notice of allowance issues (or, at the latest, when the issue fee is paid)”; Def.’s Opp’n at 13 (“the USPTO’s interpretation of

Section 154(b)(1)(B)(i)—which is embodied in the regulation set forth as 37 C.F.R.

1.703(b)(1)—is valid because it is consistent with the plain language and design of the statute as a whole”). The USPTO interprets clause (i) as excluding from Part B delay all time after the filing of an RCE, while the plaintiff interprets this clause as limiting the excluded time only from the filing of the RCE until the notice of allowance or, alternatively, the payment of the issue fee. As noted, the *Exelixis II* court agreed with the USPTO’s interpretation.²¹ In determining whether the proper construction of clause (i) is plain and its effect on PTA, the Court begins with the text.²²

Clause (i) of section 154(b)(1)(B) excludes from the computation of Part B delay “any time consumed by continued examination of the application requested by the applicant under section 132(b).” 35 U.S.C. § 154(b)(1)(B)(i). According to the plaintiff, the “key interpretive question” is “which portion of the time is ‘consumed by’ that ‘examination.’” Pl.’s Reply at 8 (emphasis in original). In the plaintiff’s view, the “ordinary meaning of ‘examination’ of a patent—whether continued or initial—is that it concludes when a notice of allowance issues (or, at the latest, when the issue fee is paid)” and “[a]ny subsequent delay is *not* time ‘consumed by continued examination’ and should not count against the applicant for purposes of calculating Part B delay.” *Id.* The USPTO disputes that either a notice of allowance or payment of an issue fee is the end-date of an “examination.” Rather, USPTO points out that the patentee and the Patent Office have obligations after issuance of a notice of allowance and, consequently, the

²¹ In urging the Court to find the *Exelixis II* decision “unpersuasive,” the plaintiff faults the reasoning in that opinion for “jump[ing] straight from a conclusion that the statute is silent with respect to RCEs filed after the three-year period to examining whether the PTO’s interpretation was reasonable and therefore entitled to deference” and “fail[ing] to deploy all ordinary tools of statutory interpretation” Pl.’s Supplemental Notice, at 2, ECF No. 30. The Court disagrees with this characterization of the cogent reasoning in the *Exelixis II* opinion.

²² The plaintiff correctly notes that the *Exelixis II* court did not address “whether a patent applicant is entitled to an adjustment for Part B delay following a request for continued examination for the days between the payment of the issue fee and issuance of the patent,” which is the basis for the plaintiff’s claim that it is entitled to at least 321 days, for Part B delay. Pl.’s Supplemental Notice, at 4, ECF No. 30.

examination continues “up until the issuance of a patent.” Def.’s Opp’n at 22. The USPTO’s interpretation is embodied in challenged regulation 37 C.F.R. § 1.703(b)(1), which excludes from Part B-delay the entire period from the request for continued examination until the date when the patent issues.

The plaintiff offers two principle arguments for its position that the “plain and unambiguous” meaning of clause (i) is that an examination ends upon issuance of a notice of allowance or payment of the issue fee. Pl.’s Reply at 8. As a threshold matter, the very argument of the plaintiff that the end-date of an RCE examination could be either of two dates – the date of the notice of allowance or issue fee payment – amounts to a concession that the end-date is not entirely clear. Putting that aside, however, the Court next addresses the plaintiff’s arguments that, no matter which of its two proffered end-dates is the correct interpretation of clause (i), setting the end-date of an RCE examination as issuance of the patent, as the USPTO construes this clause, is wrong.

First, the plaintiff contends that the “language of the statute is not ‘any time *after* a request for continued examination’” but rather “the language is ‘any time *consumed by* continued examination.’” Pl.’s Reply at 8. (emphasis in original). According to the plaintiff, the choice to use the words “consumed by” rather than “after” suggests that Congress meant for the time period covered by clause (i) to be finite and encompass only the time attributable to applicant-requested delay. *Id.* The USPTO counters that the use of the adjective “any” in clause (i) indicates Congress’s intent broadly to exclude all of the time consumed by an RCE and militates against a narrow reading of the statute as only defining a finite period. Def.’s Opp’n at 14.

Neither party’s argument is persuasive. With respect to the USPTO’s reliance on the adjective “any,” the plaintiff is correct that even if “any” time “consumed by continued

examination” counts against the applicant for purposes of calculating Part B delay, this simply “begs the question” of what time is time actually “consumed by continued examination.” Pl.’s Reply at 15. The word “any” “can broaden to the maximum, but never change in the least, the clear meaning of the phrase selected by Congress here.” *Freeman v. Quicken Loans, Inc.*, 132 S. Ct. 2034, 2042 (2012). Thus, the USPTO’s focus on the word “any” does not really help determine the end-date of a “continued examination” within the meaning of clause (i).

The plaintiff’s argument suffers from the same problem, however. Whether clause (i) uses the words “consumed by” or “after” to exclude time when a request for continued examination is made, the end date could still be issuance of the patent, as the USPTO contends, or some shorter time period if the end date of the subject examination can conclude earlier, as the plaintiff contends. Consequently, whether a different choice of words than “consumed by” might produce a different interpretative result also begs the question and, again, turns on the meaning of “continued examination” and, more specifically, when such examination ends.²³

Second, the plaintiff points to USPTO regulations in support of its interpretation that “any time consumed by continued examination” encompasses only the time from the lodging of a request for continued examination until the notice of allowance issues. Pl.’s Reply at 11; *see also* Pl.’s Supplemental Notice at 4 (“‘examination’ unambiguously ends when the notice of

²³ In fact, the plaintiff’s example of substituting the word “after” for “consumed by” in clause (i), in an effort to undercut the defendant’s interpretation, only demonstrates the ambiguity in this clause. Indeed, if the word “after” were used in place of “consumed by,” the provision would essentially read as follows: Part B delay would “*not include[e]*” any time “*after continued examination requested by the applicant under section 132(b).*” This could be interpreted to exclude from Part B delay all time “after” the request is made for such continued examination, consistent with the defendant’s position. Yet, this alternative phrasing of the clause could also be interpreted to refer to a time period occurring “after” completion of the continued examination, suggesting both (1) that there is such a time period between completion of the examination and before issuance of the patent, as the plaintiff suggests, and (2) that only such post-completion time is counted against Part B delay (*i.e.*, including as part of Part B delay the time spent on the continued examination itself). Perhaps, because of the confusion that use of the word “after” would engender, the term “consumed by” was used to focus the exclusion from Part B delay of the time period covered by the request for continued examination. In short, the plaintiff’s example fails to clarify the intended end date of a “continued examination,” which is the key issue here.

allowance issues”). Specifically, the plaintiff argues that 37 C.F.R. § 1.703(b)(4) treats any time “consumed by” appellate review before the Board of Patent Appeals and Interferences or a federal court, under 35 U.S.C. § 154(b)(1)(B)(ii), as ending at the issuance of a notice of allowance and that this same end date should apply to an RCE. Pl.’s Mem. at 13. In essence, the plaintiff’s argument boils down to the following: since clause (ii) of subparagraph (B) uses the same wording of “any time consumed by” as in the disputed clause (i), the end date in the disputed clause should be the same.

The fallacy of the plaintiff’s reasoning is apparent: although the initial phrasing is identical in both clauses, the operative terms for purposes of the end-dates are entirely different: clause (i) excludes time for a “continued examination” and clause (ii) does so for appellate review or other enumerated proceedings. Contrary to the plaintiff’s view that USPTO “identifies no sound reason for recognizing that issuance of a notice of allowance ends appellate review but refusing to recognize such issuance also ends a “continued examination,” Pl.’s Reply at 2, there is a stark difference between “examination” and “appellate review.” As the USPTO notes, the period of “appellate review by the Board” is a finite period defined by the pendency of an appeal (which is a discrete proceeding before the Board) and concludes when the appeal is no longer pending before the Board. Def.’s Opp’n at 28–29 (citing 37 C.F.R. § 41.35) (“Jurisdiction over appeal.”)).²⁴ By contrast, the USPTO’s jurisdiction over an application continues until the patent issues. This is why, for example, the agency is held accountable for Part A delay when it delays issuance of a patent beyond the four-month “grace” period after payment of the issue fee. This

²⁴ This distinction between appellate review and the RCE process is corroborated by the description of Part C delay. Specifically, Part C delay adds to the PTA any delay due to appellate review or other enumerated proceedings and directs that PTA is accrued for “each day of the pendency of the proceeding, order or review, as the case may be.” 35 U.S.C. § 154(b)(1)(C). The use of the term “pendency of the proceeding” appears to contemplate an end to such proceeding short of the issuance of the patent itself. By contrast, the statute nowhere refers to the “pendency” of a continued examination.

does not, however, clearly answer the question of whether the examination continues for as long as the USPTO has jurisdiction over the application.

Accordingly, contrary to the positions of both parties, the Court finds that the end-date of a “continued examination” under clause (i) of subparagraph (B) is ambiguous.

C. The USPTO’s Interpretation of 35 U.S.C. § 154(b)(1)(B)(i) Is Persuasive

The conclusion that section 154(b)(1)(B) and its clause (i) are ambiguous regarding the effect on the PTA determination of an RCE made more than three years after the application is filed, requires that the Court review the USPTO’s interpretation of this provision under the *Skidmore* level of deference. *See supra* Part II.D. The Federal Circuit has instructed that “even where *Chevron* is inapplicable, an agency pronouncement ‘may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency.’” *Fannie Mae v. United States*, 379 F.3d 1303, 1308–09 (Fed. Cir. 2004) (quoting *Skidmore*, 323 U.S. at 139). The weight given to an agency’s non-definitive regulation “will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade.” *Skidmore*, 323 U.S. at 140.

Thus, the Court next turns to whether the USPTO’s interpretation, as reflected in 37 C.F.R. § 1.703(b), that “the time consumed by” an RCE under section 154(b)(1)(B) extends until the issuance of the patent, has the “power to persuade.” *Skidmore*, 323 U.S. at 140. Evaluation of the reasonableness and persuasiveness of the USPTO’s interpretation is set against the plaintiff’s view that time is not “consumed by continued examination” under clause (i), after issuance of a notice of allowance (or, alternatively, issue fee payment) and that, consequently, Part B delay accrues for each day post-such notice or issue payment after the three-year statutory

deadline. *See* Compl. ¶ 32. The Court concludes that the USPTO interpretation of section 154(b)(1)(B)(i) has substantial “power to persuade” for the five reasons set out below.

1. *USPTO’s Interpretation of Section 154(b)(1)(B)(i) Is Long-Standing And Formally Adopted Contemporaneously With AIPA*

The USPTO’s interpretation of section 154(b)(1)(B), as reflected in the challenged regulation, 37 C.F.R. §1.703(b), has been consistently applied by the USPTO following the formal adoption of the regulation through notice and comment rule making. *See Warner-Lambert Co. v. United States*, 407 F.3d 1207, 1209 (Fed. Cir. 2005) (noting “consistency of the classification with earlier and later pronouncements” and “the formality with which the particular ruling was established” as factors to consider under *Skidmore* to determine degree of deference). Specifically, this regulation, which excludes from Part B-delay any time after an RCE is filed, whether before or after the three-year “guaranteed” review period has lapsed, has been in effect for over a decade, since October 18, 2000, which was six months after the date of enactment of AIPA on May 29, 2000. *See* Final Rule, 65 FR at 56,366. Thus, this regulation was adopted virtually contemporaneously with the enactment of AIPA containing the statutory provision, which is the subject of the implementing regulation.

In adopting the Final Rule, the USPTO rejected the plaintiff’s position. Specifically, a comment submitted during consideration of the Final Rule objected to “the exclusion from the three year period in § 1.703(b) of the period of time in which a request for continued examination under 35 U.S.C. 132(b) and § 1.114 is processed,” and further objected that “filing a request for continued examination should not preclude an applicant from obtaining a term adjustment for printing delays of a patent.” *Id.* at 56,375. The USPTO responded to this comment, explaining that Part B delay no longer accrues after the filing of an RCE since “any further processing or examination of the application, including granting of a patent, is by virtue

of the continued examination given to the application under 35 U.S.C. 132(b) and § 1.114.” *Id.* at 56,376 (“Response” to “Comment 8”). Nonetheless, the applicant would still be eligible for Part A or C delay adjustments. *Id.* This response also addressed the specific objection to the exclusion from Part B delay after the filing of an RCE of time spent on “printing delays of a patent,” *id.*, which “printing delays” presumably occur after issue payment as part of the final processing for the issuance of a patent. The USPTO explained how Part A delay continued to accrue after the filing of an RCE through the following example: two years after the application’s filing date, an RCE is filed; then, “three years after the filling date of the application, the issue fee is paid (and all outstanding requirements are satisfied), but the patent does not issue as a patent until four years after the application’s filing date.” *Id.* Giving full effect to the four-month “grace” period that applies to Part A delay, 35 U.S.C. § 154(b)(1)(A)(iv), the USPTO concluded that “the applicant may be entitled to an eight-month term adjustment because the application did not issue within four months of payment of the issue fee.” *Id.*

This Court agrees with the conclusion of the *Exelixis II* court that the USPTO’s satisfaction of three factors regarding the formality of adoption by the agency of its interpretation, the timing of adoption contemporaneously with enactment of the statute subject to interpretation, and the duration of consistent application by the agency of the interpretation, is “significant.” 919 F. Supp. 2d at 700 (citing *Cathedral Candle*, 400 F. 3d 1352, 1367 (Fed. Cir. 2005); *Rubie’s Costume Company v. United States*, 337 F.3d 1350, 1358–59 (Fed. Cir. 2003); *Baird v. Sonnek*, 944 F. 2d 890 F. 2d 890, 894 (Fed. Cir. 1991)). As the Supreme Court has observed, “[t]he length of time the agencies have held [views regarding interpretation of statutory language] suggests that they reflect careful consideration, not ‘post hoc

rationalizatio[n],” *Kasten v. Saint-Gobain Performance Plastics Corp.*, 131 S. Ct. 1325, 1335–36 (2011) (quoting *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 50 (brackets in original), and “add[s] force” to the conclusion that deference is appropriate, *id.* at 1336. *See also Astrue v. Capato*, 132 S. Ct. 2021, 2034 (U.S. 2012) (finding *Chevron* deference appropriate to agency’s “longstanding interpretation is set forth in regulations published after notice-and-comment rulemaking”); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) (“[T]he consistency of an agency’s position is a factor in assessing the weight that position is due”); *cf. INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (“An agency interpretation of a relevant provision which conflicts with the agency’s earlier interpretation is entitled to considerably less deference than a consistently held agency view.”) (internal quotations and citation omitted). These factors favor giving deference to the USPTO’s interpretation of section 154(b)(1)(B)(i).

2. *USPTO Interpretation Of the End-Date For “Continued Examination” Is Consistent With Other Statutory Provisions and Regulations*

Contrary to the plaintiff’s contention that the end-date for the continued examination under section 154(b)(1)(B)(i) is the issuance of a notice of allowance or issue fee payment, the Patent Act, implementing USPTO regulations and case law regarding the USPTO’s authority to scrutinize an application following such notice or payment consistently adhere to the principle that the examination period extends until the Director issues a patent. For example, the Patent Act provision titled “Examination of application” states that: “The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” 35 U.S.C. § 131. The USPTO correctly points out that “[n]otably, Section 131 does not state that, at the conclusion of an examination, the Director shall issue a Notice of Allowance.” Def.’s Opp’n at 23.

Similarly, USPTO regulation 37 C.F.R. § 1.313, titled “Withdrawal from issue,” contemplates circumstances when an application may be withdrawn from issue even after issuance of a notice of allowance or issue fee payment. The expressly enumerated grounds for withdrawal of an application by the USPTO “at its own initiative,” after an applicant has paid the issue fee, are instructive in construing the length of time of a “continued examination.” These grounds include, for example, “mistake” by the USPTO or “patentability of one or more claims,” both of which may be uncovered through the examination process. 37 C.F.R. § 1.313(b)(1), (3). Moreover, USPTO regulations impose on applicants the obligation “to disclose to the Office all information known to that individual to be material to patentability” while “an application is being examined,” which duty to disclose regarding pending claims is further explained to apply “until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned.” 37 C.F.R. § 1.56(a). By its plain terms, this regulation does not lift the disclosure duty upon issuance of the notice of allowance or payment of the issue fee and, thus, by implication, continues the duty through issuance of the patent, unless that issuance is short-circuited by cancellation, withdrawal or abandonment. *See* Def.’s Opp’n at 16 (arguing that examination process continues until the patent is issued “because 37 C.F.R. § 1.56 imposes a duty on the applicant to disclose information material to patentability as long as the application is pending before the USPTO—*i.e.*, until a patent is granted or the application is abandoned”).

In short, USPTO regulations consistently support the defendant’s position that an examination of a patent application need not stop when a notice of allowance is provided or when the applicant pays the issue fee but rather is authorized to continue until the patent issues.

The USPTO’s position regarding the scope of the USPTO’s authority to reject claims in the patent application up until the issuance of the patent has also been confirmed by the Federal

Circuit in *Blacklight Power, Inc. v. Rogan*, 295 F.3d 1269, 1273 (Fed. Cir. 2002). In that case, the court construed the requirement in 35 U.S.C. § 151 that USPTO “shall” issue the patent upon payment of the issue fee, as subject to the same section’s “preface condition,” stating: “[i]f it appears that applicant is entitled to a patent under the law” *Id.* The court held that USPTO was authorized to withdraw a patent application after notice of allowance, payment of the issue fee, notification of the issue date, and publication of the drawing and claim in the *Official Gazette*, in order to continue examination of the application and resolve remaining questions as to patentability. *Id.* (“We conclude that § 151 does not prohibit withdrawal by the [US]PTO of a patent application after the issue fee has been paid.”). The USPTO is thus correct in relying on *Blacklight* as “clearly permit[ting] the [USPTO] to continue examination of the application to resolve any remaining questions of patentability up until the issuance of the patent.” Def.’s Opp’n at 22.

Likewise, in *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361 (Fed. Cir. 2005), the court reviewed the “prosecution history for guidance” on claim construction, *id.* at 1370, noting that the examiner continued examination of a patent even after a notice of allowance had been sent and, in fact, requested the applicant to respond to a protest petition filed after such notice, *id.* at 1372. Only when the applicant’s response to the post-allowance protest narrowed the claims and satisfied the examiner, did the examiner allow the patent to issue. *Id.* See also *Sampson v. Dann*, 466 F. Supp. 965, 975 (D.D.C. 1978) (noting that USPTO withdrew “on its own initiative a number of applications involving computer programming after payment of the fee following” a Supreme Court decision “that certain such programs are not patentable”). These cases confirm that the USPTO has authority to scrutinize the patentability of the application until a patent issues and, thus, the examination may continue until that end date.

The plaintiff counters with two related arguments that, contrary to the USPTO's interpretation of *Blacklight Power* and *Seachange*, "examination—whether continued or otherwise—ends upon issuance of a notice of allowance." Pl.'s Reply at 8. First, the plaintiff contends that the USPTO has drawn a new and "supposed" distinction between an "examination," which lasts until patent issuance, and "prosecution," which "concludes upon issuance of a notice of allowance." Pl.'s Reply at 8 (citing Def.'s Opp'n at 15 n.6, 23). According to the plaintiff, this distinction "has never before [been] advanced," *id.*, and is contradicted by other long-standing USPTO policy treating the terms "examination" and "prosecution" as meaning "the same thing," *id.* (citing Final Rule, 65 FR at 56,377). The Final Rule explained in response to a comment that regulation §1.704 provides a parenthetical descriptor for "prosecution" as "(processing or examination)" since the USPTO agreed with the comment that, as used in 35 U.S.C. §154(b)(2)(C)(i) and (ii), the terms mean the same thing. Final Rule, 65 FR at 56,377 ("Response" to "Comment 14").²⁵ The plaintiff also cites the discussion in *Blacklight Power* where the court refers to "permit[ting] reopening of prosecution" and a "return[] to examination," which, according to the plaintiff, "demonstrates, at best, that 'examination' and 'prosecution' are used interchangeably." Pl.'s Reply at 10 (citing 295 F.3d at 1271–73). Thus, according to the plaintiff's reasoning, if the USPTO agrees that prosecution ends on issuance of the notice of allowance, this must also be the end date for an examination. *Id.*²⁶

²⁵ Indeed, the statutory section 154(b)(2)(C) under discussion at this part of the Final Rule describes, in clause (i), reductions in PTA due to applicant caused delay arising from the applicant's failure "to engage in reasonable efforts to conclude prosecution of the application," and provides further detail, in clause (ii), of when such delay is "deemed" to occur due to applicant delay in responding to USPTO notices, thereby delaying "processing or examination of an application." USPTO was careful in the Final Rule to tie its agreement regarding the interpretation of the terms "prosecution" and "examination" to the use of these terms in this specific statutory section, where the focus is on the actions of the applicant that may cause delay.

²⁶ The plaintiff also cites as support for its position certain language used on the Notice of Allowance issued for the '788 patent that "THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED

The plaintiff makes a logical leap too far, predicated on a conflation of terms that address the processing of a patent application from different focal points. As the USPTO points out, “examination” is what the USPTO does—*see* 35 U.S.C. § 131—and “prosecution” is what the applicant does—*see* 35 U.S.C. § 133 (stating that an application is to be regarded as abandoned upon the applicant’s failure to timely prosecute its application).” Def.’s Reply Supp. Cross-Mot. Summ. J. Re PTA (“Def.’s Reply”) at 4, ECF No. 28. Thus, while the terms “prosecution” and “examination” may sometimes be used “interchangeably,” as the plaintiff observes, to describe certain time periods where both the agency and the applicant are simultaneously fulfilling their roles, it does not necessarily follow that the end date for the USPTO’s responsibility for an examination ends at the same time that the prosecution period closes. At the close of the prosecution period, upon issuance of a notice of allowance or an office action with a final rejection of the claims, the applicant is no longer allowed to amend its claims as a matter of right. *Id.* at 4 (citing 37 CFR § 1.114(b)). By contrast, examination by the USPTO may continue, even after prosecution is closed, up until the date when the patent issues.

Second, the plaintiff argues that the patent application process supports its construction of the statute by “distinguish[ing] between the examination period and the post-examination period of patent procurement.” Compl. ¶ 32. In support of this construction, the plaintiff cites 35 U.S.C. § 151 for the proposition that a patent applicant does not receive a notice of allowance unless “it appears that applicant is entitled to a patent under the law.” *Id.* While conceding “it is procedurally possible to reopen examination after a notice of allowance issues,” the plaintiff nonetheless observes that this “fact [] does not imply that every patent application is still being

FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.” Pl.’s Mot., Ex. 7 at 1. The plaintiff’s reliance on this notice is misplaced, however. The notice simply does not state that all examination processes have been concluded and that examination has ended. Rather, this notice merely indicates that the applicant may not make further changes in the meaning of the allowed claims.

examined throughout that period.” Pl.’s Reply at 11. Instead, according to the plaintiff, an examiner no longer has jurisdiction over an application once a notice of allowance is issued and for the examiner to take further action, the application “must be *returned to examination*.” Pl.’s Reply at 9–10 (citing USPTO Manual of Patent Examining Procedure (“MPEP”) §§ 1305, 1309 for proposition that “[j]urisdiction of the application remains with the primary examiner until the Notice of Allowance is mailed,” after which time examiner no long has jurisdiction over the application unless the application is returned to examiner). According to the plaintiff, this is what occurred in *Blacklight Power*, where the examination did not continue between the notice of allowance and the issuance of the patent, but rather the patent application was returned to examination. *Id.* The flaw in the plaintiff’s argument is that it too narrowly focuses on the examiner’s role in the processing the application while ignoring the necessary steps of other agency officials to complete the full examination. As the USPTO points out, “although MPEP § 1305 indicates that the primary examiner’s jurisdiction over the application ends when the Notice of Allowance is mailed, the MPEP also indicates that other groups involved with examination retain some jurisdiction over the application after both the Notice of Allowance and payment of the issue fee.” Def.’s Reply at 7. The USPTO cites as an example MPEP § 1308, which states that both the Technology Center Directors and the Office of Petitions have been delegated the authority to withdraw an application from issue after payment of the issue fee under 37 C.F.R. §§ 1.313(b) and (c), respectively, when the patentability of the claims come under question. *See* MPEP § 1308 (Sections I and II); *see also* MPEP § 1308.01 (regarding new rejections based on a prior art reference after allowance of claims). Moreover, MPEP § 1305 expressly contemplates further examination after a Notice of Allowance is issued: namely,

reviewing and entering amendments upon the recommendation of the examiner and with the approval of the Director, pursuant to 37 C.F.R. § 1.312.

As noted, the end-date of a “continued examination” under clause (i) of section 154(b)(1)(B) is ambiguous but the USPTO has successfully demonstrated that an examination, including one performed pursuant to an RCE, ends upon issuance of the patent.

3. USPTO Interpretation Does Not Undercut AIPA “Guarantees”

The plaintiff contends that construing clause (i) of section 154(b)(1)(B) as the USPTO urges, would exclude from Part B delay the time spent on administrative delay attributable to USPTO after notice of allowance, but before issuance of the patent. This result, according to the plaintiff, would undercut the purpose of Part B delay to allow applicants to recoup PTA attributable to administrative delays resulting in failure to issue a patent within 3 years of the application filing and thereby treat the period between the notice of allowance and patent issue as if it were applicant delay, when it is not. Pl.’s Mem. at 2; *see also*, Pl.’s Mem. at 8 (“[T]he Patent Office denied an extension for its own delay between issuance of the Notice of Allowance on June 1, 2010 and issuance of the patent on October 26, 2010”); Pl.’s Mem. at 9 (“[T]he Patent Office counted its own delay after notice of allowance, but before issuance of the patent, as “time consumed by continued examination.”); Pl.’s Reply at 9 (“[T]he Patent Office attributes to the patent applicant the delay between issuance of a notice of allowance and issuance of a patent, but *only* when that delay occurs following a request for continued examination” and thereby “wrongly attributes its own delay to applicants”); Pl.’s Reply at 12 (“Abraxis did not cause the delay at issue here. The delay consists of the time between the Patent Office’s issuance of a notice of allowance and that Office’s issuance of the patent itself.”); Compl. ¶ 36 (“[A] patentee who has filed an RCE would be effectively punished” under the USPTO’s interpretation). The

plaintiff charges that this interpretation “contravenes the purpose of the Patent Term Guarantee Act,” which was enacted “to restore patent term eroded by ‘delays caused by the USPTO that were beyond the control of the applicant.’” Pl.’s Mem. 10 (quoting H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.)).

The USPTO contests this view of the legislative history, explaining that “when the Conference Report is reviewed as a whole, it is clear that Congress intended to broadly exclude all of the time consumed by an RCE” from a Part B determination. Def.’s Opp’n at 24.

According to the USPTO, its interpretation does not result in longer examination delays because the agency is still subject to the Part A guarantee and if the USPTO takes longer than four months to issue the patent after the applicant pays the issue fee the PTA is adjusted accordingly. *Id.* at 25; *see also* 35 U.S.C. § 154(b)(1)(A)(iv). Moreover, the USPTO points out that the time consumed by the RCE process is properly attributed to the applicant, not to the agency:

“Because an RCE is only commenced at the applicant’s request, part of the *quid pro quo* for continued examination is that the period of time which accrues after the applicant files an RCE is properly attributable to the applicant and excluded from the Part B delay in a [patent term adjustment] calculation.” Def.’s Opp’n at 17–18.

The plaintiff’s argument that the USPTO’s interpretation effectively punishes applicants for filing RCEs, *see* Pl.’s Reply at 12, is not quite right. An applicant filing an RCE will receive Part B delay for every day starting from the end of the three-year statutory period until the RCE is filed, just as the plaintiff has here. *See* Figure 1 (Periods 1 and 2). If the applicant receives a notice of allowance and timely pays the issue fee, any day beyond four months following the payment of the fee will also be added to the effective patent term, but under Part A delay rather than under Part B delay. *See* Figure 1 (Period 6). The crux of the plaintiff’s position is that the

four month “grace” period provided under Part A for the USPTO to complete the administrative process to issue the patent should be counted as Part B delay, and treated as agency delay when it occurs after the three-year statutory deadline. Yet, that is not how the statute treats it. The statute makes no differentiation in treatment of the four-month “grace” period based upon whether it occurs within or after three years of the application filing date. In other words, the plaintiff is asking the Court to re-write the statute to eliminate the grace period (and thereby treat the four-month period as agency delay), when it occurs three years after the application filing date due to the timing of the filing of an RCE after the three-year statutory deadline. No such limitation appears in the statute to disallow the four-month grace period in this circumstance, and the Court will not impute such a modification.

4. *USPTO Interpretation Does Not Treat Similarly-Situated Applicants Differently*

The plaintiff claims that the USPTO’s regulation at 37 C.F.R. §1.703(b)(1) is “arbitrary, capricious, and an abuse of discretion,” because an application delayed following an RCE is treated differently than an application delayed during an initial patent examination or by appellate review in terms of the accrual of Part B delay. Pl.’s Reply at 12, 16. The USPTO disputes that an applicant who files an RCE is similarly situated to an applicant who does not engage in an RCE or appellate process, and argues that the difference in circumstances is appropriately reflected in the different treatment of PTA under the statute and the regulations. Def.’s Opp’n at 26–28.

The plaintiff’s argument that the USPTO’s rule treats similarly situated applicants differently fails for two reasons. First, the Court agrees with the USPTO that applicants who file RCEs are not similarly situated with those who are granted notices of allowance without RCE-prompted review. Specifically, an application that prompts an initial examiner rejection and

subsequent RCE differs from more properly framed applications, which proceed to patent issue without an RCE. As the *Exelixis II* court reasoned, “[t]he filing of an RCE opens a body of proceedings that may occasion additional processing delay” and that “such delay emanates solely from an applicant’s original failure to file an application fit for a notice of allowance.” *Exelixis II*, 919 F. Supp. 2d at 26. An RCE implies an applicant-caused delay that is incompatible with the purpose of the Part B patent term adjustment, which was adopted to compensate for USPTO-caused delay. Notices of allowance issued without the filing of an RCE are for applications that presented properly framed claims upon initial filing. This certainly does not appear to be the case with the application for the ’788 patent, where the RCE filing eliminated entirely twenty-one of the twenty-five original claims and revised the remaining four original claims. See Pl.’s Mot., Ex. 6 (“Pl.’s RCE Filing”), Part 1, at 2–3, ECF No. 20-8. Thus, section 154(b)(1)(B) broadly excludes “any time consumed” by the continued examination prompted by the flaws in the initial application while applications without such flaws accrue Part B delay when the patent does not issue until after the three-year statutory deadline.

Second, applicants who file RCEs are not similarly situated with those who are granted notices of allowance after successfully appealing an erroneously issued notice of rejection because the successful appeal establishes that the delay resulted from USPTO-caused error. Consistent with that distinction, the USPTO awards a patent term adjustment under Part C for the delay caused by the appellate review and, when the patent issues after the three-year deadline, under Part B for the processing time between the notice of allowance and the issuance of the patent. Def.’s Opp’n at 28; see also 35 U.S.C. §154(b)(1)(C)(iii); 37 C.F.R. §1.703(b)(4). In contrast, when an applicant decides not to appeal a rejection of an application, but instead takes advantage of the RCE process to seek further consideration and revision of its claims, the

applicant's choice causes the delay and the application is, consequently, ineligible for Part B PTA for days consumed by the RCE. Applicants engaging in "continued examination" excluded under Part B and those engaging in "appellate review" included as Part C delay are simply not similarly situated.²⁷

5. *The USPTO's Interpretation is Reasonable in Context of the Statute*

The USPTO's interpretation of 35 U.S.C. § 154(b)(1)(B)(i) is supported by the overall structure of this section by avoiding attributing delay to the USPTO under Part B that the statute likewise does not attribute to the agency under Part A. Specifically, Part A provides the USPTO four months following the payment of the issue fee to issue the patent without counting that time as delay to be added to the PTA. 35 U.S.C. § 154(b)(1)(A)(iv). If a patent is not issued within that four-month period, every day beyond that time will be added on to the effective patent term as Part A delay. The plaintiff's argument that the notice of allowance (or, alternatively, payment of the issue fee), after the three-year deadline terminates an RCE and triggers accrual of Part B delay, Pl.'s Reply at 1, would result in a windfall of PTA to an applicant in the form of Part B delay that would otherwise not be counted under Part A.

The USPTO reasonably construes the statute as not providing for Part B PTA for days following the notice of allowance and payment of the issue fee, when this entire period follows the filing of an RCE, which counts as the beginning of applicant-prompted delay until the issuance of the patent.²⁸ The plaintiff's position that, when the four-month grace period provided

²⁷ Even if the applicants were considered similarly situated, the defendant notes that the Federal Circuit has held that courts "must enforce, not criticize or correct" the statute, "[r]egardless of the potential of the statute to produce slightly different consequences for applicants in similar situations." Def.'s Opp'n at 26 n.12 (citing *Wyeth*, 591 F.3d at 1370–71 (citing *Harbison v. Bell*, 556 U.S. 180 (2009) (Thomas, J., concurring))).

²⁸ Notably, The House of Representatives has recently passed the "Innovation Act," H.R. 3309, which "clarified" section 154(b)(1)(B)(i) and adopted, in full, the USPTO's construction of this provision. Specifically, this bill would "clarify that no B-delay patent-term adjustment may be awarded for time consumed by a request for continued examination (RCE), regardless of when the RCE was requested" and "that B delay may not be awarded for any of the time accrued after the applicant has restarted prosecution by filing an RCE." H.R. Rep. No. 113-279 at 68 (2013)

for Part A delay occurs after the three-year statutory deadline, the policy underlying Part B delay requires treating that time as agency delay, may hold true in some circumstances, which are treated under the statute as agency-caused delay (*e.g.*, successful appellate review), but not when, as here, that same four-month period occurs after the filing of an RCE. Thus, the USPTO's interpretation of section 154(b)(1)(B)(i) is reasonable that the filing of an RCE after the three-year statutory deadline triggers a delay attributable to the applicant that ends upon issuance of the patent.

Accordingly, the USPTO's decision to deny a Part B patent term adjustment for the time between the notice of allowance and the issuance of the patent will be upheld.²⁹

IV. CONCLUSION

For the reasons explained above, the Court concludes that the two provisions in the Patent Act at issue in this lawsuit, 35 U.S.C. § 154(b)(1)(B) and its clause (i), are ambiguous but that the USPTO's regulation, 37 C.F.R. §1.703(b)(1), which is challenged by the plaintiff, provides a reasonable and persuasive interpretation of the provision. Accordingly, USPTO's Motion for Summary Judgment is granted and the plaintiff's Renewed Motion for Summary Judgment Regarding the Calculation of Part B Delay for the United States Patent No. 7,820,788 is denied.

(Section by Section Summary). In explaining the reason for these clarifying amendment, the House Judiciary Committee Report rejected the reasoning in *Exelixis I* and *Novartis* observing that “[t]hese decisions create an unfortunate incentive for applicants to delay filing RCEs until after the 3-year mark. They also threaten to invite a return to the pre-URAA abuses that had been eliminated by the adoption of a patent term that runs from a patent's filing date rather than from its issuance.” *Id.* at 41.

²⁹ The plaintiff argues in the alternative that the “time consumed by continued examination” ends when the applicant pays the issue fee. Compl. ¶ 49. Since the Court concludes that the USPTO's calculation of the patent term adjustment is a reasonable construction of the statute, the plaintiff's alternative claim is denied.

An Order accompanies this Memorandum Opinion.

Date: January 8, 2014



Digitally signed by Beryl A. Howell
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BERYL A. HOWELL
United States District Judge