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ALEXANDRIA, VIRGINIA

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

EXELIXIS, INC., A Delaware Corporation,	)	
Plaintiff,	)	
v.	)	1:12cv574 (LMB/TRJ)
HONORABLE DAVID J. KAPPOS, Under Secretary of Commerce for Intellectual Property and Director Of the United States Patent and Trademark Office,	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiff Exelixis, Inc. ("Exelixis") has sued David J. Kappos, the Director of the United States Patent and Trademark Office ("PTO"), under 35 U.S.C. § 154 and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 et seq., claiming that the PTO improperly determined the amount of patent term adjustment ("PTA") to which one of Exelixis's patents is entitled. Before the Court are the parties' cross-motions for summary judgment. For the reasons discussed below, the PTO's Motion for Summary Judgment [Dkt. No. 16] will be granted and Exelixis's Motion for Summary Judgment to Correct the Patent Term Adjustment of U.S. Patent No. 8,067,436 [Dkt. No. 13] will be denied.

I. BACKGROUND

A. Legal Background

An individual seeking to patent an invention must file a patent application with the PTO, which after a period of review determines whether to issue a patent or to reject the application by issuing a notice of rejection. See 35 U.S.C. §§ 111, 131-132. If an applicant continues to prosecute a rejected application, the PTO can make the rejection "final" upon a second examination. 37 C.F.R. § 1.113. The applicant then has the option to appeal the PTO's decision as erroneous to the Board of Patent Appeals and Interferences,[1] 35 U.S.C. § 134, or to file a Request for Continued Examination ("RCE") in an attempt to overcome the final rejection. An RCE must include an accompanying fee and a "submission" such as "an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability," but the RCE cannot "introduce new matter into the disclosure of the invention." 37 C.F.R. §§ 1.114(c), 1.17(e); 35 U.S.C. § 132(a).

[1] Effective September 16, 2011, the Leahy-Smith America Invents Act changed references to 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. Because Exelixis filed its Request for Continued Examination and received a notice of allowance before that date, this Opinion will consistently refer to that appellate body as the "Board of Patent Appeals and Interferences."

If, upon receipt and examination of the RCE, the PTO concludes that the applicant's claims are patentable, it sends a notice of allowance to the applicant, who has three months to pay an issue fee. 37 C.F.R. § 1.311. Once payment is received, the patent may issue. Id. § 1.314. In the notice of allowance, the PTO provides an estimate of the length of the term for which the allowed patent will be enforceable, once it issues. This calculation is known as patent term adjustment ("PTA").

In 1994, Congress changed the effective term of a patent from 17 years starting from the date the patent was issued to 20 years starting from the date the patent application was filed. See Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809. Concerned that under the new regime, PTO-caused delays in processing an application could consume significant amounts of the effective term of a patent, Congress addressed the problem in 1999 by allowing the term of a patent to be extended (or "adjusted") when such delays occurred. See American Inventors Protection Act of 1999, Pub L. No. 106-113, §§ 4001-4008, 113 Stat. 1356. Under 35 U.S.C. § 154(b)(1), PTA "rebates" are available through three provisions; an "A-clause" requiring "prompt Patent and Trademark Office responses" by certain examination deadlines, a "B-clause" providing for "no more than [a] 3-year application pendency" between an application's filing date and the issuance of the patent, and a "C-clause" awarding

PTA "for delays due to interferences, secrecy orders, and appeals."

The "B-clause" is the provision at issue in this litigation, and will be the focus of this Opinion. By its terms, the B-clause generally entitles a patent applicant to expect that the PTO will not take more than three years to examine and resolve a patent application. If PTO examination extends beyond the three years and the application is ultimately granted, the applicant may be entitled to an adjustment to the patent's term. Such adjustment is based on a one-day extension for each day that the PTO exceeds the three-year deadline.

There are, however, some exceptions to the B-delay provision. Critical to this litigation is the provision under 35 U.S.C. § 154(b)(1)(B)(i), which states that "any time consumed by continued examination of the application requested by the applicant under section 132(b)" (via the filing of an RCE) does not count toward that three-year period.[2] Pursuant to

[2] 35 U.S.C. § 154(b)(1)(B) states as follows:

> **(B) Guarantee of no more than 3-year application pendency.**—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—

a congressional directive to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," 35 U.S.C. § 154(b)(3)(A), the PTO interpreted that exception by engaging in notice-and-comment rulemaking and promulgating a regulation that became effective October 18, 2000. Under that regulation, the exception in § 154(b)(1)(B) signifies that once an RCE is filed, whether before or after the three-year "guaranteed" review period has passed, no further B-delay adjustment will be made to the term of the patent. 37

> **(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 time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or
> **(iii)** any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph 3(C),
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> 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.

The "limitations" to which the B-clause is "[s]ubject" include PTA reductions to account for when "periods of delay attributable to grounds specified in paragraph (1) overlap," id. at § 154(b)(2)(A); when part of a patent term is disclaimed beyond a certain expiration date, id. at § 154(b)(2)(B); or when there is applicant-generated delay, defined as time during which "the applicant failed to engage in reasonable efforts to conclude prosecution of the application," id. at § 154(b)(2)(C).

C.F.R. § 1.703(b);[3] Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56,366, 56,369 (Sept. 18, 2000) (to be codified at 37 C.F.R. pt. 1). In other words, if an applicant files an RCE, and as a result, is successful in obtaining approval of the application, the patent's term is not extended for the time from the filing of the RCE until the issuance of the patent.

B. Factual Background

Exelixis is the owner of United States Patent No. 8,067,436 ("the '436 patent") entitled "C-Met Modulators and Methods of Use," which covers compounds that inhibit and regulate enzymes associated with certain cancers.

The administrative record ("A.R.") documents the events that led to the patent's issuance, which are represented visually on the timeline[4] below:

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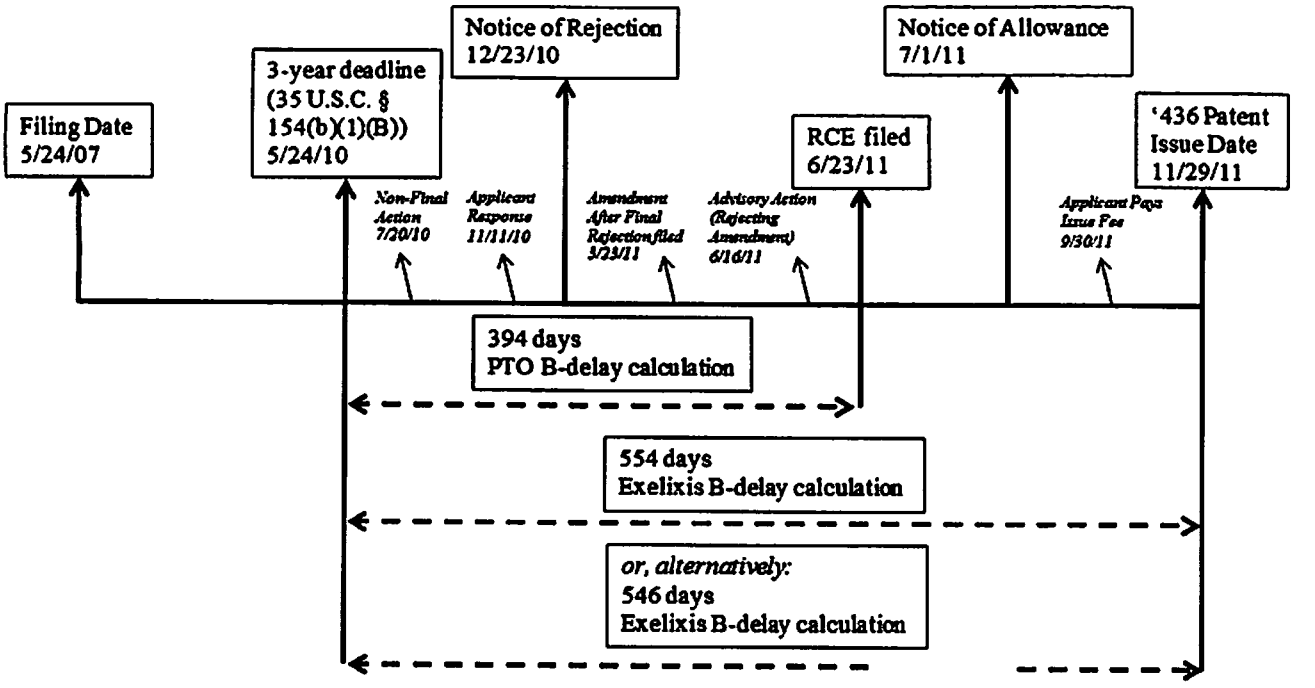
[3] 37 C.F.R. § 1.703(b) reads in pertinent part as follows:

> The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed . . . and ending on the date a patent was issued, but not including the sum of the following periods: (1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued; . . . ."

[4] The timeline is demonstrative only, and is not drawn to scale.



To summarize, the '436 patent application was filed on May 24, 2007, as a continuation of an abandoned 2006 application, which followed an abandoned 2004 application and several provisional applications dating as far back as September 2003. A.R. at 1. When it was filed in May 2007, the '436 patent application contained 54 independent claims and 16 dependent claims.[5]

Over the course of the next two years, Exelixis submitted four "Preliminary Amendments," each of which amended or cancelled all of the original claims in its application and proposed dozens of new claims.[6] See supra at n.5. Its last

[5] See "Transaction History" for the '436 patent, http://portal.uspto.gov/external/portal/pair.

[6] Those Preliminary Amendments were filed on January 29, 2008, May 13, 2008, April 22, 2009, and June 3, 2009, respectively. See A.R. at 6-8; see also supra at n.5.

Preliminary Amendment, filed on June 3, 2009, included only numbered claims 83 to 114 for the PTO's review. See A.R. at 11; see also supra at n.5.

On July 20, 2010, more than three years after the '436 patent application was filed, the PTO took its first action when it issued a non-final rejection as to the pending claims in part because of concern about the breadth of Exelixis's claims as to the types of cancer the invention could potentially treat:

> Claims 101-105 and 107-114 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating certain cancers such as breast, ovarian, colorectal, prostate, and lung cancer, does not reasonably provide enablement for a method of treating all proliferative disorders or cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.
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> Claims 107-114 are drawn to a "method of inhibiting proliferative activity...", and treating several cancers, namely, stomach cancer, esophageal carcinoma, kidney cancer, liver cancer, ovarian carcinoma, cervical carcinoma, large bowel cancer, small bowel cancer, brain cancer, lung cancer, bone cancer, prostate carcinoma, pancreatic carcinoma, skin cancer, Hodgkin's disease, or non-Hodgkin's lymphoma. Like claim 105, the scope of the recited method covers the treatment for cancers of various organs, and thus, is unduly broad.
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> ***
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> There has never been a compound capable of treating cancer generally, let alone inhibiting

> "preproliferative activity in a cell". [sic] Different types of cancers affect different organs and have different modes of growth and harm to the body as well as different vulnerabilities. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Therefore, it is beyond the skill of oncologists today to get an agent to be effective against all cancers or all hyperproliferative disorders in general.

A.R. at 15-17.

Exelixis responded on November 11, 2010, by cancelling all but five of its previous claims, amending two of the five remaining claims, and adding 16 new claims. Id. at 50-61. On December 23, 2010, the PTO issued a final notice of rejection, finding that the "[a]mended remaining claims and new claims have not overcome the previous rejection of [35 U.S.C.] 112/1st paragraph (Scope of Enablement)." Id. at 64. The PTO reiterated several of the reasons from its first notice of rejection, expressing dissatisfaction with the breadth of Exelixis's claims "that said drug would be effective to treat any cancer." Id. at 66. Three months later, Exelixis filed a significantly leaner version of its application containing only six claims,[7] but in a June 16, 2011 Advisory Action, the PTO again advised Exelixis that its response still "fail[ed] to place this application in condition for allowance" because it lacked "descriptive support for the cancers currently (but never

[7] See supra at n.5.

originally) claimed" and "[o]nly lung cancer, ovarian carcinoma and prostate carcinoma are seen to be described in the list of cancers . . . ." Id. at 70-72.

On June 23, 2011, Exelixis filed a Request for Continuing Examination ("RCE"), which described a recent telephone interview in which the examiner had indicated that she would be amenable to allowing a patent for narrowed claims that referred only to "lung cancer, ovarian cancer, and prostate cancer." Id. at 78 (emphasis in original). Accordingly, Exelixis's RCE reduced the application to four claims that referred only to those three cancers, excising all references to other types of cancer. See id. at 80-81. Eight days later, on July 1, 2011, the PTO issued a notice of allowance, which stated that the application "has been examined and is allowed for issuance as a patent" and that "[p]rosecution on the merits is closed," and adjusted the life of the patent by 394 days to account for B-delay.[8] Id. at 82-84, 114-15. Exelixis paid the issue fee on

[8] The PTO clarified at A.R. 114:

> [T]he Office calculated the period of "B delay" as 394 days . . . based on the application being filed under 35 U.S.C. 111(a) on May 24, 2007, and the patent not having issued as of the day after the three year date, May 25, 2010, and a request for continued examination under 132(b) having been filed on June 23, 2011. In other words, the entire 160-day period from the date of filing of the request for continued examination, June 23, 2011 to the date of issuance of the patent on November 29, 2011 was not included in the "B delay."

September 30, 2011, and the '436 patent issued on November 29, 2011. Id. at 87, 99. Exelixis twice petitioned for an increase to the PTA that the PTO had calculated, and after its requests were refused, it filed the Complaint in the instant civil action, seeking an additional 160 days of B-delay PTA, or in the alternative, an additional 152 days of B-delay PTA. Id. at 88-98, 100-121.

II. DISCUSSION

At issue in this civil action are related questions of law about the effect on B-delay PTA of filing an RCE after the expiration of the three-year statutory "guarantee" for patent issuance.

A. Standard of Review

Summary judgment is appropriate where "there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Because the parties do not contest any factual matters, this action involves a purely legal determination as to whether the PTO's method for calculating PTA under 35 U.S.C. § 154(b)(1)(B), as embodied in its regulation, 37 C.F.R. § 1.703(b), is contrary to law.

The PTO's determination of Exelixis's PTA is subject to judicial review under the Administrative Procedure Act, see 35 U.S.C. § 154(b)(4)(A), which provides that 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). An agency abuses its discretion "where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1281 (Fed. Cir. 2005).

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). Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (finding that "[b]ecause Congress has not vested the Commissioner with any general substantive rulemaking power," PTO regulations "cannot possibly have the 'force and effect of law'" and "[t]hus, the rule of controlling deference set forth in Chevron does not apply"). Skidmore deference to an agency's regulatory interpretation "arises . . . solely from, inter alia, the thoroughness of its consideration and the validity of its reasoning, i.e., its basic power to persuade if lacking power to control." Kessler, 80 F.3d at 1550. Specifically, the court must analyze whether "the agency has conducted a careful analysis of the statutory issue," "the agency's position has been consistent and reflects agency-wide policy," and "the

agency's position constitutes a reasonable conclusion as to the proper construction of the statute, even if [the court] might not have adopted that construction without the benefit of the agency's analysis." Cathedral Candle Co. v. U.S. Int'l Trade Comm'n, 400 F.3d 1352, 1366 (Fed. Cir. 2005).

B. Analysis

The parties agree that the effective term of the '436 patent should be extended by the 394 days of B-delay running from the day after the three-year statutory deadline passed until the filing of the RCE. Beyond this point the parties' positions differ. Exelixis argues that the PTO's regulation improperly deprived it of PTA for both the 8 days between the filing of the RCE and the notice of allowance and the 152 days between the notice of allowance and the issuance of the patent. Exelixis contends that it is entitled to both additional adjustments (for total B-delay PTA of 554 days), or in the alternative, if the time the RCE was pending is excluded, at least the additional 152-day adjustment (for total B-delay PTA of 546 days). The PTO opposes both of those adjustments.

1. Time Between Filing an RCE and Notice of Allowance

No party disputes, and this Court finds, that the unambiguous text of 35 U.S.C. § 154(b)(1)(B) clearly provides that the filing of an RCE tolls the guaranteed three-year time period in which the PTO is expected to resolve a patent

application when the RCE is filed before the expiration of that three-year period. Exelixis argues that the statute is limited to that effect because it does not also state that the filing of an RCE after the three-year period has any effect on B-delay.

Other courts to review this issue have found that argument persuasive. See Exelixis v. Kappos ("Exelixis I"), -- F. Supp. 2d --, No. 1:12cv96, 2012 WL 5398876, at *8 (E.D. Va. Nov. 1, 2012), as amended Nov. 6, 2012; Novartis AG v. Kappos, -- F. Supp. 2d --, No. 10-cv-1138, 2012 WL 5564736, at *13 (D.D.C. Nov. 15, 2012) (adopting reasoning of Exelixis I). In Exelixis I, the court concluded that because the statute's "plain and unambiguous language . . . does not address the filing of an RCE after the expiration of the three year clock," then "once the three year clock has run, PTA is to be awarded on a day for day basis regardless of subsequent events." 2012 WL 5398876, at *6. Therefore, the court ruled,

> the plain and unambiguous language of subparagraph (B) requires that the time devoted to an RCE serves to toll the running of the three year clock, if the RCE is filed within the three year period; subparagraph (B) does not address RCE's filed after the running of the three year period nor does it require that the time consumed by an RCE filed after the running of the three year clock be deducted from PTA. Put simply, RCE's have no impact on the PTA after the three year deadline has passed and subparagraph (B) clearly provides no basis for any RCE's to reduce PTA; instead, RCE's operate only to toll the three year guarantee deadline, if, and only if, they are filed within the three years of the application filing date.

Id. at *7.

As in Exelixis I, the parties to this civil action also attempt to frame legislative silence on the effect of RCEs filed after the three-year period as evidence of deliberate intent by Congress in favor of their respective positions. Exelixis highlights the omission of RCE time from the part of the statute providing for PTA reductions,[9] and the PTO underscores the omission of RCE time from the part of the statute awarding PTA increases.[10]

Drawing any inference from congressional silence is a highly doubtful exercise. See, e.g., Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426 (Fed. Cir. 1988) (expressing skepticism that an inference "can be drawn at all from silence" on the part of Congress). But the Exelixis I court's conclusion as to that

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[9] See Pl. Exelixis, Inc.'s Reply Br. in Supp. of Mot. for Summ. J. to Correct the Patent Term Adjustment of U.S. Patent No. 8,067,436 and in Opp'n to Def.'s Cross-Mot. for Summ. J. ("Pl.'s Reply"), at 12 (citing § 154(b)(2)).

[10] See Mem. in Supp. of Def.'s Cross-Mot. for Summ. J. and in Opp'n to Pl.'s Mot. for Summ. J. ("Def.'s Mot."), at 18 (citing § 154(b)(1)(C)). The PTO also makes the bizarre argument that the Court should insert a "then" clause into the text of the statute to render its syllogism more clearly consistent with the government's position. See id. at 11-12; Reply Mem. of Law in Supp. of Def.'s Cross-Mot. for Summ. J. ("Def.'s Reply"), at 4-6. That argument is unavailing. As written, the statute is silent as to the effect of RCEs filed after the three-year period on PTA, and this Court must do more than infer legislative intent from legislative omission.

silence results in treating RCEs filed before and after the three-year period in directly opposite ways; a consequence that even that court concedes will produce "absurd results" but nevertheless refuses to confront because of its certainty about "the plain language of subparagraph (B)." 2012 WL 5398876, at *8. With all due respect to our colleague, 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. To the contrary, we find 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, and that accordingly, the PTO's regulation deserves Skidmore deference because it is a "reasonable conclusion as to the proper construction of the statute." Cathedral Candle, 400 F.3d at 1366.

Congress gave the PTO broad discretion to regulate how PTA is determined and RCEs are processed. See 35 U.S.C. § 154(b)(3)(A) (requiring that the PTO "shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection"); id. § 132(b) (providing that the PTO "shall prescribe regulations to provide for the continued examination

of applications for patent at the request of the applicant"). Although § 154(b)(1)(B) is titled a "[g]uarantee of no more than 3-year application pendency," the statute 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. Any PTA available under the statute will also be reduced by the PTO for "time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." See id. § 154(b)(2)(C). Congress provided an example of what constitutes such failure - an applicant taking "in excess of 3 months . . . to respond to a notice from the [PTO] making any rejection, objection, argument, or other request" - and allowed the PTO discretion to delimit other circumstances in which such a reduction would be appropriate. See id. § 154(b)(2)(C)(iii) (providing that the PTO "shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added)).

The PTO used its discretion to promulgate 37 C.F.R. § 1.703(b), the PTA regulation at issue in this litigation. That regulation is consistent with abundant evidence of congressional intent concerning the effect of an applicant

filing an RCE on the award of B-delay PTA. Specifically, Congress intended that an applicant should not be penalized by delay attributable to the PTO, but should also not benefit when the delay was "requested by" or otherwise attributable to the applicant.[11] See 35 U.S.C. § 154(b)(1)(B). This balancing of the equities is reflected in a legislative conference report that discusses the award of PTA for "administrative delays caused by the USPTO that were beyond the control of the applicant" so as to "compensate applicants fully for USPTO-caused administrative delays" and to reward "diligent applicants." H.R. Rep. No. 106-464, at 125 (Nov. 9, 1999) (Conf. Rep.).[12] As the conference report unequivocally states, RCE-triggered time "consumed in the continued examination of the application . . . shall not be considered a delay by the USPTO." Id. at 126 (emphasis added).

Moreover, legislators were particularly concerned about the potential for applicants to manipulate procedural devices to

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[11] On this point, the Court concurs with the opinion in Exelixis I, which states that "[t]he statute's purpose is to ensure that an applicant is provided with a PTA remedy for delays in examination and processing attributable to the PTO and to reduce any PTA by delays attributable to the applicant." 2012 WL 5398876, at *6.

[12] See, e.g., Lisa Seachrist, Congress Taking Initial Step Toward Patent System Reform, Medical Device Daily (Apr. 1, 1999) (reporting agreement between partisans on legislation that "calls for the restoration of lost time resulting from delays in the PTO and the courts, as long as the patent applicant isn't the source of those delays").

prolong the PTO's examination. The decision to measure 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."[13] The RCE procedure has

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[13] House Panel Examines Bills on Patent Law Reforms, 51 Pat. Trademark & Copyright J. (BNA) 50 (1995); see also 5 Donald S. Chisum, Chisum on Patents § 16.04 (explaining that the purpose of the 20-year-from-filing-date patent term "was to eliminate so-called 'submarine patents,' granted only after years, even decades, of prosecution in the PTO by use of continuing applications, and after the concerned industry invested in the patented technology unaware of latent dominating patent rights"); 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."); President's Comm'n on the Patent System, "To Promote the Progress of . . . Useful Arts" in an Age of Exploding Technology 33-34 (1966) (recommending the change to a twenty year patent term measured from the date of filing to "induce the applicant to present claims promptly that he believes patentable and avoid delaying the prosecution of the application" by "filing continuing applications solely to delay the start of a patent term").

"eclipsed" the mostly-retired CPA as the means for further prosecution of an application after a final rejection. Chisum on Patents § 13.03. Not only does an RCE permit applicants to retain their accrued PTA (unlike the filing of a CPA, see 37 C.F.R. § 1.704(c)(12)), but there is currently no limit on the number of times an applicant is permitted to file an RCE to raise "new arguments" or "new evidence" after a final notice of rejection has been issued.[14] Thus, availability of unlimited

[14] Recent attempts by the PTO to set such limitations have been unsuccessful. In 2007, the PTO administratively restricted the number of RCEs that could be filed, permitting an applicant to file a single RCE as a matter of right, and allowing a second RCE to be filed in extraordinary situations if the applicant provided an explanation for why the new amendment, argument, or evidence presented in the RCE could not have been presented previously. See Changes to Practice for Continued Examination Filings, 72 Fed. Reg. 46,716, 46,720 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (observing that "unrestricted continued examination practice . . . does not provide adequate incentives to assure that the exchanges between an applicant and the examiner during the examination process are efficient," and that "[PTO] resources absorbed by the examination of additional continued examination filings are diverted away from the examination of new applications, thus increasing the backlog of unexamined applications"). The PTO was enjoined from enforcing the regulation by an opinion that was vacated and reconsidered in further appellate proceedings. See Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008), aff'd in part and vacated in part sub nom. Tafas v. Doll, 559 F.3d 1345 (Fed. Cir. 2009), vacated and reh'g en banc granted, 328 F. App'x 658 (Fed. Cir. 2009), stayed, 331 F. App'x 748 (Fed. Cir. 2009). The PTO then appears to have mooted the appeal by rescinding its own rules. See Tafas v. Kappos, 586 F.3d 1369, 1371 (Fed. Cir. 2009) (finding that "the USPTO has rescinded the rules that formed the basis of this litigation" and therefore dismissing the appeal as moot); 74 Fed. Reg. 52,686, 52,686-87 (Oct. 14, 2009) (to be codified at 37 C.F.R. pt. 1) (stating that the rules that had been "the subject of litigation since August of 2007 and ha[d] never taken

RCEs creates the potential for the very abuses that spurred reform of the laws on patent terms in the first place. In light of this legislative history and legitimate, pragmatic congressional concern, 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.

The PTO's regulation also avoids the absurd result of treating an RCE filed before the termination of the three-year period differently than one that is filed after the three-year period. The 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. The regulation reasonably construes the statute by preventing an applicant from using its control over the initiation of "continued examination" to extend the term of the patent. To strike the regulation would imply that Congress created a paradox whereby 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. This consequence would violate the canon that "a statutory

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effect" were "objectionable to a large segment of the patent user community," and therefore "the [PTO] has decided that it is no longer interested in pursuing the changes . . . that were the subject of the District Court's decision").

construction that causes absurd results is to be avoided if at all possible." Timex V.I., Inc. v. United States, 157 F.3d 879, 886 (Fed. Cir. 1998) (citing Haggar Co. v. Helvering, 308 U.S. 389, 394 (1940)).

It is also significant that the PTO's regulation has been in force for over a decade and was promulgated through notice-and-comment a year after Congress enacted the underlying statute. Cf. Cathedral Candle, 400 F.3d at 1367 (giving weight to an agency's position because it was not "formulated belatedly in response to litigation in this case or others, nor [was it] inconsistent with positions the [agency] has previously taken"); Rubie's Costume Company v. United States, 337 F.3d 1350, 1358-59 (Fed. Cir. 2003) (concluding that an agency's ruling "which was consistently applied for almost ten years and was neither a sudden and unexpected change nor a failure to take account of prior inconsistent interpretations, has 'power to persuade'" in the Skidmore analysis); Baird v. Sonnek, 944 F.2d 890, 894 (Fed. Cir. 1991) (according particular deference to an agency's contemporaneous construction of a statute).[15]

[15] Plaintiff argues that the PTO has "undermine[d] [its] attempt to cast an RCE as an instrument of 'willful delay'" by exhibiting an inconsistent position on the value of the RCE, citing a partial quotation of a post on the public blog of PTO Director David Kappos to imply that the PTO views the RCE solely as a "valuable tool" in patent prosecution. See Pl.'s Reply at 24; Pl. Exelixis's Br. in Supp. of Mot. for Summ. J. to Correct the Patent Term Adjustment of U.S. Patent No. 8,067,436 ("Pl.'s

The reasonableness of the PTO's regulation is further underscored by the facts of this litigation. Exelixis originally filed an extremely broad application containing 70 claims that it then unilaterally cancelled, amended, and augmented four separate times over the course of 18 months. When the PTO issued a preliminary rejection of Exelixis's fifth set of claims, it explained that the claims purported to treat a wide variety of cancers for which there was inadequate support in the record. In its next revision, Exelixis still did not respond to those concerns satisfactorily because the PTO issued a final rejection with the more summary explanation that the

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Mot."), at 5. But as the PTO points out, the quoted blog post expresses the more nuanced view that although "[t]here are many valid reasons for filing RCEs," there are also "reasons for filing RCE's that are less consistent with the shared goal of compact prosecution and reduction of the USPTO backlog," which include "presenting new claims not included in the original application, or continuing to prosecute broad claims that were rejected in the original case." See Def.'s Reply at 10 n.11 (quoting Bob Stoll, RCE Filings: The Facts, Director's Forum: David Kappos' Public Blog (July 26, 2010, 9:17 AM), http://www.uspto.gov/blog/director/entry/rce_filings_the_facts). Indeed, the PTO has stated elsewhere that filing an RCE could constitute the kind of applicant delay that is expressly penalized by 35 U.S.C. § 154(b)(2)(C). See, e.g., Revision of Patent Term Adjustment Provisions Relating to Appellate Review, 76 Fed. Reg. 81,432, 81,435 (proposed Dec. 28, 2011) (to be codified at 37 C.F.R. pt. 1) (explaining, in the context of describing the PTO's authority to define the circumstances that constitute an applicant's failure to reasonably conclude processing of an application, that an applicant "may delay or prevent the passing of jurisdiction of the application to the [Board of Patent Appeals and Interferences] by: . . . (3) seeking further prosecution before the examiner by filing a request for continued examination under 37 CFR 1.114").

"[a]mended remaining claims and new claims have not overcome the previous rejection." A.R. at 64.[16] By the time Exelixis filed its RCE, it had reduced the application to only four claims that finally addressed the PTO's concerns by limiting the claims to treatment of those cancers for which the record provided adequate documentation. Had Exelixis initially filed a narrowly-tailored application, rather than seeking an overly-broad patent, the extended examination would not have been necessary. For these reasons, the Court concludes that the PTO's regulation denying PTA for the time period during which an RCE is under consideration, regardless of when the RCE is filed, is a reasonable implementation of the statute, and that under that regulation, the PTO properly did not award plaintiff the 8 days of PTA for the time between the filing of the RCE and the notice of allowance.

2. Time Between Notice of Allowance and Issuance

The second issue in this civil action concerns whether Exelixis, after filing an RCE outside the three-year deadline, is entitled to B-delay PTA for the time between the PTO's issuance of the notice of allowance and the issuance of the patent. Again, the applicable statute does not address the issue except insofar as it delegates to the PTO responsibility

[16] Exelixis does not argue, and the facts do not suggest, that any of the notices of rejection were improvidently issued by the PTO or are otherwise attributable to PTO error.

for establishing procedures for the calculation and determination of PTA. See 35 U.S.C. § 154(b)(3)(A).

Exelixis argues that even if § 154(b)(1)(B) is deemed to exclude from B-delay PTA the time between filing an RCE and the PTO issuing a notice of allowance, the time between issuance of the notice of allowance and issuance of the patent is distinguishable because that time period began after the PTO had already informed Exelixis that its application "has been examined and is allowed for issuance as a patent," A.R. at 82, and thus, after the period that was "consumed" by PTO review of the RCE. See Pl.'s Reply at 19-25. The PTO responds that even after a notice of allowance issues, there remain continuing duties on the part of the applicant and the PTO to react to any material changes to patentability until the patent is issued. See, e.g., 37 C.F.R. §§ 1.313, 1.56(a). Exelixis asserts that those duties do not rise to the level of "continued examination" within the meaning of the statute, and frames the work done after a notice of allowance as purely ministerial tasks precedent to patent issuance that are not attributable to the applicant and are usually considered by the PTO to merit B-delay PTA. Specifically, Exelixis describes as inconsistent the PTO's policy of awarding such time to an applicant who has successfully appealed a final rejection and been granted a notice of allowance, see id. § 1.703(b)(4), and withholding the

same time from an applicant who has filed an RCE and been granted a notice of allowance, see id. § 1.703(b)(1).

Exelixis's argument fails because applicants who file RCEs before receiving notices of allowance are not similarly situated with those who are granted notices of allowance without needing RCE-prompted review. The filing of an RCE opens a body of proceedings that may occasion additional processing delay, but as the PTO clearly indicated in its notice-and-comment rulemaking over a decade ago, such delay emanates solely from an applicant's original failure to file an application fit for a notice of allowance. See 65 Fed. Reg. 56,366, 56,376 (Sept. 18, 2000) ("Once a request for continued examination . . . is filed in an application, any further processing or examination of the application, including granting of a patent, is by virtue of the continued examination given to the application . . . .").

This applicant-caused delay is incompatible with the concept of B-delay PTA, which is fundamentally anchored to PTO-caused delay. See supra at Part II.B.1. By contrast, an applicant's successful appeal of a notice of rejection implies no such applicant-related deficiency, but rather that the delay resulted from error by the PTO. Consistent with this distinction, the PTO duly awards B-delay PTA for the consequences of its own error - that is, for the time consumed by the appellate review and for the processing time between the

notice of allowance and the issuance of the patent. See 35 U.S.C. § 154(b)(1)(C)(iii); 37 C.F.R. § 1.703(b)(4). Thus, when the applicant decides not to appeal a rejection to claim error by the PTO, but instead takes advantage of the RCE process to further amend its application, all proceedings following the RCE filing - including the otherwise routine processing that directly precedes patent issuance - are "by virtue of the continued examination given to the application," and are ineligible for B-delay PTA. This regulation is consistent with the statute and will be accorded Skidmore deference. Accordingly, the PTO's decision to deny any B-delay PTA for the time between the notice of allowance and the issuance of the patent will be upheld.

III. CONCLUSION

For the reasons stated above, the PTO's Motion for Summary Judgment [Dkt. No. 16] will be GRANTED and Exelixis's Motion for Summary Judgment to Correct the Patent Term Adjustment of U.S. Patent No. 8,067,436 [Dkt. No. 13] will be DENIED by an appropriate Order to be issued with this Memorandum Opinion.

Entered this 28th day of January, 2013.

Alexandria, Virginia

/s/
Leonie M. Brinkema
United States District Judge