UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF MASSACHUSETTS, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 10-00894 (ESH)**
HON. DAVID J. KAPPOS,	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiffs University of Massachusetts and Medarex, Inc. have sued David J. Kappos, the Under Secretary of Commerce for Intellectual Property and the Director of the U.S. Patent and Trademark Office ("PTO"). Plaintiffs bring this suit under 35 U.S.C. § 154 and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq*., claiming that defendant improperly determined the patent term adjustment ("PTA") to which they are entitled for patent '559. Before the Court are plaintiffs' Motion for Summary Judgment and defendant's Cross-Motion for Summary Judgment. For the reasons set forth below, plaintiffs' motion will be denied and defendant's motion will be granted.

BACKGROUND

I. LEGAL FRAMEWORK

Prior to 1994, U.S. patents were granted for a term of seventeen years from the date the patent issued. In 1994, Congress adjusted the term of a U.S. patent to twenty years from the date the application was filed to bring the U.S. in line with other countries' patent terms. However,

because the examination of a patent application often takes more than three years from filing to the issuance of a patent, this meant that many patentees received effective patent terms of less than the historical seventeen-year period. Thus, in 1999, Congress amended the Patent Act by creating patent term adjustments ("PTA") to extend patent terms in response to unreasonable delays in the examination of a patent application. *See* 35 U.S.C. § 154(b).

The Patent Act created several types of PTA. First, a patentee can accrue PTA if the PTO fails to take certain specified actions within fixed windows of time. Specifically, § 154(b)(1)(A) provides, in relevant part, that:

> [I]f the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to … provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after …the date on which an application was filed under section 111(a) …the term of the patent shall be extended 1 day for each day after the end of the period specified … until the action [notification or notice of allowance] is taken.

For example, if the PTO does not issue an Office action responding to a patent application within 14 months after the application was filed, the patentee will be awarded one day of PTA for every day from the end of the 14-month period until the first Office action is issued. *Id.* This type of PTA is known as "A delay." The PTO notifies the patentee of the amount of A delay that has been awarded when it issues the Notice of Allowance.

The PTO has promulgated a set of final rules interpreting the proper calculation of A delay under § 154(b)(1)(A), through notice-and-comment rulemaking. First, 37 C.F.R. § 1.702(a) restates the text of the statute, providing that the patent term shall be adjusted if the issuance of the patent was delayed due to the failure of the PTO to "[m]ail at least one of a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 not later than fourteen months after the date on which the application was filed [.]" Second, 37 C.F.R. § 1.703(a) provides that the period of adjustment shall include "[t]he number of days, if any, in

the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) or fulfilled the requirements of 35 U.S.C. § 371 and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first[.]" Third, 37 C.F.R. § 1.704(a),(b), which restates the text of 35 U.S.C. § 154(b)(2)(c)(i),(ii), provides that the term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application," which is defined to include "any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request[.]" This is known as "applicant delay."

A second type of PTA – known as "B delay" – accrues if the PTO fails to issue a patent within three years of the filing of the application. *See* 35 U.S.C. § 154(b)(1)(B). After determining the proper amount of A and B delay, the PTO must determine the extent of any overlap between the two types of delay. While plaintiffs initially challenged the PTO's calculations regarding B delay and the overlap between A delay and B delay,[1] the PTO resolved both issues to plaintiffs' satisfaction on remand, leaving the calculations of A delay as the only remaining matter in dispute.

II. BACKGROUND

The subject of this case is U.S. Patent No. 7,625,559 ("'559"), entitled "Antibodies Against *Clostridium Difficile* Toxins and Uses Thereof." (Plaintiffs' Motion for Summary Judgment ("Pl. Mot") at 4.) "The patent is for monoclonal antibodies, and antigen binding

[1] The method of determining A/B delay overlap was changed in response to the Federal Circuit's decision in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), which was issued after the instant case was filed. The parties consented to remand for the PTO to apply *Wyeth*.

portions thereof, that specifically bind to toxins of *Clostridium difficile* ("*C. difficile*"), and methods of making and using the same." (*Id*.) The patent application was filed with the PTO on February 4, 2005. (*Id*.) The original patent application addressed "three main embodiments of the invention – monoclonal antibodies that bind to *C. difficile* toxin A, or toxin B, or both toxin A + toxin B." (*Id*.) The application included other "embodiments" as well, such as methods for making the antibodies and methods of treatment using the antibodies. (*Id*. at 5.) In total, the application included 80 claims. (*Id*.)

On July 13, 2007, the PTO issued a first Office action establishing a "restriction requirement" pursuant to 35 U.S.C. § 121. (*Id*.) "Restriction is the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application." Manual of Patenting Exam Procedure ("MPEP") § 802.02. The procedure is authorized by 35 U.S.C. § 121 ("If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.") *See also* 37 CFR § 1.142. In the first restriction requirement issued in this matter, the Examiner divided the claims into ten different groups, each of which was purportedly related to a different and distinct invention. (Pl. Mot. at 5.) "The Examiner lumped the majority of the antibody claims together in a single Group I" and failed to divide the claims based on "whether the antibody, or antigen binding portion thereof, could specifically bind to either *C. difficile* toxin A or toxin B." (*Id*. at 6-7.) This ran counter to the classification scheme devised by plaintiffs.

On October 9, 2007, plaintiffs filed a Preliminary Amendment and Response to the Restriction Requirement. (*Id*. at 8.) They "elected" Group VIII – defined as a "'composition'

comprising both an antibody that specifically binds to *C. difficile* toxin A and an antibody that specifically binds to *C. difficile* toxin B" – for continued examination, canceled original claims 1-80, and added new claims 81-95, "which fell within the elected Group VIII." (*Id*. at 7, 8.) Plaintiffs did not challenge the groupings designated by the Examiner in their Response. (Plaintiffs' Reply Brief in Support of Their Motion and Opposition to Defendant's Cross-Motion ("Pl. Reply") at 3.)

After submitting the Amendment and Response, plaintiffs' attorneys engaged in phone discussions with the Examiner and her supervisor. During those calls, plaintiffs' attorneys expressed their view that the restriction requirement was erroneous insofar as "no groups were defined by the Examiner separately for antibodies or portions thereof, that bind specifically to *C. difficile* toxin A or toxin B, as had been described and claimed in the applicants' original application." (Pl. Mot. at 9). It was agreed that a new restriction requirement should be issued "to correct the fundamental errors in the Restriction Requirement." (*Id*.) "Since the applicants already had complied with the Examiner's first Restriction Requirement by making an election and canceling the 'non-elected' claims, it was suggested by the Examiner's Supervisor that the applicants file a Supplemental Amendment to add the canceled claims back into the application, so the Examiner could essentially start over and issue a proper restriction requirement." (*Id*.)

Applicants submitted a Supplemental Amendment and Response on November 21, 2007, in which they noted in the "Remarks" section:

> Applicants thank Examiner Lakia J. Tongue and the Examiner's supervisor, Bruce R. Campbell, for the numerous teleconferences during [which] the Restriction Requirement issued on July 13, 2007 was discussed.
>
> Based on these discussions, it is Applicants['] understanding that the Restriction Requirement set forth in the Office Action mailed July 13, 2007 (Paper No. 20070621) will be vacated due to errors on the part of the U.S. Patent and Trademark Office ("PTO") and a corrected restriction requirement will be issued in due time. Accordingly, as requested by Examiner Campbell, Applicants submit this Supplemental Amendment

> and Response adding claims corresponding to the originally filed claims, so as to facilitate the PTO in re-issuing the Restriction Requirement. Please amend the application as set forth below. (*Id*. at 10.)

In the Supplemental Amendment, plaintiffs "amended and broadened claims 81, 82, and 89-91 by adding additional, alternative limitations to the claims" and "added new claims 96-131 to the application." (Defendant's Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment ("Def. Mot.") at 10.) The parties agree that most of the added claims "found support in (or corresponded to) the claims that were first presented in the original application." (Def. Mot. at 10; Pl. Reply at 6.) There is some disagreement, however, as to whether certain added claims were entirely new or merely reflected "minor changes to the wording" of the claims. (Def. Mot. at 10 *but see* Pl. Reply at 6.) In the administrative proceeding, the PTO referred to plaintiffs' "new claims" without qualification. (PTO Decision Upon Remand and Reconsideration of Patent Term Adjustment ("PTO Decision"), ECF No. 14 at 4.)

On February 21, 2008, the Examiner issued another Office action establishing a new restriction requirement. (Pl. Mot. at 11.) The new restriction requirement divided the claims based on the different toxins of *C. difficile*. (*Id*.) Applicants filed a response to the second restriction requirement, in which they wrote: "A Restriction Requirement issued in the above-referenced application on July 13, 2007. Due to errors on the part of the U.S. Patent and Trademark Office, the original Restriction Requirement of July 13, 2007 was vacated and a new Restriction Requirement issued on February 21, 2008." (*Id*. at 12.)

On May 1, 2009, the PTO issued a Notice of Allowance and a Determination of Patent Term Adjustment under 35 U.S.C. § 154(b), which indicated that the '559 patent was entitled to 434 days of PTA. (Complaint ¶ 13.) On July 31, 2009, plaintiffs filed an Application for Patent

Term Adjustment Including Request for Reconsideration, requesting a minimum PTA of 1,255 days. (*Id*. ¶ 14.) On October 27, 2009, the PTO issued a Response to the first Request for Reconsideration and Statement and dismissed the first Request for Reconsideration as premature because it "relates to the Office's failure to issue the patent within three years of the file date." (*Id*. ¶ 15.) On December 1, 2009, the '559 patent issued with a PTA of 623 days. (*Id*. ¶ 16.) On January 21, 2010, plaintiffs filed a second Request for Reconsideration of Patent Term Adjustment, requesting a final corrected PTA of 1,276 days. (*Id*. ¶ 17.)

III. PROCEDURAL HISTORY

On May 28, 2010, not having received a response to their second Request for Reconsideration, plaintiffs filed suit, alleging that the PTO had improperly calculated the amount of PTA to which their '559 patent was entitled. (Pl. Mot. at 1.) On August 23, 2010, this Court granted a consent motion to remand the case to the PTO for recalculation and adjustment of the patent term in accordance with the recently issued decision of the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010).

On March 12, 2012, the PTO issued its Decision Upon Remand and Reconsideration of Patent Term Adjustment, granting the requested relief in part and finding a PTA of 1,070 days, including 465 days of A delay, rather than the 688 days of A delay that applicants calculated based on the date of the second restriction requirement. (*Id*. at 1, 3.) The PTO found that "the amendment was expressly suggested by the [E]xaminer and therefore should not have been considered an application delay under 37 CFR § 1.704(c)(8)," but it also found that the mailing of the first restriction requirement stopped the clock for purposes of calculating A delay because "the Examiner mailed a new restriction requirement to address applicant's new claims, not because the Examiner was vacating the first restriction requirement." (Def. Mot. at 12.) The

PTO noted "[a] review of the record does not reflect any showing in the record where the [E]xaminer expressly asserts that the Office action of July 13, 2007 was vacated by the [E]xaminer." (PTO Decision at 4.) On April 11, 2012, plaintiffs filed notice of the PTO's decision with this Court. (Pl. Mot. at 1.) On April 27, 2012, the parties submitted a joint proposal for further proceedings. (*Id*.) Currently before the Court are plaintiffs' Motion for Summary Judgment and defendant's Cross-Motion for Summary Judgment.

ANALYSIS

I. LEGAL STANDARDS

A. Judicial Review of Patent Term Adjustments

The APA provides judicial review of an agency action to a party who has suffered a legal wrong because of that action. 5 U.S.C. § 702. The APA gives the court authority to "decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." 5 U.S.C. § 706. It further provides that "the reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." *Id.*

The arbitrary and capricious standard "presumes the validity of agency action, requiring [the court] to determine whether the agency has considered the relevant factors and 'articulate[d] a rational connection between the facts found and the choice made.'" *AT&T Corp. v. FCC*, 220 F.3d 607, 616 (D.C. Cir. 2000) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)). The court "may reverse only if the agency's decision is not supported by substantial evidence, or the agency has made a clear error in judgment." *Id.* (quoting *Kisser v. Cisneros*, 14 F.3d 615, 619 (D.C. Cir. 1994)).

B. Motion for Summary Judgment

Normally, a motion for summary judgment under Rule 56 shall be granted if "the pleadings, depositions, answers to interrogatories, . . . admissions on file, . . . [and] affidavits . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986) (quoting Fed. R. Civ. P. 56(c)). "In a case involving review of a final agency action under the [APA], however, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006) (citation omitted).

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." *Id.* at 90 (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)). Thus, "when an agency action is challenged" solely with "arguments about the legal conclusion to be drawn about the agency action," then the case on review presents only a question of law and can be resolved on the administrative record pursuant to a motion for summary judgment. *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). In that instance, a "district court[ ] reviewing agency action under the APA's arbitrary and capricious standard do[es] not resolve factual issues, but operate[s] instead as [an] appellate court[ ] resolving legal questions." *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996).

In this case, the only issue for review is the legal question of whether the PTO's determination of A delay for plaintiffs' '559 patent was a valid and appropriate exercise of agency discretion.

C. Standard of Review

"If the statute is clear and unambiguous '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.'" *Board of Governors, FRS v. Dimension Financial Corp*., 474 U.S. 361, 368 (1986) (quoting *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc*., 467 U.S. 837, 842-43 (1984). Where a statute is silent or ambiguous on a particular issue, however, and "where Congress has authorized an agency to promulgate substantive rules under a statute it is charged with administering," the court "must uphold the agency's interpretation of an ambiguity or omission in that statute if the interpretation is a reasonable one." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549 (Fed. Cir. 1996) (citing *Chevron*, 467 U.S. at 842-45). The Federal Circuit has previously determined that the PTO does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. *See Merck*, 80 F.3d at 1549-50. Indeed, 35 U.S.C. § 154(b)(3)(A) limits the PTO's authority to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments." 35 U.S.C. § 154(b)(3)(A). Thus, the PTO's determination is not entitled to *Chevron* deference. *See Merck*, 80 F.3d at 1549-50; *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008).

Instead, the PTO is only entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), which depends 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, if lacking power to control." *Id.* at 140; *see also Merck*, 80 F.3d at 1550.

In other words, a court will only defer to an agency interpretation if, among other things, "the agency's position constitutes a reasonable conclusion as to the proper construction of the statute." *Cathedral Candle Co. v. United States Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005).

II. PLAINTIFFS' CLAIM

The crux of plaintiffs' claim is that the A delay for patent '559 should have been calculated to include the entire period from April 5, 2006 (the fourteen-month deadline) up until and including February 21, 2008, when the second restriction requirement was issued, effectively nullifying the "fundamentally flawed" first restriction requirement. Defendant maintains that the PTO properly calculated the period of A delay as running from April 5, 2006 until July 13, 2007, when the first restriction requirement was issued in satisfaction of the statutory mandate to "provide at least one of the notifications under section 132." 35 U.S.C. § 154(b)(1)(A).

Under the APA, the Court functions as an appellate authority addressing legal questions, *Ludwig*, 82 F.3d at 1096, and only in rare circumstances, not present here, will the Court disturb the agency's factual findings.[2] Nevertheless, while purportedly agreeing that there are no facts in dispute, the parties argue about whether plaintiffs' Supplemental Amendment included new claims or merely restated the original, canceled claims, and whether the second restriction requirement was intended to vacate the first restriction requirement or merely to respond to the

[2] "In all cases agency action must be set aside if the action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements. In certain narrow, specifically limited situations, the agency action is to be set aside if the action was not supported by 'substantial evidence.' And in other equally narrow circumstances the reviewing court is to engage in a *de novo* review of the action and set it aside if it was 'unwarranted by the facts.'" *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413-14 (1971) (internal citations omitted), *abrogated on unrelated grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977).

"new" claims.[3] The PTO has decided these disputes based on the evidence before it, and the Court has no basis to disturb the PTO's factual findings.

Specifically, the PTO found that the second restriction requirement was issued in response to plaintiffs' "new" claims in their Supplemental Amendment and was not intended to vacate the first restriction requirement. (PTO Decision at 4.) Plaintiffs' continued assertions to the contrary are unsupported by the facts, as the PTO found that the record reflected no "express assertion" by the Examiner that the first restriction requirement was vacated. (*Id*.) Moreover, the Court is unconvinced by plaintiffs' attempts to attribute an adoptive admission to defendant by arguing that the Examiner "never refuted or denied" plaintiffs' statements in their correspondence that the restriction requirement had been vacated. (Pl. Mot. at 10, 12.) As the PTO noted, in a decision discussed at length in § III *infra*, "the mere use of the word 'vacate' in a subsequent Office action, especially during the give-and-take process of examination, does not alone entitle a patentee to A-delay under 37 C.F.R. 1.702(a) and 1.703(a)." *In re: Patent No. 7,803,385, Matthew C. Coffee, Decision on Application For Patent Term Adjustment, May 24, 2012* ("*Oncolytics*"), Ex. A to Pl. Mot., at 4 n.1.[4] It is therefore immaterial whether an Examiner explicitly characterizes or implicitly acknowledges an Office action to be "vacated."

The question is whether, *as a matter of law*, when an applicant successfully convinces an Examiner to change a ruling contained in an Office action, regardless of whether it is classified

[3] Plaintiffs also argue that they did no actually "traverse" the first restriction requirement because the "[t]he entire framework of the Restriction Requirement was wrong" so "[t]he problem required far more radical steps to fix." (Pl. Reply at 5.) This is, as defendant puts it, "a distinction without a difference." (Def. Reply at 4 n.3.) "A traverse of a requirement to restrict is a statement of the reasons upon which the applicant relies for his or her conclusion that the requirement is in error." MPEP § 818. The undisputed facts are that plaintiffs explained to the Examiner their reasons for believing that the first requirement was incorrect, and thereafter, the Examiner issued a new requirement.

[4] Captioned in the district court as *Oncolytics Biotech Inc. v. David J. Kappos, C.A.*, No. 11-621 (D.D.C. filed March 25, 2011).

as a vacatur, that renders the first Office action "a nullity for purposes of calculating A delay under Section 154(b)(1)(A)." (Def. Mot. at 21.) Because the statute is clear and unambiguous, the Court need not decide what level of deference to accord the agency's decision. "As in any case of statutory construction, [the Court's] analysis begins with the language of the statute . . . . And where the statutory language provides a clear answer, it ends there as well." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (citation and internal quotation marks omitted). In this case, the Court finds that the statute provides a clear answer: the A delay clock stops ticking when the first Office action is issued, regardless of what transpires thereafter.

Plaintiffs insist that the first restriction requirement was so "fundamentally flawed" that it "stood in the way of further prosecution." (Pl. Reply at 3.) Plaintiffs make a convincing case that it was necessary to persuade the Examiner to revise the restriction requirement. This is, however, irrelevant to the question of calculating A delay. The patent prosecution process involves significant back and forth, during which it is assumed that the PTO will sometimes make mistakes and applicants will have the opportunity to correct those mistakes. The statute implicitly acknowledges as much, s*ee, e.g.*, 35 U.S.C. §132 (providing for reexamination of rejected applications), and this pattern of exchange is built into the agency's duly promulgated regulations, s*ee*, *e.g.*, 37 CFR §1.143 ("If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefor."); §1.144 ("After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement."); §1.111 ("If the Office action after the first examination [] is adverse in any respect, the applicant or patent owner, if he or she persists in his or her application for a patent or reexamination proceeding, must reply and request reconsideration or further

examination, with or without amendment."). The statute does not provide, however, that such corrections will affect the calculation of A delay. This is because the purpose of PTA is to "compensate patent applicants for *certain reductions* in patent term that are not the fault of the applicant," H.R. Rep. No. 106-464, at 125 (1999) (Conf. Rep.) (emphasis added), not to guarantee the correctness of the agency's every decision.

Under § 154(b)(1)(A), "A delay" is calculated based on the time that passes between the fourteen-month deadline and the mailing of the first Office action. The statute does not require that the first Office action be correct. The statute does not require that the first Office action ultimately stand, either completely unaltered or with only minor tweaks. The statute does not award additional A delay if an applicant successfully convinces the PTO that the Office action was erroneous. And the statute does not provide, either explicitly or implicitly, that an Office action, once taken, can be rendered a nullity. What the statute does say is that:

> [I]f the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to…*provide at least one of the notifications under section 132* or a notice of allowance under section 151 not later than 14 months after…the date on which an application was filed under section 111(a)…the term of the patent shall be extended 1 day for each day after the end of the period specified… *until the action [notification or notice of allowance] is taken.*

35 U.S.C. § 154(b)(1)(A) (emphasis added). Or, as the regulations restate more concisely, the period of adjustment shall include "[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. §111(a) or fulfilled the requirements of 35 U.S.C. § 371 and *ending on the date of mailing of [] an action under 35 U.S.C. § 132.*"

Plaintiffs do not dispute, nor can they, that "an action" is clearly defined under 35 U.S.C. § 132 as a rejection, an objection, or a requirement.[5] And plaintiffs do not dispute that a requirement was issued in this case on July 13, 2007. Therefore, the PTO correctly interpreted the statute to find that the period of A delay ends on that date. For the PTO or the Court to take into account whether the restriction requirement was subsequently modified or reversed would be to rewrite the statutory provisions regarding A delay in contravention of well-established law. *Blount v. Rizzi*, 400 U.S. 410, 419 (1971) ("…it is for Congress, not this Court, to rewrite the statute….").

The correctness of the PTO's statutory interpretation is further reinforced when considered in comparison to another provision of the statute, for "[w]here Congress includes particular language in one section of the statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Immigration and Naturalization Serv. v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987) (citation and internal quotation marks omitted). As defendant points out, Section 154(b)(1)(C)(iii) (providing for "C delay") "does award PTA time based on the ultimate success of the applicant in overcoming a position taken by the Examiner during prosecution, such as, for example, in a successful appeal to the Board of Patent Appeals and Interferences." (Defendant's Reply in Support of Defendant's Cross-Motion for Summary Judgment ("Def. Reply") at 6 n.4.) The fact that Congress decided to provide for an adjustment in that context strengthens the presumption that it intentionally decided not to include any such provision in §154(b)(1)(A). The presumption is especially strong in this instance because "'the two [provisions] are

[5] *See also* 65 Fed. Reg. at 56368 ("*A written restriction requirement*, a written election of species requirement, . . . and a notice of allowability (PTOL-37) are each an action issued as a result of the examination conducted pursuant to 35 U.S.C. 131. As such, *each of these Office actions is a notification under 35 U.S.C. 132."* (emphasis added).)

interrelated and closely positioned, both in fact being parts of' the same statutory scheme." *Doe v. National Bd. of Med. Exam'rs*, 199 F.3d 146, 155 (3rd Cir. 1999) (quoting *HCSC-Laundry v. United States*, 450 U.S. 1, 6 (1981) (per curiam)).

Plaintiffs emphasize the PTO's "admission" that the Supplemental Amendment was submitted at the request of the Examiner. (Pl. Mot. at 18-19; PTO Decision at 5.) Indeed, the PTO found that because the Examiner requested the Supplemental Amendment, the delay caused by its submission should not be considered applicant delay that would lead to a reduction of PTA. (Pl. Mot. at 18-19; PTO Decision at 5.) But the PTO found that the same delay also should not count as A delay. The PTO's decision to treat that time period as neither applicant delay nor A delay reflects a reasonable interpretation of the respective regulatory provisions at issue. Under 37 CFR § 1.704(c)(8), which controls applicant delay determinations, a "patentee is not considered to fail in reasonable efforts to prosecute the application if the [E]xaminer expressly requests that the patentee submit the amendment or supplemental paper." In contrast, neither the statute nor the regulations provide for any parallel adjustment of A delay based on whether the Examiner requests a supplemental submission after issuing the first Office action. Therefore, the fact that the Examiner requested the Supplemental Amendment is relevant for the purposes of calculating applicant delay, but irrelevant for the purposes of calculating A delay.

III. THE *ONCOLYTICS* CASE

Plaintiffs argue that the PTO's decision in the instant case is inconsistent with a prior PTO decision on remand from this Court, and is thus arbitrary and capricious. In that case, *Oncolytics*, the PTO issued an initial Office action with a restriction requirement on March 12, 2009. The applicant replied by "traversing the election requirement," or proposing a regrouping of the claims, and provisionally electing certain claims. The PTO thereafter issued a second

Office action on August 24, 2009, accepting the applicant's proposed regrouping and rejecting the elected claims on the merits, thereby "fixing" the applicant's election. The PTO then issued a third Office action on January 6, 2010, rejecting the applicant's traversal of the original restriction, rejecting the applicant's election of regrouped claims, adopting the applicant's original election of claims and making the election final, and rejecting the elected claims on the merits. The applicant replied to the third Office action on March 24, 2010 and supplemented his reply on May 6, 2010. Finally, on June 8, 2010, the PTO issued a Notice of Allowance with a Determination of PTA. (Pl. Mot. at 20; Def. Mot. at 23 n.10); *see Oncolytics* at 1-2. In sum, the PTO initially accepted the applicant's regrouping but rejected his claims on the merits, then rejected his regrouping and still rejected his claims on the merits, before finally deciding to allow his claims on the merits.

After the patent issued, the patentee argued that the PTA should be calculated based on the January 6, 2010 Office action because the "Office action mailed August 24, 2009, failed to meet the requirements of 35 U.S.C. § 132(a) and was vacated by a Supervisory Patent Examiner." (Ex. A to Pl. Mot.) The PTO initially denied the requested PTA on several grounds, including (1) "the fact that the Office later withdrew the non-final Office action does not negate the fact that the Office took action within the meaning of 37 CFR 1.702(a)(2) . . . ;" (2) "the [E]xaminer does not have the authority to vacate, rescind, or withdraw an Office action;" and (3) "[t]he vacatur of an Office action signifies that the Office action has been set aside . . . . The vacatur of an Office action, however, does not signify that the vacated Office [a]ction is void *ab initio* and is to be treated as if the USPTO had never issued the Office action." (Pl. Mot. at 21 n.13, quoting *Oncolytics* Complaint, Ex. C and E) (plaintiffs' emphasis removed). As plaintiffs point out, many of these arguments echo those made by the PTO in the instant case. (*Id.*)

However, upon remand from the district court, the PTO reversed course in *Oncolytics* and awarded the PTA demanded by the patentee. The PTO wrote in its decision, "[u]pon reconsideration of all the facts of this case, the USPTO has determined that the specific facts of this case constitute the *rare occurrence* in which it is appropriate for the USPTO to treat an Office action issued in an application as a non-event for the purposes of calculating USPTO delay under 37 CFR 1.702(a)(2) and 1.703(a)(2)." *Oncolytics* at 4. (emphasis added). Plaintiffs argue that the divergence in the PTO's ultimate decision in *Oncolytics* and in the instant case prove that the PTO has acted arbitrarily and capriciously here.

Plaintiffs' argument does not withstand scrutiny. First, defendant convincingly distinguishes *Oncolytics* by explaining that in that case, "the USPTO changed the identity of the claims that were actually being examined in the application after they already had been fixed by a rejection on the merits[, while] [i]n the case at bar, the claims were never fixed and no action on the merits occurred before the Office actions were allegedly 'vacated.'" (Def. Mot. at 23 n. 10.) This is a meaningful distinction. Here, plaintiffs successfully convinced the PTO to issue a new, different restriction requirement before plaintiffs' elections were made final. In *Oncolytics*, the applicant was initially successful in doing the same, but then the PTO spontaneously reversed course a second time, after the elections were made final. It is clear that the PTO's actions in *Oncolytics* were anomalous and caused significant delay at applicants' expense. By contrast, in the instant case, the PTO was immediately responsive to plaintiffs' arguments for a revised restriction requirement and made the necessary corrections before the process had progressed any further.

Second, the Court recognizes that in the *Oncolytics* case, it could be argued that the PTO failed to "acknowledge and provide an adequate explanation for its departure from established

precedent," opening the door to a finding that it acted arbitrarily and capriciously *in that case*. *Jicarilla Apache Nation v. Department of the Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010) (citations and internal quotation marks omitted). However, neither side challenged the PTO's ruling in *Oncolytic*s. In the instant case, the PTO appears to have returned to its usual practice, consistent with the clear and unambiguous language of the statute, of refusing to treat an Office action as a "non-event" for the purposes of calculating A delay. Thus, the Court cannot conclude that the PTO acted arbitrarily and capriciously *in this case*.

CONCLUSION

For the foregoing reasons, the Court denies plaintiffs' Motion for Summary Judgment and grants defendant's Cross-Motion for Summary Judgment. A separate Order accompanies this Memorandum Opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

DATE: November 9, 2012