UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS AG, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 10-cv-1138 (ESH)**
	)	
HON. DAVID J. KAPPOS,	)	**(Consolidated)**
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION

Plaintiffs Novartis AG and Novartis Vaccines and Diagnostics, Inc. ("Novartis") 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 amount of patent term adjustment to which they are entitled. 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 granted in part and denied in part, and defendant's motion will be granted in part and denied in part.

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, two of which are at issue here. First, a patentee can accrue PTA if the PTO fails to take certain specified actions within fixed windows of time. *See* 35 U.S.C. § 154(b)(1)(A). 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 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. Because the Notice of Allowance is sent well before a patent is actually granted, the determination of A Delay is known as a Pre-Issuance Determination.

A second type of PTA 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). This type of PTA is known as "B Delay." Specifically, § 154(b)(1)(B) provides that:

> if the issue of an original patent is delayed due to the failure of the [PTO] 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

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),

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 PTO has promulgated two final rules interpreting the proper calculation of B Delay under § 154(b)(1)(B). First, 37 C.F.R. § 1.702(b) states that the patent term shall be adjusted if the issuance of the patent was delayed due to the failure of the PTO to issue a patent within three years after the filing date, "but not including: (1) any time consumed by continued examination of the application under 35 U.S.C. § 1.703(b)." Second, 37 C.F.R. § 1.703(b) states that the period of adjustment under § 1.702(b) is to be the number of days beyond three years from the filing date, but not including the number of days between the filing of a request for continued examination ("RCE") and the date the patent is issued. In other words, § 1.703(b) provides that: (1) patentees cannot accrue B Delay for time consumed by an RCE, regardless of when it was filed, and (2) "time consumed by" an RCE includes all of the time from the filing of the RCE to the issuance of the patent. Because B Delay accrues until the actual date of issuance, the PTO does not determine the proper amount of B Delay until the patent is granted.

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. 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). Prior to *Wyeth*, the PTO interpreted the period

of B Delay to include the entire time between the filing of an application and the issuance of a patent more than three years later. Thus, if a patent took longer than three years to issue, any A Delay that occurred during the pendency of the application by definition overlapped with the period of B Delay, and was not awarded to the patentee as PTA. As the Federal Circuit explained, "[u]sing this framework, the PTO use[d] either the greater of the A delay or B delay to determine the appropriate adjustment, but never combine[d] the two." *Wyeth*, 591 F.3d at 1368. In *Wyeth*, the Federal Circuit held that the PTO's interpretation of the overlap provision was erroneous; A Delay and B Delay should be aggregated so long as that aggregation would not require counting the same calendar day twice. *See id.* at 1369-70.

After the Federal Circuit's decision in *Wyeth*, the PTO announced that it would not seek further review of that decision and would implement the court's interpretation of A/B Delay Overlap when determining the appropriate amount of PTA for issued patents beginning on March 2, 2010. (AR166-67.) The PTO also announced that it would permit recalculation of PTA for patents issued prior to March 2, 2010, so long as the request for reconsideration was filed within 180 days of the grant of the patent. (AR170.) Thus, only patents that had been granted within the 180 days prior to that announcement were eligible for a recalculation of their PTA using the new post-*Wyeth* interpretation.

Because the overlap determination depends on the amount of B Delay, it is also done at the time the patent is granted. The final determination of PTA, which factors in just A Delay but also B Delay and any overlap between A and B Delay, is therefore known as an Issuance Determination.

II. PROCEDURAL HISTORY

On July 6, 2010, Novartis filed suit, alleging that the PTO had improperly calculated the amount of PTA to which eleven of its patents were entitled. (Complaint [ECF No. 1].) Novartis argued first that the PTO acted improperly in refusing to apply the post-*Wyeth* interpretation of A/B Delay Overlap to patents granted prior to September 2, 2009 ("the *Wyeth* Claim"). Second, Novartis challenged the PTO's interpretation of the effect of an RCE on the determination of B Delay ("the RCE Claim"). On February 16, 2012, this Court ordered that this case be consolidated with three other matters—*Novartis v. Doll*, No. 09-cv-1203, *Novartis v. Kappos*, No. 11-cv-0659, and *Novartis v. Kappos*, No. 11-cv-0821—all of which raise the same legal issues. Given the consolidation of the four cases, the PTA determinations for twenty-three of Novartis' patents are now at issue.

Plaintiffs filed a Motion for Summary Judgment on May 16, 2012. ([Dkt. No. 35] ("Pls.' Mot.").) Defendant then filed a Cross Motion for Summary Judgment and Opposition to plaintiffs' motion on June 18, 2012. ([Dkt. No. 38] ("Def.'s Mot.").) On July 18, 2012, plaintiffs filed an Opposition to defendant's Cross Motion and a Reply to defendant's Opposition to its Motion. ([Dkt. No. 40] ("Pls.' Reply").) And finally, on August 20, 2012, defendant filed a Reply to plaintiff's Opposition. ([Dkt. No. 42] ("Def.'s Reply").)

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 set aside an agency action that is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations." *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., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (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." *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, the discovery and disclosure materials on file, and any 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. Fed. R. Civ. P. 56(a), (c); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "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 a legal question as to whether the PTO's determination of PTA for each of Novartis' patents was a valid and appropriate exercise of agency discretion.

C. Standard of Review

In answering this question, it is necessary to determine what level of deference the PTO's determination is entitled to. Under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), "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). However, 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." *See Cathedral Candle Co. v. United States Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005).

II. TIMELINESS

Challenges to PTA determinations are governed by 35 U.S.C. § 154(b)(4)(A). That section provides:

> An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.[1]

[1] For complaints filed on or after September 16, 2011, the U.S. District Court for the Eastern District of Virginia now has jurisdiction over actions under 35 U.S.C. § 154(b). Pub. L. 112-29 at § 9(a), 125 Stat. 284, 316.

35 U.S.C. § 154(b)(4)(A). Defendant does not dispute that timely complaints were filed with respect to three of the Novartis Patents—U.S. Patent Nos. 7,807,155 ("the '155 patent"), 7,968,518 ("the '518 patent"), and 7,973,031 ("the '031 patent"). (Def.'s Mot. at 10.) However, the PTO asserts that because the complaints relating to the remaining patents were filed more than 180 days after the grant of each of those patents, Novartis is foreclosed from seeking additional PTA for those patents. (*Id.* at 10-11.)

As an initial matter, Novartis asserts that the 180-day limitation of § 154(b)(4)(A) does not apply to its claims. By its terms, § 154(b)(4)(A) applies to determinations "under paragraph (3)" of that section. Novartis asserts that § 154(b)(3) governs only Pre-Issuance PTA Determinations, meaning determinations of A Delay. (Pls.' Mot. at 31-32.) Novartis points to several portions of that subsection to support its position. For example, § 154(b)(3)(B)(i) states that: "the Director shall . . . make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination *with the written notice of allowance* under section 151." 35 U.S.C. § 154(b)(3)(B)(i) (emphasis added). Because neither B Delay nor A/B Overlap has been determined at the time a Notice of Allowance is issued, Novartis contends that this section should not apply to challenges to those determinations. (*Id.*) Similarly, § 154(b)(3)(D) states that the Director "shall proceed to grant the patent *after* completion of the Director's determination of a patent term adjustment under the procedures established under this subsection." 35 U.S.C. § 154(b)(3)(D) (emphasis added). In Novartis' view, the fact that the statute suggests that the PTA determination must be made prior to the grant of the patent indicates that it relates only to Pre-Issuance Determinations. (*Id.* at 32.) Thus, because no Pre-Issuance PTA Determinations are implicated here, Novartis argues that 35

U.S.C. § 154(b)(3) is irrelevant, and the 180-day limitations period of 35 U.S.C. § 154(b)(4)(A) does not apply. Instead, according to Novartis, the general six-year statute of limitations of the APA (*see* 28 U.S.C. § 2401(a)) applies to Novartis' appeal of Issuance PTA Determinations. (*Id.* at 34.)

The Court disagrees. Section 154(b)(3) is entitled "Procedures for patent perm adjustment determination" and is the only section of the statute to address the PTO's procedures for determining PTA. From its plain language, it is clearly intended to relate to all PTA determinations, regardless of when they occur. Indeed, the very language Novartis points to—that the Director "shall proceed to grant the patent after completion of the Director's determination"—clearly requires that the Director make a full determination of all types of PTA because both A Delay and B Delay (as well as any overlap between the two) must be determined before the patent is granted.

In addition to being consistent with the plain meaning of the statute, this interpretation avoids absurd results. Congress clearly intended to include strict controls on judicial review of PTA determinations. Under Novartis' interpretation, only Pre-Issuance Determinations would be subject to those controls, while the final, complete PTA determinations that accompany an issued patent would not. Instead, a patentee would have 180 days in which to challenge the calculation of A Delay but six years in which to challenge B Delay and A/B Delay Overlap.

In reaching this conclusion, this Court is persuaded by the recent opinion in *Janssen Pharmaceutica N.V. v. Kappos*, 844 F. Supp. 2d 707 (E.D. Va. 2012), that 35 U.S.C. § 154(b)(4)(A) provides the exclusive means for judicial challenges to the PTO's PTA determinations. *Id.* at 713. That court held:

> [I]n a case in which a patentee is challenging the number of days of PTA calculated by the USPTO, whether that calculation occurred before the patent was issued or afterwards, such a decision is governed by §§ 154(b)(3) and (b)(4)(A). In other words, any challenge to a PTA determination is governed by § 154(b)(4)(A).

Id. The court reasoned that a contrary holding would be "entirely inconsistent with the Congressional intent plain on the face of the statute—to strictly limit the forum and timing for seeking judicial review of these very specific USPTO decisions." *Id.* As such, the 180-day limitation prescribed by that section applies to the PTA determinations at issue here.

A. Ordinary Tolling

Judicial review of agency actions is ordinarily tolled until the agency action is final. *See Clifton Power Corp. v. FERC*, 294 F.3d 108, 110 (D.C. Cir. 2002) (citing *Interstate Commerce Comm'n v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 284 (1987)). "A request for administrative reconsideration renders an agency's otherwise final action non-final with respect to the requesting party." *Clifton*, 294 F.3d at 110 (citing *United Transp. Union v. Interstate Commerce Comm'n*, 871 F.2d 1114, 1116 (D.C. Cir. 1989)). Thus, judicial review of an agency action must be tolled during the period of agency reconsideration. As the Supreme Court explained in *Locomotive Engineers*:

> [W]here a petition for reconsideration has been filed within a discretionary review period specifically provided by the agency (and within the period allotted for judicial review of the original order) . . . the petition tolls the period for judicial review of the original order, which can therefore be appealed to the courts directly after the petition for reconsideration is denied.

482 U.S. at 279.

With respect to U.S. Patent No. 7,470,792 ("the '792 patent"), Novartis filed a petition for PTA reconsideration with the PTO within two months of issuance, as directed by 37 C.F.R. §

1.705(d), raising the same claim that is now before this Court. Within 180 days of the PTO's denial of reconsideration (but more than 180 days after the issuance of the patent), Novartis filed suit in this court. Thus, Novartis argues that the 180-day limitation period should have been tolled by its filing of a petition for reconsideration, rendering its claim with respect to the '792 patent timely.[2]

The PTO asserts that the ordinary tolling rule does not apply to § 154(b)(4)(A). First, the PTO argues that applying the normal tolling rule to § 154(b)(4)(A) would read out the language "after the grant of the patent" from the statute. (Def.'s Mot. at 27.) However, it is well established that "a statutory provision setting the limitations period is *not* incompatible with a tolling rule." *Bristol-Myers Squibb Co. v. Kappos*, 841 F. Supp. 2d 238, 243, *motion for reconsideration denied*, 2012 WL 4127636 (D.D.C. Sept. 20, 2012). Indeed, this Circuit has applied the ordinary tolling rule to numerous statutes providing for specific limitations periods that are triggered by specified dates. *See, e.g.*, *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 920-21 (D.C. Cir. 1998) (tolling 90-day limitations period beginning from the date of the challenged promulgation or denial); *Los Angeles SMSA Ltd. P'ship v. FCC*, 70 F.3d 1358, 1359 (D.C. Cir. 1995) (tolling a 30-day limitation period beginning on "the date upon which public notice is given of the decision or order complained of"). Thus, the mere fact that § 154(b)(4)(A)

[2] The PTO correctly points out that Novartis did not allege that ordinary tolling applied in its Second Amended Complaint. (Def.'s Mot. at 26 n. 10.) Although it remains an "open question" in the D.C. Circuit as to "whether the Federal Rules permit parties to impliedly consent to 'try' issues not raised in their pleadings through summary judgment motions," the Court will follow the majority of circuits that do allow constructive amendment of the pleadings under Rule 15(b) through summary judgment motions. *See Turner v. Shinseki*, 824 F. Supp. 2d 99, 122 n.23 (D.D.C. 2011) (collecting cases).

sets a specific date from which the 180-day limitation period is to run—the date the patent is granted—does not render the general tolling rule inapplicable.

Next, the PTO argues that the language of § 154(b)(4)(A) suggests that Congress clearly intended "to depart from the ordinary judicial treatment of agency orders under reconsideration." (Def.'s Mot. at 27-28 (quoting *Stone v. INS*, 514 U.S. 386, 393 (1995)).) Specifically, the PTO argues that by tying the 180-day limitation to the date of patent grant and expressly providing that the issuance of the patent should proceed regardless of any reconsideration sought by the applicant, *see* 35 U.S.C. § 154(b)(3)(D), Congress clearly intended to override the application of the general tolling rule. (*Id.* at 28.)

The same argument by the PTO was rejected in *Bristol-Myers Squibb*, 841 F. Supp. 2d at 244-45. The Court concluded defendant's arguments do not "support a conclusion that Congress intended for the ordinary tolling rule not to apply to Section 154(b)(4)(A)." *Id.* at 244. To the contrary, § 154(b)(4)(A) expressly states that Chapter 7 of Title 5—which includes the general tolling rule—applies to any actions arising under that section, a fact this Court recently noted "indicates that Congress affirmatively intended for the tolling rule to apply to judicial review of patent term adjustment determinations." *Bristol-Myers Squibb*, 2012 WL 4127636, at *6. Thus, nothing about § 154(b)(4)(A) "direct[s] this Court to take any action inconsistent with the normal tolling rule." *Bristol-Myers Squibb*, 841 F. Supp. 2d at 245.

Because the Court holds that the general tolling rule applies, and because Novartis filed its complaint with respect to the '792 patent within 180 days after the denial of its petition for reconsideration, Novartis' claim with respect to that patent was timely filed.

B. Equitable Tolling

With respect to the nineteen remaining patents that were neither timely filed nor susceptible to ordinary tolling, Novartis argues that the 180-day limitations period should be equitably tolled.

The Court must first determine if § 154(b)(4)(A) is susceptible to equitable tolling. That question turns on whether the statute is jurisdictional in nature. The law on what constitutes a "jurisdictional" statute is, to say the least, far from clear. *See, e.g.*, *Gonzalez v. Thaler*, 132 S. Ct. 641, 648 (2012) ("Recognizing our 'less than meticulous' use of the term in the past, we have pressed a stricter distinction between truly jurisdictional rules, which govern 'a court's adjudicatory authority,' and nonjurisdictional 'claim-processing rules,' which do not.") (quoting *Kontrick v. Ryan*, 540 U.S. 442, 454-55 (2004)); *Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 183 (D.C. Cir. 2012) ("In recent years, the terminology of jurisdiction has been put under a microscope at the Supreme Court. And the Court has not liked what it has observed—namely, sloppy and profligate use of the term 'jurisdiction' by lower courts and, at times in the past, the Supreme Court itself.") (Kavanaugh, J., dissenting).

In light of these recent admonishments to construe the meaning of "jurisdictional" narrowly, it is perhaps more prudent to conclude that § 154(b)(4)(A) should be viewed as a "claim-processing rule"—one that "seek[s] to promote the orderly progress of litigation by requiring that the parties take certain procedural steps at certain specified times," *Henderson v. Shinseki*, 131 S. Ct. 1197, 1203 (2011), and therefore, it is entitled to a "rebuttable presumption in favor of equitable tolling." *Holland v. Florida*, 130 S. Ct. 2549, 2560 (2010) (internal

quotation marks omitted). The Court, however, need not resolve this knotty question, because it finds that § 154(b)(4)(A) should not be equitably tolled under the circumstances of this case.

Equitable tolling is available to a petitioner who has been diligent in pursuing his rights, but for whom some extraordinary circumstance stood in the way and prevented timely filing. *Holland*, 130 S. Ct. at 2562. The decision to equitably toll a statute of limitations is made on a "case-by-case" basis depending on the facts of the case. *Id.* at 2563.

With respect to its *Wyeth* Claim, Novartis argues first that it lacked knowledge of its claim until the Federal Circuit's decision on January 7, 2010, in *Wyeth* changed the law with respect to A/B Delay Overlap. (Pls.' Mot. at 48-49.) Additionally, Novartis argues that it reasonably relied on the PTO's longstanding and consistent use of its pre-*Wyeth* method of calculating A/B Delay Overlap; according to Novartis, up until the *Wyeth* decision forced the PTO to use the correct interpretation of A/B Delay Overlap, Novartis reasonably believed that it would have been futile to file a lawsuit appealing the PTO's PTA determinations under that method of calculation. (*Id.*) Thus, Novartis suggests that the 180-day limitation should have been equitably tolled until the PTO's January 20, 2010 announcement that it would not seek further appellate review of the Federal Circuit's *Wyeth* decision.

With respect to its RCE Claim, Novartis goes even further, asserting that because no federal court has yet ruled on the viability of this claim, the statute of limitations has not yet begun to run. (*Id.* at 49.) Novartis insists that it was not until this claim was raised by Abbott Laboratories in *Abbott v. Kappos*, 10-cv-1853 (D.D.C.), filed on October 29, 2010, that Novartis even became aware that this was a possible claim. (*Id.*)

Novartis' arguments are unpersuasive. In effect, Novartis' position amounts to a contention that the statute of limitations should not begin to run until such time as a federal court has actually ruled on and upheld the very claims they seek to pursue. But of course, Novartis was free to raise the same issues that Wyeth and Abbott Laboratories raised in their lawsuits within the 180 days after their patents were granted. As this Circuit has previously noted:

> The only sure way to determine whether a suit can be maintained is to try it. The application of the statute of limitations cannot be made to depend upon the constantly shifting state of the law, and a suitor cannot toll or suspend the running of the statute by relying upon the uncertainties of controlling law. It is incumbent upon him to test his right and remedy in the available forums. These suits were not commenced until through the labor of others the way was made clear.

Commc'ns Vending Corp. of Arizona, Inc. v. FCC, 365 F.3d 1064, 1075 (D.C. Cir. 2004) (quoting *Fiesel v. Bd. of Educ.*, 675 F.2d 522, 524-25 (2d Cir. 1982)). It is of no moment that the PTO had consistently applied its pre-*Wyeth* interpretation of A/B Delay Overlap; the question is not what the PTO would have done in response to a request for reconsideration, but rather what a federal court would have done in reviewing the PTO's interpretation. That was both unasked and unanswered until Wyeth raised exactly this issue in its lawsuit, just as Novartis was free to do at any point within 180 days of its patents being granted.

Regardless, contrary to Novartis' argument, a change in law is not such an extraordinary circumstance as to justify the application of equitable tolling. *See Nihiser v. White*, 211 F. Supp. 2d 125, 130-31 (D.D.C. 2002). Indeed, this case is analogous to *Venture Coal Sales Co. v. United States*, 370 F.3d 1102 (Fed. Cir. 2004), in which Venture Coal argued that its injury from the Coal Sales Tax was "inherently unknowable" until the tax was held unconstitutional in *Ranger Fuel Corp. v. United States*, 33 F. Supp. 2d 466 (E.D. Va. 1998). *See Venture Coal*, 370

F.3d at 1107. The Federal Circuit rejected that argument and noted that, just like Novartis here, Venture Coal argued "not that it lacked *sufficient facts* on which it could sue, but rather it did not know the *legal theory* on which its refund claim might succeed." *Id.*; *see also Nihiser*, 211 F. Supp. 2d at 131 ("[A]ll the relevant facts were known. It was the meaning of the law that was misunderstood.") (quoting *Catawba Indian Tribe of South Carolina v. United States*, 982 F.2d 1564, 1572 (Fed. Cir. 1993)). The court pointed out that "Venture Coal was entitled to challenge the Coal Sales Tax when it paid the taxes as much as were the plaintiffs in *Ranger Fuel*." *Venture Coal*, 370 F.3d at 1106.

None of the cases relied on by Novartis undercut *Venture Coal*. In each case, the "change in circuit precedent" that was found sufficient to justify equitable tolling related to the statute of limitations itself; in other words, the law changed in such a way that the petitioners' habeas filings, which would otherwise have been considered timely, no longer were. *See, e.g.*, *Shelton v. Purkett*, 563 F.3d 404, 407 (8th Cir. 2009) ("Because Shelton's petition was just barely timely under *Nichols*, it is clear that under the *Riddle* rule . . . Shelton's petition was untimely."); *Griffin v. Rogers*, 399 F.3d 626, 636 (6th Cir. 2005) ("This 30-day window was adopted by the *Palmer* Court in January 2002 . . . [y]et Griffin failed to file within this 30-day window in October 1998, over three years before the time frame was adopted in this circuit."); *York v. Galetka*, 314 F.3d 522, 528 (10th Cir. 2003) (allowing equitable tolling because petitioner filed his habeas petition over a year before the Supreme Court decision holding that pendency of federal habeas petition does *not* toll statute of limitations); *Harris v. Carter*, 515 F.3d 1051, 1055-56 (9th Cir. 2008) ("[Harris] filed successive petitions for state post-conviction relief while ensuring that enough time would remain to file a federal habeas petition under the

then-existing *Dictado* rule. The Supreme Court's overruling of the *Dictado* rule made it impossible for Harris to file a timely petition."). In these and other similar cases, equitable tolling was justified because the unforeseeable change in law made it impossible for the petitioners to file their petitions in a timely fashion. That is a far cry from this case. Novartis benefited from the change in law but it could have (as Wyeth did) attempted to effectuate that very change through a timely challenge to the PTO's PTA determinations.

In light of these considerations, even assuming that § 154(b)(4)(A) is not jurisdictional, the facts in this case do not justify the application of the equitable tolling doctrine to Novartis' nineteen untimely complaints.

C. Discovery Rule

As its final attempt to skirt the 180-day limitation of § 154(b)(4)(A), Novartis argues that its untimely complaints should be permitted under the discovery rule. The "discovery rule" provides that "a cause of action accrues when the injured party discovers—or in the exercise of due diligence should have discovered—that it has been injured." *Hardin v. Jackson*, 625 F.3d 739, 743 (D.C. Cir. 2010) (quoting *Nat'l Treasury Emps. Union v. FLRA*, 392 F.3d 498, 501 (D.C. Cir. 2004)).

This is nothing more than a rehash of Novartis' equitable tolling argument. Novartis claims that it did not discover that it had suffered an injury until a definitive federal court ruling was issued on the merits of its legal claims. (*See* Pls.' Mot. at 53-54.) For its *Wyeth* Claim, that ruling came from the Federal Circuit in January 2010. For its RCE Claim, however, no such court ruling has occurred to date and so Novartis suggests that it has not yet discovered any injury resulting from the PTO's actions.

As is the case with the equitable tolling doctrine, it can be debated as to whether the discovery rule even applies to § 154(b)(4)(A). The PTO suggests that because Congress specified that the statute of limitations would begin to run as of the date the patent was granted, Congress implicitly rejected the use of a discovery rule, whereby the statute of limitations would begin to run when the injury is first discovered by the injured party. (Def.'s Mot. at 24-25.)

However, as previously discussed, the Court need not resolve this question because it finds that the discovery rule, even if available under § 154(b)(4)(A), would not be applicable to this case. The injury that Novartis alleges is a procedural one—that the PTO misapplied the statutory procedure for PTA determination and harmed Novartis' interest in obtaining the full patent term to which it is entitled. However, as of the date that each patent was granted, Novartis knew the amount of PTA it had been awarded and knew what procedure the PTO had used in making that determination; all of the *facts* underlying Novartis' injury were both knowable and in fact *known* by Novartis as of that date. Thus, the 180-day limitations period began to run on that date, and Novartis' failure to challenge the PTA determinations within that 180-day period rendered nineteen complaints untimely.

The Court will now turn to the merits relating to the four patents (the '155, '518, '031, and '792 patents) as to which Novartis has raised timely claims.

III. RCE CLAIM

For three of the four timely-challenged patents, Novartis asserts that the PTO improperly calculated the amount of B Delay to which it was entitled under § 154(b)(1)(B). That section provides:

> [I]f 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) . . . the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

35 U.S.C. § 154(b)(1)(B). As explained above, the PTO has promulgated a regulation interpreting § 154(b)(1)(B) as meaning: (1) that any time consumed by an RCE is excluded from the B Delay determination, even if it occurs after the three-year window has closed; and (2) that "time consumed by" an RCE extends until the issuance of the patent. *See* 37 C.F.R. § 1.703(b)(1). Novartis challenges both of these interpretations. Because 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.

The PTO and Novartis disagree about the proper interpretation of § 154(b)(1)(B). Both parties agree that the statutory provision has two parts: a "trigger" provision and a "remedy" provision. First, it identifies a three-year period running from the date of the filing of the application. If a patent is not issued within that three-year period—the "trigger"—then the statute provides for a "remedy." The parties disagree, however, about whether the "not including" clause applies to the trigger or to the remedy.

The PTO has interpreted the "not including" clause to be a part of the remedy provision; in other words, if a patent has not issued within three years of its filing date, the patentee shall be entitled to a day-for-day patent term adjustment for every day until the patent issues, but "not including" any time consumed by an RCE. (*See* Def.'s Mot. at 33.) Novartis insists that the clause applies to the trigger. Under Novartis' view, if the patent is not issued within the three-year period, "not including" time consumed by an RCE, then the patentee is entitled to the day-

for-day remedy. (Pls.' Mot. at 21-22.) In other words, the filing of an RCE tolls the running of the three-year clock, but if the three-year clock runs out, the applicant would be entitled to a day-for-day patent term adjustment for every day until the patent issues, regardless of what activity occurred during that time—even an RCE. (*Id.*)

This exact issue was recently decided by the Eastern District of Virginia in *Exelixis, Inc. v. Kappos*, 2012 WL 5398876 (E.D. Va. Nov. 1, 2012). The issue in that case—as here—was "whether § 154(b)(1)(B) requires that, or even addresses whether, any PTA be reduced by time attributable to an RCE where, as here, the RCE is filed *after* the expiration of the three year guarantee period specified in that statute." *Id.* at *2 (emphasis added). Like Novartis, Exelixis argued that "the PTO improperly calculated B delay by not providing a day for day PTA for time consumed by the RCE filed after the three year period had expired." *Id.* at *5. And just as it did in this case, the PTO argued that "the time consumed by an RCE is always excluded from the calculation of B delay because, in the PTO's view, any time consumed by an RCE is subtracted from the PTA awarded under subparagraph (B), regardless of when the RCE is filed." *Id.*

Judge Ellis agreed with Exelixis' interpretation. First and foremost, he concluded that the plain and unambiguous language of § 154(b)(1)(B) makes clear that the three-year clock is tolled by the filing of an RCE, but 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 *6. In other words, the "not including" language of § 154(b)(1)(B) "clearly and unambiguously modifies and pertains to the three year period and does not apply to, or refer to, the day for day PTA remedy." *Id.*

Second, Judge Ellis noted that the plain meaning of § 154(b)(1)(B) was supported by that section's structure and purpose. Specifically, the statute is designed to provide compensatory

PTA for delays attributable to the PTO, while reducing PTA for delays attributable to the applicant. However, the filing of an RCE is not one of the listed categories of "applicant delay" provided for in § 154(b)(2)(C). Thus, Judge Ellis concluded that it was erroneous for the PTO to punish applicants for filing RCEs. *Id.* at *6-7.

Judge Ellis also thoroughly dispensed with the very arguments that the PTO has raised in this case. For example, in response to the PTO's insistence that its construction of § 154(b)(1)(B) should be entitled to *Skidmore* deference, Judge Ellis pointed out that "*Skidmore* deference is unwarranted, when, as here, the statute is unambiguous." *Id.* at *8. Similarly, he flatly rejected the PTO's argument that the plain language of § 154(b)(1)(B) renders the subsequent section—§ 154(b)(1)(C)—superfluous. *Id.* at *8 n. 16. And finally, Judge Ellis addressed the PTO's argument that Exelixis' proposed construction could lead to disparate treatment of some similarly-situated applicants, depending on which side of the three-year line the applicant files his RCE on. *Id.* In doing so, he reiterated the Federal Circuit's admonishment that, "[r]egardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities." 591 F.3d at 1370. Judge Ellis also noted that it is within the PTO's power to minimize this disparate treatment by issuing timely notices of rejection such that RCEs must be filed within the three-year period. *Exelixis*, 2012 WL 5398876, at *8.

This Court finds Judge Ellis' well-reasoned opinion to be persuasive. It will therefore adopt his rationale for concluding that the PTO's interpretation is contrary to the plain and unambiguous language of § 154(b)(1)(B), and that it contravenes the structure and purpose of the statute.

Additionally, the Court notes one further consideration, not addressed by the parties in this case but raised by Abbott Biotherapeutics in *Abbott v. Kappos*, 10-cv-1853 (D.D.C.) that helps to bolster the conclusion reached here. Abbot notes that the PTO's position here—as embodied in 37 C.F.R. § 1.703(b)—is in conflict with another of the PTO's regulations. (*See* Plaintiff's Reply at 6-7, *Abbott v. Kappos*, No. 10-1853, July 18, 2012 [ECF No. 31].) Specifically, § 1.703(b) applies the "not including" language of § 154(b)(1)(B) to the "remedy" provision of that section. It states that:

> The period of adjustment under § 1.702(b) is the number of days, if any, in the prior beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) . . . , 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 an [RCE] was filed and ending on the date the patent was issued.

37 C.F.R. § 1.703(b). That section is therefore consistent with the PTO's position in this litigation: the "trigger" occurs if a patent is not issued within three years after the application's filing date, and the "remedy" consists of day-for-day PTA after that time, but does not include any time consumed by an RCE. (Def.'s Mot. at 32-33.)

However, that regulation is in tension with the immediately preceding PTO regulation, 37 C.F.R. § 1.702(b), which applies the "not including" language of § 154(b)(1)(B) to the "trigger" provision of that section and considers RCE in determining whether the three-year clock has run. It states:

> [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).

37 C.F.R. § 1.702(b). In other words, § 1.702(b) adopts the plain meaning of § 154(b)(1)(B), which is advocated by Novartis but disputed by the PTO in this case. It 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. Thus, if both regulations 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).

In response to Abbott's argument, the PTO appears to offer no explanation of the inconsistency between § 1.702(b) and its position in this litigation, or the inconsistency between § 1.702(b) and § 1.703(b). Instead, the PTO ignores both the plain language of the statute and the text of § 1.702(b) and advocates an inconsistent interpretation of § 1.703(b). These apparent inconsistencies further bolster the Court's view that the PTO's interpretation of § 154(b)(1)(B) is contrary to law.

In sum, the PTO's interpretation of § 154(b)(1)(B) contravenes the plain meaning of the statutory language and therefore must be set aside as "not in accordance with law" and "in excess of statutory . . . authority" pursuant to 5 U.S.C. § 706(2)(A) and (C).

IV. *WYETH* CLAIM

In *Wyeth*, the Federal Circuit held that the PTO's interpretation of § 154(b)(2)(A) regarding the calculation of A/B Delay Overlap was improper. *See* 591 F.3d at 1372. After the Federal Circuit's ruling, the PTO announced that it would not seek further review of the decision and would use the proper method of calculating A/B Delay Overlap both going forward and for patents issued before March 2, 2010, so long as the request for recalculation was filed within 180

days of the issuance of the patent.[3] (AR166-175). Novartis argues that the PTO's decision not to apply the post-*Wyeth* calculation method to the patents issued before September 2, 2009 was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. (Pls.' Mot. at 17-18.) Although Novartis initially alleged that eleven of the patents at issue in this case were entitled to additional PTA because of the PTO's failure to apply *Wyeth*, only one of those patents—the '792 patent—was timely challenged in this Court.

As an initial matter, it is noteworthy that the PTO failed to respond to Novartis' *Wyeth* claim, so the Court may treat this argument as conceded. *See Day v. D.C. Dep't of Consumer & Regulatory Affairs*, 191 F. Supp. 2d 154, 159 (D.D.C. 2002).

Regardless, under the PTO's own policy, the *Wyeth* method of calculating A/B Delay Overlap should have been applied to the '792 patent. Specifically, on March 10, 2010, the PTO wrote a letter to the Patent Public Advisory Committee in which it explained its position on the application of *Wyeth* to previously-issued patents. The PTO explained:

> The USPTO is acting consistent with the judicial review provisions of 35 U.S.C. § 154(b)(4) in limiting patent term adjustment recalculations to patentees who either: (1) filed a request for patent term adjustment recalculation that has not yet been decided within the 180-day period in 35 U.S.C. § 154(b)(4); or (2) are currently engaged in a challenge, in the USPTO *or the courts*, to the USPTO's patent term adjustment determination that was commenced within the 180-day period in 35 U.S.C. § 154(b)(4).

[3] Novartis asserts that this effectively set the cut-off date for recalculation at September 2, 2009. However, it appears to the Court that the post-*Wyeth* interpretation was actually available to patents issued on or after August 1, 2009. The policy discussed above was announced in the Federal Register on February 1, 2010; thus, for any patent issued on or after August 1, 2009 (180 days prior to that announcement), the patentee would have been able to seek reconsideration of its PTA determination. Regardless, the PTO has not disputed Novartis' characterization of its policy. Moreover, only one of the patents at issue in this case was granted in the window between August 1 and September 2, 2009—U.S. Patent No. 7,576,221—and as the challenge to that patent was not timely filed, this appears to be a distinction without a difference.

(AR183 (emphasis added).) Novartis first filed a complaint in this Court regarding the '792 patent on June 30, 2009. (*See Novartis v. Doll*, 09-1203 [ECF No. 1] (D.D.C. June 30, 2009).) As explained above, although that complaint was not filed within 180 days of the issuance of the '792 patent, it was filed within 180 days of the PTO's denial of its request for reconsideration. Thus, under normal tolling rules, which this Court has held apply to § 154(b)(4), at the time of the Federal Circuit's *Wyeth* decision, Novartis was "currently engaged in a challenge, in . . . the courts, to the USPTO's patent term adjustment determination that was commenced within the 180-day period in 35 U.S.C. § 154(b)(4)." (AR183.) The PTO's refusal—with no explanation whatsoever—to follow its own policy and apply *Wyeth* to the '792 patent contravenes the APA. In particular, the PTO failed to consider the relevant factors and to "articulate[] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made,'" as required by the arbitrary and capricious standard. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

In addition to violating its own policy, the PTO's refusal to apply *Wyeth* to the '792 patent is contrary to well-established law. The '792 patent was issued on December 30, 2008, a full two months after the district court opinion in *Wyeth*. 580 F. Supp. 2d 138. Novartis sought agency reconsideration of its PTA determination in February 2009, in part based on the district court's *Wyeth* ruling. (A1011-14.) In June 2009, the PTO declined to apply the *Wyeth* method of calculating overlap to the '792 patent. (A1015-21.) This was erroneous. The Supreme Court has made it clear that it is "error to refuse to apply a rule of federal law retroactively after the case announcing the rule has already done so." *James B. Beam Distilling Co. v. Georgia*, 501 U.S. 529, 540 (1991). The district court's *Wyeth* opinion was applied retroactively to Wyeth;

Wyeth's patent terms were adjusted in accordance with the newly-announced rule in that case. Thus, when Novartis filed for reconsideration almost five months later, the PTO abused its discretion by refusing to calculate Novartis' patent consistently with the method adopted in *Wyeth*. Its decision to do so "violate[d] the principle of treating similarly situated parties the same." *Nat'l Fuel Gas Supply Corp. v. FERC*, 59 F.3d 1281, 1289 (D.C. Cir. 1995).

For these reasons, the Court finds that the PTO erred in not applying either this Court's or the Federal Circuit's *Wyeth* decision to the '792 patent.

V. FIFTH AMENDMENT TAKINGS CLAIM

As its final argument, Novartis asserts that by applying its erroneous interpretations of § 154(b)(1)(B), the PTO deprived Novartis of its property interest in its patent term without compensation in violation of the Takings Clause of the Fifth Amendment. (Pls.' Mot. at 54.)

With respect to the nineteen patents for which Novartis did not timely challenge the PTA determinations under § 154(b)(4)(A), this argument is untimely and cannot now be raised.

Moreover, the Court need not address this argument as it relates to the remainder of Novartis' patents. With respect to Novartis' RCE Claim, this argument is moot, as the Court has already ordered the very remedy that Novartis seeks. Specifically, this Court ruled that the PTO's refusal to award B Delay for time consumed by an RCE filed after the three-year deadline was erroneous and ordered the PTO to recalculate the PTA determinations for three of Novartis' patents. (*See supra* Section III.) Similarly, the Court has already ruled that the PTO acted arbitrarily and capriciously in not applying the *Wyeth* method of calculating A/B Delay Overlap to the '792 patent, and has ordered the PTO to recalculate the PTA determinations for that patent.

(*See supra* Section IV.) Thus, the Court need not determine whether either of the PTO's errors amounted to a constitutional violation.

CONCLUSION

For the reasons stated above, plaintiffs' motion for summary judgment is granted in part and denied in part, and defendant's motion for summary judgment is granted in part and denied in part. A separate Order accompanies this Memorandum Opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

DATE: November 15, 2012