

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DAIICHI SANKYO COMPANY, LIMITED,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 10-215 (RWR)
)	
TERESA STANEK REA,)	
)	
Defendant.)	
)	

MEMORANDUM OPINION

Plaintiff Daiichi Sankyo Company, Limited ("Daiichi") brings suit under 35 U.S.C. § 154(b)(4)(A) and the Administrative Procedure Act, 5 U.S.C. § 501 et seq., against the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("USPTO")¹ alleging that the USPTO improperly calculated the patent term adjustments ("PTA") for Daiichi's United States Patent Nos. 7,365,205 ("`205 patent"), 7,342,014 ("`014 patent"), and 7,576,135 ("`135 patent"). Daiichi and the USPTO cross-move for summary judgment. Because Daiichi did not timely file its challenge to the USPTO's PTA determinations, the USPTO's cross-motion for summary judgment will be granted and Daiichi's cross-motion for summary judgment will be denied.

¹ Teresa Stanek Rea is substituted as the defendant under Federal Rule of Civil Procedure 25(d).

BACKGROUND

I. LEGAL BACKGROUND

In the United States, patents are granted “for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.” 35 U.S.C. § 154(a)(2). “However, the prosecution of a patent application may take more than three years. In order to ensure that all patents have terms of at least seventeen years,” the Patent Act allows the Director of the USPTO to adjust the term of a patent to account for certain delays that may occur during patent prosecution (i.e., to make a PTA determination). Janssen Pharmaceutica, N.V. v. Rea, 928 F. Supp. 2d 102, 103 (D.D.C. 2013); see also 35 U.S.C. § 154(b).

One category of delay that is excluded from the calculation of the patent term, known as “A delay,” “extend[s] the term of the patent one day for each day the PTO does not meet certain examination deadlines[.]” Wyeth v. Kappos (Wyeth II), 591 F.3d 1364, 1367 (Fed. Cir. 2010) (citing 35 U.S.C. § 154(b)(1)(A)). This delay is excluded because the Patent Act guarantees “prompt Patent and Trademark Office responses.” 35 U.S.C. § 154(b)(1)(A). “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.” Novartis AG v. Kappos, 904 F. Supp. 2d 58, 61 (D.D.C. 2012).

A second category of excludable delay, known as “B delay,” “extends the term of the patent one day for each day issuance is delayed due to the PTO’s failure ‘to issue a patent within 3 years after the actual filing date of the application in the United States.’” Wyeth II, 591 F.3d at 1367 (quoting 35 U.S.C. § 154(b)(1)(B)). This delay is excluded because the Patent Act guarantees “no more than [a] 3-year application pendency.” 35 U.S.C. § 154(b)(1)(B). “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.” Novartis, 904 F. Supp. 2d at 61.

“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.” Id. at 62. “To the extent that periods of [A delay and B delay] overlap, any [PTA] shall not exceed the actual number of days the issuance of the patent was delayed.” 35 U.S.C. § 154(b)(2)(A). “Because the overlap determination depends on the amount of B Delay, it is also done at the time the patent is granted.” Novartis, 904 F. Supp. 2d at 62.

In 2004, the USPTO issued a regulation explaining its methodology to calculate A/B Overlap. See Revision of Patent Term Extension and Patent Term Adjustment Provisions, 69 Fed.

Reg. 21706-01 (Apr. 22, 2004) ("2004 Notice"). On September 30, 2008, in Wyeth v. Dudas (Wyeth I), 580 F. Supp. 2d 138, 141-42 (D.D.C. 2008), the district court found that the USPTO's A/B Overlap methodology, as described in the 2004 Notice, was contrary to the plain language of § 154(b). The USPTO appealed the decision, and the Federal Circuit affirmed the district court's decision in Wyeth II. Wyeth II, 591 F.3d at 1369-70.

On February 1, 2010, the USPTO issued an Interim Procedure setting forth its procedure for recalculating PTAs using the correct A/B Overlap methodology. See Interim Procedure for Patentees to Request a Recalculation of the Patent Term Adjustment, 75 Fed. Reg. 5043-01 (Feb. 1, 2010). The Interim Procedure established that the USPTO would recalculate the PTA for any patent that had been issued in the 180 days before the announcement of the Interim Procedure -- that is, any patent issued on or after August 5, 2009. Id. at 5044.

The final determination of PTA -- which factors in A Delay, B Delay, and A/B Overlap -- is done at the time the patent is granted. Novartis, 904 F. Supp. 2d at 62. If the patent applicant disagrees with the PTA determination, the applicant may "request reconsideration of any patent term adjustment determination made by the Director," id. § 154(b)(3)(B)(ii), "within two months of the date the patent issued," 37 C.F.R. § 1.705(d) (2012). "[O]n petition of the interested party,"

("Rule 183 petition") the two-month limitation "may be suspended or waived by the Director or the Director's designee" "[i]n an extraordinary situation, when justice requires." 37 C.F.R. § 1.183 (2013).

II. FACTUAL BACKGROUND

Daiichi is the assignee of the '205, '014, and '135 patents. 2d Am. Compl. ¶ 8. Patent Application Serial No. 10/481,262 issued as the '205 patent on April 29, 2008. Id. ¶ 9. The patent issued with a notice that its term would be extended by 504 days under 35 U.S.C. § 154(b) (i.e., the final PTA determination is 504 days) subject to the patentee's terminal disclaimer over the '014 patent.² Id. ¶¶ 9, 31.

Patent Application Serial No. 10/773,344 issued as the '014 patent on March 11, 2008. Id. ¶ 10. The patent issued with a notice that its term would be extended by 357 days under 35 U.S.C. § 154(b) subject to the patentee's terminal disclaimer over the '205 patent. Id. ¶¶ 10, 33.

² A "terminal disclaimer" is a statement in which an applicant or patent owner "disclaims or dedicates to the public the entire term or any terminal part of the term of a patent or patent to be granted." See Manual of Patent Examining Procedures § 1490(II) (citing 37 C.F.R. § 1.321(b)); see also 35 U.S.C. § 253(b) (providing that "any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted"). In other words, the patent applicant or owner gives up the term of a granted patent which would extend beyond the expiration date of a prior patent. As such, the term of the granted patent expires on the same date that the prior patent expires.

Patent Application Serial No. 10/540,259 issued as the '135 patent on August 18, 2009. Id. ¶ 11. The patent issued with a notice that its term would be extended by 86 days under 35 U.S.C. § 154(b) subject to the patentee's terminal disclaimer over the '014 and '205 patents. Id. ¶¶ 11, 35. In other words, Daiichi disclaimed the part of the '135 patent term that extended beyond the expiration date of the '014 and '205 patents. Thus, in effect, the '135 patent expires on the same day as the '014 and '205 patents expire.

On February 2, 2009, Daiichi requested that the Director reconsider her March 11, 2008 and April 28, 2008 PTA determinations for the '014 and '205 patents respectively and filed Rule 183 petitions seeking a waiver of the two-month limit for filing a request for reconsideration. Id. ¶ 43. The USPTO denied Daiichi's Rule 183 petitions and denied its requests for reconsideration as untimely. Def.'s Cross-Mot. & Opp'n, Exs. 3-4.

On February 12, 2010, Daiichi filed suit against the USPTO alleging that the USPTO improperly calculated the PTA for the '135 patent. Daiichi asserted that the correct PTA for the '135 patent is 504 days. Compl. ¶ 1. In April 2010, the matter was "remanded to the USPTO for recalculation and adjustment of plaintiff's patent term [for the '135 patent] in accordance with [Wyeth II]." Order, entered 4/20/10. On remand, the USPTO

recalculated the PTA for the '135 patent and issued a Certificate of Correction stating that "[s]ubject to any disclaimer, the term of the ['135] patent is extended or adjusted under 35 U.S.C. § 154(b) by 503 days." Def.'s Cross-Mot. & Opp'n, Ex. 1. However, because the '135 patent is terminally disclaimed by the '014 and '205 patents, any part of the term of the '135 patent that extends beyond the terms of the earlier '014 and '205 patents is disclaimed. "Accordingly, although the USPTO has reinstated the term it denied the '135 patent at issuance, the reinstatement has no practical effect" because the terms of the '014 and '205 patents expire before the amended term of the '135 patent expires. See Pl.'s Mot. for Summ. J., Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. ("Pl.'s Mem.") at 4.

On November 9, 2010, Daiichi filed an amended complaint alleging that the USPTO also incorrectly calculated the PTA for the '014 and '205 patents.

The parties now cross-move for summary judgment.

DISCUSSION

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

In a case involving review of a final agency action under the APA, . . . [the court has a] limited role of . . . reviewing the administrative record. 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. Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.

Nat'l Parks Conservation Ass'n v. Jewell, Civil Action No. 12-1690 (RWR), 2013 WL 4616972, at *2 (D.D.C. Aug. 30, 2013) (alterations, internal quotation marks, and citations omitted) (quoting Ctr. for Food Safety v. Salazar, 898 F. Supp. 2d 130, 138 (D.D.C. 2012)).

A patent applicant can challenge the USPTO's PTA determination under 35 U.S.C. § 154(b)(4)(A). The Act provided at the time³ that

[a]n 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. [The APA] shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

35 U.S.C. § 154(b)(4)(A) (2006). The '014 patent issued on March 11, 2008, and the '205 patent issued on April 28, 2008.⁴

³ As the parties note, see Joint Submission Regarding Amendments to 35 U.S.C. § 154(b), the relevant statutory language has been amended. However, the parties agree that the original version of § 154(b) applies here. Id. at 2.

⁴ Under § 154(b)(4)(A), the 180-day limitations period for the '014 patent ended on September 7, 2008 and the 180-day limitations period for the '205 patent ended on October 25, 2008.

However, Daiichi did not bring this suit until February 10, 2010.⁵ Accordingly, the USPTO argues that because Daiichi did not file its complaint within 180 days of issuance of the '014 or '205 patents, Daiichi's suit is untimely. Daiichi argues that the 180-day limitations period does not apply to this case but that, even if it does, the limitations period should be equitably tolled. The USPTO counters that the statute of limitations is jurisdictional and not subject to equitable tolling.⁶

I. WHETHER 35 U.S.C. § 154(b) (4) (A) APPLIES TO FINAL PTA DETERMINATIONS

Daiichi contends that § 154(b) (4) (A) does not apply to the final PTA determinations at issue in this case. Instead, Daiichi asserts that, under the plain language of the statute, the 180-day limitations period applies only to the USPTO's determination of A Delay. Section 154(b) (4) (A) applies to an applicant's challenge of a determination made "under paragraph (3)." Section 154(b) (3) provides:

⁵ Moreover, Daiichi did not seek review of the USPTO's PTA determinations of the '014 and '205 patents in its original complaint. Instead, it first challenged the USPTO's determinations in its first amended complaint, which was filed on November 9, 2010.

⁶ The USPTO does not argue that its interpretation of § 154(b) is entitled to deference under Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), and courts to have considered this issue have found that the USPTO's determination is not entitled to such deference because the USPTO does not have authority to issue substantive rules, see Novartis, 904 F. Supp. 2d at 64; Wyeth I, 580 F. Supp. 2d at 141.

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall -

(i) 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 of the application under section 151; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

35 U.S.C. § 154(b) (3). Daiichi admits that § 154(b) (3) (A) "provides the authority for and requires the Director of the USPTO to establish general procedures for determining PTA." Pl.'s Mem. at 13. However, § 154(b) (3) (B) refers to the PTA determination sent with the notice of allowance. Because only the A Delay determination is sent at that time, Daiichi argues that "the unambiguous interpretation of Section 154(b) (3) is that it relates solely to [A Delay]." Pl.'s Mem. at 12. Thus, Daiichi argues that the "paragraph (3)" determination referred to in § 154(b) (4) (A) includes only the Director's determination of A Delay, and the general APA statute of limitations applies to an applicant's challenge of a final PTA determination.

When interpreting a statute, courts begin by looking at the statutory text. Caminetti v. United States, 242 U.S. 470, 485 (1917). "[I]f a statute is 'plain and unambiguous,' . . . '[the court's] analysis ends with the text.'" Cook v. Food & Drug Admin., 733 F.3d 1, 9 (D.C. Cir. 2013) (quoting Chao v. Day, 436

F.3d 234, 235 (D.C. Cir. 2006)). The plain meaning of a "paragraph (3)" determination is any determination that could be made under § 154(b)(3). This includes any PTA determination made under the regulations the Director promulgated under § 154(b)(3)(A), which includes A Delay, B Delay, and A/B Overlap, as well as the Director's A Delay determination referred to in § 154(b)(3)(B). This interpretation of "paragraph 3" includes the entirety of the determinations that could be made under § 154(b)(3) and does not construe "paragraph (3)" to mean only "paragraph (3)(B)." Congress knows how to limit a provision to a certain subparagraph. See Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 176-77 (1994) (comparing statutory provisions and finding that "Congress knew how to impose aiding and abetting liability when it chose to do so"). For example, earlier in § 154, Congress referred specifically to "an adjustment under paragraph (2)(c)" rather than referring generally to "paragraph (2)." See 35 U.S.C. § 154(b)(3)(C) (stating that "[t]he Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C)" in certain circumstances). Because in § 154(b)(4)(A) Congress used the broader phrase, "paragraph (3)," the plain meaning of the statute is that the 180-day limitations period applies to any determination made under § 154(b)(3) -- including the final PTA determination.

Furthermore, Daiichi's argument was squarely rejected in Novartis, 904 F. Supp. 2d 58, and Janssen Pharmaceutica, N.V. v. Kappos, 844 F. Supp. 2d 707 (E.D. Va. 2012). In Novartis, Judge Huvelle considered that the title of the subsection -- Procedures for patent term adjustment determination -- is generic and does not suggest that the section is limited only to A Delay, and the fact that it "is the only section of the statute to address the PTO's procedures for determining PTA," and found that the section "is clearly intended to relate to all PTA determinations, regardless of when they occur." Novartis, 904 F. Supp. 2d at 65. She further reasoned that her interpretation of the statute is not only "consistent with the plain meaning of the statute," but also it "avoids absurd results." Id. Specifically, she sought to avoid an interpretation of the statute where "a patentee would have 180 days in which to challenge the calculation of A Delay but six years [under the APA, 28 U.S.C. § 2401(a),] in which to challenge B Delay and A/B Delay Overlap." Id.

In Janssen, Judge Brinkema found that "[o]n its face, § 154(b)(4)(A) applies to all PTA decisions made by the Director applying the USPTO's own regulations before issuance of a patent." Janssen, 844 F. Supp. 2d at 712. She stated that the plain intent of the statute is "to strictly limit the forum and timing for seeking judicial review of these very specific USPTO decisions." Id. at 713. Thus, she reasoned that if applicants

could seek post-issuance review of the USPTO's PTA determinations under the APA, "the very limitations on judicial review Congress included in the patent statute" "would [be] eviscerate[d]." Id. She further explained that "it would be absurd for Congress to impose limitations on the specific statutory judicial review mechanisms (i.e., § 154(b)(4)(A)) when it simultaneously intended to allow a patentee to seek generic APA review of the very same question, (i.e., the number of days of PTA to which the . . . patent is entitled) without any of those same restrictions." Id. (emphasis and internal quotation marks omitted). Accordingly, she held that

in 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.

II. EQUITABLE TOLLING

Daiichi argues that the 180-day limitations period is not jurisdictional and should be equitably tolled in this case. The USPTO opposes.

A. Whether § 154(b)(4)(A) is jurisdictional

"The Supreme Court has distinguished between prescriptions that may be 'properly typed jurisdictional,' and those better classified as 'claim-processing rules[.]'" Menominee Indian Tribe of Wis. v. United States, 614 F.3d 519, 523 (D.C. Cir.

2010) (quoting Scarborough v. Principi, 541 U.S. 401, 413-14 (2004)). A jurisdictional rule "governs a court's adjudicatory capacity, that is, its subject-matter or personal jurisdiction." Henderson ex rel. Henderson v. Shinseki, 131 S. Ct. 1197, 1202 (2011). Claim-processing rules are those "that seek to promote the orderly progress of litigation by requiring that the parties take certain procedural steps at certain specified times." Id. at 1203. Unlike a jurisdictional rule, "a nonjurisdictional federal statute of limitations is normally subject to a 'rebuttable presumption' in favor 'of equitable tolling.'" Holland v. Florida, 130 S. Ct. 2549, 2560 (2010) (quoting Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 95-96 (1990)).

Under the "'readily administrable bright line'" rule the Supreme Court established in Arbaugh v. Y&H Corp., 546 U.S. 500 (2006), to decide whether a rule is jurisdictional, courts "look to see if there is any 'clear' indication that Congress wanted the rule to be 'jurisdictional.'" Henderson, 131 S. Ct. at 1203 (quoting Arbaugh, 546 U.S. at 515-16). "Congress, of course, need not use magic words in order to speak clearly on this point. '[C]ontext, including [the Supreme] Court's interpretation of similar provisions in many years past, is relevant.'" Id. (quoting Reed Elsevier, Inc. v. Muchnick, 559 U.S. 154, 168 (2010)).

For example, courts have found that 28 U.S.C. § 2253(a), (b), and (c)(1), 28 U.S.C. § 2501(a), and 28 U.S.C. § 2401(a) contain unambiguous jurisdictional language. See Gonzalez v. Thaler, 132 S. Ct. 641, 649 (2012) (28 U.S.C. § 2253(a), (b), and (c)(1)); John R. Sand & Gravel Co. v. United States, 552 U.S. 130, 132-34 (2008) (28 U.S.C. § 2501(a)); Spannaus v. U.S. Dep't of Justice, 824 F.2d 52, 55 (D.C. Cir. 1987) (28 U.S.C. § 2401(a)). Section 2501(a) states: "Every claim of which the United States Court of Federal Claims *has jurisdiction shall be barred* unless the petition thereon is filed within six years after such claim first accrues." 28 U.S.C. § 2501(a) (emphasis added). Section 2401(a) provides that "every civil action commenced against the United States *shall be barred* unless the complaint is filed within six years after the right of action first accrues." 28 U.S.C. § 2401(a) (emphasis added). Section 2253(a) states: "In a habeas corpus proceeding or a proceeding under section 2255 before a district judge, the final order *shall be subject to review*, on appeal, by the court of appeals for the circuit in which the proceeding is held." 28 U.S.C. § 2253(a) (emphasis added). Section 2253(b) limits that grant to the appeals court, stating that

[t]here *shall be no right of appeal* from a final order in a proceeding to test the validity of a warrant to remove to another district or place for commitment or trial a person charged with a criminal offense against the United States, or to test the validity of such person's detention pending removal proceedings.

28 U.S.C. § 2253(b) (emphasis added). Section 2253(c) (1) provides that “[u]nless a circuit justice or judge issues a certificate of appealability, an appeal may not be taken to the court of appeals from” a final order in habeas corpus proceeding or proceeding under 28 U.S.C. § 2255. 28 U.S.C. § 2253(c) (1) (emphasis added).

Although “[f]iling deadlines . . . are quintessential claim-processing rules,” Henderson, 131 S. Ct. at 1203, the USPTO argues that, like the jurisdictional statutes listed above, § 154(b) (4) (A) bars any suit that is filed after a certain limitations periods and thus, should be considered jurisdictional. See 35 U.S.C. § 154(b) (4) (A) (2006) (stating that a patent applicant has a “remedy by a civil action” that is filed “within 180 days after the grant of the patent”). However, the USPTO has not demonstrated that § 154(b) (4) (A) includes unambiguous jurisdictional terms such as “jurisdiction,” that it states that suits not filed timely are “barred,” or that it explicitly establishes procedures that must be met before the applicant can file suit. Compare 28 U.S.C. § 2501(a), 28 U.S.C. § 2401(a), 28 U.S.C. § 2253(a), 28 U.S.C. § 2253(b), and 28 U.S.C. § 2253(c) (1), with 35 U.S.C. § 154(b) (4) (A) (“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.”). Thus, the USPTO has not shown that § 154(b)(4)(A) “speak[s] in jurisdictional terms or refer[s] in any way to the jurisdiction of the district courts.” Zipes v. Trans World Airlines, Inc., 455 U.S. 385, 394 (1982). Because courts should be hesitant to find that a rule is jurisdictional, see Gonzalez, 132 S. Ct. at 648, and the USPTO has not shown that § 154(b)(4)(A) contains jurisdictional language, the court holds that the provision is not jurisdictional. Cf. Novartis, 904 F. Supp. 2d at 67 (finding that “it is perhaps more prudent to conclude that § 154(b)(4)(A) should be viewed as a ‘claim-processing rule’” “[i]n light of . . . recent admonishments to construe the meaning of ‘jurisdictional’ narrowly”). Because § 154(b)(4)(A) is not jurisdictional, there is a rebuttable presumption that it is subject to equitable tolling.⁷

B. Whether § 154(b)(4)(A) should be equitably tolled

“[E]quitable tolling -- as a method for adjusting the rights of two ‘innocent parties’ -- merely ensures that the plaintiff is not, by dint of circumstances beyond his control, deprived of a ‘reasonable time’ in which to file suit.” Chung v. U.S. Dep’t of Justice, 333 F.3d 273, 279 (D.C. Cir. 2003) (quoting Cada v. Baxter Healthcare Corp., 920 F.2d 446, 452 (7th Cir. 1990)).

⁷ The USPTO does not attempt to rebut this presumption.

"Generally, a litigant seeking equitable tolling bears the burden of establishing two elements: (1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way." Pace v. DiGuglielmo, 544 U.S. 408, 418 (2005). Courts must decide whether to equitably toll a statute of limitations period on a "'case-by-case basis.'" Holland, 130 S. Ct. at 2563 (quoting Baggett v. Bullitt, 377 U.S. 360, 375 (1964)). However, courts "extend[] equitable relief only sparingly." Irwin, 498 U.S. at 96.

Daiichi argues that the statute of limitations should be equitably tolled because extraordinary circumstances prevented it from timely pursuing its rights. Specifically, Daiichi asserts that it reasonably relied on the correctness of the USPTO's methodology for calculating A/B Overlap described in the 2004 Notice, and thus, did not challenge the USPTO's PTA determination for the '014 and '205 patents. Pl.'s Mem. at 28-29. Accordingly, Daiichi contends that the 180-day limitations period should be equitably tolled until the district court decided Wyeth I in September 2008.⁸

⁸ Daiichi's argument assumes that, under general tolling principles, the 180-day limit would have been tolled while its petitions for reconsideration and Rule 183 petitions were pending before the Director. Because Daiichi has not shown that the limitations period should be equitably tolled in this case, whether the limitations period was tolled by Daiichi filing petitions for reconsideration and Rule 183 petitions is not addressed.

To toll a statute of limitations, a

[p]laintiff must either show that defendant has concealed its acts with the result that plaintiff was unaware of their existence or it must show that its injury was "inherently unknowable" at the accrual date. . . . In [the second] situation the statute will not begin to run until plaintiff learns or reasonably should have learned of his cause of action.

Japanese War Notes Claimants Ass'n of Phil., Inc. v. United States, 373 F.2d 356, 359 (Ct. Cl. 1967) (footnote omitted) (quoting Urie v. Thompson, 337 U.S. 163, 169 (1949)). In particular, equitable tolling may be appropriate where failure to meet a statute of limitations "is the result of justifiable reliance on the advice of [a] government officer." See Jarrell v. U.S. Postal Serv., 753 F.2d 1088, 1092 (D.C. Cir. 1985); see also Bull S.A. v. Comer, 55 F.3d 678, 681 (D.C. Cir. 1995). In determining whether equitable tolling is justified in such a case, courts distinguish between a government officer's or agency's advice on the limitations period and the officer's or agency's understanding of the party's substantive legal rights.

On the one hand, a statute of limitations may be equitably tolled where a party reasonably relies on a government officer's incorrect advice regarding the limitations period. For example, in Bull, the Commissioner of Patents and Trademarks gave Bull S.A. an incorrect renewal deadline for Bull's trademark in a signed and sealed Certificate of Renewal. Bull, 55 F.3d at 679. Bull applied to renew its trademark on the incorrect deadline in

the Certificate of Renewal, but was informed that it had missed the correct, statutory renewal deadline, and that it was unable to renew its trademark. Id. The D.C. Circuit found that the statutory renewal deadline should be equitably tolled because Bull justifiably relied on the Commissioner's incorrect renewal deadline. Id. at 682 ("The facts of this case support Bull's claim of justifiable reliance: Bull received an official government document, published under the signature and Seal of the Commissioner, that certified a renewal lasting until May 15, 1992. Once in receipt of this document, and, as detailed below, absent any circumstances that would alert Bull to the error, Bull was entitled to rely on its validity." (emphasis omitted)).

On the other hand, a statute of limitations may not be equitably tolled where a party relies on the government officer's or agency's interpretation of the party's legal rights. See, e.g., Venture Coal Sales Co. v. United States, 370 F.3d 1102 (Fed. Cir. 2004); Catawba Indian Tribe of S.C. v. United States, 982 F.2d 1564 (Fed. Cir. 1993).⁹ In Venture Coal Sales, the

⁹ In Catawba Indian Tribe, the Federal Circuit considered whether the Catawba Indian Tribe's claims were barred by a six-year statute of limitations. Catawba Indian Tribe, 982 F.2d at 1569. In that case, the Tribe argued that a representative of the Bureau of Indian Affairs had assured the Tribe that the Catawba Indian Tribe Division of Assets Act, 25 U.S.C. §§ 931-938 (1988), would not affect the Tribe's rights to its ancestral lands. Catawba Indian Tribe, 982 F.2d at 1567. Later, the Supreme Court construed the Act in such a way as to cause the Tribe to lose a portion of its land. See id. at 1571-72. The Tribe argued that the statute of limitations for claims regarding

plaintiffs paid a Coal Sales Tax on all of the coal they produced. Id. at 1103. In 1997, the district court in the Eastern District of Virginia held the Coal Sales Tax unconstitutional because it violated the Export Clause of the United States Constitution, U.S. Const. art. I, § 9, cl. 5. Id. (citing Ranger Fuel Corp. v. United States, 33 F. Supp. 2d 466 (E.D. Va. 1998)). The plaintiffs argued that "the statute of limitations should be tolled because it did not know nor could it have known in the exercise of reasonable diligence that its claims [for a refund] had accrued." Id. at 1107. The plaintiffs asserted that their claims were "inherently unknowable" until the tax was held unconstitutional in 1997. Id. The Federal Circuit found that the plaintiffs knew that they had paid the Coal Sales Tax and knew of the Export Clause, and concluded that the plaintiffs "had all the facts necessary to initiate a claim against the United States." Id. The Federal Circuit rejected the plaintiffs' argument that equitable tolling was justified because the plaintiffs "did not know the *legal theory* on which

the Tribe's lands did not begin to run until the Supreme Court's decision. Id. The Federal Circuit recognized that equitable tolling may be justified in "the case when the facts necessary to know of the harm were intentionally withheld from the plaintiff by the defendant." Id. at 1572. However, it inferred that equitable tolling is not permissible where "all the relevant *facts* were known" but the plaintiff, such as the Tribe, misunderstood "the meaning of the law." See id. Thus, the court concluded that the statute of limitations should not be equitably tolled. See id.

[their] refund claim might succeed.” Id. The court explained that “‘ignorance of rights which should be known is not enough’” to toll a statute of limitations. Id. (alteration omitted) (quoting Japanese War Notes Claimants Ass’n, 373 F.2d at 359).

Daiichi insists that Bull should be applied in this case. However, unlike Bull, Daiichi does not argue that the USPTO misled it about the § 154(b)(4)(A) 180-day deadline or that Daiichi was otherwise unaware of the statute of limitations. Daiichi asserts that this is a “distinction without a difference,” Reply Mem. of P. & A. in Supp. of Pl.’s Mot. for Summ. J. & Mem. of P. & A. in Opp’n to Def.’s Cross-Mot. for Summ. J. (“Pl.’s Reply & Opp’n”) at 18, but provides no support for its assertion that Bull applies to this case despite this distinguishing factor.

Alternatively, Daiichi argues that Wyeth I was a change in law that justifies equitable tolling. See Pl.’s Reply & Opp’n at 15-17 (arguing that “[t]olling is appropriate here due to . . . [the] shift in law occasioned by Wyeth”). However, Daiichi has not shown that it was unable to pursue its rights until “such time as a federal court . . . ruled on and upheld the very claims [it] seek[s] to pursue.” Novartis, 904 F. Supp. 2d at 68. As in Venture Coal, Daiichi possessed all the facts necessary to challenge the USPTO’s PTA determinations before Wyeth I was decided. Daiichi does not dispute that it knew of the PTA

determinations for the '014 and '205 patents, the USPTO's methodology for calculating PTAs described in its 2004 Notice, and 35 U.S.C. § 154(b). Thus, Daiichi "was free to raise the issues that Wyeth . . . raised in [its] lawsuit[] within the 180 days after [its] patents were granted." Novartis, 904 F. Supp. 2d at 68. Accordingly, Daiichi has not shown that extraordinary circumstances exist that warrant equitable tolling.¹⁰

Even if Daiichi could demonstrate that extraordinary circumstances justify equitable tolling, it has not shown that it diligently pursued its rights to challenge the USPTO's PTA determinations. Daiichi asserts that it would have been futile to challenge the PTAs for the '014 and '205 patents before the district court decided Wyeth I but that it "diligently acted to preserve its rights" by filing Rule 183 Petitions and motions for reconsideration of the PTA determinations for the '014 and '205 patents less than 180 days after the Wyeth I decision and amending its complaint to challenge the PTA determinations for the '014 and '205 patents promptly after the USPTO denied its Rule 183 Petitions and motions for reconsideration. Pl.'s Mem.

¹⁰ Daiichi also argues that equitable tolling of the statute of limitations for its challenges of the '014 and '205 PTA determinations is necessary to correct the patent term for the '135 patent. Pl.'s Mem. at 31; Pl.'s Reply & Opp'n at 19-20. However, Daiichi does not provide any support for its argument that such a related effect justifies equitably tolling the statute of limitations. Furthermore, this argument does not explain why Daiichi did not timely challenge the '014 and '205 PTA determinations.

at 29-30. In Communications Vending Corp. of Arizona, Inc. v. FCC, 365 F.3d 1064, 1075 (D.C. Cir. 2004), the D.C. Circuit rejected a similar argument. In that case, the court found that the plaintiff's argument that it would have been futile to pursue its claim in light of the agency's interpretation of the governing law did not excuse the party from timely filing its claim. The court explained:

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.

Id. (quoting Fiesel v. Bd. of Educ., 675 F.2d 522, 524-25 (2d Cir. 1982)). Confronted in Novartis with the same argument as Daiichi raises in this case, Judge Huvelle relied on Communications Vending to conclude:

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 [the patent applicant] was free to do at any point within 180 days of its patents being granted.

Novartis, 904 F. Supp. 2d at 68. Thus, Daiichi has not shown that it was justified in not pursuing its rights until after Wyeth I was decided. Instead, Daiichi sat on its rights for

almost a year after the '014 and '205 patents issued, and has not demonstrated that equitable considerations exist for not diligently pursuing its rights to challenge the PTA determinations.

CONCLUSION

Section 154(b)(4)(A) applies to final PTA determinations. Although § 154(b)(4)(A) is subject to equitable tolling, Daiichi has not shown that extraordinary circumstances prevented it from timely challenging the PTA determinations for the '014 and '205 patents or that it has been diligently pursuing its rights. Therefore, the USPTO's motion for summary judgment will be granted and Daiichi's motion for summary judgment will be denied. A separate Order accompanies this Memorandum Opinion.

SIGNED this 3rd day of December, 2013.

/s/
RICHARD W. ROBERTS
Chief Judge