

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ACTELION PHARMACEUTICALS LTD.,)

Plaintiff,)

v.)

HON. DAVID J. KAPPOS,)

Defendant.)

Civil Case No. 10-01145 (RJL)

FILED

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MEMORANDUM OPINION
September 22 2013 [## 9, 10]

Plaintiff Actelion Pharmaceuticals Ltd. (“Actelion” or “plaintiff”) brought this suit against defendant David J. Kappos in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“USPTO”). Plaintiff claims that USPTO improperly determined the amount of patent term adjustment to which it is entitled. Before the Court are plaintiff’s Motion for Summary Judgment and defendant’s Cross-Motion for Summary Judgment. Upon consideration of the pleadings, record, and relevant law, plaintiff’s motion is DENIED and defendant’s motion is GRANTED.

BACKGROUND

Patents are issued by USPTO for a term ending 20 years from the date the patent application was filed, as opposed to the date the patent is issued. 35 U.S.C. § 154(a)(2). As a result, delays by USPTO in examining a patent application can reduce the effective term of that patent. *See Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010). To

address this issue, Congress provided that a patent term will be extended to account for certain delays. *See id.*; 35 U.S.C. § 154(b).

The procedures for determining such a “patent term adjustment” (“PTA”) are governed by § 154(b)(3). Several types of delay can figure into calculating the overall PTA, two of which are relevant for plaintiff in this case. First, so-called “A Delay” days accrue if USPTO fails to take certain specified actions within certain time periods, such as failing to respond to a patent application within 14 months of its filing. *See* § 154(b)(1)(A). Second, “B Delay” days accrue if USPTO fails to issue a patent within three years of the filing of the application. *See* § 154(b)(1)(B). After determining the proper amounts of A and B Delay, USPTO determines the extent of any overlap between the two types of delay to arrive at the overall PTA. *See* § 154(b)(2)(A).

USPTO makes an initial PTA determination prior to patent issue and includes it with the written “notice of allowance” informing an applicant that he is entitled to a patent. *See* 35 U.S.C. § 154(b)(3)(B)(i); 37 C.F.R. § 1.705(a) (2006). The applicant must pay an issue fee within three months; once payment occurs, USPTO issues the patent and determines the final PTA as of the date of the patent grant, noting this determination on the face of the patent. *See* 35 U.S.C. § 151; 37 C.F.R. § 1.705(d) (2006). If the applicant disagrees with the PTA, the statute entitles him to “one opportunity to request reconsideration of any [PTA] determination made by the Director.” 35 U.S.C. § 154(b)(3)(B)(ii).

Further, the statute permits the applicant to appeal USPTO’s PTA determination to a federal district court. Specifically, the statutory provision, entitled “Appeal of patent term adjustment determination,” provides:

An applicant dissatisfied with a determination made by the Director under paragraph (3) [Procedures for patent term adjustment determination] 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. Chapter 7 of title 5 [5 U.S.C. §§ 701-706] shall apply to such action . . .

§ 154(b)(4)(A) (2010).¹

On January 7, 2010, in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the Federal Circuit rejected USPTO’s method for determining A and B Delay overlap, finding that USPTO had relied on an erroneous interpretation of 35 U.S.C. § 154(b).² Following the *Wyeth* decision, USPTO changed its method for making future PTA determinations to align with the court’s holding. In addition, USPTO created an “Interim Procedure,” effective February 1, 2010, that permitted patentees to request a PTA recalculation from USPTO so long as their patent was issued prior to March 2, 2010 and their request for recalculation was filed within 180 days of the patent grant. See Interim Procedure, 75 Fed. Reg. 5043, 5043 (Feb. 1, 2010). Thus, in effect, only patents granted

¹ Effective September 16, 2011, the U.S. District Court for the Eastern District of Virginia now has jurisdiction for civil actions brought under this statute. See Pub. L. 112-29 at § 9(a), 125 Stat. 284, 316.

² Prior to the *Wyeth* decision, USPTO interpreted the “period of delay” for B Delay to include the entire time between the filing of an application and the issuance of a patent more than three years later. If USPTO took longer than three years to issue a patent, therefore, any A Delay that occurred during the pendency of the application necessarily overlapped with the period of B Delay, and was not credited to the patentee’s total PTA. Under this rubric, USPTO used either the greater of the A Delay or B Delay to determine the appropriate adjustment, but did not combine the two. *Wyeth*, 591 F.3d at 1368. In *Wyeth*, the Federal Circuit found USPTO’s interpretation of the overlap provision to be erroneous, and held that 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.

within the 180 days prior to February 1, 2010, were eligible for a PTA recalculation using the new post-*Wyeth* interpretation of A and B Delay overlap.

The material facts are not in dispute in the instant case. Plaintiff, a pharmaceutical company, holds U.S. Patent No. 7,094,781 (the “‘781 Patent”). Compl. [Dkt. # 1] ¶¶ 3, 9. The application for the ‘781 Patent was filed on May 27, 2003. *Id.* ¶ 8. USPTO issued the ‘781 patent on August 22, 2006, with a PTA of 312 days using its pre-*Wyeth* method of calculating A and B Delay overlap. *Id.* ¶ 11; Pl.’s Mot. Summ. J. and Mem. Supp. [Dkt. # 9] (“Pl.’s Mot.”) at 4. Plaintiff never filed a request for reconsideration of its PTA with USPTO. Def.’s Cross-Mot. Summ. J. and Mem. Supp. [Dkt. # 10] (“Def.’s Mot.”) at 2. And Plaintiff filed this civil action on July 6, 2010—more than 180 days after the August 22, 2006 patent grant. *See* Compl.

STANDARD OF REVIEW

Summary judgment is appropriate when the record shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The court will accept as true the evidence of the non-moving party, and draw “all justifiable inferences” in his favor. *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 255 (1986) (citation omitted). A genuine dispute about a material fact only exists if “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248.

ANALYSIS

Plaintiff moves for summary judgment, seeking a recalculation of its PTA based on the post-*Wyeth* methodology for computing A and B Delay overlap.³ Plaintiff attempts to achieve this result by bringing three claims. First, plaintiff claims USPTO improperly calculated its PTA and directly appeals that calculation under 35 U.S.C. § 154(b)(4)(A). Compl. ¶¶ 18-24; Pl.’s Mot. at 11-13. Next, plaintiff argues USPTO’s implementation of its post-*Wyeth* methodology and its failure to provide plaintiff the remedy of recalculating its PTA under that new methodology violated the Administrative Procedure Act (“APA”), 5 U.S.C. § 551 *et seq.* Compl. ¶¶ 25-28; Pl.’s Mot. at 13-15. Lastly, plaintiff argues USPTO’s failure to correct its PTA was a “taking” of property without due process or just compensation in violation of the Fifth Amendment of the Constitution. Compl. ¶¶ 29-30; Pl.’s Mot. at 16-18. Defendant cross-moves for summary judgment, arguing that plaintiff’s appeal under that statute is untimely, and that its APA and “taking” arguments are meritless.⁴ *See generally* Def.’s Mot. Because all material facts in this case are undisputed, and for the reasons discussed below, summary judgment in favor of defendant is appropriate.

³ Plaintiff asserts that such a recalculation would increase its PTA from 312 days to 361 days. Compl. ¶ 1.

⁴ I agree with defendant that plaintiff’s “taking” argument is meritless, and thus summarily dispose of it here, because plaintiff has proffered no legal support for the proposition that a patent *term* is a constitutionally protected property interest. *See, e.g., United States v. Willow River Power Co.*, 324 U.S. 499, 503 (1945) (threshold inquiry for Fifth Amendment taking claim is whether the interest is a property right).

I. Statutory Claim

Challenges to USPTO's determination of a PTA are governed by 35 U.S.C. § 154(b)(4)(A), which specifically provides that such appeals must be filed with this District Court "*within 180 days after the grant of the patent.*" § 154(b)(4)(A) (emphasis added). Plaintiff filed the instant action on July 6, 2010, well over 180 days—in fact, *nearly four years*—after the '781 Patent was granted on August 22, 2006. The plain language of the applicable statute therefore renders plaintiff's complaint untimely. The only question, then, is whether the 180-day filing deadline should not apply to plaintiff for some reason.

Plaintiff argues that the time limit in § 154(b)(4)(A) is not jurisdictional and is instead a "claim-processing rule," and therefore it should be equitably tolled to allow plaintiff's suit due to the change in the law effectuated by *Wyeth*. See Pl.'s Mot. at 11-13; *Holland v. Florida*, 130 S. Ct. 2549, 2560 (2010) (non-jurisdictional statutes of limitation may be equitably tolled). Defendant counters that § 154(b)(4)(A)'s time limit is jurisdictional and thus bars plaintiff's claim because jurisdictional filing deadlines are not susceptible to equitable tolling. See Def.'s Mot. at 5-10; *Dolan v. United States*, 130 S. Ct. 2533, 2538 (2010) (court may not extend a jurisdictional deadline for equitable reasons). In the alternative, defendant argues that, even if the time limit is non-jurisdictional, plaintiff does not warrant the extraordinary remedy of equitable tolling. See Def.'s Mot at 10-16.

Thus, as an initial matter, this Court must decide whether the statute is jurisdictional. See *Henderson ex. rel. Henderson v. Shinseki*, 131 S. Ct. 1197, 1202

(2011) (“federal courts have an independent obligation to ensure that they do not exceed the scope of their jurisdiction, and therefore they must raise and decide jurisdictional questions that the parties either overlook or elect not to press”); *Obaydullah v. Obama*, 688 F.3d 784, 788 (D.C. Cir. 2012). For the following reasons, I find that the 180-day time limit for seeking judicial review is, in fact, jurisdictional, and because plaintiff filed suit after that deadline, plaintiff’s statutory claim under § 154(b)(4)(A) is untimely and this Court lacks subject matter jurisdiction to hear it.

For threshold requirements to bringing suit, such as the time limit at issue here, the Supreme Court has drawn a distinction between “jurisdictional” rules and “claim-processing rules.” A jurisdictional rule is one that “governs a court’s adjudicatory capacity, that is, its subject-matter or personal jurisdiction.” *Henderson*, 131 S. Ct. at 1202; *see also Kontrick v. Ryan*, 540 U.S. 443, 455 (2004). By contrast, non-jurisdictional “claim-processing rules” are “rules that seek to promote the orderly progress of litigation by requiring that the parties take certain procedural steps at certain specified times.” *Henderson*, 131 S. Ct. at 1203.

The distinction between jurisdictional conditions and claim-processing rules is, most unfortunately, less clear than this simple formulation might suggest.⁵ In order to

⁵ “While perhaps clear in theory, the distinction between jurisdictional conditions and claim-processing rules can be confusing in practice. Courts—including [the Supreme Court]—have sometimes mischaracterized claim-processing rules or elements of a cause of action as jurisdictional limitations.” *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 161 (2010). As a result of “profligate” use of the term “jurisdictional” by courts, *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 510 (2006), the Supreme Court has endeavored to narrow the meaning of “jurisdictional” in an attempt to “bring some discipline to the use of this term.” *Henderson*, 131 S. Ct. at 1202; *see Gonzalez v. Thaler*, 132 S. Ct. 641, 648 (2012). In particular, the Supreme Court has focused the relevant inquiry on Congress’ intent and emphasized that rules should be presumed to be non-jurisdictional absent a clear intent otherwise.

determine whether a given rule is jurisdictional, therefore, a court must look to Congress' intent. *See id.* at 1203 (the court must “look to see if there is any ‘clear’ indication that Congress wanted the rule to be ‘jurisdictional’”).⁶ In turn, to ascertain Congress' intent, a court must examine the “condition's text, context, and relevant historical treatment.” *Chevron Mining, Inc. v. NLRB*, 684 F.3d 1318, 1328 (D.C. Cir. 2012) (quoting *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 166 (2010)); *see also Henderson*, 131 S. Ct. at 1204-06 (examining text of the time limit provision, its placement within the statute, and “the singular characteristics of the review scheme that Congress created” to ascertain Congress' intent). In the absence of such a clear intent, a court should presume that a rule is *not* jurisdictional. *See Arbaugh v. Y&H Corp.*, 546 U.S. 500, 515-16 (2006); *Reed Elsevier, Inc.*, 559 U.S. at 161; *Henderson*, 131 S. Ct. at 1202.

In the instant case, the Court's inquiry starts and ends with the text of the statutory provision because its language clearly indicates Congress' intent for the 180-day time limit to be jurisdictional. *See Gonzalez v. Thaler*, 132 S. Ct. 641, 648 (2012) (rule is jurisdictional if Congress “clearly states that a threshold limitation on a statute's scope shall count as jurisdictional” (quoting *Arbaugh*, 546 U.S. at 515)); *see also Menominee Indian Tribe of Wisconsin v. United States*, 614 F.3d 519, 524 (D.C. Cir. 2010) (if Congress “clearly stated” the limitation is jurisdictional, “our inquiry is over”). Section 154(b)(4)(A) places jurisdiction in a particular forum—the U.S. District Court for the District of Columbia—for review of particular claims—appeals of USPTO PTA

⁶ In *Henderson*—in the specific context of statutory time limits for review of administrative agency decisions—the Supreme Court expressly disclaimed applying “a categorical rule regarding review of administrative decisions.” *Henderson*, 131 S. Ct. at 1204. Instead, the Court reiterated that ascertaining Congress' intent is the relevant inquiry.

determinations filed *within 180 days of the patent grant*. The statute thus “speak[s] in jurisdictional terms,” *Arbaugh*, 546 U.S. at 515, because it defines and limits the subject matter jurisdiction of this particular District Court: Congress clearly identified not only *which court* could hear these claims, but *when*. See *Bowles v. Russell*, 551 U.S. 205, 210-13 (2007) (holding statute-based time limit in 28 U.S.C. § 2107(c) is jurisdictional and stating, “[b]ecause Congress decides whether federal courts can hear cases at all, it can also determine when, and under what conditions, federal courts hear them”). There can be no doubt that if plaintiff had filed its claim in a different federal District Court, that court would have had no difficulty in concluding it lacked subject matter jurisdiction. Similarly, there is no reason why the 180-day time limit—which is part of the same and only statutory grant of jurisdiction—should be construed any differently by this Court as non-jurisdictional. Because the statutory provision both confers jurisdiction on this Court and identifies the point at which that jurisdiction ends, Congress’ jurisdictional grant to this Court is inextricably tied to that time limit. See *United States v. McGaughy*, 670 F.3d 1149, 1157-58 (10th Cir. 2012) (finding time limit set forth in Fed. R. Crim. P. 35 to be jurisdictional because the Rule is incorporated by reference in 18 U.S.C. § 3582(c), the statute granting courts authority to correct sentencing errors, and thus the time limit “is an integral part of the statutory grant of authority”); cf. *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 393-94 (holding Title VII provision specifying time limit for filing charges with Equal Employment Opportunity Commission (“EEOC”) is not jurisdictional, in part because “it does not speak in jurisdictional terms *or refer in any way to the jurisdiction of the district courts*” (emphasis added)). Indeed, this Court would not otherwise have

jurisdiction over a § 154(b)(4)(A) claim without the very statutory grant that contains the time limit. *Cf. Scarborough v. Principi*, 541 U.S. 401, 413-14 (2004) (holding statute-based time restriction is *not* jurisdictional because “[it] relates only to postjudgment proceedings auxiliary to cases *already within* that court’s adjudicatory authority” (emphasis added)).

Moreover, a review of § 154(b)(4)(A)’s context—namely, its structure and the placement of the time limit clause—further bolsters my conclusion that the time limit is jurisdictional. The 180-day time limit is located not only in the *same section* of the statute, but also in the *same provision* and the *same sentence* as the clause placing jurisdiction in this Court. This placement clearly evinces Congress’ intent that the time limit be jurisdictional. *Cf. Zipes*, 455 U.S. at 393-94 (holding Title VII provision specifying time limit for filing charges with EEOC is not jurisdictional, in part because it “appears as an entirely *separate provision* [from the Title VII jurisdiction provision located in the same section of the statute],” while conversely, “[t]he provision granting district courts jurisdiction . . . does not limit jurisdiction to those cases in which there has been a timely filing with the EEOC” (emphasis added)); *Arbaugh*, 546 U.S. at 515-16 (holding employee numerosity requirement for bringing Title VII action is not jurisdictional, in part because it is located in a separate provision in a *separate section* of the statute from Title VII’s jurisdiction-granting provision); *Reed Elsevier, Inc.*, 559 U.S. at 163-65 (holding statute requiring litigant to register his copyright claim before bringing an infringement action is not jurisdictional, in part because the requirement is located in a separate provision in a *different statute* from the applicable jurisdiction-granting statutes).

And while “[m]ere proximity will not turn a rule that speaks in nonjurisdictional terms into a jurisdictional hurdle,” *Gonzalez*, 132 S. Ct. at 651, here the 180-day time limit is not simply proximal to the jurisdiction-granting provision, it is an integral part of the sentence itself.

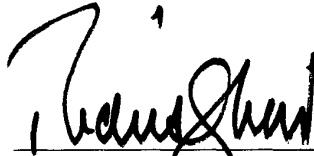
Finally, as for relevant historical treatment, the Court is not aware of, nor have the parties located, any precedent construing § 154(b)(4)(A).⁷ In the absence of prior treatment of the particular provision, the Supreme Court’s ““interpretation of similar provisions in many years past, is relevant to whether a statute ranks a requirement as jurisdictional.”” *Gonzalez*, 132 S. Ct. at 648 n.3 (quoting *Reed Elsevier, Inc.*, 559 U.S. at 168 (2010)). Here, defendant argues that § 154(b)(4)(A) is structurally similar to the statutes held to be jurisdictional in *Gonzalez v. Thaler* and *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130 (2008). See Def.’s Mot. at 8-9; Def.’s Reply to Pl.’s Opp’n [Dkt. # 14] at 3-4. But the Court need not turn to comparing statutes to decipher Congress’ intent in this case because the text of § 154(b)(4)(A) clearly indicates that Congress meant for the 180-day time limit to be jurisdictional.⁸ It really is that simple! Accordingly, defendant’s motion must be, and is, GRANTED.⁹

⁷ Plaintiff argues that my colleague on this Court, Judge Sullivan, recently held that § 154(b)(4)(A) is not jurisdictional and is subject to equitable tolling. Pl.’s Mot. at 11. But plaintiff is mistaken. In *Bristol-Myers Squibb Co. v. Kappos*, 841 F. Supp. 2d 238 (D.D.C. 2012), the court held the statute was subject to *general* tolling where the plaintiff had filed a timely request for reconsideration with USPTO. The court did *not* reach the question of whether the statute was jurisdictional, nor did it address equitable tolling. Further, to the extent Actelion’s pleadings could be construed as arguing that general tolling should apply, it is clear that argument fails. Under general tolling principles, a request for administrative reconsideration renders an agency’s action non-final and thus tolls any time limit for seeking judicial review of that agency action. See *Clifton Power Corp. v. FERC*, 294 F.3d 108, 110 (D.C. Cir. 2002). Since Actelion never sought administrative reconsideration, general tolling does not apply in this case.

⁸ In reaching this decision, the Court is mindful of the nuances and complexities of the case law addressing the legal character of threshold requirements. Threshold *time limits*, in particular, have

CONCLUSION

Thus, for the foregoing reasons, the Court DENIES plaintiff's Motion for Summary Judgment and GRANTS defendant's Cross-Motion for Summary Judgment. A separate Order consistent with this decision accompanies this Memorandum Opinion.



RICHARD J. LEON

United States District Judge

elicited divergent treatment from courts. Compare *Bowles v. Russell*, 551 U.S. 205, 210-13 (2007) (holding 28 U.S.C. § 2107(c)'s time limit for filing appeal is jurisdictional, and highlighting the Supreme Court's "longstanding treatment of statutory time limits for taking an appeal as jurisdictional") and *United States v. McGaughy*, 670 F.3d 1149, 1156 (10th Cir. 2012) ("[until *Gonzalez v. Thaler*,] *Bowles* seemed to provide clear guidance to the lower courts—statutory time limits are jurisdictional, non-statutory time limits are not") with *Henderson*, 131 S. Ct. at 1203 (stating "[f]iling deadlines, such as the [statute-based] 120-day filing deadline at issue here, are quintessential claim-processing rules" and rejecting the idea that *Bowles* held "categorically that every deadline for seeking judicial review in civil litigation is jurisdictional") and *Menominee Indian Tribe of Wisconsin v. United States*, 614 F.3d 519, 523 (D.C. Cir. 2010) ("Filing deadlines, statutory or not, are generally nonjurisdictional"). Nonetheless, as I have explained, Congress' intent is sufficiently clear from the text of § 154(b)(4)(A) to resolve the question here. See *Henderson*, 131 S. Ct. at 1203 ("Congress is free to attach the conditions that go with the jurisdictional label to a rule that we would prefer to call a claim-processing rule").

⁹ Plaintiff also argues that USPTO's implementation of *Wyeth*—its Interim Procedure for PTA determinations that did not apply *Wyeth* retroactively to all patents—violated the APA because it (1) was arbitrary and capricious, and (2) was not promulgated via notice-and-comment rulemaking pursuant to 5 U.S.C. § 553. See Pl.'s Mot. at 13-15. Neither argument is persuasive. First, plaintiff is foreclosed from using an APA claim to circumvent § 154(b)(4)(A)'s 180-day time limit to attain a PTA recalculation. "The APA provides for a limited waiver of sovereign immunity for '[a] person suffering legal wrong because of agency action . . . [h]owever, a plaintiff may not rely on this waiver 'if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.'" *Fraternal Order of Police v. Gates*, 562 F. Supp. 2d 7, 11 (D.D.C. 2008) (citing 5 U.S.C. § 702). Here, a statute—35 U.S.C. § 154(b)(4)(A)—expressly waives sovereign immunity for appeals of PTA determinations and makes them reviewable under the APA's judicial review provisions, 5 U.S.C. §§ 701-706. Therefore, plaintiff may not attempt an end-run around that statute's time limit by seeking redress under the APA generally. See *id.*; 5 U.S.C. § 704 (permitting judicial review only for "[a]gency action made reviewable by statute and final agency action for which there is *no other* adequate remedy" (emphasis added)). Second, USPTO was not required to use notice-and-comment rulemaking to devise the Interim Procedure because it is a procedural rule, not a substantive rule. See 5 U.S.C. § 553(b)(A); *Chamber of Commerce of the United States v. United States Dep't of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999).