

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

MICHELLE LEE,
*Deputy Under Secretary of Commerce for
Intellectual Property & Deputy Director of the
United States Patent & Trademark Office,*

Defendant.

Civil Action No. 10-1110 (BAH)

Judge Beryl A. Howell

MEMORANDUM OPINION

The plaintiff, Merck Sharp & Dohme Corp., brings suit against the defendant, Michelle Lee, the Deputy Under Secretary of Commerce for Intellectual Property & Deputy Director of the United States Patent and Trademark Office (“USPTO”), alleging that the defendant improperly calculated the adjustment period for its patent term.¹ Pending before the Court is the plaintiff’s Motion for Summary Judgment, ECF No. 18, and the defendant’s Cross-Motion for Summary Judgment, ECF No. 19. For the reasons set forth below, the plaintiff’s motion is granted and the defendant’s motion is denied.

I. BACKGROUND

A. Legal Background

Before enactment of the Uruguay Round Agreements Act (“URAA”) in 1994, the effective term of a patent ran seventeen years from patent issuance. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (“Prior to June 8, 1995, U.S. patents had an expiration date

¹ On January 13, 2014, Ms. Lee assumed the duties and functions of the Under Secretary of Commerce for intellectual Property and Director of the USPTO, a position that is currently vacant. Accordingly, in accordance with Federal Rule of Civil Procedure 25(d), Ms. Lee has been substituted as the named defendant.

under 35 U.S.C. § 154 measured as 17 years from the date the patent issued, except where terminal disclaimers were filed.”). The URAA amended the effective term of a patent from seventeen years commencing from issuance to twenty years from the date of filing. *See* 35 U.S.C. § 154(a)(2). Since the expiration of a patent is now keyed to the date on which the application for the patent was filed, delays by the USPTO during the prosecution of a given patent application may result in a reduction of the overall patent term. “[T]o compensate for certain application-processing delays caused by the PTO” that “now reduce a patent's term,” *Novartis AG v. Lee*, 740 F.3d 593, 596 (Fed. Cir. 2014), 35 U.S.C. § 154(b) provides that an applicant can receive an adjustment in patent term for various categories of USPTO delay. The delays at issue in this case are termed “A delays” and “B delays.”

“A delays” are set forth in 35 U.S.C. § 154(b)(1)(A), which is entitled “Guarantee of Prompt Patent and Trademark Office Responses.” An “A delay” accrues when the USPTO fails to take a specific action on the patent application within the time frame provided by statute and runs until that action is taken. An “A delay” “extends the term of the patent one day for each day the PTO does not meet certain examination deadlines” *Wyeth v. Kappos*, 591 F.3d 1364, 1367 (Fed. Cir. 2010).

“B delays” are set forth in 35 U.S.C. § 154(b)(1)(B), which is entitled “Guarantee of No More than 3-Year Application Pendency.” A “B delay” accrues when the USPTO fails to issue a patent within three years after the actual filing date of the application and runs until the patent is issued. *Id.* A “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’” *Wyeth*, 591 F.3d at 1367 (quoting 35 U.S.C. § 154(b)(1)(B)).

“A delays” and “B delays” are both subject to limitation under 35 U.S.C. § 154(b)(2). Under 35 U.S.C. § 154(b)(2)(A), to the extent that the periods of A delays and B delays overlap, the period of any adjustment in the length of the patent will “not exceed the actual number of days the issuance of the patent was delayed.”

The Director of the USPTO is charged with granting a patent term adjustment in accordance with the provisions of 35 U.S.C. § 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that “[t]he 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, notwithstanding any appeal taken by the applicant of such determination.” If a party wishes to appeal a decision of the Director, 35 U.S.C. § 154(b)(4), titled “Appeal of Patent Term Adjustment Determination,” provides, in pertinent part, that a “dissatisfied” applicant “shall have remedy by a civil action,” which is filed “in the United States District Court for the District of Columbia within 180 days after the grant of the patent.”²

Prior to 2010, the USPTO’s practice was to “use[] either the greater of the A delay or B delay to determine the appropriate adjustment but never [to] combine[] the two.” *Wyeth*, 591 F.3d at 1368. In 2010, the Federal Circuit in *Wyeth v. Kappos* rejected the USPTO’s practice, holding such a practice could not be reconciled with the language of the statute. *See id.* at 1371. According to the Court, the “B delay” is the period between the three-year mark after filing and the date the patent issues. *Id.* at 1369. An overlap between “A delays” and “B delays” occurs only when a violation of both provisions occurs at the same time. *Id.* In such a situation, the USPTO must add the “A delays” and “B delays” together and then reduce the adjustment by the

² As of September 16, 2011, the U.S. District Court for the Eastern District of Virginia is the proper venue for civil actions brought under this statute. *See* Pub. L. No. 112-29 at § 9(a), 125 Stat. 284, 316.

overlap between the delays, such that no calendar day is counted twice. *Id.* at 1371. The USPTO has now adopted the *Wyeth* standard.

B. Factual Background

The plaintiff is the assignee of the 7,326,708 patent (“the ’708 patent”). Compl. ¶ 9. The USPTO determined, under the pre-*Wyeth* standard, that under 35 U.S.C. § 154(b) the patent term adjustment for the ’708 patent was 657 days. Compl., Ex. 1, ECF No. 1–2. The defendant does not dispute that the determination of 657 days is incorrect in light of *Wyeth* because the USPTO failed to properly account for the “B delays.” *Compare* Pl.’s Statement of Undisputed Material Facts & Mem. Supp. Mot. Summ. J. at ¶¶ 22–24, ECF No. 18-1, *with* Def.’s Statement of Material Facts at ¶¶ 22–24, ECF No. 19 (noting only that such facts are not “material to the timeliness question.”). Under the *Wyeth* standard, the defendant does not dispute that the correct patent term adjustment for the ’708 patent is 883 days. *Id.*

C. Procedural Background

Although the ’708 Patent was issued on February 5, 2008, the plaintiff did not file this action, challenging the defendant’s determination of the patent term adjustment, until June 30, 2010—over two years after the patent issuance and only “after the 180 days provided for in 35 U.S.C. § 154(b)(4)(A).” *See* Pl.’s Statement of Material Facts ¶¶ 1, 25.

Prior to filing cross motions for summary judgment, the parties submitted a Joint Meet and Confer Report to the Court explaining their proposed schedule for the determination of the case. *See* Jt. Meet & Confer Rpt., ECF No. 15. Whereas, the plaintiff requested “a short period of discovery” prior to the filing of dispositive motions, the defendant sought to resolve the case “by cross motions for summary judgment without discovery.” *Id.* at 1–2. In its report to the Court, the plaintiff did not identify the reasons for its discovery request. *See id.* The defendant stated

its belief that “discovery is not appropriate” because “this action is a review of an administrative action that is to be done on the administrative record.” *Id.* at 5. To resolve the scheduling dispute, the parties appeared for a status hearing to address the need for discovery and to set a briefing schedule. *See* Transcript of Initial Status Conference (March 9, 2012) (“Status Hearing”), ECF No. 17. During the Status Hearing, the plaintiff stated its position that “there is probably going to be fact evidence [because] equitable tolling is a fact-bound inquiry.” *Id.* at 6. Primarily, the plaintiff was concerned that, in response to the plaintiff’s evidence in support of equitable tolling, the defendant would request to depose the plaintiff’s affiants and, absent discovery, the plaintiff would be unable to address any counter-evidence put forth by the defendant. *Id.* at 6. The defendant stated its view that the case was “straightforward” and that “[i]f the court rules that equitable tolling doesn’t apply, then the complaint is untimely and the government wins” but if “equitable tolling does apply, then the plaintiff wins.” *Id.* at 7.

In view of the defendant’s statement that the plaintiff would win “if equitable tolling does apply,” both the Court and the plaintiff sought to clarify the defendant’s position at the status hearing:

[Plaintiff’s Counsel]: Judge, I just want to make sure we are clear. Based on the government's comments, it seems like the only position or argument they are advancing is one of statutory construction, or one if equitable tolling applies they concede it applies in this case as a factual matter. If that's the case, then this case is much more simple. And it's really an issue of law, and I think there is a lot of Supreme Court precedents recently on that. And if the government is willing to concede that, we are ready to go forward.

[The Court]: Well, that's how I understood the government's statements in its Meet and Confer.

[Plaintiff’s Counsel]: So they don't contest a predicate that we meet the factual predicate for equitable tolling, just whether in fact equitable [tolling] can apply as a matter of law.

[The Court]: We are both understanding your position correctly; correct?

[Defense Counsel]: May I have a brief moment, Your Honor?

[The Court]: Yes, you may.

[Defense Counsel]: I think that's right, Your Honor.

Id. at 9–10.

As a result of the defendant's concession after conferring with colleagues during the status hearing, the Court dispensed with discovery and entered a scheduling order for the filing of cross motions for summary judgment. *See* Minute Order of March 9, 2012. Pending before the Court is the plaintiff's Motion for Summary Judgment, ECF No. 18, and the defendant's Cross-Motion for Summary Judgment, ECF No. 19.

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 56, summary judgment may be granted when the Court finds, based upon the pleadings, depositions, and affidavits and other factual materials in the record, “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), (c); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Wyeth Holdings Corp. v. Sebelius*, 603 F.3d 1291, 1296 (Fed. Cir. 2010); *Immunocept, L.L.C. v. Fulbright & Jaworski, L.L.P.*, 504 F.3d 1281, 1286 (Fed. Cir. 2007). The court must “credit all of the nonmovant's evidence and draw all justifiable inferences in its favor.” *Augme Technologies, Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1329 (D.C. Cir. 2014). Nevertheless, the nonmoving party must “adduce more than a mere scintilla of evidence in its favor.” *ERBE Elektromedizin GmbH v. Canady Technology LLC*, 629 F.3d 1278, 1287 (Fed. Cir. 2010). Summary judgment is properly granted against a party who “fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986);

Anderson, 477 U.S. at 248; *Wavetronix LLC v. EIS Electronic Integrated Systems*, 573 F.3d 1343, 1354 (Fed. Cir. 2009). In this case, the pending cross motions for summary judgment seek review of the plaintiff's legal challenge to USPTO's calculation of the patent term adjustment for the '708 patent. "[W]hen an agency action is challenged[] . . . [t]he entire case on review is a question of law, and only a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). This Court need not and ought not engage in lengthy fact finding, since "[g]enerally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions." *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085 (D.C. Cir. 1996); *see also Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) ("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.") (quotation marks and citation omitted); *McDonough v. Mabus*, 907 F. Supp. 2d 33, 42 (D.D.C. 2012); *Wilson v. McHugh*, 842 F. Supp. 2d 310, 315 (D.D.C. 2012); *Caez v. United States*, 815 F. Supp. 2d 184, 188 (D.D.C. 2011).

The parties agree on the material facts related to the calculation of the patent term adjustment for the '708 patent. The Court concurs that no material facts are in dispute and that this case presents a purely legal issue, warranting the entry of summary judgment for the party entitled to prevail as a matter of law.

III. DISCUSSION

The issue in this case is whether the time limit in 35 U.S.C. § 154(b)(4)(A)—providing that a plaintiff has 180 days to file a lawsuit contesting a USPTO patent term adjustment

determination—is subject to equitable tolling and, if so, whether equitable tolling applies to the plaintiff. The defendant does not dispute that the patent term adjustment determination for the plaintiff’s ’708 patent conflicts with the Federal Circuit’s decision in *Wyeth* and is therefore not in accordance with the law. The plaintiff does not dispute that it filed this legal challenge to the patent term adjustment outside of the 180-day window specified in 35 U.S.C. § 154(b)(4)(A). Nevertheless, the plaintiff argues that the Court should equitably toll the 180-day window, while the defendant maintains that 35 U.S.C. § 154(b)(4)(A) is a jurisdictional provision and is not subject to equitable tolling.³ *See* Def.’s Mem. Supp. Cross-Mot. Summ. J. & Opp’n Pl.’s Mot. Summ. J. (“Def.’s Mem.”) at 5, ECF No. 18-1.

The Court will therefore address: (1) whether the time limit in § 154(b)(4)(A) is a jurisdictional restraint on this Court’s power; (2) whether, if not, § 154(b)(4)(A) is subject to equitable tolling as a matter of law; and (3) whether, if § 154(b)(4)(A) is subject to equitable tolling, such tolling is appropriate in the instant case.

A. Section 154(b)(4)(A) Is Not Jurisdictional

“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.” *Grocery Mfrs. Ass’n v. E.P.A.*, 693 F.3d 169, 183 (D.C. Cir. 2012) (Kavanaugh, J., dissenting). Accordingly, the Supreme Court has “tried in recent cases to bring some discipline”

³ The USPTO does not argue that its interpretation of § 154(b) is entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837 (1984) or *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The Federal Circuit has held that the USPTO is not owed *Chevron* deference because it has no authority to issue substantive rules. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996); *see also Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) (“Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency.”). Moreover, deference is inappropriate when examining whether the Court has jurisdiction in the first instance. *See Fox Television Stations, Inc. v. F.C.C.*, 280 F.3d 1027, 1038–39 (D.C. Cir. 2002) (“[A]n agency’s interpretation of a statutory provision defining the jurisdiction of the court [is not] entitled to . . . deference under *Chevron*.”).

to the description of procedural rules as “jurisdictional.” *Henderson ex rel. Henderson v. Shinseki*, 131 S. Ct. 1197, 1202 (2011). The Supreme Court has drawn a distinction between procedural rules that may be “properly typed ‘jurisdictional,’” and rules “better classified as claim-processing rules.” *Menominee Indian Tribe of Wis. v. United States*, 614 F.3d 519, 523 (D.C. Cir. 2010) (internal quotation marks omitted). A jurisdictional rule “governs a court’s adjudicatory capacity, that is, its subject-matter or personal jurisdiction.” *Henderson*, 131 S. Ct. at 1202. Since each court has “an independent obligation” to ensure that it has subject matter over a dispute, a court must dismiss a case for lack of subject matter jurisdiction, even if months have been spent on the litigation and even if the parties have acknowledged the court’s jurisdiction. *Id.* By contrast, a claims-processing rule “serve[s] to inform a plaintiff of the time he has to file a claim or to ‘protect a defendant’s case-specific interest in timeliness.’” *Menominee*, 614 F.3d at 523 (quoting *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130, 133 (2008)).

To distinguish between jurisdictional rules and claim-processing rules, the Supreme Court has adopted a “‘readily administrable bright line’ for determining whether to classify a statutory limitation as jurisdictional.” *Sebelius v. Auburn Reg’l Med. Ctr.*, 133 S. Ct. 817, 824 (2013) (quoting *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 516 (2006)). A court must “inquire whether Congress has ‘clearly state[d] that the rule is jurisdictional.’” *Id.* (quoting *Arbaugh*, 546 U.S. at 515–16 (alterations in original)). A clear statement, however, does not require Congress to “incant magic words” but rather to “speak clearly.” *Id.* Even if “the limitation lacks a clear jurisdictional label,” the context and historical treatment of the statute may indicate that a provision is indeed jurisdictional. *See Menominee*, 614 F.3d at 524 (internal quotation omitted); *see also Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 166 (2010) (holding that a court must

look to “the conditions text, context and relevant historical treatment” of a statute). “[A]bsent such a clear statement . . . ‘courts should treat the restriction as nonjurisdictional in character.’” *Auburn Reg’l*, 133 S. Ct. at 824 (quoting *Arbaugh*, 546 U.S. at 515–16).

The Court will therefore examine the jurisdictional language of § 154(b)(4)(A) along with its context and history.

1. Section 154(b)(4)(A) Does Not Speak in Jurisdictional Terms

The statute at issue in the instant action, 35 U.S.C. § 154(b)(4), “Appeal of Patent Term Adjustment Determination,” provides, in relevant part: “(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. . . .”

Ordinarily, “[f]iling deadlines . . . are quintessential claim-processing rules.” *Henderson*, 131 S.Ct. at 1203; *see also Menominee*, 614 F.3d at 523 (“Filing deadlines, statutory or not, are generally nonjurisdictional.”). Nevertheless, the defendant maintains that 35 U.S.C. § 154(b)(4) is jurisdictional and bars the plaintiff from seeking relief in this court. *See* Def.’s Mem. Support at 5. The defendant makes three principal arguments in support of its position. Specifically, the defendant points to three statutes with statutory provisions alleged to be similar to the patent provisions at issue here and that courts have found to be jurisdictional. These statutes are 28 U.S.C. § 2253(a), (b) and (c)(1), 28 U.S.C. § 2501(a), and 28 U.S.C. § 2401(a). *See Gonzales v. Thaler*, 132 S.Ct. 641, 647–50 (2012) (acknowledging that 28 U.S.C. § 2253(a), (b), and (c)(1) are jurisdictional provisions but finding that 28 U.S.C. § 2253(c)(3) was nonjurisdictional); *John R. Sand & Gravel Co.*, 552 U.S. at 134–39 (declining to overturn prior precedent holding that 28 U.S.C. §2501(a) was jurisdictional); *Spannaus v. United States Dep’t of Justice*, 824 F.2d 52, 55

(D.C. Cir. 1987) (holding that 28 U.S.C. § 2401(a) was jurisdictional). The cases relied upon by the defendant cannot bear the weight the defendant places upon them.

Gonzalez v. Thaler found that Section 2253(a) speaks in jurisdictional terms when it states that “district courts’ final orders in habeas proceedings ‘*shall be subject to review, on appeal, by the court of appeals.*’” 132 S.Ct. at 647 (emphasis added). Likewise, Section 2253(b) speaks in jurisdictional terms when it states “[t]here *shall be no right of appeal* from a final order in a proceeding to test the validity of a warrant [of] remov[al].” *Id.* (alterations in original and emphasis added). Finally, Section 2253(c)(1) was jurisdictional because it stated that “[u]nless a circuit justice or judge issues a certificate of appealability, *an appeal may not be taken to the court of appeals . . .*” *Id.* at 648 (emphasis added). These statutory provisions plainly do not discuss time limits. Rather, the statutes concern whether an appellate court has the power to hear a claim in the first instance. As a result, the statute speaks in jurisdictional terms when it discusses the “right of appeal,” states that “an appeal may not be taken,” or provides that an order is “subject to review, on appeal, by the court of appeals.” There is no such similar language contained in 35 U.S.C. § 154(b)(4)(A), which, in contrast, discusses only a time limit for filing an action.

In *John R. Sand & Gravel Co.*, the Supreme Court relied not on any jurisdictional language found in 28 U.S.C. § 2501(a), but rather upon “basic principles of *stare decisis.*” 552 U.S. at 139. The Supreme Court acknowledged that decisions dating back to 1883 treated Section 2501(a) as jurisdictional and declined to upset that determination even in light of intervening case law seeking to rein in the description of such provisions as “jurisdictional.” *Id.* at 134, 138–39. There are no such *stare decisis* principles at issue here, where no appellate court has yet addressed the issue.

Spannaus also cannot save the defendant’s argument. As an initial matter, subsequent Supreme Court case law has eroded the decision’s foundations. See *Felter v. Kempthorne*, 473 F.3d 1255, 1260 (D.C. Cir. 2007) (discussing tension between the holding of *Irwin v. Dep’t of Veterans Affairs*, 498 U.S. 89 (1990) and *Spannaus*); see also *Harris v. Fed. Aviation Admin.*, 353 F.3d 1006, 1013 n.7 (D.C. Cir. 2004) (same). Moreover, the statute at issue in *Spannaus*, 28 U.S.C. § 2401, differs from 35 U.S.C. § 154(b)(4) in important ways. Section 2401(a) states that “every civil action commenced against the United States *shall be barred* unless the complaint is filed within six years” (emphasis added). This echoes the language of Section 2501(a), upheld in *John R. Sand & Gravel Co.*, which required that “[e]very claim of which the United States Court of Federal Claims has jurisdiction *shall be barred* unless the petition thereon is filed within six years” (emphasis added). As discussed above, *John R. Sand & Gravel Co.* was decided on the basis of *stare decisis*, not a finding of jurisdictional language. Nevertheless, even assuming that both Sections 2401 and 2501 “speak in jurisdictional terms,” the statute at issue does not. Section 154(b)(4) states only that an aggrieved party “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 civil action is not “barred” by the running of the time period.

The statute at issue in *Henderson v. Shinseki* provides the better statutory analogy. *Henderson* examined 38 U.S.C. § 7266(a), which provides that “[i]n order to obtain review by the Court of Appeals for Veterans Claims . . . a person adversely affected by [a decision of the Board of Veterans Appeals] shall file a notice of appeal with the Court within 120 days” According to the Supreme Court: “This provision ‘does not speak in jurisdictional terms or refer in any way to the jurisdiction of the [Veterans Court].’” 131 S.Ct. at 1204 (alterations in

original) (quoting *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 394 (1982)). The statutory language at issue here—an aggrieved party “shall have a remedy by civil action . . . within 180 days after the grant of the patent”—likewise “does not speak in jurisdictional terms.” *See Henderson*, 131 S.Ct. at 1204.

The defendant discounts the precedential value of *Henderson* because that case concerned an “Article I tribunal” and the special case of veterans benefits. *See* Def.’s Mem. at 8. Although *Henderson* addressed Article I tribunals, nothing in its reasoning, or that of other recent cases, suggests that it should be limited to statutes concerning Article I tribunals. Indeed, *Henderson* recognized precedent treating as nonjurisdictional statutes providing for district court review of administrative actions within set time-limits. *See* 131 S.Ct. at 1204 (“[L]ong before Congress enacted VJRA, we held that the deadline for obtaining review of Social Security benefits decisions in district court, 42 U.S.C. § 405(g), is not jurisdictional.” (citing *Bowen v. City of New York*, 476 U.S. 467, 478 & n.10 (1986))). Additionally, although acknowledging the “canon that provisions for benefits to members of the Armed Services are to be construed in the beneficiaries’ favor,” the Court also stated clearly that “the language of § 7266 provides no clear indication that Congress wanted that provision to be treated as having jurisdictional attributes.” *Id.* at 1205–06 (internal quotation marks omitted). The fact that the statute concerned veterans’ benefits simply buttressed the Court’s view, based on the statutory text, that the time-limit is nonjurisdictional. Congress must make a clear statement that a rule is jurisdictional, *see Auburn Reg’l Med. Ctr.*, 133 S.Ct. at 824, and given the lack of jurisdictional language, the context of the statute, and the special solicitude for veterans’ benefits, the Court in *Henderson* declined to read a clear statement into the statute.

Nevertheless, one court in this district has determined that 35 U.S.C. § 154(b)(4)(A) “speaks in jurisdictional terms.” In *Actelion Pharmaceuticals Ltd. v. Kappos*, 972 F. Supp. 2d 51 (2013), *aff’d without opinion* 565 Fed. App’x. 887 (Fed. Cir. 2014), the court held that Section 154(b)(4)(A) was jurisdictional “because its language clearly indicates Congress’ intent for the 180-day time limit to be jurisdictional.” 972 F. Supp. 2d at 56. The court reasoned that because the statute vested review exclusively in the District Court for the District of Columbia, the statute “defines and limits the subject matter jurisdiction of this particular District Court.” *Id.*

An alternative reading of Section 154(b)(4)(A) is that this provision granted venue to this District Court. The legislative history supports this alternative reading. Specifically, when §154(b)(4)(A) was amended to provide venue in the Eastern District of Virginia, the House Report noted that:

In 1999, as part of the American Inventors Protection Act (AIPA), Congress established that as a general matter the venue of the USPTO is the district where it resides. The USPTO currently resides in the Eastern District of Virginia. However, Congress inadvertently failed to make this change uniformly throughout the entire patent statute. As a result, certain sections of the patent statute . . . continue to allow challenges to USPTO decisions to be brought in the District of Columbia, a place where the USPTO has not resided in decades.

Because the USPTO no longer resides in the District of Columbia, the sections that authorize venue for litigation against the USPTO are consistently changed to reflect the venue where the USPTO currently resides.

H.R. Rep. No. 112-98, pt.1, at 49 (June 1, 2011).

This Court concludes that Section 154(b)(4)(A) does not strip the power to hear challenges from district courts; rather, it identifies the proper venue for the exercise of that power. *See Wachovia Bank v. Schmidt*, 546 U.S. 303, 316 (2006) (“Subject-matter jurisdiction . . . poses a ‘whether,’ not a ‘where’ question: Has the Legislature empowered the court to hear cases of a certain genre?”). Likewise, another court in this District, has held that § 154(b)(4)(A)

was not jurisdictional as it did not speak in jurisdictional terms for the same reasons identified above. *See Daiichi Sankyo Co. v. Rea*, No. 10-215, 2013 WL 6234571, at *7 (D.D.C. Dec. 3, 2013).⁴

2. *The Context and History Do Not Indicate that § 154(b)(4)(A) Is Jurisdictional*

Neither the context nor the history of 35 U.S.C. § 154(b)(4)(A) suggests the provision should be deemed jurisdictional. The heading of the provision “Contents and term of patent; provisional rights” does not suggest the statute is jurisdictional, nor do any other subchapters provide guidance. *See Henderson*, 131 S.Ct. at 1205 (examining context of statute within statutory scheme). Moreover, no clear line of precedent marks this rule as jurisdictional. *See Auburn Reg’l Med. Cntr.*, 133 S.Ct. at 825 (“This case is scarcely the exceptional one in which a ‘century’s worth of precedent and practice in American courts’ rank a time limit as jurisdictional.” (citing *Bowles v. Russell*, 551 U.S. 205, 209, n.2 (2007))).

* * *

Ultimately, the defendant has offered no justification to depart from the Supreme Court’s recent caselaw in which it has “repeatedly held that filing deadlines ordinarily are not jurisdictional” and has “described them as ‘quintessential claim-processing rules.’” *Auburn Reg’l*, 133 S.Ct. at 825 (citing *Henderson*, 131 S.Ct. at 1203). After “looking to the condition’s text, context, and relevant historical treatment,” *Reed Elsevier*, 559 U.S. at 166, Congress has not “clearly state[d]” that “the limitation should ‘rank . . . as jurisdictional.’” *Menominee*, 614 F.3d at 524 (ellipses and alterations in original) (quoting *Arbaugh*, 546 U.S. at 516). Accordingly, the

⁴ A third decision did not reach the question of whether the statute was jurisdictional, because even if the statute were not, the plaintiff could not demonstrate equitable tolling under the facts of the case. *See Novartis AG v. Kappos*, 904 F. Supp. 2d 58 (D.D.C 2012) *aff’d in part rev’d in part on other grounds sub nom. Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014) (“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.”).

Court holds that the 180 day filing period for a civil action contained in Section 154(b)(4)(A) is not jurisdictional.

B. Section 154(b)(4)(A) Is Subject to Equitable Tolling

“[A] non-jurisdictional federal statute of limitations is normally subject to a ‘rebuttable presumption’ in favor of ‘equitable tolling.’” *Holland v. Florida*, 560 U.S. 631, 645–46 (2010) (emphasis in original) (quoting *Irwin v. Dep’t of Veterans Affairs*, 498 U.S. 89, 95–96 (1990)); see also *Young v. United States*, 535 U.S. 43, 49 (2002) (“It is hornbook law that limitations periods are customarily subject to equitable tolling.” (internal quotation marks omitted)); *Daiichi Sankyo Co.*, 2013 WL 6234571, at *7 (“Because § 154(b)(4)(A) is not jurisdictional, there is a rebuttable presumption that it is subject to equitable tolling.”). In *Irwin v. Dep’t of Veterans Affairs*, the Supreme Court extended the presumption of equitable tolling to statutes governing suits against the government. 498 U.S. at 95–96 (“The same rebuttable presumption of equitable tolling applicable to suits against private defendants should also apply to suits against the United States.”). As such, there is a heightened presumption in favor of equitable tolling for statutes—like Section 154(b)(4)(A)—that were enacted post-*Irwin*, as Congress was “on notice” that the Court would give statutes a presumption of equitable tolling. See *Holland*, 560 U.S. at 646 (“The presumption’s strength is...reinforced by the fact that Congress enacted [the statute] after the Supreme Court decided *Irwin* . . .”).

Courts examine several factors to determine whether the presumption has been rebutted: “[T]he provision’s ‘detail, its technical language, the iteration of limitations in both procedural and substantive forms, . . . the explicit use of exceptions,’ . . . its ‘unusually emphatic form,’ and the ‘underlying subject matter’” *Menominee*, 614 F.3d at 530 (quoting *United States v. Brockamp*, 519 U.S. 347, 350, 352 (2010)). Importantly, any “focus on the regulatory scheme as

a whole is misplaced,” as the proper inquiry focuses on the statutory provision at issue. *Id.* Therefore, the fact that the statutory patent regime is complex and highly technical as a whole is irrelevant. Section 154(b)(4)(A) is straightforward, contains but a single limitation (the time limit), and lacks explicit exceptions. Moreover, Section 154(b)(4)(A) concerns a time limit for review by a district court as opposed to an agency’s internal review mechanisms. *See Auburn Reg’l*, 133 S. Ct. at 827 (“We have never applied the *Irwin* presumption to an agency’s internal appeal deadline”). There is nothing in the provision to suggest that Congress did not intend for equitable tolling to apply. Thus, the *Irwin* presumption has not been rebutted and 35 U.S.C. 154(b)(4)(A) is subject to equitable tolling.⁵

C. Equitable Tolling Applies in this Case

The case would be easily resolved on the factual issue of equitable tolling, but for the concession made at the Status Hearing by the defendant that the plaintiff met “the factual predicate for equitable tolling.” Status Hearing at 9–10. “[F]actual stipulations are ‘formal concessions . . . that have the effect of withdrawing a fact from issue and dispensing wholly with the need for proof of the fact.’” *Christian Legal Soc. v. Martinez*, 561 U.S. 661, 676 (2010) (ellipses in original) (quoting 2 K. Broun, MCCORMICK ON EVIDENCE § 254, p. 181 (6th ed. 2006)). Where a concession is “a knowing and intentional decision and not a mere oversight,” counsel may be held to its concession. *See United States v. Olejiya*, 754 F.3d 986, 993 (D.C. Cir. 2014) (discussing stipulation in context of sentencing hearing). Indeed, a court “will not review a belated challenge on an issue a party agreed not to dispute” *United States v. Laslie*, 716

⁵ In determining whether a limitations period may be equitably tolled, the D.C. Circuit has previously required that the plaintiff’s injury be “of a type familiar to private litigation.” *Menominee*, 614 F.3d at 529. In *Holland v. Florida*, however, the Supreme Court permitted equitable tolling under the Antiterrorism and Effective Death Penalty Act, a statute with no such private analogue. *See* 560 U.S. 631 (applying *Irwin* presumption without analysis of private litigation analogue); *Auburn Reg’l*, 642 F.3d 1145, 1149 n. 3 (D.C. Cir. 2011), *rev’d* 133 S.Ct. 817 (2013). In addressing whether equitable tolling applies to Section 154(b)(4)(A), courts have not engaged in such an analysis. *See, e.g., Novartis AG v. Lee*, 740 F.3d 593, 600 (Fed. Cir. 2014); *Daiichi Sankyo Co.*, 2013 WL 6234571 at *10.

F.3d 612, 615 (D.C. Cir. 2013). Similarly, “[u]pon entering into a stipulation on an element, a defendant waives his right to put the government to its proof of that element.” *United States v. Harrison*, 204 F.3d 236, 240 (D.C. Cir. 2000).

The defendant expends much energy in its briefing attempting to escape from the statement made by counsel during the Status Hearing in this matter. This is not surprising. Every court to consider the issue of whether a patent holder equitably tolls 35 U.S.C. § 154(b)(4)(A) when they bring suit after the 180-day window because of the changed law announced in *Wyeth* has rejected the equitable tolling argument. *See, e.g., Novartis AG v. Lee*, 740 F.3d 593, 600 (Fed. Cir. 2014) (“Novartis has not demonstrated that the 180-day rule of paragraph (b)(4) should be equitably tolled on the ground that Novartis could properly wait to challenge the PTO’s adjustment determinations until some other patentee undertook and completed the task of establishing the legal standard this court adopted in *Wyeth*.”); *Daiichi Sankyo Co.*, 2013 WL 6234571 at *10 (refusing to apply equitable tolling where the plaintiff “has not shown that it was justified in not pursuing its rights until after *Wyeth I* was decided”). Unfortunately for the defendant, however, counsel’s concession at the Status Hearing forecloses this argument.

At the Status Hearing, the Court asked whether the defendant’s position was properly understood to be that the plaintiff met “the factual predicate for equitable tolling,” but that equitable tolling was not available as a matter of law. Status Hearing at 9–10. After taking time to confer with other counsel, counsel for the defendant responded: “I think that’s right, your Honor.” *Id.* As a result of this concession, the plaintiff was denied the opportunity to further develop facts in support of its equitable tolling argument. The defendant will not be permitted to now escape from this concession. *See Oscanyan v. Arms Co.*, 103 U.S. 261, 263 (1881) (“The

power of the court to act in the disposition of a trial upon facts conceded by counsel is as plain as its power to act upon the evidence produced.”). Accordingly, in light of the defendant’s concession, the Court finds that equitable tolling is appropriate in this matter and that the present action was timely filed in this Court.

IV. CONCLUSION

For the foregoing reasons, the defendant’s motion for summary judgment is denied. The plaintiff’s motion for summary judgment is granted. Accordingly, the Court hereby remands the plaintiff’s claims to the USPTO for recalculation and adjustment of the patent term in accordance with *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). An appropriate Order accompanies this Memorandum Opinion.

Date: November 6, 2014



Digitally signed by Hon. Beryl A. Howell
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BERYL A. HOWELL
United States District Judge