

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

JANSSEN PHARMACEUTICA, N.V.,

Plaintiff,

v.

TERESA STANEK REA, Acting Under
Secretary of Commerce for Intellectual
Property and Acting Director of the United
States Patent and Trademark Office, *et al.*,

Defendants.

Civil Action No. 12-241 (CKK)

MEMORANDUM OPINION

(March 7, 2013)

Plaintiff Janssen Pharmaceutica, N.V., filed suit against Teresa Stanek Rea¹ in her official capacity as the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office and the United States Patent and Trademark Office (“USPTO,” collectively “Defendants”), alleging the Defendants improperly calculated the term of United States Patent No. 7,741,356 (“the ‘356 Patent”). Upon transfer of this action from the United States District Court for the Eastern District of Virginia, the Defendants moved to dismiss the complaint as untimely. Upon consideration of the pleadings,² the relevant legal authorities, and the record for purposes of this motion, the Court finds the petitions to reconsider that the Plaintiff filed with the USPTO tolled the statute of limitations for

¹ Pursuant to Federal Rule of Civil Procedure 25(d), the Court hereby substitutes Teresa Stanek Rea for David J. Kappos as a Defendant in this action.

² See Defs.’ Mot., ECF No. [32]; Pl.’s Opp’n, ECF No. [33]; Defs.’ Reply, ECF No. [34]; Pl.’s (First) Notice of Suppl. Auth., ECF No. [35]; Pl.’s (Second) Notice of Suppl. Auth., ECF No. [37].

filing suit in district court. Accordingly, the Defendants’ [32] Motion to Dismiss is DENIED.

I. BACKGROUND

A. *Patent Terms & Adjustments*

Pursuant to 35 U.S.C. § 154(c)(1), the term of a patent filed prior to June 8, 1995, is the later of (1) seventeen years from the date the patent issued; or (2) twenty years from the earliest filing date of an application on which the patent’s priority date is based. Utility patents filed after June 8, 1995, are subject to 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 historic patent term—Congress provided that certain delays during prosecution are excludable from the calculation of the patent term. *Id.* at § 154(b).

The first category of delay, known as “A delay,” occurs when the USPTO fails to take certain action within timeframes specified by statute. 35 U.S.C. § 154(b)(1)(A); *accord* 37 C.F.R. §§ 1.702(a), 1.703(a). To account for any such delays, “the term of the patent shall be extended 1 day for each day after the end of the period specified . . . until the action described . . . is taken.” 35 U.S.C. § 154(b)(1)(A). A delay includes any delay by the USPTO in issuing a notice of rejection, objection, or requirement under 35 U.S.C. § 132. 35 U.S.C. § 154(b)(1)(A)(i); *accord* 37 C.F.R. § 1.702(a).

The second category of delay, known as “B delay,” provides that, subject to certain limitations, if the USPTO fails to “issue a patent within 3 years after the actual filing date of the application in the United States . . . the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.” 35 U.S.C. § 154(b)(1)(B). Both A

and B delay may be offset by periods of delay attributable to the applicant's failure to "engage in reasonable efforts to conclude prosecution of the application." *Id.* at § 154(b)(2)(C). The Plaintiff only challenges the calculation of the A delay for the '356 Patent. *E.g.*, Compl. ¶¶ 27-28.

The Director must determine "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." 35 U.S.C. § 154(b)(3)(B); *accord* 37 C.F.R. § 1.705(a). Because the notice of allowance issues well before the patent is granted, the notice of patent term adjustment contains only the USPTO's calculation of A delay. *See* Pl.'s Ex. C (May 18, 2010 Decision on Appl. for Patent Term Adjustment) at 1 (noting "[k]nowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for" B delay). A party may seek reconsideration of the patent term adjustment included in the notice of allowance "by way of an application for patent term adjustment." 37 C.F.R. § 1.705(b). An application for patent term adjustment under section 1.705(b) must be filed by no later than the payment of the issue fee, *id.*, which is due three months from the date of the notice of allowance. MPEP § 1306 (8th ed. rev. Aug. 2012).

A revised patent term adjustment determination---including both A and B delay---will appear on the patent upon issue. 37 C.F.R. § 1.705(d). "If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued." *Id.* However, any request for reconsideration under section 1.705(d) that raises issues that were raised or could have been raised in an application for patent term adjustment under section 1.705(b), the request for reconsideration "shall be dismissed as untimely as to those issues." 37 C.F.R. § 1.705(d).

Parties may further appeal the patent term adjustment finding to the Director under 37 C.F.R. § 1.181(a) (indicating a petition may be taken to the Director “[f]rom any action or requirement of any examiner in the ex parte prosecution of an application . . . which is not subject to appeal to the Patent Trial and Appeal Board or to the court”); *see also* Defs.’ Reply at 11 (“Given the general nature of the rule, a Rule 1.181(a)(3) petitions may be submitted to request reconsideration of a USPTO decision, including a USPTO decision on a Rule 1.705(b) or 1.705(d) request for reconsideration of a PTA determination.”). The filing of a petition under section 1.181 “will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings.” 37 C.F.R. § 1.181(f).

Finally, “[a]n applicant dissatisfied with a determination made by the Director” as to the patent term adjustment under section 154(b)(3), “shall have remedy by a civil action against the Director,” filed “within 180 days after the grant of the patent.” 35 U.S.C. § 154(b)(4)(A). The statute further indicates that “Chapter 7 of title 5 shall apply to such action[s],” a cross-reference to the Administrative Procedures Act, 5 U.S.C. §§ 701-706.

B. Factual Allegations Regarding the ‘356 Patent

Patent application number 11/079,647, which eventually issued as the ‘356 patent, was filed with the USPTO on March 14, 2005. Compl. ¶ 8; Pl.’s Ex. A (the ‘356 Patent) at 1. The Plaintiff is the original assignee of the ‘356 Patent. Compl. ¶ 9; Pl.’s Ex. A at 1. The USPTO mailed the first Office Action (hereinafter the “Restriction Requirement”) on April 9, 2007. Compl. ¶ 26. Before the applicants submitted their response, the USPTO “rescinded and replaced” the action with a revised Restriction Requirement, mailed on July 16, 2007. *Id.*

The USPTO was required to issue its first notice under 35 U.S.C. § 132, in this case the Restriction Requirement, by no later than 14 months after the application was filed—that is, May

14, 2006. 35 U.S.C. § 154(b)(1)(A)(i); 37 C.F.R. § 1.702(a)(1). The USPTO calculated the A delay attendant to the delayed Restriction Requirement as 330 days, the number of days between the statutory deadline to issue the first action (May 14, 2006) and the initial issuance of the Restriction Requirement (April 9, 2007). Compl. ¶ 27. The Plaintiff contends the term of the ‘356 patent should have been adjusted an additional 98 days to account for the fact the April 9, 2007 Restriction Requirement was rescinded and replaced on July 16, 2007. *Id*

On October 14, 2008, the USPTO made a preliminary determination that the applicant was entitled to 330 days of patent term adjustment based on the first Office Action mailing date.³ Compl. ¶ 12; Pl.’s Ex. B (Req. for Recons. of Patent Term Adjustment under 37 C.F.R. § 1.705) at 2. The Plaintiff filed a request for reconsideration under 37 C.F.R. § 1.705(b) on January 13, 2009, arguing that “[b]ecause the April 9, 2007 Restriction Requirement was not proper, it is believed that the period of USPTO Delay is to be calculated as of July 16, 2007, not April 9, 2007.” Pl.’s Ex. B. at 2; *accord* Compl. ¶ 13. In response, the USPTO confirmed the determination of the relevant portion of A delay. Pl.’s Ex. C at 3 (“The subsequent mailing of a communication by the examiner altering the previous action does not negate the fact that the Office took action in this application within the meaning of § 1.702(a)(1) on April 9, 2007. The examiner does not have the authority to vacate, rescind, or withdraw an Office action.”).

The ‘356 Patent issued on June 22, 2010. Compl. ¶ 15; Pl.’s Ex. A at 1. In issuing the patent, the USPTO credited the patent with 330 days of A-delay in connection with the first office action, rather than the 428 days sought by the applicant. Compl. ¶ 15. On July 19, 2010, the applicants filed a petition pursuant to section 1.181, asking the Director to review the May

³ The USPTO calculated additional A and B delay for the ‘647 application, at least some of which the applicants disputed. The Court’s factual recitation addresses only the specific A delay at issue in this civil action.

10, 2008 decision, challenging the assertion that a later-rescinded communication satisfies the USPTO's obligation to issue a notice under 35 U.S.C. § 132. Compl. ¶ 16; Pl.'s Ex. D (Pet. Under 37 C.F.R. § 1.181 Re Decision on Application [sic] for Patent Term Adjustment). The Office of Petitions dismissed the petition on March 15, 2011, indicating that "[t]he vacatur of an Office action, [] does not signify that the vacated Office action is void *ab initio* and is to be treated as if the USPTO had never issued the Office action." Pl.'s Ex. E (Mar. 15, 2011 Decision on Appl. for Patent Term Adjustment) at 3-4; Compl. ¶ 17. The decision indicated that the "Patentee is given one (1) month or thirty (30) days, which is longer, from the mail date of this decision to respond." Pl.'s Ex. E at 5.

The applicants sought reconsideration once again on April 15, 2011, citing two grounds for relief: (1) substantively the March 15, 2011 decision was in error; and (2) the decision was not issued by the Director or another individual with the requisite statutory authority. Pl.'s Ex. F (Req. for Recons. of Pet. Decision) at 1; Compl. ¶ 18. The Director denied the request for reconsideration on September 6, 2011. Pl.'s Ex. G (Sept. 6, 2011 Decision on Appl. for Patent Term Adjustment). The decision stated in a footnote that "[t]his decision is a final agency action within the meaning of 5 U.S.C. § 704 for the purposes of seeking judicial review." *Id.* at 1, n.1.

The Plaintiff filed suit in the Eastern District of Virginia three days later. *Janssen Pharmaceutica, N.V. v. Kappos*, No. 11-969 (E.D. Va. filed Sept. 9, 2011). The Defendants moved to dismiss the Complaint, arguing that (1) section 154(b)(4)(A) vested exclusive jurisdiction over such suits in the United States District Court for the District of Columbia; and (2) the Plaintiff's claim was barred by the statute of limitations in section 154(b)(4)(A). *Janssen Pharmaceutica, N.V. v. Kappos*, 844 F. Supp. 2d 707, 708-09 (E.D. Va. 2012). The Plaintiff argued that the venue and timing requirements in section 154(b)(4)(A) did not apply because it is

challenging the patent term adjustment for the ‘356 Patent under the Administrative Procedures Act. *Id.* at 711-712. Judge Leonie M. Brinkema agreed with the Defendants that section 154(b)(4)(A) governed this action, and transferred the case to this District. *Id.* at 716. Judge Brinkema dismissed the Defendants’ timeliness arguments without prejudice. *Id.*

II. LEGAL STANDARD

The Defendants move to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and in the alternative, Rule 12(b)(6). To survive a motion to dismiss pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject matter jurisdiction. *Moms Against Mercury v. FDA*, 483 F.3d 824, 828 (D.C. Cir. 2007). The Court begins with the presumption that it does not have subject matter jurisdiction over a case. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). In determining whether there is jurisdiction, the Court may “consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court’s resolution of disputed facts.” *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003) (citations omitted). “At the motion to dismiss stage, counseled complaints, as well as pro se complaints, are to be construed with sufficient liberality to afford all possible inferences favorable to the pleader on allegations of fact.” *Settles v. U.S. Parole Comm’n*, 429 F.3d 1098, 1106 (D.C. Cir. 2005). “Although a court must accept as true all factual allegations contained in the complaint when reviewing a motion to dismiss pursuant to Rule 12(b)(1),” the factual allegations in the complaint “will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim.” *Wright v. Foreign Serv. Grievance Bd.*, 503 F.Supp.2d 163, 170 (D.D.C. 2007) (citation omitted).

Federal Rule of Civil Procedure 12(b)(6) provides that a party may challenge the

sufficiency of a complaint on the grounds it “fail[s] to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). “[A] complaint [does not] suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Rather, a complaint must contain sufficient factual allegations that, if accepted as true, “state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. In deciding a Rule 12(b)(6) motion, a court may consider “the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint,” or “documents upon which the plaintiff’s complaint necessarily relies even if the document is produced not by [the parties].” *Ward v. D.C. Dep’t of Youth Rehab. Servs.*, 768 F. Supp. 2d 117, 119 (D.D.C. 2011) (citations omitted).

III. DISCUSSION

The Defendants move to dismiss the Complaint on the grounds the Complaint was not filed within 180 days of the grant of the patent as required by 35 U.S.C. § 154(b)(4)(A). The Plaintiff contends that, consistent with the general tolling rule applicable to judicial review of agency actions, the 180-day time limit was tolled while the applicant’s petitions for reconsideration under section 1.181 were pending before the Director. The Defendants offer five arguments in support of the position that general tolling principles do not apply to section 154(b)(4)(A), four of which have been rejected by other courts in this district. Accordingly, the Court shall address the Defendants’ first through fourth arguments in summary fashion, before turning to the fifth argument, which also lacks merit.

A. General Tolling Rule Applies to Section 154(b)(4)(A)

First, the Defendants contend that the time limit set forth in section 154(b)(4)(A) is jurisdictional, and thus their motion should be evaluated under the framework of Rule 12(b)(1).

The applicability of the general tolling principles to section 154(b)(4)(A) is a matter of statutory interpretation, thus the outcome would not change regardless of whether the motion to dismiss is framed under Rule 12(b)(1) or 12(b)(6), or whether section 154(b)(4)(A) is jurisdictional as opposed to a claim-processing rule. Therefore, the Court declines to address the Defendants' argument that the time limit for filing suit set forth in section 154(b)(4)(A) is jurisdictional.

Second, the Defendants argue that the plain language of the statute is "clear and unambiguous," and thus precludes application of general tolling principles. Defs.' Mot. at 13. Specifically, the Defendants emphasize that (1) the 180-day deadline in section 154(b)(4)(A) refers to a fixed date, namely the "grant of the patent"; and (2) section 154(b)(3)(D) indicates that the patent shall be granted "notwithstanding any appeal taken by applicant of such [a patent term] determination." Defs.' Mot. at 14-15. For the reasons articulated by Judge Ellen S. Huvelle in *Novartis AG v. Kappos*, the Court rejects this argument. *Novartis AG v. Kappos*, No. 10-1138, 2012 WL 5564736, at *7-8 (D.D.C. Nov. 15, 2012); *see also Bristol-Meyers Squibb Co. v. Kappos*, 841 F. Supp. 2d 238, 243-45 (D.D.C. 2012).

Third, the Defendants assert that nothing in the legislative history indicates the statute should be read to include tolling principles. Def.'s Mot. at 15 & n.11. This argument inverts the question before the Court. The issue is not whether the statute affirmatively incorporates general tolling principles, but rather whether the text of the statute indicates "Congress intended to depart from the conventional tolling rule." *Stone v. INS*, 514 U.S. 386, 393 (1995). As set forth in detail by Judge Huvelle, nothing in the *text* of the statute indicates Congress intended to override application of the general tolling rule to section 154(b)(4)(A). *Novartis AG*, 2012 5564735, at *7-8. To the contrary, the text of section 154(b)(4)(A) "expressly states that Chapter 7 of Title 5—which includes the general tolling rule—applies to any actions arising under that section,"

which “‘indicates that Congress affirmatively intended for the tolling rule to apply to judicial review of patent term adjustment determinations.’” *Novartis AG*, 2012 WL 5564736, at *7 (quoting *Bristol-Meyers Squibb Co.*, No. 09-1330, 2012 WL 4127636, at *6 (D.D.C. Sept. 20, 2012)). Thus, the Court need not look to the legislative history.

Fourth, the Defendants attempt to distinguish the litany of cases in which courts have applied general tolling principles to similar statutory language, by emphasizing that the 180-day limitation in section 154(b)(4)(A) “‘expressly begins to run at the time an *independent event* occurs,” namely the grant of the patent, rather than the issuance of the agency’s decision. Def.’s Mot. at 19 (emphasis in original). As Judge Emmet G. Sullivan explained,

The Court does not find that there is any meaningful distinction between these two points, particularly in light of the Court’s finding that PTO’s final determinations as to the patent term adjustments are embodied in the patent itself. Thus, the filing of a motion for reconsideration would indeed “‘deactivate” the agency’s final determinations as to the challenged patent term adjustments embodied within that patent. Challenging a patent term adjustment need not “‘dislodge” or invalidate the entire patent, as the defendant appears to argue, in order for the tolling rule to apply to reconsideration of the PTO’s patent term adjustment determinations. Defendant has cited no case law that would suggest otherwise.

Bristol-Meyers Squibb Co., 2012 WL 4127636, at *4; *Novartis AG*, 2012 WL 5564736, at *7 (“The mere fact that § 154(b)(4)(A) sets a specific date from which the 180–day limitation period is to run—the date the patent is granted—does not render the general tolling rule inapplicable.”).

B. General Tolling Rule Applies to Janssen’s Complaint

The Defendant attempts to distinguish *Bristol-Meyers Squibb* because in that case the court found the 180-day deadline in section 154(b)(4)(A) was tolled as to the relevant patents by the filing of petitions for reconsideration under 37 C.F.R. § 1.705(d), filed after the patents issued. *Novartis AG*, 2012 WL 5564736, at *7; *Bristol-Meyers Squibb*, 841 F. Supp. 2d at 241.

Here, the applicant filed an application for patent term adjustment in light of the patent term adjustment disclosed in the notice of allowance, and subsequently filed petitions for reconsideration under 37 C.F.R. § 1.181 once the '356 Patent issued.

The Defendants offer two arguments in support of their contention that motions for reconsideration under section 1.705(d) should be treated differently (for tolling purposes) than motions brought under section 1.181. Neither of the Defendants' arguments is persuasive. First, the Defendants note that section 1.181(f) states that “[t]he mere filing of a petition will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings.” 37 C.F.R. § 1.181(f). From this language, the Defendants urge the Court to conclude that the Plaintiff “cannot claim that its pending 181 petition tolled the running of the 180-day statutory limitation period for the filing of the Complaint.” *Id.*

By its plain language, the disclaimer in section 1.181(f) does not apply to section 154(b)(4)(A). The Defendant does not suggest that the time limit for filing suit in district court is a “period for reply” running against the application. Nor can the second phrase of section 1.181(f) be read to apply to section 154(b)(4)(A): by definition, section 154(b)(4)(A) sets the time limit for *initiating* a proceeding in district court. Rule 1.181(f) merely indicates that the filing of a petition does not *stay* current proceedings regarding the patent application. The language in Rule 1.181(f) cannot reasonably be read to indicate that the filing of a petition for reconsideration does not *toll* the deadline for *initiating* a *new* proceeding, as the Defendant's argument would require.

Second, the Defendants contend that for policy reasons the Court should decline to find that section 1.181 petitions toll the statute of limitations. The Defendants suggest that “an applicant would be able to successively toll the 180-day limitation in Section 154(b)(4)(A) by

filing serial Rule 1.181 petitions,” enabling an applicant to “engage in lengthy post-patent issuance administrative review and improperly frustrate Congressional intent by avoiding the short statute of limitations.” Defs.’ Reply at 14. From the record before the Court, this is a problem entirely within the Defendants’ control. The Plaintiff filed a second petition under Rule 1.181 after the decision on the initial petition indicated the Plaintiff had 30 days to respond. The Director terminated the process after the applicant’s second petition for reconsideration, forcing the Plaintiff to file suit. The Defendants fail to cite any authority for the proposition that it is required to permit a party to file “serial Rule 1.181 petitions.” Regardless, judicial review of agency decisions requires balancing the parties’ interests in quick resolution of an issue, with the court’s interest in not expending resources resolving a dispute that continues to evolve on the agency level. The Defendants’ unfounded speculation notwithstanding, in striking this balance, there is no principled reason to distinguish between motions or petitions to reconsider brought under section 1.705(d) as opposed to section 1.181.

Because the general tolling rule applies, the Plaintiff was required to file suit within 180 days of the Director’s disposition of the Plaintiff’s final petition for reconsideration. *See Novartis AG*, 2012 WL 5564736, at *8. The Defendant denied the Plaintiff’s second section 1.181 petition for reconsideration on September 6, 2011, and the Plaintiff filed suit on September 9, 2011. Accordingly, the Court finds the Plaintiff’s Complaint was timely filed.

IV. CONCLUSION

For the foregoing reasons, the Court finds the Plaintiff timely filed suit in district court. The question of whether the statute of limitations at issue in this case is jurisdictional or a claim processing rule is irrelevant, therefore the Court declines to reach the issue. Two other courts in this district have rejected identical arguments from the Defendants as to why the general tolling

