

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

ACTELION PHARMACEUTICALS LTD.,

Plaintiff,

v.

HON. MICHELLE K. LEE, Under Secretary of
Commerce for Intellectual Property and
Director of the United States Patent and
Trademark Office,

Defendant.

Civil Action No. 1:16-cv-304

Memorandum Opinion

This matter comes before the Court on a Motion for Summary Judgment filed by Plaintiff Actelion Pharmaceuticals LTD., Dkt. No. 12, and a Cross Motion for Summary Judgment filed by Defendant Michelle K. Lee, Director of the United States Patent and Trademark Office (“PTO”). Dkt. No. 15. Both motions concern the interpretation of, 35 U.S.C. § 154, the statute which provides for a patent term adjustment—the amount of time added to the life of a patent due to delays during the patent application period. The dispute, amounting to a difference of four or five days of additional patent term may appear inconsequential. However, each additional day of patent term is of value to the holder, especially in the context of pharmaceutical patents.

I. Background

The questions at issue in this case are governed by an extensive statutory regime. The dispute between the parties has also progressed through multiple administrative actions before reaching the Court. Accordingly, this background describes the statutory framework at some length before turning to the administrative hearings precedent to the present action.

A. Statutory Background

The patent application in this case was filed by means of an international application pursuant to the Patent Cooperation Treaty (“PCT”). This section describes the framework for Patent Term Adjustment under United States law and then illuminates the relevant interrelationship between that framework and the PCT.

1. Patent Term Adjustment

The law governing the content and term of a patent is outlined in 35 U.S.C. § 154. Under § 154 a patent grant is issued for twenty years measured from the earliest filing date of the application. *Id.* Understanding that delays in the examination process might decrease the length of a patent term, Congress created provisions under which a patent owner can seek a patent term adjustment (“PTA”) for certain delays caused by the PTO between the filing and issuance of a patent. Section 154(b)(1) outlines the three general sources of delay for which a PTA can be sought. The first, commonly referred to as “A-Delay,” allows for a patent term extension if the PTO fails to provide a notification under § 132 or a notice of allowance within fourteen months of an application filing. 35 U.S.C. § 154(b)(1)(A)(i). The second, commonly referred to as “B Delay,” allows for a one day extension for every day that the PTO fails to issue a patent after three years have passed between the application and allowance dates. *Id.* at § 154(b)(1)(B).

Finally, a “C Delay” allows a PTA for some types of delays excluded from the computation of a “B Delay.” *Id.* at § 154(b)(1)(C).

A–Delay is applicable to this case. The relevant portion of § 154 describing A–Delay provides as follows:

(A) Guarantee of prompt Patent and Trademark Office responses.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—

(I) the date on which an application was filed under section 111(a); or

(II) the date of commencement of the national stage under section 371 in an international application;

...

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

35 U.S.C. § 154(B)(1)(A).

If an applicant is dissatisfied with the PTO's determination of PTA, § 154 grants the applicant an opportunity to request reconsideration of the PTA determination. *Id.*

§ 154(b)(3)(B)(ii). If an applicant is still dissatisfied following the PTO's reconsideration of PTA, the applicant “shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration.” *Id.*; § 154(b)(4).

2. *The Patent Cooperation Treaty*

The PCT enables applicants to file patent applications in multiple member countries by means of a single international application. While patent protection may later be sought in any

member country, the filer receives the benefit of the same filing and priority dates associated with the international application.

A patent applicant who seeks enforcement of a patent in a PCT member nation must provide paperwork and a national fee to the designated Office for that nation not later than the expiration of 30 months from the priority date. PCT Art. 22(1) (2002). The application will not be reviewed before the expiration described above unless the applicant makes an “express request” for early examination. *See id.* Art. 23. The United States incorporated the 30 month requirement at 35 U.S.C. § 371(b) while permitting an exception at the express request of the applicant. *See* 35 U.S.C. § 371(f).

The rules issued under the PCT are also legally binding on the PTO. *See Helfgott & Karas, P.C. v. Dickinson*, 209 F.3d 1328, 1335 (Fed. Cir. 2000) (finding that PCT Rule 91.1 is legally binding on the Commissioner of the PTO). Rule 80.5 of the PCT provides that:

If the expiration of any period during which any document or fee must reach a national Office or intergovernmental organization falls on a day:

- (i) on which such Office or organization is not open to the public for the purposes of the transaction of official business;
- (ii) on which ordinary mail is not delivered in the locality in which such Office or organization is situated;
- (iii) which, where such Office or organization is situated in more than one locality, is an official holiday in at least one of the localities in which such Office or organization is situated, and in circumstances where the national law applicable by that Office or organization provides, in respect of national applications, that, in such a case, such period shall expire on a subsequent day; or
- (iv) which, where such Office is the government authority of a Contracting State entrusted with the granting of patents, is an official holiday in part of that Contracting State, and in circumstances where the national law applicable by that Office provides, in respect of national applications, that, in such a case, such period shall expire on a subsequent day;

the period shall expire on the next subsequent day on which none of the said four circumstances exists.

For PCT applications, prior to the passage of the America Invents Act Technical Corrections Act (“AIA TCA”), the start date for A-Delay calculation was “the date on which an international application fulfilled the requirements of section 371.” 35 U.S.C. § 154(b)(1)(A)(i)(II) (Effective until Jan. 13, 2013). After January 14, 2013, with the passage of the AIA TCA, A-Delay was calculated from “the date of commencement of the national stage under section 371 in an international application.” 35 U.S.C. § 154(b)(1)(A)(i)(II) (Effective until Jan. 14, 2013). The AIA TCA “shall apply to all proceedings commenced on or after” January 14, 2013 (the effective date). AIA Technical Corrections Act § 1(n), 112 P.L. 274, 126 Stat. 2456, 2459.

B. Factual Background of the Complaint

The parties are generally in agreement on the factual predicate to this case. Those agreed-to facts are set forth below.

1. Plaintiff's Patent Application

This case concerns United States Patent Application No. 13/383,619 (the “’619 Application”) which was filed on January 12, 2012 and granted and issued as U.S. Patent No. 8,658,675 (the “’675 Patent”) on February 25, 2014. The ’619 Application was filed pursuant to the PCT as a national stage entry application under 35 U.S.C. § 371 and was based on an International Patent Application for the same invention filed on July 16, 2009. The PCT’s 30-month period precluding examination of a national stage application (absent an express request from the applicant to commence earlier) is calculated from the July 16, 2009 date. Consequently, Plaintiff’s 30-month deadline fell on Monday, January, 16, 2012 which is Martin Luther King, Jr. Day, a national holiday.

In its January 12, 2012 national stage patent application, Plaintiff filed a Form PTO-1390 Transmittal Letter. On that form, Plaintiff did not check the box indicating that the application was “an express request to begin national examination procedures.” Plaintiff also filed a Preliminary Amendment with its application which, under the heading “Remarks/Arguments”, states that “Applicant earnestly solicits early examination and allowance of these claims. In the event there are any questions, please do not hesitate to contact the undersigned by telephone.”

On January 26, 2012, the PTO issued a Notice of Acceptance of Application and a Filing Receipt indicating that the PTO had received “35 U.S.C. §§ 375 (c)(1), (c)(2), and (c)(4) REQUIREMENTS” on January 12, 2012 and that January 16, 2012 was the “DATE OF COMPLETION OF ALL 35 U.S.C. § 371 REQUIREMENTS[.]”

On April 26, 2013, the PTO mailed Plaintiff a Restriction Requirement which halted the accrual of “A-Delay” time. There was no “B delay” or “C delay” on this application. On February 5, 2014, the PTO mailed Plaintiff a notification indicating that the ’675 Patent would issue on February 25, 2014 and would receive 41 days of PTA.

2. Plaintiff's Administrative PTA Proceedings

On July 31, 2014, Plaintiff submitted a “Request for Recalculation of Patent Term Adjustment in view of the AIA TCA” for the ’675 Patent seeking 45 days of PTA. On September 29, 2014 the PTO issued a decision recalculating the PTA for the ’675 Patent downward from 41 to 40 days because the expiration of the 30-month delay period for the national stage commencement fell on a federal holiday.

On November 25, 2014, Plaintiff submitted a Request for Reconsideration of Patent Term Adjustment Pursuant to 37 C.F.R. § 1.705 (“the First Reconsideration Request”). Plaintiff alleged three bases for upwardly adjusting the patent term. First, the national stage processing

should have commenced on the same day that the '619 Application was filed because the filing of an application that complies with the requirements of § 371(c) is itself an express request for national stage processing. Second, national stage processing should have commenced on January 12, 2012, because Plaintiff had included a statement in the Preliminary Amendment alerting PTO that Plaintiff was expressly requesting the start of national stage processing. Third and alternatively, the '675 Patent was entitled to 41 days of PTA because it was not relevant that the 30-month period expired on a federal holiday. On September 21, 2015, the PTO denied the First Reconsideration Request.

On November 20, 2015, Plaintiff filed a Request for Reconsideration of Petition Decision on Patent Term Adjustment (“the Second Reconsideration Request”). The Second Reconsideration Request raised materially identical claims to the first. The PTO did not reverse its earlier decision and Plaintiff brought the present action in this Court.

II. Legal Standard

Summary judgment is appropriate where there are no genuine issues of material fact and the reviewing court finds that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The PTO’s patent term adjustment decisions are reviewed under the Administrative Procedure Act (“APA”). See 35 U.S.C. § 154(b)(4)(A). Under the APA, this Court can only set aside the PTO’s action if it was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). The Court’s review is therefore limited to the task of reviewing agency action to determine whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment. *Holly Hill Farm v. United States*, 447 F.3d 258, 263 (4th Cir. 2006).

III. Discussion

The Court finds that Plaintiff lacks standing because it has not shown an injury-in-fact that is fairly traceable to defendant's conduct. First, the A-Delay calculation would be the same under the pre- or post-AIA TCA. Second, under either version of the TCA, the PTO's determination that the National Stage cannot commence on a weekend or a federal holiday was not arbitrary, capricious, or an abuse of discretion and as such Plaintiff is not entitled to an additional day of PTA for the federal holiday. Therefore, Plaintiff's overall PTA calculation was accurately determined no matter whether the Court adopts the version of the statute in effect at the time the '619 Application was filed or at the time that the '675 Patent was granted to the Plaintiff.

A. The Calculation of A-Delay is the Same Under the Pre- or Post-AIA TCA

The parties dispute whether application of the pre- or post-AIA TCA would yield a different amount of PTA time. To establish Article III standing, Plaintiff must show that the application of the AIA TCA (enacted January 14, 2013) resulted in a decrease in A-Delay which was an "injury in fact that is fairly traceable to defendant's conduct", in this case the PTO's interpretation of the statute. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Defendant contends that the amount of A-Delay awarded in this case is the same under pre- or post-AIA TCA. Therefore, Plaintiff has presented no injury, and has no standing, to bring its claim.

The parties do not dispute that under the post-AIA TCA, A-Delay calculation would occur either when Plaintiff had successfully made an "express request" for national stage commencement or at the expiration of the 30 month time period referenced in § 371(b). Plaintiff contends that application of the pre-AIA TCA would provide additional PTA time because A-

Delay would have begun accruing fourteen months after “the date on which the international application fulfilled the requirements of section 371.” 35 U.S.C. § 154(b)(1)(A)(i)(II) (effective until Jan.13, 2013). Plaintiff argues that the instruction to “fulfill[] the requirements of section 371” is neither defined by the patent statute nor defined in the rules as of the filing date of the ’619 application. Therefore, Plaintiff defines “fulfillment” as compliance with §§ 371(a) and 371(c) (to the exclusion of §§ 371(b), (d) – (f)) because only these two sections impose “requirements” on the filer. Section 371(a) indicates that the International Bureau, which oversees the PCT international phase process, “may be required” to receive certain documents from the applicant. Section 371(c) requires that a patent applicant shall file with the PTO the national fee, a copy of the international application, inventors’ oaths or declarations, and under some circumstances, certain amendments and translations. Plaintiff met both of these requirements on January 12, 2012.

The parties do not dispute that §§ 371(a) and 371(c) impose obligations on a filer. Defendant contends that the language of the statute and PTO interpretation accord that to “fulfill[] the requirements of section 371” means to comply not only with the requirements of § 371 (c) but rather the “entirety” of § 371 including §§ 371(b) and (f). Defendant points to two sources of evidence which purport to show the PTO’s requirement that the entirety of § 371 must be met. First, the notice of acceptance mailed to Plaintiff on January 26, 2012, prior to the enactment of the AIA TCA, expressly provided the “date of completion of *all* 35 U.S.C. [§] 371 requirements” as January 16, 2012, the date of the expiration of the 30-month period, not January 12, 2012, the date the application was filed. (emphasis added). Second, the Manual of Patent Examining Procedure (“MPEP”), which articulates the laws and regulations that must be

followed in the examination of U.S. patent applications, in effect when Plaintiff filed its application, explains that:

“[A]n international application fulfills the requirements of 35 U.S.C. [§] 371 on the date of commencement of the national stage under 35 U.S.C. [§] 371(b) or (f), or the date the application fulfills the requirements of 35 U.S.C. [§] 371(c) if that date is later than the date of commencement of the national stage under 35 U.S.C. (b) or (f).”

Manual of Patent Examining Procedure § 2731 (2010) at 2700-12, *available at*:

http://www.uspto.gov/web/offices/pac/mpep/old/E8R8_2700.pdf.

The MPEP lays the procedure out clearly. Section 371 (c) governs the accrual of “A-Delay” only if its requirements are fulfilled after the date of commencement under §§ 371(b) and (f). The notice of acceptance letter mailed to Plaintiff on January 26, 2012 is consistent with this interpretation and set the date of accrual as the expiration date rather than the earlier date on which Plaintiff met the requirements of § 371(c). Plaintiff leans on the fact that only §§ 371(a) and (c) impose literal “requirements” on a filer. But Plaintiff’s argument disregards the plain language of § 371(f) which, like § 371(a) articulates a conditional requirement. Section 371(a) “indicates that certain documents ‘may be required’” to complete the application. By Plaintiff’s own admission, § 371(f) “imposes the conditional requirement that if an express request is made it is not valid unless the ‘requirements of subsection (c)’ have been complied with.” By their plain language, both § 371(a) and (f) are conditional requirements which may need to be met. The requirements of § 371(f) are conditioned on the applicant making an express request for national stage commencement.

As Defendant convincingly argues, Plaintiff’s characterization of the pre-AIA TCA A-Delay calculation would incoherently permit a filer to begin accruing A-Delay on the day of filing the application in compliance with only § 371(c) based on the PTO’s purported delay in reviewing the application, even if the filer refused early examination under § 371(f), because the

PTO would be prohibited by statute from reviewing the application until the end of the 30 month period as required by § 371(b).

Considering that the language of the statute references all of § 371, the language in the MEP and notice of acceptance letter are consistent with that interpretation and the alternative interpretation proposed by Plaintiff leads to an incoherent outcome, there is no material difference in PTA in this case under the pre- or post-AIA TCA.

Nevertheless, the Court must still determine whether the national stage examination deadline could expire on a federal holiday. If the term could expire on a federal holiday, then Plaintiff would be entitled to one additional day of PTA time and would have standing to challenge the PTO finding. As discussed below, the Court finds that when the national stage commencement date falls on a federal holiday, it is not an abuse of discretion for the PTO to discount that day in the PTA calculation.

B. The PTO's Determination That the National Stage Cannot Commence on a Weekend or a Federal Holiday Was Not Arbitrary, Capricious, or an Abuse of Discretion

Plaintiff argues that, even if it failed to make an “express request” for national stage commencement, the PTO still erred in advancing the national stage commencement from Monday January, 16, 2012 (Martin Luther King Jr. Day), to Tuesday, January 17, 2012. Defendant justified its approach as consistent with PCT Rule 80.5 which governs “expiration on a non-working day or official holiday.” As discussed above, PCT rules are binding on the PTO. *See Helfgott*, 209 F.3d 1328 at 1335 (Fed. Cir. 2000). A misinterpretation of the PCT rules is an abuse of discretion under the APA. *Id.* at 1337 (“the Commissioner erred in refusing to grant Helfgott's request for relief under PCT Rule 91.1. That error constitutes an abuse of discretion under the APA”). The language in the PCT Rules “must be read in their context and with a view

to their place in the overall statutory scheme.” *Davis v. Mich. Dep’t of Treasury*, 489 U.S. 803, 809 (1989).

Plaintiff offers three arguments in support of its claim. First, Plaintiff contends that the purpose of PCT Rule 80.5 is to provide a brief extension of time for applicants to file their papers and pay their fees. Plaintiff analogizes the language in PCT Rule 80.5 to Federal Rule of Civil Procedure 6(a) which states that:

[I]n computing any time period specified in these rules, in any local rule or court order, or in any statute that does not specify a method of computing time.... When the period is stated in days or a longer unit of time... include the last day of the period, but if the last day is a Saturday, Sunday, or legal holiday, the period continues to run until the end of the next day that is not a Saturday, Sunday, or legal holiday.

Fed. R. Civ. P. 6(a)(1)(C). The Fifth Circuit determined that this clause is intended “to avoid a forfeiture of rights when a deadline for acting falls on a day on which courts are closed for business.” *In re American Healthcare Mgmt, Inc.*, 900 F.2d 827, 831-832 (5th Cir. 1990). Applying the same purpose to PCT Rule 80.5, Plaintiff contends that the weekend/holiday extension should only apply where a filer’s right would be protected by extending the deadline to the next business day whereas here, the length of Plaintiff’s PTA and the rights associated with the increased patent term duration are constrained by the extension.

Second, Plaintiff argues that PCT Rule 80.5 applies only where the party is required to file additional documents with the PTO, or where the PTO must take some affirmative step either of which would not be possible on a weekend or federal holiday. On the contrary, the PTO need not take any affirmative steps in order for the 30 month period preceding national stage commencement to expire.

Third, Plaintiff argues that the language of PCT Rule 80.5 makes optional, but does not require, that timely entry to the national stage occurs on the next business day when it would

ordinarily fall on a weekend or federal holiday.

Defendant contends that applying the weekend/holiday exception to this set of facts was not a “clear error” of judgment because the PTO relied on the D.C. District Court’s decision in *ArQule v. Kappos*, where that court found that the PTO is compelled by statute to move deadlines for applicant filings which fall on weekends or holidays to the next business day. 793 F. Supp. 2d 214, 221-23 (D.D.C. 2011). The plaintiff in *ArQule* brought suit against the PTO under the APA claiming that the Office had erroneously deducted one day from the plaintiff’s patent term because of applicant delay. *Id.* at 216. The plaintiff objected to this calculation because the deadline that it had “missed” fell on a federal holiday and the plaintiff promptly filed the next day. *Id.* at 216-17. The court conducted step one of the *Chevron* analysis and found that the language of the statute was unambiguous, obviating the need for step two. *Id.* The court recognized that the weekend/holiday exception applies to a range of PTO deadlines including the on-sale bar, § 102 (b), with respect to publications and prior sale, and the foreign filing privilege pursuant to §119. *Id.* at 221-223 (analyzing cases from other districts). Furthermore, the court held that the common thread between these statutory provisions was that they “describe the period of time within which an applicant must act.” *Id.* at 223. Therefore, the court concluded that the “applicant delay” provision of PTA, which is contingent on the time at which the filer takes certain actions, necessarily incorporates the weekend/holiday exception. *Id.* at 225.

ArQule does not support the proposition that the entire applicant delay scheme is entitled to the benefit of the weekend/holiday exception. Rather, it is limited to those portions of the statutory scheme which compel the applicant to take some *action*. Section 371(b) provides that “...the national stage shall commence with the expiration of the applicable time limit.” 35 U.S.C. § 371(b). PCT Article 22(1) sets out that the time limit expires 30 months from the

international application filing date and requires that all necessary paperwork and fees be paid no later than at the date of expiration. *See* PCT Art. 22(1). In this case, Plaintiff filed all of the necessary paperwork and fees on January 12, 2012. However, Plaintiff could have filed the necessary paperwork at any date up to the 30-month deadline. An applicant who submits all necessary paperwork fees at the date of expiration, where that date of expiration falls on a weekend or federal holiday, can hardly object that the national stage would not commence until the PTO reviews the paperwork and credits the fees, all of which would not occur until the following business day pursuant to weekend/holiday exception at 35 U.S.C. § 21(b). Therefore, Plaintiff's second argument, while true with respect to its filing, is not universally true within the statutory scheme.

The language in Article 22(1) adopted through § 371(b) is also consistent with the statutory provisions which the *ArQule* court found were covered by the weekend/holiday exception which the Court finds to be a better reference for reasonableness than Plaintiff's citation to non-binding case law interpreting an unrelated provision. Section 133 stipulates that if an applicant fails "to prosecute the application within six months...or within such shorter time...the application shall be regarded as abandoned." 35 U.S.C. § 133. In this section, as in § 137, the applicant may file paperwork early or up to the date of expiration. Similarly, an action is not always necessary on the part of the PTO on the expiration day to regard the patent as abandoned under § 133 or to regard the national stage as commenced under § 137. Nevertheless, an action could be necessary on the day of expiration under either statutory regime where paperwork is filed on the final day and that day falls on a weekend or a holiday. The PTO was consistent in applying the reasoning from *ArQule* to the national stage commencement provision and appropriately construed related statutory provisions in a similar fashion. *See Beneficial Nat.*

Bank v. Anderson, 539 U.S. 1, 7–8 (2003) (“[the statute] used language similar to the statutory language construed in *Avco*, thereby indicating that the two statutes should be construed in the same way.”).

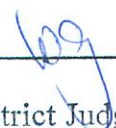
Finally, while the Court does not agree with Plaintiff’s third argument that the “plain language of Rule 80.5...extends to applicants the *option* of timely entering the national stage up to the next business day”, Dkt. No. 14 at 23, optionality with respect to applicants is immaterial to the issue at bar. Nothing in the language of Rule 80.5 gives *the PTO* any option to change the national stage commencement date depending on whether Plaintiff has already filed all necessary paperwork and fees to avoid abandonment prior to the thirty-month deadline or on the commencement day. Therefore, the PTO is acting within its authority by enforcing the weekend/holiday exception to the national stage commencement date.

While Plaintiff completed in advance the actions required under PCT Art. 22(1) as a necessary condition to U.S.C. § 371(b); the statutory scheme contemplates that a filer need not take an action until the expiration date. Because a filer can take actions on the expiration date, the PTO must be available to receive and take action on such filings—which is not possible on a weekend or federal holiday—precisely the consideration which § 21(b) is intended to ameliorate. Accordingly, Defendant’s decision to apply the weekend/holiday exception is consistent with the interpretation of similar statutory provisions and is not a clear error of judgment.

IV. Conclusion

For the reasons discussed above the Court DENIES Plaintiff’s Motion for Summary Judgment and GRANTS Defendant’s Cross Motion for Summary Judgment.

October 19, 2016
Alexandria, VA

/s/ 
Liam O’Grady
United States District Judge