

BRISTOL-MYERS SQUIBB COMPANY)
and KOSAN BIOSCIENCES INC.,)
)
Plaintiffs,)
)
v.) Civ. No. 09-1330 (EGS)
) (consolidated with Civ. No 09-2420)
DAVID KAPPOS, in his official)
capacity as Under Secretary)
of Commerce for Intellectual)
Property and Director of the)
United States Patent and)
Trademark Office,)
)
Defendant.)
)

Plaintiffs Bristol-Myers Squibb Company and Kosan Biosciences Inc. filed this action on June 17, 2009 seeking review of certain patent term adjustments granted by the Director of the United States Patent and Trademark Office ("PTO"). Plaintiffs alleged that all of the challenged PTO patent term adjustment determinations relied on an erroneous interpretation of 35 U.S.C. § 154(b) rejected by the United States Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Amended Complaint identified twenty-one patents, set forth in twenty-one separate counts, for which the PTO allegedly incorrectly determined the patent term adjustment.

Of the twenty-one patents identified by plaintiffs in this action, the Court has already ordered thirteen remanded to the PTO for recalculation and adjustment of the disputed patent term in accordance with *Wyeth*. Court's Minute Order of June 23, 2010.¹ The eight Counts remaining are Count Five, Count Six, Count Eleven, Count Thirteen, Count Seventeen, Count Eighteen, Count Nineteen, and Count Twenty.

In addition, Civil Action Number 09-2420, *Bristol-Myers Squibb Company v. Kappos*, has been consolidated with this action. One remaining Count is pending therein, namely Count Four (United States Patent No. 7,514,430).²

Defendant has filed a motion to dismiss the remaining claims, arguing that the plaintiffs failed to comply with 35

¹ Those thirteen Counts were dismissed in the same June 23, 2010 Minute Order: Count One (United States Patent No. 7,517,991), Count Two (United States Patent No. 7,504,211), Count Three (United States Patent No. 7,482,372), Count Four (United States Patent No. 7,479,496), Count Seven (United States Patent No. 7,459,562), Count Eight (United States Patent No. 7,455,835), Count Nine (United States Patent No. 7,453,002), Count Ten (United States Patent No. 7,452,678), Count Twelve (United States Patent No. 7,435,808), Count Fourteen (United States Patent No. 7,432,271), Count Fifteen (United States Patent No. 7,432,267), Count Sixteen (United States Patent No. 7,429,611), and Count Twenty-One (United States Patent No. 7,504,481).

² The remaining counts of this action were similarly remanded to the PTO for recalculation and adjustment of the disputed patent terms: Count One (United States Patent No. 7,589,193), Count Two (United States Patent No. 7,589,088), Count Three (United States Patent No. 7,557,143), and Count Five (United States Patent No. 7,491,725).

U.S.C. § 154(b)(4)(A), which requires an applicant dissatisfied with a patent term adjustment determination made by the PTO to file its appeal with the District Court "within 180 days after the grant of the patent." 35 U.S.C. § 154(b)(4)(A). Defendant asserts that all remaining counts should therefore be dismissed as untimely. Plaintiffs filed a cross-motion for summary judgment, asserting that the action is timely filed and that the disputed patent term adjustments should be remanded to the PTO for recalculation.

The parties agree that the sole legal question remaining in these cases is the timeliness of plaintiffs' appeals. For the reasons stated below, the Court finds that plaintiffs' appeals were timely filed. Accordingly, the Court hereby **DENIES** defendant's motion to dismiss and **GRANTS** plaintiffs' cross-motion for summary judgment. The remaining claims are hereby **REMANDED** to the PTO for recalculation and adjustment of the disputed patent terms in accordance with *Wyeth v. Kappos*, 591 F.3d 1364.

I. BACKGROUND

Patents are ordinarily granted "for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States." 35 U.S.C. § 154(a)(2). However, under 35 U.S.C. § 154(b)(1), a patent's term may be extended if the PTO

causes certain delays in the process or if the patent takes longer than three years to issue.³

After a patent application is filed, and "[i]f it appears that applicant is entitled to a patent under the law," the PTO issues a "written notice of allowance of the application."

Id. § 151. The notice of allowance specifies an issue fee that the applicant must pay within three months. *Id.* The PTO is required to make a determination of the period of any patent term adjustment and "transmit a notice of that determination with the written notice of allowance." *Id.* § 154(b)(3)(B)(i).

The term of the patent, issued after the applicant pays the issue fee, will include any patent term adjustment determined by the PTO. If an applicant disagrees with the patent term adjustment determined by the PTO, the statute provides that the applicant is entitled to "request reconsideration of any patent

³ In the instant case, plaintiffs assert that the PTO miscalculated the patent term adjustments for the disputed patents. In particular, plaintiffs claim that two types of patent term adjustments, known as the "A Delay" and the "B Delay," were miscalculated. Under Section 154(b)(1)(A), the "A Delay," one day is added to the patent's term for each day the PTO fails to meet certain specified deadlines. Under Section 154(b)(1)(B), the "B Delay," the statute provides that "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office 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).

term adjustment determination made by the Director." *Id.*

§ 154(b)(3)(B)(ii).

Furthermore, the statute permits the applicant to appeal the patent term adjustment to a United States District Court. Specifically, the statute provides:

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 Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5, shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

Id. § 154(b)(4)(A).⁴

In the instant case, the material facts are not in dispute. Plaintiffs did not file their appeals with this Court until more than 180 days after each of the remaining disputed patents had been issued.⁵ However, with respect to each of the disputed

⁴ Effective September 16, 2011, the United States District Court for the Eastern District of Virginia replaced the United States District Court for the District of Columbia as the appropriate court for any civil action commenced on or after that date.

⁵ This action, Civil Action Number 09-1330, was filed on July 17, 2009. Each of the remaining eight disputed patents was granted more than 180 days before this appeal was filed. Patent Number 7,470,713 (Count Five) was issued on December 30, 2008; Patent Number 7,470,712 (Count Six) was issued on December 30, 2008; Patent Number 7,446,196 (Count Nine) was issued on November 4, 2008; Patent Number 7,432,373 (Count Thirteen) was issued on October 7, 2008; Patent Number 7,429,604 (Count

patents, plaintiffs filed a request for reconsideration of the patent term adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d) within the requisite two month time period after the patent was granted. The sole question pending before this Court is whether the timely filing of the petitions for administrative reconsideration tolled the time within which plaintiffs were required to appeal to this Court.

II. STANDARD OF REVIEW

Defendant moves to dismiss the remaining counts under Rule 12(b)(1) or, in the alternative, Rule 12(b)(6). On a motion to dismiss for lack of subject-matter jurisdiction under Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject-matter jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). "The court must address the issue of jurisdiction as a threshold matter, because absent jurisdiction the court lacks the authority to decide the case on any other grounds." *Am. Farm Bureau v. EPA*, 121 F. Supp. 2d 84, 91 (D.D.C. 2000). A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a complaint. *Browning v. Clinton*, 292

Seventeen) was issued on September 30, 2008; Patent Number 7,427,493 (Count Eighteen) was issued on September 23, 2008; Patent Number 7,417,063 (Count Nineteen) was issued on August 26, 2008; Patent Number 7,417,040 (Count Twenty) was issued on August 26, 2008. Similarly, the consolidated action (Civil Action Number 09-2420) was filed on December 23, 2009, over 180 days after Patent Number 7,514,430 (Count Four) was issued on April 7, 2009.

F.3d 235, 242 (D.C. Cir. 2002). A complaint must present "enough facts to state a claim to relief that is plausible on its face" and "above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). In considering a 12(b)(6) motion, the Court must construe the complaint "'liberally in the plaintiff's favor,' 'accept[ing] as true all of the factual allegations'" alleged in the complaint. *Aktieselskabet AF 21 November 2001 v. Fame Jeans Inc.*, 525 F.3d 8, 15 (D.C. Cir. 2008) (alteration in original) (quoting *Kassem v. Wash. Hosp. Ctr.*, 513 F.3d 251, 253 (D.C. Cir. 2008)). Indeed, a plaintiff is entitled to "the benefit of all inferences that can be derived from the facts alleged." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994).

Plaintiffs have filed a cross-motion for summary judgment. Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Though the Court must draw all justifiable inferences in favor of the non-moving party in deciding whether there is a disputed issue of material fact, "[t]he mere existence of a scintilla of evidence in support of the [non-movant]'s position will be insufficient; there must be evidence on which the jury

could reasonably find for the [non-movant]." *Anderson*, 477 U.S. at 252.

III. ANALYSIS

A. The Tolling Rule

Judicial review of agency actions is ordinarily tolled until the agency action is final. See, e.g., *Clifton Power Corp. v. FERC*, 294 F.3d 108, 110 (D.C. Cir. 2002) ("The time for filing the petition for [judicial] review is tolled until all proceedings before the agency have been completed." (citing *Interstate Commerce Comm'n v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 284 (1987))). This is because "[a] request for administrative reconsideration renders an agency's otherwise final action non-final with respect to the requesting party." *Id.* (citing *United Transp. Union v. Interstate Commerce Comm'n*, 871 F.2d 1114, 1116 (D.C. Cir. 1989)). In the absence of a final agency action, this Court lacks jurisdiction.

As the Supreme Court in *Interstate Commerce Commission v. Brotherhood of Locomotive Engineers*, 482 U.S. 270, explained:

[W]here a petition for reconsideration has been filed within a discretionary review period specifically provided by the agency (and within the period allotted for judicial review of the original order) . . . the petition tolls the period for judicial review of the original order, which can therefore be appealed to the courts directly after the petition for reconsideration is denied.

Id. at 279; see also *Riffin v. Surface Transp. Bd.*, 331 F. App'x 751, 752 (D.C. Cir. 2009) ("By filing a timely petition to reopen, [plaintiff] rendered the Board's decision nonfinal"); *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 919 (D.C. Cir. 1998) ("A party's pending request for agency reconsideration renders 'the underlying action nonfinal'" (quoting *Wade v. FCC*, 986 F.2d 1433, 1434 (D.C. Cir. 1993))).

Plaintiffs argue that their appeal is not barred by the 180-day limitations period contained in Section 154(b)(4)(A) because the limitations period was tolled by the filing of their petitions for reconsideration of the patent term adjustments. Defendant, on the other hand, argues that because the statute explicitly states that an applicant must file an appeal with the courts "within 180 days after the grant of the patent," the tolling rule of *Locomotive Engineers* does not apply.

The tolling rule set forth by the Supreme Court in *Locomotive Engineers* has been nearly universally applied. The one exception identified by defendant is *Stone v. INS*, 514 U.S. 386 (1995). In *Stone*, the Supreme Court held that the tolling rule did not apply to the Immigration and Nationality Act (INA). Plaintiff, a Canadian citizen present in the United States on a visa, was ordered deported by an Immigration Judge. *Id.* at 389. The plaintiff filed administrative appeals, all of which were denied. Plaintiff then filed an action in the Court of Appeals

for the Sixth Circuit seeking review of both the original deportation order, as well as the subsequent agency order denying reconsideration. The question before the Supreme Court in *Stone* was "whether the filing of a timely motion for reconsideration of a decision by the Board of Immigration Appeals tolls the running of the 90-day period for seeking judicial review of the decision." *Id.* at 388.

The *Stone* Court concluded that the petition for reconsideration did *not* toll the period of limitations for seeking judicial review of the deportation order because certain provisions within the INA "reflect[ed] Congress' expectation that in the particular context of INS deportation orders the normal tolling rule will not apply." *Id.* at 398. The Court distinguished the Immigration and Nationality Act from the ordinary situation, explaining that:

By its terms, § 106(a)(6) [of the INA] contemplates two petitions for review and directs the courts to consolidate the matters. The words of the statute do not permit us to say that the filing of a petition for reconsideration or reopening dislodges the earlier proceeding reviewing the underlying order. The statute, in fact, directs that the motion to reopen or reconsider is to be consolidated with the review of the order, not the other way around. This indicates to us that the action to review the underlying order remains active and pending before the court. We conclude that the statute is best understood as reflecting an intent on the part of Congress that deportation orders are to be reviewed in a timely fashion after issuance, irrespective of the later filing of a motion to reopen or reconsider.

Id. at 394.

The tolling rule established by *Locomotive Engineers* is the "normal tolling rule." *Stone*, 514 U.S. at 398; see also *United Transp. Union*, 871 F.2d at 1116 ("We think it plain that a pending petition for rehearing must render the underlying agency action nonfinal (and hence unreviewable) with respect to the filing party.").

As defendant concedes, this general tolling rule applies unless the statute would be "expressly contravened by the tolling rule." Def.'s Combined Opp'n at 8. The question for this Court in the instant case is therefore whether Congress intended that the ordinary tolling rule of *Locomotive Engineers* not apply to Section 154(b)(4)(A).

B. Whether the General Tolling Rule is Inapplicable to Section 154(b)(4)(A)

Defendant makes several arguments in support of his assertion that Congress intended the limitations period of Section 154(b)(4)(A) to be exempt from the ordinary tolling rule. Defendant first argues that because "the limitation period of § 154(b)(4)(A) begins to run on a fixed date," it is "abundantly clear that [Congress] did not intend for the tolling rule to apply." Def.'s Combined Opp'n at 9. In response, plaintiffs assert that the text of Section 154(b)(4)(A) "provides no indication that Congress sought to depart from the

Locomotive Engineers rule." Pls.' Cross Mot. for Summ. J. at 20.

Defendant's argument is flawed. Section 154(b)(4)(A) does, as defendant correctly states, provide that the 180-day limitations period starts to run from the date the patent is granted. Also true is defendant's assertion that, accordingly, the statute sets a "fixed date" from which the limitation period runs. However, a statutory provision setting the limitations period is *not* incompatible with a tolling rule. While Section 154(b)(4)(A) requires that an applicant file an appeal of a patent term adjustment "within 180 days after the grant of the patent," case law from this Circuit makes clear that such a requirement is not violated by the general tolling rule.

For instance, this Circuit applied the general tolling rule in *Columbia Falls*, 139 F.3d 914, concluding that the relevant 90-day period of limitations, namely 42 U.S.C. § 6976(a)(1), would be tolled by a request for agency reconsideration. *Id.* at 919. Like Section 154(b)(A)(4) in the instant case, 42 U.S.C. § 6976(a)(1) provides for a fixed date, stating that any petition for judicial review "of action of the Administrator in promulgating any regulation . . . or denying any petition for the promulgation . . . shall be filed within ninety days *from the date of such promulgation or denial[.]*" 42 U.S.C. §

6976(a)(1) (emphasis added). The court nonetheless held that the tolling rule applied. *Columbia Falls*, 139 F.3d at 919.

Similarly, in *Los Angeles SMSA Limited Partnership v. FCC*, 70 F.3d 1358 (D.C. Cir. 1995), the court applied the general tolling rule to a statute requiring that the judicial appeal "be taken by filing a notice of appeal with the court within thirty days from the date upon which public notice is given of the decision or order complained of." 47 U.S.C. § 402(c) (emphasis added). The Circuit explained:

The filing of a petition for rehearing . . . will suspend the running of the period within which an appeal may be taken, and . . . this period begins to run anew from the date on which final action is taken on the petition or motion, whether it be denied or granted. . . . This rule applies even though a statute fixes a time within which appeal may be taken as a definite period from the entry of judgment.

Los Angeles SMSA Ltd. P'ship, 70 F.3d at 1359 (quoting *Saginaw Broad. Co. v. FCC*, 96 F.2d 554, 558 (D.C. Cir. 1938))(emphasis added).

Precedent from this Circuit therefore makes clear that merely because the statute "fixes a time within which appeal may be taken," such a provision does not exempt the statute from the ordinary tolling rule. "The time for filing the petition for review is tolled until all proceedings before the agency have been completed." *Clifton Power Corp.*, 294 F.3d at 110.

Furthermore, none of the other statutory provisions cited by defendant support a conclusion that Congress intended for the ordinary tolling rule not to apply to Section 154(b)(4)(A). Defendant argues, for example, that 35 U.S.C. § 154(b)(3)(D) is evidence of such Congressional intent. Section 154(b)(3)(D) provides that the "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." *Id.* Defendant argues that "the statute expressly contemplates that such an appeal may be initiated before the patent issues." Def.'s Mot. to Dismiss at 4. The Court disagrees.

While defendant would have this Court conclude that Section 154(b)(3)(D) renders the general tolling rule inapplicable, similar to the INA at issue in *Stone*, the Court finds otherwise. In *Stone*, the Court concluded that "Congress chose to depart from the ordinary judicial treatment of agency orders under reconsideration." *Stone*, 514 U.S. at 393. The *Stone* Court came to this conclusion based upon a 1990 amendment to the INA specifically requiring the judiciary to consolidate two separate appeals by a petitioner. Finding such language irreconcilable with the normal tolling rule, the Court stated that "the words of the statute do not permit us to say that the

filing of a petition for reconsideration or reopening dislodges the earlier proceeding reviewing the underlying order." *Id.* at 394.

Nothing in the patent statute is comparable to the INA language that prevented the application of the general tolling rule in *Stone*. Defendant's reliance on Section 154(b)(3)(D), requiring the Director to "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," is not persuasive. That language does not direct this Court to take any action inconsistent with the normal tolling rule.⁶

The application of the *Locomotive Engineers* tolling rule in this case is not only consistent with the statutory language, but also with the function of the tolling roll. The purpose of the tolling rule is to conserve judicial resources by putting only a final agency action before the Court. As this Circuit has explained, "[w]hen the party elects to seek a rehearing

⁶ Nor, contrary to defendant's assertions, does the language of 35 U.S.C. § 154(b)(4)(B) contravene the general tolling rule. Dealing only with the ability of third parties to appeal or challenge the grant of a patent, it provides that "[t]he determination of a patent term adjustment . . . shall not be subject to appeal or challenge by a third party prior to the grant of the patent." *Id.* Such a provision does not contravene the tolling rule.

there is always a possibility that the order complained of will be modified in a way which renders the complained of judicial review unnecessary." *United Transp. Union*, 871 F.2d at 1117 (quoting *Outland v. Civil Aeronautics Bd.*, 284 F.2d 224, 227-28 (D.C. Cir. 1960)). By the use of the "bright line test" of the general tolling rule, would-be plaintiffs are "discourage[d from] the filing of petitions for review until after the agency completes the reconsideration process." *TeleSTAR, Inc. v. FCC*, 888 F.2d 132, 134 (D.C. Cir. 1989).

In the instant case, once the plaintiffs filed their petitions for reconsideration with the PTO, it would have been a "pointless waste of judicial energy for the court to process any petition for review before the agency . . . acted on the request for reconsideration." *Id.*

Accordingly, the Court concludes that the general tolling rule applies to the instant case and plaintiffs' claims were timely filed.

IV. CONCLUSION

For the foregoing reasons, defendant's motion to dismiss is **DENIED**. Plaintiff's motion for summary judgment is **GRANTED**. Accordingly, the Court hereby **REMANDS** the remaining counts to the United States Patent and Trademark Office for recalculation and adjustment of the disputed patent terms in accordance with the decision of the United States Court of Appeals for the

Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364. In view of this remand, plaintiffs' remaining claims are hereby **DISMISSED** without prejudice subject to a motion for reconsideration for good cause shown upon completion of the agency's recalculation and adjustment. An appropriate Order accompanies this Memorandum Opinion.

SIGNED: Emmet G. Sullivan
United States District Court Judge
January 27, 2012