IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

MYLAN PHARMACEUTICALS, INC.,

Plaintiff,

WATSON LABORATORIES, INC.,

Intervenor-Plaintiff,

and

LUPIN PHARMACEUTICALS, INC.,

Intervenor-Plaintiff,

v. // **CIVIL ACTION NO. 1:14CV75**
(Judge Keeley)

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant,

and

TEVA PHARMACEUTICALS, USA, INC.,

Intervenor-Defendant.

ORDER GRANTING MYLAN PHARMACEUTICALS, INC.'S MOTION FOR ENTRY OF FINAL JUDGMENT, [DKT. NO. 117], AND GRANTING JUDGMENT IN FAVOR OF THE FOOD AND DRUG ADMINISTRATION

Currently pending before the Court is the unopposed motion of the plaintiff, Mylan Pharmaceuticals, Inc. ("Mylan"), for entry of final judgment in this matter. (Dkt. No. 117). For the reasons that follow, the Court **GRANTS** Mylan's motion.

I. Procedural History

Mylan filed a complaint in this case on April 25, 2014, challenging a letter decision by the FDA, addressing the marketing exclusivity eligibility of celecoxib Abbreviated New Drug

Application ("ANDA") applicants. (Dkt. No. 1). Mylan then filed a motion for preliminary injunction on April 28, 2014, seeking an injunction to enjoin the FDA from withholding final approval on May 30, 2014 to any first to file celecoxib ANDA applicant, pending either the Court's decision on the merits of this case or expiration of the 180-day celecoxib marketing exclusivity period. (Dkt. No. 9). Watson Laboratories, Inc. ("Watson") and Lupin Pharmaceuticals, Inc. ("Lupin") subsequently intervened as plaintiffs in this case, and Teva Pharmaceuticals USA, Inc. ("Teva") intervened as a defendant.

On May 15, 2014, the Court held a held a hearing on the motion for preliminary injunction, at which representatives from all parties were present. Following that hearing, the Court entered a Memorandum Opinion and Order Denying Mylan's Motion for Preliminary Injunction, finding that Mylan had failed to establish the elements necessary to obtain a preliminary injunction. (Dkt. No. 103).

On June 6, 2014, Mylan filed the instant motion for entry of final judgment pursuant to Federal Rule of Civil Procedure 65(a)(2). Teva subsequently advised the Court that it does not oppose Mylan's motion. (Dkt. No. 121). The motion is now ripe for review.

II. Factual Background

A. Celebrex® and Generic Celecoxib Products

Celebrex® is a nonsteroidal anti-inflammatory drug marketed by Pfizer Inc. ("Pfizer") under NDA No. 020998. The Orange Book currently lists four patents for Celebrex® capsules in 100 mg, 200 mg, and 400 mg strengths: U.S. Patent No. 5,466,823 ("the '823 patent") (expired on Nov. 30, 2013; pediatric exclusivity expires on May 30, 2014); U.S. Patent No. 5,563,165 ("the '165 patent") (expired on Nov. 30, 2013; pediatric exclusivity expires on May 30, 2014); U.S. Patent No. 5,760,068 ("the '068 patent")(set to expire on June 2, 2015; pediatric exclusivity expires on December 2, 2015); and U.S. Patent No. 5,972,986 ("the '986 patent")(set to expire on Oct. 14, 2017; pediatric exclusivity expires on December 2, 2015).

On November 13, 2003, Teva became the first to file an ANDA, ANDA No. 76-898, containing Paragraph IV certifications to the '823, '165, and '068 patents for generic Celebrex® ("celecoxib") capsules in 100 mg, 200 mg, and 400 mg strengths. Pfizer subsequently sued Teva for patent infringement, and on March 20, 2007, a federal district court determined that the '823, '165 and '068 patents were valid and infringed by Teva. Pfizer Inc. v. Teva

Pharms. USA, Inc., 482 F.Supp.2d 390 (D.N.J. 2007). Teva appealed, and the Federal Circuit overturned the district court's decision, holding that claims 1–4 and 11-17 of Pfizer's '068 patent were invalid. Pfizer Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1253 (Fed. Cir. 2008). The Federal Circuit issued its mandate on May 13, 2008.[1] The FDA tentatively approved Teva's ANDA on April 27, 2012.

Nearly five years after concluding its litigation with Teva, Pfizer corrected the deficiencies of the '068 patent, and on March 5, 2013, the PTO reissued the '068 patent (now under the number RE44048, "the '048 patent"). On March 7, 2013, the reissued patent was listed in the Orange Book. On that same day, Teva updated its Paragraph IV certification to cover the reissued version of the '068 patent. Mylan and Watson also submitted Paragraph IV certifications to the '048 patent on that day.

Teva, Mylan, Lupin, Watson and others successfully contested the validity of the '048 patent in the Eastern District of Virginia, thus making room for a Paragraph IV certification to be

[1]Teva, however, was unable to go to market–and thus take advantage of a marketing exclusivity period–at that time, as its ANDA had not yet received final approval.

granted on the reissued patent.[2] See G.D. Searle LLC v. Lupin Pharms., Inc., 2:13cv00121 (E.D.Va. Mar. 12, 2014). On April 17, 2014, Teva and Pfizer entered into a settlement of the '048 patent litigation, expressly allowing Teva to launch its generic version of Celebrex® in December 2014, or earlier under certain, unidentified, circumstances.[3]

B. The FDA's Letter Decision

On April 24, 2014, the FDA issued a letter decision to all celecoxib ANDA applicants, addressing the "legal and regulatory scheme governing eligibility of ANDA applicants for 180-day exclusivity under the Food Drug and Cosmetic Act ["FDCA"] as it existed prior to December 8, 2003, in a situation involving a reissued patent."[4] FDA Letter at 1. The FDA explained that it

[2]The FDA may begin approving celecoxib ANDAs on May 30, 2014, the date that Pfizer's pediatric exclusivity on the '823 and '165 patents expires.

[3]The terms of the settlement between Teva and Pfizer have not been made public.

[4]The statute governing this 180-day exclusivity changed substantially with enactment of the Medicare Prescription Drug Improvement and Modernization Act ("the MMA"), Public Law 108-173, 117 Stat. 2066 (Dec. 8. 2003). Because the first substantially complete ANDA referencing Celebrex® Capsules containing a paragraph IV certification was submitted prior to the date of enactment of the MMA, the 180-day exclusivity provisions (and implementing regulations) governing the matter before the court are those that were in effect prior to December 8, 2003. See MMA § 1102(b)(1).

"does not consider a reissued patent to be a new and distinct patent for purposes of 180-day exclusivity." Id. at 5. Rather, the FDA explained that it treats the original and reissued patent as possessing a single bundle of patent rights and thus, "under the pre-MMA scheme, a 30-month stay of approval arising from litigation based on a paragraph IV certification to the original patent remains in effect after the patent is reissued, and any applicant eligible for 180-day exclusivity based on a paragraph IV certification to the original patent remains eligible for that exclusivity after patent reissuance." Id.

The FDA ultimately concluded that:

> for purposes of 180-day exclusivity, upon the listing of a reissued patent, a prior court decision on the original patent is not regarded as having triggered 180-day exclusivity for the single bundle of patent rights represented by the original and reissued patent. In such a case, eligibility for 180-day exclusivity is only available to the applicant that first filed a paragraph IV certification to the original patent, and that applicant must make a timely submission of a paragraph IV certification to the reissued patent to remain eligible for 180-day exclusivity.

Id. at 11.

In sum, the FDA found that only a party that is first to challenge both the original patent and reissued version of that

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Unless otherwise noted, therefore, all statutory references in this brief reflect the pre-MMA version of the FDCA.

patent, in this case Teva, qualifies for 180-day marketing exclusivity. The FDA noted that this outcome "best reconciles the complicated intersection between the Hatch-Waxman Amendments and patent law, while allowing FDA to administer the FDCA in a manner that is fair, predictable and consistent with the goal of bringing generic products into the market." Id. at 10.

III. Legal Standard

Pursuant to Federal Rule of Civil Procedure 65(a)(2), district courts have discretion to consolidate the hearing on a motion for preliminary injunction with the trial on the merits. A court may order consolidation "before or after beginning the hearing on a motion for preliminary injunction." Fed. R. Civ. P. 65(a)(2).

The drafters of Rule 65(a)(2) noted that consolidation "can be exercised with particular profit when it appears that a substantial part of the evidence offered on the application for a preliminary injunction will be relevant to the merits." Fed. R. Civ. P. 65(a)(2), 1966 Advisory Committee's Note. Further, consolidation is particularly appropriate when the issues presented are "purely legal." In such cases, a "routine" accelerated trial "preserves judicial resources and saves "the parties from wasteful duplication

of effort." Now v. Operation Rescue, 747 F.Supp. 760, 768 (D.D.C. 1990).

IV. Analysis

A. Consolidation

The issues raised by the parties in this case are "undoubtedly purely legal in the relevant sense." Nat'l Park Hospitality Ass'n v. Dep't of Interior, 547 U.S. 803, 812 (2003). The Court is being asked to determine a legal issue–when are statutory exclusivity periods triggered in the case of reissued patents. The positions of the parties here "constitute bright-line rules, impervious, so far as appears, to factual variation." Teva Pharmaceuticals v. Sebelius, 595 F.3d 1303, 1309 (D.C. Cir. 2010).

Furthermore, a substantial part of the evidence offered by the parties on the motion for preliminary injunction is relevant to the merits of this case. No further factual development is necessary to enable the Court to enter final judgment. Thus, consolidation of this matter will preserve judicial resources by avoiding duplicative arguments and proceedings. See Now, 747 F.Supp. at 768. The Court therefore consolidates the hearing on the motion for preliminary injunction with its determination of the merits of this case.

B. Ruling on the Merits

Moving next to its analysis of the merits of this case, in its Memorandum Opinion and Order denying Mylan's Motion for Preliminary Injunction (dkt. no. 103), the Court analyzed Mylan's likelihood of success on the merits.[5] For the reasons stated in that Order, and for those that follow, the Court **GRANTS** judgment in favor of the FDA.

1. Deference to the FDA

The FDA's marketing exclusivity decision may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under the Administrative Procedure Act's ("APA") arbitrary and capricious standard of review, an agency's administrative decision is entitled to a presumption of validity. Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985). The reviewing court must consider whether the agency's decision was based upon consideration of the relevant factors, and whether there has been a clear error of judgment. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402,

[5]The Fourth Circuit has held that in order for a party to obtain a preliminary injunction, they must establish, among other factors, that they are likely to succeed on the merits. Real Truth About Obama, Inc. v. Fed. Election Comm'n, 575 F.3d 342, 246 (4th Cir. 2009).

416 (1971). A court must uphold the agency's action if it is "rational, based upon consideration of the relevant factors and within the scope of authority delegated to the agency by the statute." Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983).

Moreover, in reviewing the FDA's interpretation of the Hatch-Waxman Act, the Court must undertake the two-step inquiry set out in Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842 (1984). The first question under Chevron is whether "Congress has directly spoken to the precise question at issue." Id. at 842. If, however, the statute "is silent or ambiguous with respect to the specific issue," a court should proceed to the second prong of Chevron, under which "the question...is whether the agency's answer is based on a permissible construction of the statute." Id. at 843. A court need not find that the agency's interpretation was the only one that could have been adopted; rather, it must only find it was a permissible one. Id.

2. Chevron Step One

Congress has not addressed the precise question presented here. Mylan contends that the plain language of the Hatch-Waxman Act's court decision trigger clause, 21 U.S.C. § 355(j)(5)(B)(iv),

governs the instant action. The FDA, however, argues that neither the court decision trigger clause, nor the remainder of the Hatch-Waxman Act, addresses exclusivity periods for reissued patents, and consequently, it has the authority to provide its own interpretation of the matter. The FDA presents the stronger argument.

According to Mylan, the court decision trigger clause clearly provides that

> an exclusivity period begins to run on 'the date of a decision of a court in [a relevant] action...holding the patent which is the subject of the certification to be invalid or not infringed.' Applied to this case, the exclusivity period began to run on the date of the Court's decision invalidating the '068 patent, which had been the subject of certification by Teva." (Dkt. No. 85). (quoting 21 U.S.C. § 355(j)(5)(B)(iv)).

The language of the court decision trigger clause, however, is far from clear. While no court has yet examined the precise question presented, in Apotex Inc. v. FDA, 414 F.Supp.2d 61, 69 (D.D.C. 2006), the district court concluded that 21 U.S.C. 355(j)(5)(B)(iv) was silent as to how many exclusivity periods may arise in connection with a single drug product. In reaching its decision, the court noted the ambiguity inherent in the court decision trigger clause's language, and the Hatch-Waxman Act's treatment of exclusivity periods in general. Id. It further stressed the

importance of deferring to the FDA's reasonable interpretations in these situations, thereby enabling the agency to fill in the statutory gaps left by Congress. Id.

On appeal, the Court of Appeals for the District of Columbia affirmed the district judge's "thoughtful decision." It agreed that the language of the court decision trigger clause is ambiguous in its treatment of multiple exclusivity periods, and thus warranted deference to the FDA's interpretation. Apotex, Inc. v. FDA, 226 F.App'x 4, 5 (D.C. Cir. 2006) (per curiam).

Similar to the findings of the district court in Apotex, here, ambiguity exists with respect to the court decision trigger clause's treatment of exclusivity periods for reissued patents. As an initial matter, the "court-decision trigger language [] does not necessarily define what causes the exclusivity entitlement to arise." Apotex, 414 F.Supp.2d at 71. Nor does anything in the court decision trigger clause of the statute foreclose the FDA's single bundle of patent rights interpretation that, in the case of reissued patents, periods of exclusivity do not arise until after a court decision issues on the reissued patent. In fact, the FDA's interpretation avoids an incongruity that would arise if a court decision on the original patent were sufficient to trigger (and

exhaust) 180-day exclusivity, but the patent at issue was still in effect in its reissued form.

Of course, the Court acknowledges there is also little to suggest that Mylan's interpretation of the matter–that the exclusivity period is triggered at the time a court decision issues on the original patent–is inaccurate. However, "the Court's sentiments regarding which of the possible interpretations is the better or more likely approach is irrelevant under the legal calculus of Chevron step one." Id. It is enough that the court decision trigger clause is subject to more than one interpretation as to the exclusivity rights of reissued patents for the Court to conclude that the statute is ambiguous. Id.

The Court also finds ambiguity as to whether the court decision trigger clause applies to all, including reissued, patents, or only to original patents. That clause speaks to "*a* decision of a court" and "*the* patent which is subject of the certification." 21 U.S.C. § 355(j)(5)(B)(iv)(emphasis added). Mylan contends this language applies to all, not just original, patents. While the statutory rules of construction do provide that words importing the singular, such as "a" and "the", may also include the plural, it is not always the case. 1 U.S.C. § 1. In fact, the ordinary understanding of the words "a" and "the" is that

they refer to singular items. At Step One of Chevron, the Court "must assume 'that the legislative purpose is expressed by the ordinary meaning of the words used.'" Apotex, 414 F.Supp.2d at 70 (quoting Cal. Indep. Operator Sys. v. FERC, 372 F.3d 395, 400 (D.C.Cir. 2004). Thus, it appears that Congress was referring only to original, and not all, patents when it drafted the court decision trigger clause.

In addition to analyzing the plain language of the court decision trigger clause itself, the Court must look to the broader context of the relevant statutory scheme. "In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning–or ambiguity–of certain words or phrases may only become evident when placed in context." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 133, 134 (2000). Reissued patents, governed by 35 U.S.C. §§ 251 and 252, are unique entities in patent law. If a reissued patent is granted, the original patent must be surrendered. 35 U.S.C. § 251. However, 35 U.S.C. § 252 also provides for continuity between "substantially identical" claims of the original and reissued patents. A patentee may recover for all infringement which happens after the date of the original patent if the

respective "claims of the original and reissued patents are substantially identical." 35 U.S.C. § 252. If the reissued claims are not substantially identical to the original claims, the original claims are unenforceable and the patentee cannot recover for any infringing activity prior to the date of reissue. Id.

Thus, the patent statutes specifically address the distinction between "original patents" and "reissued patents"–making it clear that sometimes they are contiguous and sometimes not–while the Hatch-Waxman Act is silent on the issue; thus, Congress left it for the FDA to decide how reissued patents affect generic exclusivity rights.

Moreover, "the FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) is clearly supported by its regulation, 21 C.F.R. § 314.107[...]." Apotex Inc. v. FDA, 226 F.Appx. 4, 5(D.C. Cir. 2007). In the context of ANDA applicants who submit multiple Paragraph IV certifications, 21 C.F.R. § 314.107(b)(4) provides that ANDA approval will become effective on the last applicable certification date. Similarly, as is the case here, the FDA has determined that when Paragraph IV certifications have been filed to both a original and reissued patent, the later certification-the

reissued patent certification–is relevant in determining when exclusivity rights have been triggered. FDA Letter at 1.

The Hatch-Waxman Act therefore does not lend itself to the interpretation urged by Mylan, and "the text and reasonable inferences from it [do not] give a clear answer against the FDA." Brown v. Gargner, 513 U.S. 114, 120, 115 S.Ct. 532, 130 L.Ed.2d 462 (1994).

3. Chevron Step Two

Under Chevron Step Two, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." Chevron, 467 U.S. at 842. In its letter decision, the FDA filled the gap in the Hatch-Waxman Act's treatment of exclusivity for reissued patents by creating a "single bundle of rights" for the original and reissued patent, and found that "a 30-month stay of approval arising from litigation based on a paragraph IV certification to the original patent remains in effect after that patent is reissued (assuming the litigation giving rise to the stay continues), and any applicant eligible for 180-day exclusivity based on a paragraph IV certification to the original patent remains eligible for that exclusivity after patent reissuance." FDA Letter at 1.

The FDA reasoned that treating an original and reissued patent as a "single bundle of patent rights" is consistent with both the objectives of the Hatch-Waxman Act and also with relevant principles of patent law. It concluded that "leaving a patent listed in the Orange Book despite reissuance and requiring applicants to submit new certifications to reissued patents implements the incentive structure established by the Hatch-Waxman [Act]." (Dkt. No. 52).

The FDA's treatment of reissued patents for exclusivity purposes is consistent with the statutory treatment of reissued patents generally, including the provision that allows a pending cause of action based on an original patent to continue after reissuance to the extent the claims of the original and reissued patent are substantially identical. See 35 U.S.C. § 252. The fact that the FDA could have reached the opposite conclusion does not render the FDA's interpretation unreasonable under the APA. See Barnhart v. Walton, 535 U.S. 212, 222, 122 S.Ct. 1265, 152 L.E. 2d 330 (22).

Mylan contends that the FDA engaged in arbitrary and capricious agency action by treating first filers on the original patent in a manner different from first filers on the reissued patent. However, the FDA's decision only addresses how the agency

will determine exclusivity in a situation involving both an original and reissued patent, as well as court decisions on both the original and reissued patents. The FDA made no decision regarding any particular applicants; the impact of the FDA's decision is dependent on whether and when each applicant filed paragraph IV certifications.

Further, the cases on which Mylan relies to support its proposition held that an agency acted in an arbitrary and capricious manner when it treated similarly situated parties differently without explanation. See Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 28 (D.D.C. 1997) ("Under the Administrative Procedure Act, the FDA either must provide a rational basis for treating MBI's imaging agent as a device while simultaneously regulating essentially identical agents as drugs, or it must treat all four of these similar products in the same way."); United States v. Diapulse Corp. of Am., 748 F.2d 56, 60 (2d Cir. 1984) (court ruled against the FDA because the FDA "had not explained how the differences between the two machines affected their relative effectiveness as heat producing devices"). Those cases are inapposite; here, the FDA has provided a well-reasoned explanation for its decision. See FDA Letter at 5-6, 9-11 (stating that "[FDA] believe[s] that considering a court decision on the

original patent not to be a triggering event in these cases is consistent with the statutory scheme, and is fair to the ANDA applicants who first took on the risk of litigation by certifying to the original patent.").

Additionally, the FDA's April 24 decision comports with its decisions in three prior situations involving exclusivity and a reissued patent. Id. at 6-8. In the case of Mircette, the FDA determined that Barr Laboratories, Inc.'s ("Barr") exclusivity was triggered by a court decision finding the relevant reissued patent not to be infringed. Id. at 7. The FDA did not award a separate exclusivity period based on the first paragraph IV certification to the original patent, in accordance with the FDA's single bundle of rights theory. Id.

In Ultracet, Kali Laboratories, Inc., the first applicant to submit a paragraph IV certification to an original patent, was granted exclusivity and began marketing its product on the day of approval. Id. Over a year later, the patent was reissued. The FDA did not grant exclusivity to the first filer on the reissued patent because exclusivity had already been granted based on the original patent and the FDA believes that, "the rights to 180-day exclusivity for a reissued patent are not distinguishable from the rights to 180-day exclusivity on the original patent." Id. at 8.

Finally, in Adderall XR, Barr was the first filer on two original patents. Id. Reissued patents were issued nearly a year after Barr launched an authorized generic. Id. The FDA concluded that "Barr triggered its 180-day exclusivity on the two original patents when it began marketing an authorized generic, and the reissued patents were not treated as new and distinct patents for purposes of giving rise to new periods of 180-day exclusivity." Id.

Thus, the FDA's decision to treat an original and reissued patent as having a single bundle of rights is reasonable and allows the agency to administer the Hatch-Waxman Act in a predictable manner. This interpretation satisfies the APA's arbitrary and capricious standard of review, and is therefore permissible under Chevron Step Two. Thus, the Court finds in favor of the FDA.

IV. Conclusion

For the reasons stated, the Court:

1. **GRANTS** Mylan's motion for entry of final judgment (dkt. no. 117);

2. **CONSOLIDATES** the hearing on Mylan's motion for preliminary injunction with the trial on the merits pursuant to Federal Rule of Civil Procedure 65(a)(2);

3. **GRANTS** judgment in favor of the FDA; and

4. **ORDERS** that this case be **DISMISSED WITH PREJUDICE** and removed from its active docket.

It is so **ORDERED.**

Pursuant to Fed. R. Civ. P. 58, the Court directs the Clerk of Court to enter a separate judgment order and to transmit copies of both orders to counsel of record and all appropriate agencies.

Dated: June 16, 2014.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE