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.

MEMORANDUM OPINION AND ORDER DENYING MYLAN PHARMACEUTICALS, INC.'S MOTION FOR PRELIMINARY INJUNCTION [DKT. NO. 9]

Pending before the Court is the motion of the plaintiff, Mylan Pharmaceuticals, Inc. ("Mylan"), seeking a preliminary injunction pursuant to Federal Rule of Civil Procedure 65. (Dkt. No. 9). Mylan's motion requires the Court to consider the permissibility of the United States Food and Drug Administration's ("the FDA") interpretation of exclusivity rights under the Hatch-Waxman Act for reissued patents. For the reasons that follow, the Court **DENIES** the motion.

MEMORANDUM OPINION AND ORDER DENYING MYLAN'S MOTION FOR PRELIMINARY INJUNCTION [DKT. NO. 9]

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.

In its motion for preliminary injunction, Mylan challenges a letter decision of the FDA that it contends erroneously concluded a reissued patent does not give rise to eligibility for a period of marketing exclusivity that is separate and distinct from the period of exclusivity arising from the original patent. According to Mylan, original and reissued patents should be treated as two

distinct patents, thereby triggering separate periods of exclusivity.

During a hearing on May 15, 2014, the Court heard arguments from the parties and intervenors. It then requested supplemental briefing on whether it had subject matter jurisdiction to review the FDA's letter decision. The motion is now fully briefed and ripe for review.

II. STATUTORY AND REGULATORY BACKGROUND

A. Pharmaceutical Drug Applications:

Pharmaceutical drugs fall into two categories: drugs sold under brand names and generics. United States v. Generix Drug Corp., 460 U.S. 453, 454-55 (1983). Pioneer and generic drugs in the United States are regulated under the Food, Drug and Cosmetic Act ("FDCA"), which Congress amended extensively in 1984. This version is commonly referred to as the Hatch-Waxman Act. 21 U.S.C. § 355.

The Hatch-Waxman scheme distinguishes between New Drug Applications (NDAs) and ANDAs. To seek approval from the FDA for a brand name drug such as Celebrex®, the manufacturer must file a complete NDA. Such a filing must provide the FDA with a listing of all patents that claim the approved drug or a method of using the

drug, 21 U.S.C. § 355(j)(2)(A)(vii), and set forth data establishing that the drug is safe and effective. 21 U.S.C. § 355(b). The NDA's sponsor also must "file with the application the patent number and the expiration date of any patent which claims the drug...or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).[1]

The Hatch-Waxman Act grants brand name NDA holders a five year exclusivity period before generics may enter the market. 21 U.S.C. § 355(j). Once the NDA holder's five year exclusivity period is over, a company manufacturing a generic drug that is biologically equivalent to the pioneer drug may seek FDA approval for the drug by filing an ANDA. Id. ANDA applicants need not submit their own safety and effectiveness studies, but may instead rely on the NDA applicant's studies. Id.

ANDA applicants also must provide a certification as to whether their proposed generic drug would infringe the pioneer drug's patent. Id. Pertinent here is the fourth of the Hatch-

[1]FDA is required to publish the patent information it receives in the book titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). 21 U.S.C. § 355(b)(1).

Waxman Act's four certification options ("paragraph IV certification"), allowing ANDA applicants to certify that the NDA patent "is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug." 21 U.S.C. § 355 (j)(2)(A)(vii). Thus, "an ANDA applicant making a paragraph IV certification intends to market its product before the relevant patents have expired." aaiPharma Inc. v. Thompson, 296 F.3d 227, 232 (4th Cir. 2002). The NDA holder must receive notice that a paragraph IV certification on behalf of an ANDA applicant has been filed. If, upon receiving such notice, the patent holder sues the applicant for patent infringement within 45 days, the FDA must stay a decision on whether to approve the ANDA for 30 months, unless the patent expires or a court holds that it is invalid or not infringed during that time. 21 U.S.C. § 355(j)(5)(B)(iii).

Paragraph IV ANDA recipients receive a key 180-day marketing exclusivity advantage. 21 U.S.C. § 355(j)(5)(B)(iv). During this time, the FDA may not approve any later-filed ANDAs, thus allowing the first applicant to sell its generic drug without competition from other generic manufacturers.[2] Id. The marketing exclusivity

[2]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

period is triggered on the earlier of two dates: either (1) the date the FDA receives notice "of the first commercial marketing of the drug under the previous application" (the "commercial marketing trigger clause"), or (2) the date a court decides that the patent is either invalid or not infringed (the "court decision trigger clause"). See 21 U.S.C. § 355(j)(5)(B)(iv).

The 180-day marketing exclusivity period provides an opportunity for significant economic gain for the recipient, as it allows the first-filing ANDA applicant to be the only entity gaining profit from the sale of a generic version of the brand drug during that time. As the Federal Trade Commission has stated, this period "increases the economic incentives for a generic company to be the first to file, because the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher price until more generic products enter [the market])." Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and*

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

Policy, Ch. 3, at 12(Oct.2003), *available at http:www.ftc.gov/os/2003/10/ innovationrpt.pdf.*

B. Reissued Patents

A patent may be reissued to correct certain errors in the scope of claims or defects that would have otherwise invalidated the patent. 35 U.S.C. § 251(a). The relevant statute, 35 U.S.C. § 252, establishes the effect of reissued patents:

> The surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form, but in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent.

A reissued patent is identified by the U.S. Patent and Trademark Office ("PTO") with the letters "RE" preceding the patent number. A reissued patent must reference the original patent on its face. It also has the same expiration date as the original patent. 35 U.S.C. § 251(a).

In order to provide timely notice of reissuance to pending and potential ANDA applicants, an NDA holder must submit information regarding reissued patents to the FDA within 30 days of the date of reissuance. 21 U.S.C. § 355(c)(2). An ANDA applicant must amend any prior patent certification(s) to address the patent as reissued. 21 C.F.R. § 314.94(a)(12)(viii)(C)(1).

A reissued patent remains listed in the Orange Book until the FDA has determined either that no ANDA applicant is eligible for 180-day exclusivity as to that patent or that their exclusivity period has expired. 21 U.S.C. § 355(c)(2).

III. 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 generic manufacturer 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 held 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 Court of Appeals reversed the district court's ruling in part, 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.[3] The FDA tentatively approved Teva's ANDA on April 27, 2012.

Nearly five years after the its litigation with Teva, Pfizer corrected the deficiencies of the '068 patent, and on March 5,

[3]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.

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 granted on the reissued patent.[4] 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 that expressly allowed Teva to launch its generic version of Celebrex® in December 2014, or earlier under certain, undisclosed, circumstances.[5]

B. The FDA's Letter Decision

On April 24, 2014, the FDA issued a letter decision to all celecoxib ANDA applicants in which it addressed the "legal and

[4]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.

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

regulatory scheme governing eligibility of ANDA applicants for 180-day exclusivity under the FDCA as it existed prior to December 8, 2003, in a situation involving a reissued patent." FDA Letter at 1. The FDA explained that it "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, 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

> [f]or 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 the first party to challenge both the original patent and reissued version of that patent qualifies for 180-day marketing exclusivity. The FDA noted that this outcome "best reconciles the complicated intersection between the Hatch-Waxman [Act] 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.

IV. Legal Standards

A. Preliminary Injunctions

The Fourth Circuit has noted that "preliminary injunctions are extraordinary remedies involving the exercise of a very far-reaching power [that should be] granted only sparingly and in limited circumstances." MicroStrategy Inc. v. Motorola, Inc., 245 F.3d 335, 339 (4th Cir. 2001). In order to obtain a preliminary injunction in this case, Mylan must establish the following:

> (1) that it is likely to succeed on the merits,(2) that it is likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in it favor, and (4) that an injunction is in the public interest.

Real Truth About Obama, Inc. v. Fed. Election Comm'n, 575 F.3d 342, 346 (4th Cir. 2009), vacated on other grounds, 130 S.Ct. 2371.

Mylan bears the burden of satisfying each of the four elements with a "clear showing" that it is entitled to the extraordinary relief it seeks. Id. at 346.

B. Administrative Procedure Act

Under the Administrative Procedure Act (the "APA"), the FDA's decisions are subject to judicial review and may only be overturned if they are arbitrary and capricious. 5 U.S.C. § 706. In determining whether the FDA acted in excess of its statutory authority in interpreting exclusivity rights for reissued patents, 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 (1984).

Under Chevron Step One, courts must inquire whether "Congress has directly spoken to the precise question at issue." Id. at 842. If so, the Court "must give effect to the unambiguously expressed intent of Congress." Id. at 843. In deciding whether a statute is ambiguous, courts must consider "the overall statutory scheme, legislative history, the history of evolving congressional regulation in the area, and...other relevant statutes." Id. If Congress has not directly addressed the precise question at issue,

a court must proceed to Chevron Step Two, under which "the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id.

In conducting an analysis under Chevron Step Two, a court should defer to the agency's permissible interpretation if the agency has offered a reasoned explanation why it chose that interpretation. Id. at 843. A court ought not usurp an agency's interpretive authority by supplanting the agency's construction with its own, so long as the interpretation is not "arbitrary, capricious, or manifestly contrary to the statute." United States v. Shimer, 367 U.S. 374, 383 (1961).

V. Analysis:

A. Jurisdiction

As a threshold matter, the Court must determine if it has jurisdiction to review the letter decision of the FDA. In order for the Court to have jurisdiction in this case, there must be a final agency action that is ripe for review. 5 U.S.C. § 704. The Supreme Court of the United States has instructed courts, upon evaluating whether an agency decision is ripe for jurisdictional purposes, to look at the fitness of the issues for judicial consideration and "the hardship to the parties of withholding court

consideration." Nat'l Park Hospitality Ass'n v. Dep't of Interior, 537 U.S. 803, 808 (2004).

In Teva Pharms. USA, Inc. v. Sebelius, 638 F.Supp.2d 42, 50 (D.D.C. 2009), the district court determined that an FDA letter decision similar to the one at issue here was ripe for review. The court in Sebelius reasoned that "[w]hen the question at issue is well-defined, and when withholding judicial consideration would cause undeniable harm, as here, ripeness concerns pose no obstacle to pre-enforcement review." Id. at 1311. Further, the court provided that a determination of the "fitness for review of the legal issue presented" required an examination of "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." Id. at 1308.

Fourth Circuit precedent is consistent with the ripeness analysis in Sebelius. In determining "whether a particular agency action is final, [a court] must consider 'whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." Chamblee v. Espy, 100 F.3d 15, 17 (4th Cir. 1996)(quoting Franklin v. Massachusetts, 505 U.S. 788,797 (1992)). Further, courts should review "the practical effect of the [agency's] determination." Id.

Upon applying these factors to the case at hand, it is apparent this matter is ripe for review. First, the issues raised by the parties are "undoubtedly purely legal in the relevant sense." Nat'l Park Hospitality Ass'n, 595 F.3d at 1308. 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, similar to those of the parties in Sebelius, "constitute bright-line rules, impervious, so far as appears, to factual variation." Id. at 1309.

Also, delay in a court decision would not "afford additional 'concrete[ness]'" to the matter given that an FDA "about-face" on the issue "seems extraordinarily unlikely." Id. FDA's April 24 letter decision states that it is a determination of the "legal and regulatory scheme" governing exclusivity period for celecobix. FDA Letter at 1. Nowhere in that letter does the FDA indicate that it may change its stance on the issue. Thus, it is safe to assume the FDA's May 30 celecoxib ANDA approval determinations will comport with its April 24 letter decision.

Finally, withholding a determination in this case would adversely affect the parties and the public, as it would delay the start of generic competition for Celebrex®–a drug that has been sold exclusively by Pfizer for over 16 years. Accordingly, the

FDA's letter decision interpreting the Hatch-Waxman Act in the context of marketing exclusivity rights for reissued patents is ripe for judicial review.

B. Mylan's Likelihood of Success on the Merits

i. Deference to the FDA

In order to obtain a preliminary injunction, Mylan must first establish that it is likely to succeed on the merits of this case. Real Truth About Obama, 575 F.3d at 346. Its probability of success on the merits is informed by the deferential standard of review under the APA. 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 APA's 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, 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 is governed by the Chevron two step analysis. 467 U.S. at 842-43. 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.

ii. Chevron Step One

The parties disagree over whether Congress has addressed the precise question at issue. 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 here, 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 lauded 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 findings of the district court in Apotex, the Court concludes that ambiguity exists here 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 that 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, illustrating that 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, 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.

The Hatch-Waxman Act therefore does not lend itself to the interpretation urged here 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). Thus, the Court moves on to Chevron Step Two.

iii. Chevron Step Two

In 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). Rather, as noted earlier, its interpretation need only be permissible. Chevron, 467 U.S. at 843-844.

Mylan argues that FDA's interpretation is arbitrary and capricious because it treats first-filers on the original patent in a manner that is different from first-filers on the reissued

patent. The FDA's decision, however, 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 inapplicable here because the FDA provided a well-reasoned explanation for its decision. See FDA Letter at 5-6,

9-11. As the agency stated, "[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." Id. at 11.

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 believed 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 its 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, Mylan is unlikely to succeed on the merits of this case.

C. Irreparable Harm to Mylan

Even assuming, *arguendo,* that Mylan is likely to succeed on the merits of this case, it must still satisfy the remaining elements necessary to obtain a preliminary injunction. The second prong of the preliminary injunction test requires Mylan to establish that it is likely to suffer irreparable harm if

injunctive relief is not granted. Real Truth About Obama, 575 F.3d at 346. The irreparable harm must be actual and imminent, not remote and speculative. Direx Israel, Ltd. v. Breakthrough Medical Corp., 952 F.2d 802 (4th Cir. 1991). As the Fourth Circuit noted in Direx Israel:

> The hardship balance and the likelihood of success determination are separate, sequential steps in the application of the hardship test. [Blackwelder Furniture Co. of Statesville, Inc. v. Seilig Mfg. Co., 550 F.2d 189 (4th Cir.1977)] makes it plain that the balancing of hardship should proceed any consideration of the likelihood of success . . . . And the reason for this statement is easy to understand. The hardship test, by its very nature, is to proceed the consideration of the likelihood of success, since the outcome of the hardship test fixes the degree of proof required for establishing the likelihood of success by the plaintiff. If the hardship balance tilts sharply and clearly in the plaintiff's favor, the required proof of likelihood of success is substantively reduced. Similarly, if the hardship to plaintiff is minimal or nonexistent . . . then the burden on the plaintiff to establish likelihood of success on the merits becomes considerably greater. The likelihood of success determination is to proceed only after the hardship balance itself had been resolved. *It is obvious error to resolve the hardship test by including it in the likelihood-of-success test.*
>
> Id. at 817.

Mylan contends that it will lose "millions of dollars in lost profits" if it is not one of the first generic celecoxib manufacturers to go to the market. (Dkt. No. 22). Yet, "purely economic injury and economic loss alone, however substantial, does

not constitute irreparable harm." Mylan Pharmaceuticals, Inc. v. Thompson, 207 F.Supp.2d 476, 285 (N.D.WVa. 2001). For this reason, several courts have held that the financial harm to one generic manufacturer resulting from the FDA's award of exclusivity to another manufacturer is not irreparable. Mylan Pharms. Inc. v. Sebelius, 856 F.Supp.2d 196 (D.D.C. 2012); Sandoz Inc. v. FDA, 439 F.Supp.2d 26, 32(D.D.C. 2006) (loss of $11 million in sales over 180 days was not considered to be irreparable harm); Apotex, Inc. v. FDA, 2006 WL 1030151 at *16-17 (D.D.C. 2006)(loss of 1.4 percent of the company's revenue was not considered irreparable harm). Accordingly, Mylan has failed to satisfy its burden of establishing that it would suffer irreparable harm by not receiving preliminary injunctive relief.

D. Balance of Equities/Hardship

Mylan also must establish that the balance of equities tips in its favor. Real Truth About Obama, 575 F.3d at 346. Here, Mylan contends that, if injunctive relief is not granted and it is therefore denied shared celecoxib marketing exclusivity rights, it will suffer severe financial harm in the form of "tens of millions of dollars" in lost profits. (Dkt. No. 22).

Any financial harm that Mylan would incur in the absence of a preliminary injunction, however, will be matched, and likely

exceeded, by the financial harm that Teva, the first-filer on the original patent, would suffer due to being deprived of its right to sole 180-day marketing exclusivity. Here, Teva claims that if it is forced to share marketing exclusivity rights, it will lose an estimated four times the amount that Mylan contends it stands to lose if a preliminary injunction is not granted. (Dkt. No. 71).

Hence, the parties allege similar economic injuries. However, "if 'the plight of the defendant is not substantially different from that of the plaintiff', [then] there [can be] no imbalance of hardship found in favor of the plaintiff." Mylan, 207 F.Supp. 2d at 485 (quoting, Direx Israel, 952 F.2d at 808). Thus, Mylan has failed to establish that the balance of equities tips in its favor.

E. The Public Interest

Finally, Mylan must establish that an injunction is in the public interest. Real Truth About Obama, 575 F.3d at 346. Mylan contends that by granting an injunction and opening up the generic market to multiple first-filers, the public will be served by robust generic competition for celcoxib. (Dkt. No. 22).

However, Congress has explicitly concluded that the public interest is best served by providing 180 days of complete exclusivity as a "reward for generics that stick out their necks at the cost of a patent infringement suit," Teva Pharms. USA, Inc. v.

Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010), because it is those companies that strive to "get generic drugs into the hands of patients at reasonable prices–fast." Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809 (D.C. Cir. 2001). The present situation fits squarely within that proposition. Teva was the first and only party to file challenges both to the '068 patent and its reissue.

Requiring a true first filer to share exclusivity upon reissue is not necessarily in the public's best interest. Such a result discourages generic challenges to brand drugs over the long term, which will ultimately increase drug prices.

> The statute's grant of a 180–day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted.

Teva, 595 F.3d at 1318.

Thus, Mylan is incorrect in assuming that granting shared exclusivity in this instance will bring more generic competition into the market for celecoxib sooner. To the contrary, given that

"Congress deliberately created the 180-day exclusivity bonus," a litigant "cannot justify its [position] by proudly proclaiming that [the relief it seeks will] eviscerate[] that bonus." Id.

VI. Conclusion

In conclusion, Mylan has failed to establish the elements necessary to obtain a preliminary injunction. The Court therefore **DENIES** Mylan's motion for preliminary injunction. (Dkt. No. 9).

It is so **ORDERED.**

The Court directs the Clerk to transmit copies of this Memorandum Opinion and Order to counsel of record.

DATED: May 29, 2014.

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