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

ASTRAZENECA AB and **ASTRAZENECA PHARMACEUTICALS LP,**

Plaintiffs,

v.

CIVIL ACTION NO. 1:22-CV-35
Judge Bailey

MYLAN PHARMACEUTICALS, INC. and **KINDEVA DRUG DELIVERY L.P.,**

Defendants.

MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants' Motion to Dismiss [Doc. 29], filed June 1, 2022. In this patent infringement action brought by AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively, "Plaintiffs"), Mylan Pharmaceuticals, Inc. and Kindeva Drug Delivery L.P. (collectively, "Defendants") move for the dismissal of Count I of Plaintiffs' Complaint for failure to state a claim under Rule 12(b)(6). For the reasons that follow, the Court **DENIES** the Motion.

I.BACKGROUND

On April 26, 2022, Plaintiffs filed its Complaint. *See* [Doc. 1]. In the Complaint, Plaintiffs allege patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., and in particular under 35 U.S.C. § 271(e). More specifically, Plaintiffs allege two counts: (1) Infringement of the '558 Patent and (2) Declaratory Judgment of Infringement of the '558 Patent. *See* [Id. at 11–14].

Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

A. The Patent-in-Suit

The '558 patent, entitled "Composition for Inhalation," was issued by the United States Patent and Trademark Office ("the USPTO") on April 26, 2022, to AstraZeneca AB, upon assignment from the inventors Nayna Govind and Maria Marlow. The '558 patent is directed to pharmaceutical formulations, including Symbicort®, in which the active ingredients budesonide and formoterol are suspended in a liquid hydrofluoroalkane propellant ("HFA 227") with the excipients polyvinyl pyrrolidone ("PVP") and polyethylene glycol ("PEG").

The '558 patent is related through continuation applications to AstraZeneca's U.S. Patent Nos. 7,759,328 ("the '328 patent"), 8,143,239 ("the '239 patent"), 8,575,137 ("the '137 patent"), and 10,166,247 ("the '247 patent"). Like the '558 patent, all four patents are directed to formulations of budesonide and formoterol with HFA 227, PVP, and PEG, and all share the same specification. The parties in the above-styled case have held two trials[1] on these patents, both under the Hatch-Waxman Act.

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[1] The first trial involved the '328, '239, and '137 patents. Defendant Mylan stipulated to infringement and the trial was limited to validity. Senior District Judge Keeley entered judgment of no invalidity as to each asserted claim, rejecting Mylan's sole defense of obviousness. *See* ***AstraZeneca AB v. Mylan Pharm. Inc.***, 522 F.Supp.3d 200 (N.D. W.Va. Mar. 2, 2021) (Keeley, S.J.). The Federal Circuit affirmed the judgment of no invalidity but disagreed with the district court's claim construction of "0.001%" PVP and vacated the judgment of infringement. *See* ***AstraZeneca AB v. Mylan Pharm. Inc.*** 19 F.4th 1325 (Fed. Cir. 2021).

The second trial involved the '247 patent. Defendant Mylan stipulated to infringement, and the trial on Defendant Mylan's validity case concluded on June 22, 2022. A decision following the second trial is pending. *See* Civil Action No. 1:18-CV-193 (N.D. W.Va.) (Keeley, S.J.).

The claims asserted in the above-styled case parrot the claims at issue in the first trial–the validity of which was confirmed by this Court and the Court of Appeals–except that the limitation of "0.001% PVP" that was the subject of the Federal Circuit's ruling is replaced in the '558 patent by a concentration range of "about 0.0005 to about 0.05% PVP.

As to the second trial, Defendant Mylan's invalidity argument was directed at the '247 patent claims' requirement that the compositions be "stable"–a requirement that is not included in any claims of the '558 patent.

B. Defendants ANDA No. 211699

On June 26, 2018, Defendants submitted ANDA No. 211699 ("Mylan's ANDA") to the FDA, seeking approval to market inhalation aerosal products with budesonide and formoterol fumarate dihydrate in two strengths (160/4.5 µg and 80/4.5 µg). Mylan's ANDA products are generic versions of Plaintiffs' Symbicort® products. Defendants proposed ANDA generic product contains the same formulation as Symbicort® but with a slightly different amount of PVP. The FDA granted final approval to Mylan's ANDA on March 15, 2022.

II.DEFENDANTS' MOTION TO DISMISS

On June 1, 2022, Defendants' filed a Motion to Dismiss moving this Court to dismiss Count 1 of Plaintiffs' Complaint for failure to state a claim under Rule 12(b)(6). In support of the Motion, Defendants' argue that because the '558 patent was not even in existence during the time in which Mylan's ANDA was awaiting FDA approval, the provisions of the Hatch-Waxman Act do not apply and no relief can be afforded to Plaintiffs under the Act.

Moreover, Defendants state that Plaintiffs' claim that the submission of Mylan's ANDA infringed the '558 patent under 35 U.S.C. § 271(e)(2)(A) "cannot be" because Mylan's ANDA "was already approved *before* the '558 patent issued, mooting the need to amend its ANDA to include a Paragraph IV certification to the '558 patent, which was not even listed in the Orange Book until May 20, 2022 - three weeks *after* AstraZeneca filed this suit." *See* [Doc. 30 at 10].

Relying on ***Ferring B.V. v. Actavis, Inc.***, 2016 WL 3027446 (D. N.J. May 26, 2016)[2], Defendants assert that courts "have quickly winnowed out such claims before." *See* [Id.]. In ***Ferring***, the defendant filed its ANDA in July 2010, and the FDA approved it in December 2012. *See* ***Ferring***, 2016 WL 3027446, at *1. The plaintiffs' patent did not issue until June 2015. *See* ***id***. at *4. The court found that plaintiffs could not bring a § 271(e)(2)(A) claim on the facts alleged and dismissed the claim. *See* ***id***. at *5. In this case, Defendants argue that like in ***Ferring***, a § 271(e)(2)(A) claim must be based upon a patent that has already been issued at the time the infringing ANDA is filed.

A. Plaintiffs' Opposition to Defendants' Motion to Dismiss

In opposition, Plaintiffs' state that

> Mylan can seek dismissal of AstraZeneca's claim for infringement under § 271(e) and the related relief only by advancing multiple legal propositions unsupported by precedent or the statutory text. Mylan's argument distills to

[2] Defendants also rely on ***Celgene Corp. v. Mylan Pharm. Inc.***, 17 F.4th 1111 (Fed. Cir. 2021), ***Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*** 887 F.3d 1117 (Fed. Cir. 2018), and ***Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.***, 978 F.3d 1374 (Fed.Cir. 2020) to reinforce the rationale of ***Ferring***. *See* [Doc. 30 at 11–12].

> a complaint about timing: according to Mylan, no § 271(e) claim may lie where the filing and approval of an ANDA both precede the issuance of the infringed patent. But Mylan points to no such temporal restriction in the statute, and Federal Circuit precedent has rejected similar efforts to insert one.

[Doc. 45 at 12–13]. Plaintiffs advance three arguments in opposition of dismissal. First, Plaintiffs argue that a § 271(e)(2) claim does not require ANDA filing or a Paragraph IV Certification before patent issuance. *See* [Id. at 13–15]. Second, Plaintiffs argue that FDA approval does not bar assertion of claims under § 271(e)(2). *See* [Id. at 16–21]. Third, Plaintiffs argue that this Court possesses the authority to award relief even absent § 271(e). *See* [Id. at 21–22].

Plaintiffs rely heavily on ***Research Foundation v. Mylan Pharm. Inc.***, 2012 WL 1901267 (D. Del. May 25, 2012) (Stark, J.). In ***Research Foundation***, a case indistinguishable from the above-styled case, Judge Stark addressed a scenario where the patent did not issue until after FDA approval. The patent was issued on July 6, 2010, just five days *after* the ANDA approval on July 1, 2010. *See* ***Research Foundation***, 2012 WL 1901267, at *5. Judge Stark squarely addressed the issue presented in the above-styled case: whether relief under § 271(e)(4) was available for a patent issuing after FDA approval. After addressing and considering the Federal Circuit's precedent, Judge Stark upheld the § 271(e) claim and ordered a reset of the approval date under § 271(e)(4) based on the patent issuing after the ANDA filing and approval. *See* ***id.*** at *4, *7; *see also* ***In re Omeprazole Patent Litig.***, 536 F.3d 1361, 1367–68 (Fed. Cir. 2008) ("If the FDA has

already approved the ANDA, the district court's order would alter the effective date of the application, thereby converting a final approval into a tentative approval.").

III. STANDARD OF REVIEW

A complaint must be dismissed if it does not allege "enough facts to state a claim to relief that is plausible on its face." ***Bell Atl. Corp. v. Twombly***, 550 U.S. 544, 570 (2007); *see also* ***Giarratano v. Johnson***, 521 F.3d 298, 302 (4th Cir. 2008) (applying the ***Twombly*** standard and emphasizing the necessity of *plausibility*). When reviewing a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must assume all of the allegations to be true, must resolve all doubts and inferences in favor of the plaintiff, and must view the allegations in a light most favorable to the plaintiff. ***Edwards v. City of Goldsboro,*** 178 F.3d 231, 243–44 (4th Cir. 1999).

When rendering its decision, the Court should consider only the allegations contained in the Complaint, the exhibits to the Complaint, matters of public record, and other similar materials that are subject to judicial notice. ***Anheuser-Busch, Inc. v. Schmoke***, 63 F.3d 1305, 1312 (4th Cir. 1995). In ***Twombly***, the Supreme Court, noted that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. . . ." ***Twombly***, 550 U.S. at 555, 570 (upholding the dismissal of a complaint where the plaintiffs did not "nudge[ ] their claims across the line from conceivable to plausible.").

"[M]atters outside of the pleadings are generally not considered in ruling on a Rule 12 Motion." ***Williams v. Branker***, 462 F. App'x 348, 352 (4th Cir. 2012). "Ordinarily, a

court may not consider any documents that are outside of the Complaint, or not expressly incorporated therein, unless the motion is converted into one for summary judgment." ***Witthohn v. Fed. Ins. Co.***, 164 F. App'x 395, 396 (4th Cir. 2006). However, the Court may rely on extrinsic evidence if the documents are central to a plaintiff's claim or are sufficiently referred to in the Complaint. ***Id***. at 396–97.

IV.THE HATCH-WAXMAN ACT

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (otherwise known as the "Hatch-Waxman Act"), seeks to encourage "pioneering research and development of new drugs," as well as the "production of low-cost, generic copies of those drugs." ***Eli Lilly & Co. v. Teva. Pharm. USA, Inc.***, 557 F.3d 1346, 1348 (Fed. Cir. 2009). To that end, a manufacturer may obtain FDA approval to market a generic drug by making a certification regarding patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") as covering the NDA drug, and certifying that those patents are "invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted" ("paragraph IV certification"). ***Id***. (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). Upon receiving a paragraph IV certification, a patentee may sue the applicant for patent infringement within 45 days, thus delaying FDA approval of the ANDA. ***Id***. (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

In this case, where Plaintiffs have sued Defendants under the Hatch-Waxman Act for infringement of the patent-in-suit, the Court is tasked with deciding whether Mylan's ANDA product infringes upon the '558 patent.

V. DISCUSSION

At the motion to dismiss stage under Rule 12(b)(6), this Court finds that Plaintiffs' Complaint alleges enough facts to state a claim to relief that is plausible on its face for infringement under § 271(e)(2) by "identify[ing] the ANDA and alleg[ing] that the proposed ANDA products will infringe." ***Celgene Corp. v. Sun Pharma Gloval FZE***, 2020 WL 1921700, at *3 (D. N.J. Apr. 6, 2020). The allegations contained in Plaintiffs' Complaint go well beyond plausibility. Thus, this Court concludes that Plaintiffs have sufficiently pled infringement on one or more claims of the '558 patent.

IV.CONCLUSION

For the foregoing reasons, the Court **DENIES** Defendants' Motion to Dismiss [**Doc. 29**].

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record herein.

DATED: July 12, 2022.

JOHN PRESTON BAILEY
UNITED STATES DISTRICT JUDGE