NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. TRIS PHARMA, INC., Defendant.	**Civil Action No. 26-1739 (SRC)** **OPINION & ORDER**

CHESLER, District Judge

This matter comes before the Court on the motion to dismiss the Complaint, pursuant to Federal Rule of Civil Procedure 12(b)(6), by Defendant Tris Pharma, Inc. ("Tris.") Plaintiff Jazz Pharmaceuticals Ireland Limited ("Jazz") has opposed the motion. For the reasons explained below, the Court will deny the motion.

In brief, the Complaint alleges the following facts. This case arises from a dispute under the Hatch-Waxman Act between Jazz, manufacturer of the branded pharmaceutical Xyrem®, and Tris, a generic pharmaceutical company. Tris submitted new drug application ("NDA") No. 220138, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2), seeking approval to market a version of Xyrem® prior to the expiration of seven patents owned by Jazz which are listed in the Orange Book as covering Xyrem®. The NDA submitted by Tris contains Paragraph IV certifications applicable to all seven patents at issue. Tris sent to Jazz a notice letter which informed Jazz of the submission of these Paragraph IV certifications, and Jazz filed the Complaint in the instant case.

The Complaint asserts seven counts, one for each of the patents at issue. Every count has the same structure and alleges, in brief: 1) submission of the NDA constitutes patent infringement under 35 U.S.C. § 271(e)(2)(A); 2) if the NDA is approved, Tris will infringe under § 271(a); 3) if the NDA is approved, Tris will infringe under § 271(b); and 4) if the NDA is approved, Tris will infringe under § 271(c). Tris moves to dismiss the Complaint in its entirety, pursuant to Rule 12(b)(6), for failure to state a valid claim for relief.

In the opening brief in support of this motion to dismiss, Tris states that, while its "NDA previously contained what are commonly called 'Paragraph IV certifications' to the patents-in-suit," it subsequently amended the NDA by providing § 505(b)(2)(B) statements which "replace Tris's previous Paragraph IV certifications." (Def.'s Br. at 8.) Tris argues, in short, that these proposed changes to the NDA exclude the uses covered by the patents at issue, and that therefore all claims in the Complaint should be dismissed.[1] Essential to this argument is Tris's contention that "the claims in the complaint are 'based' on an extrinsic document," and that the Proposed Amended NDA is that document. (Def.'s Br. at 10.)

In opposition, Jazz argues that Tris's motion to dismiss relies on material extrinsic to the Complaint that cannot be considered at this juncture, the Proposed Amended NDA. Jazz contends that it had not seen any portion of the Proposed Amended NDA before filing the Complaint, and that the Complaint in no way mentions or relies on the Proposed Amended NDA. In short, Jazz argues that the Proposed Amended NDA is a document which is extrinsic to the

[1] This Opinion will refer to the NDA as originally filed as the "NDA," and the document that Tris says it subsequently modified as the "Proposed Amended NDA."

Complaint and that there is no valid legal basis for the Court to consider it on the instant motion to dismiss.

This Court finds Jazz's objection to be persuasive because it is supported by the legal principles which form the foundation of contemporary jurisprudence of the Rule 12(b)(6) motion to dismiss. Wright & Miller state the fundamental legal principles of the analysis under Rule 12(b)(6) as follows:

> Federal pleading standards are applied to determine whether a complaint in a federal court action states a claim for relief. For purposes of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), those standards dictate that (1) the complaint is construed in the light most favorable to the plaintiff, (2) its non-conclusory allegations are taken as true, and (3) all reasonable inferences that can be drawn from the pleading are drawn in favor of the pleader.

5B Charles Alan Wright et al., Federal Practice and Procedure § 1357 (4th ed.) The Complaint in this action provides detailed factual allegations about Defendant's submission of NDA No. 220138 to the FDA, containing Paragraph IV certifications for every patent-in-suit.[2] (Compl. at ¶¶ 1, 24-27.)

Tris moves to dismiss the Complaint with an argument premised largely on the contention that it subsequently took actions which change the facts about the content of NDA No. 220138. In short, under Third Circuit law, a motion to dismiss the Complaint, pursuant to Rule 12(b)(6), cannot succeed by arguing that the facts alleged in the Complaint are no longer true, because, as Wright & Miller state, the non-conclusory allegations are taken as true for the purpose of deciding a 12(b)(6) motion. The Complaint's detailed factual allegations about NDA No. 220138, the Paragraph IV certifications, the patents at issue and their listing in the Orange

[2] The parties do not dispute that the original NDA submission filed by Tris contained Paragraph IV certifications as to every patent-in-suit.

Book, and the Notice Letter dated January 9, 2026, are all taken as true for the purpose of deciding this motion.

Defendant's argument that the content of NDA No. 220138 has subsequently changed must fail because it does not reckon with this essential principle: on this motion, the Court does not find facts, but instead takes the non-conclusory allegations in the Complaint as true. Tris has given this Court no controlling authority for the proposition that this bedrock principle does not apply here.

Instead, Tris argues that, in short: 1) the Complaint references NDA No. 220138; 2) Tris has subsequently modified NDA No. 220138; and 3) therefore, the Court should rule on this motion by examining the subsequently modified NDA No. 220138.[3] The Court declines to do so, on two grounds: 1) as required by law, the Court takes the non-conclusory allegations in the Complaint as true; and 2) Tris has not persuaded that, under the circumstances of this case, the Court may look to the contents of a document cited in the Complaint that has been subsequently modified. Tris has not persuaded this Court that Third Circuit law permits the Court, on this motion, to consider the subsequent modifications that Tris claims to have made to NDA No. 220138.

The Third Circuit has held:

> Generally, a court considering a motion to dismiss under Rule 12(b)(6) may consider only the allegations contained in the pleading to determine its sufficiency. *Pryor v. Nat'l Collegiate Athletic Ass'n*, 288 F.3d 548, 560 (3d Cir. 2002). "However, the court may consider documents which are attached to or submitted with the complaint, as well as . . . . documents whose contents are alleged in the complaint and whose authenticity no party questions, but which are

[3] Tris did not include the entire modified NDA No. 220138 as an exhibit to this motion, but did attach some parts of it, such as the statements that Tris alleges to have replaced the Paragraph IV certifications.

> not physically attached to the pleading. . . ." *Id.* Similarly, "[d]ocuments that the defendant attaches to the motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to the claim." *Id.*

Santomenno ex rel. John Hancock Tr. v. John Hancock Life Ins. Co. (U.S.A.), 768 F.3d 284, 290-91 (3d Cir. 2014). In this quote, the Third Circuit stated the general rule limiting consideration to the allegations contained in the pleading, followed by three exceptions.

Tris has not persuaded this Court that the Proposed Amended NDA fits within either the general rule or any of the exceptions. The Complaint alleges that the NDA submitted to the FDA contains Paragraph IV certifications. (Complaint at ¶ 26.) This does describe the NDA and does not describe the Proposed Amended NDA. Attached to the Complaint, as filed on the docket of this case, are seven documents, the patents-at-issue. Plaintiff did not attach a copy of the NDA with the Complaint, and so the first exception ("documents which are attached to or submitted with the complaint") does not apply here. As for the second exception, "documents whose contents are alleged in the complaint and whose authenticity no party questions, but which are not physically attached to the pleading," this Court finds that the NDA is a document with contents that are alleged in the Complaint but not physically attached to the pleading, thus falling within the second exception; and that the Proposed Amended NDA – since it lacks all the Paragraph IV certifications alleged in the Complaint and thus its contents are not alleged in the Complaint – does not fall within the second exception. As to the third exception (documents attached to the motion to dismiss and referred to in the Complaint), Tris did not attach the Proposed Amended NDA as an exhibit to its moving brief, but did attach two exhibits: 1) "a true and correct copy of Tris's Proposed Label submitted with FDA as part of Tris's New Drug Application ("NDA") No. 220138;" and 2) "a true and correct copy of Tris's 505(b)(2)(B)

Statements submitted by Tris to FDA." (Pensabene Dec. ¶¶ 2, 4.) The Complaint makes no reference to these documents and they do not fall within the third exception. The Court concludes that the Complaint does not reference the Proposed Amended NDA in its allegations, and that the Proposed Amended NDA does not fall within the scope of the three exceptions provided by Third Circuit law.[4] The Court finds no valid legal basis to consider the Proposed Amended NDA, in whole or in part, as a document incorporated into the Complaint by reference.[5]

Moreover, the Complaint alleges sufficient facts to make plausible its claims for patent infringement under 35 U.S.C. § 271(e)(2)(A). Jazz persuasively cites Judge Stark's opinion in Belcher:

> In the Court's view, both the language and the purpose of the Hatch-Waxman Act establish that a plaintiff in receipt of a paragraph IV certification providing notice of the filing of an ANDA (or, as here, a paper NDA) relating to one of the plaintiff's Orange Book-listed patents may state a claim for infringement by alleging its interest in the patent, its receipt of the paragraph IV certification, the filing of the ANDA or NDA, and its contention that the defendant's proposed product will infringe.

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[4] Rather, consideration of the Proposed Amended NDA on this motion appears to be in conflict with Third Circuit law: "The rationale underlying this exception is that the primary problem raised by looking to documents outside the complaint -- lack of notice to the plaintiff -- is dissipated 'where plaintiff has actual notice . . . and has relied upon these documents in framing the complaint.'" In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997) (quoting Watterson v. Page, 987 F.2d 1, 3-4 (1st Cir. 1993)). Plaintiff states that it "had not seen any portion of" the Proposed Amended NDA when it filed the Complaint and therefore neither had actual notice of nor relied on the Proposed Amended NDA in drafting the Complaint. (Pl.'s Opp. Br. at 13.)

[5] Because the Court concludes that Tris has failed to persuade that the Proposed Amended NDA may be properly considered as incorporated by reference on this motion, the Court need not reach the question of the application of Ferring B.V. v. Watson Labs, Inc., 764 F.3d 1382, 1390 (Fed. Cir. 2014) ("For the purposes of section 271(e)(2), 'an application' means the ANDA as filed and all amendments to that application that have been allowed by the FDA.")

Belcher Pharms., LLC v. Int'l Medication Sys., 379 F. Supp. 3d 326, 330-31 (D. Del. 2019). The Complaint pleads specific facts that satisfy these requirements for pleading Hatch-Waxman infringement claims.

"[T]he defendant bringing a Rule 12(b)(6) motion must show that the plaintiff has not stated a claim." Potter v. Cozen & O'Connor, 46 F.4th 148, 155 (3d Cir. 2022). The Court concludes that, as to all claims for patent infringement under 35 U.S.C. § 271(e)(2)(A), Tris has failed to show that Plaintiff has not stated a valid claim for relief.

In addition to the claim for patent infringement under 35 U.S.C. § 271(e)(2)(A), every claim in the Complaint contains three paragraphs that Tris contends are unsupported contingent[6] future claims, should the FDA approve the NDA, for direct infringement under § 271(a), induced infringement under § 271(b), and contributory infringement under § 271(c).[7] The Court now addresses Defendant's motion to dismiss these purported contingent future claims (the "sub-claims.") Tris argues that the Complaint pleads no facts whatever to support these sub-claims. It is true that, in the paragraphs in the Complaint which assert contingent claims under § 271(a, b, c), no additional facts are pled. Tris argues that the purported contingent sub-claims are not supported by sufficient factual allegations to meet the pleading standard of Iqbal.

The problem for Tris is that it has taken the purported contingent sub-claims out of the context in which they appear, and argued as if they are stand-alone claims pled without facts which make them plausible. This Court does not agree with Tris's reading of the Complaint.

[6] Tris does not challenge these claims based on their contingent nature (e.g., a ripeness challenge).

[7] For example, in Count I, they are statements in this form: "Unless enjoined by this Court, upon FDA approval of Tris's NDA, Tris will infringe/induce infringement/contributorily infringe . . ." (Compl. at ¶¶ 31, 32, 33).

The purported sub-claims for infringement pursuant to § 271(a, b, and c) are not independently-asserted claims; they are instead contentions of likely future infringing conduct made in support of the claims for patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A), which this Court has just found state valid claims for relief.[8] As Judge Stark explained in Belcher, one necessary element of a Hatch-Waxman infringement claim is the "contention that the defendant's proposed product will infringe." Belcher, 379 F. Supp. 3d at 331. This Court reads the paragraphs in every claim that Tris views as unsupported sub-claims under § 271(a, b, and c) to be contentions that defendant's proposed product will likely infringe the patents at issue directly and by inducing infringement and contributing to infringement.

This reading of the purported contingent sub-claims is supported by the context in which they appear. The Supreme Court has stated:

> Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.

Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). In the context of these claims, this Court understands the allegations of contingent future violation of § 271(a, b, and c) to be infringement contentions, not unsupported additional claims.

[8] The Court understands that the phrasing of the sub-claims as contingent on future events reflects the design of the Hatch-Waxman Act and 35 U.S.C. § 271(e)(2). See Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997) ("The relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product.") By design, the Hatch-Waxman Act allows present adjudication of infringing activity that is likely to occur in the future, contingent on FDA approval of the ANDA or NDA.

Alternatively, these infringement contentions may be understood as infringement sub-claims that are covered by the "umbrella" of the main Hatch-Waxman claims, as explained by the Federal Circuit in Allergan, Inc. v. Alcon Labs., 324 F.3d 1322, 1330-31 (Fed. Cir. 2003):

> Preliminarily, we must determine whether, as a general matter, section 271(e)(2) may serve as an umbrella for a claim of induced infringement for a method of use patent. As noted above, the district court concluded that it could not. The district court reasoned that the type of claims that accrue upon the filing of an ANDA are limited to those claims that a patent holder could have brought in the absence of section 271(e)(1), such as an infringement claim against a generic drug manufacturer for using the patent in the development of a generic drug. The district court determined that a claim of induced infringement, based upon conduct of a third party that would occur upon approval of an ANDA, was not a claim that a patent holder could have brought before the enactment of section 271(e)(1). *Allergan*, 200 F. Supp. 2d at 1231, 63 USPQ2d at 1436. The district court concluded that "section 271(e)(2) . . . does not provide a predicate for Allergan to sue for inducing infringement." *Id.* at 1230, 63 USPQ2d at 1435.
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> We do not share the district court's view of 35 U.S.C. § 271(e)(2). To begin with, the language of section 271(e)(2) does not limit the reach of the statute to direct infringement actions to the exclusion of actions for induced infringement. Additionally, in *Glaxo*, we did not limit the scope of section 271(e)(2) to direct infringement actions. Instead, we stated that a court must employ a traditional infringement analysis, focusing on all of the elements of infringement. The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered. *Glaxo* does not preclude patentees from asserting claims for induced infringement under 35 U.S.C. § 271(e)(2). In fact, a patent holder asserting infringement of a patent that claims a FDA-approved method of use for which an ANDA seeks approval will, in many instances, have to prove induced infringement. Therefore, section 271(e)(2) may support an action for induced infringement.

The Federal Circuit thus held in Allergan that "section 271(e)(2) may serve as an umbrella for a claim of induced infringement for a method of use patent." Id. Pursuant to Allergan, each claim in the Complaint for infringement under § 271(e)(2) provides an umbrella for the purported sub-claims of induced infringement and contributory infringement.

This Court thus concludes that Tris has failed to persuade that each claim contains factually unsupported sub-claims pursuant to § 271(a, b, and c). Instead, these statements may be understood as contentions of likely future infringement which support the claims under § 271(e)(2); alternatively, they may be viewed as sub-claims under the umbrella of the claims under § 271(e)(2), as explained in Allergan. Either way, the Court finds that the Complaint asserts seven valid counts of patent infringement under the Hatch-Waxman Act. The Court finds no basis to dismiss any claim in the Complaint, in whole or in part.

The motion to dismiss the Complaint will be denied.

For these reasons,

IT IS on this 8th day of July, 2024

ORDERED that Defendant's motion to dismiss the Complaint (Docket Entry No. 10) is **DENIED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge