NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
SUSAN D. WIGENTON
UNITED STATES DISTRICT JUDGE

MARTIN LUTHER KING COURTHOUSE
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NEWARK, NJ 07101
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April 6, 2020

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LETTER OPINION FILED WITH THE CLERK OF THE COURT

Re: ***Celgene Corporation v. Sun Pharma Global FZE et al.***
Civil Action No. 19-10099 (SDW) (LDW)

Counsel:

Before this Court is Defendants Sun Pharma Global FZE, Sun Pharma Global Inc., Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries Limited's (collectively, "Defendants" or "Sun") Motion to Dismiss Plaintiff Celgene Corporation's ("Plaintiff" or "Celgene") Complaint pursuant to Federal Rules of Civil Procedure ("Rule") 12(b)(1) and 12(b)(6). This opinion is issued without oral argument pursuant to Rule 78. For the reasons discussed below, Defendants' motion is **DENIED**.

I. BACKGROUND

Under the Hatch-Waxman Act, a company seeking approval to market a generic pharmaceutical product may file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), identifying a branded drug as the "reference drug" to expedite

approval. *See generally Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 440–41 (D.N.J. 2006) (explaining Hatch-Waxman proceedings). The ANDA must contain information describing the proposed generic drug product. 21 U.S.C. § 355(j)(2)(A). If the branded drug is associated with any patents listed in the FDA's Orange Book,[1] then the ANDA must also contain a certification corresponding to each of those patents. *Id.* § 355(j)(2)(A)(vii). One such certification is a "Paragraph IV" certification, which certifies that the listed patent is invalid or will not be infringed by the proposed ANDA product. *Id.* § 355(j)(2)(A)(vii)(IV). The ANDA applicant submitting a Paragraph IV certification must give notice of such certification to the patentee. *Id.* § 355(j)(2)(B). To enable the patentee to contest the Paragraph IV certification, the Patent Act deems the submission of an ANDA with a Paragraph IV certification to be a technical "act of infringement." *See* 35 U.S.C. § 271(e)(2).

On May 30, 2018, Sun notified Celgene by letter that it had filed an ANDA containing Paragraph IV certifications against three Celgene patents listed in the Orange Book for Celgene's branded drug Revlimid®.[2] *See Celgene Corp. v. Sun Pharma Global FZE, et al.*, Civ. No. 18-11630 (D.N.J.) (the "First Sun Action") at D.E. 10 ¶ 53. Celgene sued Sun for infringement of those three patents on July 13, 2018, a suit that is pending before this Court. *Id.* at D.E. 1.

On April 16, 2019, Celgene also filed the instant suit against Sun, claiming that Sun's proposed ANDA product will infringe three additional patents that are *not* listed in the Orange Book for Revlimid®: U.S. Patent Nos. 7,977,357; 8,193,219; and 8,431,598 (collectively, the "Asserted Patents"). (*See* D.E. 1 ¶ 1.) The Asserted Patents cover, *inter alia*, different crystal forms of lenalidomide, the active pharmaceutical ingredient in Revlimid®. (*See* D.E. 32 at 1–2.) Sun subsequently filed the instant Motion to Dismiss, arguing that Celgene's claims lack subject matter jurisdiction under the Hatch-Waxman Act because the Asserted Patents are not listed in the Orange Book and are not subject to any Paragraph IV certifications from Sun. (D.E. 28.) The motion was timely briefed. (D.E. 29, 32, 41.)[3]

II. LEGAL STANDARD

A defendant may move to dismiss a complaint for lack of subject matter jurisdiction under Rule 12(b)(1) by challenging jurisdiction facially or factually. *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). A facial challenge to subject matter jurisdiction "considers a claim on its face and asserts that it is insufficient to invoke the subject-matter jurisdiction of the court." *Id*. at 358. "A factual attack, on the other hand, is an argument that there is no subject matter jurisdiction because the facts of the case . . . do not support the asserted jurisdiction." *Id.* In a factual attack, "the court may consider and weigh evidence outside the pleadings to determine if it

[1] The "Orange Book" refers to an FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, which lists patents covering branded drug products. *See* 21 U.S.C. §§ 355(b)(1) & (c)(2).

[2] Revlimid® is an FDA-approved drug used for the treatment of certain cancers, including multiple myeloma. (D.E. 1 ¶ 10.)

[3] The parties filed sur-replies disputing whether Celgene can support its pleadings in the instant suit with information it obtained from Sun under a Discovery Confidentiality Order ("DCO") in the First Sun Action. (D.E. 52, 58.) The DCO information is contained in Celgene's opposition brief but not in its Complaint. (D.E. 1, 32.) Because this Court does not rely on any DCO information to deny Sun's motion to dismiss, it declines to consider the parties' sur-replies.

has jurisdiction." *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000), *modified on other grounds by Simon v. United States*, 341 F.3d 193 (3d Cir. 2003).

On a motion to dismiss under Rule 12(b)(6), the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (citation omitted). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

III. DISCUSSION

28 U.S.C. § 1338(a) grants federal courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents." The Complaint alleges patent infringement under the Hatch-Waxman Act, which states in relevant part:

> It shall be an act of infringement to submit an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . which is claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). Thus, the plain text of the Hatch-Waxman Act does not require the submission of a Paragraph IV certification to the FDA to commit the technical "act of infringement" set forth in the statute, nor does it require that the asserted patent be listed in the Orange Book. *See Merck Sharp & Dohme Corp. v. Sandoz Inc.*, Civ. No. 12-3289, 2013 WL 591976, at *3–4 (D.N.J. Feb. 14, 2013) (noting that "[d]efendants' arguments that paragraph IV certifications are needed with respect to the [asserted] patent are belied by the plain language of 35 U.S.C. § 271" and that "[n]othing in the plain language [of § 271] suggests that infringement actions against ANDA filers must be based only on Orange Book listed patents").

Sun argues, however, that it is "black letter law" that § 271(e)(2) does not authorize a patent infringement suit against a proposed ANDA product unless the plaintiff alleges both (1) that the asserted patents are listed in the Orange Book in connection with the plaintiff's drug products and (2) that the defendants have submitted Paragraph IV certifications that the asserted patents are invalid or not infringed. (D.E. 29 at 5–6.) Neither is alleged here. In support for its contention that such a rule is "black letter law," Sun relies primarily on an unpublished district court decision from 2007, *Eisai Co. v. Mut. Pharm. Co.*, Civ. No. 06-3613, 2007 WL 4556958, at *12 (D.N.J. Dec. 20, 2007) (noting that it is "the act of filing a paragraph IV certification with respect to a patent" that "creates a cause of action for patent infringement in the patent holder" under § 271(e)(2) (quoting *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (Fed. Cir. 2002))).

However, subsequent decisions from the Federal Circuit have explicitly held that a Paragraph IV certification is not necessary to confer subject matter jurisdiction under § 271(e)(2). *See, e.g.*, *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018) (holding that "[n]othing more [is] required to establish the district court's subject matter

jurisdiction pursuant to 28 U.S.C. § 1338(a)" than "alleg[ing] that [the defendant] infringed the [asserted] patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA") (citing *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012)); *AstraZeneca*, 669 F.3d at 1377 (explaining that "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2)"). In both *Vanda* and *AstraZeneca*, the Federal Circuit rejected arguments that subject matter jurisdiction did not exist for the § 271(e)(2) claims because plaintiffs did not allege that the defendants filed a Paragraph IV certification for each asserted patent. *See Vanda*, 887 F.3d at 1124; *AstraZeneca*, 669 F.3d at 1373–77.

Subsequent decisions in the District of New Jersey have also held that a Paragraph IV certification is not required for subject matter jurisdiction following *AstraZeneca*. *See, e.g.*, *Medicines Co. v. Eagle Pharm., Inc.*, Civ. No. 16-569, 2016 WL 4418230, at *2 n.1 (D.N.J. Aug. 17, 2016) (noting that *AstraZeneca* appears to have overruled the Paragraph IV certification requirement of *Eisai*); *Merck*, 2013 WL 591976, at *3 (finding that "[d]efendants' arguments that paragraph IV certifications are needed with respect to the [asserted] patent are belied by . . . Federal Circuit and District of New Jersey case law") (citing *AstraZeneca*, 669 F.3d at 1375, and *Ahraxis Bioscience Inc. v. Navinta LLC*, Civ. No. 07-1251, D.E. 50 (D.N.J. Oct. 9, 2007)). Nor is it required that the asserted patents be listed in the Orange Book. *See Medicines Co.*, 2016 WL 4418230, at *1–2; *Merck*, 2013 WL 591976, at *4. Subject matter jurisdiction over this suit is therefore proper under the Hatch-Waxman Act.

IV. CONCLUSION

For the reasons set forth above, Defendants' motion is **DENIED**.[4] An appropriate order follows.

/s/ Susan D. Wigenton
SUSAN D. WIGENTON, U.S.D.J.

Orig: Clerk
cc: Parties
Leda D. Wettre, U.S.M.J.

[4] Because this Court has subject matter jurisdiction under § 271(e)(2), the allegations contained within the Complaint are sufficient to withstand Defendants' Rule 12(b)(6) motion because they identify the ANDA and allege that the proposed ANDA products will infringe. (D.E. 1 ¶¶ 1, 54, 65, 76); *see Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 330–32 (D. Del. 2019) (citations omitted). This Court therefore declines to address Defendants' declaratory judgment jurisdiction arguments. *See Vanda*, 887 F.3d at 1125 n.5.