NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INDUSTRIES, LTD., Defendants.	Civil Action No: 18-3632-SDW-CLW **OPINION** October 23, 2018

WIGENTON, District Judge.

Before this Court is Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva" or "Defendant") Motion to Dismiss Plaintiff Corcept Therapeutics, Inc.'s ("Corcept" or "Plaintiff") Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Jurisdiction is proper pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper pursuant to 28 U.S.C. § 1391. This opinion is issued without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated herein, the Motion to Dismiss is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY

A.

Before addressing the factual and procedural history of this patent infringement case, a brief review of the relevant statutory and administrative framework regarding the manufacture and marketing of brand-name and generic pharmaceuticals is necessary.

The Hatch-Waxman Act ("the Act"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271 and 282, "governs the Food and Drug Administration's ('FDA') approval of new and generic drugs." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008). The Act is intended to "facilitate the approval of generic drugs as soon as patents allow." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *see also Astrazeneca Pharm. LP v. Apotex Corp.*, Civ. No. 10-338, 2010 WL 5376310, at *1-3 (D. Del. Dec. 22, 2010) (discussing the history and purpose of the Act). The Act requires an entity seeking to market a new pharmaceutical drug to obtain approval from the FDA by submitting a New Drug Application ("NDA"). 21 U.S.C. § 355(a). As part of the NDA process, applicants file "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted . . .." 21 U.S.C. § 355(b)(1) and (c)(2); *see also Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) (noting that NDAs "must include . . . information about patents that cover or might cover the drugs"). That information is published in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"). *Novartis Pharm. Corp. v. Actavis, Inc.*, Civ. No. 12-366, 2012 WL 6212619, at *3 (D. Del. Dec. 5, 2012); *Purepac*, 354 F.3d at 880 (noting that the Orange Book is an "FDA publication that includes all patent information that companies have submitted to the agency").

Under the Act, companies seeking to bring a generic version of a branded prescription drug can submit an Abbreviated New Drug Application ("ANDA") to the FDA. "Like NDAs, ANDAs must address patents that cover or might cover the relevant drugs. For each patent, companies can satisfy this requirement by including in their ANDAs one of several 'certifications' that explain why the FDA should approve the application despite the patent's claim on the drug." *Purepac*,

354 F.3d at 879 (citing 21 U.S.C. § 355(j)(2)(A)(vii)). One such certification allows the ANDA applicant to assert that the branded drug patent(s) is/are invalid, unenforceable, and/or will not be infringed pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"). *See Novartis Pharm., Corp. v. Wockhardt USA LLC*, Civ. No. 12-3967, 2013 WL 5770539, at *2 (D.N.J. Oct. 23, 2013); *see also Astrazeneca*, 2010 WL 5376310 at *2 (discussing the ANDA certification process). Paragraph IV Certification filers "must provide notice of their Paragraph IV Certification to both the patent owner and the NDA holder," and that notice must "set forth a 'detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed.'" *Caraco*, 527 F.3d at 1283 (citing 21 U.S.C. § 355(j)(2)(B)(iv)).

B.

Corcept is a biopharmaceutical company and the holder of NDA No. 202107 for mifepristone tablets, which it sells under the trade name KORLYM®. (Dkt. No. 15 ¶¶ 2, 12.) KORLYM® "is an FDA-approved medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery." (*Id.* ¶ 12.) Corcept is also the holder of patent numbers 8,921,348 (the "'348 patent"), 9,829,495 (the "'495 patent") and 9,943,526 (the "'526 patent") (collectively, the "patents-in-suit") and listed those patents in the Orange Book with respect to KORLYM® when it applied for the KORLYM® NDA.[1] (*Id.* ¶¶ 9-13 and Ex. A, B, C.)

[1] The '348 patent was issued by the United States Patent and Trademark Office ("USPTO") on December 30, 2014, and is entitled "Optimizing mifepristone levels in plasma serum of patients suffering from mental disorders treatable with glucocorticoid receptor antagonists." (Dkt. No. 15 ¶ 9.) The '495 patent was issued by the USPTO on November 28, 2017, and is entitled "Method for differentially diagnosing ACTH dependent Cushing's Syndrome." (*Id.* ¶ 10.) The '526 patent was issued by the USPTO on April 17, 2018, and is entitled "Optimizing Mifepristone Levels for Cushing's Patients." (*Id.* ¶ 11.) Copies of those patents are attached to Plaintiff's Amended Complaint. (*See id.* Ex. A-C.)

Teva is a corporation "in the business of marketing, distributing, and selling pharmaceutical drugs, including generic pharmaceutical drugs." (*Id.* ¶¶ 3, 6.) No earlier than January 2018 and May 2018, Teva sent Plaintiff letters informing Plaintiff that Teva had filed ANDA No. 211436 with the FDA "seeking approval to market a generic version of Corcept's 300 mg mifepristone drug product" prior to the expiration of the patents-in-suit and had provided the FDA with a Paragraph IV Certification asserting that the claims of the patents-in-suit "are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA." (*Id.* ¶¶ 1, 27, 31-37.)

On March 15, 2018, Plaintiff filed suit in this Court against Teva and its parent company, Teva Pharmaceuticals Industries, Ltd. for patent infringement. (Dkt. No. 1.) Plaintiff Amended its Complaint on July 6, 2018[2] and Defendant moved to dismiss on July 27, 2018. (Dkt. No. 15, 22.) Plaintiff opposed the motion on August 21, 2018, and Defendant filed its timely reply on August 28, 2018. (Dkt. No. 27, 28.)

II. LEGAL STANDARD

An adequate complaint must be "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). This Rule "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted); *see also Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (stating that Rule 8 "requires a 'showing,' rather than a blanket assertion, of an entitlement to relief").

[2] In its initial Complaint, Plaintiff claimed infringement of the '348 and '495 patents. (Dkt. No. 1.) The Amended Complaint adds a claim for infringement of the '526 patent. (Dkt. No. 15.)

In considering 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*, 515 F.3d at 231 (external 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); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203 (3d Cir. 2009) (discussing the *Iqbal* standard). Determining whether the allegations in a complaint are "plausible" is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. If the "well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint should be dismissed for failing to "show[] that the pleader is entitled to relief" as required by Rule 8(a)(2). *Id.*

In conducting its analysis, the Court may only consider the contents of the complaint. Although the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion" to one for summary judgment, *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999), those materials are limited to those "*integral to or explicitly relied upon* in the complaint." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal citations omitted, emphasis in original); *see also In re Lipitor Antitrust Litig.*, 868 F.3d 231, 249 (3d Cir. 2017).

III. DISCUSSION

The filing of an ANDA, where "an applicant seeks approval to market a drug claimed by another person's valid patent" is an act of infringement. *Astrazeneca*, 2010 WL 5376310 at *1;

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