IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S, Plaintiffs, v. Hetero USA, Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V, Hetero Labs, Ltd, and Honour Lab Ltd., Defendants.	:	C.A. No. 19-1954-LPS

MEMORANDUM ORDER

WHEREAS, Plaintiffs Otsuka Pharmaceutical Co., Ltd and H. Lundbeck A/S (collectively "Plaintiffs") hold New Drug Application No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms, which was approved on July 10, 2015 for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia (D.I. 1 at ¶¶ 32-34);

WHEREAS, Defendants Hetero USA, Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V, Hetero Labs, Ltd. (collectively, "Hetero") are alleged to have filed ANDA No. 213699 with the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, or sale in the United States of brexpiprazole tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("Hetero's proposed ANDA Product"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets, and have allegedly certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") that the claims of certain of Plaintiffs' Orange Book-listed patents are invalid, unenforceable, and/or would not be infringed by Hetero's proposed ANDA Product (D.I. 1 at ¶ 56);

WHEREAS, Defendant Honour Lab Ltd. ("Honour") holds Drug Master File ("DMF") No. 32532 for brexpiprazole (D.I. 1 at ¶ 23; D.I. 14 at 2; D.I. 18 at 1);[1]

WHEREAS, Otsuka alleges it received a Paragraph IV notice letter sent by Hetero, dated September 11, 2019, for ANDA No. 213669, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act, and 21 C.F.R. § 314.95, notifying Otsuka that Hetero seeks approval to engage in the commercial manufacture, use, or sale of Hetero's proposed ANDA product before the expiration of certain of Plaintiffs' Orange Book-listed patents (D.I. 1 at ¶¶ 58-59);

WHEREAS, on October 15, 2019, Otsuka initiated the above-captioned patent infringement case, pursuant to the Hatch-Waxman Act, naming Hetero and Honour as co-defendants (D.I. 1);

WHEREAS, on January 21, 2020, Honour filed a motion to dismiss Otsuka's complaint as against it, pursuant to Federal Rule of Civil Procedure 12(b)(6) (*see* D.I. 14);

NOW, THEREFORE, IT IS HEREBY ORDERED that, having considered the relevant filings and related materials (*see, e.g.*, D.I. 1, 13-15, 18-20), Honour's Rule 12(b)(6) motion to dismiss[2] (D.I. 13) is **DENIED**.

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[1] A DMF is a submission of information to the FDA made as part of the ANDA approval process. *See* 21 C.F.R. § 314.420(a).

[2] To state a claim for relief, Federal Rule of Civil Procedure 8(a) requires that a complaint need only include a short and plain state of the claim, showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the claim is and the ground upon which it rests. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A complaint does not need to include "detailed factual allegations" but must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). When examining a Rule 12(b)(6) motion to dismiss, the Court will "accept as true all allegations in the plaintiff's complaint as well as all reasonable inferences that can be drawn from them, and [will] construe them in a light most favorable to the non-movant." *Monroe v. Beard*, 536 F.3d 198, 205 (3d Cir. 2008).

1. Section 271(e)(2)(A) of the Patent Act provides, in pertinent part, "[i]t shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . 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 . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent before the expiration of such patent." An entity who "submits" an ANDA, as that term is used in Section 271(e)(2)(A), has committed an "act of infringement" and is a proper defendant in a Hatch-Waxman patent lawsuit. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

2. An entity need not sign, prepare, or file an ANDA in order to be deemed a "submit[ter]" under Section 271(e)(2)(A), and, thus, deemed a properly-named defendant in a Hatch-Waxman lawsuit. *See Helsinn Healthcare S.A. v. Hospira, Inc.*, 2016 WL 1338601 at *7 (D.N.J. Apr. 5, 2016). Rather, an entity may also "submit" an ANDA if it participates in the preparation of the ANDA and intends to benefit directly from the ANDA. *See In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 528 (Fed. Cir. 2012); *Warner Chilcott Co., LLC v. Mylan Pharm., Inc.*, 2017 WL 603309, at *3 (E.D. Tex. Jan. 19, 2017), *report and recommendation adopted*, 2017 WL 590295 (E.D. Tex. Feb. 14, 2017). That is, "whether the entity is a submitter depends on whether it is also going to engage in the commercial manufacture, use, or sale of the proposed generic product" and whether the entity will "financially benefit, in a significant manner, from the FDA's approval of the application." *Adverio Pharma GmbH v. Alembic Pharma. Limited*, 2019 WL 581618, *4-5 (D. Del. Feb. 13, 2019) (emphasis omitted). Conversely, "an entity that merely assists in collecting materials for submission to the FDA, signs the ANDA, presents the ANDA to the FDA for approval, and acts in an ongoing manner as the liaison between the FDA and the applicant during the regulatory process, but will have no

involvement with the ANDA product following FDA approval, is not a submitter." *Id.* at *5.

3. Honour contends it is not a "submitter" and, thus, should be dismissed from this suit. Honour reasons that a "DMF holder, who does not have an agency and corporate relationship with the ANDA holder and who does not import the accused product in the United States in its own name, cannot be held liable for direct infringement subsequent to submission of an ANDA by the ANDA holder." (D.I. 14 at 5-6; *see also* D.I. 20 at 2, 7-8) Honour further argues that it is neither an agent nor subsidiary of Hetero. (D.I. 14 at 6) Otsuka responds that it has adequately pleaded facts from which the Court can plausibly infer that Honour is a "submitter" under Section 271(e)(2)(A). (D.I. 18 at 10-13)

4. The Court concludes that Otsuka's complaint meets the requirements of Federal Rule of Civil Procure 8(a) to plausibly state a claim against Honour as a "submitter." The allegations of Otsuka's complaint – when accepted as true and drawing all reasonable inferences in favor of Otsuka – plausibly state a claim that Honour will engage in the commercial manufacture, use, or sale of Hetero's proposed ANDA product and will financially benefit, in a significant manner, from the approval of that product. Specifically, the complaint alleges that Honour is "vertically integrated" with Hetero, citing publicly-available websites from which it can be plausibly inferred that Honour "is engaged in manufacturing drug products which are primarily supplied to Hetero," including brexpiprazole. (D.I. 1 at ¶ 24; *see also* D.I. 18 at 11) The complaint further alleges that Hetero and Honour "share one or more common corporate directors" and that the two entities "hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products in the United States." (D.I. 1 at ¶¶ 24-25) These allegations, together with the allegation that Honour is the holder of DMF No. 352532 for

brexpiprazole (the active ingredient in Hetero's proposed ANDA product), support the Court's conclusion.

5. The Court's conclusion is not based on the mere fact that Honour is the holder of DMF No. 32532 for brexpiprazole.[3] Rather, the Court concludes, from the totality of well-pled factual allegations, that Otsuka has plausibly alleged that Honour will supply the active pharmaceutical ingredient that will be used in Hetero's proposed ANDA product,[4] from which it plausibly follows (particularly in view of Otsuka's "vertical integration" and "unitary entity" allegations (D.I. 1 at ¶¶ 24-25)) that Honour was involved in preparation of the ANDA submission and will be involved in (and directly financially benefit from) manufacture and sale of the proposed product, after FDA approval. (*See generally* D.I. 18 at 12) (Otsuka: "Plaintiffs have pled that Honour works in unison with Hetero and will continue to do so if ANDA No. 213669 is approved.") All of this, taken as true (which the Court must at this stage), would (if ultimately proven) render Honour a submitter of the ANDA. Accordingly, the motion to dismiss will be denied.

November 20, 2020
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

[3] Honour states that it "is one of the many holders of the . . . DMF . . . for brexpiprazole." (D.I. 14 at 2)

[4] Honour contends that drawing this inference from the allegations in the complaint is "not reasonable" (D.I. 20 at 3) (internal quotation marks omitted), but the Court disagrees. As Honour elsewhere acknowledges, Otsuka's allegations "provide[] more . . . seemingly factual bases than [the deficient] complaint in *Adverio* [2019 WL 581618, at *6]." (D.I. 14 at 7) Here, the Court believes that Otsuka has adequately pled a factual basis from which it is plausible to infer that Honour has been actively involved in preparing Hetero's ANDA and would benefit directly if the ANDA is approved.