

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO.,
LTD.,

Plaintiff,

v.

TORRENT PHARMACEUTICALS
LIMITED, INC., TORRENT PHARMA
INC., and HETERO LABS LIMITED,

Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action No.
14-4671 (JBS/KMW)

MEMORANDUM OPINION

SIMANDLE, Chief Judge:

In this Hatch Waxman Act case, see 35 U.S.C. §§ 271, 281, Plaintiff Otsuka Pharmaceutical Co, Ltd. (hereinafter, "Otsuka") advances its position that the abbreviated new drug application (hereinafter, "ANDAs") of Defendants Torrent Pharmaceuticals Limited, Inc. and Torrent Pharma Inc. (collectively, "Torrent") infringe the various patents covering Otsuka's aripiprazole product, Abilify®.¹

In the aftermath of various amendments to the parties' pleadings, Otsuka now moves to dismiss Torrent's Third Counterclaim for "Unlawful Monopolization in Violation of the Sherman Act: Sham Litigation," on the grounds that its current

¹ The patents asserted by Otsuka in this infringement action specifically include U.S. Patent Nos. 8,642,760 ("the '760 patent") and 8,759,350 (hereinafter, "the '350 patent"). (See generally Third Am. Compl. at ¶ 5.)

presence on the newly-formed generic aripiprazole market precludes Torrent from demonstrating the antitrust injury necessary for antitrust standing.² (See Otsuka's Br. at 1-4; Otsuka's Reply at 1-3.) Torrent, in opposition, concedes that it launched a generic aripiprazole product in April 2015, following this Court's decision denying Otsuka's motion for injunctive relief, see Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., 99 F. Supp. 3d 461 (D.N.J. 2015), and impliedly acknowledges that its allegations of "exclusionary" conduct no longer fairly buttress its antitrust Counterclaim. (See Torrent's Opp'n at 1-6.) For that reason, Torrent turns its attention to the defense costs incurred in this action as the source of its ongoing antitrust injury. (See id. at 4-6.)

The Court has addressed the viability of similar counterclaims in Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., 118 F. Supp. 3d 646, 649 (D.N.J. 2015)³ and Otsuka Pharm. Co. v. Apotex Corp., ___ F. Supp. 3d ____, No. 14-8074, 2015 WL 4756636 (D.N.J. Aug. 11, 2015), and tracks the discussion in Torrent and

² In the alternative, Otsuka requests that the Court bifurcate and stay Torrent's Counterclaim pending resolution of the primary infringement issues. (See Otsuka's Br. at 5; Otsuka's Reply at 4.)

³ Torrent differs from this action (which also involves Torrent) in terms of the patents asserted by Otsuka. More specifically, in this action, as recounted above, Otsuka asserts the '760 and '350 patents. (See generally Third Am. Compl. at ¶ 5.) In Torrent, by contrast, Otsuka asserts U.S. Patent Nos. 8,017,615 and 8,580,796. (See Second Am. Compl. in 14-1078 at ¶ 5.)

Apotex. Torrent's commercial launch, coupled with its reliance upon costs of defense as an antitrust injury, however, places the pending action in a contextually different posture from the circumstances addressed in Torrent and Apotex.

For the reasons that follow, Otsuka's motion will be granted to the extent it seeks dismissal, and Torrent's antitrust Counterclaim will be dismissed without prejudice. The Court finds as follows:

1. **Factual and Procedural Background**.⁴ For purposes of the pending motions, the Court need not retrace the lengthy factual and procedural background of this infringement action. Rather, it suffices to note that, on November 15, 2002, Otsuka obtained Food and Drug Administration (hereinafter, the "FDA") approval to market its aripiprazole product, Abilify®, under New Drug Application (hereinafter, "NDA") No. 21-436. (See

⁴ For purposes of the pending motion, the Court accepts as true the version of events set forth in Torrent's Counterclaim, together with matters of public record. See Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014); see also ACR Energy Partners, LLC v. Polo N. Country Club, Inc., ___ F. Supp. 3d ___, Nos. 15-2677 & 15-5324, 2015 WL 6757574, at *1 n.2 (D.N.J. 2015) (same). For that reason, the Court takes note, as a matter of public record, of Torrent's FDA approval to market a generic aripiprazole product, as well as their subsequent commercial launch. See Gross v. Stryker Corp., 858 F. Supp. 2d 466, 482 n.26 (W.D. Pa. 2012) (taking note of FDA product approval information); see also Press Release, U.S. Food and Drug Administration, *FDA Approves first generic Abilify to treat mental illnesses* (April 28, 2015), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm444862.htm>.

generally Third Am. Compl. at ¶¶ 5 & 17.) Despite the exclusivity associated with Otsuka's aripiprazole patents, on June 19, 2015, Torrent filed Abbreviated New Drug Application (hereinafter, "ANDA") No. 20-1519 with the FDA, seeking approval to market generic aripiprazole tablets in the United States, prior to expiration of Otsuka's Abilify® patents. (See Countercl. at ¶¶ 8-15.) In connection with that filing, and in a subsequent notice to Otsuka, Torrent expressed the view that its generic aripiprazole product would not infringe any valid or enforceable claim of the '760 patent. (See id. at ¶ 14.)

2. Despite this representation, Otsuka initiated the pending infringement action, and Torrent's antitrust Counterclaim followed. In the Counterclaim, Torrent alleges, more specifically, that Otsuka has initiated "meritless litigation" in an effort to erect barriers to entry to, and otherwise stifle competition in, the aripiprazole market—a market long monopolized by Otsuka. (Id. at ¶¶ 26-50.) Torrent alleges, in turn, that these "exclusionary, anticompetitive, and unlawful activities ... threaten loss or damage to Torrent" by forestalling, frustrating, and preventing Torrent's ability to compete. (Id. at ¶¶ 49-50.) Against that backdrop, the Court turns to whether these allegations plausibly demonstrate an antitrust injury.

3. **Standard of Review Applicable to Otsuka's Challenge to Torrent's Antitrust Standing.**⁵ As explained in Torrent and Apotex, "[i]n order to plead an antitrust injury, the party must allege facts showing (1) that it suffered an injury of the type the antitrust laws seek to prevent, e.g., anticompetitive behavior, and (2) that the injury resulted from the adversary's unlawful or anti-competitive acts." Torrent, 118 F. Supp. 3d at 652-53 (footnote omitted); see also Apotex, ___ F. Supp. 3d ___, 2015 WL 4756636, at *3 (citations omitted) (relying upon Torrent for the same premise). Against this rubric, the "'hallmark' for evaluating the plausibility of an allegation of antitrust injury" hinges upon whether the allegedly anticompetitive conduct "'bear[s] consequence for the overall market, rather than only for [the] individual competitor." Apotex, ___ F. Supp. 3d ___, 2015 WL 4756636, at *4 (quoting Torrent, 118 F. Supp. 3d at 653 (quoting TransWeb, LLC v. 3M

⁵ As explained in Torrent and Apotex, the federal antitrust laws require an antitrust claimant to meet the "prudential requirement" of "'antitrust standing.'" Torrent, 118 F. Supp. 3d at 652 (citation omitted). In Ethypharm S.A. France v. Abbott Labs., 707 F.3d 223 (3d Cir. 2013), the Court of Appeals for the Third Circuit outlined a five-factor test relative to this inquiry, but deemed the second factor, "antitrust injury," the essential precondition for antitrust standing. Id. at 232. Here, the parties focus their analysis only on the issue of antitrust injury, and so the Court need not address the other factors.

Innovative Props. Co., No. 10-4413, 2011 WL 2181189, at *18 (D.N.J. June 1, 2011)).

4. Application of these principles here requires dismissal of Torrent's antitrust Counterclaim. Indeed, Torrent concedes that its claim rests exclusively upon its individual incurrence of defense costs in this litigation. (See generally Torrent's Opp'n at 3-6.) Torrent's newly-minted theory, however, finds no support in the allegations of Torrent's antitrust counterclaim. (See Counterclaim. at ¶¶ 26-50.) Indeed, Torrent roots its antitrust Counterclaim solely on market exclusion, not the defense costs incurred in defending against this litigation. (See, e.g., id. at ¶¶ 35-39 (generally alleging that Otsuka's "predatory" conduct evidences an intention to "injure or destroy competition" by prevent new market entrants), ¶¶ 42-45 (generally alleging that Otsuka's "meritless" infringement litigations aim to continue its "monopoliz[ation] [of] the relevant market"), ¶¶ 46-50 (generally alleging that Otsuka's "exclusionary, anticompetitive and unlawful actions" have caused "lost profits and business opportunities").) This deficiency, standing alone, requires dismissal of Torrent's Counterclaim. See Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007) (explaining that a plausible complaint must contain allegations concerning each "material elements necessary to sustain recovery").

5. Beyond this, even if the Court broadly construed Torrent's Counterclaim to include allegations directed at costs of defense and determined that these costs constitute a qualifying antitrust injury,⁶ the allegations of Torrent's Counterclaim nowhere tether Torrent's payment of defense costs in this litigation (and the related Torrent action) to harm borne by the market-at-large. See In re Hypodermic Prods. Antitrust Litig., MDL No. 1730, 2007 WL 1959224, at *5 (D.N.J. June 29, 2007) (citation omitted) (explaining that that "antitrust complaints ... should be liberally construed"). Stated differently, Torrent does not allege that Otsuka's anticompetitive conduct has, through these costs of litigation, somehow harmed the competitive landscape, nor that these costs have prevented Torrent from pursuing its entry into the aripiprazole market. See Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001) (explaining that an allegation of an

⁶ The parties dispute whether costs of defense amount to a recognized antitrust injury. (Compare Torrent's Opp'n at 4-6, with Otsuka's Reply at 3-4.) In TransWeb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295 (Fed. Cir. 2016), the Court of Appeals for the Federal Circuit appears to have recognized, at least impliedly, that costs incurred in defense of an infringement action amount to an injury derived from the antitrust wrong. Id. at 1309-12. Thus, although Transweb, LLC addressed itself to the issue of recoverable antitrust damages, its broad discussion of defense costs as an injury traceable to the claimed antitrust wrong lends obvious credence to Torrent's position. See id. Nevertheless, in view of the deficiencies recounted above, the Court need not definitively resolve this issue.

antitrust injury must reflect that the challenged activity had an "anti-competitive effect on the [overall] competitive market"). Rather, Torrent's allegations demonstrate little more than that Otsuka's claimed conduct had an adverse financial effect on a particular competitor (namely, Torrent). These limited allegations, accepted as true, however, fail to allege a qualifying antitrust injury. Id. (reasoning that an antitrust injury does not lie unless the allegedly anticompetitive conduct "has a wider impact on the [overall] competitive market"); see also Irish v. Ferguson, 970 F. Supp. 2d 317, 365 (M.D. Pa. 2013) (citations omitted) (explaining that the pleaded facts must show "that 'the challenged action has had an actual adverse effect on competition as a whole in the relevant market,'" rather than just an adverse effect on the particular competitor); Brotech Corp. v. White Eagle Int'l Techs. Grp., Inc., No. 03-232, 2004 WL 1427136, at *7 (E.D. Pa. June 21, 2004) (finding "payment of defense costs" insufficient to allege antitrust injury).

6. **Conclusion.** For all of these reasons, Otsuka's motion to dismiss will be granted, and Torrent's antitrust Counterclaim will be dismissed.⁷ Nevertheless, because Torrent may be able to

⁷ As a result, the Court need not reach the parties' positions on the bifurcation. In the event Torrent restates its antitrust Counterclaim, the Court would, however, be inclined to follow the path charted in Torrent and Apotex by bifurcating and staying the antitrust Counterclaim, pending resolution of the primary patent infringement claims. See Torrent, 118 F. Supp.

cure the deficiencies identified within this Memorandum Opinion, the Court will grant Torrent leave to amend with fourteen (14) days, to the extent such an amendment can be made consistent with counsel for Torrent's obligations under Federal Rule of Civil Procedure 11(b) and the holdings of this Memorandum Opinion.⁸

7. An accompanying Order will be entered.

May 4, 2016
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
Chief U.S. District Judge

3d at 659-60 (bifurcating and staying); Apotex, ___ F. Supp. 3d ___, 2015 WL 4756636, at *7 (same).

⁸ The Court harbors some doubts about whether any amount of pleading supplementation would add life to Torrent's antitrust Counterclaim, particularly given its commercial launch nearly one year ago. Beyond this, the nature and crux of Torrent's allegations appear better aligned with a post-judgment request for attorneys' fees under 35 U.S.C. § 285. Nevertheless, the Court leaves open the possibility that amended allegations may bring into focus the basis, if any, for Torrent's post-launch antitrust theory.