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. 14-1078 (JBS/KMW) **OPINION**

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SIMANDLE, Chief Judge:

I. INTRODUCTION

This patent infringement action, one of twenty-five related actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 281, generally concerns Plaintiff Otsuka Pharmaceutical Co, Ltd.'s (hereinafter, "Otsuka") position that Torrent Pharmaceuticals Limited, Inc.'s, Torrent Pharma Inc.'s, and Hetero Labs Limited's (hereinafter, "Torrent") proposed generic aripiprazole product infringes one or more claims of two of the various patents covering Otsuka's Abilify® aripiprazole product, U.S. Patent Nos. 8,017,615 ("the '615 patent") and 8,580,796 ("the '796 patent").

Otsuka now moves to dismiss Torrent's Fifth and Sixth Counterclaims for "Unlawful Monopolization" and for "Patent Misuse" (hereinafter, the "Counterclaims") pursuant to Federal Rule of Civil Procedure 12(b)(6) and, in the alternative, to bifurcate and stay Torrent's Counterclaims pending resolution of the primary patent infringement issues pursuant to Federal Rule of Civil Procedure 42(b). [Docket Item 43.]

Otsuka argues, in particular, that Torrent's antitrust Counterclaim must be dismissed, because Torrent has not alleged,

nor will Torrent ever suffer, the "anticompetitive injury" required for antitrust standing, and because Torrent's "cursory conclusions" fail to plausibly overcome Otsuka's *Noerr-Pennington* immunity. (Otsuka's Reply at 2-5; Otsuka's Br. at 5-11.) Ostuka similarly asserts that Torrent's patent misuse Counterclaim must be dismissed, because its allegation of baseless infringement fails as a matter of law to state a cognizable claim for patent misuse. (See Otsuka's Reply at 5-6; Otsuka's Br. at 11-12.) In the alternative, Otsuka requests that the Court follow the "'standard practice'" of bifurcating for trial the patent issues raised in this litigation from the antitrust and/or patent misuse issues. (Otsuka's Br. at 13 (citations omitted).)

Torrent, however, submits that its antitrust Counterclaim demonstrates the "real and immediate" risk of injury required for purposes of antitrust standing, because absent "this bad faith litigation," Torrent would have an "unencumbered path to launch its ANDA product." (Torrent's Opp'n at 4-5.) With regard to Otsuka's claim of *Noerr-Pennington* immunity, Torrent similarly asserts that its antitrust Counterclaim sets forth sufficient factual matter to demonstrate that this litigation constitutes a sham, because Otsuka initiated suit despite Torrent's detailed non-infringement statement and despite the fact that Torrent's abbreviated new drug application

(hereinafter, "ANDA") is non-infringing on its face. (Id. at 3-7.) Finally, Torrent submits that dismissal of its Counterclaims would, at this early stage of discovery, be inappropriate to the extent undeveloped factual issues remain concerning whether Otsuka's conduct constitutes patent misuse and/or an antitrust violation. (Id. at 8-9.)

The principal issues before the Court are whether the allegations of Torrent's Counterclaims suffice to confer antitrust standing, to overcome Otsuka's *Noerr-Pennington* immunity, and to state a plausible claim for patent misuse.

For the reasons that follow, Otsuka's motion will be granted in part and denied in part.

II. BACKGROUND

A. Factual and Procedural Background[1]

Otsuka, a pharmaceutical company primarily organized and existing under the laws of Japan, holds New Drug Application (hereinafter, "NDA") No. 21-436, approved by the Food and Drug Administration (hereinafter, the "FDA"), for aripiprazole tablets, which Otsuka markets under the trade name Abilify®. (Am. Compl. at ¶¶ 1, 17-18, 25-30.)

In connection with Abilify's® listing in the Orange Book, the FDA's book of drug products approved under the Food, Drug,

[1] For purposes of the pending motion, the Court accepts as true the facts set forth in Torrent's Answer and Counterclaims. [Docket Items 19 & 26.]

and Cosmetic Act (hereinafter, the "Orange Book"), 21 U.S.C. § 355(j), Otsuka identifies the '615 patent and the '796 patent, both of which Otsuka owns by virtue of assignment. (Id. at ¶¶ 14, 17, 26, 29.) The listing, in particular, discloses Abilify®'s active ingredient as "aripiprazole," the dosage form as a "tablet" or "oral," and the strengths as 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg. (Counterclaim at ¶ 13 (quotation marks omitted).)

In late 2013, Torrent filed ANDA No. 20-1519 with the FDA, seeking approval to market generic 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg aripiprazole tablets in the United States, prior to the expiration of the '615 and the '796 patents. (See Countercl. at ¶ 14.) Torrent's ANDA filing included a "paragraph IV certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), in which Torrent set forth its assertion that the Abilify® patents would not be infringed by the commercial manufacture, use, or sale of Torrent's generic product. (See id.)

On January 4, 2014, Torrent mailed notice of its ANDA certification to Otsuka, and provided "a detailed statement of the factual and legal bases of Torrent's ANDA certifications for the '615 and '796 patents," i.e., a detailed explanation of the bases for Torrent's position that its generic aripiprazole tablets would "not infringe any valid or enforceable claim of

the Orange Book-listed '615 and '796 patents." (Id. at ¶ 15.) In order to substantiate its non-infringement position, Torrent then provided the relevant portions of its ANDA on February 20, 2014. (Id. at ¶ 16.)

Otsuka filed an initial and Amended Complaint in this District, alleging that Torrent's proposed generic product "will, if approved and marketed," infringe at least one claim of the '615 and '796 patents. (Am. Compl. at ¶¶ 22-23, 33-34.) On October 22, 2014, Torrent filed an Answer to Otsuka's Amended Complaint and, as a relevant here, asserted Counterclaims for "Unlawful Monopolization in Violation of the Sherman Act: Sham Litigation" and for a "Declaratory Judgment of Unenforceability of the '615 and '796 Patents for Patent Misuse." (Countercl. at ¶¶ 34-62.)

Torrent's "Unlawful Monopolization" Counterclaim alleges, in particular, that Otsuka "has the power to control prices and/or exclude competition in, or prevent entry into" the aripiprazole market, and claims that Otsuka has wielded that power "to monopolize" the market. (Id. at ¶¶ 42-45.) Indeed, Torrent alleges that Otsuka "has engaged in an overall predatory scheme to monopolize the [aripiprazole market] through, but not limited to, initiating objectively baseless and sham judicial proceedings designed" to "entrench and enhance [Otsuka's] monopolistic position in the [aripiprazole] market and to stifle

and eliminate competition and competitors with no economic, market or competitive benefit." (Id. at ¶¶ 45, 47.) Torrent, accordingly, alleges that Otsuka initiated this "sham" and "bad faith" litigation against it not upon a genuine belief that Torrent's ANDA products would infringe the '615 and '796 Patents, but "for an improper purpose, and as a means of directly interfering with and harming Torrent's business and in order to forestall, frustrate and prevent competition by Torrent," in violation of the Sherman and Clayton Acts, 15 U.S.C. §§ 2, 15, and 26.[2] (Id. at ¶¶ 48-51.) Moreover, as a result of this "exclusionary" and "anticompetitive" conduct, Torrent has purportedly "suffered, and will continue to suffer," significant injury, "including lost profits and business opportunities." (Id. at ¶¶ 57-58.)

Torrent's patent misuse Counterclaim largely reiterates the allegations of its antitrust Counterclaim, and specifically alleges that Otsuka filed this action without "any good faith factual basis" to support its infringement positions against Torrent, and "for the purpose of delay[ing] Torrent's entry"

[2] As relevant here, section 2 of the Sherman Act makes it unlawful to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2. In that respect, the Sherman Act seeks to protect the public from the failures of the market and "conduct which unfairly tends to destroy competition itself." Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993).

into the aripiprazole market by "burden[ing] Torrent with litigation costs and making baseless accusations of infringement." (Id. at ¶¶ 60-62.)

The pending motion followed.

III. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), the court must generally accept as true the factual allegations of the defendant's counterclaims, and construe all "reasonable inferences" in the light most favorable to the defendant. Revell v. Port Auth. Of N.Y., N.J., 598 F.3d 128, 134 (3d Cir. 2010); see also Fleisher v. Standard Ins. Co., 679 F.3d 116, 120 (3d Cir. 2012) (same). However, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action" fails to suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, the factual allegations must be facially sufficient to demonstrate a "plausible" right to relief, by pleading factual content sufficient for the Court "to draw the reasonable inference that the [plaintiff] is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Umland v. PLANCO Fin. Serv., Inc., 542 F.3d 59, 64 (3d Cir. 2008).

In evaluating whether a counterclaim meets this pleading standard, the Court strips away conclusory statements and

reviews instead the "well-pled factual allegations, assume[s] their veracity, and then determine[s] whether" the allegations demonstrate a plausible "entitlement to relief." Iqbal, 556 U.S. at 678 (internal quotation marks omitted).

IV. DISCUSSION

As stated above, Otsuka moves to dismiss Torrent's antitrust Counterclaim for lack of standing and on immunity grounds, and moves to dismiss Torrent's patent misuse Counterclaim for failure to state a plausible claim for relief. The Court will address each issue in turn.

A. Torrent has Alleged Sufficient Facts to Demonstrate Antitrust Standing

Article III constitutional standing, a principle moored in the notion "that the judiciary's power only extends to cases or controversies," constitutes a threshold requirement in all actions in federal court. Ethypharm S.A. France v. Abbott Labs., 707 F.3d 223, 232 (3d Cir. 2013) (citing U.S. Const. art. III, § 2; Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). The principles of constitutional standing are, however, "'augmented'" by prudential considerations aimed at preserving the effective enforcement of the antitrust laws. Id. (quoting City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 264 (3d Cir. 1998)). Indeed, the Supreme Court has specifically recognized that "Congress did not intend to allow every person

tangentially affected by an antitrust violation to maintain an action to recover threefold damages for the injury to his business or property." Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 535 (1983) (citation omitted).

As a result, a party suing under federal antitrust laws, as here,[3] must meet the prudential requirement of "'antitrust standing.'"[4] Ethypharm S.A. France, 707 F.3d at 232 (citation omitted). In Associated Gen. Contractors of Cal., Inc., the Supreme Court articulated the considerations relevant to whether a complainant possesses antitrust standing, which the Court of Appeals for the Third Circuit subsequently organized into the following multifactor test:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the

[3] Section 4 of the Clayton Act provides the statutory authority for a private antitrust cause of action, and specifically states that, "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws" may maintain a "private action for treble damages." 15 U.S.C. § 15.

[4] Unlike Article III standing, lack of antitrust standing does not deprive a court of subject matter jurisdiction. Ethypharm S.A. France, 707 F.3d at 232 (citation omitted). Rather, it bars "a plaintiff from recovering under the antitrust laws." Id. (citation omitted)).

> existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

Ethypharm S.A. France, 707 F.3d at 232-33 (citing In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1165–66 (3d Cir. 1993)) (hereinafter, the "AGC factors"). Of these factors, the second, antitrust injury, constitutes the "'necessary but insufficient condition of antitrust standing.'" Id. (citation omitted). Thus, in the absence of a plausible allegation of antitrust injury, the only factor challenged by Otsuka in this instance, the Court need not address the remaining AGC factors.

Therefore, the Court notes that, in 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. See In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014) (quoting In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 534 (D.N.J. 2004)). The federal antitrust laws, however, foster "'the protection of competition not competitors.'" Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 76-77 (3d Cir. 2010); see also Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc., 429 U.S. 477, 488 (1977) (citation omitted) (noting that Congress enacted the antitrust

laws "for 'the protection of competition, not competitors'"). As a result, 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.[5] Irish v. Ferguson, 970 F. Supp. 2d 317, 365 (M.D. Pa. 2013) (citations omitted); see also Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001) (noting that an antitrust injury does not lie unless the allegedly anticompetitive conduct "has a wider impact on the [overall] competitive market"). Moreover the alleged injuries must, as with all types of standing, be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" City of L.A. v. Lyons, 461 U.S. 95, 102 (1983); see also Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 321 (3d Cir. 2007) ("The prospective harm to competition must not ... be speculative.")

In seeking to dismiss Torrent's federal antitrust claim, Otsuka asserts that Torrent cannot be heard to claim that the pendency of this litigation has caused Torrent to suffer any

[5] In that respect, the antitrust injury requirement helps ensure that the claimed harm "'corresponds to the rationale for finding a violation of the antitrust laws in the first place,'" e.g., anticompetitive behavior, and prevents a party from basing a suit upon "'losses that stem [only] from competition.'" W. Penn Allegheny Health Sys., Inc., 627 F.3d at 101 (citations omitted); see also Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001) (noting that an antitrust injury does not lie unless the allegedly anticompetitive conduct "has a wider impact on the [overall] competitive market").

antitrust or anticompetitive injury, because Torrent "voluntarily chose[] not to surmount the legal and regulatory" hurdles to its market entry until after the April 2015 expiration of the primary compound patent for Abilify, U.S. Patent No. 5,006,528 (hereinafter, the "'528 Patent"), and because Torrent's allegations of delayed market entry lack the immediacy required for purposes of antitrust standing. (Otsuka's Br. at 5-7; Otsuka's Reply at 2-4.) The Court, however, finds Otsuka's position without merit.

Critically, the hallmark for evaluating the plausibility of an allegation of antitrust injury is, as stated above, that the actions alleged to be anticompetitive when viewed "as a whole" bear consequence for the overall market, rather than only for an individual competitor. TransWeb, LLC v. 3M Innovative Props. Co., No. 10-4413, 2011 WL 2181189, at *18 (D.N.J. June 1, 2011)

Distilled to its essence, Torrent's Counterclaim alleges that Otsuka has initiated meritless infringement actions in order to "stifle and eliminate competition and competitors," to exclude or prevent competitors' entry into the aripiprazole market, and to maintain its exclusive monopoly over the aripiprazole market. (Countercl. at ¶¶ 34-58.) The Counterclaim further alleges that, as result of Otsuka's purportedly "exclusionary, anticompetitive and unlawful activities," Otsuka has been able to maintain its aripiprazole

monopoly to the detriment of competition and consumers and has, in particular, hampered Torrent's ability to enter and compete, resulting in "lost profits and business opportunities." (Id. at ¶¶ 54, 57-58.)

In these respects, Torrent's Counterclaim plausibly alleges the elements of an antitrust injury, namely, an injury of the type protected by the antitrust laws, and that the injury derived, at least in part, from anti-competitive acts. Indeed, the pursuit of litigation that forestalls entry into the generic market, as alleged here, constitutes "anti-competitive behavior" of the type the antitrust laws seek to prevent. AstraZeneca AB v. Glenmark Generics Ltd., No. 14-665, 2014 WL 5366050, at *1 (D. Del. Oct. 9, 2014); see also Angelico v. Lehigh Valley Hosp., Inc., 184 F.3d 268, 275 n.1 (3d Cir. 1999) (noting that, "protecting a competitor's ability to compete" clearly rests within "the interest of competition"). Moreover, Torrent has specifically alleged that Otsuka's pursuit of "objectively baseless and sham judicial proceedings" has adversely affected competition in the overall aripiprazole market by encumbering the path of generic entry and effectively extending Otsuka's long-held monopoly.[6] See Rochester Drug Co-op., Inc. v.

[6] The Court notes, as a matter of public record, that Otsuka has initiated litigation against every ANDA filer. See Otsuka Pharm. Co., Ltd. v. Alembic Global Holding SA, Civil Action No. 14-2982 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA

Braintree Labs., 712 F. Supp. 2d 308, 316 (D. Del. 2010) (finding similar allegations sufficient). Therefore, the Court rejects Otsuka's position that Torrent has failed to plead a cognizable antitrust injury.

Nor does the Court find that these alleged injuries constitute conjectural possibilities, rather than the real and immediate injury required for purposes of antitrust standing. See Broadcom Corp., 501 F.3d at 321. Indeed, even if Torrent

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Inc., Civil Action No. 14-3168 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd., Civil Action No. 14-3306 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Intas Pharm. Ltd., Civil Action No. 14-3996 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA Inc., Civil Action No. 14-3168 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus., Ltd., Civil Action No. 14-4307 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Mylan Inc., Civil Action No. 14-4508 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Torrent Pharm., Inc., Civil Action No. 14-4671 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Zhejiang Huahai Pharm. Co., Civil Action No. 14-5537 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Ajanta Pharm. Ltd., Civil Action No. 14-5876 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Teva Pharm. USA, Inc., Civil Action No. 14-5878 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Intas Pharm. Ltd., Civil Action No. 14-6158 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus., Ltd., Civil Action No. 14-6397 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Teva Pharm. USA, Inc., Civil Action No. 14-6398 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd., Civil Action No. 14-6890 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Lupin Ltd., Civil Action No. 14-7105 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Actavis Elizabeth LLC, Civil Action No. 14-7106 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA Inc., Civil Action No. 14-7252 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Alembic Pharm., Ltd., Civil Action No. 14-7405 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Apotex Corp., Civil Action No. 14-8074 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Hetero Drugs, Ltd., Civil Action No. 15-161 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Amneal Pharm. Co, Ltd., Civil Action No. 15-1585 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Sandoz Inc., Civil Action No. 15-1716 (JBS/KMW); Otsuka Pharm. Co., Ltd. v. Indoco Remedies Ltd., Civil Action No. 15-1967 (JBS/KMW).

"voluntarily" declined to mount any legal challenge to Otsuka's aripiprazole monopoly until after the expiration of the '528 Patent in April 2015, the exclusivity associated with the '528 Patent has since passed, and therefore interposes no present barrier to Torrent's entry into the aripiprazole market as Otsuka's active competitor. Nor does the status of Torrent's FDA approval render the alleged injury any less imminent, because the FDA's own records reflect that Torrent obtained final FDA approval for its ANDA product on April 28, 2015.[7] See Press Release, FDA, FDA approves first generic Abilify to treat mental illnesses (Apr. 28, 2015), available at, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm444862.htm. As a result, the pendency of this litigation constitutes the only encumbrance to Torrent's free ability to enter the aripiprazole market, rendering the alleged injuries both real and immediate.[8]

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[7] In deciding the pending motion to dismiss, the Court "may take judicial notice of public records [or documents] of the FDA" relating to the aripiprazole products at issue in this litigation. Kaiser v. Depuy Spine, Inc., 944 F. Supp. 2d 1187, 1192 n.2 (M.D. Fla. 2013) (citation omitted); see also Rollins v. St. Jude Med., 583 F. Supp. 2d 790, 805 (W.D. La. 2008) (citation omitted) (same).

[8] For that reason, the Court rejects Otsuka's reliance upon Ethypharm S.A. France. Indeed, in Ethypharm S.A. France, the Court of Appeals for the Third Circuit found the plaintiff could not "be considered a competitor for purposes of antitrust injury," because "legal barriers particular to the pharmaceutical market" precluded the plaintiff's from marketing a competing product. 707 F.3d at 236. Here, however, the legal

Moreover, even if Torrent's Counterclaim relies, at least in part, upon some ultimate facts, such as that Otsuka's actions evince a "specific intent to restrain competition," (id. at ¶ 45), Torrent need not "'plead detailed evidentiary matter in order to survive a motion to dismiss.'"[9] In re Niaspan Antitrust Litig., 42 F. Supp. 3d at 756 (citations omitted). Rather, the inquiry for purposes of the pending motion to dismiss turns upon the plausibility of the allegations, not upon whether Torrent has "alleged sufficient facts to 'compel' the inference" that Otsuka committed the alleged violations. Id. Here, Torrent's allegations, accepted as true, support an inference that Torrent has suffered an antitrust law injury flowing from Otsuka's allegedly anticompetitive conduct. (See generally Countercl.) These allegations therefore suffice at the pleading stage to state a plausible claim for relief, particularly given the fact that the existence of antitrust injury "involves complex questions of fact," often ill-suited for resolution upon a "motion[] to dismiss." Schuylkill Energy Res., Inc. v. Pa.

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barriers that once plagued Torrent's ability to enter the aripiprazole market, namely, expiration of the '528 Patent and final FDA approval, no longer present any impediment. Therefore, in the absence of this litigation, Torrent could immediately become, without reticence, Otsuka's lawful competitor.

[9] Nor are direct factual allegations of Torrent's chances of litigation success required; "inferential allegations" can suffice. See In re Niaspan Antitrust Litig., 42 F. Supp. 3d at 757 n.18 (citations omitted)

Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997) (citing Brader v. Allegheny Gen. Hosp., 64 F.3d 869, 876 (3d Cir. 1995) (collecting cases)); see also In re Niaspan Antitrust Litig., 42 F. Supp. 3d at 757 n.19 (collecting cases that have declined to resolve the existence of antitrust injury through motions to dismiss).

For all of these reasons, the Court rejects Otsuka's argument that Torrent's antitrust Counterclaim should be dismissed for lack of antitrust standing, and turns to Otsuka's position that *Noerr-Pennington* immunity bars the Counterclaim.

B. Torrent Alleges Sufficient Facts to Plausibly Overcome Otsuka's *Noerr-Pennington* Immunity

Under the *Noerr-Pennington* doctrine, a patent owner's initiation of patent infringement litigation receives presumptive immunity from attack under the antitrust laws. See generally Eastern R.R. Presidents Conference v. Noerr Motor Freight, 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965); see also Rochester Drug Co-op., Inc., 712 F. Supp. 2d at 316 (considering *Noerr-Pennington* immunity in the patent infringement context). Parties who file "sham litigation" are, however, excepted from the benefit of immunity under *Noerr–Pennington*. Prof'l Real Estate Investors v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60–61 (1993). An allegation of sham litigation consists of two elements:

first, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. (internal quotations and citations omitted). Second, "the baseless lawsuit [must] conceal[] an attempt to interfere directly with the business relationships of a competitor," rather than reflect a legitimate effort to obtain judicial review. Id.

In seeking the dismissal of Torrent's antitrust Counterclaim, Otsuka argues that Torrent pleads little more than "bare labels and legal conclusions," by claiming that Otsuka initiated "objectively baseless and sham judicial proceedings," "baselessly and improperly wielded the '615 and '796 Patents," and that the pending litigation qualifies as "both objective and subjectively baseless." (Otsuka's Br at 8-10 (citation omitted).) Those allegations, standing alone, do indeed constitute conclusory allegations of the type routinely found insufficient to overcome *Noerr-Pennington* immunity under the federal pleading standards. Nevertheless, Torrent's Counterclaim includes more detailed factual matter.

Indeed, in addition to the allegations cited by Otsuka, Torrent specifically alleges that it provided a "detailed statement of the factual and legal bases" for its position on the non-infringement of Torrent's ANDA, and that it subsequently provided the confirming "portions" of Torrent's ANDA.

(Countercl. at ¶¶ 15-16.) Torrent therefore alleges that the infringement claims asserted by Otsuka in this litigation lack an objectively reasonable basis, because "[n]o reasonable litigant could expect to secure favorable relief against Torrent upon the merits under the '615 and '796 patents." (Id. at ¶¶ 45, 47, 49-50.) Moreover, because Otsuka "initiated litigation" despite Torrent's allegedly dispositive evidence of noninfringement, Torrent submits that Otsuka filed this action "in bad faith, for an improper purpose, and as a means of directly interfering with," forestalling, frustrating, and preventing competition by Torrent, and not in order to "obtain an adjudication of a valid claim." (Id. at ¶¶ 46, 49.)

These allegations, accepted as true for purposes of this Rule 12(b)(6) motion, plausibly allege facts sufficient to overcome Otsuka's presumptive antitrust immunity under the *Noerr-Pennington* doctrine.[10] See, e.g., Abraxis Bioscience, Inc.

[10] Torrent's submission of Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii) compels no different result. Indeed, in its Paragraph IV certification, Torrent specifically certified that the Torrent aripiprazole tablets would "not infringe any valid claim of the '615 and '796 patents." (Countercl. at ¶ 15.) In that respect, even though Torrent's certification provided the technical act of constructive infringement necessary to initiate an action under 35 U.S.C. § 271(e)(2)(A), nothing in a paragraph IV certification necessarily compels the institution of an infringement suit. Indeed, it is commonplace for NDA owners not to file suit after analyzing the contents of an ANDA filer's notice and certification, and the case law cited by Otsuka provides little support for its position that the filing of a paragraph IV

v. Navinta LLC, No. 07-1251, 2008 WL 2967034, at *7 (D.N.J. July 31, 2008) (finding the defendant's limited allegations sufficient to overcome *Noerr-Pennington* immunity in connection with a motion to dismiss); Knoll Pharm. Co. Inc. v. Teva Pharm. USA, Inc., No. 01-1646, 2001 WL 1001117, at * 4 (N.D. Ill. Aug. 24, 2001) (finding the objectively baseless prong met where the defendant in an infringement action alleged that, before the plaintiff filed suit, the defendant sent a detailed letter providing the bases for the defendant's position on invalidity); In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 643-44 (E.D. Mich. 2000) (denying motion to dismiss antitrust claim on *Noerr-Pennington* grounds where the claimant alleged that the plaintiff prosecuted the infringement action solely as a basis for litigation to delay and exclude the claimant from the market).

Moreover, even assuming the allegations proved insufficient, the inquiry into whether Otsuka maintains in this

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certification renders this litigation per se reasonable. Critically, in Celgene, the Court considered the factual and legal basis of the litigation in the context of a request for sanctions under Federal Rule of Civil Procedure 11, not in connection with a *Noerr-Pennington* analysis. See 2008 WL 2856469, at *3. In AstraZeneca AB v. Mylan Labs., Inc., 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010), a case that relied upon Celgene, then addressed the defendant's antitrust counterclaims and *Noerr-Pennington* immunity, following "a 42-day bench trial" on the allegations of the plaintiff's claims and based, at least in part, upon the public records associated with that lengthy bench trial. Id. at *4. No such record has been developed in this instance.

action "objectively and subjectively baseless" infringement claims turns upon issues of reasonableness and intent—issues which are premature to consider upon the present record. Indeed, resolution of these inherently factual issues requires consideration of whether Otsuka undertook a reasonable investigation in advance of pursuing its infringement claims, whether Otsuka undertook this action for an improper and anticompetitive purpose, and whether a reasonable litigant could have realistically expected success on the merits at the time of filing. All of these determinations require inquiry into issues of fact, which cannot be resolved in the context of a motion to dismiss, and prior to discovery. See S3 Graphics Co., Ltd. v. ATI Techs. ULC, No. 11-1298, 2014 WL 573358, at *3 (finding resolution of *Noerr-Pennington* immunity "not proper before discovery"); Shionogi Pharma, Inc. v. Mylan, Inc., No. 10-1077, 2011 WL 3860680, at *6 (D. Del. Aug. 31, 2011) (declining to resolve the application of *Noerr-Pennington* immunity upon a motion to dismiss); Hoffman-La Roche Inc. v Genpharm Inc., 50 F. Supp. 2d 367, 380 (D.N.J. 1999) ("Reasonableness is a question of fact, and the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss.")

For all of these reasons, the Court rejects Otsuka's argument that Torrent's Counterclaim should be dismissed on *Noerr-Pennington* immunity. If, however, Torrent fails to meet

its burden of proof as to "sham" litigation" upon litigation of the patent infringement claims[11] and upon discovery as to Torrent's Counterclaims, Otsuka may renew its claim of *Noerr-Pennington* immunity. Moreover, even if Torrent ultimately overcomes *Noerr-Pennington* immunity, in order to succeed on its Counterclaim, Torrent must still establish a substantive antitrust violation. See Organon Inc. v. Mylan Pharm., Inc., 293 F. Supp. 2d 453, 461 (D.N.J. 2003) (citation omitted).

The Court next addresses whether Torrent states a plausible Counterclaim for patent misuse

C. Torrent Fails to Allege a Plausible Claim of Patent Misuse

Several decades-worth of Supreme Court jurisprudence makes clear that the defense of patent misuse must be based upon allegations that the patentee "extend [ed] the term of his [patent] monopoly beyond that granted by law." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 136 (1969); see also Blonder–Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343–44 (1971) (generally describing the public's "paramount interest" in restraining patent monopolies to "their legitimate scope"); Transparent–Wrap Mach. Corp. v. Stokes & Smith Co., 329 U.S. 637, 643–44 (1947) ("a patentee [is

[11] The Court will, as stated below, bifurcate and stay Torrent's antitrust Counterclaim, pending resolution of the patent infringement issues.

limited] to the monopoly found within the four corners of the grant" and may not use that monopoly power "to acquire a monopoly not embraced in the patent").

In applying the Supreme Court's long line of patent misuse decisions, the Court of Appeals for the Federal Circuit has further stated that a claim of patent misuse requires an allegation that the patent owner "'impermissibly broaden[ed] the physical or temporal scope' of the patent grant with an anticompetitive effect."[12] Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (quoting Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1001 (Fed. Cir. 1986). District courts throughout this Circuit have, in turn, uniformly enforced the requirement that a plausible claim for patent misuse include an allegation of a patentee's attempt to impermissibly broaden the physical or temporal scope of the disputed patent. See, e.g., Micron Tech., Inc. v. Rambus Inc., 917 F. Supp. 2d 300, 320 n.19 (D. Del. 2013); Altana Pharma AG v. Teva Pharm. USA, Inc., No. 04-2355, 2012 WL 2068611 (D.N.J.

[12] Torrent attempts to sidestep this elemental requirement, but provides no support for its position that a claim of patent misuse can survive without an allegation of an impermissibly broadened patent. Nor does Torrent's sole citation to Altana Pharma AG v. Teva Pharm. USA, Inc., No. 04-2355, 2012 WL 2068611 (D.N.J. June 7, 2012), compel any contrary result. Indeed, in Altana, the defendants specifically alleged that the plaintiff engaged in patent misuse by amending certain license agreements to treat the disputed patent as if it remained "in force for an additional six months past the expiration date." Id. at *2. Torrent has proffered no similar allegation in this instance.

June 7, 2012); Cordance Corp. v. Amazon.com, Inc., 727 F. Supp. 2d 310, 333-34 (D. Del. July 23, 2010); In re Gabapentin Patent Litig., 648 F. Supp. 2d 641, 652 (D.N.J. 2009).

Here, the Court need not belabor Torrent's Sixth Counterclaim for patent misuse, which alleges, in its entirety, that:

> 59. Torrent restates and realleges each of the foregoing paragraphs as if fully set forth herein.
>
> 60. [Otsuka] does not have any good faith factual basis to allege that the products described in the Torrent ANDA infringe any claim of the '615 and '796 patents, and nevertheless filed and are continuing to maintain this lawsuit.
>
> 61. [Otsuka] filed this action without regard for the merits of its infringement claims and instead did so for the purpose of delay Torrent's entry in into the marketplace for aripiprazole tablets by, inter alia, burdening Torrent with litigation costs and making baseless accusations of infringement.
>
> 62. The claims of the '615 and '796 patents are unenforceable as a result of Plaintiff's patent misuse, including [Otsuka's] bad faith assertion of the '615 and '796 patents against Torrent.

(Countercl. at ¶¶ 59-62.) As is evident from even a cursory review of Torrent's pleading, Torrent's Counterclaim hinges upon Otsuka's allegedly bad faith conduct in pursuing its "baseless" patent infringement action against Torrent. Torrent, however, has failed to plead any allegation that Otsuka has impermissibly broadened the physical or temporal scope of the '615 and '796 patents with an anticompetitive effect. Indeed, Torrent's

responsive pleading, in its entirety, contains no allegation concerning any improper expansion of the physical or temporal breadth of the disputed patents. Torrent's Counterclaim therefore lacks an essential allegation, and fails to state a plausible claim for relief as a matter of law. Torrent's patent misuse Counterclaim will, accordingly, be dismissed. Nevertheless, because it remains conceivable that Torrent could plausibly allege this additional requirement, this dismissal will be without prejudice and the Court will grant Torrent leave to file a motion to amend to attempt to assert a counterclaim for patent misuse within fourteen (14) days. Any proposed amended counterclaim must be consistent with this Opinion's directives and findings.

The Court last addresses Otsuka's request to bifurcate and stay.

D. Torrent's Antitrust Counterclaim Will be Bifurcated and Stayed

To the extent Torrent's Counterclaims survive Otsuka's motion to dismiss, as the antitrust Counterclaim has, the parties uniformly assert that the Court should bifurcate and stay the Counterclaim pending resolution of the patent infringement issues. (See Otsuka's Br. at 13; Torrent's Opp'n at 1 (noting Torrent's "accordance with Otsuka's request" to bifurcate and stay); Otsuka's Reply at 6.)

Federal Rule of Civil Procedure 42(b) provides, in relevant part, that the Court may "order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims," in order to encourage "convenience, to avoid prejudice, or to expedite and economize." FED. R. CIV. P. 42(b). In determining whether to bifurcate under Rule 42(b), courts possess broad discretion. See Barr Lab., Inc. v. Abbott Lab., 978 F.2d 98, 115 (3d Cir. 1992) (citing Idzojtic v. Pa. R.R. Co., 456 F.2d 1228, 1230 (3d Cir. 1972)). Nevertheless, in order to properly exercise that discretion, courts must carefully balance "considerations of convenience, avoidance of prejudice, and efficiency," and must preserve the litigant's constitutional right to a jury. See Celgene Corp. v. BarrLab., Inc., No. 07-286, 2008 WL 2447354, *1 (D.N.J. June 13, 2008); FED. R. CIV. P. 42(b) ("When ordering a separate trial, the court must preserve any federal right to a jury trial.").

Considering the various factors presented in this action, and the parties' agreement, the Court finds the bifurcation and stay of Torrent's antitrust Counterclaim warranted. Critically, resolution of the patent infringement issues may render Torrent's antitrust Counterclaim moot, thereby serving the interests of judicial economy. Bifurcation of antitrust Counterclaim and patent infringement claims further enhances "the parties' right to jury trial by making the issues the jury

must consider less complex." Warner Lambert Co. v. Purepac Pharm. Co., Nos. 98-2749, 99-5948, 00-2053, 2000 WL 34213890, *11 (D.N.J. Dec. 22, 2000) (internal quotation marks omitted). In that respect, the Court will follow the practice of separating for trial patent issues and antitrust issues. In re Innotron Diagnostics, 800 F.2d 1077, 1084 (Fed. Cir. 1986) (affirming the severance of patent and antitrust claims as in the interests of judicial economy); see also Eurand Inc. v. Mylan Pharm. Inc., No. 08-889, 2009 WL 3172197, at *2 (D. Del. Oct. 1, 2009) (granting motion to sever and stay antitrust and patent misuse counterclaims and affirmative defenses from the patent infringement action); See Abraxis Bioscience, Inc., 2008 WL 2967034, at *8 (denying a motion to dismiss, but granting an alternative request to bifurcate and stay antitrust counterclaims).

For all of these reasons, the Court will bifurcate Torrent's antitrust Counterclaim, and will stay discovery with respect to this Counterclaim pending resolution of the patent infringement issues.

V. CONCLUSION

For the reasons stated above, Otsuka's motion will be denied with respect to Torrent's antitrust Counterclaim, and granted with respect to Torrent's patent misuse Counterclaim, with leave to amend. Torrent's antitrust Counterclaim will,

however, be bifurcated and stayed pending resolution of the patent infringement issues. An accompanying Order will be entered.

June 22, 2015
Date

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