IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI PHARMA, INC., et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
MYLAN, INC. et al.	:	NO. 10-1077

MEMORANDUM RE: MOTION TO DISMISS AMENDED COUNTERCLAIM

Baylson, J. **August 31, 2011**

I. Introduction

Plaintiffs-Counter-Defendants Shionogi Pharma, Inc. ("Shionogi") and CIMA Labs Inc. ("CIMA") (collectively, "Counter-Defendants") move to dismiss the antitrust counterclaim filed by Defendant-Counter-Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") for failure to state a claim upon which relief can be granted (ECF No. 56/57). This Court granted with leave to amend Plaintiffs' prior motion to dismiss Mylan's counterclaims for monopolization and attempted monopolization, and combination and conspiracy in restraint of trade, because the allegations of conspiracy, monopoly power, geographic market, and product market were deficient.[1] Thereafter, Mylan filed an Amended Counterclaim (ECF No. 53) for Declaration of Non-Infringement of the '341 Patent (Count I); Declaration of Invalidity of the '341 Patent (Count II); and Monopolization and Attempted Monopolization in Violation of 15 U.S.C. § 2 (Count III).

Counter-Defendants now move to dismiss Count III (the "Antitrust Counterclaim"), on

[1] Shionogi Pharma, Inc. v. Mylan, Inc., No. 10-1077, 2011 WL 2550835, at *1 (D. Del. June 10, 2011). In their prior motion to dismiss, Counter-Defendants also contended that Mylan lacked antitrust standing, an issue on which the Court reserved decision. See id.

three grounds: 1) Mylan lacks antitrust standing; 2) Counter-Defendants' patent infringement lawsuit does not constitute monopolistic behavior upon which Mylan can state a claim under Section 2 of the Sherman Act; and 3) Mylan failed to plead a relevant geographic market.

The Court finds that the Amended Counterclaim cured the deficiencies in Mylan's original counterclaim, and that Mylan has antitrust standing. The Court will deny Counter-Defendants' Motion to Dismiss.

II. Factual Background

This civil action arises out of U.S. Patent No. 6,740,341 B1 ("the '341 patent"), titled "Taste Masking Rapid Release Coating System." Am. Countercl. ¶ 11. Counter-Defendants own and/or exclusively license and have the rights to enforce the '341. Am. Countercl. ¶ 12. The '341 patent relates to the tablet design for masking a pharmaceutical's ill taste. Am. Countercl. ¶ 13. Shionogi holds and is listed in the Food and Drug Administration ("FDA")'s Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as the owner of the New Drug Application ("NDA") for Orapred ODT®, an orally disintegrating prednisolone tablet. Am. Countercl. ¶¶ 14-19. CIMA manufactures Orapred ODT®. Am. Countercl. ¶ 20.

Mylan filed with the FDA an Abbreviated New Drug Application ("ANDA") for prednisolone phosphate orally disintegrating tablets (the "Proposed Product"). Am. Countercl. ¶ 23. Mylan intends to market the Proposed Product as a therapeutic equivalent to, or generic formulation of, Orapred ODT®. Am. Countercl. ¶ 33.

On October 25, 2010, Mylan notified the Counter-Defendants that it sought FDA approval of its ANDA for a non-infringing Proposed Product before the expiration of the '341

patent listed in the Orange Book. Am. Countercl. ¶ 27. Mylan attached its certification that the Proposed Product has no "spacing layer" and would not infringe the '341 patent, which excludes tablets without a "spacing layer." Am. Countercl. ¶ 28. The Counter-Defendants accepted Mylan's Offer of Confidential Access to review the ANDA and received samples of the Proposed Product, which revealed the absence of a spacing layer. Am. Countercl. ¶¶ 29-30.

Counter-Defendants filed suit alleging infringement of the '341 patent on December 9, 2010, triggering an automatic 30-month stay of FDA approval of Mylan's ANDA. Am. Countercl. ¶¶ 25-26. Mylan alleges that Counter-Defendants lacked a good faith basis to file the patent infringement suit, and that they did so to prevent Mylan from entering the market. Am. Countercl. ¶¶ 31-32.

Mylan alleges that the relevant product market is prednisolone in the form of orally disintegrating tablets. Am. Countercl. ¶ 37. The Amended Counterclaim alleges that prednisolone orally disintegrating tablets have been "recognized in the industry as a separate and distinct product" and sets forth detailed allegations concerning the unique properties of the tablets. Am. Countercl. ¶¶ 37-64. Because there is no competitor to Orapred ODT®, its sale price is substantially higher than the price of other forms of prednisolone and corticosteroids. Am. Countercl. ¶¶ 65-67.

Mylan alleges that the relevant geographic market is the United States, due to the significant barriers to entry for importation of foreign drugs, and the fact that Orapred ODT® is the only orally disintegrating prednisolone tablet sold in the United States. Am. Countercl. ¶¶ 68-77.

III. The Parties' Contentions

A. Shionogi and CIMA's Contentions

First, Counter-Defendants contend that Mylan is neither a consumer or a competitor in a relevant market and therefore lacks antitrust injury and antitrust standing. Specifically, Counter-Defendants argue that the absence of tentative approval by the FDA bars Mylan from bringing an antitrust claim because Mylan cannot show it is ready to enter the market. Second, Counter-Defendants argue that Mylan has not alleged an antitrust violation and brought the Antitrust Counterclaim as a cloaked defense to the patent infringement claims. Counter-Defendants assert that the allegations concerning their purportedly sham infringement suit and high market share do not show that Counter-Defendants engaged in monopolistic behavior. Third, Counter-Defendants contend that Mylan has alleged that the United States is the relevant geographic market in a conclusory manner.

B. Mylan's Contentions

First, Mylan responds that it has antitrust standing as a generic drug competitor who shows intention to enter the market and preparedness to do so. Mylan asserts that it need not allege tentative FDA approval to be a generic drug competitor. Second, Mylan contends that Counter-Defendants committed an antitrust violation by filing an infringement suit that is objectively baseless and intended to harm Mylan, a potential competitor. Mylan asserts that Counter-Defendants knew based on the Proposed Product samples and the Offer of Confidential Access that the Proposed Product is non-infringing. Third, Mylan contends that it sufficiently alleged a geographic market.

IV. Legal Standard

A. Jurisdiction

The District Court has jurisdiction over the patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a), and jurisdiction over the Sherman Act counterclaims under 28 U.S.C. §§ 1331 and 1337(a).

B. Motion to Dismiss

When deciding the motion to dismiss a counterclaim pursuant to Federal Rule of Civil Procedure 12(b)(6), the court limits its review to the face of the counterclaim. Barefoot Architect, Inc. v. Bunge, 632 F.3d 822, 835 (3d Cir. 2011). The Court must accept as true all well-pleaded factual allegations and construe them in the light most favorable to the non-moving party. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008).

Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief."
The Third Circuit has addressed the effect of the Supreme Court's most recent pleading-standard decisions, Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009). See Phillips, 515 F.3d at 233–34. Twombly established a three-pronged approach for all civil actions: first, the court must identify the elements Plaintiff must plead to state a claim; second, the court asks whether the complaint sets forth factual allegations or conclusory statements; third, if the complaint sets forth factual allegations, the court must assume their veracity and draw reasonable inferences in favor of the non-moving party, but then must determine whether the factual allegations plausibly give rise to an entitlement to relief. Santiago v. Warminster Twp., 629 F.3d 121, 130 & n. 7 (3d Cir. 2010); see Iqbal, 129 S. Ct. at 1950, 1953. For the second step, the court should separate the factual and legal elements of the claims, must accept the well-pleaded facts as true, and may disregard any legal conclusions. Fowler v.

UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).

To state a claim, a plaintiff must allege circumstances with enough factual matter to suggest the required claim exists. Phillips, 515 F.3d at 234. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements of the claims, Iqbal, 129 S. Ct. at 1949; Phillips, 515 F.3d at 234. "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to reasonably infer that the defendant is liable for the misconduct alleged.'" Gelman v. State Farm Mut. Auto. Ins. Co., 583 F.3d 187, 190 (3d Cir. 2009) (quoting Iqbal, 129 S. Ct. at 1949).

V. Discussion

To state a claim for monopolization under Section 2 of the Sherman Act,[2] a plaintiff must plead two elements: "'(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 75 (3d Cir. 2010) (quoting Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481 (1992)).

A. Antitrust Standing

Antitrust standing is a prudential, rather than constitutional, limitation on the district

[2] "Every person who shall 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, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court." 15 U.S.C. § 2 (West 2011).

court's jurisdiction. City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 264 (3d Cir. 1998) (affirming grant of defendants' motion to dismiss where plaintiff did not satisfy the "threshold inquiry" of antitrust standing, i.e., whether "the plaintiff [is] a proper party to bring a private antitrust action").

The Third Circuit applies a five-factor balancing test to determine whether a plaintiff has antitrust standing:

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

Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 320 (3d Cir. 2007) (quoting Barton & Pittinos, Inc. v. SmithKline Beecham Corp., 118 F.3d 178, 181 (3d Cir. 1997)). Whether the plaintiff has suffered an "antitrust injury" is subsumed in the balancing test for antitrust standing. 2660 Woodley Road Joint Venture v. ITT Sheraton Corp., 369 F.3d 732, 741 (3d Cir. 2004). "A plaintiff who is neither a competitor nor a consumer in the relevant market does not suffer antitrust injury." Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 415 (3d Cir. 1997).

Counter-Defendants rely on City of Pittsburgh v. West Penn Power Co. to support their argument that a regulatory bar, i.e. the absence of FDA approval of the Proposed Product, rather than their monopolistic behavior, impeded Mylan's entry to the market. In West Penn, the Third Circuit affirmed the suit's dismissal for lack of antitrust standing, where the plaintiff city failed to show a causal connection between a proposed merger of two utility companies (the alleged

violation), and a decrease in competition (the alleged harm), where only one of the utility companies had prior approval to provide services in designated zones. West Penn, 147 F.3d 256 at 265-69. The Third Circuit found that "[t]he presence of the regulatory scheme and need for approval in connection with the choice of utilities to serve the Redevelopment Zones cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise." Id. at 267-68. The court held that "[t]he absence of antitrust injury and causal connection clearly defeat the City's standing." Id. at 268.

However, the Third Circuit limited its West Penn holding to the facts, stating: "We make clear that this ruling is fact specific to the current climate in which the instant facts developed, namely, in the era of 'regulated electric utility monopolies.'. . ." Id. at 269. Indeed, subsequent decisions in the Third Circuit have found that West Penn does not control outside of its unusual factual circumstances. For example, in In re Warfarin Sodium Antitrust Litig., 214 F.3d 395 (3d Cir. 2000), the Third Circuit distinguished West Penn: "We can reasonably posit, however, that if not for this regulatory quirk, the City would have been entitled to section 16 relief because the proposed merger would have eradicated competition, a result prohibited under the Clayton Act, and detrimental to the City's electrical customers." Id. at 401 (holding that purchasers of the pharmaceutical Coumadin had antitrust standing to sue DuPont, the manufacturer of Coumadin, for its efforts to keep a generic competitor out of the market, which injured plaintiffs by inflating the price for the drug). See also In re Metoprolol Succinate Direct Purchaser Antitrust Litig., Civ. A. Nos. 06-52 (GMS), 06-71(GMS), 2010 WL 1485328, at *5-6 (D. Del. April 13, 2010) (Sleet, J.) (finding West Penn was limited to its regulatory context and did not support defendant's contention that "federal law and the FDA approval process prohibited generic

manufacturers from entering the metoprolol succinate-based prescription drug market").

Courts have also rejected Counter-Defendants' argument that a generic manufacturer lacks antitrust standing if its product has not received FDA approval. In Andrx Pharmaceuticals., Inc. v. Biovail Corp. International, 256 F.3d 799 (D.C. Cir. 2001), the Court of Appeals for the District of Columbia held that a potential competitor could demonstrate antitrust standing: "A competitor that has not yet entered the market may also suffer injury but courts require a 'potential' competitor to demonstrate both its intention to enter the market and its preparedness to do so." Id. at 806 (citing Hecht v. Pro-Football, Inc., 570 F.2d 982, 994 (D.C. Cir. 1977)). A potential competitor's "'indicia of preparedness include adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry, 'such as the consummation of relevant contracts and procurement of necessary facilities and equipment.'" Id. at 807 (quoting Hecht, 570 F.2d at 994). Although FDA approval was a regulatory prerequisite to enter the pharmaceutical market, a proposed competitor "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable." Id. at 807-08 (affirming the district court's dismissal of antitrust claim for deficient allegation of injury-in-fact, but reversing decision to dismiss with prejudice because it was possible for a generic manufacturer to plead an injury despite not having obtained FDA approval).

Similarly, in In re Metoprolol Succinate Direct Purchaser Antitrust Litigation, Judge Sleet rejected the argument that tentative FDA approval was dispositive to cross the antitrust standing threshold. 2010 WL 1485328, at *7. The court denied the defendant pharmaceutical company's motion to dismiss a generic manufacturer's antitrust claim for failure to allege tentative FDA

approval. Id. See also Rochester Drug Co-op., Inc. v. Braintree Labs., 712 F. Supp. 2d 308, 317 (D. Del. 2010) (Robinson, J.) (plaintiff direct purchasers' allegation that "as a result of [the patent holder]'s scheme, the ANDA approval process was delayed by the FDA" with respect to a potential generic competitor, inflating the price of the drug, was sufficient to allege a causal link); In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (Kauffman, J.) (denying the patent holder's motion to dismiss because the possibly frivolous filing of patent litigation triggered a stay of FDA approval for up to 30 months); Bristol Meyer-Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 545-46 (D.N.J. 2000) (Walls, J.) (denying motion for summary judgment on antitrust counterclaim and finding that potential competitor "need not demonstrate that the FDA has first approved its product" to allege antitrust standing).

Here, Mylan has alleged that it submitted its ANDA and has the intention and preparedness to enter the market, demonstrating it is a potential competitor. Am. Countercl. ¶¶ 23, 33. Mylan has alleged a causal connection between the alleged violation - the patent litigation filed by Counter-Defendants - and the alleged harm - keeping Mylan out of the market, which inflates the price for consumers who cannot buy the generic version. Am. Countercl. ¶¶ 31, 34-35. The other factors of the Broadcom Corp. balancing test also weigh in favor of Mylan having antitrust standing. For example, as a potential competitor, Mylan has been directly injured by the alleged scheme. There are no more direct victims who should file suit and no potential for duplicative recovery at this point. Therefore, Mylan has antitrust standing as a potential competitor.

B. Sham Litigation

Having determined that Mylan is a proper Counter-Plaintiff, the Court must examine whether Mylan stated a claim under Section 2 of the Sherman Act. The Counter-Defendants move to dismiss on the ground that their filing a patent infringement lawsuit against Mylan does not constitute an antitrust violation.

Under the Noerr-Pennington doctrine,[3] "[t]hose who petition government for redress are generally immune from antitrust liability." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993). Parties who file "sham litigation" are excepted from the benefit of immunity under Noerr-Pennington. Id. 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. at 60. Second, "the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor . . .." Id. at 60-61 (internal citations and quotation marks omitted).

Whether the underlying litigation is baseless is a factual issue not to be determined on a motion to dismiss. In In re Metoprolol, the plaintiff purchasers alleged that the defendant patent holder filed "sham" lawsuits against generic manufacturers who filed an ANDA for a proposed competitive product. 2010 WL 1485328, at *10. The district court denied the defendant's motion to dismiss the antitrust claim, explaining that it "cannot make such a finding [whether the defendant's patent infringement suits against the generic manufacturers were objectively baseless] at the motion to dismiss stage, because it is fact intensive." Id. Therefore, the allegation "that AstraZeneca brought patent infringement suits against generic manufacturer

[3] The doctrine arose from Eastern R.R. Presidents Conference v. Noerr Motor Freight, 365 U.S. 127 (1961) and United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

ANDA filers despite knowing that their metoprolol succinate patents were invalid" was sufficient to state a claim for an antitrust violation. Id. Counter-Defendants' attempt to minimize or distinguish In re Metoprolol is not persuasive.

Counter-Defendants rely on AstraZeneca AB v. Mylan Laboratories, Inc., No. M-21-81 (BSJ), 2010 WL 2079722 (S.D.N.Y. May 19, 2010) (Jones, J.), aff'd 412 F. App'x 297 (Fed. Cir. 2011) (non-precedential), in which the sham litigation exception was found not to apply. In determining the underlying patent litigation was not objectively baseless, Judge Jones relied on the prior denial of Mylan's motion for summary judgment on AstraZeneca's non-infringement claim, which found there were material disputes of fact, and the findings of fact from a 42-day bench trial, in which AstraZeneca proved two of three contested limitations. Id. at *4. Thus, the procedural posture of AstraZeneca permitted the court to make factual findings that this Court cannot make here.

In this case, Mylan alleged that the patent litigation was objectively baseless, because Counter-Defendants reviewed the samples and confidential information showing the Proposed Product had no spacing layer, which was a feature of the patented tablet design. Am. Countercl. ¶¶ 30-31. Mylan further alleged that Counter-Defendants' actual motivation in filing the lawsuit was to delay FDA approval of Mylan's ANDA for the Proposed Product. Am. Countercl. ¶ 32. Mylan's allegations are analogous to the antitrust claim in In re Metoprolol, which survived a motion to dismiss because the questions of fact as to the merit of the purportedly unfounded infringement litigation would be determined at a later stage. Thus, Mylan has sufficiently pleaded an antitrust violation. Only after discovery will it be possible to determine whether Counter-Defendants' infringement suit is founded.

C. Geographic Market

Finally, Counter-Defendants revisit their argument from their prior successful motion to dismiss that Mylan has not adequately pled a geographic market. To allege liability under Section 2 of the Sherman Act, a complaint must include allegations that the defendant has obtained "the ability to control prices and exclude competition in a given market." Broadcom Corp., 501 F.3d at 307 (citing United States v. Grinnell Corp., 384 U.S. 563, 571 (1966)). The Third Circuit defines the geographic market as "'the area in which a potential buyer may rationally look for the goods or services he or she seeks.'" Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 726-27 (3d Cir. 1991) (quoting Pa. Dental Ass'n v. Medical Service Ass'n of Pa., 745 F.2d 248, 260 (3d Cir.1984)). "The mere delineation of a geographical area, without reference to a market as perceived by consumers and suppliers, fails to meet the legal standard necessary for the relevant geographic market." Id. at 727. For example, in Andela v. Am. Ass'n For Cancer Research, 389 F. App'x 137 (3d Cir. 2010) (non-precedential), the Third Circuit found that the plaintiff's conclusory allegation that the relevant geographic marketplace was "the world" did not adequately define the product market. Id. at 141.

In its Amended Counterclaim, Mylan supported its allegation that the relevant geographic market is the United States with facts, including references to consumers and suppliers. Mylan alleges that consumers in the United States may only purchase orally disintegrated prednisolone tablets that have received FDA approval for sales within the United States; that FDA regulations prohibit importation of drugs from outside of the United States; that the only orally disintegrated prednisolone tablet available for purchase in the United States is Orapred ODT; that there are no generic versions on the market; and that on information and belief, Orapred ODT is prescribed

for, sold to, and used by consumers across the country. Am. Counterclaim ¶¶ 68-72. These allegations sufficiently delineate a geographic market for Mylan to state a claim under Section 2 of the Sherman Act.

VI. Conclusion

For the foregoing reasons, the Court will deny Counter-Defendants' Motion to Dismiss the Antitrust Counterclaim.[4] An appropriate Order follows.

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[4] If requested, the Court will schedule a pretrial conference to consider, if fair to the parties and possibly reducing the cost of discovery, structuring discovery to make an early determination whether genuine factual disputes exist on specific claims or defenses.