UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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AMERICAN SALES COMPANY, INC.,

Plaintiff,

-against-

ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP, KBI, INC., KBI-E, INC. and THE PROCTER & GAMBLE COMPANY,

Defendants.

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10 Civ. 6062 (PKC)

MEMORANDUM AND ORDER

P. KEVIN CASTEL, U.S.D.J.,

Plaintiff American Sales Company, Inc. ("American Sales") asserts that the defendants commenced sham patent litigation to perpetuate an unlawful monopoly over the anti-heartburn drug Prilosec OTC. The Complaint alleges that this conduct violated section 2 of the Sherman Act, 15 U.S.C. § 2. The defendants move to dismiss the Complaint. Because the Complaint does not plausibly allege a relevant product market, the defendants' motion is granted. Moreover, even if the plaintiff had plausibly alleged a relevant product, its claims against defendants KBI, Inc. and KBI-E, Inc. would be dismissed for failure to satisfy Rule 8, Fed. R. Civ. P.

BACKGROUND

For the purposes of the defendants' motion, all nonconclusory factual allegations are accepted as true. Matson v. Bd. of Educ. Of City School Dist. of N.Y., 631 F.3d 57, 63 (2d Cir. 2011); see also Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009). As

the non-movants, all reasonable inferences are drawn in favor of the plaintiffs. Matson, 631 F.3d at 63.

American Sales brings its claims as a purported class action on behalf of direct purchasers of the drug Prilosec Over the Counter omeprazole magnesium ("Prilosec OTC").[1] (Compl. ¶ 1.) Prilosec OTC is a "proton pump inhibitor" medication used to treat frequent heartburn. (Compl. ¶¶1, 46, 82.)

According to the Complaint, the defendants launched an "agreement, joint venture or conspiracy" to monopolize the market for Prilosec OTC. (Compl. ¶¶ 36, 38, 99.) The Complaint asserts that defendants extended their exclusive rights to market and sell Prilosec OTC by filing sham litigation against generic pharmaceutical companies who sought Food and Drug Administration ("FDA") approval to market and sell generic omeprazole magnesium. (Compl. ¶¶ 40-47, 59-78.) Broadly summarized, under the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), a branded drug's patent owner may, in certain circumstances, temporarily prevent generic competition from entering the market by filing a patent infringement suit. (Compl. ¶¶ 16, 25, 27.) When a patent infringement suit is filed, the FDA automatically blocks the generic manufacturer from bringing its product on the market, regardless of the suit's merits. (Compl. ¶ 27-28.) In so doing, the FDA acts in a purely ministerial capacity, and does not look to the merits of the underlying infringement claim. (Compl. ¶ 28.) By commencing "sham" patent infringement litigation against generic pharmaceutical companies, the defendants triggered the FDA's automatic exclusivity provision. (Compl. ¶¶ 59-78.) According to the Complaint, this amounted to anti-

[1] Although the Complaint does not expressly allege as much, it is apparent that omeprazole magnesium is the name of the chemical compound that constitutes Prilosec OTC, and that Prilosec OTC is the brand named used by the defendants in marketing their product. (E.g., Compl. ¶¶ 40-41, 43-44.)

competitive conduct that facilitated wrongful monopoly power over the relevant product market of over-the-counter omeprazole magnesium, which was marketed by defendants under the brand name Prilosec OTC. (Compl. ¶¶ 98-102.) Following the defendants' unsuccessful patent infringement claims against generic manufacturers, generic omeprazole magnesium was made available for purchase in December 2009. (Compl. ¶ 72.)

MOTION TO DISMISS STANDARD

Rule 8(a)(2), Fed. R. Civ. P., requires "'a short and plain statement 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 grounds upon which it rests.'" Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (ellipsis in original) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). In Twombly, which arose in the context of a Sherman Act claim, the Supreme Court held that to survive a motion to dismiss under Rule 12(b)(6), a plaintiff must provide the grounds upon which the claims rest, through factual allegations sufficient to raise a right to relief above the speculative level. Id. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 129 S. Ct. at 1949. "The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully." Id. Legal conclusions and "[t]hreadbare recitals of the elements of a cause of action" do not suffice to state a claim, as "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Id. at 1949-50. As Twombly explained, in the antitrust context, "'a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.'" 550 U.S. at

558 (quoting Associated Gen. Contractors of Cal., Inc. v. Carpenters, 459 U.S. 519, 528 n.17 (1983)).

The Supreme Court has described the motion to dismiss standard as encompassing a "two-pronged approach" that requires a court first to construe a complaint's allegations as true, while not accepting the veracity of a legal conclusion couched as a factual allegation. Iqbal, 129 S. Ct. at 1950. Second, a court must consider whether the complaint "states a plausible claim for relief," which is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id.

DISCUSSION

I. THE COMPLAINT FAILS TO ALLEGE A PLAUSIBLE PRODUCT MARKET.

"For a monopoly claim '[t]o survive a Rule 12(b)(6) motion to dismiss, an alleged product market must bear a rational relation to the methodology courts prescribe to define a market for antitrust purposes – analysis of the interchangeability of use or the cross-elasticity of demand, and it must be plausible.'" Chapman v. N.Y. State Div. for Youth, 546 F.3d 230, 237 (2d Cir. 2008) (quoting Todd v. Exxon Corp., 275 F.3d 191, 200 (2d Cir. 2001)). "Cross-elasticity of demand exists if consumers would respond to a slight increase in the price of one product by switching to another product." AD/SAT, Div. of Skylight, Inc. v. Associated Press, 181 F.3d 216, 227 (2d Cir. 1999).

"The goal in defining the relevant market is to indentify market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." Geneva Pharma. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004). Definition of the product market often requires "a deeply fact-intensive inquiry," and courts are hesitant to grant motions to dismiss for failure to plead a relevant market. Todd, 275 F.3d

at 199-200. At the same time, when a proposed product market "'clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss must be granted.'" Chapman, 546 F.3d at 238 (quoting Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 436 (3d Cir. 1997)). Any limitation in defining the relevant market must be at least "theoretically reasonable . . . ." Id. "'The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.'" Coniglio v. Highwood Services, Inc., 495 F.2d 1286, 1292 (2d Cir. 1974) (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 325(1962)). An analysis of the relevant product market "must recognize meaningful competition where it is found to exist," and may encompass "'well-defined submarkets, which, in themselves, constitute product markets for antitrust purposes.'" United States v. Continental Can Co., 378 U.S. 441, 449 (1964) (quoting Brown Shoe, 370 U.S. at 325).

"Cases in which dismissal on the pleadings is appropriate frequently involve either (1) failed attempts to limit a product market to a single brand, franchise, institution, or comparable entity that competes with potential substitutes or (2) failure even to attempt a plausible explanation as to why a market should be limited in a particular way." Todd, 275 F.3d at 200 (collecting cases). For example, a particular athletic team, pizza brand or Broadway show does not constitute its own market. Id. at 200 n.3; see also Global Discount Travel Services, LLC v. Trans World Airlines, Inc., 960 F. Supp. 701, 705 (S.D.N.Y. 1997) ("A consumer might choose to purchase a certain product because the manufacturer has spent time and energy differentiating his or her creation from the panoply of products in the

market, but at base, Pepsi is one of many sodas, and NBC is just another television network.") (Sotomayor, J.).

The plaintiff's allegations as to relevant product market are limited, vague and conclusory. The Complaint asserts as follows:

> The relevant product market is omeprazole magnesium, i.e., Prilosec OTC and omeprazole magnesium OTC. Omeprazole magnesium is a proton pump inhibitor. During the class period, there were no bioequivalent interchangeable omeprazole magnesium products.

(Compl. ¶ 82.) The Complaint includes few additional allegations about the characteristics of Prilosec OTC, and, indeed, makes no attempt to distinguish Prilosec OTC from potential competitor products. It alleges that "Prilosec OTC is a popular and successful proton pump inhibitor medication for the treatment of certain stomach problems." (Compl. ¶ 1.) Prilosec OTC uses a formulation of omeprazole that includes magnesium, as opposed to prescription Prilosec, which does not use magnesium. (Compl. ¶ 41.) According to the plaintiff, the defendants "specifically represented that omeprazole magnesium is a different product from omeprazole." (Compl. ¶ 41.) Plaintiff asserts that Prilosec OTC "was neither bioequivalent nor therapeutically equivalent to prescription Prilosec (omeprazole)." (Compl. ¶ 45.) The Complaint alleges that "[o]n June 20, 2003, the FDA approved omeprazole magnesium as Prilosec OTC, but only for the treatment of 'frequent heartburn' and not for any of the other uses that prescription Prilosec (containing only omeprazole) was approved." (Compl. ¶ 46.)

These allegations do not plausibly allege a relevant product market consisting solely of Prilosec OTC and its generic counterpart. The plaintiff has failed to allege any product characteristics or evidence of consumer buying patterns that limit Prilosec OTC's interchangeability of use or the cross-elasticity of demand. Todd, 275 F.3d at 200. For

instance, the Complaint has not attempted to allege why a consumer would not view any other number of products as adequate substitutes for treatment of frequent heartburn. Similarly, the Complaint has not alleged why Prilosec OTC constitutes its own market among purchasers of proton pump inhibitor products. It is further unclear from the Complaint what significance (if any) is to be attributed to the product's status as a proton pump inhibitor, as the Complaint fails even to define a proton pump inhibitor. The Court is left to speculate whether a relevant product market could include any product used to treat frequent heartburn; a narrower market consisting of proton pump inhibitors; the single-product market proposed by plaintiff; or any number of formulations. To the extent that plaintiff asserts no products are interchangeable with Prilosec OTC, it is a legal conclusion unsupported by allegations describing Prilosec OTC or the competitive landscape of heartburn-treatment products. Because it is conclusory, the allegation is not afforded the assumption of truth.

The Complaint falls well below the threshold to allege a relevant product market. Unlike other rulings in which proposed market definitions have been dismissed as implausibly narrow, see, e.g., Todd, 275 F.3d at 200 n. 3 (collecting cases), in this case, the plaintiff has not articulated how a single anti-heartburn drug has characteristics so unique that a consumer would not respond, or has not responded, to a slight price increase by purchasing a different product, see AD/SAT, 181 F.3d at 227. Further, the plaintiff's opposition memo appears to misapprehend the requirement to plead a relevant product market, and at times conflates allegations of product market with the related but distinct requirement that a plaintiff adequately plead market power. (Opp. Mem. at 5-8.)

To the extent that the plaintiff's opposition memo attempts to defend the

Complaint's market definition, it sets forth factual representations well beyond the four corners of the Complaint. "[A] party is not entitled to amend its complaint through statements made in motion papers." Wright v. Ernst & Young LLP, 152 F.3d 169, 178 (2d Cir. 1998).

Elsewhere, the plaintiff incorrectly characterizes a previous ruling by this Court in an unrelated case. It asserts that this Court has previously distinguished Prilosec products from other products used to treat gastrointestinal disorders. Yet in the cited portions of Mylan Pharmaceuticals, Inc. v. Procter & Gamble Co., 443 F. Supp. 2d 453, 455-56 (S.D.N.Y. 2006), this Court merely summarized representations made in Local Rule 56.1 Statements at the summary judgment stage. To conflate this Court's review of a summary judgment record in a Lanham Act case with an actual finding of fact relevant to the present monopolization claim reflects a deep misapprehension of a court's function at the summary judgment stage.

Plaintiff correctly notes that in Geneva Pharmaceuticals, 386 F.3d at 495-99, the Second Circuit concluded that the summary judgment record supported a narrow market definition consisting of only generic warfarin. That conclusion was anchored by a detailed analysis of consumer price sensitivities across various products, different consumer allegiances to various brands, products' distinct methods of distribution, and direct evidence going toward industry perception of the competitive field. See id. While a plaintiff's allegations at the pleading stage are likely to be far less thorough than a record available at summary judgment, the plaintiff has not alleged facts supporting its narrow product definition.

For the foregoing reasons, I conclude that the Complaint fails to allege a

plausible product market consisting of Prilosec OTC, and the Complaint is dismissed.

II. THE COMPLAINT'S ALLEGATIONS AS TO KBI INC. AND KBI-E INC. FAIL TO SATISFY RULE 8(a), FED. R. CIV. P.

Separately, defendants KBI, Inc. ("KBI") and KBI-E Inc. ("KBI-E") have moved to dismiss the Complaint on grounds that it fails to delineate which conduct is alleged to be attributed to them. The Complaint alleges that KBI and KBI-E "have exclusive rights" to patents owned by AstraZeneca AB, and that they participated in litigation seeking to enforce those patents. (Compl. ¶¶ 13-14.) As shorthand, the Complaint defines the phrase "AZ" to encompass defendants AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, KBI and KBI-E. (Compl. Intr.)

Rule 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." If a complaint is "so confused, ambiguous, vague, or otherwise unintelligible that its true substance, if any, is well disguised," it should be dismissed. Salahuddin v. Cuomo, 861 F.2d 40, 42 (2d Cir. 1988). A complaint should offer "specification" as to the "particular activities by any particular defendant . . . ." In re Elevator Antitrust Litig., 502 F.3d 47, 50 (2d Cir. 2007). Then-District Judge Chin has observed that Rule 8(a) "requires that a complaint against multiple defendants indicate clearly the defendants against which relief is sought and the basis upon which relief is sought against the particular defendants." Martin v. City of N.Y., 2008 WL 1826483, at *1 (S.D.N.Y. Apr. 23, 2008) (quotation marks omitted).

The Complaint's allegations as to the KBI entities are not coherent. The Complaint identifies each of them individually. (Compl. ¶¶ 13-14.) It asserts that they held rights to patents owned by AstraZeneca AB and entered into agreements with Proctor & Gamble to promote Prilosec OTC. (Compl. ¶ 36.) The Complaint otherwise lumps the KBI

entities in with all other non-Procter & Gamble defendants by broadly using the abbreviation "AZ." For instance, the Complaint asserts that "AZ" exercised sole control over manufacturing, volume and sales price. (Compl. ¶ 37.) It asserts that "AZ" conducted new studies in hopes of obtaining market exclusivity. (Compl. ¶¶ 43, 47.) "AZ" is alleged to own the trademark for Prilosec and to hold marketing approval for Prilosec OTC. (Compl. ¶¶ 38, 49.) An annual report issued by "AZ" in 2009 is alleged to reflect control over Prilosec OTC. (Compl. ¶39.)

While the Complaint is premised in part on a "joint venture or conspiracy" between all defendants (Compl. ¶ 38), the Complaint's lack of clarity in attributing conduct traceable to the KBI entities is a basis for dismissal of claims against them. A defendant is entitled to know, at the very least, what allegedly unlawful conduct a plaintiff seeks to attribute to it. As to the KBI entities, the Complaint fails to comport with the basic standards of notice pleading.

III. PLAINTIFF MAY MOVE TO AMEND ITS COMPLAINT.

At the conclusion of its opposition memorandum, the plaintiff requests that, in the event that the court grants the motion to dismiss, it be granted leave to replead. Rule 15(a)(2), Fed. R. Civ. P., provides that "[t]he court should freely give leave [to amend] when justice so requires." The standard, although liberal, allows motions for leave to amend to be denied where the court finds "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . futility of amendment, etc." See Foman v. Davis, 371 U.S. 178, 182 (1962).

The plaintiff has not previously amended its complaint, and the abundant flaws in the current pleading were not previously explored by the Court in a pre-motion conference. (Docket # 42 (waiving pre-motion conference requirement).) The plaintiff may move to amend its complaint to adequately allege all elements of a monopolization claim. Plaintiff may file its motion to amend (annexing the proposed pleading) no later than May 20, 2011; defendants may respond by June 20, 2011; and plaintiffs may reply by July 8, 2011. If no such motion is filed by May 20, 2011, the Clerk is directed to enter judgment for the defendants.

CONCLUSION

The motion to dismiss is GRANTED. The Clerk is directed to terminate the pending motions. (Docket # 45, 49.)

SO ORDERED.

P. Kevin Castel
United States District Judge

Dated: New York, New York
April 14, 2011