IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

APOTEX, INC. AND APOTEX CORP., Plaintiffs,	)	
v.	)	Civ. No. 12-196-SLR
SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD.) AND ALLERGAN, INC., Defendants,	)	

MEMORANDUM

At Wilmington this 1st day of May, 2015, having reviewed defendants' motion to dismiss the amended complaint for failure to state a claim (D.I. 37), and the papers filed in connection therewith; the court issues its decision based on the following reasoning:

1. **Background.** On February 16, 2012, plaintiffs Apotex, Inc. and Apotex Corp. (collectively, "plaintiffs") filed a complaint alleging certain antitrust violations concerning defendants Senju Pharmaceutical Co., Ltd. ("Senju"), Kyorin Pharmaceutical Co., Ltd. ("Kyorin"), and Allergan, Inc.'s ("Allergan) (collectively "defendants") aqueous liquid gatifloxacin ophthalmic products, Zymar and Zymaxid. (D.I. 1) Specifically, plaintiffs alleged that defendants (1) monopolized in violation of Section 2 of the Sherman Act; (2) conspired to monopolize in violation of Section 2 of the Sherman Act; and (3) contracted, combined, or conspired to restrain trade in violation of Section 1 of the Sherman Act. (*Id.*). On May 24, 2012, defendants filed a motion to dismiss and also moved to stay the action pending the resolution of the appeal involving the re-examined

'045 patent by the United States Court of Appeals for the Federal Circuit.[1] (D.I. 14; D.I. 17) On February 7, 2013, the court stayed the present action pending resolution of the appeal. (D.I. 32) On March 31, 2014, the Federal Circuit issued its ruling affirming the court's dismissal of the patent infringement action. *Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344 (Fed. Cir. 2014) (O'Malley, J., dissenting). On August 18, 2014, plaintiffs filed an amended complaint, asserting the same three causes of action as in the original complaint. (D.I. 36) The court has jurisdiction pursuant to U.S.C §§ 1331 and 1337(a) and 15 USC § 15.

2. **Standard.** A motion filed under Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of a complaint's factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). A complaint must contain "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." *Twombly*, 550 U.S. at 545 (internal quotation marks omitted) (interpreting Fed. R. Civ. P. 8(a)). Consistent with the Supreme Court's rulings in *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Third Circuit requires a two-part analysis when reviewing a Rule 12(b)(6) motion. *Edwards v. A.H. Cornell & Son, Inc.*, 610 F.3d 217, 219 (3d Cir. 2010); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, a court should separate the factual and legal elements of a claim, accepting the facts and disregarding the legal conclusions. *Fowler*, 578 F.3d. at 210-11. Second, a court should determine whether the remaining well-pled facts sufficiently show that the plaintiff "has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Iqbal*, 556

[1] *Senju Pharm. Co. v. Apotex Inc.*, Civ. No. 11-1171 (D. Del.).

U.S. at 679). As part of the analysis, a court must accept all well-pleaded factual allegations in the complaint as true, and view them in the light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002); *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). In this regard, a court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384-85 n.2 (3d Cir. 1994).

3. The court's determination is not whether the non-moving party "will ultimately prevail" but whether that party is "entitled to offer evidence to support the claims." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). 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 element]." *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64.

4. **Analysis.** Liability under § 2 of the Sherman Act

> requires "(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." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). Monopoly power is the ability to control prices and exclude competition in a given market. *Id.* at 571. If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power. *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 380 (3d Cir. 2005).

Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 306-07 (3d Cir. 2007). Defining the scope of the market is a question of fact on which plaintiff has the burden of proof. *Id.* at 307 (citing *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997); *Weiss v. York Hosp.*, 745 F.2d 786, 825 (3d Cir. 1984)). "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." *Brown Shoe Co. v. U.S.*, 370 U.S. 294, 325 (1962). "Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that 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 may be granted." *Queen City Pizza,* 124 F.3d at 436 (citations omitted).

5. Plaintiffs define the relevant market in their amended complaint as "the market for gatifloxacin ophthalmic solution, which includes Zymar®, Zymaxid®, and generic equivalents thereof." (D.I. 36 at ¶ 92) In support of this market definition, the amended complaint alleges that "[g]atifloxacin ophthalmic solution is not reasonably interchangeable with other ophthalmic solution products that treat bacterial infections of the eye [because] . . . gatifloxacin has specific antibacterial properties that provide for a unique spectrum of treatment that differs from other ophthalmic solution antibiotic products, including other ophthalmic solution quinolone products." (*Id.* at ¶ 96) "Gatifloxacin ophthalmic solutions are the only approved quinolone antibiotic ophthalmic solutions that contain the preservatives and permeability enhancers disodium edetate and benzalkonium chloride . . . ." (*Id.* at ¶ 97) Allergan switched consumers from

Zymar to Zymaxid without losing sales, despite the price increase. These "non-transitory price increases establish that the gatifloxacin ophthalmic solution market was inelastic before the introduction of any therapeutic equivalents and thus other antibiotic ophthalmic solution products were not reasonably interchangeable with gatifloxacin." (*Id.* at ¶¶ 99-100)

6. Defendants point out that a search of the FDA's website reveals multiple products (other than Zymar and Zymaxid) that treat bacterial infections of the eye. (D.I. 38 at 15) Construing the allegations in plaintiffs' amended complaint in the light most favorable to plaintiffs, the court concludes that plaintiffs have alleged a plausible relevant market and offered some explanation as to why the market should be limited, sufficient to pass muster at the motion to dismiss stage. That is, in the case at bar, as "in most cases, proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers." *Queen City Pizza, Inc.*, 124 F.3d at 436. "Reasonable interchangeability of use" of a product used to treat a bacterial infection of the eye is a factual issue, not properly addressed by the court at this juncture. *See, e.g., Knoll Pharms. Co., Inc. v. Teva Pharms. USA, Inc.*, Civ. No. 01 C 1646, 2001 WL 1001117, at *4 (N.D. Ill. Aug. 24, 2001) (denying motion to dismiss where counterclaims limited relevant product market to hydrocodone bitartrate/ibuprofen and finding that the "allegations are sufficient at the pleading stage" and "[w]hether or not the alleged market is in fact the relevant one ... is a matter for proof and not pleading."); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680-81 (E.D. Mich. 2000) (denying a motion to dismiss and finding that plaintiffs "have adequately pled a relevant market with regard to their antitrust claims. The determination whether there

are additional products that are 'reasonably' interchangeable with Cardizem CD involves questions of fact not properly addressed in a Rule 12(b)(6) motion to dismiss.").

7. **Conclusion.** For the aforementioned reasons, defendants' motion to dismiss (D.I. 37) is denied. An order shall issue.

United States District Judge

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KYORIN PHARMACEUTICAL CO., LTD.	)	
AND ALLERGAN, INC.,	)	
	)	
Defendants,	)	
	)	

ORDER

At Wilmington this 1st day of May 2015, consistent with the memorandum issued this same date;

IT IS ORDERED that defendants' motion to dismiss (D.I. 37) is denied.

United States District Judge