IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DELCOR ASSET CORPORATION and MYLAN PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-1653-RGA
GLENMARK PHARMACEUTICALS LIMITED, GLENMARK PHARMACEUTICALS INC., USA and STIEFEL WEST COAST, LLC,	)	
Defendants.	)	

GLENMARK'S OPPOSITION
TO MYLAN'S MOTION TO DISMISS GLENMARK'S THIRD COUNTERCLAIM

HEYMAN ENERIO
GATTUSO & HIRZEL LLP
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

Attorneys for Defendants Glenmark Pharmaceuticals Limited, and Glenmark Pharmaceuticals Inc., USA

OF COUNSEL:

Maureen L. Rurka
Kathleen B. Barry
Claire A. Fundakowski
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
Ph: (312) 558-5600
Fax: (312) 558-5700
mrurka@winston.com
kbarry@winston.com
cfundakowski@winston.com

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INTRODUCTION

Mylan[1] instituted this suit against Glenmark knowing that there was no basis to assert Glenmark infringed the two patents at issue. Both patents require that Glenmark's ANDA Product contain a base. Glenmark's ANDA Product does not contain a base, nor anything that acts like a base. Glenmark has repeatedly explained this to Mylan. Glenmark went out of its way to provide its ANDA to Mylan early—before suit was filed—so Mylan could see this fact for itself, and to obviate the need for this suit. Mylan chose to file suit anyway. Glenmark's Third Counterclaim alleges that by doing so, Mylan has violated antitrust law. Now Mylan seeks to avoid liability for its actions. But as detailed in Glenmark's Third Counterclaim, Mylan's lawsuit against Glenmark should not have been filed and was done only to take advantage of the automatic 30-month stay that is part of the Hatch-Waxman process.

In the face of these facts, Mylan's motivation for filing this lawsuit must be questioned. Without a basis for asserting infringement, the only plausible reason for filing this suit would be to invoke the Hatch-Waxman Act's automatic 30-month stay for FDA approval of Glenmark's ANDA. Wanting to initiate the 30-month stay to keep a competitor off the market is not a proper basis for filing a lawsuit; it is an improper exercise of Mylan's market power in violation of the antitrust laws. In response, Glenmark counterclaimed alleging monopolization and attempted monopolization under § 2 of the Sherman Act.

Even after Glenmark counterclaimed for monopolization and attempted monopolization, Mylan still has not explained its basis for infringement despite Glenmark's requests.[2] Mylan's

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[1] For purposes of this brief, Mylan Pharmaceuticals Inc. ("MPI") and its subsidiary Delcor Asset Corporation ("Delcor") will be referred to collectively as "Mylan."

[2] In separate correspondence, Mylan has taken the position that it is not obligated to provide its positions on infringement until the infringement contentions. *See* February 9, 2018 Correspondence between Kathleen B. Barry and Derek S. Neilson (attached as Exhibit A). Mylan

refusal to provide any colorable basis for bringing suit in face of Glenmark's clearly non-infringing ANDA Product makes this case remarkably different from the typical ANDA case.

Rather than explain its basis for filing suit, Mylan responded by moving to dismiss the antitrust counterclaim. Tellingly, the focus of Mylan's motion is not to challenge Glenmark's allegations that Mylan initiated this suit fully aware that Glenmark's ANDA Product will not infringe any claim of U.S. Patent Nos. 7,141,237 ("the '237 patent") and 7,374,747 ("the '747 patent"). Glenmark's Counterclaim (D.I. 12) ¶¶ 23−28, 54. Mylan's motion also does not dispute that, by initiating this lawsuit, Mylan delayed Glenmark's entry into the market. *Id.* ¶¶ 20, 38−42, 55. Mylan's motion does not dispute that by excluding Glenmark from the topical clindamycin foam market, Mylan has intentionally minimized competition and maintained prices above those that would flow from Glenmark's market entry. *Id.* ¶¶ 55−56, 63.

Instead, Mylan dedicates nearly its entire brief to challenging Glenmark's *market definition*, an issue of fact that is fully supported by the pleadings, and which must be accepted as true at the pleadings stage. Mylan's scant remaining arguments challenge Glenmark's allegations with respect to monopoly power. Mylan, however, does not address Glenmark's direct evidence that Mylan engaged in clear and substantial anticompetitive activity to exclude Glenmark from the alleged market for topical clindamycin foam. Mylan's arguments as to the market definition are simply an effort to distract from its anticompetitive conduct.

Glenmark's Third Counterclaim sufficiently alleges that Mylan violated § 2 of the Sherman Act. Glenmark respectfully requests this Court deny Mylan's partial motion to dismiss.

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has provided no substantive basis for why Glenmark's ANDA Product uses a base, despite having to have a good faith basis to believe so to satisfy Rule 11 and justify the filing of its Complaint.

STATEMENT OF FACTS

MPI is the holder of NDA No. 050801, which covers Evoclin®, a clindamycin foam product sold in the United States indicated for treatment of acne vulgaris in patients 12 years and older. *Id.* ¶¶ 30−32. MPI listed the '237 and '747 patents in the Orange Book in connection with NDA No. 050801. *Id.* ¶ 34. Stiefel West Coast, LLC ("Stiefel") owns the '237 and '747 patents, and Delcor purports to be an "exclusive licensee" of the '237 and '747 patents.[3] *Id.* ¶¶ 22, 29.

Glenmark submitted an ANDA to the FDA to market a generic version of Evoclin® and notified MPI and Stiefel that Glenmark's ANDA Product does not contain a "base," a limitation required by every claim of the '237 and '747 patents. *Id.* ¶¶ 26−28, 36−39. Glenmark also sent its ANDA to MPI and Delcor so they could confirm Glenmark's representation. Despite receipt of Glenmark's express evidence to the contrary, Mylan filed the present action asserting infringement, thereby triggering a 30-month stay on the approval of Glenmark's ANDA Product. *Id.* ¶¶ 20, 42; Glenmark's Answer (D.I. 12) ¶ 39.

Mylan's infringement action is both objectively and subjectively baseless and, for purposes of this motion, undisputedly motivated by anticompetitive intent. Accordingly, Glenmark filed its Third Counterclaim alleging monopolization and attempted monopolization under § 2 of the

[3] Ordinarily, an "exclusive licensee" indicates that the patentee has promised "to refrain from granting to anyone else a license in the area of exclusivity." *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998). Despite Delcor's claim to be an "exclusive licensee," the record is at best ambiguous as to whether patent owner Stiefel has promised not to license to anyone other than Delcor. Stiefel has admitted that Perrigo, too, has a license to the '237 and '747 patents, and admitted only that Delcor "claims" to be the exclusive licensee of the '237 and '747 patents. Stiefel Answer to Crossclaims (D.I. 26) ¶¶ 29, 33. Mylan denied Glenmark's pleading that "Perrigo has a license to the '237 and '747 patents," claiming that such an allegation was "vague and ambiguous" and "may implicate the disclosure of confidential information." Mylan's Answer (D.I. 30) ¶ 33. Mylan's Complaint does not allege that MPI is a licensee at all. *See* Mylan's Complaint (D.I. 1) ¶ 20. It is thus unclear whether Mylan even has standing to sue Glenmark for infringement of the '237 and '747 patents.

Sherman Act. Glenmark's Counterclaim (D.I. 12) ¶¶ 54, 57, 58. Mylan subsequently moved to dismiss Glenmark's Third Counterclaim alleging failure to state a claim. *See* Mylan's Motion to Dismiss (D.I. 28).

LEGAL STANDARD

When assessing the sufficiency of a claim on a motion to dismiss, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (alterations and citation omitted). Rule 8(a)(2) requires "only 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) (alterations and citation omitted). To satisfy this standard, a claim for relief "does not need detailed factual allegations," but must include factual allegations sufficient "to raise a right to relief above the speculative level." *Id.* Dismissal is inappropriate where, drawing all reasonable inferences in favor of the non-movant, the allegations allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

ARGUMENT

Glenmark's Third Counterclaim states a claim for monopolization and attempted monopolization under § 2 of the Sherman Act. To state a claim for monopolization, a party must allege: "(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). A claim for attempted monopolization requires "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific

intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Accepting Glenmark's factual allegations as true and drawing all reasonable inferences in Glenmark's favor, Glenmark's Third Counterclaim demonstrates that Mylan violated § 2 of the Sherman Act.

I. GLENMARK'S THIRD COUNTERCLAIM PLAUSIBLY ALLEGES MONOPOLY POWER

Mylan claims that Glenmark's Third Counterclaim inadequately alleges monopoly power through (1) "conclusory assertions, entirely devoid of factual support," Mylan's Opening Brief (D.I. 29) at 13, that do not provide the requisite specificity; (2) lack of "facts concerning Mylan's share of the relevant market;" and (3) a lack of factual allegations regarding Mylan's ability to raise prices. *Id.* Mylan's arguments miss the mark. The case law permits Glenmark to demonstrate monopoly power through direct evidence of detrimental effects on competition in a relevant market. The pleadings sufficiently demonstrate a plausible claim that Mylan possesses monopoly power in the relevant market for topical clindamycin foam.

Monopoly power is "the power to control prices or exclude competition." *Grinnell*, 384 U.S. at 571. Monopoly power "can be proven directly through evidence of control over prices or the exclusion of competition, or it may be inferred from a firm's large percentage share of the relevant market." *Geneva Pharm. Tech. Corp. v. Barr Labs Inc.*, 386 F.3d 485, 500 (2d Cir. 2004); *Re/Max Int'l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999) (same). Mylan demands allegations regarding its share of the relevant market, but "[m]arket share is just a way of estimating market power, which is the ultimate consideration. When there are better ways to estimate market power, the court should use them." *Allen-Myland v. IBM Corp.*, 33 F.3d 194, 209 (3d Cir. 1994) (citation omitted). "[P]roof of actual detrimental effects [on competition] . . . can obviate the need for an inquiry into market power, which is but a surrogate for detrimental

effects." *F.T.C. v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460−61 (1986) (alteration and citation omitted)).

In this case, Glenmark's factual allegations detail how Mylan engaged in anticompetitive conduct to exclude Glenmark from the relevant market for topical clindamycin foam and maintain prices that the counterclaims allege are supracompetitive. This is direct evidence of detrimental effects on competition. This satisfies Glenmark's pleading obligation to plausibly allege monopoly power.

Evidence of Mylan's anticompetitive conduct is clearly set forth in Glenmark's counterclaims. Every claim of the '237 and '747 patents requires a "base." Glenmark's Counterclaim (D.I. 12) ¶¶ 23−28, 54. The patent applicant added the "base" limitation during prosecution to overcome a final rejection, in which the patent applicant argued, *inter alia*, "with the addition of a base, the composition is unexpectedly stable and efficacious." *Id.* ¶ 23 (quoting April 27, 2006 Reply to Office Action at 12). The '237 and '747 patent specifications define "base" as "bicarbonates, carbonates, and hydroxides such as alkali or alkaline earth metal hydroxide as well as transition metal hydroxides." *Id.* ¶ 24 (quoting '237 patent at col. 6 ll. 56−60; '747 patent at col. 6 ll. 56−60). The patent applicant likewise advocated for an identical definition of "base" during prosecution. *Id.*

Mylan was on notice that Glenmark's ANDA Product does not contain a base. On September 29, 2017, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Glenmark sent MPI and Stiefel a Notice Letter, which specifically articulated "that none of the ingredients in Glenmark's ANDA Product is a 'base' or an equivalent of a 'base' as used in the intrinsic record." *Id.* ¶¶ 27, 38, 39. Glenmark further produced its ANDA, which provided Mylan with "the opportunity to confirm that Glenmark's ANDA Product did not infringe." *Id.* ¶ 41. The reason

Glenmark does not infringe is simple: "Glenmark's ANDA Product only contains ingredients that could objectively correspond to claim limitations other than the 'base' limitation." *Id.* ¶¶ 27, 28. The allegations in ¶ 28 are exemplified by the following claim chart:

'237 and '747 Patent Claim Limitations	**Glenmark's ANDA Product**
Clindamycin	Clindamycin
a C_1–C_6 alcohol	a C_2 alcohol, ethanol
a C_{14}–C_{22} alcohol	a C_{16} alcohol, cetyl alcohol a C_{18} alcohol, stearyl alcohol
Water	purified water
a surfactant	a surfactant, polysorbate 60
an aerosol propellant	an aerosol propellant, propane/butane/isobutane
a base	—
an emollient[4]	an emollient, propylene glycol

It is settled law that "[u]nder the "all elements" rule, to find infringement, the accused device must contain 'each limitation of the claim, either literally or by an equivalent.'" *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1379 (Fed. Cir. 2008). Because Glenmark's ANDA Product does not contain a base, Glenmark does not infringe any claim of the '237 and '747 patents.

Mylan nonetheless initiated this suit, alleging Glenmark infringes one or more unspecified claims of the '237 and '747 patents. Mylan has had multiple opportunities to explain its theory of infringement as to Glenmark's ANDA Product and what ingredient in Glenmark's ANDA Product is a "base." The ideal time to do so would have been in its complaint, but in a throw-back to the minimal pleading requirements outlined in abrogated Form 18, Mylan's complaint cursorily alleges

[4] While the first seven limitations are present in each claim of the '237 and '747 patents, an emollient is claimed in dependent claims of the '237 and '747 patent. *Id.* ¶ 28; *see also* '237 patent claim 10 ("The composition of claim 1, *further comprising* an emollient."), '747 patent claim 17 ("The method of claim 1, *further comprising* an emollient.") (emphases added).

that the submission of Glenmark's ANDA "constitutes infringement of one or more claims" of the '237 and '747 patents, "including without limitation claim 1."[5] Mylan's Complaint (D.I. 1) ¶¶ 41, 59. Mylan provides no factual basis for its allegations of infringement. *Id.* Mylan could have also explained its theory of infringement at the scheduling conference, when Glenmark expressly informed the Court that Mylan had failed to provide any explanation of what constitutes a base in Glenmark's ANDA Product. *See* Rule 16 Scheduling Conference Transcript, at 8:18−25 (Feb. 13, 2018) (attached as Exhibit B). Mylan declined to do so. It could have done so in response to multiple email requests from Glenmark. *See* Exhibit A. Again, Mylan declined to do so.

Mylan's motivation for filing suit can be explained by the framework of the Hatch-Waxman Act. If a patent holder files suit within 45 days of receiving an ANDA applicant's notice letter, "[t]he patent holder's filing of an infringement suit against the generic manufacturer triggers a 30-month period, beginning on the date of the patent holder's receipt . . . in which the FDA will not approve the ANDA." Glenmark's Counterclaim (D.I. 12) ¶ 27. Mylan, a repeat player on the generics' side of ANDA litigation, knows well the consequences of filing an action for patent infringement against an ANDA. Mylan filed this infringement suit on November 15, 2017. *Id.* ¶ 42. Glenmark alleges that Mylan "engaged in the predatory and anticompetitive acts described herein, with the specific intent to trigger the 30-month period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) to delay the entry of Glenmark's ANDA Product." *Id.* ¶ 59. Glenmark further alleges that as a result of Mylan's sham litigation, "Glenmark is being forced to expend unjustified costs, including the costs of its legal defense." *Id.* ¶ 62.

[5] While Mylan acknowledges that the claims require a base when discussing the '237 and '747 patents, its infringement allegations are silent as how Glenmark's ANDA Product infringes that limitation. *Compare* Mylan's Complaint (D.I. 1) ¶¶ 15, 17, *with* ¶¶ 23−75. Glenmark reserves the right to move to dismiss Mylan's complaint for failure to state a claim.

The instant sham litigation has not only harmed Glenmark, it has also harmed consumers. Glenmark's Third Counterclaim sufficiently alleges that Mylan has delayed Glenmark's entry into the market for its own benefit, and at the detriment to consumers. Glenmark alleges that "consumers of the relevant product have or will be harmed by the reduction in competition and increase of prices if Plaintiffs are permitted to prevent the planned entry of Glenmark's ANDA Product." *Id.* ¶ 63. Specifically, "but for Plaintiffs' predatory and anticompetitive acts, entry of Glenmark's ANDA Product would reduce prices in the relevant market and directly benefit consumers." *Id.* ¶ 56. These allegations are plausible, and indeed are consistent with the very purpose of the Hatch-Waxman Act. As explained by Representative Waxman, "the ultimate goal of [the Hatch-Waxman Act] was to provide low-cost, generic drugs for millions of Americans" and provide "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984); *see also F.T.C. v. Actavis*, 570 U.S. 136, 142 (2013) ("The Hatch–Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition." (alterations and citation omitted)). By preventing entry of Glenmark's lower-priced alternative, Mylan has "maintained pricing for the Evoclin® product that exceeds competitive levels." Glenmark's Counterclaim (D.I. 12) ¶ 55. Again, Mylan's motion does not dispute that the entry of Glenmark's ANDA Product will lead to lower prices of clindamycin foam products, nor do they dispute that prices for Evoclin® would fall upon Glenmark's entry. *See* Mylan's Opening Brief at 13 (referencing pricing only when arguing that Glenmark does not allege that "Plaintiffs have an unrestricted ability to raise prices without fear of losing sales"). And, any attempt to do so at the motion to dismiss stage would be improper.

Thus, Glenmark's Third Counterclaim plausibly alleges—and Mylan's subsequent conduct supports—that Mylan has gamed the Hatch-Waxman system by initiating the instant sham

litigation, that Mylan has delayed Glenmark's entry into the alleged relevant market, and that Mylan has subsequently forced consumers to pay more for drug products than they would but for Mylan's anticompetitive conduct. These allegations are more than sufficient to demonstrate the potential for genuine adverse effects on competition. *See, e.g., Actavis*, 570 U.S. at 153−54 (holding that Plaintiffs sufficiently alleged that delaying the entry of generic competitors of AndroGel had the "potential for genuine adverse effects on competition," by potentially prolonging the patentee's "exclusive right to sell its product"); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003) (explaining that when a potential generic competitor is excluded from the relevant market in the Hatch-Waxman context, "the anticompetitive effects of exclusion cannot be seriously debated"). Because Glenmark's allegations show Mylan's predatory and anticompetitive conduct has caused actual detrimental effects to both Glenmark and consumers, Glenmark has satisfied its burden of pleading monopoly power. *See, e.g., Fineman v. Armstrong World Indus.*, 980 F.2d 171, 202 (3d Cir. 1992) (explaining "proof of actual detrimental effects" is stand-alone proof of monopoly power); *Meijer, Inc. v. Ranbaxy, Inc.*, No. 15-cv-11828, 2016 WL 4697331, at *15 (D. Mass. Sept. 7, 2016) (holding that where Plaintiffs pled "actual detrimental effects on the market and financial harm to consumers, Plaintiffs have successfully pled that Defendants wielded monopoly power"); *Cf. Indiana Fed'n of Dentists*, 476 U.S. at 461 ("market power . . . is but a 'surrogate for detrimental effects'") (citation omitted).

Glenmark also plausibly alleges market power through circumstantial evidence. Glenmark alleges that MPI and Perrigo are the "only two companies that market topical clindamycin foam in the United States." Glenmark's Counterclaim (D.I. 12) ¶ 32. Delcor purports to be the exclusive licensee of the '237 and '747 patents, *id.* ¶ 29, and Glenmark alleges that "Perrigo has a license to

the '237 and '747 patents and pays a royalty for use of the '237 and '747 patents." *Id.* ¶ 33. Mylan's power to set the price of clindamycin foam products is thus limited only by one competitor who, taking these allegations together, pays Mylan a royalty in order to market a topical clindamycin foam product. These allegations are sufficient to support a plausible inference that Mylan possesses monopoly power in the relevant market. For this reason too, Glenmark's Third Counterclaim adequately alleges monopoly power.

II. GLENMARK'S THIRD COUNTERCLAIM PLAUSIBLY ALLEGES THE RELEVANT MARKET

Mylan challenges Glenmark's market definition as failing to plausibly encompass all interchangeable substitute products. Mylan's Opening Brief (D.I. 29) at 6−13. Mylan's argument is critically flawed for two reasons. First, Mylan fails to recognize that the scope of the relevant market is a question of *fact*. At the pleadings stage, this Court must accept Glenmark's factual allegations as true and draw all reasonable inferences in Glenmark's favor. Second, Glenmark has sufficiently pled facts to establish that clindamycin foam for the treatment of acne is not reasonably substitutable in the minds of those making purchasing decisions with respect to those products. Thus, Glenmark has sufficiently alleged a viable relevant product market at this stage of the case, and Mylan's motion should be denied.

A. Mylan's Arguments Fail to Recognize that the Relevant Market is an Issue of Fact

Courts have long held that "a pronouncement as to market definition is not one of law, but of fact." *Columbia Metal Culvert Co. v. Kaiser Aluminum & Chemical Corp.*, 579 F.2d 20, 28 (3d Cir. 1978); *Hayden Pub. Co. v. Cox Broad. Corp.*, 730 F.2d 64, 70 n.8 (2d Cir.1984) (same). "Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one." *Brown Shoe Co. v. United States*, 370 U.S. 294, 336 (1962). "Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to

dismiss for failure to plead a relevant product market." *Todd v. Exxon Corp.*, 275 F.3d 191, 199−200 (2d Cir. 2001) (Sotomayor, J.); *E.I. u Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 443 (4th Cir. 2011) (same); *Double D Spotting Serv., Inc. v. Supervalu, Inc.*, 136 F.3d 554, 560 (8th Cir. 1998) (noting that "courts are hesitant to dismiss antitrust actions before the parties have had an opportunity for discovery"). Thus, the question of whether the boundaries of the relevant market are properly set is a highly fact-bound inquiry that requires an analysis of the demand conditions for specific products and is best performed with the benefit of a full discovery record. For this reason alone, regardless of Mylan's reasons for disagreeing with Glenmark's market definition, resolution at the pleadings stage is inappropriate.

Mylan ignores the fact-intensive nature of the relevant market question and instead cites a string of cases that are inapposite here. To argue Glenmark's market definition is implausible, Mylan analogizes cases rejecting proposed market definitions regarding products entirely distinguishable from the products comprising Glenmark's alleged relevant market. *See generally* Mylan's Opening Brief (D.I. 29) at 6−12. Mylan has not shown that the types of facts needed to plausibly allege a "market for treatment with topical clindamycin foam," Glenmark's Counterclaim (D.I. 12) ¶ 53, are necessarily the same as the facts needed to plausibly allege a market for "ingredients, supplies, materials, and distribution services used by and in the operation of Domino's pizza stores," *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997), a market defined as "a specific type of heavy construction equipment," Mylan's Opening Brief (D.I. 29) at 7−8 (citing *Int'l Constr. Prod. LLC v. Caterpillar Inc.*, No. 15-108-RGA, 2016 WL 264909, at *8 (D. Del. Jan. 21, 2016)), or a market limited to "TWA airline tickets for travel between cities," *id.* at 11 (quoting *Glob. Disc. Travel Servs., LLC v. Trans World Airlines, Inc.*, 960 F. Supp. 701, 706 (S.D.N.Y. 1997)). Opinions assessing markets related to

pizza stores, heavy construction equipment, and airline tickets—and further, very narrowly defined markets in those industries—simply have no bearing on the proprietary of Glenmark's proposed market of topical clindamycin foam, particularly at the pleadings stage of this case.

Even in the pharmaceutical context, Mylan ignores the fact that market definition is a highly fact intensive question unsuitable for resolution on the pleadings. Mylan cites examples of ANDA cases where proposed market definitions were held implausible and then asserts that "topical antibiotic acne treatments—like topical clindamycin foam—are no different than contraceptives or heartburn medications." Mylan's Opening Brief (D.I. 29) at 12. The facts may or may not ultimately bear that out. But that is the point—whether Mylan is right or wrong is a factual question, not a legal one. The extent to which topical antibiotic acne treatments are substitutable is factual. Mylan says the substitutability is broad; Glenmark says it is narrow in this context. Who is right can only be determined after assessment of the full record, not Mylan's ipse dixit. This is especially so as to whether acne treatments are different than contraceptives or heartburn medications. Mylan's argument, thus, is not a legal one, but rather a factual one that is plainly unsuitable for a motion to dismiss. Furthermore, Mylan makes no attempt to explain how the demand conditions for orally administered drugs used to systemically treat various conditions translates to the fact-specific demand conditions for acne medication topically applied to one's skin.

At the motion to dismiss stage, Glenmark need only plead that its market definition is *plausible*, not probable. *See Iqbal*, 556 U.S. at 678 ("The plausibility standard is not akin to a probability requirement[.]" (alterations and quotation omitted)). The distinction between plausibility and probability is readily apparent from the case *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited*, discussed on page 12 of Mylan's opening brief. In that case,

Mylan, who was asserting a monopolization claim, argued that the relevant product market was a "single-product market: branded and generic Doryx." *Mylan*, No. 12-cv-3824, 2015 WL 1736957, at *8 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421, 436 (3d Cir. 2016). At the pleadings stage, the party moving to dismiss Mylan's monopolization claim argued that Mylan's market definition was "implausible," overly narrow, and failed to "explain the[] rationale for limiting the relevant product market to this subset of a single molecule." Brief of Defendants at 47, 50, *Mylan*, No. 12-cv-3824 (E.D. Pa. Oct. 1, 2012), D.I. 84. The district court denied Defendants' motion to dismiss and deferred consideration of this inherently factual issue for summary judgment. *See Mylan*, 2015 WL 1736957, at *6 (citing D.I. 280). Although Mylan's proposed market was ultimately rejected, that ruling was *only* at the summary judgment stage, after considering the parties' extensive factual evidence and competing testimony from the parties' experts. *Id.* at *8−11. Thus, at the motion to dismiss stage, Mylan's own prior case supports that any decision on the fact intensive question of market definition should be deferred until after fact discovery.

B. Glenmark's Proposed Relevant Market Is Fully Supported by the Pleadings

Mylan also complains that Glenmark's Third Counterclaim does not address reasonable interchangeability by failing to allege "what topical clindamycin foam is, how it is used, or what makes it unique from comparable products." Mylan's Opening Brief (D.I. 29) at 7. Glenmark alleges that the relevant market is a "market for treatment with topical clindamycin foam," further alleges that clindamycin foam is indicated for the treatment of acne vulgaris, and provides facts describing the ***unique*** characteristics of topical clindamycin foam as compared to other treatments for acne. Glenmark's Counterclaim (D.I. 12) ¶¶ 31, 53; *see also, e.g.*, '237 patent col. 1 l. 40−col. 2 l. 3. Glenmark's allegations and the '237 and '747 patents provide Mylan with detailed factual support for Glenmark's market definition, and thus for this additional reason, the Court should deny Mylan's motion to dismiss. *See, e.g.*, *Twombly*, 550 U.S. at 555 (explaining that the purpose

of the pleading requirements is "to give the defendant fair notice of what the claim is and the grounds upon which it rests").

As a threshold matter, contrary to Mylan's allegations, Glenmark does not propose an implausibly narrow "single-product relevant market." *See* Mylan's Opening Brief (D.I. 29) at 10−13. Glenmark's market definition is comprised of an active ingredient, clindamycin, and a particular dosage form, topical foam. Glenmark's Counterclaim (D.I. 12) ¶ 53. As Mylan acknowledges, Glenmark specifically alleges that *two* companies market topical clindamycin foam in the United States—Mylan and Perrigo.[6] Mylan's Opening Brief (D.I. 29) at 13; Glenmark's Counterclaim (D.I. 12) ¶ 32. Mylan's product and Perrigo's product are ***not*** identical. Mylan's product contains a base, i.e. potassium hydroxide, and Perrigo's product does not contain a base. Because Glenmark has identified two "reasonably interchangeable" clindamycin foam products for the treatment of acne vulgaris, Glenmark has not pled a "single-product relevant market." Glenmark further alleges that its proposed ANDA Product would be part of the "relevant market," i.e. the market for the two products. *Id.* ¶ 55. Thus, Mylan is simply incorrect that Glenmark is pleading a "single-product relevant market."

Further, the plausibility of Glenmark's proposed relevant market is supported by the pleadings. The '237 and '747 patents—attached to Mylan's Complaint and the very subject of Mylan's litigation—thoroughly detail the uniqueness of topical clindamycin foam as compared to other treatments for acne. *See, e.g.*, '237 patent at col. 1 l. 40−col. 2 l. 3, col. 21 ll. 51−56, col. 27

[6] Curiously, although Mylan admits that MPI sells Evoclin® in the United States and that Perrigo sells topical clindamycin foam in the United States, Mylan denies Glenmark's allegations. Mylan's Answer (D.I. 30) ¶ 32. While certainly not clear from its answer or motion to dismiss, Mylan apparently disputes that MPI and Perrigo are the only companies selling topical clindamycin foam products in the United States. Here, again, it would be helpful for Mylan to explain its position on this issue. Given Mylan's reticence on the basis for its infringement allegations, Glenmark expects that it will only get information on this subject through discovery.

l. 62−col. 28 l. 2.[7] These details are sufficient to allow Glenmark's alleged relevant market to survive the pleadings stage. Glenmark's limitation of the market to topical clindamycin products is supported by the '237 and '747 patents' disclosure that due to undesirable side effects, "it is desirable to administer clindamycin topically." *Id.* at col. 1 ll. 34−37. While other forms of topical clindamycin products are available on the market—in the form of gels, lotions, and solutions, *id.* at col. 1 ll. 40−42—the '237 and '747 patents disclose that foam products offer advantages particularly relevant to the treatment of acne. "Lotion and gel topical dosage forms have the disadvantage of extended rub-in and may leave oily residues. The solution form readily runs off the site of application, and therefore it is difficult to apply controlled amounts using the solution form." *Id.* at col. 1 ll. 43−47. In contrast, foam is "non-runny, easy to apply, and uses a low residue vehicle." *Id.* at col. 1 ll. 51−52; *id.* at col. 24 ll. 33−36 ("In contrast to products currently available on the market, the Foam formulation provides for elegant, rapid, and non-staining drug delivery, leaving very little residue on the skin."). In addition, foam formulations "provide enhanced delivery of an active compound(s) across the skin compared to gel compositions, and without the concomitant disadvantages associated with solution formulations." *Id.* at col. 1 l. 65−col. 2 l. 3.

The '237 and '747 patents outline numerous studies comparing clindamycin foam to other topical products for acne. These studies repeatedly conclude that clindamycin foam is different in ways that fact discovery will likely show renders those other topical products not reasonably substitutable in the minds of those making purchasing decisions with respect to those products. For example, in Example 6, the '237 and '747 patents describe a clinical study comparing the

[7] As a divisional of the '237 patent, the '747 patent specification contains identical or similar disclosures as the '237 patent. For simplicity, Glenmark cites only to the '237 patent.

efficacy of topical clindamycin foam with topical clindamycin gel. *Id.* at col. 17 ll. 27−35. The study reports that the total number of acne lesions, number of inflammatory lesions, and number of non-inflammatory lesions were less when using topical clindamycin foam as compared to topical clindamycin gel. *Id.* at Table 6. The patents thus conclude that topical clindamycin foam "is significantly more effective than the clindamycin gel composition." *Id.* at col. 18 ll. 36−39. Studies in Example 7 of the '237 and '747 patents detail similar results. *Id.* at col. 18 l. 43−col. 22 l. 5. In Example 10, the '237 and '747 patents detail yet another study, and conclude topical clindamycin foam "is superior to a clindamycin gel formulation for enhanced delivery of clindamycin across the skin at a higher flux rate," and that unlike topical clindamycin solution, "does not readily run off the site of application, providing for the administration of a more controlled amount of clindamycin." *Id.* at col. 27 l. 62−col. 28 l. 2.

Drawing all reasonable inferences in Glenmark's favor and accepting its allegations as true, the above-described disclosures, among others in the '237 and '747 patents, are more than sufficient for the Court to reasonably infer that Glenmark's proposed market definition is plausible and thus cannot be rejected on the face of the pleadings. Therefore Mylan's motion to dismiss should be denied.

CONCLUSION

For the foregoing reasons, Glenmark's Third Counterclaim plausibly alleges that Mylan violated Section 2 of the Sherman Act. Glenmark respectfully requests this Court deny Mylan's partial motion to dismiss.

OF COUNSEL:

Maureen L. Rurka
Kathleen B. Barry
Claire A. Fundakowski
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
Ph: (312) 558-5600
Fax: (312) 558-5700
mrurka@winston.com
kbarry@winston.com
cfundakowski@winston.com

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

Attorneys for Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA

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