IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC.,	:	
Plaintiff,	:	
	:	
v.	:	**Civil Action No. 2:14-cv-02094-**
	:	**ES-MAH**
CELGENE CORPORATION,	:	
Defendant.	:	
	:	
	:	

PLAINTIFF MYLAN PHARMACEUTICALS INC.'S BRIEF IN OPPOSITION TO DEFENDANT CELGENE CORPORATION'S MOTION TO DISMISS

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INTRODUCTION

This case is not about the "dramatic risk" of Thalomid and Revlimid (Mot. at 1); it is about the "dramatic risk" to Celgene's bottom line if it faces lower-priced generic competition. Thalomid and Revlimid are Celgene's two "lead" products. It reaps as much as $170-310 per dose for Thalomid and $430 per dose for Revlimid. Compl. ¶ 2. While generic competition would provide substantial savings to the patients who need these drugs, it would substantially reduce Celgene's sales.

Realizing this fact, Celgene devised an anticompetitive scheme to wrongfully maintain its monopolies. Celgene's strategy was simple: prevent generic firms' access to the Thalomid and Revlimid samples they need to conduct the studies required for FDA approval, and thereby eliminate the possibility of lower-priced generic competition. First, it imposed distribution restrictions on wholesalers and pharmacies that prevented generic manufacturers from obtaining samples of the drugs through normal channels. Second, having made itself the sole source of potential samples, it refused to engage in good faith negotiations with generic firms, like Mylan, to provide access to these samples. While Celgene now attempts to invoke "safety" concerns to justify its conduct, its actions in making demands well beyond anything reasonably necessary to ensure patient safety show that Celgene's assertions are pretextual. Celgene's real interest is in preserving its monopoly profits at the expense of both competition and everyone who pays for these drugs.

Faced with Mylan's 380 paragraphs of detailed allegations, Celgene filed a motion to dismiss premised on faulty legal theories and an assortment of factual assertions unmoored from the Complaint and the documents incorporated by reference therein. Like the two previous federal judges—including Judge Hillman of this Court—that have held allegations virtually identical to Mylan's allegations here sufficient to state a claim, this Court should deny Celgene's motion.

Exclusionary Conduct. The heart of Celgene's motion is its attack on Mylan's monopolization claims under Section 2 of the Sherman Act. *See* Mot. at 14-23. Seeking to cast this case as one concerning the right of a company to choose unilaterally with whom it will deal, Celgene claims Mylan has failed to plead exclusionary conduct. But this case involves a combination of Celgene's unilateral refusal to deal *and* its anticompetitive restrictions on resellers that foreclose generic competitors from obtaining the samples they need to conduct bioequivalence studies and enter the market. Celgene's argument thus mischaracterizes the conduct at issue.

And even if the case solely concerned a unilateral refusal to deal, Celgene's conduct in providing its products to researchers and others upon request but refusing to sell to Mylan despite Mylan's agreement to pay retail price, indemnify Celgene from any possible liabilities, and conform to protocols that have been extensively reviewed and accepted by the FDA, shows its refusal has no purpose other than the preservation of its monopoly power. The fact that no generic competitor can enter

without Thalomid and Revlimid samples also makes those samples an essential facility, further justifying the treatment of Celgene's conduct as exclusionary. Since there is no regulatory provision ensuring access to Thalomid and Revlimid samples, the Sherman Act provides the sole means of policing Celgene's anticompetitive conduct, so Celgene must defend its conduct before this Court.

Contracts in Restraint of Trade. Celgene's distribution restrictions are subject to scrutiny under the Sherman Act Section 1 rule of reason. *Cf*. Mot. at 23-27. The restrictions far exceed anything required by the safety regulations for Thalomid and Revlimid, and Celgene's position that wholesalers and pharmacists are its "agents" both strains credulity and depends on factual claims that have no grounding in the record. Celgene thus cannot obtain dismissal of Mylan's Section 1 claims either.

Statute of Limitations. Celgene's statute of limitations affirmative defense cannot justify dismissal on the pleadings as to Thalomid. *See* Mot. at 27-30. Mylan has alleged conduct with respect to both Thalomid and Revlimid within the limitations period, meaning the entire premise of Celgene's argument is wrong. And the rule that a damages claim does not accrue until the competitor actually begins to suffer lost profits would bar Celgene's argument in any event, for the Complaint does not allege that Mylan would have begun selling generic Thalomid prior to April 3, 2010.

Relevant Market. Celgene's relevant market arguments simply misstate the legal standards for alleging a relevant antitrust market. *See* Mot. at 30-36. Mylan has

directly alleged that no other products exhibit significant cross-elasticity of demand with Thalomid and Revlimid, so no product could meaningfully constrain Celgene's pricing aside from a bioequivalent generic. Celgene's apparent belief that other substitutes exist does not render Mylan's allegations implausible; indeed, the extraneous documents Celgene improperly relies on show that the purported "substitutes" are so different from the products at issue in this case that including them in the market defies common sense. At a minimum, it is plain that Celgene cannot win the fact-intensive market definition inquiry at the pleadings stage.

Antitrust Injury. Mylan alleges that its harm (exclusion from the market) flows from the anticompetitive effects of Celgene's strategy to prevent generic competition. That is all that is required to establish antitrust injury. But Celgene seeks to impose an additional requirement that Mylan plead around Celgene's patents. *See* Mot. at 36-38. Celgene offers no authority for its claim that the mere potential of a successful patent infringement suit provides a complete defense at the pleadings stage to an antitrust damages claim. And even if Celgene's argument was accepted, injunctive relief would still be appropriate to ensure Mylan could enter as soon as Celgene's patents lapse. Its assertions at best represent a defense to Mylan's damages claims for consideration at a later stage, and therefore provide no basis for dismissal.

State-Law Claims. Mylan has alleged that defendants deployed unlawful tactics for the malicious purpose of preventing entry of generic competition and that

this conduct deprived Mylan of the economic benefits of competing in the relevant markets. Those allegations suffice to state a claim under New Jersey's antitrust statute, tortious interference law, and unfair competition statute. *Cf*. Mot. at 38-40.

No Basis for Dismissal. In the end, Celgene cannot win early dismissal based on citations to Billy Joel lyrics and its own disagreement with the allegations in the Complaint. Mylan has plainly discharged its pleading burden, so the case should proceed expeditiously to discovery and a final disposition on the merits.

STATEMENT OF FACTS

Regulatory Framework. A company must obtain FDA approval before selling a pharmaceutical product. Compl. ¶ 20. In 1984, Congress passed the Hatch-Waxman Act, which established an Abbreviated New Drug Application ("ANDA") process for generic drug approval. *Id.* ¶ 6. The ANDA process allows a generic applicant to demonstrate bioequivalence to the brand drug product, rather than replicate full clinical trials required for a New Drug Application ("NDA"). *Id.* ¶ 24. The process "speed[s] the introduction of low-cost generic drugs to market, thereby furthering drug competition." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (internal citations and quotations omitted).

To demonstrate bioequivalence to the brand and file an ANDA, a generic manufacturer must obtain samples of the brand drug. Compl. ¶ 26. Even if the brand drug is covered by a patent, it is not an act of infringement to use the samples to

complete bioequivalence testing. *Id.* ¶ 23; 35 U.S.C. § 271(e)(1) ("*Bolar* Amendment"). Congress exempted this activity from patent infringement liability to ensure that generic firms did not have to wait until patent expiration to begin generic drug development, which would extend the "patentee's de facto monopoly" beyond the patent term. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990); Compl. ¶ 23. Typically, a generic manufacturer obtains brand samples through normal distribution channels (i.e., purchasing from a wholesaler). Compl. ¶ 27.

For some drugs with potentially serious side effects, the FDA requires the brand to develop a Risk Evaluation and Mitigation Strategies ("REMS") program to assure safe use of the product. *Id.* ¶ 30. The REMS program may restrict marketplace distribution of the brand product, which, in some cases, requires a generic manufacturer to request to purchase limited samples from the brand firm directly, rather than through traditional channels. *Id*. ¶ 30, 64, 70. Anticipating that brand firms could abuse REMS programs to prevent generic competition, Congress made clear that brand firms were not to use the REMS process to "block or delay" generic drug approval. *Id.* ¶ 31; FDC Act § 505-1(f)(8).

Thalomid. Celgene sells Thalomid (branded thalidomide). Compl. ¶ 2, 57. Because of safety concerns, FDA requires a REMS program for Thalomid. *Id.* ¶ 4. Celgene's REMS program for Thalomid is known as the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S."). *Id.* ¶ 4.

Mylan began developing a generic version of Thalomid in September 2003. *Id.* ¶ 73. Due to the restrictions in Celgene's S.T.E.P.S. program, Mylan could not obtain Thalomid samples for bioequivalence testing from normal wholesale channels. *Id.* ¶ 7; 75. Instead, Mylan was forced to request samples directly from Celgene. *Id.* ¶ 64.

Mylan requested limited Thalomid samples from Celgene in October 2004. *Id.* ¶ 75. After much delay, in December 2005, Celgene finally provided a substantive response to Mylan's request, stating that it needed written confirmation from the FDA to distribute samples outside of the S.T.E.P.S. program and recommending that Mylan contact the agency. *Id.* ¶¶ 75-79.

Though the FDA had previously told Mylan to request samples directly from Celgene, in January 2006, Mylan submitted a letter to the agency explaining that Celgene refused to provide samples absent written authorization from the FDA. *Id.* ¶¶ 80-81. With that letter, Mylan submitted its proposed protocols for its bioequivalence studies, noting that the studies would "only enroll healthy vasectomized males and females not of child-bearing potential." *Id.* ¶ 82. In February 2007, the FDA provided comments to Mylan's January 2006 submission. *Id.* ¶ 83. It noted that while "certain restrictions are needed to ensure safe use of the drug . . . it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in [ ] bioequivalence testing." *Id.* Following the FDA's guidance, Mylan submitted the

safety protocols for its thalidomide bioequivalence studies. *Id.* ¶ 84. In September 2007, the FDA accepted Mylan's safety protocols. *Id.* ¶ 86.

In November 2007, Mylan informed Celgene of its approval, offering to pay full value for the requested Thalomid samples, and the FDA sent Celgene a letter authorizing Celgene to transfer the requested amount of Thalomid to Mylan for testing purposes. *Id.* ¶¶ 87-88, 91. But Celgene failed to provide samples. Instead, knowing that it could no longer use the FDA as an excuse to delay providing Mylan with samples, Celgene (for the first time) propounded a series of massive information requests on Mylan. *Id.* ¶¶ 90-129. The vast majority of information requested bore no relevance to the handling of Thalomid samples for bioequivalence testing. *Id.* ¶ 95. For example, one request sought Mylan's policies for the "storage and use of hazardous substances," including biohazard handling and disaster recovery plans; another asked for five years worth of information on inspections of Mylan's manufacturing facilities. *Id.* ¶¶ 96, 97, 107. But Mylan must implement appropriate general safety protocols under FDA regulations, so much of this information was related to subjects within the FDA's—not Celgene's—purview. *Id.* ¶ 93.

Despite the fact that, given FDA approval of Mylan's protocols, this information was not necessary, Mylan acceded to Celgene's arbitrary and increasingly burdensome demands, producing hundreds of pages of confidential information to Celgene. *Id.* ¶¶ 103, 107, 120. Mylan even agreed that it would indemnify Celgene

for any liability resulting from Mylan's studies. *Id.* ¶¶ 108, 112, 113-17, 120. However, as Mylan fulfilled one unreasonable demand after another, Celgene stood ready to erect new barriers. *Id.* ¶¶ 117, 128. It became clear to Mylan that Celgene's ever-expanding demands were merely a pretext for its scheme to prevent Mylan from developing a competing generic version of Thalomid and that—under no set of circumstances—would Celgene ever provide samples to Mylan. *Id.* ¶ 128.

Based on its five years of tortured negotiations with Celgene, Mylan recognized that further engagement with the company would be "fruitless." *Id.* However, Mylan did not stop efforts to obtain Thalomid samples for bioequivalence testing. It continued to try to acquire samples from wholesalers, but due to the overbroad restrictions in Celgene's S.T.E.P.S. program, these efforts continued to be unsuccessful. *Id.* ¶ 7. Mylan also cooperated with the Federal Trade Commission's ("FTC") ongoing antitrust investigation of Celgene's efforts to prevent generic competition to Thalomid and Revlimid by refusing to provide samples for bioequivalence testing (*Id.* ¶ 8); but not even a federal antitrust investigation could deter Celgene from perpetuating its anticompetitive scheme.

Revlimid: Celgene sells Revlimid (branded lenalidomide). *Id.* ¶¶ 2, 57. Like Thalomid, FDA requires a REMS program for Revlimid. *Id.* ¶ 4. Celgene's REMS program for Revlimid is called RevAssist. *Id.*

Mylan began developing generic lenalidomide in January 2009. Compl. ¶ 131. Again, because of Celgene's RevAssist program, Mylan could not obtain samples through normal distribution channels. *Id.* ¶ 132.

During the period of August 2009 to May 2012, Mylan prepared safety protocols consistent with Celgene's RevAssist REMS program, and submitted these protocols to the FDA in August 2012. *Id.* ¶ 134, 135. After implementing FDA's comments, Mylan received approval for its safety protocols for its lenalidomide bioequivalence studies in July 2013. *Id.* ¶ 142.

In anticipation of FDA approval, in May 2013, Mylan contacted Celgene and requested the purchase of limited Revlimid samples for bioequivalence testing, offering to pay market value. *Id.* ¶ 143. In response, Celgene issued a voluminous information request—nearly identical to its January 2008 information request relating to Thalomid—and added new requests as it went along. *Id.* ¶¶ 144-46, 152-155. In addition, it rejected Mylan's offer to enter into an indemnification agreement, which included nearly every concession to terms Celgene requested during the Thalomid negotiations. *Id.* ¶ 151, 156. Knowing Celgene's playbook of barriers and delay from its experience with attempting to obtain Thalomid samples, Mylan filed the instant suit rather than further engage in continued hopeless "negotiations" with Celgene.

Celgene's History of REMS Abuse. Celgene boldly asserts that it has provided samples of the products in question to other generics when they are able to

meet Celgene's "safety, reputational, business, and liability concerns." Mot. at 2, 22. To support this assertion, Celgene uses examples of companies that managed to obtain samples *notwithstanding* Celgene's REMS abuse, falsely implying that it engaged in good faith negotiations with these potential competitors to provide the product.

For example, Celgene notes that Barr Laboratories submitted an ANDA for Thalomid. Mot. at 2-3. But, as part of its patent litigation[1] against Barr, Celgene raised an "unclean hands" defense, claiming that Barr "obtained [Thalomid samples] in violation of the product labels and S.T.E.P.S. system by improperly purchasing the drug from a pharmacy." Celgene's Reply to Countercl. ¶ 278 (D.N.J. Dec. 28, 2007). Celgene further claims that Lannett announced that it has completed bioequivalency testing for generic thalidomide. Mot. at 10. However, as discussed further below, Lannett had to *sue* Celgene under the antitrust laws—alleging the same conduct that Mylan is alleging here—to obtain samples. To the extent Celgene provided samples as part of a settlement, it was due to the risk of treble damages under the antitrust laws, and not a sudden resolution of its pretextual "safety" concerns.

[1] Barr claimed that Celgene violated antitrust and other laws when it engaged in a "deliberate and intentional pattern of conduct in attempting to prevent or delay Barr's final approval of its generic thalidomide products." This pattern of conduct included "Celgene's interference with Barr's supplier of active pharmaceutical ingredient." Barr Lbs. Memo. of Law in Opp'n to Celgene's Motion to Dismiss, *Celgene Corp. v. Barr Labs., Inc.*, No. 2:07-cv-00286 (D.N.J. Nov. 12, 2007) at 2.

Similarly, Celgene notes that Natco Pharma has submitted an ANDA for Revlimid. Mot. at 12. But, Celgene fails to mention that, in its current patent litigation against Natco, it asserted an "unclean hands" defense, claiming that Natco obtained Revlimid samples illicitly and/or inequitably. *See* Celgene's Brief in Opposition to Defendant's Motion to Strike Celgene's First Unclean-Hands Affirmative Defense, *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197, at 1 (D.N.J. Apr. 7, 2014). In sum, far from voluntarily providing samples to generics that meet its conditions, Celgene is a REMS abuse recidivist.

Precedent Related to REMS Abuse. Two judges have previously denied motions to dismiss lawsuits alleging virtually identical facts. *Lannett Co. v. Celgene Corp.*, No. 08-3920 (E.D. Pa. filed March 31, 2011); *Actelion Pharms. Ltd. v. Apotex*, Inc., No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013). In *Lannett*, Judge Savage summarily denied Celgene's motion to dismiss after receiving extensive briefing on the issues presented. And in *Actelion*, Judge Hillman issued a fully reasoned ruling from the bench following oral argument and full briefing (including an amicus from the FTC), denying a motion to dismiss antitrust counterclaims indistinguishable from Mylan's claims here. *See* Transcript of Proceedings 115-17, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013) ("I find that the determination of whether plaintiff's refusal to deal here, sell samples, amounts to protected and lawful conduct should await full discovery, and I will allow the case to

proceed that way."). Indeed, Mylan's case is more compelling than the prior cases because its research protocols have already been reviewed and accepted by the FDA.

ARGUMENT

To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007). The *Twombly* standard "'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 v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). Furthermore, "it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *West Penn Allegheny Health Sys. Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010). There need only be "some showing sufficient to justify moving the case beyond the pleadings to the next stage of litigation." *Phillips*, 515 F.3d at 234-35.

I. MYLAN SUFFICIENTLY STATES A SECTION 2 CLAIM

Monopolization under Section 2 of the Sherman Act has two elements: (1) possession of monopoly power, and (2) 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." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 343 (3d Cir. 2012) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563,

570-17 (1966)). Celgene's main argument for dismissal is that Mylan has failed to allege the second element, anticompetitive conduct. *See* Mot. at 14-23.

A. Mylan Sufficiently Alleges Anticompetitive Conduct

Anticompetitive conduct is "conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits," or "[c]onduct that impairs the opportunities of rivals . . . in an unnecessarily restrictive way." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007) (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003)). It "can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties." *West Penn*, 627 F.3d at 109 (quoting *LePage's*, 324 F.3d at 152).

Mylan alleges that Celgene designed and enforced a comprehensive anticompetitive scheme to prevent Mylan and others from obtaining Thalomid or Revlimid samples from any available source. *See, e.g.*, Compl. ¶¶ 2, 7, 11, 65, 71-72, 130, 145, 158-69. This includes both its unilateral refusal to sell to Mylan and its overbroad distribution restrictions on downstream entities. Third Circuit law clearly establishes that the proper inquiry in an antitrust case is whether the defendant's alleged actions "considered together" harmed competition. *See LePage's*, 324 F.3d at 162; *West Penn*, 627 F.3d at 108.[2] Thus, the entire premise of Celgene's Section 2

[2] *See also In re Neurontin Antitrust Lit.*, No. 02-1390, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) (Hochberg, J.) ("Courts have routinely upheld the validity of

argument—that Mylan challenges a purely unilateral refusal to deal—is false. Mylan challenges Celgene's conduct as a whole, and even if one or more aspects of Celgene's conduct individually were lawful, they may be challenged as a part of Celgene's overall scheme to achieve and maintain monopoly power in violation of Section 2. *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 359 (D.N.J. 2009) (Hochberg, J.) (quoting *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946)).

But even focusing on just the unilateral refusal to deal element of Celgene's overall anticompetitive strategy shows that Mylan has a valid antitrust claim. Celgene has refused to sell Thalomid and Revlimid samples to Mylan despite the fact that Celgene provides these samples to non-competitors, Mylan has offered to pay full retail value for the samples, and the FDA has deemed Mylan's protocols to ensure safety acceptable. Compl. ¶¶ 86, 142, 161-63, 192, 211. The sole reason for Celgene's refusal to provide samples was to keep Mylan from competing with lower-priced generic versions of Celgene's products. *See* Compl. ¶¶ 2, 7, 11, 65, 71-72, 129, 157, 164, 170. Celgene cannot show that these allegations, as a matter of law, do not state a plausible Section 2 claim. *See Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 894-95 (N.D. Cal. 2011) (defendant's refusal to provide its competitors with the

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'overall monopolization scheme' claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently violative of antitrust laws."); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (same).

drug on the same terms it provided the drug to its retail customers could constitute an anticompetitive refusal to deal). And any suggestion that the lack of a clear refusal precludes Mylan's claims fails, for "[c]ourts have previously found an unlawful refusal to deal where the defendant would agree only to unreasonable terms and conditions amounting to a practical refusal to deal." *See Steward Health Care Sys., LLC v. Blue Cross & Blue Shield*, C.A. No. 13-405 S, 2014 U.S. Dist. LEXIS 20304, at *20 (D.R.I. Feb. 19, 2014) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 592 (1985), and *Safeway*, 761 F. Supp. 2d at 894-95).[3]

1. Mylan sufficiently alleges that Celgene's refusal to deal was motivated by a desire to maintain its monopoly power

While antitrust law places a high value on a firm's right to refuse to deal with other firms, that right is not absolute. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (quoting *Aspen Skiing*, 472 U.S. at 601). "Under certain circumstances a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2." *Id.* The Supreme Court in *Aspen Skiing*, for example, held a defendant violated § 2 when it unilaterally ceased participation in an economically profitable joint venture and, thereafter, refused to sell to the plaintiff,

[3] *See also Del. & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 179-80 (2d Cir. 1990) ("[T]here need not be an outright refusal to deal in order to find that denial of an essential facility occurred. It is sufficient if the terms of the offer to deal are unreasonable."); *Fishman v. Estate of Wirtz*, 807 F.2d 520, 541 (7th Cir. 1986) ("Agreeing to deal on unreasonable terms is merely a type of refusal to deal.").

even at its own retail price. 472 U.S. at 608-10. After examining the facts, the Court concluded the defendant "was not motivated by efficiency concerns" and "elected to forgo . . . short-run benefits because it was more interested in reducing competition . . . over the long run[.]" *Id.* at 608-610.

Later, in *Trinko*, the Court again recognized that a monopolist's refusal to deal may violate the antitrust laws. In that case, the Court distinguished the facts before it from those in *Aspen Skiing*, reasoning that the *Trinko* defendant's prior conduct told the Court "nothing about dreams of monopoly." That is, unlike *Aspen Skiing*, where the defendant's actions were indicative of anticompetitive malice, in *Trinko* the plaintiff failed to allege facts that evidenced such intent. Additionally, the Court found "a more fundamental" distinction between the cases: in *Aspen Skiing* the defendant was refusing to sell to the plaintiff services it already sold to others at retail, while in *Trinko* the plaintiff alleged defendant refused to sell services not otherwise marketed or available to the public. 540 U.S. at 409-10.

Here, Celgene's conduct was not motivated by efficiency concerns and demonstrates an obvious decision to deviate from a prior course of conduct in order to realize an anticompetitive effect.[4] While Celgene was refusing to sell any samples to

[4] *Pacific Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438 (2009), is inapposite, as in that case the Court examined "price-squeeze" conduct, not the scope of a monopolist's duty to deal. *Id.* at 442, 445-46.

Mylan, it was simultaneously providing samples to other entities, including researchers, who were not participating in its S.T.E.P.S. or RevAssist programs, but who were not competitors to Celgene. *See* Compl. ¶¶ 161-163. It refused to sell to Mylan even though Mylan offered to pay retail prices for the samples and had received FDA approval of its safety protocols. *Id*. ¶¶ 86, 142, 192, 211. Mylan has also alleged Celgene's proffered safety concerns are pretextual. *Id*. ¶¶ 7, 158, 192. Mylan has thus sufficiently alleged a Section 2 violation.

Moreover, the reasons the Court refused to impose antitrust liability in *Trinko* are not present here. Celgene already sells Thalomid and Revlimid in the marketplace,[5] contrary to *Trinko*, where the refusal to deal addressed services not otherwise available at retail. And the FDA regulations covering REMS drugs here neither create a duty to deal nor grant the FDA the authority to compel brands to deal with generics. *See Actelion*, *supra*, ECF No. 93 at 115:24-116:2. This regulatory regime is therefore distinguishable from that in *Trinko*, where FCC rules regulated the conduct at issue and where antitrust would add little value.

[5] Providing Mylan samples would not require Celgene to "forfeit its statutory right to exclude." Mot. at 15. As dicussed above, the *Bolar* Amendment specifically creates an exemption to the traditional patent rules "for uses reasonably related to the development and submission of information" for FDA approval. 35 U.S.C. § 271(e)(1).

The unilateral refusal to deal allegations of this case are thus sufficient to state a claim under a straightforward application of *Aspen Skiing*. The Complaint alleges that Celgene refuses to provide Thalomid and Revlimid samples even if compensated at retail price, refuses to sell to Mylan even though it has provided samples to others, and will not sell its samples even with express regulatory authorization and an offer of indemnification from Mylan. These allegations "support[] an inference that [Celgene] was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits . . . in exchange for a perceived long-run impact on [generic competition]." 472 U.S. at 610-11. *Trinko* expressly preserved this theory of Section 2 liability for refusals to deal (540 U.S. at 408-09), so Mylan states a valid unilateral refusal to deal claim under *Aspen Skiing*. *Accord Nobody in Particular Presents, Inc. v. Clear Channel Commc'ns, Inc.*, 311 F. Supp. 2d 1048, 1107-08 (D. Colo. 2004) ("*NIPP*").

Finally, this case is distinguishable from *Trinko* in that Celgene not only unilaterally refused to deal with Mylan, but further forbade its wholesale distributors and pharmacies from dealing with Mylan. *See* Compl. ¶¶ 72, 75-76, 158. These vertical agreements between Celgene and its wholesale distributors and authorized pharmacies add a component to the refusal to deal analysis that simply was not present in *Trinko* or the other cases Celgene cites, where the issue was a purely unilateral refusal to deal. They are additional evidence of Celgene's anticompetitive intent to foreclose Mylan from access to necessary inputs, and of its exploitation of its

monopoly power over Thalomid and Revlimid. Celgene thus cannot escape liability for its exclusionary conduct.

2. *Trinko* does not render Celgene's conduct *per se* lawful

The basic premise of Celgene's Motion is that, post-*Trinko*, it is per se lawful for a monopolist to refuse to deal with competitors under any circumstances, unless the monopolist both (a) had a prior course of dealing with the competitor and (b) sacrificed profits in refusing to deal. But neither the Supreme Court nor the Third Circuit has ever required an antitrust plaintiff to allege either, let alone both, of these purported "requirements."[6] To the contrary, in *Trinko*'s analysis of the refusal to deal claim, it was not the *fact* of the prior course of dealing (or the commensurate profit sacrifice) that the Court found persuasive, but rather what the defendant's prior course of dealing *suggested*—namely, whether it was motivated by "competitive zeal" or by "anticompetitive malice." 540 U.S. at 409. *Accord Helicopter Transp. Servs., Inc. v. Erickson Air-Crane, Inc.*, No. CV-06-3077, 2008 WL 151833, at *9 (D. Or. Jan. 14, 2008) ("The Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim.").

[6] Indeed, the Supreme Court has held a monopolist liable for its refusal to deal even when no prior course of dealing was alleged. *See Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973).

In any event, Mylan has alleged a marked departure from a prior course of dealing. Celgene has engaged in a course of voluntary conduct whereby it has provided Thalomid and Revlimid samples to others entities, including research organizations, yet it has refused to provide the same samples to Mylan because it fears potential competition. Compl. ¶¶ 65, 71, 160-63. These allegations, coupled with Mylan's allegations that Celgene's safety concerns are pretextual, state a refusal to deal claim. *Id*. ¶¶ 7, 158, 170, 192.[7]

3. Sales to Mylan do not pose "additional risks"

Celgene's argument that it would face increased exposure for product liability and other lawsuits is essentially an assertion that Celgene had valid business justifications for its actions. Mylan alleges that Celgene had no legitimate reasons for refusing to sell samples to Mylan—and specifically alleges facts demonstrating its

[7] In order to rebut the allegation in the Complaint that Celgene has provided samples to research organizations not subject to REMS, Celgene argues that all research organizations using Thalomid and Revlimid for clinical studies obtained them through, and are subject to, Celgene's REMS programs. Mot. at 12. First, this argument is improper as it argues with allegations in Mylan's well-pled complaint. *See, e.g.*, Compl. ¶ 65, 71, 161-63. Second, it is unsupported. For example, when "Revlimid REMS" is searched (as Celgene suggests) on the National Institute of Health's clinicaltrials.gov website, the result lists only ***one study***, which Celgene quotes from in its motion to dismiss. However, when "Revlimid Celgene" is searched (as Mylan suggests in its complaint ¶ 71 n.14) without the word "REMS," the results lists ***284 studies***. *See* ClinicalTrials.gov, http://clinicaltrials.gov/ct2/search (last visited June 13, 2014) (search "Revlimid REMS" compared with "Revlimid Celgene").

proffered safety and liability concerns are pretextual—and these allegations must be taken as true at this stage. *See Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). The existence and extent of business justifications is a factual question that cannot be resolved at the motion to dismiss stage. *See Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005) ("Bell Atlantic's second defense—that its refusal to deal was economically justified—depends upon a question of fact and therefore is not cognizable in support of a motion to dismiss.").

Further, Celgene offers no reason why its potential products liability exposure would *increase* if it provided samples to Mylan. The provision of limited samples would be a one-time sale for purposes of bioequivalence testing. The FDA has approved Mylan's proposed protocols for handling the samples. And Mylan repeatedly stated that it was willing to enter into indemnification agreements indemnifying Celgene for any liability resulting from Mylan's studies. *See* Compl. ¶¶ 108-09, 112, 113-17, 120, 151, 156. Thus, Celgene was facing no liability increase.

The only cases to which Celgene cites to support its argument suggest that a brand drug manufacturer may be held liable for a negligent failure to include adequate warnings on a drug's labeling, even if a prescription is filled with a generic rather than the brand drug. But the burden is *always* on the brand manufacturer to ensure the warning labels for its products are adequate, and Hatch-Waxman requires AB-rated generics to have labels *identical to the brand's*. *See PLIVA, Inc. v. Mensing*, 131 S.

Ct. 2567, 2574-75 (2011) ("A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. . . . A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.") (citations omitted). In other words, generic entry cannot impact the brand's exposure for failure to warn—the brand will be negligent or not based upon its *own* labeling. And given the extensive disclosure of potential risks from both products on their labels, Celgene cannot identify any concrete product liability risk.

Celgene's arguments regarding avoiding patent litigation are equally unavailing. The Hatch-Waxman Act incentivizes generics to challenge invalid patents or those they believe they do not infringe. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Under this framework, patent litigation may or may not occur with respect to any given drug. Here, however, Celgene has assured itself immunity from patent challenge by refusing to deal with Mylan or any other generic. That is not a business justification; it is an act of raw exclusion.

B. Mylan Sufficiently Alleges an Essential Facilities Claim

In addition to its refusal to deal claim, Mylan also sufficiently alleges an essential facilities claim. To plead an essential facilities claim, a plaintiff must allege: "(1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) denial of the use of the

facility to a competitor; and (4) the feasibility of providing the facility." *Delaware Health Care, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1287 (D. Del. 1995) (citation omitted); *NIPP*, 311 F. Supp. 2d at 1109-14. Mylan has pled that: (1) Celgene maintains control of Thalomid and Revlimid samples, which any generic must obtain in order to conduct the bioequivalence studies necessary to file an ANDA and enter the market; (2) Mylan cannot practically or reasonably conduct these studies or enter without first obtaining the samples; (3) Celgene has, itself, denied Mylan access to the Thalomid and Revlimid samples, and has further foreclosed all access to the samples by entering agreements with distributors, wholesalers, and pharmacies preventing them from selling to Mylan; and (4) Celgene frequently provides Thalomid and Revlimid to other customers, and could just as easily sell the samples to Mylan.[8]

Celgene's arguments for dismissal of Mylan's essential facilities claims have no merit. *First*, Celgene's argument that compelling it to sell its patented products would contravene rights granted by the Patent Act again ignores the fact that Congress has altered the application of traditional patent rules in this context. The bioequivalence testing Mylan seeks to do is *not* patent infringement under the *Bolar* Amendment. Congress added this Amendment to prevent the *de facto* extension of a patent holder's

[8] Contrary to Celgene's suggestions, the essential facilities doctrine is applicable post-*Trinko*. The Supreme Court in *Trinko* had the opportunity to repudiate the doctrine, but explicitly refused to do so. *See* 540 U.S. at 411.

monopoly that would result if generics were prohibited from beginning bioequivalence testing until after the patent expired: this testing takes time and resources, and if it could not commence until after a patent expired, the monopolist is essentially immunized from competition well past the patent's expiration. *Eli Lilly*, 496 U.S. at 670. Unsurprisingly, Celgene's exact argument was rejected in *Actelion*. No. 1:12-cv-05743 (ECF No. 93).

Second, Celgene's contention that Thalomid and Revlimid samples are not "essential" asks the court to consider factual questions on this motion to dismiss and to reject the truth of Mylan's well-pled allegations. Celgene argued in *Lannett*, as did the brand manufacturer in *Actelion*, that the samples were not essential because other avenues of entry were available. But this argument was rejected in each case.[9] *Actelion*, No. 1:12-cv-05743 (ECF No. 93); *Lannett*, No. 2:08-cv-03920. Here, Mylan alleges that obtaining Thalomid and Revlimid samples is essential to enter the market as an AB-rated generic.[10] Compl. ¶¶ 24-26, 74, 158, 192. Moreover, as Mylan explains at length in its Complaint, the purpose of Hatch-Waxman was to provide an

[9] Other courts have similarly recognized that the availability of alternatives is a factual question inappropriate for resolution at the pleading stage. *See Ohio Bell Tel. Co. v. CoreComm Newco, Inc.*, 214 F. Supp. 2d 810, 818 (N.D. Ohio 2002); *Jamsports & Entm't, LLC v. Paradama Prods., Inc.*, No. 02-C-2298, 2003 WL 1873563, at *12-13 (N.D. Ill. Apr. 15, 2003).

[10] The FDA may refuse to consider an ANDA application if the application is submitted as a 505(b)(2) application for a duplicate of a listed drug (i.e., an AB-rated generic version of the brand drug). 21 C.F.R. § 314.101(d)(9).

ANDA process to spur generic entry, which has saved consumers billions of dollars. *Id.* ¶¶ 21, 24, 34-35. To force a generic to enter as a brand by submitting a NDA would undermine Hatch-Waxman and reduce the availability of low-cost generic alternatives in the marketplace. These allegations sufficiently allege essentiality.

Third, Celgene claims that the holder of the "facility" must be using the facility to secure monopoly power in a "downstream" market. But the Third Circuit has never recognized this as a requirement for an essential facilities claim. In any event, Celgene does seek to monopolize the downstream markets for sale of thalidomide and lenolidomide in addition to the manufacture of those products through its distribution restrictions, so this argument does nothing to advance Celgene's defense. And again, both *Lannett* and *Actelion* rejected the exact same argument. *See Lannett*, No. 2:08-cv-03920 (ECF No. 29, at 15).

Fourth, Celgene's argument that Mylan "has not shown Celgene's safety, reputational, regulatory, business, and liability concerns do not exist," again misunderstands the standard at this stage of litigation. Mot. at 21. These alleged concerns are proffered business justifications, the existence and extent of which are factual questions. *See Covad*, 398 F.3d at 676; *Actelion*, No. 1:12-cv-05743 (ECF No.

93, at 116:19-25). Mylan has specifically alleged that these claims are pretextual, and its allegations are more than sufficient to carry its pleading burden.[11]

Fifth, Celgene's argument regarding the REMS statute completely misconstrues Mylan's claims. Mylan does not allege that the REMS statute *creates* a duty to deal, which the FDA can oversee and enforce—which is precisely why this case differs from *Trinko*, as discussed above. And Celgene's argument that Congress considered but did not enact laws requiring brand manufacturers of REMS drugs to provide samples to generics distorts both antitrust law and Congressional intent. The *default* is that antitrust law applies to conduct that may be exclusionary. And Congress' failure to enact a law does not alter the default. In fact, the Supreme Court rejected this precise argument in *Otter Tail*. *Otter Tail*, 410 U.S. at 372.[12] Mylan may thus proceed on an essential facilities theory as well.

II. MYLAN SUFFICIENTLY STATES A SECTION 1 CLAIM

Mylan alleges that Celgene imposes distribution restrictions on wholesalers, distributors, and pharmacies. *See* Compl. ¶¶ 72, 75-76, 132, 158. Such restrictions

[11] Moreover, Celgene must still show that its justifications outweigh the competitive harm caused by its conduct. *See Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 829-30 (3d Cir. 2010). It has not even attempted to do so.

[12] *See also United States v. National Assoc. of Secs. Dealers, Inc.* 422 U.S. 694, 719-20 (1975) ("Implied antitrust immunity is not favored, and can be justified only by a convincing showing of clear repugnancy between the antitrust laws and the regulatory system.").

are evaluated under Section 1 of the Sherman Act under the rule of reason.[13] Celgene offers two arguments for dismissal of Mylan's Section 1 claims: (1) Celgene's claim that its distribution agreements did not cause Mylan's injury and (2) its assertion that Mylan fails to allege concerted action. Mot. at 24-27. Both arguments fail.

Causation: Celgene claims that the FDA-mandated REMS program, not its distribution agreements that implement REMS, caused Mylan's injury. *See* Mot. at 24-25. Its argument is foreclosed by controlling law: the Third Circuit has recognized that injury flowing from a manipulation of the pharmaceutical regulatory regime qualifies as antitrust injury. *See In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000) (rejecting application of *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256 (3d Cir.1998), to pharmaceutical cases).

Further, Celgene's argument misstates the regulatory regime. While the FDA mandates the *existence* of REMS for some drugs, it does not provide step-by-step directions for implementation. It is up to the brand to set up its program in a way that ensures safety but does not preclude generic competition. *See* Compl. ¶¶ 26-31; *see also* FDC Act § 505-1(f)(8). In fact, the FDA has specifically approved sales of

[13] *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 881-82 (2007); *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 44-45 (1984) (O'Connor, J., concurring); *Z.F. Meritor*, 696 F.3d at 281; *Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc.*, 530 F.3d 204, 224-25 (3d Cir. 2008); *United States v. Am. Express Co.*, No. 10–CV–4496, 2014 WL 1817427, at *5 (E.D.N.Y. May 7, 2014).

Thalomid and Revlimid to Mylan for the purpose of bioequivalence studies. *See* Compl. ¶¶ 86, 91 136-37. Thus, there is nothing inherent in the regulatory regime that requires exclusion of Mylan, so Celgene's exclusionary agreements with wholesalers are properly subject to Section 1 scrutiny.

Concerted Action: Celgene proposes a novel requirement for pleading a Section 1 claim: according to Celgene, Mylan must plead that Celgene's distributors are "competitors in [the] alleged market" and that they had "independent reason to harm competition." Mot. at 27. No case establishes such a pleading requirement, nor would any legal principle require such a rule. Mylan discharged its pleading burden by directly alleging the existence of restrictive distribution contracts between Celgene and downstream entities. *See West Penn*, 627 F.3d at 99 ("If a complaint includes non-conclusory allegations of direct evidence of an agreement, a court need go no further on the question whether an agreement has been adequately pled.").

Celgene's argument assumes that its distributors are mere "servicing entities" rather than independent wholesalers. Mot. at 26. But there are no facts pleaded in the Complaint suggesting that, and Mylan has no obligation to plead a rebuttal to every potential affirmative defense Celgene may invoke. *See Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007). If Celgene wishes to argue at summary judgment or at trial that all of the wholesalers, distributors, and pharmacies selling Thalomid and Revlimid are its agents or that they had no knowledge of Celgene's anticompetitive

intent, it is free to do so.[14] But Celgene cannot obtain dismissal of Mylan's Section 1 claims on the pleadings based on its own factual assertions.

III. MYLAN'S THALOMID CLAIMS ARE TIMELY

Celgene's statute of limitations argument (Mot. at 27-30) is meritless. In the first place, statute of limitations issues are not ordinarily appropriate for resolution on a motion to dismiss. *See United States v. Jones*, 916 F. Supp. 383, 386 (D.N.J. 1995) (*Bethel v. Jendoco Constr. Corp.*, 570 F.2d 1168, 1174 (3d Cir. 1978)).

More importantly, Mylan alleges that it sought samples within the limitations period and was refused, which alone completely rebuts Celgene's statute of limitations argument. *See* Compl. ¶ 7. Moreover, Mylan's damages claims as to Thalomid would not have accrued, and the limitations period would not have started to run, until Mylan had concrete, measurable damages, *i.e.*, lost profits from sales of generic Thalomid that it would have made but for Celgene's anticompetitive conduct. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338-42 (1971); *Samsung Elecs. Co. v. Panasonic Corp.*, 747 F.3d 1199, 1204-05 (9th Cir. 2014); *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir. 1993);

[14] Notably, the Third Circuit cases cited by Celgene all involved summary judgment decisions. *See Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1135 (3d Cir. 1995) (discussing factual record at summary judgment); *Harold Friedman, Inc. v. Kroger Co.*, 581 F.2d 1068, 1074 & 1078 (3d Cir. 1978) (same). *But see Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 999-1000 & 1007-1013 (3d Cir. 1994) (finding sufficient evidence to infer concerted action).

Harold Friedman Inc. v. Thorofare Markets Inc., 587 F.2d 127, 137 (3d Cir. 1978). Given the need to formulate a product, conduct bioequivalence studies, prepare and submit regulatory filings, and launch the product, the date on which Mylan would have entered absent Celgene's refusal to sell it Thalomid samples would have been after 2009 and well within the limitations period. *See* Compl. ¶¶ 6, 26, 159.

Furthermore, the continuing violation doctrine also makes Mylan's claims timely. *See West Penn*, 627 F.3d at 106; *see also Samsung*, 747 F.3d at 1202-04; *Lower Lake Erie*, 998 F.2d at 1171-72. Mylan has alleged that Celgene's anticompetitive refusal to deal policy persists to this day and has been manifested by overt acts within the limitations period. *See* Compl. ¶¶ 152-57. And Celgene has not merely acted unilaterally: it has coerced its distributors into also refusing to sell to Mylan, meaning each renewal of its distribution agreements renews its anticompetitive policy. *See id*. ¶¶ 7, 72, 158. The continuing violations doctrine thus independently renders Mylan's Thalomid claims timely.[15]

[15] Celgene claims in a footnote that Mylan's declaratory and injunctive relief claims as to Thalomid are barred by the doctrine of laches. Mot. at 28 n.17. This claim is also not appropriate for resolution on a motion to dismiss. *See Kaufhold v. Caiafa*, 872 F. Supp. 2d 374, 380 (D.N.J. 2012) (citing *Compagnie Des Bauxites de Guinee v. L'Union Atlantique S.A. d'Assurances,* 723 F.2d 357, 363 (3d Cir. 1983)); *Oliver v. SD-3C LLC*, --- F.3d ----, No. 12-16421, 2014 WL 1910788, at *2-4 (9th Cir. May 14, 2014). Further, in the antitrust context, the party invoking the doctrine of laches must prove prejudice from the delay in bringing suit. *See Lower Lake Erie*, 998 F.2d at 1174. Defendants have identified no prejudice from any alleged delay.

IV. MYLAN SUFFICIENTLY PLEADS THE RELEVANT MARKETS

Monopoly power (required for Mylan's Section 2 claims[16]) is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). Monopoly power can be proven through two methods: (1) direct evidence of power to control prices or exclude competition, or (2) indirect evidence such as the defendant's share of the relevant market and the existence of barriers to entry.[17] *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). Celgene's motion to dismiss does not even address direct evidence of monopoly power. Thus, Celgene's claim that Mylan has failed to adequately allege a relevant market is not only incorrect; it is also insufficient to establish that the Complaint is deficient on the ultimate issue of adequately alleging monopoly power.

Relevant product market definition is a "deeply fact-intensive inquiry" and "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,

[16] If the monopoly power requirement for Section 2 is met, so is the market power requirement for Section 1. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 186 (3d Cir. 2005) ("Monopoly power under § 2 requires . . . something greater than market power under § 1.").

[17] Celgene does not contest Mylan's allegations regarding the substantial barriers to entry in each of the relevant markets. Compl. ¶¶ 43, 53.

J.).[18] In spite of this precedent, Celgene asks this Court to decide this "deeply fact-intensive inquiry" on a motion to dismiss. Specifically, Celgene argues that Mylan's relevant product market definition is deficient for three reasons: (1) a single drug cannot constitute a relevant product market; (2) Mylan's relevant market section of its complaint—which spans twenty paragraphs—provides insufficient allegations to make its relevant markets plausible; and (3) this Court should take judicial notice—by considering evidence outside of the complaint—that "competing drugs" to Thalomid and Revlimid exist. Mot. at 30-36. None of these arguments has any merit.

First, multiple cases have found that an antitrust market can consist of a branded drug and its generic equivalents, depending on the facts. *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (finding that relevant market is limited to ciprofloxacin and does not include competing branded antibiotics), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008).[19] Thus, Celgene's argument that the relevant markets are implausible as a matter of law fails.

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[18] *See also Newcal Indus., Inc. v. IKON Office Solution*, 513 F.3d 1038, 1045 (9th Cir. 2008); *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199 (3d Cir. 1992); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 547 (D.N.J. 2000).

[19] *See also La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343 (HB), 2008 WL 169362, at *7 (S.D.N.Y. Jan. 18, 2008); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000); *Knoll Pharms. Co. v. Teva Pharms. USA, Inc.*, No. 01 C 1646, 2001 WL 1001117, at *3-4 (N.D. Ill. Aug. 24, 2001); *Mutual Pharm. Co. v. Hoechst Marion Roussel, Inc.*, No. Civ. A. 96-1409, 1997 WL 805261, at *3

Celgene cites two cases from this court, but neither is even remotely applicable. Mot. at 32. In *United States v. Ciba Geigy Corp.*, the court found—***after a trial on the merits***—that "[t]he evidence in this case has demonstrated that there is no identifiable HCT [hydrochlorothiazide] market . . . isolated from the medical equivalence and competitive pressures of other products." 508 F. Supp. 1118, 1153 (D.N.J. 1976). In *Teva Pharmaceuticals Industries v. Apotex, Inc.*, the court dismissed Apotex's Section 2 counterclaim without prejudice because it (1) had three different "conflicting and variable" definitions of the relevant market; (2) did not even reference cross-elasticity of demand or reasonable interchangeability; and (3) contained "no allegations regarding market power." No. 07-5514, 2008 WL 3413862, at *8-9 (D.N.J. Aug. 8, 2008). Neither case is at all analogous to this one, for this case is only at the pleadings stage and Mylan has made extensive allegations clearly defining the relevant markets based on cross-elasticity of demand and alleging Celgene's market power in the relevant markets. *See also Am. Sales Co. v. AstraZeneca AB*, No. 10-6062, 2011 WL 1465786, at *3-4 (S.D.N.Y. Apr. 14, 2011) (dismissing case where allegations only spanned one paragraph).

Second, Celgene argues that Mylan's relevant market section of its complaint provides insufficient allegations to make its relevant markets plausible. Relevant

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(E.D. Pa. Dec. 17, 1997). *Accord FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1238-41 (8th Cir. 2011) (two medicines for same condition in different product markets).

product market is assessed by "an appraisal of the 'cross-elasticity' of demand in the trade." *EI du Pont*, 351 U.S. at 394. *See also Broadcom*, 501 F.3d at 307. Cross-elasticity measures "the extent to which consumers will change their consumption of one product in response to a price change in another," all else being equal. *Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 469 (1992). In other words, if a slight increase in the price of product A causes consumers to switch to product B (i.e., positive cross-elasticity of demand), then product B constrains product A's ability to charge monopoly prices, and they are part of the same relevant market. Two products may "compete" with one another to some degree, yet not be part of the same antitrust market because they do not provide a significant price constraint. *See Kodak*, 504 U.S. at 469-71; *In re Mushroom Direct Purchaser Antitrust Litig.*, 514 F. Supp. 2d 683, 698 (E.D. Pa. 2007).

Here, Mylan alleges that there is *no product* that constrains Celgene's ability to charge monopoly prices for Thalomid. *See* Compl. ¶¶ 39-40. Similarly, Mylan alleges that no product constrains Celgene's ability to charge monopoly prices for Revlimid. *See id.* ¶¶ 49-50. Because no other product besides an AB-rated generic product—even one with a similar indication—"is sufficient to prevent the anticompetitive effects of Celgene's conduct" (i.e., the charging of monopoly prices for Thalomid and Revlimid), Mylan alleges that the relevant markets in this case are

limited to each drug and its generic equivalents. *See id*. ¶¶ 36-38, 46-48. These allegations are more than sufficient at this stage of the litigation.

Mylan also alleges that the relevant markets are limited to thalidomide capsule products and lenalidomide capsule products because Celgene is the *only* company with FDA-approved products containing these active ingredients and other products are not reasonably interchangeable with Thalomid and Revlimid due to differences in "price, use, qualities, characteristics, and/or distinct customers or end users." *Id.* ¶¶ 37, 44, 47, 54. In the context of pharmaceuticals, even if two products have an overlapping indication, they may not be economic substitutes for one another because of, for example, differences in side effect profiles of the drugs or use with a particular patient population. *See SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1062-1065 (3d. Cir. 1978); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 996 (N.D. Ill. 2003); *Mutual Pharm. Co. v. Hoechst Marion Roussel, Inc.*, No. 06-1409, 1997 U.S. Dist. LEXIS 20038, at *5 (E.D. Pa. Dec. 17, 1997).

Lastly, Celgene resorts to attempting to introduce documents extraneous to Mylan's Complaint. In addition to being wholly improper on a motion to dismiss (*see West Penn*, 627 F.3d at 97 n.6), Celgene's own exhibits show that the drugs Celgene claims are economic substitutes for Thalmoid and Revlimid are significantly differentiated from those products by, for example:

- delivery method (e.g., decatabine is administered by injection (Mot. Ex. J));

- indication (e.g., ibrutinib is indicated for patients who have received at least one prior therapy, Revlimid is specifically indicated for patients "whose disease has relapsed or progressed after two prior therapies, one of which included bortezomid" (Mot. Ex. K));
- and side effect profiles (e.g., cyclophosphamide, a chemotherapy drug, carries risk of several side effects not implicated by Thalomid, such as immunosuppression, bone marrow failure, and toxicity to multiple organ systems (Mot. Ex. H); similarly, clofazimine is associated with "a discoloration of the skin from red to brownish-black" which "may take several months or years to disappear" (Mot. Ex. I)).[20]

While Celgene is free to try to argue that, despite their considerable differences, these products can constrain its monopoly pricing for Thalomid and Revlimid, it may not do so on a motion to dismiss. Mylan has clearly pled plausible relevant markets.

V. MYLAN SUFFICIENTLY PLEADS ANTITRUST INJURY

Mylan alleges harm to it flowing from harm to competition. Specifically, Mylan alleges that: (1) it needs Thalomid and Revlimid samples to complete

[20] Also, unlike the claimant in *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08-3710, 2010 WL 1222012 (S.D.N.Y Mar. 29, 2010), Mylan differentiates Thalomid and Revlimid throughout the complaint with respect to price (Compl. ¶¶ 2, 10); active ingredient (*Id.* ¶ 3); indications/use (*Id.* ¶¶ 3, 37, 47); and distribution restrictions (*Id.* ¶¶ 3, 63, 69).

bioequivalence testing (Compl. ¶ 6); (2) Celgene has prevented Mylan from obtaining samples (*Id.* ¶ 72-157); (3) but for Celgene's anticompetitive conduct, Mylan would have filed its thalidomide ANDA substantially earlier and would not have been delayed in preparing its lenalidomide ANDA (*Id.* ¶ 165); (4) Mylan's generic products would be priced substantially below Celgene's brand products (*Id.* ¶ 166); and (5) as a result, Celgene has delayed lower-cost generic competition (potentially indefinitely) while consumers continue to pay monopoly prices (*Id.* ¶ 11, 167-68). These allegations describe injury "of the type the antitrust laws were intended to prevent," for the injury is "attributable to an anti-competitive aspect of the practice under scrutiny." *See West Penn*, 627 F.3d at 101, 105 (citation omitted). *See also Hammes v. AAMCO Transmissions, Inc.*, 33 F.3d 774, 783 (7th Cir. 1994) (Posner, J.) (competitor who "wanted to compete by underselling" incurs antitrust injury).

The fact that Celgene has patents related to Thalomid and Revlimid does not preclude Mylan from alleging plausible antirust injury. *Cf.* Mot. at 36-38. But for Celgene's anticompetitive conduct, Mylan alleges that it would have obtained samples and been able to file ANDAs for generic versions of thalidomide and lenalidomide. Compl. ¶ 165. At that point, after evaluating Mylan's ANDA formulations, Celgene may or may not have had a good faith basis to sue Mylan for patent infringement. In other words, Mylan's ANDA formulations may or may not infringe Celgene's asserted patents, which may or may not be valid. But the *potential* that a Mylan

product *might* infringe a Celgene patent does not negate antitrust injury at the pleading stage; at best, it creates an affirmative defense to Mylan's damages claims at trial.

Indeed, the Supreme Court in *FTC v. Actavis, Inc*. found that the simple fact of a patent does not immunize conduct from antitrust scrutiny. *See* 133 S. Ct. at 2232. While a valid and infringed patent may permit the owner to exclude competitors and charge monopoly prices, "an *invalidated* patent carries with it no such right. . . . [a]nd even a valid patent confers no right to exclude products or processes that do not actually infringe." *Id.* at 2231. At this stage of the litigation, Celgene cannot demonstrate that Mylan's antitrust injury allegations are invalid as a matter of law.

Further, the whole point of the *Bolar* Amendment was to allow bioequivalence testing to occur *before* patent expiration. Compl. ¶ 23; 35 U.S.C. § 271(e)(1); *Eli Lilly*, 496 U.S. at 670. Thus, even if some of Celgene's patents are valid and would be infringed by a generic product, Celgene's conduct injures Mylan (and competition) by making certain that generic entry *cannot* occur upon expiration of those patents, making declaratory and injunctive relief appropriate. *See* Compl. ¶¶ 176-86.

VI. MYLAN SUFFICIENTLY PLEADS ITS STATE LAW CLAIMS

New Jersey Antitrust Act. Mylan has stated a claim under the Sherman Act, and therefore has stated a claim under the New Jersey Antitrust Act. *See* N.J. Stat. Ann § 56:9-18; *Ideal Dairy Farms, Inc. v. Farmland Dairy Farms, Inc.*, 282 N.J. Super 140, 186-187 (App. Div. 1995).

Tortious Interference. Mylan sufficiently alleges wrongful conduct, malice, and a protected interest for its tortious interference claims:

- **Wrongful conduct** includes violations of any law. *See C.R. Bard v. Wordtronics Corp.*, 235 N.J. Super. 168, 174 (Law Div. 1989). By stating a claim for violations of the Sherman Act, Mylan alleges "wrongful conduct."
- **Malice**, or lack of a valid business justification, can be inferred from the use of wrongful means. *See Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1167 (3d Cir. 1993). Mylan alleges that Celgene is motivated by a desire to prevent and delay generic competition, and that it has used illegitimate means to accomplish its goals. Compl. ¶¶ 72, 158, 165-167.
- **A protected interest** exists where there is a reasonable probability that the plaintiff would have received an economic benefit but for the defendant's conduct. *See Printing Mart-Morristown v. Sharp Elecs. Corp.*, 116 N.J. 739, 759 (1989). Mylan alleges that, but for Celgene's interference, it could have sold generic thalidomide and lenalidomide sooner. Compl. ¶ 165, 168.

Unfair Competition. Mylan's tortious interference allegations also support an unfair competition claim. *See Coast Cities Truck Sales, Inc. v. Navistar Int'l Transp. Co.*, 912 F. Supp. 747, 786 (D.N.J. 2005).

CONCLUSION

Celgene's motion to dismiss should be denied.

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Respectfully submitted,

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