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

MYLAN PHARMACEUTICALS INC., Plaintiff, v. CELGENE CORPORATION, Defendant.	Civil Action No. 2:14 cv-02094-ES-MAH Hon. Esther Salas, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J. **RETURN DATE: JULY 7, 2014** **ORAL ARGUMENT REQUESTED**

BRIEF IN SUPPORT OF DEFENDANT CELGENE CORPORATION'S MOTION TO DISMISS

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INTRODUCTION AND SUMMARY OF ARGUMENT

The drugs at the heart of this dispute—thalidomide (Thalomid®) and lenalidomide (Revlimid®, designated by the FDA as a thalidomide analogue)—are both wonderful and daunting. Though Plaintiff Mylan Pharmaceuticals Inc. acknowledges the life-extending benefits these drugs offer to "critically ill patients," (Compl. ¶ 3), it also attempts to obscure their dramatic risks. Specifically, Mylan concedes that the FDA "conditioned approval" of both drugs "on rigorous restrictions on the[ir] distribution," (*id.* ¶¶ 4, 60, 66), but never explains why. Nowhere does Mylan's complaint mention birth defects, not even the dry scientific term teratogenic. Mylan's effort is pointless. Whether through magazines, the FDA website, or Billy Joel's lyrics, it is common knowledge—and subject to judicial notice—that even a single dose of thalidomide can result in fetal death or tragic disfigurement.[1]

When Defendant Celgene Corporation sought approval of Thalomid® to treat the "disfiguring lesions associated with ENL, a complication of . . . leprosy,"

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[1] *See, e.g.*, *The Thalidomide Disaster*, Time (Aug. 10, 1962); Margaret Hamburg, *50 Years After Thalidomide: Why Regulation Matters* (Feb. 7, 2012), http://1.usa.gov/QUDTdC (Exh. A); Billy Joel, *We Didn't Start The Fire*, on Storm Front (Columbia Records 1989); *see generally* Fed. R. Evid. 201(b).

Judicial notice is permissible on a motion to dismiss. *See In re Lipitor Antitrust Litig.*, No. 12-2332, 2013 WL 4780496, at *1 (D.N.J. Sept. 5, 2013) ("On motions to dismiss …[a] court may also properly look at public records, including judicial proceedings, the relevant patents and the patents' prosecution histories.") (citing, *e.g.*, *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d. 244 , 256 n.5 (3d Cir. 2006) and *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410 , 426 (3d Cir. 1999)). All exhibit letters refer to exhibits to the Certification of Kevin McDonald, filed concurrently.

the FDA invoked its restricted distribution regulations for the first time. (*See* Compl. ¶¶ 59-60.) Celgene developed patented methods for selling these drugs while minimizing the risk of fetal exposure. These efforts produced among the earliest examples of programs now known as Risk Evaluation and Mitigation Strategies ("REMS"). Celgene's REMS require the certification, training, and monitoring of the doctors who prescribe these dangerous drugs and the pharmacies who dispense them. The process is rigorous and expensive, but it allows Celgene to track the delivery of every dose of these drugs to every patient.

Here, Mylan claims that Celgene is legally obliged to sell Thalomid® and Revlimid® to Mylan so it can develop generic versions of those drugs, but that Celgene has refused. More precisely, as the complaint's description of the parties' negotiations shows, Mylan alleges that Celgene has refused to sell those products on terms that *Mylan* deems acceptable. Mylan also claims that, without receiving product from Celgene, it is incapable of filing an abbreviated new drug application ("ANDA") seeking FDA approval of generic Thalomid® and Revlimid®.

Mylan makes these assertions, even though it knows (1) Celgene in fact *has* sold Thalomid® to other generics when it received FDA approval to do so and the generics satisfied Celgene's safety, reputational, business, and liability concerns, and (2) at least one ANDA for each drug *has* been filed. Barr Laboratories filed an ANDA referencing Thalomid® in 2006. *See* Compl. at 5, *Celgene Corp. v. Barr*

Labs., Inc., No. 2:07-cv-00286-SDW (D.N.J. filed Jan. 18, 2007) (ECF No. 1).[2] Natco Pharma filed an ANDA referencing Revlimid® in 2010. *See* Compl. at 6, *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197-SDW (D.N.J. filed Oct. 8, 2010) (ECF No. 1). Critically, both ANDAs generated patent suits by Celgene, asserting multiple patents for each drug. Rather than litigate, Barr gave up and withdrew its Thalomid® ANDA. As to Revlimid®, patent litigation is ongoing against Natco, in which Celgene has now asserted 22 patents.

Mylan may wish to ignore the risks associated with Celgene's drugs, and Celgene's patents, but it cannot ignore the antitrust principles that doom its claims:

Sherman Act Section 2*: *No Duty To Deal. The antitrust laws respect and protect the right of a "manufacturer . . . freely to exercise his own independent discretion as to parties with whom he will deal." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). The flaw in this complaint was best described by Judge Diane Wood: "[A] complaint . . . which takes the form 'X is a monopolist, [and] X didn't help its competitors enter the market so that they could challenge its monopoly . . .' does not state a claim under Section 2. The reason is because the antitrust laws do not impose that kind of affirmative duty . . . ." *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 400 (7th Cir. 2000). The Supreme Court's decision in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004), which adopted Judge Wood's reasoning, is fatal to Mylan's monopolization

[2] This Court may take judicial notice of these court proceedings and the fact that the ANDAs were filed. *See Mar. Elec. Co. v. United Jersey Bank*, 959 F.2d 1194, 1200 n.3 (3d Cir. 1991); *see also supra*, 1 n.1.

claims. Thus, even if Celgene's insistence on appropriate procedures and guarantees were not motivated by the safety of fetuses and the survival of its business, antitrust law still would not require it to deal with its potential rivals.

This is an even easier case than *Trinko*. The products that Mylan claims an absolute right to purchase are patented. *Trinko* is thus bolstered by the independent bar to antitrust liability for refusing to sell a patented good. *United States v. Ciba Geigy Corp.*, 508 F. Supp. 1118, 1149-51 (D.N.J. 1976). As explained below, moreover, a sale to a generic seeking to file an ANDA portends for Celgene (1) the expense of protracted patent litigation when the ANDA is filed, and (2) exposure to products liability in those states that purport to hold the *branded* drug maker liable for defects in the *generic* product. Celgene has no antitrust duty to bear such risks on terms Mylan finds suitable. (*See* Part I, below.)

Sherman Act Section 1: No Causation/No Concerted Action. Aware that its monopolization theory is weak, Mylan brings several counts under Section 1. Mylan alleges that its inability to obtain the drugs from Celgene's distributors establishes a concerted refusal to deal. But these claims are doubly flawed. First, while the REMS requirements for both drugs do not prevent Celgene from selling directly to generics (with FDA permission), the REMS restrictions plainly do bar sales to Mylan by distributors. Thus, Mylan cannot plead causation because its inability to buy the drugs from Celgene's distributors, as opposed to Celgene itself, flows from the FDA-mandated REMS. *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998). Second, the Third Circuit has made clear that Celgene's distributors, who are not alleged to have any discretion in selling only to

authorized purchasers, nor any competitive interest in Mylan's exclusion from the market, are incapable of concerted action under Section 1. *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1135 (3d Cir. 1995). (*See* Part II, below.)

Thalomid®: Statute of Limitations. Mylan faces a dilemma. Unless it pleads that Celgene refused to deal, it has no antitrust claim. If it makes that claim as to Thalomid®, it must place the refusal outside the 4-year statute of limitations. It has chosen the latter. Mylan alleges that it "recognized" that Celgene's June 2009 information request constituted a complete refusal to supply Thalomid®, thus "end[ing]" Mylan's attempt to obtain Thalomid®. (Compl. ¶ 132.) There is no allegation of any conduct related to Thalomid® during the limitations period. The antitrust counts related to Thalomid® are thus time-barred. (*See* Part III, below.)

All Antitrust Claims: Market Definition. Mylan alleges that each drug constitutes an independent, single-product market. That is, Mylan contends that Revlimid® and Thalomid® have no competitors whatsoever, including each other. But the complaint lacks any factual allegations sufficient to justify the inference that such single-product markets are plausible. All of the antitrust claims should be dismissed for failure to allege a relevant market. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436-37 (3d Cir. 1997). (*See* Part IV, below.)

All Antitrust Claims: No Injury to Lawful Competition. Finally, Mylan's attempt to ignore the array of patents on both drugs cannot succeed. These patents are listed in the Orange Book and subject to judicial notice.[3] They include patents

[3] *See* http://1.usa.gov/1jV9xn4 at 1058-60, 1154-55 (Exh. B); *see also Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 (3d Cir. 2004) (taking judicial

covering the basic Revlimid® compound; composition of matter and method of use patents for Thalomid® and Revlimid®; and patents on Celgene's REMS. Mylan has not, and indeed, *cannot* allege that it will defeat these presumptively valid patents in court. *Whitmore v.Arkansas*, 495 U.S. 149, 159-60 (1990).("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.") It has been established for more than a century that the antitrust laws do not protect infringing competition. A plaintiff alleging exclusion must therefore allege that it was ready, willing, *and legally able* to enter. Mylan has not done so, and thus cannot plead antitrust injury. (*See* Part V, below.)

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All of Mylan's claims are based on a false premise: that because (in Mylan's view) the Hatch-Waxman Act seeks to favor generic entry, the antitrust laws somehow obligate Celgene to make that entry as easy as possible. But the message of *Trinko* is that any advantages generics receive from other laws do not by their existence amend the *antitrust* laws, which benefit "competition, not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977).

> The fundamental fallacy in the plaintiffs' theory is that the duties [other laws] impose[] . . . are coterminous with the duty of a monopolist to refrain from exclusionary practices. They are not. . . . [A]ffirmative duties to help one's competitors . . . do not exist under

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notice of records available on the PTO website); *Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1167 (9th Cir. 2012) (taking judicial notice of records maintained on FDA's website); *Fellner v. Tri-Union Seafoods, L.L.C.* No. 06-0688, 2010 WL 1490927, at *6 n.8 (D.N.J. Apr. 13, 2010) (same); *see generally supra*, 1 n.1.

the unadorned antitrust laws.

Goldwasser, 222 F.3d at 399-400. Mylan's complaint should be dismissed.

STATEMENT OF FACTS

The early history of thalidomide is well-known and tragic. Sold in the 1950s as a treatment for morning sickness, thalidomide was never approved in the United States because of safety concerns. (*See* Compl. ¶ 58.) The concerns were well-founded. Exposure to even small doses of thalidomide can cause severe fetal deformities and even death. (*See* Exh. C at 4 (FDA label for Thalomid®).)[4]

Approval of Thalomid®. In the 1990s, Celgene submitted a New Drug Application to the FDA seeking approval of thalidomide to treat "the debilitating and disfiguring lesions of ENL, a complication of . . . leprosy." (Compl. ¶ 59.) The FDA's review of Celgene's application was atypical. The agency sponsored numerous workshops involving the National Institutes of Health, thalidomide victims associations, and others. When the FDA ultimately approved Thalomid® in July 1998, it invoked its regulations governing restricted distribution, 21 C.F.R. § 314.520, for the first time. (*Cf.* Compl. ¶ 29.) The FDA "conditioned" its approval "on rigorous restrictions on the distribution of thalidomide to prevent it from being prescribed or taken improperly." (*Id.* ¶ 60.)

Distribution Restrictions. Celgene adopted the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S."), a first-of-its-kind restricted distribution program aimed at achieving zero fetal exposure to Thalomid®. (Compl. ¶ 4.) When the 2007 Food and Drug Administration Amendments Act

[4] *See* http://1.usa.gov/1jV8jIv; *see also supra* 1n.1, 5 n.3.

gave the FDA statutory authority to condition the approval of drug applications on the adoption of acceptable safety protocols, called Risk Evaluation and Mitigation Strategies, the FDA deemed S.T.E.P.S. to be an approved REMS. (*Id.*)

Celgene's Thalomid® REMS protocol, now on the FDA's website (Exh. D),[5] imposes numerous restrictions on healthcare providers, pharmacies, and Celgene:

- **Healthcare providers** must be specially trained and certified. To become certified, the doctors must agree to: (a) counsel patients regarding the risks of Thalomid®, (b) submit to Celgene a Physician-Patient Agreement Form whereby the patient acknowledges the risks of severe birth defects and fetal death and agrees to return unused drugs to Celgene or their doctor, (c) administer a pregnancy test and provide contraception to the patient, and (d) complete a survey designed to look for signals of at-risk behavior (*e.g.,* pending or outdated pregnancy test), report the patient's pregnancy test results, assign an appropriate risk category, and confirm or re-enforce patient understanding of contraceptive requirements. **Only once all these steps are completed will the doctor be provided with a unique authorization number necessary for a pharmacy to fill a prescription.**

- **Pharmacies** must be certified. To become certified, a pharmacy must agree to: (a) accept only prescriptions with a unique authorization number, (b) obtain another unique confirmation code from Celgene, (c) complete a checklist regarding the patient's risk category, (d) counsel patients regarding the risks of Thalomid®, (e) dispense no more than a 28-day supply with no refills, and (f) accept unused Thalomid® from a patient and return to Celgene.

- **Celgene** is responsible for ensuring that healthcare providers and pharmacies meet the above requirements. Celgene must also maintain a secure database of all certified doctors, and ensure that only certified doctors prescribe thalidomide. Likewise, Celgene must monitor and ensure that all patients are properly assigned to an appropriate risk category (based on the likelihood of fetal exposure). Finally, Celgene must conduct real time monitoring of pharmacy dispensing activity and also conduct audits, and periodically report on the effectiveness of its REMS to the FDA.

[5] *See* http://1.usa.gov/RLxxxL; *see also supra* 1 n.1, 5 n.3.

(Exh. D.) In short, Celgene is responsible for safety at every step of distribution.

Celgene's Continued Investment. In addition to bearing the costs of its REMS program, Celgene continued to invest in Thalomid® research. (Compl. ¶ 65.) The use of Thalomid® in these clinical studies is entirely consistent with the Thalomid® REMS program, including training HCP personnel, testing patients, and tracking drugs. (Exh. D.) Following clinical studies, the FDA approved Thalomid® in 2006 to treat multiple myeloma in combination with dexamethasone. (*Id.* ¶ 61.) Celgene patented this method of using thalidomide, and also holds patents on Thalomid®'s composition and the Thalomid® REMS protocol. *See supra* 5 n.3. The last of these patents will expire in 2023.

Other Generic Companies' Requests. Notwithstanding these patents, and the FDA-mandated distribution restrictions, various generic companies have requested samples of Thalomid® to conduct bioequivalency testing. Bioequivalency testing is necessary to file an ANDA, which permits the applicant to rely on the clinical studies performed by the sponsor of the brand name drug and thus reduces the cost of obtaining FDA approval. (Compl. ¶¶ 6, 24.)

To date, Celgene is aware of one generic company that has submitted an ANDA for Thalomid®, Barr Laboratories Inc. Because Barr certified that Celgene's Thalomid® patents were not valid or not infringed, Celgene sued for patent infringement. *See Barr Labs*, No. 2:07-cv-00286-SDW (D.N.J.). Celgene dismissed this suit after Barr withdrew its ANDA. *Id.*, at ECF No. 160.

Like Mylan, Lannett Company requested that Celgene provide samples of Thalomid® for bioequivalency testing. When Celgene insisted on satisfaction of

its safety, regulatory, reputational, business, and liability concerns before agreeing, Lannett filed suit. *See* Compl., *Lannett Co. v. Celgene Corp.*, No. 08-3920 (E.D. Pa. filed Aug. 15, 2008) (ECF No. 1). That suit was settled, and Lannett has announced that it has completed bioequivalency testing. *See, e.g.*, Lannett Co., *Lannett Provides Product Development Update on Thalidomide Capsules* (Oct. 8, 2013), http://bit.ly/lannett-press-release (Exh. E).

Mylan's Request. Mylan "began efforts to develop a generic equivalent to . . . Thalomid" in 2003. (Compl. ¶ 73.) After failing to obtain Thalomid® from distributors, Mylan requested samples from Celgene. (*Id.* ¶ 75.) Celgene responded that it was willing to sell Thalomid® to Mylan, but correctly stated that it needed the FDA's approval in light of the distribution restrictions in Celgene's REMS. (*Id.* ¶ 79.) In response, the FDA promised to "exercise its enforcement discretion to permit Celgene to provide" Mylan with samples, but only after Mylan provided "sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects." (*Id.* ¶ 83.) Mylan submitted study protocols on May 1, 2007. (*Id.* ¶ 84.) On September 11, 2007, the FDA told Mylan that its protocols were "acceptable," but would require implementation of additional elements "that Mylan would need to follow." (*Id.* ¶ 86.)

Celgene requested additional information from Mylan to assure itself that the product would be handled, and the studies conducted, in a manner that would not only prevent fetal exposures, but also minimize the risk to Celgene's reputation and business, including its exposure to products liability suits or the potential withdrawal of FDA approval in the event of fetal exposure. (Compl. ¶¶ 90-101.)

For example, Celgene asked Mylan to produce its procedures for storing and using hazardous substances (such as Thalomid®); its history of compliance with FDA safety requirements; and its liability insurance coverage. (*Id.* ¶¶ 96-99.)

Mylan claims to have produced the information Celgene requested. (Compl. ¶¶ 107, 121.) But when Celgene asked for clarification and follow-up information regarding "Mylan's protocols for thalidomide bioequivalence testing . . . [and] insurance coverage," Mylan balked. (*Id.* ¶ 124.) Mylan determined that "further engagement with Celgene would be fruitless" and chose not to provide any of the requested information to Celgene. (*Id.* ¶ 128.) Mylan does not allege any conduct regarding Thalomid® from 2009 until filing this lawsuit.

Revlimid®. Celgene discovered lenalidomide, developed it, and received FDA approval in 2005. (Compl. ¶ 66.) Celgene holds patents on Revlimid®'s chemical compound, its crystalline forms, methods of use, and aspects of its REMS programs. *See supra* 5 n.3. The last of these patents expires in 2027.

Revlimid® is approved for the treatment of a subset of multiple myeloma, myelodysplastic syndrome, and mantle cell lymphoma patients. (Compl. ¶ 47.) Like Thalomid®, "lenalidomide . . . may cause birth defects or embryo-fetal death." (Exh. F.)[6] Accordingly, "the FDA conditioned approval [of Revlimid®] on distribution . . . to prevent it from being prescribed or taken improperly." (Compl. ¶ 66.) The Revlimid® REMS program contains functionally similar requirements to the Thalomid® REMS. (Exh. G.)[7] As with Thalomid®, clinical studies

[6] *See* http://1.usa.gov/TINp5X; *see also supra* 1 n.1, 5 n.3.

[7] *See* http://1.usa.gov/1oCsgXa; *see also supra* 1 n.1, 5 n.3.

involving Revlimid® require participants to qualify through the REMS program. As the website on which Mylan expressly relies states: "Per standard Revlimid REMS® program requirements, all physicians who prescribe lenalidomide for research subjects enrolled into this trial, and all research subjects enrolled into this trial, must be registered in, and must comply with, all requirements of the Revlimid REMS® program." *See* http://clinicaltrials.gov/ct2/search (search Revlimid® REMS) (cited in Compl. ¶ 65 n.9).

Celgene is aware of one generic that submitted an ANDA for Revlimid®, Natco Pharma. Because Natco certified that Celgene's Revlimid® patents were invalid or not infringed, Celgene sued for infringement. *See Natco Pharma Ltd.*, No. 2:10-cv-05197-SDW (D.N.J.). This case is pending, but Natco has never contested its infringement of the Revlimid® compound patent, and Natco has stipulated to infringement of certain REMS patents. *Id.*, at ECF No. 305.

In 2009, Mylan began unspecified "efforts to develop a generic equivalent" to Revlimid®. (Compl. ¶¶ 130-31.) Three years later, Mylan submitted safety protocols for its proposed bioequivalency study to the FDA. (*Id.* ¶¶ 134-135.) The agency twice requested additional documentation and required implementation of additional elements. (*Id.* ¶¶ 136, 141.) The FDA ultimately determined that "the protocols submitted by Mylan were 'adequate,'" (*id.* ¶ 142), and Mylan notified the FDA that it could inform Celgene of its decision in January 2014. (*Id.* ¶ 149.)

On March 11, 2014, Mylan informed Celgene of the FDA's determination, demanded the product, and acknowledged Celgene's demand for indemnity due to products liability exposure by proposing indemnity terms "agreeable to Mylan."

(Compl. ¶¶ 150-151.) Nine days later, Celgene reiterated its need for missing information relevant to safety and liability concerns. (*Id.* ¶¶ 152-56.) Mylan chose not to provide any additional information, including basic information about its liability insurance coverage, but instead filed this suit.

LEGAL STANDARD

Rule 12(b)(6) requires dismissal of claims where the supporting allegations are not "plausible" and fail to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). Given the high costs of antitrust discovery, "something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up [discovery] . . . ., with the right to do so representing an *in terrorem* increment of the settlement value." *Id.* at 557-58 (quotation marks and citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court should give no weight to "legal conclusions" or to "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* Likewise, the Court need not credit "conflicting pleadings that make no sense, or that would render a claim incoherent, or that are contradicted either by statements in the complaint itself or by documents upon which its pleadings rely, *or by facts of which the Court make take judicial notice*." *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2001) (emphasis added).

ARGUMENT

I. SECTION 2 DOES NOT IMPOSE AN AFFIRMATIVE DUTY ON CELGENE TO ASSIST ITS POTENTIAL RIVALS

A. Longstanding Antitrust Law Rejects An Affirmative Duty To Deal Absent Both Prior Dealings And Irrational Profit Sacrifice

Celgene has no antitrust duty to sell its drugs to Mylan. The Sherman "[A]ct does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." *Colgate*, 250 U.S. at 307. This core principle of antitrust law recognizes the difference between concerted and unilateral action. *See Trinko*, 540 U.S. at 410 n.3. "It is not enough that a single firm appears to 'restrain trade' unreasonably, for even a vigorous competitor may leave that impression." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 767 (1984). Thus, the Supreme Court and Courts of Appeal have repeatedly reaffirmed that even monopolists have no general affirmative duty to deal with rivals.[8]

Trinko applied this long-standing rule to "conclude that Verizon's alleged insufficient assistance . . . to rivals is not a recognized antitrust claim under this Court's existing refusal-to-deal precedents." 540 U.S. at 410. The same is true here. Celgene's alleged refusal to provide samples of its drugs is not a recognized antitrust claim. Indeed, Mylan does not even allege that Celgene *refused* to sell its

[8] *See, e.g.*, *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984) (A "business . . . has a right to deal, or refuse to deal, with whomever it likes, as long as it does so independently."); *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1069 (3d Cir. 1979) ("We seriously doubt that an arbitrary or discriminatory unilateral refusal to deal by a lawful monopolist is actionable . . . .").

drugs, only that Celgene sought "overbroad" and "unduly burdensome" information prior to agreeing to sell. (*E.g.*, Compl. ¶ 126.) Thus, this case is even more like *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, where the Supreme Court held that "a firm [with] no antitrust duty to deal with its competitors . . . certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous." 555 U.S. 438, 450 (2009).

Indeed, the Supreme Court's repeated rejection of an antitrust duty to deal is especially relevant here, given Celgene's Thalomid® and Revlimid® patents. "Compelling . . . firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist . . . to invest in those economically beneficial facilities." *Trinko*, 540 U.S. at 407-08. The Supreme Court, the Federal Circuit, and this Court have all rejected any antitrust doctrine that would require a patentee to forfeit its statutory right to exclude, including in the pharmaceutical antitrust context.[9]

In contrast, *Trinko* was a closer case. There, it was undisputed that—as Mylan alleges with respect to the REMS statute (discussed below)—Verizon violated the federal communications statute by failing to provide rivals access to its systems. 540 U.S. at 406-08. But *Trinko* rejected the argument that any such statutory violation created a new duty to deal under the antitrust laws. *Id.* at 406.

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[9] *See* 35 U.S.C. § 154; *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902) ("An owner of a patent has the right to sell it *or to keep it* . . . ." (emphasis added)); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000) ("Xerox was under no obligation to sell or license its patented parts and did not violate the antitrust laws by refusing to do so."); *Ciba Geigy*, 508 F. Supp. at 1149-51 ("CIBA was free to refuse to sell HCT to any other company.").

To the contrary, as the Court reiterated in *Linkline*, "the defendant has no antitrust duty to deal with its rivals at wholesale; any such duty arises only from FCC regulations, not from the Sherman Act." *Linkline*, 555 U.S. at 450.

Trinko also explained that the rare exception to the rule against finding an affirmative duty to deal found in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), was "at or near the outer boundary of § 2 liability." *Trinko*, 540 U.S. at 409. In *Aspen*, the alleged monopolist had (1) terminated a long-running, prior course of dealing with its rival, and (2) sacrificed short-run profits (by refusing to sell to the rival at retail) that could only be recouped by the elimination of the rival from the market. *See id.* (describing *Aspen*).

Subsequent cases in this Circuit and elsewhere confirm that both prior dealings and profit sacrifice are necessary to allege a duty to deal. "The unilateral-monopolization claims . . . do not fall within the sole exception to the right of refusal to deal: the complaint does not allege . . . a prior relationship . . . ." *In re Elevator Antitrust Litig.*, 502 F.3d 47, 54 (2d Cir. 2007); *see also, e.g.*, *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 316 (3d Cir. 2007); *Only v. Ascent Media Group, LLC*, No. 06-2123, 2006 WL 2865492, at *4 n.7 (D.N.J. Oct. 5, 2006).

Neither factor is present here. Specifically, while Mylan claims that Celgene has sold its product at retail to distributors and consumers, Mylan nowhere claims that Celgene terminated a prior course of dealing "with its rivals," as required by *Trinko*, 540 U.S. at 409; *see also, e.g.*, *Miniframe Ltd. v. Microsoft Corp.*, No. 11-7419, 2013 WL 1385704, at *5 (S.D.N.Y. Mar. 28, 2013) ("[A] prior course of dealing between an alleged monopolist and its end users is not equivalent to the

monopolist's prior cooperation with a rival.").

Nor has Mylan alleged that Celgene irrationally sacrificed profit. If refusing retail sales were sufficient to plead a duty to deal, the *Colgate* doctrine would be gutted. Moreover, Celgene's retail price *for consumers* reflects the costs and risks for sales *within Celgene's REMS programs*. Sales to generics pose additional risks, as Mylan's complaint implicitly concedes. First, ingestion of these two teratogenic drugs by unknown, healthy subjects entails risk of fetal exposure, which is why Mylan discusses its safety measures at length. (*E.g.*, Compl. ¶¶ 84, 135.) But Celgene need not accept others' conclusions that the these measures are adequate.

Second, Celgene would face increased exposure to products liability suits for sales to generic ANDA filers. Some courts have accepted the notion that a branded drug manufacturer may be liable for injuries caused by *the generic drug* it did not sell.[10] Far from denying that these risks exist in any sale to Celgene's potential rivals, Mylan makes lengthy allegations regarding its willingness to indemnify Celgene. (Compl. ¶¶ 108-112.) But Celgene is not required to accept these risks even with indemnification.

Third, any adverse event related either to these sales, and any subsequent

[10] *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008) (branded manufacturers liable for injuries caused by generics); *see also, e.g.*, *Dolin v. SmithKline Beecham Corp.*, No. 1:12-cv-06403, slip op. (N.D. Ill. Feb. 28, 2014); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010). That risk is underscored by Supreme Court decisions finding that certain state tort claims against branded drug companies are *not* preempted , while similar claims against generic drug companies *are* preempted. *Compare Wyeth v. Levine*, 555 U.S. 555 (2009) *with PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

generic sales, may injure Celgene's business reputation, and could lead to the loss of its entire market if the FDA forces withdrawal of the drugs after an adverse event. Thus, an Attorney Advisor to the FTC concluded with respect to thalidomide that "it is easy to imagine [Celgene] reasonably opting to forgo the relatively small profits earned from the sale of samples of REMS restricted drugs in order to . . . limit the likelihood that the drug is used or misused in a way that causes harm." Jan M. Rybnicek, *When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies*, Comp. Policy Int'l, Apr. 2014, at 2.

Finally, Celgene knows that any sale to a generic filing an ANDA will likely lead to protracted and expensive patent litigation. To enter prior to 2023 (for Thalomid®) or 2027 (for Revlimid®), Mylan must certify that the patents are invalid or not infringed. Celgene has sued every ANDA filer to date who has done so, and the complaint alleges no fact to indicate that Mylan's generic would be different. Nor could it. The compound patent on Revlimid® alone claims the drug's active ingredient, which any generic must contain by law. (Compl. ¶ 25.)

In sum, neither of the two prerequisites for an antitrust duty to deal are present here. Celgene had never previously sold its drugs to Mylan. As for "irrationally" bypassing a retail sale, Mylan does not and cannot dispute that Celgene's sale of product to Mylan entails significant risks (*e.g.*, products liability) and potential expenses (*e.g.*, patent litigation) that Celgene's other "retail" sales to patients do not. Mylan cannot argue that Celgene had no basis in efficiency to deny Mylan's request. Celgene had no duty to deal with its rival.

B. No Exception To The General Rule Against Affirmative Antitrust Duties Can Apply To Save Mylan's Claims

Unable to meet the *Trinko* standard, Mylan attempts to create a duty to deal under two different theories. Both fail.

Essential Facilities. The so-called essential facilities doctrine did not change the result in *Trinko*, nor can it here.[11] Mylan's alleged need for Celgene's drugs to file an ANDA is no greater than the local carrier's need for network access in *Trinko*, yet *Trinko* rejected the essential facilities claim. 540 U.S. at 411.

Even if the doctrine has any separate meaning after *Trinko*, it has never applied to patented goods. "To find a patent an 'essential facility' . . . would subvert the plain meaning and purpose of the Patent Act." *SolidFX, LLC*, 935 F. Supp. 2d at 1083 (citation omitted)).[12] Celgene's patents covering Thalomid® and

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[11] *Trinko* disparaged the doctrine as being "crafted by some lower courts" but "never recognized" by the Supreme Court. 540 U.S. at 410-411. Thus, courts, enforcers, and commentators have all questioned the doctrine's vitality. *See, e.g.*, *SolidFX, LLC v. Jeppesen Sanderson, Inc.*, 935 F. Supp. 2d 1069, 1083 (D. Colo. 2013); U.S. Dep't of Justice, *Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act* 175 (2008) ("The Department agrees that the essential-facilities doctrine is a flawed means of deciding whether a unilateral, unconditional refusal to deal harms competition."); IIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 772d3 (3d ed. 2005) ("One is hard-pressed to see any separate vitality remaining in the essential facility doctrine.").

[12] *See also, e.g.*, *Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186, 190 (2d Cir. 2012) ("[Section] 2 does not obligate RIM to share its patented platform technology, from which RIM derives the lawful power to exclude others' use."); *Applera Corp. v. MJ Research, Inc.*, 349 F. Supp. 2d 338 , 348 (D. Conn. 2004) (quoted in *SolidFX*); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 761 F. Supp. 185, 192 (D. Mass. 1991) ("If manufacturers of complex and innovative systems were required to share with competitors . . . because they had a possibly absolute advantage through producing the system, the incentives of copyright and patent laws would be severely undermined.").

Revlimid® thus doom Mylan's essential facilities argument.

In any event, Mylan cannot show that Celgene's drugs are "essential." To be essential, a facility must be "vital to the claimant's competitive viability." *Monarch Entm't Bur. v. N.J. Highway Auth.*, 715 F. Supp. 1290, 1300 (D.N.J. 1990). Where there are alternative means of competing, a facility is not essential. Here, Mylan could bring a competing product to market by filing a NDA or a § 505(b)(2) application. To be sure, these routes are more costly than an ANDA. But that is not relevant to the essential facilities analysis. "[T]he most economical route is not an essential facility when other routes are available." *Midw. Gas Servs., Inc. v. Ind. Gas. Co.*, 317 F.3d 703, 714 (7th Cir. 2003).[13] Indeed, Mylan provides no reason why an NDA is cost-efficient for Celgene, but not for itself. *See Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 530 (5th Cir. 1999) (costs faced by monopolist are not barriers when faced by new entrants).

Likewise, Mylan cannot show that Celgene's drugs are a "facility." A facility must be used to leverage monopoly power into a downstream market. *See, e.g.*, *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990) ("[T]he central concern in an essential facilities claim is whether market power in one market is being used to create or further a monopoly in another market."); *The Interface Grp. v. Mass. Port Auth.*, 816 F.2d 9, 12 (1st Cir. 1987) (Breyer, J.) ("The doctrine aims to prevent a firm with monopoly power

[13] *See also, e.g.*, *Monarch*, 715 F. Supp. at 1301 n.2 (potential of building alternative at cost of $20,000,000 precludes essential facilities claim); *Cyber Promotions, Inc. v. America Online, Inc.*, 948 F. Supp. 456, 464 (E.D. Pa. 1996) (cost of building competing network not relevant).

from extending that power 'from one stage of production to another, and from one market into another.'" (citation omitted)). Thus, the seminal cases applying the doctrine concern natural monopolies controlling access to secondary markets.[14] Nothing of the kind is alleged here. The doctrine has never been applied to make an essential facility of the very product the defendant sells.

Finally, even if Mylan had alleged every other element of an essential facilities claim, it has not shown that Celgene's safety, reputational, regulatory, business, and liability concerns do not exist. Mylan cannot allege that the products liability law of California does not exist, nor can it deny that Celgene's reputation and business may be injured by every mistake that Mylan makes. As a result, Mylan's conclusory allegation regarding the feasibility of a sale on *Mylan's* terms, (*e.g.*, Compl. ¶ 232), need not be credited. *City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1380 (9th Cir. 1992) (feasibility element of essential facilities claim raises "the familiar question of whether there is a legitimate business justification for the refusal to provide the facility"); *see Cyber Promotions*, 948 F. Supp. at 464 (reputational concerns sufficient to demonstrate infeasibility).

REMS Statute. Mylan's reliance on 21 U.S.C. § 355-1(f)(8) fares no better. As explained below, that statute does not mean what Mylan claims and does not apply to Celgene's actions. But even if it did (and was violated), such a hypothetical violation of the REMS statute would parallel *Trinko*, where a

[14] *United States v. Terminal R.R. Ass'n*, 224 U.S. 383 (1912) (bridge controlling access to passenger market); *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973) (transmission lines controlling access to distribution market).

violation of the duty to cooperate with competitors under communications law was stipulated. That violation still did not amend the antitrust laws to create a new duty to deal. *Trinko*, 540 U.S. at 415-16.

Nor can the REMS statute mean that Celgene had a duty to provide samples to Mylan. Congress twice considered, and rejected, provisions that would have imposed that exact duty. *See* H.R. 2900, 110th Cong. § 901 (2007); *cf.* S. 3187, 112th Cong. § 1331 (2012). This Court should not substitute its judgment for that of Congress. *Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended.").[15]

In any event, Mylan fails to allege that Celgene "used" its REMS. Celgene has never claimed that its REMS prevents it from selling to Mylan. As explained above, Celgene has its own reasons for insisting that its safety, reputational, regulatory, business, and liability concerns be satisfied. Celgene's terms are separate and apart from Celgene's REMS. When other generics have met Celgene's terms, Celgene has provided samples to them, notwithstanding the REMS. In brief, Celgene is not using its REMS to "block" Mylan's ANDA at all.

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No doubt Mylan will try to avoid all the precedent above by pointing out that two district courts have denied motions to dismiss in similar situations. One court denied a motion to dismiss in a one sentence order without hearing, despite

[15] The FDA has the power to enforce 21 U.S.C. § 355-1(f)(8) through monetary penalties. *See* Rybnicek, *supra*, at 4 (citing 21 U.S.C. § 333(f)(4)(A)).

promising to conduct arguments. *See* Tr. at 171, *Lannett*, No. 08-3920 (E.D. Pa. July 7, 2010) (ECF No. 48) ("I'm not going to decide it without giving you an opportunity to be heard."). The other court simply deferred ruling on the merits, without deciding whether the antitrust plaintiffs stated a claim. *See* Tr. at 117, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013) ("That's a decision I need not make and do not reach here. The question, sole question, is whether or not discovery should proceed . . . ."). Neither decision is binding. More importantly, because the *Lannett* and *Actelion* courts acted without written opinion, neither has the power to persuade.

The fundamental point is that no court—not even *Lannett* and *Actelion*—has compelled the sale of a patented prescription drug whose distribution is restricted for safety reasons. Mylan's error lies in assuming that any advantages the Hatch-Waxman Act gives to generics "are coterminous with the duty of a monopolist to refrain from exclusionary practices. They are not." *Goldwasser*, 222 F.3d at 399. Mylan's Section 2 claims should be dismissed.

II. MYLAN'S SECTION 1 CLAIMS FAIL TO PLEAD CAUSATION AND CONCERTED ACTION

Section 1 of the Sherman Act prohibits "[e]very contract, combination . . ., or conspiracy, in restraint of trade." 15 U.S.C. § 1. Section 1's core concern is with agreements that "deprive[] the marketplace of independent centers of decision-making that competition assumes and demands." *Copperweld Corp.*, 467 U.S. at 769. Mylan's Section 1 claims fail for two independent reasons. The complaint fails to allege both causation and concerted activity, which are threshold

requirements for Section 1 liability. Counts Five, Six, and Seven therefore fail.

A. The Distribution Agreements Did Not Cause Mylan's Injury

As noted, Celgene has sold its drugs directly to generic companies (with the consent of the FDA and after Celgene's safety, reputational, business, and liability concerns have been satisfied). But the decision to sell was and is Celgene's alone. The complaint contains no allegation that Celgene's distributors participated in or were even aware of Celgene's alleged refusal to sell samples directly to Mylan.

In its Section 1 counts, however, Mylan complains of its inability to obtain the drugs not from Celgene directly, but rather indirectly from the pharmacies and wholesalers participating in Celgene's restricted distribution plan. Mylan thus alleges a conspiracy based on Celgene's agreement with its wholesale distributors and specialty pharmacies that they will "limit distribution of [Thalomid® and Revlimid®] to only those entities Celgene permits under its [REMS] program[s]," (Compl. ¶¶ 262, 275), and "not to sell its retail products to 'unapproved' buyers," (*id.* ¶ 160). But Mylan's complaint also concedes that these restrictions are "FDA imposed." (*Id.* ¶ 4 (asserting that Celgene's distributors carry out the "FDA imposed rigorous restrictions on the distribution of Thalomid and Revlimid" contained in the REMS programs).) It is the REMS programs themselves that require the drugs to be prescribed and distributed in a closely controlled manner. (*See* Exhs. D, G.) The complaint thus acknowledges that the distributor agreements impose no greater restriction on the wholesalers' and pharmacies' ability to sell the drugs to Mylan than the FDA-mandated REMS programs themselves.

The Section 1 claims thus fail for lack of causation: "The presence of the regulatory scheme. . . cuts the causal chain and converts what might have been deemed antitrust injury . . . into only a speculative exercise." *City of Pittsburgh*, 147 F.3d at 267-68; s*ee also, e.g.*, *RSA Media, Inc. v. AK Media Group*, 260 F.3d 10, 15 (1st Cir. 2001) (no antitrust injury where plaintiff "was excluded because of the Massachusetts regulatory scheme"). Mylan does not contend that it is an authorized purchaser of either drug under the applicable REMS. In the absence of any allegations that the distribution agreements imposed greater restrictions than the regulatory scheme, Mylan's Section 1 allegations fail to plead causation.

B. Mylan Fails To Allege Concerted Action

Mylan does not claim that Celgene's pharmacies or wholesalers have any competitive interest in excluding Mylan, nor discretion in selling only to authorized purchasers. That is fatal to the Section 1 claims.

Because Section 1 proscribes only concerted action, a "unity of purpose or a common design and understanding or a meeting of minds in an *unlawful arrangement* must exist to trigger section 1 liability." *Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 999 (3d Cir. 1994) (citations omitted and emphasis added). Simple agreements with an agent or servicing entity that has no competitive interest either in the market or in harming the plaintiff "do not suddenly bring together economic power that was previously pursuing divergent goals." *Copperweld Corp.*, 467 U. S. at 769. The Third Circuit and others have thus declined to extend Section 1 to "agreements facilitating a restraint of trade when a party has simply entered into a permissible contract with the defendant or

when the defendant has enforced a contractual right . . . ." *Harold Friedman, Inc. v. Kroger Co.*, 581 F.2d 1068, 1078 (3d Cir. 1978).

The rule that concerted action does not exist simply because two businesses enter a contract derives from the "traditional rule" that agents and principals cannot conspire. *Nurse Midwifery Assocs. v. Hibbett*, 918 F.2d 605, 615 (6th Cir. 1990). Whether or not formally agents, servicing entities will "be treated as agents … for antitrust purposes" when the relationship does not implicate Section 1 concerns. *Id.* at 613; *N. Am. Produce Corp. v. Nick Penachio Co.*, 705 F. Supp. 746, 750 (E.D.N.Y. 1988) ("[A]lthough the contract provides that plaintiff is an independent contractor, this is not dispositive. [The alleged conspirator] may be an independent businessman, but for antitrust purposes, it may be an agent.").[16] Where, as here, the agent has no independent interest in reducing competition, it cannot conspire under Section 1.

Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125 (3d Cir. 1995), is directly on point. There, Siegel alleged that Carrier Express had conspired with its non-exclusive sales agents and an independent management company (Oak Management) to exclude Siegel from the market. The court refused to find a conspiracy under Section 1 merely because Oak Management was "[c]ontractually obligated to manage Carrier Express affairs." *Id.* at 1135. The court pointed out

[16] *See generally Daimler AG v. Bauman*, 134 S. Ct. 746, 759 (2014) ("Agencies, we note, come in many sizes and shapes: 'One may be an agent for some business purposes and not others so that the fact that one may be an agent for one purpose does not make him or her an agent for every purpose.' 2A C. J. S., Agency §43, p. 367 (2013) (footnote omitted).").

that "Oak Management did not compete with Carrier Express," nor did it have an independent reason to inflict competitive harm on the plaintiff. *Id.* Thus, the two entities "could not conspire . . . under section 1." *Id.* Likewise, in *Friedman*, the Third Circuit applied the same rule to reject a claim of conspiracy between a grocery store and the company it hired to remove equipment from a property its competitor sought to lease. There, as here, the plaintiff did not even allege that "the party combining with the defendant [had] knowledge of the defendant's anticompetitive purpose." *Friedman*, 581 F.2d at 1074.

So, here, Mylan does not allege that the pharmacies or wholesalers are competitors in either alleged market; nor that they had any independent reason to harm competition; nor that they were even aware of Celgene's allegedly anticompetitive purpose. The complaint merely alleges that the distributors and pharmacies entered into contracts that limited distribution to purchasers authorized by the FDA-imposed REMS program. (*See, e.g.*, Compl. ¶¶ 160, 275.) Such an agreement is insufficient to sustain a Section 1 claim.

III. THE ALLEGED REFUSAL TO SELL THALOMID® SAMPLES IN 2009 IS BARRED BY THE STATUTE OF LIMITATIONS

The complaint asserts "counts" of three types: those based on the alleged refusal to supply Thalomid® alone, those based on the refusal to supply Revlimid® alone, and those based on the alleged refusal to supply both drugs. Because all alleged conduct affecting Thalomid® occurred more than 4 years ago,

all antitrust claims based on Thalomid® should be dismissed.[17]

All private antitrust actions must be commenced within 4 years after the cause of action is created. 15 U.S.C. § 15b. The statute of limitations runs when the plaintiff allegedly becomes injured by the defendant. *Rotella v. Wood*, 528 U.S. 549, 555, 557 (2000) (explaining that the "Clayton Act's injury-focused accrual rule was well established" when RICO was enacted); *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997) (same).

Mylan's complaint could not be more clear that the last conduct or event of any kind relevant to its Thalomid® request occurred in 2009. The last referenced correspondence was Celgene's letter dated June 24, 2009. (Compl. ¶ 122.) At that time, according to the complaint, "Mylan recognized that further engagement with Celgene would be fruitless . . . ." (*Id.* ¶ 128.) As a result, "Mylan's difficulty with Celgene . . . *ended* in Mylan's *complete inability* to obtain samples of Thalomid." (*Id.* ¶ 132 (emphasis added).)

The complaint alleges no fact occurring later than June 2009 related to Thalomid®. Nor does the complaint contain facts indicating that the statute is subject to tolling. Because June 2009 was nearly five years prior to commencement of this action, the Thalomid® counts are barred by the four-year

[17] This argument applies not only to the counts referencing Thalomid alone (Counts 1, 3, 5, and 8), but also to the counts which rely on both drugs (Counts 7 and 10), because it renders those counts duplicative of the Revlimid®-only counts (Counts 6 and 9). Likewise, Mylan's request for injunctive and declaratory relief should be partially dismissed to the extent they are based on Thalomid®. *See Santana Prods. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 138-39 (3d Cir. 2005) (once the limitations period runs, laches is presumed and the plaintiff must show that the delay was both reasonable and not prejudicial).

statute. 15 U.S.C. § 15b; N.J.S.A. § 56:9-14.

The courts have routinely applied these principles to preclude claims based on alleged refusals to deal. In *Rx.com v. Medco Health Solutions, Inc.*, some pharmacies allegedly excluded internet pharmacies from using their networks. 322 F. App'x 394, 396 (5th Cir. 2009). Rx.com applied for admission but was denied multiple times, the last of which occurred four and a half years before it filed suit. *Id.* The court rejected the claim as time-barred because Rx.com "failed to offer evidence of 'a specific act or word of refusal during the limitations period.'" *Id.* at 397 (citation omitted). *Charlotte Telecasters, Inc. v. Jefferson-Pilot Corp.*, 546 F.2d 570 (4th Cir. 1976), is to the same effect. There, a competitor conspired with the city council to deny a television franchise to the plaintiff. On August 7, 1967, plaintiff asked for reconsideration, but the council did not act. *Id.* Plaintiff filed a lawsuit on September 7, 1971. *Id.* Although the court explained that plaintiff's claims could be characterized as a continuing violation, *id.* at 573, the statute of limitations barred recovery because the last act occurred on August 7, 1967. *Id.*

These decisions make sense. Where, as here, there is no allegation of any conduct within four years, it does the plaintiff no good to argue that it still suffers from the original refusal. *See Glessner v. Kenny*, 952 F.2d 702, 708 (3d Cir. 1991) (explaining that "the mere continuation of damages into a later period will not serve to extend the statute of limitations"). The so-called continuing violation doctrine must be "occasioned by continual unlawful acts, not continual ill effects." *Cowell v. Palmer Twp.*, 263 F.3d 286, 293 (3d Cir. 2001), *abrogated on other grounds as stated in Lincoln v. Magnum Land Serv., LLC*, No. 13-3137, 2014 WL

1015939, at *5 n.9 (3d Cir. Mar. 18, 2014). There must be "some injurious act actually occurring during the limitations period, not merely the abatable but unabated inertial consequences of some pre-limitations actions." *Fleer Corp. v. Topps Chewing Gum, Inc.*, 415 F. Supp. 176, 182 (E.D. Pa. 1976).

The Thalomid® antitrust claims are therefore time-barred. Without any allegations after 2009, Mylan cannot plead "how any new act caused . . . harm over and above the harm that the earlier act caused." *Klehr*, 521 U.S. at 190.

IV. MYLAN DOES NOT PLEAD PLAUSIBLE RELEVANT MARKETS

Every antitrust count in the complaint is based on markets defined so narrowly that they each consist solely of one product sold only by Celgene. Mylan thus attempts to turn Celgene into a monopolist by definition. But the complaint contains no factual allegations to indicate that Mylan's narrow market definitions are plausible, nor that the alternative treatments for multiple myeloma, leprosy, myelodysplastic syndrome, and mantle cell lymphoma are not viable economic substitutes for Thalomid® and Revlimid®. Mylan asks this Court to infer that Celgene faces no competition at all, *i.e.*, that consumers in the "market" face only two choices: (1) pay whatever price Celgene demands, or (2) leave their diseases untreated. The courts are clear that such a complaint must contain factual allegations to justify the "counterintuitive" inference that Thalomid® and Revlimid® are "so unique that [they] suffer[] no actual or potential competitors." *Apple Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1198 (N.D. Cal. 2008). This complaint does not.

Defining a product market is a necessary element of any antitrust claim,

whether under § 1 or § 2. *See, e.g.*, *Columbia Metal Culvert Co. v. Kaiser Alum. & Chem. Corp.*, 579 F.2d 20, 26 (3d Cir. 1978). The scope of an antitrust product market is "determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Reasonable interchangeability "implies that one product is roughly equivalent to another for the use to which it is put," regardless of whether "there might be some degree of preference for the one over the other." *Allen-Myland, Inc. v. IBM Corp.*, 33 F.3d 194, 206 (3d Cir. 1994). In the pharmaceutical context, the rule of reasonable interchangeability means that a proposed antitrust market must be defined with reference to a drug's therapeutic use or indication. *Ciba Geigy*, 508 F. Supp. at 1153-55; *see generally* M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 Antitrust L.J. 633, 676 & n.203 (2003).

The Third Circuit is clear that the burden to define a relevant market applies to the pleadings. "Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a . . . market that clearly does not encompass all interchangeable substitute products . . ., the relevant market is legally insufficient and a motion to dismiss may be granted." *Queen City*, 124 F.3d at 436. Complaints that allege narrow markets without providing a plausible explanation are routinely dismissed. *See generally, e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) ("Cases in which dismissal on the pleadings is appropriate frequently involve either (1) failed attempts to limit a product market to a single

brand, franchise, institution, or comparable entity that competes with potential substitutes or (2) failure even to attempt a plausible explanation as to why a market should be limited in a particular way."). Courts are especially suspicious of market allegations, like Mylan's here, that include only the products that the accused 'monopolist' happens to sell—the "strange red-haired, bearded, one-eyed man-with-a-limp classification." *Belfiore v. N.Y. Times Co.*, 654 F. Supp. 842, 846 (D. Conn. 1986), *aff'd*, 826 F.2d 177 (2d Cir. 1987).

Numerous courts—including this Court—have rejected markets limited to a particular drug or class of drugs without accounting for therapeutic substitutes. *See, e.g.*, *Teva Pharms. Inds. v. Apotex, Inc.*, No. 07-5514, 2008 WL 3413862, at *8 (D.N.J. Aug. 8, 2008) (rejecting market of carvedilol products because plaintiff did not address alternative treatments for heart failure); *Ciba Geigy*, 508 F. Supp. at 1155 (rejecting market of hydrochlorothiazide products because they "compete in a market composed of all products indicated for the treatment of hypertension").[18]

American Sales Co. v. AstraZeneca AB, No. 10-6062, 2011 WL 1465786

[18] One court in this circuit has dismissed pharmaceutical antitrust claims filed by Mylan for failure to allege "facts showing a product market of reasonably interchangeable commodities from the perspective of the consumer." *Shionogi Pharma, Inc. v. Mylan, Inc.,* No. 10-1077, 2011 WL 12550835, at *6 (D. Del. June 10, 2011); *see also, e.g.*, *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 577 (S.D.N.Y. 2011) ("[The plaintiff] must allege sufficient facts about other treatments to make its proposed product market plausible."); *Kaiser Found. v. Abbott Labs.*, No. 02-2443, 2009 WL 3877513, at *8 (C.D. Cal. Oct. 8, 2009) (rejecting market limited to Hytrin and its generic copies because it "excluded other alpha-blockers"); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 996 (N.D. Ill. 2003) (Posner, J.) (it "cannot merely be assumed" that Paxil does not compete with other antidepressants).

(S.D.N.Y. Apr. 14, 2011), is on point. There, as here, the plaintiff alleged a relevant product market consisting solely of the active ingredient in the alleged monopolist's product, without accounting for other drugs approved for the same indication. *Id.* at *3. There—unlike here—the antitrust plaintiff at least attempted to explain this limitation by claiming that the alleged monopolist's product was formulated differently and had slightly different indications. *Id.* Nonetheless, the Court rejected the antitrust plaintiff's bald assertion that "no products are interchangeable" as a mere "legal conclusion unsupported by allegations describing . . . the competitive landscape of [potentially alternative] products." *Id.*

The result should be the same here. Mylan's complaint is devoid of any "allegations describing the competitive landscape" of myeloma, ENL, MDS, and MCL treatments. Indeed, Mylan states that it does not know "if any" such treatments exist. (Compl. ¶¶ 37, 47.) Thus, Mylan's allegation that these *unknown* products "are not reasonably interchangeable with" Thalomid® or Revlimid® "due to, for example, price, use, qualities, characteristics and/or distinct customers," (*id.*), should be rejected as a "legal conclusion," or, given the disjunctive "and/or," a mere conjecture, unsupported by any facts. *Am. Sales*, 2011 WL 1465786, at *3.

Paragraphs 37 and 47 thus do not allege any facts to support Mylan's alleged Thalomid® and Revlimid® markets, respectively. Nor do Mylan's two remaining paragraphs in support of each market, (Compl. ¶¶ 39-40, 49-50), fare any better. These additional allegations are simply "labels and conclusions, . . . a formulaic recitation of" the elements necessary to establish a relevant market without any facts. *Twombly*, 550 U.S. at 544. The absence of any factual meat on Mylan's

barebones allegations is best demonstrated by their repetition:

Thalidomide	**Lenalidomide**
39. A small, but significant, non-transitory price increase above the competitive level for Thalomid by Celgene would not have caused a loss of sales sufficient to make the price increase unprofitable.	49. A small, but significant, non-transitory price increase above the competitive level for Revlimid by Celgene would not have caused a loss of sales sufficient to make the price increase unprofitable.
40. Thalomid price levels did not exhibit significant, positive cross-elasticity of demand with respect to price with any other product.	50. Revlimid price levels did not exhibit significant, positive cross-elasticity of demand with respect to price with any other product.

These allegations are copied verbatim from the government's guidelines for defining product markets. *See, e.g.*, U.S. Dep't of Justice & FTC, *Horizontal Merger Guidelines* § 4.1 (2010). Such formulaic labeling cannot substitute for facts or forestall dismissal. *See, e.g.*, *Tal v. Hogan*, 453 F.3d 1244, 1261 (10th Cir. 2006) (affirming dismissal where complaint lacked facts supporting "use of antitrust buzz-words and parroting of general antitrust theories"); *Apple Inc.*, 586 F. Supp. 2d at 1198 (rejecting similar allegation regarding non-transitory price increase because it "merely restates a commonly used test for market definition without providing any factual basis").

That Mylan's market definitions are implausible is best demonstrated by its placement of Thalomid® and Revlimid® in different markets, despite Mylan's allegations that the two drugs are analogues and its allegations that the drugs have overlapping indications. (Compl. ¶¶ 66, 369-70.) The plaintiff in *Bayer Schera* tried the same gambit—pleading that Yasmin and Yaz each constituted a unique

market despite having similar chemical formulations and an overlapping indication for birth control. The Court easily dismissed such allegations: "Because Sandoz has not offered any explanation for Yasmin and Yaz's alleged uniqueness, the asserted relevant product markets are irrational and illogical, and Sandoz's antitrust counterclaims must be dismissed . . . ." *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08-3710, 2010 WL 1222012, at *5 (S.D.N.Y Mar. 29, 2010).

In sum, Mylan's complaint falls into both categories identified by *Todd* as suspect. Not only does Mylan plead disfavored single-drug markets, but it also makes no attempt to explain why there are no substitutes for that drug (in part because Mylan concedes that it does not know "if any" alternatives to Thalomid® or Revlimid® exist, (Compl. ¶¶ 37, 47)). As stated in *Todd*, this complaint may be dismissed for its "failure even to attempt a plausible explanation as to why a market should be limited in a particular way." 275 F.3d at 200; *accord, e.g.*, *Apple Inc.*, 586 F. Supp. 2d at 1198.

This deficiency, although fatal to Mylan's complaint, is understandable. If forced to allege facts concerning substitutes for Thalomid® and Revlimid®, Mylan would have to acknowledge the publicly available evidence that competing drugs exist. Specifically, facts subject to judicial notice show that there are several drugs indicated for the same uses as Thalomid® and Revlimid®, including but not limited to: cyclophosphamide for multiple myeloma and lymphoma; clofazimine for ENL; decitabine for myelodysplastic syndrome; and ibrutinib for mantle cell

lymphoma.[19] These drugs demonstrate that Mylan has failed to meet its burden to allege a properly defined antitrust market. The complaint should be dismissed.

V. CELGENE'S PATENTS PRECLUDE ANTITRUST INJURY

Mylan's claim is based on the assumption that, but for Celgene's conduct, it would otherwise have obtained FDA approval and launched a generic version of both drugs. But Mylan has skipped a step. Mylan cannot allege that it would be able to launch a lawful generic version of Thalomid® or Revlimid®, unless it can overcome the numerous presumptively valid patents that Celgene has listed with the FDA covering each drug. As a matter of law, Mylan cannot do so.

Antitrust injury is necessary for any private antitrust claim. 15 U.S.C. §§ 15, 26. It is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick*, 429 U.S. at 489. Antitrust injury exists only where there is harm to competition: "Where the defendant's conduct harms the plaintiff without adversely affecting competition generally, there is no antitrust injury." *Paladin Assocs., Inc. v. Mont. Power Co.*, 328 F.3d 1145, 1158 (9th Cir. 2003); *cf. Alberta Gas Chemicals, Ltd. v. E. I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1241 (3d Cir. 1987).

Conduct that eliminates competition can only cause antitrust injury if the competition eliminated is *lawful*. *See In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no liability for precluding illegal importation of drugs). Patents create a lawful restraint of competition, and "a lawfully acquired

[19] *See* Exhibits H-K, which are the FDA-approved labels for these drugs, respectively, as retrieved from the FDA's website. *See also supra* 1 n.1, 5 n.3.

patent creates a monopoly that does not violate the antitrust laws." *Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111 (6th Cir. 1989); *see also Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907) ("[T]he public [i]s not entitled to profit by competition among infringers."); *Hynix Semiconductor Inc. v. Rambus Inc*., 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("[A]n infringer" has "no legal right to be competing."). Thus, cases that allege exclusion stemming from the existence of lawful patents fail to state a claim.

Even if Mylan obtained samples of Thalomid® or Revlimid®, there are many steps preceding actual market entry. Mylan would still have to (1) decide it was economically viable to launch a generic version of Thalomid® or Revlimid®, (2) develop its own version of the drug, (3) demonstrate bioequivalency, (4) create a REMS program for safe distribution, and (5) get FDA approval. Even assuming Mylan could surmount all of those hurdles, Mylan would have to contend with the numerous patents that are listed in the Orange Book for Thalomid® and Revlimid®. *See supra* 5 n.3. Revlimid® is still covered by a compound patent, meaning the molecule itself is patented until 2019. Revlimid® is also covered by several polymorph patents, the last of which does not expire until 2027. And both Revlimid® and Thalomid® have numerous other patents covering composition, method of use, and Celgene's REMS programs.

Barr withdrew its Thalomid® ANDA after Celgene sued for infringement. *See Barr Labs.*, No. 2:07-cv-00286-SDW (D.N.J.), at ECF No. 160. Likewise, Natco does not contest that its generic infringes the Revlimid® compound patent, and certain of Celgene's REMS patents. *See Natco Pharma Ltd.*, No. 2:10-cv-

05197-SDW (D.N.J.), at ECF No. 105. Mylan does not allege that it would prevail in any patent case against Celgene, nor can it do so under the law. *Whitmore*, 495 U.S. at 159-60 ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."); *accord., e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 993 ("No one can be *certain* that he will prevail in a patent suit.'' (original emphasis)).

In sum, no injury to competition is possible unless Mylan can lawfully compete, and Celgene's patents stand in the way. *See Axis*, 870 F.2d at 1107 (affirming dismissal because the "patents, not the purchase of Mechaneer, foreclosed Axis' entry into the market. Thus, the anticompetitive act of purchasing Mechaneer did not cause the plaintiff's alleged injury.").

VI. MYLAN'S STATE-LAW CLAIMS FAIL FOR SEVERAL REASONS

As a last effort to buttress its federal claims, Mylan alleges a smattering of state law violations. But these counts cannot save Mylan's complaint.

Antitrust Claims. The New Jersey Antitrust Act contains a harmonization provision instructing courts to interpret it consistently with the Sherman Act. *See* N.J.S.A.§ 56:9-18. Thus, Mylan's state antitrust claims fail for the same reasons that the Sherman Act claims fail. *E.g.*, *Coast to Coast Entm't, LLC v. Coastal Amusements, Inc.*, No. 05-3977, 2005 U.S. Dist. LEXIS 26849, at *28 n.11 (D.N.J. Nov. 7, 2005).

Tortious Interference. Where plaintiffs added tortious interference counts to antitrust claims, the failure to show an antitrust violation has doomed the tortious interference theory. *See, e.g.*, *id.* at *69-70 ("[A]side from the alleged

antitrust violations, [plaintiff] has proffered no evidence that suggests that the defendants employed wrongful means."); *E Z Sockets, Inc. v. Brighton-Best Socket Screw Mfg. Inc.*, 307 N.J. Super. 546, 560 (Ch. Div. 1996), *aff'd o.b.*, 307 N.J. Super. 546 (App. Div. 1997). Here, Mylan has failed to allege wrongful conduct, malice, and a reasonable probability that it would obtain an economic advantage.

- **Wrongful conduct** is lacking because Celgene's actions were not illegal. *See Ideal Dairy Farms, Inc. v. Farmland Dairy Farms, Inc.*, 282 N.J. Super. 140, 205 (App. Div. 1995) (competitor's interference claims require "conduct which is fraudulent, dishonest, or illegal.").
- **Malice** is lacking because Mylan alleges that Celgene acted "to advance its own financial interest." *See Mu Sigma, Inc. v. Affine, Inc.*, No. 12-1323, 2013 WL 3772724, at *5 (D.N.J. July 17, 2013) (citing *Dello Russo v. Nagel*, 358 N.J. Super. 254, 268 (App. Div. 2003)).
- **A protected interest** is lacking because Mylan does not name even one specific relationship that was interfered with, much less allege that it is capable of overcoming Celgene's patents, *see supra* § V. *Novartis Pharms. Corp. v. Bausch & Lomb, Inc.*, No. 07-5945, 2008 WL 4911868, at *7 (D.N.J. Nov. 13, 2008); *see also, e.g.*, *Mu Sigma*, 2013 WL 3772724, at *5.

Each of these deficiencies is independently fatal to the tortious interference claim.

Unfair Competition. Courts have also rejected attempts to repackage antitrust claims under an unfair competition theory. "There is no distinct cause of action for unfair competition." *C.R. Bard, Inc. v. Wordtronics Corp.*, 235 N.J. Super. 168, 172 (Ch. Div. 1989); *see, e.g.*, *Diversified Indus., Inc. v. Vinyl Trends, Inc.*, No. 13-6194, 2014 WL 1767471, at *6 (D.N.J. May 1, 2014) (collecting cases dismissing unfair competition claims as duplicative of tortious interference).[20]

[20] To the extent that unfair competition exists as a stand-alone cause of action, it focuses primarily on the prevention of consumer confusion. *See, e.g.*, *Eli*

Coast to Coast and *E Z Sockets* are particularly instructive. In both cases, as here, plaintiffs attempted to bring antitrust and related state law claims against a manufacturer for refusing to sell its goods. In rejecting the antitrust claims, both courts relied on *Monsanto*, where the Supreme Court held that "a manufacturer has a right to deal or refuse to deal with whomever it likes." *Coast to Coast*, 2005 U.S. Dist. LEXIS 26849, at *44 (quoting *Monsanto*, 465 U.S. at 761); *see E Z Sockets*, 307 N.J. Super. at 554. Because the antitrust claims failed, the defendants were "insulated from th[e] tortious interference claim under the cloak of competitor's privilege." *E Z Sockets*, 307 N.J. Super. at 560; *see Coast to Coast*, 2005 U.S. Dist. LEXIS 26849, at *70 (same).

The result should be the same here. Mylan's antitrust claims should be rejected because Celgene has a right to choose the businesses with whom it will deal, and upon what terms. *See supra* § I. That right dooms Mylan's state law claims, which fall with the antitrust claims.

CONCLUSION

For these reasons, Mylan's complaint should be dismissed in its entirety.

Lily & Co. v. Roussel Corp., 23 F. Supp. 2d 460, 494 (D.N.J. 1998) (citing, *inter alia*, *SK&F, Co. v. Premo Pharm. Lab., Inc.*, 625 F.2d 1055, 1062 (3d Cir.1980)).

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