

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Civil 14-2094 ES

MYLAN PHARMACEUTICALS,

PLAINTIFF

V.

ORAL OPINION

CELGENE CORPORATION,

DEFENDANT.

NEWARK, NEW JERSEY
DECEMBER 22, 2014

B E F O R E: HONORABLE ESTHER SALAS,
UNITED STATES DISTRICT JUDGE

Pursuant to 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above-entitled proceedings.

S/ LYNNE JOHNSON

Lynne Johnson, CSR, CM, CRR
Official Court Reporter

LYNNE JOHNSON, CSR, CM, CRR
OFFICIAL COURT REPORTER
UNITED STATES DISTRICT COURT
P.O. BOX 6822
LAWRENCEVILLE, NJ 08648
EMAIL: CHJLAW@AOL.COM.

1 THE COURT: Before the Court is Defendant Celgene
2 Corporation's motion to dismiss the Complaint filed by Mylan
3 Pharmaceuticals, Inc. (D.E. No. 17). The Court has
4 considered the briefs submitted by the parties and the
5 Federal Trade Commission, (D.E. Nos. 17-1, 24, 26-3, and 31),
6 as well as the arguments presented by counsel at oral
7 argument on December 9, 2014. For the reasons below, the
8 Court GRANTS *without prejudice* in part and denies in part
9 Celgene's motion to dismiss.

10 **II. LEGAL STANDARD**

11 To survive a motion to dismiss, a complaint must
12 only allege "enough facts to state a claim to relief that is
13 plausible on its face." *Bell Atl. Corp. V. Twombly*, 550 U.S.
14 544, 570 (2007). A claim has facial plausibility when the
15 plaintiff pleads factual content that allows the court to
16 draw the reasonable inference that the defendant is liable
17 for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S.
18 662, 678 (2009). "The plausibility standard is not akin to a
19 'probability requirement,' but it asks for more than a sheer
20 possibility that a defendant has acted unlawfully." *Id.*

21 "When reviewing a motion to dismiss, '[a]ll
22 allegations in the complaint must be accepted as true, and
23 the plaintiff must be given the benefit of every favorable
24 inference to be drawn therefrom.'" *Malleus v. George*, 641
25 F.3d 560, 563 (3d Cir. 2011) (quoting *Kulwicki v. Dawson*, 969

1 F.2d 1454, 1462 (3d Cir. 1992)). But the court is not
2 required to accept as true "legal conclusions," and
3 "[t]hreadbare recitals of the elements of a cause of action,
4 supported by mere conclusory statements, do not suffice."
5 *Iqbal*, 556 U.S. at 678.

6 The Third Circuit has expressly cautioned that "it
7 is inappropriate to apply *Twombly*'s plausibility standard
8 with extra bite in antitrust and other complex cases." *West*
9 *Penn Allegheny Health Sys. Inc. V. UPMC*, 627 F.3d 85, 98 (3d
10 Cir. 2010).

11 **III. FACTS**

12 Celgene is a branded drug company that manufactures
13 and distributes two life-saving but dangerous drugs:
14 Thalidomide (Thalomid) and lenalidomide (Revlimid). (Compl.
15 ¶¶ 2-3).

16 Thalomid was approved in 1998 to treat lesions
17 associated with leprosy. (*Id.* ¶ 59). It was later indicated
18 for co-use with another drug to treat multiple myeloma. (*Id.*
19 ¶ 3). In connection with the FDA approval of Thalomid,
20 Celgene adopted the System for Thalidomide Education and
21 Prescribing Safety (S.T.E.P.S.), a program for distributing
22 the drug in accordance with strict safety protocols. (*Id.* ¶
23 4). In 2007, when Congress gave the FDA statutory authority
24 to condition the approval of drug application on acceptable
25 safety protocols, called Risk Evaluation and Mitigation

1 Strategies (REMS), S.T.E.P.S. was deemed an approved REMS
2 program (D.E. No. 17-1 ("Moving Br.") At 7-8). Celgene has
3 several patents covering Thalomid, the last of which expires
4 in 2023. (*Id.* At 9).

5 Remlivid was approved in 2005 for the treatment of
6 a subset of multiple myeloma, myelodysplastic syndrome, and
7 mantle cell lymphoma patients. As with Thalomid, Celgene
8 distributes Remlivid through a REMS program. Celgene's
9 patents on Remlivid extend through 2027. (*Id.* At 11).

10 Mylan, a generic drug company, alleges that Celgene has
11 maintained an unlawful monopoly over Thalomid and Revlimid by
12 preventing lower-priced generic competition from entering the
13 market. (Compl. ¶ 2). Specifically, Mylan alleges that
14 Celgene "used REMS as a pretext to prevent Mylan from
15 acquiring the necessary samples to conduct bioequivalence
16 studies." (*Id.* ¶ 7). The FDA requires any generic drug
17 application to include bioequivalence studies comparing the
18 generic product with the branded product. (*Id.* ¶ 8).

19 **a. Thalomid**

20 Mylan began efforts to develop a generic version of
21 Thalomid in September 2003. (Compl. ¶ 13). It originally
22 tried to obtain samples through wholesale distribution
23 channels, but was unable to do so because of the S.T.E.P.S.
24 program. (*Id.* ¶ 75).

25 In October 2004, Mylan sent a letter to Celgene

1 through a third party requesting to purchase Thalomid
2 samples. Seven months later, it sent a second request.
3 Celgene responded in June 2005, confirming that Thalomid is
4 unavailable through wholesale distribution and stating that
5 it was against policy to deal with intermediaries in the sale
6 of Thalomid. (*Id.* ¶¶ 75-76).

7 Mylan reached out to Celgene directly in September
8 2005. (*Id.* ¶ 77). One month later, Celgene wrote back to
9 explain that it needed additional time to respond given the
10 requirement that Thalomid is distributed exclusively through
11 S.T.E.P.S. (*Id.* ¶ 77-78). In December 2005, Celgene responded
12 that it would need the FDA's agreement to allow samples to be
13 distributed outside of S.T.E.P.S. and recommended that Mylan
14 contact the FDA. (*Id.* ¶ 79).

15 Mylan contacted the FDA in January 2006, requesting
16 that the FDA provide Celgene with written authorization for
17 it to provide Thalomid samples and providing the protocols
18 for its 3 planned studies. (*Id.* ¶¶ 80-82). The FDA responded
19 to request that Mylan provide either an investigational new
20 drug ("IND") application or a more detailed study protocol.
21 (*Id.* ¶ 83). Mylan submitted the requested study protocols in
22 May 2007. (*Id.* ¶ 84).

23 In September 2007, the FDA responded that Mylan's
24 Thalomid protocols were "acceptable," and included additional
25 recommendations that Mylan would need to follow in conducting

1 its studies. (*Id.* ¶ 86). Mylan informed Celgene of the FDA's
2 letter in November 2007 and reiterated its request for
3 samples. It followed up again in December. (*Id.* ¶¶ 87-89).
4 In January 2008, Celgene responded and asserted that it could
5 still not provide samples due to "concerns about distributing
6 Thalomid outside of the S.T.E.P.S. program [that] are
7 independent of FDA's regulatory oversight." It instead
8 requested that Mylan produce to Celgene ten categories of
9 information relating to Mylan's planned use of the samples,
10 history of FDA compliance, product liability insurance, etc.
11 (*Id.* ¶¶ 90-99).

12 Mylan responded in February, agreeing to deliver
13 the information on a confidential basis and enclosing a
14 confidentiality agreement. Celgene responded with proposed
15 edits to the agreement in April and June 2008. The agreement
16 was executed in June 2008, and Mylan sent its materials to
17 Celgene. (*Id.* ¶¶ 102-07). In addition, Mylan stated that it
18 would agree to indemnify Celgene for any liability resulting
19 from Mylan's studies. (*Id.* At 108).

20 Celgene responded with a draft indemnification
21 agreement in August 2008, and Mylan sent a responsive letter
22 in October 2008 expressing concerns about the agreement's
23 overbreadth. (*Id.* ¶¶ 113-14). The parties eventually reached
24 agreement on the terms of indemnification in April 2009. (*Id.*
25 ¶¶ 120).

1 In October 2008, while the negotiations over the
2 indemnification agreement were ongoing, Celgene sent Mylan a
3 second request for information. Mylan responded with
4 additional information in April 2009. Celgene again sought
5 more materials about Mylan's insurance coverage in June 2009.
6 (*Id.* ¶¶ 118-20).

7 Finally, after attempting to engage with Celgene
8 for almost five years to procure samples, Mylan "recognized
9 that further engagement with Celgene would be fruitless."

10 (*Id.* ¶ 128).

11 **b. Revlimid**

12 Mylan alleges that Celgene followed a "nearly
13 identical path of delay" for Revlimid, and that it worked to
14 obtain samples from August 2009 to May 2012. (*Id.* ¶¶ 130,
15 134).

16 Mylan submitted its safety protocols for Revlimid
17 bioequivalence studies to the FDA in August 2012. The FDA
18 deemed them "acceptable" in October 2012 but requested
19 additional information. (*Id.* ¶ 135-36). In addition, the FDA
20 told Mylan that it would be willing to inform Celgene that
21 the FDA had received sufficient assurance regarding any
22 planned testing. (*Id.* ¶ 137). In November 2012, Mylan
23 provided additional information requested by the FDA and gave
24 the FDA permission to notify Celgene once Mylan's protocols
25 were approved. In February, the FDA requested additional

1 information and identified more recommendations, and Mylan
2 responded again in May 2013. In July 2013, the FDA informed
3 Mylan that its protocols were adequate and that it would
4 notify Celgene to request that Celgene provide Mylan with
5 samples. (*Id.* ¶¶ 138-142).

6 Mylan wrote to Celgene in May 2013 to inform
7 Celgene that the FDA letter was forthcoming and to request
8 the samples. In response, Celgene advised Mylan that it
9 needed to wait until it received notice from the FDA. In
10 addition, as it had for Thalomid, Celgene requested
11 additional information from Mylan and indicated that it would
12 require an indemnification agreement. (*Id.* ¶¶ 143-147).

13 In January 2014, Mylan submitted to the FDA (at its
14 request) a formal Disclosure Authorization to the FDA
15 allowing it to contact Celgene and share with it the fact
16 that the FDA had received a request from Mylan for assistance
17 in obtaining samples. In March 2014, following final
18 endorsement of its safety profiles, Mylan again sent a letter
19 to Celgene notifying that it would not engage in
20 back-and-forth correspondence as it did with Thalomid and
21 asking Celgene to provide samples by March 14, 2014. (*Id.* ¶¶
22 149-50). It also sent an executed indemnification agreement.
23 (*Id.* ¶ 151).

24 Celgene responded on March 20, 2014 that it
25 required eight additional categories of information. It also

1 did not sign the agreement, indicating that it would consider
2 the terms after receiving the additional information. (*Id.* ¶¶
3 152-56).

4 **III. DISCUSSION**

5 **a. § 2 CLAIMS**

6 Celgene urges the Court to dismiss Mylan's claims under § 2
7 of the Sherman Act. A plaintiff alleging a § 2 violation must
8 plead: (1) monopolization; and (2) "the willful acquisition
9 or maintenance of that power as distinguished from growth or
10 development as a consequence of a superior product, business
11 acumen, or historic accident." *Verizon Communs., Inc. V. Law*
12 *Offices of Curtis v. Trinko, LLP*, 540 U.S. 398, 407 (2004)
13 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563,
14 570-71 (1966)). Here, the parties dispute element (2), also
15 known as requirement of "anticompetitive" or "exclusionary"
16 conduct. Celgene argues that its conduct is not exclusionary
17 as a matter of law because Section 2 does not impose an
18 affirmative duty to deal with competitors except under
19 limited circumstances, which it argues are inapplicable here.
20 (Moving Br. At 14). Mylan argues that that Celgene's conduct
21 falls within the scope of cases where a duty to deal applies.
22 (D.E. No. 24 ("Opp. Br.") at 14). The Court finds that Mylan
23 has pled facts that may plausibly give rise to a duty to
24 deal, and therefore denies Celgene's motion to dismiss
25 Mylan's § 2 claims.

1 In general, there is no affirmative duty to deal
2 with competitors. *United States v. Colgate & Co.*, 250 U.S.
3 300, 307 (1919). However, this right is not unqualified, and
4 an affirmative duty to deal may arise under limited
5 circumstances. See generally *Trinko*; *Aspen Skiing Co. V.*
6 *Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985); *Otter Tail*
7 *Power Co. V. United States*, 410 U.S. 336 (1973). The parties
8 primarily dispute the scope of the exception, and the factors
9 that must be present for an affirmative duty to
10 arise—particularly, whether a prior course of dealing between
11 the parties is required.

12 Celgene argues that there is an affirmative duty to
13 deal with competitors only when (1) there is a prior course
14 of dealing between the parties; and (2) the alleged
15 monopolist irrationally forsook short-term profits for
16 long-term anticompetitive gain—in other words, its actions
17 made “no economic sense.” (Moving Br. At 14). Mylan responds
18 that it only needs to plead the second factor, and that there
19 is no requirement of a “prior course of dealing” between the
20 parties. (Opp. Br. At 20).

21 The parties (and the Court’s) consideration of the
22 scope of the exception to the “no duty to deal” rule begins
23 with *Aspen Skiing*. In *Aspen Skiing*, the Supreme Court held
24 that a defendant violated § 2 when it terminated a
25 long-standing, profitable business relationship in which the

1 parties offered joint ski passes to both parties' ski
2 mountains. *Aspen Skiing*, 472 U.S. at 587-95. The Supreme
3 Court wrote that the "most significant" evidence supporting §
4 2 liability was the suggestion that the defendant's conduct
5 was not "justified by any normal business purpose." *Id.* At
6 608. To the contrary, the defendant "elected to forgo []
7 short-run benefits because it was more interested in reducing
8 competition in the Aspen market over the long run." *Id.*
9 *The Supreme Court revisited Aspen Skiing* nearly 20 years
10 later in *Trinko*. In *Trinko*, the Supreme Court held that
11 Verizon's failure under the Telecommunications Act of 1996 to
12 facilitate market entry by competitors did not state a § 2
13 claim. It held that "*Aspen Skiing* is at or near the outer
14 boundary of § 2 liability," *Trinko*, 540 U.S. at 409, and
15 proceeded to distinguish *Aspen Skiing* on a series of facts.
16 Significantly, the Supreme Court explained that, in *Aspen*
17 *Skiing*, the "unilateral termination of a voluntary (*and thus*
18 *presumably profitable*) course of dealing suggested a
19 willingness to forsake short-term profits to achieve an
20 anticompetitive end." *Id.* (Emphasis in original). In *Trinko*,
21 on the other hand, "the complaint does not allege that
22 Verizon ever engaged in a voluntary course of dealing with
23 its rivals," and therefore "its prior conduct sheds no light
24 upon whether its lapses from the legally compelled dealing
25 were anticompetitive." *Id.* Thus, the Supreme Court reasoned

1 that "prior course of dealing" was relevant to the § 2
2 inquiry insofar as it served as a proxy for the larger
3 inquiry of whether the defendant's conduct was
4 anticompetitive.

5 *Trinko* also distinguished itself from *Aspen Skiing*
6 on grounds that, in *Aspen Skiing*, the defendant refused to
7 sell a product to its competitor at retail price even though
8 it had sold it at that price to others. *Id.* This fact was
9 further indicative of anticompetitive conduct, and missing
10 from the record in *Trinko*. *Id.* There can be no dispute that
11 the question of whether a defendant sold its product at
12 retail -- like the issue of "prior course of dealing" -- is
13 relevant to determining whether Section § 2 liability
14 applies. But it appears that the *Trinko* Court considered
15 these facts not for their independent significance, but
16 rather for what they suggest: A willingness to engage in
17 irrational, anticompetitive conduct.

18 The Third Circuit cases to consider the scope of
19 the "no duty to deal" do not appear to adopt a strict
20 requirement that a party must plead "prior course of dealing"
21 for its claims to proceed. Celgene has not cited a case in
22 the Third Circuit where a motion to dismiss was granted for
23 failure to allege a prior course of dealing. To the
24 contrary, the cases in our Circuit that have considered the
25 scope of the affirmative duty to deal suggest that a "prior

1 course of dealing" is relevant but not dispositive in
2 determining whether such a duty applies.

3 In *BroadCom Corp. V. Qualcomm Incorp.*, 501 F.3d 297
4 (3d Cir. 2007), the Third Circuit determined that the limited
5 exception to the "no duty to deal" rule applied even though
6 the plaintiff did not plead a prior course of dealing.

7 (Footnote 1) *Id.* At 316. The Third Circuit explained that
8 the Supreme Court "created an exception to this [no duty to
9 deal] rule by holding that the decision of a defendant who
10 possessed monopoly power to terminate a voluntary agreement
11 with a small rival evidenced the defendant's willingness to
12 forego short-run profits for anticompetitive purposes." *Id.*
13 At 316 (citing *Aspen Skiing*, 472 U.S. at 610-611) (emphasis
14 added). Though the plaintiff in *BroadCom* did not allege a
15 prior course of dealing, the Third Circuit found that there
16 was other anticompetitive conduct that distinguished the
17 facts from *Trinko* and aligned it more closely with *Aspen*
18 *Skiing*. (Footnote 2) *Id.*

19 For example, the defendant, QualComm, marketed the
20 allegedly withheld technology for inclusion in an
21 industry-wide standard and voluntarily agreed to license it
22 on certain terms. *Id.* Thus, under *BroadCom*, a prior course
23 of dealing is relevant as "evidence[] of the defendant's
24 willingness to forego short-term profits for anticompetitive
25 purposes," but where other such evidence exists, the failure

1 to plead prior dealing is not a death knell. *Id.*

2 Likewise, the district court cases in our Circuit
3 do not appear to require pleading a prior course of dealing.
4 Perhaps most significantly, two courts in the District of New
5 Jersey have denied motions to dismiss on facts similar to
6 those currently before the Court. *Actelion Pharm. Ltd. V.*
7 *Apotex, Inc.*, No. 12-5743, D.E. No. 90 (D.N.J. Oct. 21, 2013)
8 (denying motion for judgment on the pleadings "for reasons
9 stated during oral argument"); *Lannett Co., Inc. V. Celgene*
10 *Corp.*, No. 8-3920, D.E. No. 42 (E.D. Pa. Mar. 30, 2011)
11 (denying motion to dismiss without comment). (Footnote 3)

12 In *Actelion*, as here, a branded pharmaceutical
13 manufacturer refused to sell samples of a product distributed
14 pursuant to a REMS program to its generic competitor. Also
15 as here, the defendant argued that the plaintiff's claims
16 should be dismissed for failing to allege a prior course of
17 dealing between the parties. Judge Hillman ruled during oral
18 argument that the § 2 claims could proceed, noting that "if
19 the defendants can prove that the plaintiffs are motivated
20 not so much by safety concerns but instead motivated by the
21 desire to use the REMS or REMS equivalent, to use exclusive
22 distribution agreements and to use a otherwise legitimate
23 refusal to deal together to maintain and extend a monopoly,
24 then they may very well make out a Section 2 claim." *Id.* at
25 117. Judge Hillman also noted that facts other than prior

1 course of dealing—such as the “refusal to sell at retail” and
2 attempt to control prices—were evidence of anticompetitive
3 conduct in *Aspen Skiing* and, accordingly, determinative of
4 its outcome. *Id.* at 13-14. Accordingly, the fact that the
5 plaintiff in *Actelion* did not plead a prior course of dealing
6 did not automatically preclude a § 2 claim because it pled
7 other facts to demonstrate that the defendant’s actions were
8 motivated only by long-term anticompetitive gain.

9 Most recently, the Eastern District of Pennsylvania had the
10 opportunity to address the scope of an affirmative duty to
11 deal in *In re Suboxone (Buprenorphine Hydrochloride and*
12 *Naloxone) Antitrust Litigation*, No. 13-2445, D.E. No. 97
13 (E.D. Pa. Dec. 3, 2014). There, the court held that the
14 exception described in *Aspen Skiing* did not apply because
15 there was no prior course of dealing between the parties.
16 However, *Suboxone* is distinguishable from this case because
17 it did not consider whether facts other than prior dealing
18 demonstrated the defendant’s willingness to forego short-term
19 profits for anticompetitive gain. In fact, the *Suboxone*
20 court recognized that “*Lannett* and *Actelion* are
21 distinguishable because the elements to assure safe use in
22 those cases prevented the generics from obtaining the
23 brand-name pharmaceutical to conduct bio equivalency testing
24 during the REMS process.” *Id.* At 28. The *Suboxone* court would
25 have been aware that the plaintiffs in *Lannett* and *Actelion*

1 did not plead a prior course of dealing, and therefore
2 recognizes that other facts in those cases (and this one) may
3 give rise to § 2 liability.

4 To be sure, there are cases that weigh "prior
5 course of dealing" more heavily. For example, the Second
6 Circuit has dismissed § 2 claims for failing to allege a
7 prior course of dealing between the parties. *In Re Elevator*
8 *Antitrust Litig.*, 502 F.3d 47, 53 (2007). In reaching
9 its decision, the Second Circuit relied on the Supreme
10 Court's reasoning that the "unilateral termination of a
11 voluntary (*and thus presumably profitable*) course of dealing
12 suggested a willingness to forsake short-term profits to
13 achieve an anticompetitive end." *Id.* (Quoting *Trinko*, 540
14 U.S. at 409) (emphasis in original). Thus, even though *In Re*
15 *Elevator* dismissed claims for failing to allege prior
16 dealing, its focus was still on the willingness to forsake
17 short-term profits for an anticompetitive end. It does not
18 address whether other factors could also indicate such a
19 willingness.

20 Indeed, the Supreme Court has "never held that
21 termination of a preexisting course of dealing is a necessary
22 element of an antitrust claim," *Helicopter Transport Servs.,*
23 *Inc. V. Erickson Air-Crane, Inc.*, No. 7-3077, 2008 WL 151833,
24 at *9 (D. Or. Jan. 14, 2008), and there remains valid Supreme
25 Court law imposing an affirmative duty to deal when no prior

1 course of dealing was alleged. *Otter Tail Power Co. V. United*
2 *States*, 410 U.S. 366 (1973). There, the defendant was "in
3 the business of providing a service to certain customers
4 (power transmission over its network), and refused to provide
5 the same service to certain other customers." *Trinko*, 540
6 U.S. at 410 (citing *Otter Tail*, 410 U.S. at 371, 377-78). In
7 this way, the facts in *Otter Tail* align with the facts before
8 this Court—there is no prior course of dealing between the
9 parties themselves, but there was prior business between
10 Celgene and other generic companies and research
11 organizations. The Supreme Court's finding of an affirmative
12 duty in *Otter Tail* (as well as its discussion of that case in
13 *Trinko* without overruling it) lends further support to
14 Mylan's argument that a prior course of dealing is not
15 required.

16 Here, Mylan essentially admits that it has not
17 plead a prior course of dealing between the parties.
18 Nevertheless, the Court finds that Mylan's Complaint pleads
19 facts that, if true, may give rise to a plausible § 2 claim.
20 To start, Mylan has pled that there is no legitimate business
21 reason for Celgene's actions, which it argues are solely
22 motivated by its goal to obtain long-term anticompetitive
23 gain. (See, e.g., Compl. ¶¶ 158-170).

24 It has further pled that Celgene has sold samples
25 of Thalomid and Revlimid at retail and provided it to

1 research organizations, but refuses to sell to Mylan because
2 of its anticompetitive goals. *Id.* Though Celgene vigorously
3 disputes these allegations, the Court finds that Mylan's
4 pleadings are sufficient to allow the case to proceed to
5 discovery, especially because the Court's inquiry at this
6 stage does not require any probability of success. The Court
7 is convinced that Mylan has pled its § 2 claims with
8 sufficient detail to justify moving the case beyond the
9 pleadings to the next stage of litigation.

10 **b. SECTION § 1 CLAIMS**

11 Mylan's § 1 claim alleges that Celgene devised an
12 anticompetitive scheme to prevent Mylan and others from
13 filing ANDAs for generic versions of Thalomid and Revlimid,
14 and that Celgene entered into unlawful agreements with
15 wholesale distributors and pharmacies to unduly restrain
16 trade.

17 A plaintiff asserting a Section 1 claim must assert
18 four elements: (1) a concerted action by defendants (2) that
19 produced anti-competitive effects within the relevant product
20 and geographic markets; (3) that the concerted actions were
21 illegal; and (4) that plaintiff was injured as a proximate
22 result of the concerted action. *Howard Hess Dental Labs. Inc.*
23 *V. Dentsply Intern., Inc.*, 602 F.3d 237, 253 (3d Cir. 2010).
24 Here, Celgene challenges that Mylan has adequately pled
25 elements (1) and (4)--concerted action and proximate

1 causation. The Court finds that Mylan has not adequately
2 pled a concerted action between Celgene and its alleged
3 coconspirators and therefore grants Celgene's motion to
4 dismiss Mylan's § 1 claims. Because the Court dismisses
5 these claims based on failure to plead concerted action, it
6 does not need to reach whether proximate causation is
7 present.

8 "The essence of a Section 1 claim is the existence
9 of an agreement." *Gordon v. Lewiston Hosp.*, 423 F.3d 184, 207
10 (3d Cir. 2005) (citing *Mathews v. Lancaster Gen'l Hosp.*, 87
11 F.3d 624, 639 (3d Cir. 1996). Unilateral action does not
12 support Section 1 liability. Rather, there must be a "unity
13 of purpose or a common design and understanding or meeting of
14 the minds in an unlawful arrangement." *Siegel Transfer, Inc.*
15 *V. Carrier Express, Inc.*, 54 F.3d 1125, 1131 (3d Cir. 1995)
16 (quoting *Copperweld Corp. V. Independent Tube Corp.*, 467 U.S.
17 752, 771 (1984)). To establish concerted action, there must
18 be a "relationship between pressure from one conspirator and
19 the anticompetitive decision of another conspirator." *Gordon*,
20 423 F.3d at 207 (citing *Big Apple BMW v. BMW of North*
21 *America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

22 Celgene argues that Mylan has merely alleged the
23 existence of agreements with agents and servicing entities
24 that have no competitive interest in the market, no interest
25 in harming Mylan, and no knowledge of Mylan's anticompetitive

1 objective. (Br. at 25-27). Celgene argues that these
2 allegations cannot give rise to a § 1 claim. (*Id.* At 26). It
3 adds that, to meet the § 1 pleading requirements, Mylan must
4 allege that independent actors agreed to a common plan or
5 scheme. (D.E. No. 31 ("Rep. Br.") at 17). (Footnote 4)

6 Mylan responds that Celgene's purported pleading
7 burden is too high. It states that it has discharged its
8 pleading burden by "directly alleging the existence of
9 restrictive distribution contracts between Celgene and
10 downstream entities," (Opp. Br. At 29), and that "unity of
11 purpose is not required" in pleading a § 1 claim. (December
12 9, 2014 Hearing Transcript ("Tr.") at 69).

13 Mylan's argument that it does not need to plead any
14 unity of purpose relies on *Fineman v. Armstrong World Indus.,*
15 *Inc.*, 980 F.2d 171 (3d Cir. 1992). In *Fineman*, the Third
16 Circuit reversed a directed verdict on the Plaintiff's § 1
17 claim, which the district court granted after "determining
18 that 'under no set of circumstances based on this record
19 could the jury reasonably find that Stern shared Armstrong's
20 purpose of eliminating TINS from competition in the video
21 magazine market.'" *Id.* At 212. The Third Circuit found the
22 district court's approach "misplaced as it renders section 1
23 claims unavailable to private litigants suffering antitrust
24 injury as a result of concerted action in a vertical matrix."
25 Instead of requiring that the coconspirators share a *motive*,

1 the Third Circuit held that "the emphasis is on the
2 participant's 'commitment to [the] scheme [which is] designed
3 to achieve an unlawful purpose.'" *Id.* (Quoting *Edward J.*
4 *Sweeny*, 637 F.2d at 111) (emphasis in original). It further
5 held that a "rational factfinder could infer commitment to
6 the scheme among coconspirators "despite differing motives."
7 *Id.*

8 The Third Circuit in *Fineman* thus discharged the
9 requirement that a plaintiff must plead an identical motive
10 among co-conspirators perpetuating a restraint on trade. This
11 is logical given that, in an alleged vertical conspiracy, the
12 interests of the coconspirators are different by nature—in
13 fact, the Third Circuit noted that it "cannot conceive of a
14 situation in which vertically aligned co-conspirators seeking
15 to destroy a competitor of only one could satisfy this
16 requirement [of identical motive]." *Id.* At 213.

17 Yet the Court in *Fineman* did *not* eliminate the
18 requirement that a plaintiff alleging a § 1 violation must
19 plead an agreement to a common scheme or design—regardless of
20 each coconspirator's motive for agreeing to it. In fact,
21 Third Circuit in *Fineman* reiterated the key factors for § 1
22 liability articulated by it earlier in *Harold Friedman v.*
23 *Thorofare Markets, Inc.*, 587 F.2d 127, 143 (3d Cir. 1978).
24 There, the Third Circuit held that "knowledge of the
25 defendant's purpose to restrain trade is an important factor"

1 and "at least two members of the combination stood to benefit
2 by the restraint of trade . . . Thus, in a sense, two members
3 of the combination shared a common purpose insofar as they
4 both benefited from the restraint of trade." *Id.* In *Fineman*,
5 the Third Circuit found that both of these factors were
6 present—the alleged conspirators had knowledge of the
7 anticompetitive goal and stood to benefit from it, giving
8 rise to a plausible § 1 violation. *Fineman*, 980 F.3d at 214.
9 *Fineman* may fairly be read to hold plaintiff does not need to
10 plead that § 1 coconspirators share a common motive, but it
11 does not support Mylan's argument that a § 1 plaintiff does
12 not need to plead any agreement to a common plan or scheme
13 whatsoever. (FOOTNOTE 5)

14 The Third Circuit reaffirmed the § 1 pleading
15 standard in *Siegel Transfer, Inc. V. Carrier Express, Inc.*,
16 54 F.3d 1125 (3d Cir. 1995), in which the Circuit held that
17 there was no § 1 violation because the alleged coconspirators
18 were "[c]ontractually obligated to manage Carrier Express
19 affairs" and represented a single enterprise." *Siegel*
20 *Transfer, Inc. V. Carrier Express, Inc.*, 54 F.3d 1125, 1135
21 (3d Cir. 1995). As such, they were not capable of
22 conspiracy. *Id.* Third Circuit reiterated that § 1 liability
23 requires a "unity of purpose or a common design and
24 understanding or meeting of the minds in an unlawful
25 arrangement." *Id.* At 1131 (quoting *Copperweld Corp. V.*

1 *Independent Tube Corp.*, 467 U.S. 752, 771 (1984)).

2 The most recent case that Mylan relies on, *West Penn*, also
3 fails to support the sufficiency of its pleadings. Mylan
4 cites *West Penn* for the proposition that “[i]f a complaint
5 includes non-conclusory allegations of direct evidence of an
6 agreement, a court need go no further on the question whether
7 an agreement has been adequately pled.” *West Penn*, 627 F.3d
8 at 99. Yet Mylan ignores *West Penn*’s explicit definition of
9 an “agreement,” which is “a unity of purpose, a common design
10 and understanding, a meeting of the minds, or a conscious
11 commitment to a common scheme.” *Id.* (Citing *Copperweld*, 467
12 U.S. at 771).

13 For example, in *West Penn*, the Plaintiff
14 specifically alleged that the coconspirators “. . . Formed an
15 agreement to protect one another from competition. Plaintiff
16 asserts that UPMC agreed to use its power in the provider
17 market to exclude Highmark’s rivals from the Allegheny health
18 insurance market, and that in exchange Highmark agreed to
19 take steps to strengthen UPMC and to weaken its primary
20 rival, *West Penn*.” *Id.* At 100.

21 Thus, while a contract may be an “agreement”
22 pursuant to § 1 if there is evidence that it represents a
23 unity of purpose, meeting of the minds, or conscious
24 commitment to a common scheme, Mylan has not pointed to any
25 case holding that it is enough to simply plead that a

1 contract exists. In fact, the Third Circuit has held that
2 there is no agreement under § 1 "when a party has simply
3 entered into a permissible contract with the defendant or
4 when the defendant has enforced a contractual right with
5 another party." *Friedman, Inc. V. Kroger Co.*, 581 F.2d 1068,
6 1078 (3d Cir. 1978). Mylan appears to conflate evidence of a
7 contract with evidence of an unlawful "agreement" to restrain
8 trade under § 1.

9 Here, the Court finds that Mylan's Complaint fails
10 to assert non-conclusory allegations of an unlawful agreement
11 between Celgene and its distributors or competitors that
12 would give rise to § 1 liability. In fact, the only
13 paragraphs in the Complaint that Mylan points to as
14 supporting its allegations of a common scheme are ¶¶ 261,
15 262, 274, and 275. (Tr. At 100). Those paragraphs allege
16 that *Celgene* devised an anticompetitive scheme to prevent
17 Mylan and others from entering the markets for Thalomid and
18 Revlimid, and that *Celgene* entered into unlawful
19 agreements to restrict distribution of those products. *Id.*
20 Nowhere does Mylan plead that *Celgene's* distributors and
21 pharmacists shared its purpose (even if they had different
22 motives for doing so), or that they had a common
23 anticompetitive goal. For example, there are no allegations
24 that *Celgene's* pharmacists or distributors stood to benefit
25 from the alleged anticompetitive scheme. *See Friedman*, 980

1 F. 2d at 1073. Nor does the Complaint allege that Celgene's
2 distributors and pharmacists even had *knowledge* of Celgene's
3 anticompetitive intent. *Id.* ("[K]nowledge of the defendant's
4 purpose to restrain trade is an important factor.").

5 Finally, the Court further finds that Mylan has not
6 even alleged that the purpose of the agreements between
7 Celgene and its distributors was to unduly restrain commerce.
8 Third Circuit has held that "contractual restraints fall
9 within the prohibition of Section 1 only when their purpose
10 and effect is found to have imposed an undue restraint on
11 commerce." *Garhman v. Univ. Res. Holding, Inc.*, 641 F. Supp.
12 135, 1371 (D.N.J. 1986) (quoting *Sitkin Smelting v. FMC*
13 *Corp.*, 575 F.2d 440, 447 (3d Cir. 1978). Thus, even if
14 evidence of the contracts was sufficient to constitute an
15 "agreement" under § 1, any restraint of trade appears to be
16 collateral to the main purpose of the contracts, which is to
17 distribute Revlimid and Thalomid pursuant to Celgene's REMS
18 programs. Mylan has not alleged that the restraint of trade
19 is a central purpose of the agreements between Mylan and its
20 distributors and pharmacies. *See generally Friedman v.*
21 *Kroger*, 581 F.2d at 1073; *Fineman*, 980 F.3d at 213.

22 Based on all of the above, the Complaint fails to "raise a
23 reasonable expectation that discovery will reveal evidence of
24 [an] illegal agreement," *Twombly*, 550 U.S. at 556, and
25 Mylan's claims under § 1 of the Sherman Act must be

1 dismissed. The Court does not need to independently consider
2 Celgene's "causation" element because it finds that Mylan
3 failed to adequately plead concerted action.

4 **c. Statute of Limitations**

5 The parties agree that a four-year statute of
6 limitations applies to Mylan's claims in this case. 15 U.S.C.
7 § 15(b). The statute of limitations runs from when the
8 plaintiff allegedly becomes injured by the defendant. The
9 Court finds that this statute of limitations does not bar
10 Mylan's claims as to Thalomid or its claims that rely on both
11 Thalomid and Revlimid.

12 As an initial matter, the Court finds that Mylan
13 adequately pled that Celgene refused samples within the
14 limitations period: "Throughout this entire period, Celgene
15 has engaged in a scheme (described at length below) to
16 continuously prevent and/or stall all of Mylan's efforts to
17 obtain samples of Thalomid and Revlimid." (Compl. ¶ 7).
18 In addition, the Court finds that Mylan has pled that
19 Celgene's continued refusal to deal throughout the
20 limitations period constitutes an injurious act. *In re Lower
21 Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d
22 Cir. 1993), held that "continuing and accumulating damage may
23 result from intentional, concerted inaction. The purposeful
24 nature of the inaction—here an ongoing refusal to sell or
25 lease—obviously constitutes an injurious act, although

1 perhaps not an overt one in the commonly-understood sense."
2 It further held that: "[A] conspiracy's refusal to deal,
3 which began outside the limitations period, may be viewed as
4 a continuing series of acts upon which successive causes of
5 actions may accrue. Far from requiring that the plaintiff
6 tie its damages to specific acts, the [Fifth Circuit]
7 acknowledged that a continuing conspiracy may give rise to
8 continually accruing rights of action, and the court simply
9 required the plaintiff to support its allegation that the
10 defendant had continued during the period in suit to refuse
11 to deal." *Id.* At 1173 (internal quotations and citations
12 omitted).

13 In *West Penn*, the Third Circuit reaffirmed that
14 holding, and declined to time-bar claims on the grounds that
15 the actions alleged to have occurred within the limitations
16 period were "merely 'reaffirmations' of acts done or
17 decisions made outside of the limitations period." *West Penn*,
18 627 F.2d at 106. There the Court held that the Defendant's
19 argument would mean that "a plaintiff who suffers [damage
20 from a continuing antitrust violation] is barred not only
21 from proving violations and damages more than four years old,
22 but is barred forever from complaining of [the continuation]
23 of the unlawful conduct." *Id.* At 108 (internal quotations and
24 citations omitted).

25 The Court finds this reasoning applicable here.

1 Celgene's continued refusal to deal constitutes an overtly
2 injurious act that has occurred within the four-year
3 limitations period. As a result, the Court will not bar
4 Mylan's claims based on the applicable statute of
5 limitations.

6 **d. Relevant Market**

7 Defining the "relevant market" for purposes of a
8 monopoly is a necessary element of any antitrust claim,
9 whether under § 1 or § 2. The scope of an antitrust product
10 market is determined by the "reasonable interchangeability of
11 use or the cross-elasticity of demand between the product
12 itself and the substitutes for it." *Brown Shoe Co. V. United*
13 *States*, 370 F.2d 20, 26 (3d Cir. 1978).

14 "In most cases, the proper market definition can
15 only be determined after a factual inquiry into the
16 commercial realities faced by consumers." *Queen City Pizza v.*
17 *Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). As
18 such, courts typically decline to dismiss antitrust claims
19 based on failure to plead the relevant market. That said,
20 there is no *per se* rule prohibiting dismissal on this cases,
21 and plaintiffs have the burden of defining the relevant
22 market. "Cases in which dismissal on the pleadings is
23 appropriate frequently involve either (1) failed attempts to
24 limit a product market to a single brand, franchise,
25 institution, or comparable entity that competes with

1 potential substitutes, or (2) failure even to attempt a
2 plausible explanation as to why a market should be limited in
3 a particular way." *Todd v. Exxon Corp.*, 275 F.3d 191, 200 (2d
4 Cir. 2001).

5 Mylan has pled that the relevant market "in which
6 to assess the anticompetitive effects of Celgene's conduct"
7 concerning Thalomid and Revlimid is the market for each
8 product plus bioequivalent generic versions. (Compl. ¶¶ 36,
9 46). Celgene argues that Mylan's single-market pleading is
10 legally deficient, and that Mylan fails to explain why the
11 market should be limited in this way. (Moving Br. At 30-36).
12 Celgene is correct that courts are skeptical of
13 single-product market definitions. *See, e.g., Am. Sales Co.,*
14 *Inc. V. Astrazeneca AB*, No. 10-6062, 2011 WL 1465786
15 (S.D.N.Y. Apr. 14, 2011) (rejecting market consisting solely
16 of pharmaceutical product and its generic counterpart). Here,
17 however, the Court declines to find Mylan's market definition
18 legally insufficient on its face because there are factual
19 questions that must be resolved. For example, it specifically
20 alleged that the availability of other treatments for the
21 indications that Thalomid and Revlimid are prescribed are not
22 sufficient to prevent the anticompetitive effects of
23 Celgene's conduct. (Compl. ¶¶ 37, 47).

24 Discovery is needed to determine, among other
25 things, whether these allegations are true or whether, as

1 Celgene contends, other products serve as adequate market
2 substitutes. (See Rep. Br. At 20-23).

3 Based on the above, the Court declines to dismiss
4 Mylan's claims based on a failure to allege the relevant
5 market.

6 **e. No Injury**

7 Injury is a necessary element of any antitrust
8 claim. 15 U.S.C. §§ 15, 26. Celgene argues that Mylan has
9 failed to allege an injury because it has not shown that it
10 would be able to enter the market with generic versions of
11 the products at issue. (Moving Br. At 36-37). The Court
12 disagrees.

13 Though Celgene is correct that there are barriers
14 to Mylan entering the market with generic versions of
15 Thalomid and Revlimid, the bar is not absolute. For example,
16 Mylan could argue that Celgene's patents are invalid or
17 attempt to enter the market with a product that it alleges in
18 noninfringing. In addition, Mylan is injured by Celgene's
19 preventing it from entering the market immediately upon the
20 expiration of its patents. In sum, the Court denies Celgene's
21 motion to dismiss Mylan's claims for failure to assert an
22 injury.

23 **f. Conclusion**

24 For the reasons above, the Court grants Celgene's
25 motions to dismiss *without prejudice* for Mylan's claims under

1 § 1 of the Sherman Act, counts 5-7, as well as the portions
2 of Mylan's New Jersey Antitrust Act claims, counts 8 and 9,
3 arising under Section 56:9-3. The Court denies Celgene's
4 motion to dismiss with respect to the remaining counts.

5 SO ORDERED this 22nd day of December, 2014.

6
7
8 (Adjourned)
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

1

2

FOOTNOTES

3

4

FOOTNOTE 1. The Third Circuit acknowledged that though *BroadCom* was not a strict "refusal to deal case," if it "were to analyze it as such, [it] would find that the Complaint does not run afoul of established Supreme Court precedent" because the limited exception to the "no duty to deal" rule applied. *BroadCom*, 501 F.3d at 316.

10

11

12

13

14

15

16

17

18

19

20

21

22

FOOTNOTE 2. At oral argument, Counsel for Celgene argued that there was a "current relationship" between the parties in *BroadCom* because "Broadcom had already committed the license on FRAND terms." (Tr. At 34). However, it does not appear that Broadcom and Qualcomm ever reached a license agreement. Rather "Broadcom claims to have been preparing to enter the UMTS chipset market for several years . . . [And] Qualcomm allegedly demanded that Broadcom license Qualcomm's UMTS technology to non-FRAND terms. Broadcom refused, and commenced this action." *Broadcom*, 501 F.3d at 305. The Court does not agree that this constitutes a prior course of dealing between the parties as contemplated in *Aspen Skiing* and *Trinko*.

23

24

25

FOOTNOTE 3. Additionally, in *Only v. Ascent Media Grp., LLC*, No. 6-2123, 2006 WL 2865492 (D.N.J. Oct. 5, 2006), the Judge Hochberg noted in a footnote that there are three

1 "exceptional circumstances where a duty [to deal] may be
2 recognized": First, the *Trinko* court "recognized that a
3 'concerted' refusal to deal may violate the Sherman Act under
4 its prior decisions." Second, a "sudden refusal to deal on
5 fair terms following a longstanding and mutually profitable
6 business relationship may approach to boundary of Section Two
7 liability." And third, there may be a limited exception when
8 a defendant refuses to make available access to "essential
9 facilities." *Id.* At *4 n.7. Therefore, at least one court in
10 this Circuit has noted that a "concerted" refusal to deal may
11 constitute an exception separate and apart from a prior
12 course of dealing. *Id.*

13 FOOTNOTE 4. There is also an implication in
14 Celgene's briefs that vertical agreements between
15 manufacturers and distributors, such as those alleged here,
16 are not suitable for § 1 claims. The Court notes that these
17 types of agreements may give rise to such claims when
18 adequately pled. *See, e.g., United States v. Ciba Geigy*
19 *Corp.*, 508 F. Supp. 1118, 1146 (D.N.J. 1976) ("Although these
20 contracts were reached in a vertical, supplier-purchaser,
21 context, they, in fact, were designed to limit horizontal
22 competition Such agreements are more pernicious
23 antitrust violations than simple vertical restraints. . .
24 .").

25 FOOTNOTE 5. In fact, the Third Circuit has

1 rejected arguments similar to Mylan's. In *Howard Hess Dental*
2 *Labs. Inc. V. Dentsply Intern., Inc.*, 602 F.2d 237 (3d Cir.
3 2010), plaintiffs attempted to rely on *Fineman* to justify
4 pleadings that "do not offer even a gossamer inference of any
5 degree of coordination" The Third Circuit wrote that
6 though *Fineman* held that vertically aligned co-conspirators
7 need not share an identical motive, "nothing in that case
8 excuses the Plaintiffs from alleging an agreement. . . ." *Dentsply*,
9 602 F.3d at 256 n.8.

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25