NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, Plaintiff, v. PAR STERILE PRODUCTS, LLC, et al., Defendants.	Civil Action No: 16-4544 (SDW) (LDW) **OPINION** February 10, 2017

WIGENTON, District Judge.

Before this Court is Defendants Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc.'s ("Par" or "Defendants") Motion to Dismiss Plaintiff Fresenius Kabi USA, LLC's ("Fresenius" or "Plaintiff") Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

Jurisdiction is proper pursuant to 28 U.S.C. § 1331 and §1367(a). Venue is proper pursuant to 28 U.S.C. § 1391. This opinion is issued without oral argument pursuant to Federal Rule of Civil Procedure 78.

For the reasons stated herein, the Motion to Dismiss is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY

Fresenius and Par are pharmaceutical companies that have marketed and sold Intravenous Vasopressin Injection ("IVI"), which is "a potentially life-saving antidiuretic drug that is primarily used in the acute critical care setting to restore blood pressure." (Compl. ¶ 4.) IVI was marketed and sold as an unapproved drug in the United States dating back to before 1938 and until 2014. (*Id*. at ¶¶ 44-5.) Both Fresenius and Par sold IVI as an unapproved drug during this time. (*Id*. at ¶¶ 43-4.) However, the FDA published a policy guide in 2011 encouraging manufacturers of unapproved drugs to comply with approval provisions and indicating it would remove unapproved products from the market. (*Id*. at ¶ 46.) Par sought FDA approval to market and sell its IVI, Vasostrict, in September 2012, and received approval to do so in April 2014. (*Id*. at ¶¶ 47-8.)

Fresenius alleges Par thereafter commenced a campaign to force Fresenius out of the IVI market, including by purportedly contacting the FDA on multiple occasions regarding Fresenius' sale of its IVI. (*Id*. at ¶¶ 50-1.) In December 2014, the FDA instructed Fresenius to cease manufacture of its IVI by January 2015 and distribution by March 2015. (*Id*. at ¶ 53.) Currently, Par is the only company with FDA approval to sell IVI for use in the United States, giving Par 100% share of the relevant market. (*Id*. at ¶ 72.) Fresenius alleges this has resulted in a 2600% increase in IVI prices, from $5.13 per vial to 138.60 per vial. (*Id*. at ¶¶ 55, 72.)

Obtaining FDA approval of a version of an already-approved drug requires a drug manufacturer to file an Abbreviated New Drug Application ("ANDA") establishing that its version of the drug is pharmaceutically and therapeutically equivalent to the FDA-approved drug. (*Id*. at ¶¶ 36, 59.) This necessitates including information about the manufacture and testing of the active pharmaceutical ingredient ("API") used in the proposed product. (*Id*. at ¶ 61.) Typically, API is

purchased from a specialty chemical manufacturer ("API Supplier"), and then combined "with solubilizers, stabilizers, and other excipients to produce the finished product." (*Id*.)

Fresenius alleges that access to API suppliers with an active Drug Master File ("DMF") is "essential" for an ANDA application to enter and compete in the market. (Compl. ¶¶ 9, 65.) An ANDA applicant may incorporate by reference an API Supplier's active DMF, so long as the API Supplier authorizes such a reference, in its application. This permits the applicant to include required information about the manufacture and testing of the API that is otherwise confidential. (*Id*. at ¶¶ 62-5.)

Fresenius avers that there are only three Vasopressin API Suppliers with an active DMF filed with the FDA to manufacture Vasopressin API in the United States: BCN, Bachem, and PolyPeptide Labs. (*Id*. at ¶¶ 57, 76.) All three API Suppliers are purportedly subject to exclusive dealing arrangements, and Fresenius alleges two of these agreements are with Par.[1] (*Id*. at ¶ 68.) Fresenius contends this is the result of Par's strategy to maintain its monopoly by using anticompetitive exclusive dealing to "lock up difficult-to-source API" in order to prevent competitors from entering the IVI market. (*Id*. at ¶¶ 75, 111.)

Fresenius contends these exclusive agreements have substantially foreclosed its ability to purchase Vasopressin API, file an ANDA, and obtain FDA approval to enter the IVI market. (*Id*. at ¶¶ 69, 138-9.) Alleging that Par's actions constitute anticompetitive conduct that the antitrust laws were intended to prevent, Fresenius has brought the instant antitrust action. Par moves to

[1] BCN formerly was Fresenius' supplier of Vasopressin API. (Compl. ¶ 80.) Fresenius alleges Par induced BCN to enter an exclusive contract by sharing the monopoly profits it is earning in the IVI market. (*Id*. at ¶¶ 19, 94-5.) Fresenius further alleges it has reason to believe Bachem's exclusive agreement is also with Par. (*Id*. at ¶¶ 100-6.) Fresenius does not, however, identify the entity with which PolyPeptide Labs entered into exclusive agreement. (*Id*. at ¶¶ 107-9.)

dismiss the Complaint, arguing that Fresenius lacks antitrust standing, and that it has insufficiently pleaded its claims.

II. LEGAL STANDARD

An adequate complaint must be "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). This Rule "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level[.]" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted); *see also Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (stating that Rule 8 "requires a 'showing,' rather than a blanket assertion, of an entitlement to relief").

In considering a motion to dismiss under Rule 12(b)(6), the Court should conduct a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the factual and legal elements of a claim should be separated. *Id*. The Court must accept all of the Complaint's well-pleaded facts as true and construe the Complaint in the light most favorable to Plaintiff, but may disregard any legal conclusions. *Id*. at 210–11; *see also Phillips*, 515 F.3d at 231. Second, the Court must determine whether the facts alleged in the Complaint are sufficient to show that Plaintiff has a "plausible claim for relief." *UPMC Shadyside*, 578 F.3d at 211. In other words, a complaint must do more than allege Plaintiff's entitlement to relief; it must "show" such entitlement with its facts. *Id*. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Determining whether the allegations in a complaint are "plausible" is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. If the "well-pleaded facts do not permit the court to infer more than the mere

possibility of misconduct," the complaint should be dismissed for failing to "show[] that the pleader is entitled to relief" as required by Rule 8(a)(2). *Id.* There is no heightened pleading standard in antitrust cases, and the general principles governing Rule 12(b)(6) motions apply. *In re Mercedes-Benz Anti-Trust Litig.*, 157 F. Supp. 2d 355, 359 (D.N.J. 2001).

III. DISCUSSION

A. Antitrust Standing

The Third Circuit has instructed Courts to consider the following factors in evaluating whether a plaintiff has antitrust standing: "(1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages." *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 171 (3d Cir. 2015), *cert. denied*, 136 S. Ct. 2451 (2016). Defendants argue that Plaintiff fails to satisfy these first two factors. (Defs.' Br. at 8, 18.)

i. Antitrust Injury

Plaintiff's allegations sufficiently establish antitrust injury to withstand a motion to dismiss. While Defendant's argument that no antitrust injury has in fact occurred may prove to be well-founded after the parties have had the benefit of discovery, this Court must assume at this stage that Plaintiff can prove the facts it has alleged. Fresenius avers Par engaged in anticompetitive practices to substantially lock up difficult-to-source API in order to prevent competitors from entering the market, and has sufficiently alleged facts to support this claim.

(Compl. ¶¶ 88-9, 94-9, 104-6.) Such actions, if borne out through the course of discovery, may constitute an injury of the type antitrust laws were intended to prevent.

ii. Causal Connection

At the pleading stage, an antitrust Plaintiff is not required to dispose of every alternative theory of causation. Rather, "Plaintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended to prevent, and that their injury flows from the Defendants' anti-competitive conduct." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004). Plaintiff alleges that Defendant engages in anticompetitive conduct to prevent competitors from entering the market, and has obstructed Plaintiff's efforts to obtain a Vasopressin API Supplier in order to produce IVI. (Compl. ¶¶ 14-16.) These allegations are sufficient to demonstrate causation.

B. Sherman Act Allegations

i. Unlawful Exclusive Dealing

"Generally, a prerequisite to any exclusive dealing claim is an agreement to deal exclusively." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270 (3d Cir. 2012). "The legality of an exclusive dealing arrangement depends on whether it will foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *Id*. at 271.

Plaintiff alleges Defendants have market power in the relevant market, which Plaintiff defines as IVI approved by the FDA for sale in the United States. (*See* Compl. ¶¶ 26, 71.) Defendants allegedly exploited their monopoly power by increasing the price of IVI by 2600%. (Compl. ¶¶ 8.) Plaintiff further contends that it has been completely foreclosed from the IVI market because all three of the Vasopressin API Suppliers with active DMFs are subject to exclusive contracts, two of which allegedly are with Defendants. (*Id*. at ¶¶ 94, 106.) This is

sufficient to establish substantial foreclosure at the pleading stage. *See Eisai, Inc. v. Sanofi Aventis U.S.*, LLC, 821 F.3d 394, 403 (3d Cir. 2016) ("Although the test is not total foreclosure, the challenged practices must bar a substantial number of rivals or severely restrict the market's ambit.")

ii. Group Boycott

The Third Circuit has instructed that "a boycott is made out where there is concerted action with a purpose either to exclude a person or group from the market, or to accomplish some other anti-competitive objective, or both." *Malley-Duff & Assocs., Inc. v. Crown Life Ins. Co.*, 734 F.2d 133, 142 (3d Cir. 1984) (internal marks omitted). Plaintiff claims that Defendants entered into exclusive dealing arrangements to exclude other market entrants, which sufficiently alleges such concerted action with an anti-competitive objective at the pleading stage.

iii. Monopolization

To state a claim for monopolization, Plaintiff must allege "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007).

Plaintiff has alleged, and Defendants do not appear to dispute, that Defendants have a monopoly in the relevant market. (Compl. ¶¶ 26, 71; Defs.' Br. at 29.) Plaintiff contends that Defendants willfully maintain this monopoly power through "an extensive anticompetitive scheme" that includes blocking access to Vasopressin API Suppliers with an active DMF to prevent potential competitors from filing ANDAs. (Compl. ¶¶ 14-17.) Such assertions are sufficient to state a claim for monopolization.

iv. Attempted Monopolization

To assert a claim of attempted monopolization, a Plaintiff must allege "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 454 (1993); *see also Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 406 (3d Cir. 2016) ("Phrased another way, the would-be monopolist must make use of monopoly power to foreclose competition, to gain a competitive advantage, or to destroy a competitor.") "Direct evidence of specific intent need not be shown; it may be inferred from predatory or exclusionary conduct." *Pennsylvania Dental Ass'n v. Med. Serv. Ass'n of Pennsylvania*, 745 F.2d 248, 261 (3d Cir. 1984).

Plaintiff alleges Par successfully "locked up" Vasopressin API sources in part by inducing Plaintiff's former API Supplier to enter an exclusive contract that exceeds the total value of the entire IVI market in the United States. (Compl. ¶¶ 94-5, 121-122, 136.) This supports Plaintiff's claim that "Par has leveraged its position as the sole FDA-approved manufacturer of [IVI] to prohibit actual or potential competitors…from accessing Vasopressin API." (*Id*. at ¶ 14.) This alleged exclusionary conduct is sufficient to establish specific intent at this stage.[2]

v. Conspiracy to Monopolize

"A Section 2 conspiracy claim has four elements: (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 253 (3d Cir. 2010). A plaintiff is required to allege facts

[2] Plaintiff's allegations regarding statements made by Par characterizing their API source as a "defense" only further support the element of specific intent at the pleading stage. (Compl. ¶ 17.)

plausibly suggesting "a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement." *Id*. at 254.

Plaintiff devotes several paragraphs of its Complaint alleging that BCN representatives identified Par's purported "extremely rich offer" that involved "a significant payment upon execution and additional future payments for every year that BCN did not support any other market entrant for IVI." (Compl. ¶¶ 88-94.) Plaintiff alleges this contract is valued at over ten million dollars, whereas the entire U.S. market for IVI is purportedly worth hundreds of thousands of dollars. (*Id*. at ¶¶ 94-5.) Certainly, BCN would have understood the intended effect of such an arrangement to be Defendants' monopolization of the IVI market. Plaintiff's non-conclusory allegations regarding this contract are therefore sufficient for this Court to infer specific intent at this stage.

C. State Law Claims

i. NJ Antitrust Claims

The New Jersey Antitrust Act mandates that it "shall be construed in harmony with ruling judicial interpretations of comparable Federal antitrust statutes and to effectuate, insofar as practicable, a uniformity in the laws of those states which enact it." N.J. Stat. Ann. § 56:9-18. This Court, having concluded that Plaintiff sufficiently pleaded its federal antitrust claims, finds that Plaintiff adequately pleaded its state law claims.

ii. Tortious Interference

The elements of a claim for tortious interference with a prospective economic advantage under New Jersey law are: "(1) a plaintiff's reasonable expectation of economic benefit or advantage, (2) the defendant's knowledge of that expectancy, (3) the defendant's wrongful, intentional interference with that expectancy, (4) in the absence of interference, the reasonable

probability that the plaintiff would have received the anticipated economic benefit, and (5) damages resulting from the defendant's interference." *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 186 (3d Cir. 1992).

Plaintiff's allegation that Defendants engaged in an "extensive anticompetitive scheme" by entering into exclusive arrangements to restrict entry of competitors, if proven, would constitute intentional illegal behavior. Furthermore, Plaintiff's contentions that BCN, one of the only three suppliers with an active DMF, formerly supplied Vasopressin API for Plaintiff are sufficient at this stage to plausibly assert that Defendants knew of Plaintiff's prospective relationship. This Court therefore will not dismiss Plaintiff's for claim for tortious interference with a prospective economic advantage.

IV. CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss is **DENIED**. An appropriate order follows.

/s/ Susan D. Wigenton
SUSAN D. WIGENTON, U.S.D.J

Orig: Clerk
cc: Leda D. Wettre, U.S.M.J.
Parties