IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SPRING PHARMACEUTICALS, LLC, Plaintiff, *v.* RETROPHIN, INC., MARTIN SHKRELI, MISSION PHARMACAL COMPANY, and ALAMO PHARMA SERVICES, INC., Defendants.	)	Civil Action No. 2:18-cv-04553-JCJ

MEMORANDUM IN SUPPORT OF RETROPHIN, INC.'S MOTION TO DISMISS SPRING PHARMACEUTICALS, LLC'S COMPLAINT

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Defendant Retrophin, Inc. ("Retrophin") respectfully submits this Memorandum of Law in Support of its Motion to Dismiss the Complaint ("Motion") filed by Spring Pharmaceuticals, LLC ("Spring"), pursuant to Rule 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

Spring brings claims against Defendants under the Sherman Antitrust Act for monopolization, conspiracy to monopolize, and unlawful restraints of trade, as well as parallel claims under state laws. The core of Spring's complaint is that it purportedly desires to bring to market a generic version of tiopronin, which Retrophin sells under the brand name Thiola, and that Defendants violated the antitrust laws by failing to help Spring take advantage of an expedited drug development process under the Hatch-Waxman Act that allows generic manufacturers to bypass normal Food and Drug Administration ("FDA") procedures required to obtain marketing approval for a drug. In particular, Spring claims that Defendants declined to provide Spring with samples of Thiola so that Spring could conduct "bioequivalence" testing required to obtain expedited FDA approval, and that this prevented Spring from entering the market.

This motion consists of two parts. Part I is made pursuant to Federal Rule of Civil Procedure 12(b)(1) and demonstrates that Spring lacks Article III standing because Spring has not suffered an "injury in fact" traceable to any Defendant. The Complaint conspicuously says nothing about Spring's background or experience, except to say that the company was formed in November 2017, and it identifies no individuals associated with Spring. However, it is evident from publicly available materials that Spring is not, as it claims, a "generic pharmaceutical company" "ready to begin development" of a generic version of Thiola. Rather, publicly available materials indicate that it is a made-for-litigation shell company posing as a generic pharmaceutical company in an apparent attempt to exploit the treble damages provisions of the antitrust laws. Its "CEO"—Jialue Charles Li—is a former associate from Spring's litigation counsel, Winston & Strawn, LLP

("Winston & Strawn"). The only other individual identified as associated with Spring is Mr. Li's wife, Peimin Flora Hua, who according to publicly available materials is a Certified Public Accountant ("CPA") employed by Freddie Mac. The only addresses Spring has provided are a P.O. Box and a "virtual office" in McLean, Virginia near Mr. Li and Ms. Hua's home. Its website has no content.

Because these facts contradict Spring's allegations in the Complaint, the Court should not accept the allegations as true. Indeed, the record before the Court demonstrates that Defendants have *not* delayed or prevented Spring's entry into the market. Therefore, Spring has not suffered an "injury in fact," let alone one that is traceable to any Defendant. Accordingly, Spring lacks Article III standing.

Part II is made pursuant to Federal Rule of Civil Procedure 12(b)(6) and demonstrates that even if Spring's allegations are accepted as true, Spring fails to state a claim upon which relief can be granted for five primary reasons.[1]

First, Spring lacks antitrust standing. To show antitrust injury—a key requirement for antitrust standing—Spring must plead that Retrophin caused injury to its "business or property." 15 USC § 15. *Potential* competitors, as opposed to present competitors, that have not been injured in an *existing* "business or property," can demonstrate injury, or causation, only if they sufficiently plead they had the "intention and preparedness" to enter a business and would have done so but-for the defendant's alleged anticompetitive conduct. Because Spring fails to plead that it has any experience bringing a generic drug to market, that it has taken substantial steps to enter the market, such as consummating any contracts or obtaining necessary licenses, or that it has the wherewithal

[1] If the Court concludes that it lacks subject matter jurisdiction because Spring lacks Article III standing, then it need not, and should not, consider Retrophin's Rule 12(b)(6) motion.

to enter the market, it fails to plead sufficient "intention and preparedness" to enter the market as the law requires, and therefore fails to adequately allege that it has suffered antitrust injury.

Second, Spring fails to plead a claim for monopolization under Section 2 of the Sherman Act. Spring alleges that Retrophin's alleged failure to respond to a request for samples of Thiola prevented its entry into the market. But the law does not create an obligation for companies to cooperate with their rivals. The allegations in the Complaint do not fall within the narrow exception to this rule, articulated in *Aspen Skiing*, which the Supreme Court has held lies near the "outer limit" of Section 2 liability.

Third, Spring fails to plead an unlawful agreement as required to sustain its claims under Section 1 of the Sherman Act and its conspiracy to monopolize claim under Section 2 of the Sherman Act. It alleges purely unilateral, as opposed to concerted, conduct, and its attempt to rely on contracts that are themselves legal to allege an anticompetitive conspiracy "designed" to "achieve an unlawful objective," fails as a matter of law. Moreover, the Supreme Court has made clear that a corporation cannot conspire with itself. Thus, a conspiracy cannot be based on joint conduct by a company and its officers or by entities acting as a "single enterprise."

Fourth, both Spring's Section 1 and Section 2 claims fail because Spring fails to adequately plead a relevant market.

Fifth, Spring's state law claims fail because no Pennsylvania case explicitly provides for the recovery of damages in a private action for an unlawful restraint of trade or monopolization. And even if Spring's claims were recognized under Pennsylvania's common law, they would fail for the same reasons its federal claims fail.

FACTUAL BACKGROUND

A. Retrophin and Thiola.

Defendant Retrophin[2] is a biopharmaceutical company that develops and commercializes treatments for rare diseases, including Thiola, an FDA-approved treatment for cystinuria. (Compl., ¶¶ 2, 43). Cystinuria is a rare genetic disease—affecting approximately 20,000 Americans—that causes recurring kidney stones. (*Id.*, ¶¶ 81-82). For some patients suffering from cystinuria, drugs like Thiola[3] offer relief. (*Id.*, ¶¶ 83, 85).

Apart from making drugs for rare diseases available for patients who need them, Retrophin re-invests revenue from its commercialized pharmaceutical portfolio to fund research and development of novel pharmaceutical therapies for other rare diseases. (Bansal Decl., Ex. A). For example, during the nine months preceding September 30, 2018 (the most recently publically available information), Retrophin invested over 75 percent of its revenues in research and development for rare diseases. (Bansal Decl., Ex. B).

Retrophin acquired an exclusive license for Thiola in 2014 and began marketing it. (Compl., ¶ 7). Notably, although Thiola is not patent-protected, no manufacturer has developed a generic version of it, (*id.*, ¶ 2), likely because of the small population affected by cystinuria, coupled with

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[2] Although the Complaint names Martin Shkreli as a defendant and discusses him at length, it ignores that he has had no role at Retrophin since 2014.

[3] In addition to Thiola (tiopronin), Cuprimine (penicillamine) and Depen (a branded generic of penicillamine) are other FDA-approved pharmaceutical treatment indicated for cystinuria. The FDA recently granted Revive Therapeutics orphan drug designation status for the use of bucillamine—a tiopronin derivative frequently used abroad—to treat cystinuria. (*See* Declaration of Deepti Bansal in Support of Defendant Retrophin's Motion to Dismiss ("Bansal Decl."), Exhibit ("Ex.") A). Judicial notice is permissible on a motion to dismiss. Courts will often take notice of materials produced by or filed with government agencies. *See, e.g.*, *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (taking judicial notice of SEC filings); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 (E.D. Pa. 2003) (taking judicial notice of materials publish on FDA website).

the degree of investment necessary to adequately distribute the product and provide the necessary support to the patients with this rare disease. Indeed, before Retrophin acquired the rights to Thiola, the drug was on the FDA's drug shortage list. (Bansal Decl., Ex. C).

B. Spring is Formed as a Vehicle to File this Litigation.

Spring is a new entity that has never engaged in any business. (Compl., ¶¶ 3, 68). It was formed in November 2017, less than a year before Winston & Strawn filed this lawsuit on Spring's behalf. (*Id.*, ¶ 68). The only two individuals Retrophin has been able to identify as being affiliated with Spring in any way are its "CEO," Mr. Li, who was until recently an associate at Winston & Strawn, litigation counsel to Spring in this lawsuit, and his wife, Ms. Hua, a CPA.[4]

According to his biography from the Winston & Strawn website, Mr. Li's practice focused on antitrust litigation and complex commercial litigation. (*See* Bansal Decl., Ex. D). Mr. Li appears to have kept apprised of developments in antitrust law—he is listed as a registered attendee on behalf of Winston & Strawn for meetings of the ABA Section of Antitrust in 2016 and 2017, as well as the ABA Section of Antitrust Law Antitrust in Healthcare Conference in 2018. (*Id.*, Exs. E-G.).

Ms. Hua, Mr. Li's wife, is a Risk and Controls Manager at Freddie Mac according to her LinkedIn page. (*Id.*, Ex. H). She graduated from the University of Virginia with a degree in taxation and is a Certified Public Accountant with the Virginia Board of Accountancy. (*Id.*). Public records indicate that Ms. Hua and Mr. Li jointly own a property in McLean, Virginia. (*Id.*, Ex. I). Neither Mr. Li nor Ms. Hua appears to have any experience in the pharmaceutical industry.

[4] The Complaint does not identify any individuals associated with Spring. As discussed below, *infra*, p. 6, Retrophin received communications from Mr. Li and Ms. Hua on behalf of Spring. Retrophin has been unable to identify any other individuals affiliated with Spring.

Spring's website consists of a single page with the company's contact information and no information about products, research, leadership, or employees. (*Id.*, Ex. J).

Spring does not even have an office. The address Spring provided to the Commonwealth of Virginia State Corporation Commission (*Id.*, Ex. K), and to Retrophin (*Id.*, Ex. L)—2010 Corporate Ridge, Suite 700, McLean, Virginia—is a Regus office offering "virtual" and shared workspace. (*Id.*, Ex. M).

The only public record of Spring's funding sources is a lien by litigation financing firm Vannin Capital LLC filed on August 10, 2018, two months before Winston & Strawn filed this lawsuit on behalf of Spring. (*Id.*, Ex. N).

C. Spring "Sets Up" the Litigation Under False Pretenses.

On January 19, 2018, just two months after Spring was formed as an LLC, Retrophin received a fax from Spring. (Compl., ¶ 73; Bansal Decl., Ex. O). The fax represented that Spring was a "generic pharmaceutical company currently developing a generic version of tiopronin." (Bansal Decl., Ex. O). It asked to purchase ten bottles, containing 100 tablets per bottle, of Thiola for the purposes of conducting bioequivalence studies. (*Id.*). Ms. Hua, who as noted above, is a Risk and Controls Manager at Freddie Mac, signed the fax, which listed Spring's address as a P.O. Box in McLean, Virginia, where Mr. Li and Ms. Hua jointly own a property. (*See id.*, Exs. O, H, and I).

On June 22, 2018, Retrophin received a letter from Spring sent by certified mail. (Compl., ¶ 75; Bansal Decl., Ex. L). The letter was signed by Mr. Li, who represented he was the "new CEO" of Spring, "a generic pharmaceutical company trying to develop generic tiopronin." (Bansal Decl., Ex. L). Mr. Li asked to buy samples of Thiola and listed Spring's address as 2010 Corporate Ridge, Suite 700, McLean, Virginia, a Regus facility offering "virtual" offices. (*Id.*; *see also* Ex. M.).

It is not clear from publicly available materials whether Mr. Li was still employed at Winston & Strawn at the time these requests were made.

D. The Development and Commercialization of Generic Drugs.

Developing and commercializing a generic drug requires time, resources, experience, and capital. A wide array of federal laws govern the industry, including the Federal Food, Drug, and Cosmetic Act ("FFDC"), codified as 21 USC Section 301 et seq., as modified by the Drug Price Competition Act of 1984 (also known as the Hatch-Waxman Amendments) and Generic Drug User Fee Amendments ("GDUFA"), as well as specific FDA regulations and guidance.

Generic manufacturers tend to avoid developing products for small markets (*i.e.*, less than $100 million) because it is likely unprofitable. (Compl., Ex. A., pp. 30, 43). After identifying a target drug, the manufacturer must develop a formulation with the same "active ingredients, route of administration, dosage form, strength, labeling, and conditions of use as, that brand drug." (Compl., ¶ 30). This requires access to development and manufacturing facilities that comply with the FDA's Current Good Manufacturing Practice ("cGMP") regulations, as well as a team with the requisite skills and knowledge to formulate and test the product. *See* 21 CFR §§ 210-11. The manufacturer must also secure active and inert ingredients that comply with the FDA's cGMP regulations. *See id.* Beyond the formulation itself, the FDA also requires the manufacturer to develop and test containers that are safe, have effective closure mechanisms, and are impermeable to light and/or water.[5]

[5] *See* 21 USC § 351(a)(3); *FDA Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics - Chemistry, Manufacturing, and Controls Documentation* (May 1999), *available at* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070551.pdf.

Only after developing a generic formulation can a manufacturer proceed to bioavailability and bioequivalence testing to assess similarity between the branded drug and generic product. The FDA has set forth comprehensive study protocols for both bioavailability and bioequivalence testing.[6] All testing must meet the FDA's rigorous safety and scientific standards.

Perhaps the most significant hurdle in bringing a generic to market is the manufacturer securing FDA approval through a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA"). *See* 21 USC § 355. Even the less stringent ANDA process requires hundreds of pages of forms and submissions covering a host of information on the development, composition, manufacturing, testing, and labeling of a generic. *See* 21 CFR § 314.94. For this reason, the FDA initially rejects many ANDAs and applicants must go through the laborious process of refiling.[7] If the FDA accepts the ANDA, it takes months or even years before the ANDA is reviewed and approved.[8]

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[6] *FDA Guidance for Industry: Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA* (Dec. 2013), available at https://www.fda.gov/downloads/drugs/guidances/ucm377465.pdf.

[7] *FDA Activities Report of the Generic Drug Program (FY 2018)*, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm625314.htm (noting that in FY 2018, 1044 ANDA were submitted, the FDA refused to receive 127 ANDA, and 606 ANDA were withdrawn); *FDA Guidance for Industry: ANDA Submissions – Refuse to Receive Standards* (Dec. 2016) at 3, *available at* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf (noting that the FDA refused to receive more than 1 in 10 ANDAs between 2013 and 2015 because of filing deficiencies).

[8] "Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA)," Testimony of Janet Woodcock, Director, FDA Center for Drug Evaluation and Research, before the Committee on Oversight and Government Reform (Jan. 28, 2016), *available at* https://www.fda.gov/newsevents/testimony/ucm484304.htm (noting that the FDA set a performance goal of 10 to 15 months for "first action" on ANDA applications).

ARGUMENT

I. SPRING LACKS CONSTITUTIONAL STANDING.

Article III of the United States Constitution limits federal court jurisdiction to actual cases or controversies. *Ballentine v. U.S.*, 486 F.3d 806, 814 (3d Cir. 2007). Several doctrines shape the boundaries of cases and controversies,[9] but "perhaps the most important of these doctrines is the requirement that a litigant have standing to invoke the power of a federal court." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012). "Absent Article III standing, a federal court does not have subject matter jurisdiction to address a plaintiff's claims, and they must be dismissed." *Common Cause of Pa. v. Pennsylvania*, 558 F.3d 249, 257 (3d Cir. 2009). Federal Rule of Civil Procedure 12(b)(1) is the proper vehicle with which to seek dismissal for lack of standing. *Ballentine*, 486 F.3d at 810 ("A motion to dismiss for want of standing is also properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter.").

Jurisdiction is a threshold question and the Court may not adjudicate a claim unless and until its jurisdiction is established. *Feingold v. State Farm Mut. Auto. Ins. Co.*, 517 Fed. App'x 87, 88 (3d Cir. 2013) (affirming plaintiff could not pursue claims without Article III standing). Courts "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991). The burden of establishing standing rests squarely on the complainant, and it must meet this burden for each claim alleged. *Ballentine*, 486 F.3d at 810 ("On a motion to dismiss for lack of standing, the plaintiff bears the burden of establishing the

[9] "The justiciability doctrines include standing, ripeness, mootness, the political-question doctrine, and the prohibition on advisory opinions." *Coastal Outdoor Advert. Grp., LLC v. Union, N.J.*, 676 F. Supp. 2d 337, 344 (D.N.J. 2009), *aff'd* 402 Fed. App'x 690 (3d Cir. 2010). Only standing is at issue in this Motion.

elements of standing."); *In re Schering*, 678 F.3d at 245 ("[A] plaintiff who raises multiple causes of action must demonstrate standing for each claim he seeks to press.").

A plaintiff can establish it has standing only if: (1) the plaintiff suffers an injury in fact which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) there is a causal nexus between that injury and the conduct complained of; and (3) it is likely a favorable decision will redress the injury. *Ballentine*, 486 F.3d at 814. "These requirements ensure that plaintiffs have a personal stake or interest in the outcome of the proceedings, sufficient to warrant . . . invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on . . . [their] behalf." *Joint Stock Soc'y v. UDV N. Am., Inc.*, 266 F.3d 164, 175 (3d Cir. 2001).[10]

In challenging standing, a defendant may pursue either a factual or facial challenge. *In re Schering*, 678 F.3d at 243. A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the actual truth of the jurisdictional allegations. *See id.*; *CNA v. U.S.*, 535 F.3d 132, 145 (3d Cir. 2008). In making a factual attack, the defendant may use sworn testimony to expose the plaintiff's failure to comport with subject-matter jurisdiction prerequisites. *Kwan v. U.S.*, 84 F. Supp. 2d 613, 616-17 (E.D. Pa. 2000).[11] This Motion is a factual attack.

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[10] Article III standing and antitrust standing are separate and distinct doctrines. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 302-03 (3d Cir. 2012). "An antitrust plaintiff must establish both for the Court to hear its claims. *Id*. "[A] Plaintiff['s] failure to do so [] renders any inquiry into antitrust (statutory) standing unnecessary." *Id.*

[11] A defendant may make a factual challenge before answering the complaint. *Berardi v. Swanson Mem'l Lodge No. 48 of Fraternal Order of Police*, 920 F.2d 198, 200 (3d Cir. 1990). ("[A] facially sufficient complaint may be dismissed before an answer is served if it can be shown by affidavits that subject matter jurisdiction is lacking."); *Knauss v. U.S.*, 2012 WL 176685, at *1 (E.D. Pa. 2012) (Joyner, J.) ("A factual challenge under Rule 12(b)(1) may be made prior to service of an answer.").

There are "three important procedural consequences" when a defendant raises a factual attack: (1) no assumption of truthfulness attaches to plaintiff's allegations; (2) the burden to establish subject matter jurisdiction shifts to the plaintiff; and (3) the Court may make "decisive" factual findings. *CNA*, 535 F.3d at 139.

Here, Spring asserts six causes of action, the basis for each of which is the allegation that Retrophin injured Spring or continues to injure Spring by excluding it or delaying its entry into the market. (Compl., ¶¶ 106, 117, 139, 159, 165, 169). Because Spring alleges the same injury for each claim, this motion challenges the sufficiency of this injury for each claim in a single analysis. *Finkelman v. NFL*, 810 F.3d 187, 203 n.98 (3d Cir. 2016) ("[Plaintiff] alleges the same injury for purposes of his Ticket Law and unjust enrichment claims. We therefore need not engage in a claim-by-claim discussion of standing.").

A. Spring Has Not Suffered an Actual Injury, Much Less One Traceable to Retrophin.

As far as Retrophin has been able to determine based on publicly-available information and without the benefit of discovery, Spring is not a generic pharmaceutical company; it has not developed, is not developing, and is not "ready to begin development" of a generic version of tiopronin. Rather, it is a company apparently formed by a former associate of Winston & Strawn (litigation counsel in this lawsuit), and his wife, a CPA, as a vehicle to bring this litigation. *Supra*, pp. 5-6. As such, its alleged inability to obtain samples of Thiola has not resulted in an "actual or imminent" injury-in-fact, and any alleged harm is not traceable to any Defendant. Spring lacks Article III standing.

The evidence summarized above, *supra*, pp. 5-7, suggests that Spring does not even have a genuine intention of manufacturing and selling a generic version of Thiola. But even if it had such an intention, that would not be sufficient to confer standing under Article III. *Lujan v. Defs. of*

Wildlife, 504 U.S. 555, 564 (1992) ("Such 'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the 'actual or imminent' injury that our cases require."); *see also Joint Stock Soc'y*, 266 F.3d at 177 ("[A]s things now stand, any future diminution of sales in this country, or any potential barrier to entering the United States vodka market, is conjectural or hypothetical since the plaintiffs have not expressed an intention to ship vodka here unless they are able to use the Smirnov name."); *ZF Meritor, LLC*, 696 F.3d at 302 (holding "vague assertions of desire, without any descriptions of concrete plans" insufficient to establish injury of market exclusion); *MGM Resorts Int'l Glob. Gaming Dev., LLC v. Malloy*, 861 F.3d 40, 47-48 (2d Cir. 2017) ("initial studies of the viability" without "any concrete plans" render injury "too remote and conjectural to support Article III standing"); *Energy Transp. Grp., Inc. v. Mar. Admin.*, 956 F.2d 1206, 1215 (D.C. Cir. 1992) ("potential harm is too speculative" where plaintiff was "involved in negotiations" to enter market but "has shown little evidence that such entry is probable"); *Space Expl. Techs. Corp. v. Boeing Co*., 2006 WL 7136649, at *5-6 (C.D. Cal. 2006) ("Although SpaceX has alleged many facts to show it is a potential competitor in the EELV–Class Markets, it nevertheless has failed to articulate an injury sufficient to satisfy constitutional standing requirements" because it "could not compete."), *aff'd*, 281 F. App'x 769 (9th Cir. 2008). Thus, a "recently formed compan[y] that wish[es] to . . . sell" products in a new market has not suffered an actual injury where it cannot demonstrate it was "meaningfully or adequately prepared" to do so. *Joint Stock Soc'y*, 266 F.3d at 170, 173.

Furthermore, to establish standing, the alleged injury must also be "fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court." *Ballentine*, 486 F.3d at 814. Where a potential competitor "simply [does]

not have the capability and experience required to compete," injury resulting from "allegedly anticompetitive conduct" is not traceable to the defendant. *Space Expl. Techs. Corp.*, 2006 WL 7136649, at *6–7; *Comsat Corp. v. F.C.C.*, 250 F.3d 931, 937 (5th Cir. 2001) ("[Plaintiff's] inability to enter the interstate market undermines its ability to meet the requirement that the challenged action be fairly traceable to the alleged injury."). Relatedly, a plaintiff must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Comsat Corp.*, 250 F.3d at 935. An injury is not redressable where, despite a favorable opinion, other obstacles will prevent alleviation of the harm. *See Coastal Outdoor Advert. Grp.*, 402 F. App'x at 692 (injury not redressable where cure was "contingent upon [plaintiff] securing municipal permits"). "Redressability is closely related to traceability," and courts consider them "two sides of a causation coin." *Coastal Outdoor Advert. Grp.*, 676 F. Supp. 2d at 348.

It is difficult to imagine a more extreme case of a plaintiff lacking the "capability and experience required to compete." *Space Expl. Techs. Corp.*, 2006 WL 7136649, at *6-7. As explained above, Spring was not even formed as an entity until less than a year before this lawsuit was filed. *Supra*, p. 5. It has never produced a drug (or anything else for that matter). *Supra*, p. 5. It has no office, and the only individuals affiliated with Spring are its "CEO," Mr. Li, who was until recently a litigation and antitrust associate at Winston & Strawn, litigation counsel to Spring in this lawsuit, and his wife, Ms. Hua, a CPA who works at Freddie Mac. *Supra*, p. 5. The only public record of funding sources is a lien by litigation financing firm Vannin Capital LLC filed on August 10, 2018, two months before Winston & Strawn filed this lawsuit on behalf of Spring. *Supra*, p. 6.

On the basis of this record, Spring plainly lacks the experience and resources needed to commercialize a generic version of tiopronin. Accordingly, Spring has not suffered an injury-in-fact that is traceable to the challenged conduct, nor redressable by this Court, and therefore lacks

Article III standing. This Court therefore does not have jurisdiction and should dismiss the Complaint.

B. Retrophin Reserves the Right to Seek Discovery Relating to Spring's Standing.

Retrophin has made a factual challenge to Spring's standing and the allegations of the Complaint are therefore not entitled to the presumption of truth. *CNA*, 535 F.3d at 139. On the basis of the record now before the Court, the Complaint should be dismissed. *Renne*, 501 U.S. at 316 (courts "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record").

To the extent Spring seeks to rebut the factual record now before the Court, Retrophin reserves the right to seek limited discovery to test Spring's assertions. *See Canavan v. Beneficial Fin. Corp.*, 553 F.2d 860, 865 (3d Cir. 1977) ("When a defendant moves to dismiss for lack of jurisdiction, either party should be allowed discovery on the factual issues raised by that motion."); *see, e.g.*, *Askew v. Trustees of the Gen.l Assembly of the Church of the Lord Jesus Christ of the Apostolic Faith, Inc.*, 776 F. Supp. 2d 25, 27 (E.D. Pa. 2011) (dismissing after ordering "standing-related discovery"), *aff'd*, 684 F.3d 413, 417 (3d Cir. 2012); *Astra Oil Trading NV v. PRSI Trading Co. LP*, 2009 WL 928672, at *2 (S.D.N.Y. 2009) (granting defendant jurisdictional discovery where record underdeveloped). Focused jurisdictional discovery promotes judicial efficiency as "[j]urisdictional discovery will usually be less burdensome than merits discovery, given the more limited scope of jurisdictional inquiries." *Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 109 (3d Cir. 2015).

II. SPRING FAILS TO STATE A CLAIM.

If Spring establishes its standing and the Court's jurisdiction (which it cannot do), the Court should dismiss the Complaint under Rule 12(b)(6) for failure to state a claim. 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); *see also Gelman v. State Farm Mut. Auto. Ins. Co.*, 583 F.3d 187, 190 (3d Cir. 2009).

"The costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint." *Twombly*, 550 U.S. at 558. 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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A court must dismiss an antitrust complaint when the plaintiff fails to plead facts to support an essential element of its claim, such as antitrust standing. *See Brunson Comm'ns, Inc. v. Arbitron, Inc.*, 239 F. Supp. 2d 550, 570-71 (E.D. Pa. 2002) (dismissing antitrust claims under the Sherman Act where the complaint "provided no factual allegations" that would support a core element of the claim).

As set forth below, the Complaint should be dismissed because: (1) Spring lacks antitrust standing; (2) Spring fails to plead a claim for monopolization; (3) Spring fails to plead a conspiracy; and (4) Spring fails to properly define a relevant product market. Its state law claims fail for the same reasons.

A. Spring Lacks Antitrust Standing.

To establish antitrust standing, a plaintiff must show it: (1) "suffered antitrust injury," and (2) is "the most effective plaintiff from among those who have suffered loss." *Alberta Gas Chems. Ltd. v. E.I. Du Pont de Nemours*, 826 F.2d 1235, 1240 (3d Cir. 1987), *cert. denied*, 486 U.S. 1059 (1988); *see also Korea Kumho Petrochemical v. Flexsys Am. LP*, 2008 WL 686834, at *3 (N.D. Cal. 2008) ("Courts vet a plaintiff's ability to establish antitrust injury at the pleading stage, because a plaintiff's ability to establish antitrust injury depends . . . on its underlying theory of

injury."). To show antitrust injury, Spring must plead Retrophin caused injury to its "business or property." 15 USC § 15; *see also Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489 (1977) (to prove antitrust standing, plaintiffs must plausibly allege they have suffered "injury of the type the antitrust laws were intended to prevent and that *flows from that which makes defendants' acts unlawful*" (emphasis added)).

Potential competitors that have not been injured in an *existing* "business or property" can demonstrate injury only if they sufficiently plead they had the "intention and preparedness" to enter a business, and would have done so, but for the defendant's alleged anticompetitive conduct. *Triangle Conduit & Cable Co. v. Nat'l Elec. Prod. Corp.*, 152 F.2d 398, 399 (3d Cir. 1945) ("The antitrust laws have the limited purpose of affording compensation to those who have at least the intention and preparedness of engaging in a designated business and who are actually injured in their business or property by an unlawful act. The situation of such plaintiff must be different from that of the general public."); *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, 2010 WL 331704, at *3 (E.D. Pa. 2010) ("[P]laintiff who was a 'potential' competitor during the time of the alleged unlawful behavior—in other words, a competitor who had not yet entered the market—must demonstrate intention and preparedness to enter the market in order to show injury."); *see also Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 994 (D.C. Cir. 1977) ("[E]very business must have started somewhere . . . [b]ut it does not follow from this that [the starting phase] is business, at least not for the purposes of the antitrust laws.").

As this Court put it in *Roxane Labs., Inc.*, "[i]f a plaintiff was unprepared to enter the market, then the defendant's behavior was not a but-for cause of plaintiff's inability to enter the market." 2010 WL 331704, at *3; *see also Out Front Prods., Inc. v. Magid*, 748 F.2d 166, 170 (3d Cir. 1984) (If a plaintiff cannot show it was "poised and ready to enter the market" "there is unlikely to be any

plausible evidence to show that defendants impeded this effort. Certainly, the law will not countenance a dormant plaintiff who springs into action only when it is time to file suit.").

Courts have adopted this standard in order to prevent treble recovery by opportunistic plaintiffs with speculative claims seeking windfall recoveries. *See e.g.*, *DeGregorio v. Segal*, 443 F. Supp. 1257, 1260-61 (E.D. Pa. 1978) ("Congress did not intend . . . to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation . . . . Treble damage relief has been confined, at least in the Third Circuit, to those individuals whose protection is the fundamental purpose of the antitrust laws."); *Laurie Visual Etudes, Inc. v. Chesebrough-Pond's, Inc.*, 473 F. Supp. 951, 955 (S.D.N.Y. 1979) ("One purpose of the requirement for standing to sue to recover damages for alleged antitrust conduct is to prevent the treble recovery provision of section 4 from in terrorem use by plaintiffs having speculative claims or seeking windfall recoveries."); Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: *An Analysis of Antitrust Principles and Their Application* (hereinafter Areeda & Hovenkamp, Antitrust Law), ¶¶ 349, 392 ("The preparedness hurdle . . . precludes opportunists from filing antitrust damage claims when they actually had no prior intention of entering the market in question"; "Refusing either to insulate wrongdoers from private attack or to grant treble damage windfalls to all nascent firms claiming exclusion, the courts entertain damage claims for precluded entry, but not too readily"; "[t]he nascent firm's claim has proved troubling . . . plaintiffs in the hundreds could say they would have entered. . . . Even if we could identify the most likely entrants among the claimants, we may doubt that they would have prospered when most new businesses fail anyway.").

In determining whether a plaintiff has the "intention or preparedness" to compete, courts look to objective signs, "the absence of any one of which may defeat the allegation," including: "(1) plaintiff's background and experience in the proposed business; (2) any affirmative action by

plaintiff to engage in the activity; (3) plaintiff's ability to finance the enterprise; and (4) consummation of contracts to enter the business." *Reaemco, Inc. v. Allegheny Airlines*, 496 F. Supp. 546, 554 (S.D.N.Y. 1980); *see also Brotech Corp., v .White Eagle Int'l Techs. Grp., Inc*., 2004 WL 1427136, at *5 (E.D. Pa. 2004) (same); *Out Front Prods*., 748 F.2d at 170 (same).

"A simple hope or expectation to enter a business is insufficient." *DeGregorio*, 443 F. Supp. at 1262; *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 611 F. Supp. 379, 386 (N.D.N.Y. 1985) ("An antitrust plaintiff cannot establish standing by merely stating that it could have been ready, willing and able to enter the business."), *aff'd*, 781 F.2d 879 (Fed. Cir. 1985); *Hecht*, 570 F.2d at 994 ("[C]ourts have drawn the line at the point where promotion transcends the level of hopes, desires, and expectations and reaches a certain stage of maturity and concreteness, a stage where it is accompanied by certain indicia of ultimate success."); *Broadcasters, Inc v. Morristown Broadcasting Corp.*, 185 F. Supp 641, 644 (D.N.J. 1960) (finding lack of antitrust standing because "plaintiffs were not engaged in a commercial venture or enterprise at the time this suit was brought; they entertained nothing more than an expectation that they would be so engaged in the license were granted"); *Reaemco, Inc.*, 496 F. Supp. at 554 (finding lack of antitrust standing because plaintiff's "chief asset was a hope and a hypothetical plan"). Minimal efforts will not suffice. *See*, *e.g.*, *In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 11 F.3d 1460, 1465–66 (9th Cir. 1993) (concluding plaintiff's efforts to enter an industry were "pie in the sky" where plaintiff "had not taken substantial demonstrable steps to enter the market," "had no experience," "no demonstrated ability to raise the money to enter the market," "had no product," and had only "talked" and "sen[t] some letters" to potential customers). A real capability to engage in the business and the taking of ***substantial steps*** toward entry are essential to demonstrate standing. *Id.*; *Brotech Corp.*, 2004 WL 1427136, at *5; *Out Front Prods*., 748 F.2d at 170.

Spring is, *at most*, a prospective competitor to Retrophin, (*see also, e.g.*, Compl., ¶¶ 3, 68, 78-80), and accordingly can demonstrate antitrust standing only if it sufficiently pleads an "intention and preparedness" to sell a generic version of Thiola. It has not done so. Indeed, the entirety of Spring's allegations regarding its "preparedness and intent" to sell a generic version of Thiola is limited to three short paragraphs. (Compl., ¶¶ 78-80).[12] Spring makes *no* allegations about *any* "background and experience," let alone anything regarding the developing and marketing of pharmaceutical products through the ANDA approval process. It makes no allegation that it has had any success in developing and selling generic drugs in the United States. It makes no allegations concerning the qualifications, experience, or number of its founders, principals, and employees. It does not because it cannot. Indeed, it admits that it is a new entity that has never engaged in any business. (*Id.*, ¶¶ 3, 68). And, Spring has not alleged that it has the expertise or resources necessary to navigate the complexities of the FDA regulatory approval process.

This stands in sharp contrast to *Roxane Labs., Inc.* in which this Court found that a potential competitor, an established generic drug manufacturer, had the "intent and preparedness" to enter the market because it was "a longstanding generic drug manufacturer with over 20 years of experience marketing generic drugs in the United States," "had manufacturing and distribution networks in place at the relevant time," "possessed a familiarity with the FDA approval process," and "reasonably believed that FDA approval was probable." 2010 WL 331704, at *4. Further, the court found that Roxane had taken "affirmative actions to enter the market." *Id.*

Spring seeks to bypass the requirement that it demonstrate its own experience and preparedness by alleging it has "been in negotiations" and "reached an agreement" with a contract

[12] These are facts Spring has in its possession and could have alleged without burden.

development and manufacturing organization ("CDMO") that will develop a generic version of Thiola. (Compl., ¶ 78). It alleges the vendor "is confident in its ability to develop a bioequivalent product" and "has a track record of success." (*Id.*). It does not, however, identify the CDMO, provide any details about its background and history with the FDA, or provide any detail about its "track record of success." It also alleges it has "been in discussions with expert consultants." (*Id.*, ¶ 79). But Spring may not rely, as it tries to do here, on the ability to subcontract to demonstrate its own preparedness. As courts have recognized, if a plaintiff could rely on the ability to hire subcontractors, the preparedness requirement would be rendered meaningless since anyone with the financial wherewithal to hire an experienced subcontractor could always show it was prepared to enter the market. *See Indium Corp of Am.*, 611 F. Supp. at 385-86.

Moreover, Spring does not adequately allege that it has the financial wherewithal to bring a drug to market. It merely vaguely states, without support, that it has "secured financing to bring the generic product to market, sufficient to include product development and regulatory submission." (Compl., ¶ 80). It does not state "the extent of investment," from where it secured it, and whether it has a written contract to receive funds and on what terms. Moreover, "product development and regulatory submission" are only the beginning stages of bringing a product to market. To sell a generic in the market, Spring would still have to market, sell, distribute, and manufacture the drug. Spring pleads that it has "plans to invest" in the sales, marketing, and supply of the generic Thiola, (*id.*, ¶ 80), but provides zero details of what those plans are, how it will execute those plans, and whether it has the financial capital to support those plans. Spring pleads too little. *Cavanaugh v. Cascor, Inc.*, 1996 WL 283676 at *3 n.5 (E.D. Pa 1996) (finding plaintiff lacked standing, in part, because it had "not demonstrated that he had the financial ability to enter the market"); *Sunbeam Television Corp. v. Nielsen Media Research*, 711 F.3d 1264, 1273

(11th Cir. 2013) (noting that in "capital intensive" industries, "a plaintiff must show the potential competitor prepared cash flow estimates and financial statements in order to determine the profitability of the expansion [and] had existing capabilities that would have allowed it to serve the market, took affirmative steps to obtain necessary government permits, etc."); *see also Korea Kumho Petrochemical*, 2008 WL 686834, at *4 (threadbare allegations regarding general "business plans" to enter relevant market did not establish preparedness); *see also Bubar v Ampco Foods Co.*, 752 F.2d 445, 453 (9th Cir. 1985) ("Because the corporation was only a potential competitor, the speculative nature of the harm is increased because of the uncertainty that it would ever have been financially able to become a competitor.").

Spring's allegations of intent and preparedness are of the type that courts routinely have found to be insufficient to confer antitrust standing. For example, in *Peller v. Int'l Boxing Club, Inc.*, the court found that a plaintiff without former fight promotion experience who undertook substantial negotiations and reached an oral agreement toward the promotion of a professional boxing match, including preliminary financial arrangements and discussions with boxers, lacked antitrust standing. 227 F.2d 593 (7th Cir. 1955). The court held that, because plaintiff had "never engaged in the fight promotion business" and had "entered into a series of separate negotiations which might have ripened into advantageous agreements, "at most, (plaintiff) only . . . desired to enter the business." *Id*. at 596. Indeed, here, Spring acknowledges that it "desir[es]" to enter the market. (Compl., ¶ 3).

Likewise, in *Laurie Visual Etudes, Inc.*, the plaintiff developed and held a patent on a medical device, and argued it was prepared to distribute that device but for the defendant's conduct. 473 F. Supp. 951, 955 (S.D.N.Y. 1979). The plaintiff contracted with a manufacturer to make the device, contingent upon its locating a distributor, and entered into substantial negotiations with

potential distributors, including the defendant, that collapsed. *Id.* at 957. The plaintiff sued the defendant for preventing its entry into the medical devices business, asserting it would have entered the market but for the defendant because its officers had prior extensive business experience in distributing other products, money had been invested to develop the patent, an agreement had been entered for production of the device, negotiations for contracts to distribute the goods were in progress, and it retained consultants who made field investigations of competitive patterns. *Id.* at 951. The court held that the plaintiff lacked standing to sue because it did not satisfy the preparedness criteria, noting the plaintiff's newness in the medical devices field, its failure to demonstrate the financial capacity to develop the device, and its inability to secure a distribution arrangement. *Id.* at 956-57. It concluded that the plaintiff was not a "competitor, hovering on the edge of the market," and "the only reason for [the plaintiff's] non-entry . . . has been its own incapacity." *Id*. at 956-58. Similarly, here, it is Spring's own "incapacity" that causes its harm.

In sum, Spring has no genuine intention or preparedness to enter the market, but rather, has developed a business model to extract payment in the form of treble damages. It has not distinguished itself in any way from the infinite universe of possible entrants, or the "general public," as this Circuit requires. *Triangle Conduit*, 152 F.2d at 399. It is precisely the type of "opportunist" plaintiff seeking a windfall payment that courts and scholars have warned against. The Court should dismiss its Complaint.

B. Spring Has Not Adequately Alleged a Monopolization Claim.

Even if Spring could show that it has antitrust standing to pursue its claims (and it cannot), Spring's claims would still fail because the Complaint does not allege a cognizable theory of antitrust liability. With respect to its Section 2 monopolization claim, Spring must show: "(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." *U.S. v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). Simple possession of monopoly power is not enough; a defendant must also engage in exclusionary conduct to violate Section 2. *See* Areeda & Hovenkamp, *Antitrust Law*, § 650a(1). "The [Sherman Act] directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself." *U.S. v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)).

1. Retrophin Has Not Engaged in Exclusionary Conduct Because It Has No Duty to Aid Its Rivals.

The Supreme Court has made clear that no company, *not even a monopolist*, has a duty to aid its rivals. *Verizon Commc'ns v. Law Offices of Curtis v. Trinko*, 540 U.S. 398, 415 (2004); *see also U.S. v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (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."); *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 . . . ."); *Only v. Ascent Media Grp., LLC*, 2006 WL 2865492, at *4 (D.N.J. 2006) ("There is no general duty to deal, and a company's refusal to do business with a potential business partner ordinarily does not give rise to a claim for relief under Section Two of the Sherman Act," other than in "exceptional circumstances."); *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 400 (7th Cir. 2000) ("[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."). Thus, only in narrow circumstances can a monopolist's refusal to cooperate with rivals violate Section 2, and the courts have "been very cautious in recognizing such exceptions." *Trinko*, 540 U.S. at 408. This is because the compelled sharing of resources: (1)

"lessen[s] the incentive . . . to invest" in those resources; (2) "requires [federal courts] to act as central planners" despite their being "ill suited" to assume this role; and (3) "facilitate[s] the supreme evil of antitrust: collusion." *Id.* at 407-08. Indeed, as the Supreme Court has made clear, the Sherman Act is the "the Magna Carta of free enterprise" and "[c]ompelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law." *Id.* at 407-08, 415.

The Supreme Court found an exception in *Aspen Skiing v. Aspen Highlands Skiing*, 472 U.S. 585 (1985), but subsequently distinguished the case as a "limited exception" that lay "at or near the outer boundary of § 2 liability." *Trinko*, 540 U.S. at 409. In *Aspen Skiing* a monopolist chose to end a long-standing partnership with a competitor to offer bundled ski lift tickets to both companies' mountains. *Aspen Skiing*, 472 U.S. at 585. The Court found that the monopolist's new willingness to "forego . . . short-run benefits" supported the argument that the monopolist was "interested in reducing competition . . . over the long run by harming its smaller competitor" and had engaged in exclusionary conduct in violation of Section 2 of the Sherman Act. *Id.* at 608.

Spring tries, but fails, to fit its allegations within the *Aspen Skiing* exception, alleging that Defendants "sacrifice[ed] short-term profits to achieve anticompetitive ends." (Compl., ¶ 67). However, if that alone were sufficient to allege an antitrust violation, the *Aspen Skiing* exception would swallow the general rule that competitors need not aid their rivals. Nearly every failure to aid a rival involves a sacrifice in short-term profits, and the freedom to choose with whom to deal allows that.

But more fundamentally, Spring fails to allege that Retrophin, in fact, sacrificed short-term profits. Unlike in *Aspen Skiing*, Spring has not alleged that Retrophin discontinued a mutually beneficial and long-standing relationship. Rather, it alleges that Retrophin did not respond to a

request to purchase a mere *10 bottles* of Thiola. (*See* Compl., ¶¶ 73, 75; Bansal Decl., Exs. O and L[13]). To allegedly forego such a *de minimus* sale opportunity comes nowhere close to the sort of economically irrational behavior that the Supreme Court found in *Aspen Skiing* and, thus, does not evidence anti-competitive intent. Rather, as in *Trinko*¸ Retrophin's conduct "sheds no light upon the motivation of its refusal to deal." *Trinko*, 540 U.S. at 409.[14]

Furthermore, a legitimate competitor has available to it other means by which it can enter the tiopronin market. Specifically, it could develop a tiopronin formulation under the NDA

[13] The Court may take notice of documents relied upon in the Complaint when considering a 12(b)(6) motion. *See In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1426 (3d Cir. 1997) ("[A] document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment."); *Fallon v. Mercy Catholic Medical Center of Southeastern Pennsylvania*, 877 F.3d 487, 493 (E.D. Pa. 2017) ("[W]hen deciding a motion to dismiss . . . a court may consider a document that is integral to or explicitly relied upon in the complaint.").

[14] It is worth noting in this context that Spring has not alleged nor is there any public record that Spring is an authorized drug distributor under California law, which prohibits a manufacturer, such as Retrophin, from furnishing a "dangerous drug" to an "unauthorized person." Cal. Bus. & Prof. § 4163(a). A dangerous drug is, among other things, a drug that is only available through prescription, such as Thiola. Cal. Bus. & Prof. § 4022. An "authorized person" is defined as either (a) "a person to whom the board has issued a permit"; or, (b) "any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located." 16 CA ADC § 1783. Spring does not allege, and there appears to be no public record, that Spring is registered as a drug establishment with the FDA, that it is a licensee registered with the California State Board of Pharmacy, or that it is an authorized distributor of pharmaceuticals under California or Virginia law.

pathway. *See infra*, pp. 27-29;[15] *see also Natco Pharma Ltd. v. Gilead Sciences, Inc.*, 2015 WL 5718398, at *5 (D. Minn. 2015) (reasoning that "[e]ven accepting Natco's allegations as true, Natco has failed to allege anticompetitive conduct based on a refusal to deal . . . [because the drug] is not completely unavailable," and thus, it can enter the market without the Defendant).

Lastly, Spring suggests that because Hatch-Waxman Act was designed to facilitate generic entry, the antitrust laws obligate Retrophin to make that entry as easy as possible. (*See, e.g.*, Compl., ¶¶ 37, 39.). But as the Supreme Court unequivocally stated in *Trinko*, statutes and regulations benefitting competitors do not create an antitrust duty to deal. 540 U.S. at 408-11; *Goldwasser*, 222 F.3d at 399 ("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.").

Congress should decide if branded-drug companies should have an affirmative duty to provide samples. As the Seventh Circuit articulated, "Congress could have chosen a simple antitrust solution to the problem of restricted competition. . . . It did not." *Goldwasser*, 222 F.3d at 399-400.

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[15] Significantly, this case is distinguishable from other district court cases where the branded drugs were patent-protected at the time the competitor sought to compete and therefore the route to market for the would-be competitor (importantly, an established drug manufacturer) was through the ANDA paragraph IV process. *See, e.g., Mylan Pharms. v. Celgene Corp.*, 2014 WL 12810322, at *1 (D.N.J. 2014) ("Celgene has several patents covering Thalomid, the last of which expires in 2023;" "Celgene's patents on Remlivid extend through 2027"); *In re Thalomid and Revlimid Antitrust Litig.*, 2015 WL 9589217, at *21 (D.N.J. 2015) ("Celgene has amassed what it describes as a significant portfolio of unexpired patents which cover Thalomid and Revlimid as medicines."); *Lannett Co., Inc. v. Celgene Corp.*, No. 2:08-cv-3920-TJS, ECF No. 29-5 (Defendant Celgene Corporation's Memorandum of Law In Support of its Motion to Dismiss) at p. 3 (E.D. Pa. July 7, 2010) ("Celgene holds several patents…the last of these patents does not expire until 2023"); *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH, ECF No. 44-1 (Memorandum of Law In Support of Plaintiffs' Motion for Judgment On the Pleadings and to Dismiss Counterclaims) at p. 3 (D.N.J. Jan. 16, 2013) ("Tracleer is patent-protected"; "Zavesca is a patent-protected drug."). In both *Lannett* and *Actelion*, the courts did not issue a substantive written opinion.

2. Thiola Is Not an Essential Facility.

Nor can Spring claim that Thiola samples are an "essential facility" that Retrophin must provide because Spring cannot enter the market without them. (*See, e.g.*, Compl., ¶¶ 120-22, 143, 146, 148-49, 150). Indeed, the Supreme Court has never recognized the "essential facilities" doctrine and expressly labeled it a "limited exception" "crafted by some lower courts." *Trinko*, 540 U.S. at 409-11 (citing Phillip E. Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 Antitrust L.J. 841 (1989)). Since then, lower courts and commenters alike have questioned the vitality and prudence of the doctrine. Indeed, this Court credited *Trinko* with "call[ing] the use of the [essential facilities] doctrine into question except in the most extreme cases." *Pocono Invitational Sports Camp v. Nat'l Collegiate Athletic Ass'n*, 317 F. Supp. 2d 569, 587 n.23 (E.D. Pa. 2004); *see also* Areeda and Hovenkamp, *Antitrust Law*, ¶ 771c ("[W]e state our belief that the essential facility doctrine is both harmful and unnecessary and should be abandoned.").

To the extent the essential facilities doctrine is alive at all, it is in the context of monopoly "leveraging" in which a firm uses monopoly power in one market to exert power in a downstream market. *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983) (concern under essential facilities doctrine is that a monopolist "can extend monopoly power from one state of production to another, and from one market into another"), *cert. denied*, 464 U.S. 891 (1983); *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."); Areeda & Hovenkamp, *Antitrust Law*, § 771(a) ("It should be clear that the essential facility doctrine concerns vertical integration—in particular, the duty of a vertically integrated monopolist to share some input in a vertically related market, which we call market #1, with someone operating in an upstream or

downstream market, which we shall call market #2. If the facility is truly 'essential,' then the #1 monopoly facility also establishes a #2 monopoly."). Here, there is no allegation of monopoly leveraging across markets, and the essential facilities doctrine does not apply.

In the limited circumstances where courts have applied the "essential facilities" doctrine, the cases have concerned access to physical facilities, such as pipelines, bridges, or railroads. *See, e.g., U.S. v. Terminal R.R. Ass'n of St. Louis,* 224 U.S. 383 (1912) (railroad bridge); *Otter Tail Power Co. v. U.S.*, 410 U.S. 366 (1973) (electric transmission lines). "The notion that withholding of technical information and samples of pre-release chip violates the Sherman Act, based on essential facility jurisprudence, is an unwarranted extension of precedent and can not [sic] be supported on the premises presented." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1357-58 (Fed. Cir. 1999); *see also Daisy Mountain Fire Dist. v. Microsoft Corp.*, 547 F. Supp. 2d 475, 489-90 (D. Md. 2008) ("[T]he essential facilities doctrine should not be applied in a case involving technological innovations or information."). To attempt to analogize samples of a drug to a bridge, a pipeline, or a railroad is to stretch the doctrine impermissibly far.

Perhaps most fundamentally, the denied facility must actually be *essential*. Where there are alternative means of competing, a facility is not essential. Thus, even if no other entity had samples of Thiola, because a legitimate generic competitor has other ways to enter the market, the samples are not "essential." Areeda & Hovenkamp, *Antitrust Law*, ¶ 736.2b (Supp. 1986) ("[A] facility is not essential if plaintiff can effectively compete without it."); Herbert Hovenkamp, *Unilateral Refusals to Deal, Vertical Integration, and the Essential Facility Doctrine* (Univ. of Penn Law Legal Scholarship Repository, Jul. 2008) at p. 35 ("A rule that permits firms to obtain from a larger rival inputs that they or other rivals could possibly construct for themselves reduces rather than increases competitive incentives."); *Cyber Promotions, Inc. v. Am.Online, Inc*., 948 F. Supp. 456,

464 (finding defendant had not established essential facilities doctrine because it "has not shown any reason why it could not (other than perhaps because it would have to pay its own way) use its own servers to create its own commercial online internet service or advertising website").

Here, a potential generic competitor can attempt to bring a competing product to market by filing a NDA rather than the short-cut approach under the ANDA process, as discussed above. *Supra*, p. 9. This may be more burdensome than filing an ANDA, but the most economical route is not an essential facility when other routes are available. *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 449-50 (2009) (A monopolist "certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous."); *Trinko*, 540 U.S. at 407-08, 415-16 ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition"; "Firms may acquire monopoly power by establishing an infrastructure that renders them uniquely suited to serve their customers. Compelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law."); *see also Midw. Gas Servs., Inc. v. Ind. Gas. Co.*, 317 F.3d 703, 714 (7th Cir. 2003). As the court in *Goldwasser* explained, duplicating an incumbent's facilities may require a large investment, take substantial time, and require a lot of effort, but that does not mean the incumbent's facilities are "essential." 222 F. 3d at 399.

C. Plaintiff Has Not Alleged a Conspiracy to Monopolize or to Restrain Trade.

"A plaintiff asserting a Section 1 claim" must adequately plead "four elements: (1) a concerted action by defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that plaintiff was injured as a proximate result of the concerted action." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l*, 602 F.3d 237, 253 (3d Cir. 2010). "The existence of an agreement is the hallmark of a Section 1 claim." *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 117 (3d Cir. 1999); *Gordon*

v. Lewistown Hosp., 423 F.3d 184, 207 (3d Cir. 2005) ("The essence of a Section 1 claim is the existence of an agreement.").

For "concerted action" to be found, plaintiff must show that the defendant was a party to a "contract, combination . . . or conspiracy." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984). Instead of assigning each of these last three terms a distinct meaning, courts have interpreted them collectively to require "some form of concerted action," *In re Baby Food Antitrust Litig.*, 166 F.3d at 117 & n.3, showing that a "unity of purpose or a common design and understanding or a meeting of the minds in an unlawful arrangement." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 331 (3d Cir. 2010). A plaintiff "must present evidence sufficient to carry its burden of proving that there was such an agreement" which "tends to exclude the possibility that the [defendants] were acting independently." *Monsanto*, 465 U.S. at 763-64.

"In order to succeed on a conspiracy to monopolize theory brought under § 2 of the Sherman Act, a plaintiff must prove: (1) the existence of a combination or conspiracy to monopolize; (2) overt acts done in furtherance of the combination or conspiracy; (3) an effect on an appreciable amount of interstate commerce; and (4) a specific intent to monopolize." *ID Sec. Sys. Canada, Inc. v. Checkpoint Sys., Inc.*, 249 F. Supp. 2d 622, 657–58 (E.D. Pa. 2003), *amended*, 268 F. Supp. 2d 448 (E.D. Pa. 2003). Within this framework, as well, a plaintiff must first establish an antitrust conspiracy to monopolize and bears "the burden of providing sufficient evidence to establish that the conspirators 'had a conscious commitment to a common scheme designed to achieve an unlawful objective.'" *Friedman v. Del. Cty. Mem'l Hosp.*, 672 F. Supp. 171, 196 (E.D. Pa. 1987) (quoting *Edward J. Sweeney & Sons, Inc. v. Texaco, Inc.*, 637 F.2d 105, 111 (3d Cir. 1980)).

Spring has not met the threshold requirement of pleading "concerted action" because it has not sufficiently alleged that Retrophin and the other defendants had a "meeting of the minds in an unlawful arrangement" or a "conscious commitment to a common scheme designed to achieve an unlawful objective." Rather, it simply alleges that defendants entered into lawful agreements to license and distribute Thiola. Therefore, there is no antitrust agreement and the Court need not analyze other factors to dismiss Spring's conspiracy claims (which include both its Section 1 claim (Count IV) and its Section 2 conspiracy to monopolize claim (Count III)).

1. Spring Alleges Only Unilateral Conduct, Rather Than a Conscious Commitment.

Section 1 of the Sherman Act does not proscribe independent action by a single entity, regardless of its purpose or effect on competition; it only covers "concerted" action. *Monsanto*, 465 U.S. at 761 ("Independent action is not proscribed" by Section 1); *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984) (holding Section 1 does not reach conduct that is "wholly unilateral"); *Siegel Transfer Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1131 (3d Cir. 1995) ("Proof of concerted action requires evidence that two or more distinct entities agreed to take action against a plaintiff.").

Spring asserts, with no support, that "Retrophin, in concert with Mission and Alamo, continued to implement, extend, and profit from the unlawful monopoly" (Compl., ¶ 61; *see also* ¶ 153), but its claims are wholly based on *unilateral* conduct. (*See, e.g.*, Compl., ¶ 54 ("Retrophin moved the drug into closed distribution."), ¶ 55 ("Retrophin will place Thiola into closed distribution."), ¶ 58 ("Retrophin raised the product's price."), ¶ 56 ("Retrophin appointed a . . . specialty pharmacy as the exclusive distributor of Thiola."), ¶ 57 ("Retrophin then significantly raised the price of Thiola"), ¶ 135 ("Retrophin . . . with the specific intent to move the drug into a restricted distribution scheme designed to prevent generic entry, and to thereafter set and preserve

monopoly level prices.")). Even where Spring alleges Alamo, Mission, and Retrophin acted to exclude it, Spring seems to allege they acted independently, in parallel, and fails to allege the three acted *together* pursuant to a "common scheme designed to achieve an unlawful objective." (*See, e.g.*, *id.*, ¶ 13 ("*Each* of Retrophin, Mission, and Alamo has refused to sell samples of Thiola to Plaintiff." (emphasis added)), ¶ 67 ("*[E]ach* of Retrophin, Mission, and Alamo has refused to sell samples of Thiola to Plaintiff." (emphasis added)), ¶ 77 ("Defendants have *each* refused to sell the required samples." (emphasis added)), ¶ 137 ("Most recently, by means of their refusal to provide essential samples to Spring, *each* of Retrophin, Mission, and Alamo has acted for the specific purpose of, and in furtherance of, monopolizing the Relevant Market." (emphasis added))).

To the contrary, Spring merely alleges the defendants entered into legitimate and legal contracts, including a Trademark License & Supply Agreement with Mission (what Spring alleges is the "Agreement") and a Master Services Agreement with Alamo. (*Id.*, ¶ 51 ("Retrophin acquired an exclusive license to market, sell, and commercialize Thiola in the United States."), ¶ 52 ("The Agreement also required Retrophin to appoint Alamo, Mission's Pennsylvania-based subsidiary, as the exclusive provider of sales force services pursuant to an incorporated Master Services Agreement." (quotations omitted)), ¶ 153 ("Defendants entered into a continuing contract, combination, or conspiracy to unreasonably restrain trade and commerce in violation of Section 1 of the Sherman Act.")). It does not allege these contracts are a "common scheme" to refuse to sell samples of Thiola. Nor does it allege that Retrophin instructed Mission or Alamo to refuse to sell samples to Spring or other generics pursuant to the Agreement, or that the Agreement itself restricted the sale of samples. Indeed, the Complaint contains no allegation that Mission or Alamo participated in, or were even aware of, Retrophin's alleged refusal to sell samples to Spring, and vice versa. *See Harold Friedman, Inc. v. Kroger Co.*, 581 F.2d 1068, 1074, 1078 (3d Cir. 1978)

("[F]or there to be concerted activity . . . the party combining with the defendant must have knowledge of the defendant's anticompetitive purpose."), *abrogated on other grounds by Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 748 (3d Cir. 1996). Spring does not allege that the purpose of the agreements was to unduly restrain trade or that the restraint of trade was the central purpose of the agreements. *See Mylan Pharms.*, 2014 WL 12810322, at *8 (finding plaintiff failed to adequately plead concerted action because the alleged restraint of trade was not central to the agreement between defendant and its distributors). And, Spring alleges no conspiracy outside of these formal agreements.

Spring cannot merely plead a contract exists. The Third Circuit has held that there is no agreement under Section 1 "when a party has simply entered into a permissible contract with the defendant or when the defendant has enforced a contractual right with another party." *Harold Friedman, Inc.*, 581 F.2d at 1078; *see also Garshman v. Universal Res. Holding, Inc.*, 641 F. Supp. 1359, 1370-71 (D.N.J. 1986) ("Contractual restraints fall within the prohibition of Section 1 only when their purpose and effect is found to have imposed an undue restraint on commerce."); *Mylan*, 2014 WL 12810322, at *8 (finding no agreement under Section 1 because plaintiff had "not pointed to any case holding that it is enough to simply plead that a contract exists" and where "[defendant] appears to conflate evidence of a contract with evidence of an unlawful 'agreement' to restrain trade under § 1"). Indeed, "[a] contract can serve as the basis for a Section 1 claim only if it embodies an agreement to unlawfully restrain trade. . . . Were this not the case, contractual partners would potentially be on the hook for any future conduct the other party engages in under color of the contract." *Procaps S.A. v. Patheon, Inc.*, 845 F.3d 1072, 1081 (11th Cir. 2016) (citations omitted); *see also* Areeda & Hovenkamp, *Antitrust Law*, ¶ 1473(a) ("There is rarely any doubt about the existence of some agreement—usually an express contract—between the principal and the agent.

But the alleged restraint is not typically the subject of the . . . agreement defining the parties' duties to each other.").

Rather, participants must actively commit to a scheme such that there is a "unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement." *Monsanto*, 465 U.S. at 764. Spring must show that the conspirators "communicated its acquiescence or agreement," and the agreement to which it acquiesced was "designed to achieve an unlawful objective." *Id.* at 764 & n.9; *see also Gordon*, 423 F.3d at 207 ("[C]oncerted action . . . requires proof of a causal relationship between pressure from one conspirator and an anticompetitive decision of another conspirator.").

At most, here, Spring has pleaded an agreement to license and distribute Thiola, not an agreement to refuse to sell samples to Spring. It has not alleged that defendants, pursuant to the Agreement, go beyond "merely performing [their] business function[s]." *See Harold Friedman, Inc.*, 581 F.2d at 1073; *see also Sheet Metal Duct, Inc. v. Lindab, Inc.*, 2000 WL 987865, at *6 & n.9 (E.D. Pa. 2000) (finding no conspiracy where plaintiff's "bare claim under Section 1 [wa]s that the exclusive distributorship arrangement itself constitutes the conspiracy to restrain trade" because relationship was a "legal exclusive distributorship"); Areeda & Hovenkamp, *Antitrust Law*, ¶ 1474(c) ("[V]ertical agreements are ubiquitous and essential to distribution . . . in vertical cases involving distribution restraints . . . the question must be whether the *right kind* of agreement exists. The distinction is particularly important when the plaintiff seeks to impose antitrust liability on some 'pawn,' such as a broker, distributor, or other intermediary when the intermediary lacks any motive to restrain . . . they are not complicit in vertical restraints simply because they were employed in a transaction later challenged as anticompetitive."). Therefore, Spring has not alleged

"a meeting of the minds in an *unlawful arrangement*." *Monsanto*, 465 U.S. at 764 (emphasis added) (quotations omitted).

In the absence of facts, Spring tries to plead its case through insinuation, suggesting that because Mission and Alamo would profit from the alleged antitrust conspiracy, they somehow must be involved in it. (Compl., ¶52 ("The Agreement also required Retrophin to appoint Alamo . . . providing Mission an additional form of compensation under the exclusive deal."), ¶ 64 ("Mission, for its part, continues to manufacture and supply Thiola exclusively to Retrophin in exchange for a cut of Retrophin's product sales benefitting from this anticompetitive distribution scheme."), ¶ 65 ("Alamo continues to serve as the exclusive sales force services provider for Thiola, benefitting from Retrophin's anticompetitive distribution scheme"), ¶ 136 ("Shkreli and Retrophin accomplished this scheme by entering into exclusive agreements with Mission and Alamo—entities that stood to profit from, and in fact perpetuated, the unlawful contractual and distribution scheme."), ¶ 156 ("Pursuant to these agreements, Mission and Alamo continue to profit from, and participate in, the exclusionary and unlawful distribution scheme.")).

But the law holds the contrary. "[P]arallel conduct by alleged co-conspirators is not sufficient to show an agreement. Indeed, [e]ven 'conscious parallelism,' a common reaction of 'firms in a concentrated market [that] recogniz[e] their shared economic interests and their interdependence with respect to price and output decisions' is 'not in itself unlawful.'" *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 321. The Supreme Court has required that "a § 1 plaintiff's offer of conspiracy evidence must tend to rule out the possibility that the defendants were acting independently." *Twombly*, 550 U.S. at 554. Indeed, "[c]ommon economic experience . . . show[s] that independent self-interest is an obvious alternative explanation for defendants' common

behavior," rather than an anticompetitive conspiracy. *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 326.

Moreover, in analyzing vertical conspiracies between an entity and its agent or an intermediary, any "benefit" or "stake in the restraint" must be "distinct from merely selling its own services for their usual market price" to support the finding of a conspiracy. Areeda & Hovenkamp, *Antitrust Law*, ¶ 1474(a), (c) ("While the broker has agreed to perform the brokerage function in exchange for a commission, it has not agreed to engage in predatory pricing merely by virtue of the brokerage contract. Likewise, a firm engaged in tying or exclusive dealing might distribute its goods through an independent broker, warehouse, or delivery agent who is compensated by a commission"; "The broker who merely earns its commission or the distributor taking its usual markup does not share a conscious commitment to a common scheme designed to achieve an unlawful objective."). Here, of course, Spring does not allege that Mission or Alamo receive some benefit beyond a usual and customary licensing royalty or commission. *Supra*, p. 32. And, of course, because they do not compete with Retrophin, Spring has not alleged they have a competitive interest, or would receive any competitive advantage, in excluding Spring or generic companies from the market. Therefore, Spring has failed to properly plead concerted action as the law requires.

2. Retrophin Cannot Conspire with Itself.

Spring also tries to allege an agreement between Retrophin and its employees (Martin Shkreli) and agents (Mission and Alamo). (*See, e.g.*, Compl., ¶¶ 62, 133 ("Defendants Shkreli, Retrophin, Mission, and Alamo entered into exclusive agreements with the specific intent to monopolize the Relevant Market.")). But, of course, a corporate parent cannot conspire with its own subsidiaries or individual employees under Section 1 of the Sherman Act. *Copperweld Corp.*, 467 U.S. at 769-771; *Siegel Transfer, Inc.*, 54 F.3d at 1134 ("A corporation can act only through its agents, thus the acts of corporate directors, officers, and employees on behalf of the

corporation are the acts of the corporation and a corporation cannot conspire with itself."). Thus, any allegations of a conspiracy between Retrophin and Shkreli must fail.

Likewise, the Third Circuit has found that entities that act as a single economic unit cannot conspire. *Siegel Transfer*, 54 F.3d at 1135 (holding there was no Section 1 violation because the alleged coconspirators were "[c]ontractually obligated to manage Carrier Express affairs" and "represented a single enterprise."); *see also Pink Supply Corp. v. Hiebert*, 788 F.2d 1313, 1317 (8th Cir. 1986) (holding that manufacturer and its sales representatives lacked conspiratorial capacity because they were "so closely intertwined in economic interest and purpose . . . as to amount to a unified economic consciousness incapable of conspiring with itself."). As the Court said in *Copperweld*, antitrust scrutiny should be focused on concerted action that "deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands." 467 U.S. at 769. This is because agreements with an agent or servicing entity that have 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." *Id.*

Here, Spring alleges that Mission and Alamo are contractually obligated to manage Retrophin's affairs. *Supra*, p. 32. Accepting those allegations as true, then Mission, Alamo, and Retrophin, represent a "single enterprise" incapable of conspiring under the antitrust laws. *Siegel Transfer, Inc.*, 54 F.3d at 1135; *see also Peerless Heater Co. v. Mestek, Inc.*, 2000 WL 637082, at *6 (E.D. Pa. 2000) (holding that "the economic interests of the sales representatives were completely aligned with that of [defendant]" and so defendant "was incapable of engaging in an antitrust conspiracy with its sales representatives."). Thus, any allegations of a conspiracy between Retrophin, Mission, and Alamo must be dismissed.

D. Spring Does Not Properly Plead a Relevant Market.

Spring's claims require it to plead properly a relevant product market in which the alleged harm occurred. *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. U.S.*, 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). "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 v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997); *see also Fresh Made, Inc. v. Lifeway Foods, Inc.*, 2002 WL 31246922, at *5-6 (E.D. Pa. 2002). 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. *See, e.g.*, *U.S. v. Ciba Geigy*, 508 F. Supp. 1118, 1153-55 (D.N.J. 1976).

Complaints that allege narrow markets without providing a plausible explanation are routinely dismissed. *See generally, e.g.*, *Todd.*, 275 F.3d at 199-200 ("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 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). That is because "[m]arket definition is generally a matter of degree. Even a monopolist is subject to limitations on how far it can increase price." *Todd*, 275 F.3d at 204.

Spring has narrowly defined the market so that it only includes one product, Thiola, stating there are "no substitutes." (Compl., ¶¶ 83, 92.) But the Complaint contains no factual allegations to indicate that this narrow market definition is plausible, and in fact, undermines its argument by acknowledging that Cuprimine is an FDA approved substitute for the treatment of cystinuria. (*Id.*, ¶ 83.). Other therapies for cystinuria are also available. *See supra*, at note 3, p. 4. Thus, Thiola is not "so unique that it suffers no actual or potential competitors." *Apple Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1198 (N.D. Cal. 2008).

Courts in this Circuit have rejected markets limited to a particular drug or class of drugs without accounting for therapeutic substitutes. *See, e.g.*, *Teva Pharms. Indus. v. Apotex, Inc*., 2008 WL 3413862, at *8 (D.N.J. 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 just hydrochlorothiazide products because they "compete in a market composed of all products indicated for the treatment of hypertension"); *see also Shionogi Pharma, Inc. v. Mylan, Inc.*, 2011 WL 2550835, at *6 (D. Del. 2011) (dismissing antitrust claims for failure to allege "facts showing a product market of reasonably interchangeable commodities from the perspective of the consumer"); *see also Kaiser Found. v. Abbott Labs.*, 2009 WL 3877513, at *8 (C.D. Cal. 2009) (rejecting market limited to Hytrin and its generic copies because it "excluded other alpha-blockers").

American Sales Co. v. AstraZeneca AB is particularly instructive. 2011 WL 1465786 (S.D.N.Y. 2011). 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. 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 where there are clear alternatives to Thiola for the treatment of cystinuria.

E. Spring's State Law Claims Fail.

Spring's state law claims fail because Pennsylvania does not have an antitrust statute and "[n]o court to date has held that a private remedy is available for damages under Pennsylvania's common law on antitrust violations." *XF Enterprises, Inc. v. BASF Corp.*, 47 Pa. D. & C.4th 147, 150 (Com. Pl. 2000); *Lakeview Ambulance and Med. Servs., Inc. v. Gold Cross Ambulance and Med. Servs., Inc.*, 1995 WL 842000, at *4 (Pa. Com. Pl. 1995) ("[N]o authority has been found holding that there exists in Pennsylvania a common law action for anti-trust violations when a competing public service business is attempting to prevent another business from entering its market area."). Causes of action for unfair competition exist under Pennsylvania common law in limited circumstances, but should not be extended here, where Spring simply repackages its antitrust claims under an unfair competition label. *See* Compl., ¶¶ 161-65 (Count V); *Lakeview Ambulance*, 1995 WL 842000, at *2 ("[U]nfair competition does not extend to discouragement of setting up competitive businesses where there is no appreciable deception intended to confuse one's goods for another's goods.").

Courts also disallow allegations of "unjust enrichment" used to cloak antitrust claims. *See* Compl., ¶¶ 166-69 (Count VI); *Stutzle v. Rhone-Poulenc S.A.*, 2003 WL 22250424, at *2 (Pa. Com. Pl. 2003) ("Since the Pennsylvania legislature and the courts have not created a cause

of action for damages sustained as a result of the antitrust violations . . . plaintiffs failed to allege within their complaint how the benefit to defendants was unjust. Moreover, to allow plaintiffs to use a claim for unjust enrichment as a means for collecting damages which are not allowable by Pennsylvania's antitrust law, is not a proper use of the claim and can only lead to mischief."); *In re K-Dur Antitrust Litig.*, 2008 WL 2660778, at *3 (D.N.J. 2008) (Where "unjust enrichment claim is fundamentally based on the same facts and alleged wrongdoing that form the basis of the . . . antitrust claims," and "[i]n view of the fact that neither Pennsylvania's legislature, nor its courts have created a cause of action for damages sustained as a result of antitrust violations, I conclude that [plaintiff] cannot use his unjust enrichment claim as a means to pursue damages that are not allowable under Pennsylvania's antitrust law.").

Even if Spring's claims were recognized under Pennsylvania's common law, they would fail for the same reasons its federal claims fail. *Fresh Made, Inc.*, 2002 WL 31246922, at *9 (dismissing state law allegations of unfair competition that "essentially mirror" Sherman Act claims"). Spring's state law claims should be dismissed.

CONCLUSION

For all the foregoing reasons, Retrophin respectfully asks the Court to dismiss the Complaint with prejudice. Retrophin requests oral argument on this motion to the extent it would assist the Court in analyzing and deciding the motion.

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Respectfully Submitted,

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* *Pro hac vice* applications pending.

CERTIFICATE OF SERVICE

I certify that on January 15, 2019, I filed this document on the Court's docket using the Court's CM/ECF system. Based on the Court's records, all counsel of record were served with a copy of the foregoing document by electronic means.

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