IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SAGE CHEMICAL, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 22-1302-CJB
	)	
SUPERNUS PHARMACEUTICALS, INC., *et al.*,	)	
	)	
	)	
Defendants.	)	

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MEMORANDUM OPINION

May 9, 2024
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

In this case, Plaintiffs Sage Chemical, Inc. ("Sage") and TruPharma, LLC ("TruPharma" and collectively with Sage, "Plaintiffs") bring antitrust claims against Defendants Supernus Pharmaceuticals, Inc. ("SPI"), MDD US Enterprises, LLC (f/k/a USWM Enterprises, LLC), MDD US Operations, LLC (f/k/a US WorldMeds, LLC), US WorldMeds Partners, LLC, USWM, LLC, Paul Breckinridge Jones, Herbert Lee Warren, Jr., Henry van den Berg, Kristen L. Gullo and Britannia Pharmaceuticals Limited ("Britannia").[1] Pending before the Court is Defendants' Omnibus Motion to Dismiss the operative First Amended Complaint ("FAC"), which was filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 49) For the reasons set forth below, the Court DENIES the Motion.

I. BACKGROUND

A. Factual Background

Parkinson's disease ("PD"), a progressive disorder affecting the nervous system, is primarily treated with a medication called levodopa. (D.I. 16 at ¶ 7) With long-term use, levodopa can wear off before another dose can safely be taken, and patients may begin suffering from PD symptoms during this period in what are known as "off episodes." (*Id.*) These symptoms can include unpredictable, sudden episodes where the patient experiences significant difficulty moving, tremors, anxiety, stiffness, and/or intense and painful muscle cramping. (*Id.*)

[1] Defendants SPI, MDD US Enterprises, LLC (f/k/a USWM Enterprises, LLC) and MDD US Operations, LLC (f/k/a US WorldMeds, LLC) will be referred to collectively herein as "Supernus." (*See* D.I. 16 at ¶ 43) Defendants US WorldMeds, LLC (i.e., the entity as it was known pre-sale to SPI), USWM Enterprises, LLC (i.e., the entity as it was known pre-sale to SPI), US WorldMeds Partners, LLC, USWM, LLC, Paul Breckinridge Jones, Herbert Lee Warren, Jr., Henry van den Berg and Kristen L. Gullo will be referred to collectively herein as the "US WorldMeds Defendants" or "US WorldMeds." (*Id.* at ¶ 56) Defendants Jones, Warren, Jr., van den Berg and Gullo will be referred to collectively herein as the "Individual Defendants." All Defendants together will be referred to collectively herein as "Defendants."

Injectable apomorphine hydrochloride can alleviate off-episode symptoms in as little as ten minutes. (*Id.* at ¶ 8)

This case is about Defendants' branded drug Apokyn® ("Apokyn") (also known as apomorphine hydrochloride injection), which is a prescription-only medication indicated for the treatment of off episodes in patients with advanced PD. (*Id.* at ¶¶ 1, 10) Apokyn is an FDA-approved combination product that includes a multi-dose apomorphine cartridge (the "Apokyn Cartridge") that is subcutaneously injected using a pen injector (the "Apokyn Pen"). (*Id.* at ¶ 11) The Apokyn Pen is a multi-use pen that is intended to be reused. (*Id.* at ¶¶ 11-12) Apokyn is sold in packs containing multiple Apokyn Cartridges. (*Id.* at ¶ 12) The Apokyn instructions for use indicate that a patient should not "use the pen for more than 1 year after the first use or after the expiration date on the carton." (*Id.*)

Apokyn was approved by the United States Food and Drug Administration ("FDA") in 2004, and it received exclusivity until April 2011. (*Id.* at ¶¶ 13, 14, 87) As of that date, the FDA's Orange Book did not list any patents for Apokyn. (*Id.* at ¶¶ 14, 87)

Shortly after Apokyn's exclusivity expired, Britannia, which owns Apokyn's North American development and marketing rights, appointed US WorldMeds, LLC (or "USWMO")[2] to commercialize Apokyn in the United States in exchange for royalty payments. (*Id.* at ¶¶ 16, 36, 38) The entities entered into an agreement on or around January 15, 2016 under which US WorldMeds, LLC received certain intellectual property ("IP") and product rights with respect to Apokyn, including the right to use and market the drug in the United States, with Britannia retaining certain IP and product rights regarding Apokyn, including the right to use and market

[2] Again, US WorldMeds, LLC has since been renamed MDD US Operations, LLC. (D.I. 16 at ¶ 41; *see also* D.I. 57 at 5)

the drug in the rest of the world aside from the United States. (*Id.* at ¶ 16) In June 2020, SPI, a pharmaceutical company that develops and commercializes products that treat central nervous system diseases, acquired US WorldMeds, LLC, including the United States rights to Apokyn. (*Id.* at ¶¶ 35, 57)[3]

On July 24, 2018, Sage, a pharmaceutical company "dedicated to developing and commercializing niche pharmaceutical products[,]" filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic apomorphine cartridge that was compatible with the Apokyn Pen. (*Id.* at ¶¶ 3, 33, 96)[4] Sage partnered with TruPharma, a pharmaceutical company that commercializes branded and generic prescription drugs for the United States market, to market and sell the generic cartridge. (*Id.* at ¶¶ 32, 34, 158) The FDA confirmed that Sage's ANDA was substantially complete on August 30, 2018; the agency provided a goal date for completing its review of March 23, 2019. (*Id.* at ¶ 97) However, the FDA did not ultimately

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[3] The FAC alleges that Defendant USWM, LLC and prior US WorldMeds entities, including US WorldMeds, LLC, have held themselves out under the name "US WorldMeds" as a privately-held specialty pharmaceutical company. (D.I. 16 at ¶ 40) During the time relevant to this litigation, US WorldMeds has "operated through several entities, including through US WorldMeds, LLC and USWM Enterprises, LLC until these entities were sold to [SPI.]" (*Id.*) USWM Enterprises, LLC (now known as MDD US Enterprises, LLC) was formed as a parent company to US WorldMeds, LLC. (*Id.* at ¶ 42)

Upon SPI's acquisition of the US WorldMeds entities, Defendants USWM, LLC and US WorldMeds Partners, LLC were created, and US WorldMeds now operates through USWM, LLC and US WorldMeds Partners, LLC. (*Id.* at ¶¶ 40, 44, 45)

The Individual Defendants are employees of the US WorldMeds entities; at least as of the time of the filing of the FAC, they held the same positions at USWM, LLC that they held at US WorldMeds, LLC prior to its sale to SPI. (*Id.* at ¶ 52) Jones is the Founder and Chief Executive Officer; Warren is the Chief Operating Officer; van den Berg is the Senior Vice President and Gullo is the Vice President, Development and Regulatory Affairs. (*Id.*)

[4] Sage's ANDA was the first ANDA referencing Apokyn as the reference listed drug (or "RLD") that was approved by the FDA. (*Id.* at ¶ 87)

approve Sage's ANDA until February 23, 2022. (*Id.* at ¶¶ 97, 167) The FDA's announcement stated that approval was for Sage's "drug cartridges only, which are compatible for use with the Apokyn Pen, the brand-name pen injector." (*Id.* at ¶ 172 & ex. G) The announcement further noted that the Apokyn Pen supplied by the brand manufacturer "is distributed and packaged separately"; the FDA instructed patients to first obtain the Apokyn Pen through a specialty pharmacy before being prescribed the generic cartridge. (*Id.*)

Plaintiffs allege that the US WorldMeds Defendants, Britannia and (as of 2020) Supernus executed a scheme to delay and restrain the entry of a generic version of Apokyn into the market—all in order to protect Apokyn's profits shared among Defendants. (*Id.* at ¶¶ 2, 17) Plaintiffs allege that this scheme included the following conduct:

- Defendants established a limited distribution network for and imposed restrictions on distributors and purchasers of Apokyn, which made it "exceedingly difficult" for Sage to gain access to Apokyn samples—samples that Sage needed in order to conduct certain FDA-required tests or respond to certain FDA requests during the ANDA approval process. (*Id.* at ¶¶ 18, 99-110);

- The US WorldMeds Defendants filed a series of three sham citizen petitions ("Citizen Petitions") to complicate the FDA review process and delay final approval of a generic version of Apokyn. (*Id.* at ¶¶ 19, 89-95, 111-15, 139-51);

- Defendants interfered with Sage's relationship with Defendants' supplier, Becton, Dickinson and Company ("BD"), which was the sole manufacturer of compatible apomorphine injection pens. (*Id.* at ¶¶ 20, 117) In late 2018 and early 2019, Sage was in discussions with BD regarding the potential for BD to supply such pens to Sage; BD had provided Sage with a proposal for Sage's purchase of an entire lot of pens and had told Sage that it did not enter into exclusive arrangements. (*Id.* at ¶¶ 21, 118, 120) Yet in September 2019, the US WorldMeds Defendants and Britannia renegotiated their February 2019 supply agreement for pens with BD; in the new agreement, BD was prohibited from selling pens to Sage or to anyone else who would use them in the United States to administer "apomorphine to treat symptoms of [PD]" (the "September 2019 Agreement"). (*Id.* at ¶¶ 20, 120-22 (internal

quotation marks omitted)) The September 2019 Agreement also required BD to terminate its negotiations with Sage. (*Id*.) Thereafter, BD told Sage that it could not supply Sage with pens after all. (*Id.* at ¶ 120);

- After Sage's generic cartridge product received FDA approval, Defendants interfered with launch of the product. Defendants sell Apokyn to a "limited network" of three primary specialty pharmacies (the "specialty pharmacies"): Accredo Health Group, Inc., CVS Specialty Pharmacy ("CVS Specialty") and Optum Rx Specialty. (*Id.* at ¶¶ 23, 161) In preparation for FDA approval, TruPharma had been in contact with buyers for the specialty pharmacies, and upon FDA approval it completed contracts with these pharmacies for the supply of generic cartridges. (*Id.* at ¶¶ 23, 173-79) SPI then coerced the specialty pharmacies to cancel orders for the generic cartridges, threatening to sue the pharmacies and terminate its distribution agreement with them if a generic cartridge was dispensed for use with the Apokyn Pen. (*Id.* at ¶¶ 23-24, 181-88); and

- Despite the fact that Sage's generic has been FDA approved, SPI falsely advertises on its website that Apokyn is "the only FDA-approved therapy in the United States" for the treatment of PD off episodes. (*Id.* at ¶¶ 26, 212 (internal quotation marks and emphasis omitted))

Plaintiffs allege that as a result of this conduct, Defendants have blocked competition and maintained nearly 100% of the relevant market for Apokyn. (*Id.* at ¶¶ 2, 6)[5] Average annual costs for Apokyn totals $98,000 per patient per year, with much of these costs paid for by the government pursuant to Medicare. (*Id.* at ¶¶ 2, 169, 234) SPI, and the US WorldMeds Defendants before it, have raised the price for Apokyn by more than 30% in the last five years. (*Id.* at ¶¶ 6, 229)

Additional facts relevant to resolution of the instant Motion will be discussed in Section III.

[5] As of the time of the filing of the FAC, less than 1% of patients have been able to access generic apomorphine cartridges. (D.I. 16 at ¶ 233)

B. Procedural History

Plaintiffs filed this action on October 3, 2022. (D.I. 2) On October 26, 2022, Plaintiffs filed the operative FAC. (D.I. 16) The FAC contains six Counts:

- Count 1: Agreements that Unreasonably Restrain Trade, Violations of Section 1 of the Sherman Act, 15 U.S.C. § 1; Section 3 of the Clayton Act, 15 U.S.C. § 14; New Jersey Antitrust Act, N.J.S.A. 56:9-3, (*id.* at ¶¶ 285-93);

- Count 2: Tying, Violations of Sections 1 & 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; Section 3 of the Clayton Act, 15 U.S.C. § 14; New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a), (*id.* at ¶¶ 294-303);

- Count 3: Monopolization and Attempted Monopolization in the Alternative, Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2; New Jersey Antitrust Act, N.J.S.A. 56:9-4(a), (*id.* at ¶¶ 304-17);

- Count 4: False, Deceptive, and Misleading Promotion/Advertising, Violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), (*id.* at ¶¶ 318-21);

- Count 5: Tortious Interference with Contract, (*id.* at ¶¶ 322-27); and

- Count 6: Tortious Interference with Prospective Economic Advantage, (*id.* at ¶¶ 328-35).

On January 10, 2023, Defendants filed the instant Motion. (D.I. 49)[6] The Federal Trade Commission ("FTC") filed a brief as *amicus curiae* on March 20, 2023. (D.I. 93) The Motion was fully briefed as of April 12, 2023. (D.I. 101) The Court[7] heard argument on the Motion on October 12, 2023. (D.I. 177 (hereinafter, "Tr."))

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[6] Certain Defendants also filed additional motions to dismiss the FAC on other grounds; those remain pending. (D.I. 48; D.I. 51; D.I. 54)

[7] On March 3, 2023, the parties jointly consented to the Court's jurisdiction to conduct all proceedings in this case, including trial, the entry of final judgment and all post-trial proceedings. (D.I. 78)

II. LEGAL STANDARD

When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting all of the complaint's well-pleaded facts as true, but disregarding any legal conclusions. *Id.* at 210-11. Second, the court determines whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In assessing the plausibility of a claim, the court must "'accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

III. DISCUSSION

With their Motion, Defendants make numerous arguments as to why all counts of Plaintiffs' FAC should be dismissed. The main thrust of these arguments is that it was Plaintiffs' own business choices (chiefly, Plaintiffs' decision to develop only a generic cartridge, instead of developing both a cartridge and a pen) that led to the failed launch of Plaintiffs' generic cartridge—and not any alleged anticompetitive conduct by Defendants. (D.I. 57 at 2; D.I. 100 at 2; Defendants' Omnibus Motion to Dismiss Plaintiffs' Amended Complaint Slides ("Defendants' Slides") at 1-3; Tr. at 26-27)

For the reasons explained below, the Court concludes that Plaintiffs sufficiently pleaded viable claims and that many of Defendants' arguments are more appropriate for later stages of this case. Below, it will address Defendants' arguments on a count-by-count basis.

A. Count 1: Agreements that Unreasonably Restrain Trade

Defendants assert that Count 1 should be dismissed because: (1) Plaintiffs fail to allege an overarching conspiracy among Defendants; (2) Plaintiffs fail to allege anticompetitive conduct; and (3) Plaintiffs fail to allege antitrust injury. (D.I. 57 at 12-27) The Court will take these arguments up in turn.

1. Whether Plaintiffs have sufficiently alleged an overarching conspiracy

Section 1 of the Sherman Act prohibits agreements that unreasonably restrain trade. *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 99 (3d Cir. 2010); *see also, e.g.*, *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 331 (3d Cir. 2018) ("To state a Section 1 claim, then, a plaintiff must allege (1) an agreement (2) to restrain trade unreasonably.").[8] Unilateral activity by a defendant cannot give rise to a Section 1 violation, because a defendant "has the right to deal, or refuse to deal, with whomever it likes, as long as it does so independently." *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 465 (3d Cir. 1998) (internal quotation marks and citation omitted). Instead, "a plaintiff must plead some form of concerted action . . ., in other words, a unity of purpose or a common design and understanding or a meeting of the minds or a conscious commitment to a common scheme[.]" *Lifewatch Servs. Inc.*, 902 F.3d at 333 (internal quotation marks and citation omitted). An agreement may be pleaded

[8] Defendants assert that Plaintiffs' state law claims in Counts 1, 2 and 3 rise and fall with their federal claims. (D.I. 57 at 2 n.2 (citing *Sickles v. Cabot Corp.*, 877 A.2d 267, 270 (N. J. Super. Ct. App. Div. 2005)). Accordingly, the Court herein focuses on Plaintiffs' federal antitrust claims, with the same conclusions applying to Plaintiffs' claims arising under the New Jersey Antitrust Act.

by alleging direct or circumstantial evidence. *UPMC*, 627 F.3d at 99. "If a complaint includes non-conclusory allegations of direct evidence of an agreement, a court need go no further on the question [of] whether an agreement has been adequately pled." *Id.*

The FAC alleges that Defendants engaged in overt acts that supported the same "conscious commitment to a common scheme designed to achieve an unlawful objective—the suppression of price competition through the delay and restraint of generic competition." (D.I. 16 at ¶ 286) In support of this assertion, Plaintiffs point to their allegations that[9]:

- US WorldMeds entered into agreements with the specialty pharmacies that created a restricted distribution system for Apokyn, thus denying Plaintiffs access to samples of the brand cartridges and pens required for development work on their generic product, (D.I. 86 at 28; *see also* D.I. 16 at ¶¶ 58, 99, 103, 288);

- In July 2019, US WorldMeds filed the second of three allegedly sham Citizen Petitions to delay generic approval, asserting that the FDA should require that any ANDA referencing Apokyn seek approval of both the pen and cartridge components of Apokyn, (D.I. 86 at 28; *see also* D.I. 16 at ¶¶ 58, 111-13, 134) The Individual Defendants are alleged to have been involved in the submission of the Citizen Petitions along with US WorldMeds. (D.I. 16 at ¶¶ 64-67);

- Around the same time, Britannia and US WorldMeds interfered with Sage's discussions with BD for a supply of pens. These Defendants executed the September 2019 Agreement with BD to foreclose generic access to pens, after BD communicated to Sage

[9] The Court notes that Plaintiffs' briefing was, at times, hard to follow. This was due in part to the fact that Plaintiffs did not respond on a point-by-point basis to each of Defendants' numerous arguments roughly in the order in which Defendants made those arguments. Instead, Plaintiffs' answering brief jumped around between issues in a different (and sometimes hard-to-discern) order of its own. (Tr. at 148-49) The Court has done its best to parse out Plaintiffs' responses to each of Defendants' arguments.

The Court further notes that Plaintiffs' incredibly voluminous slide deck—including a whopping 170 slides—at times appears to make reference to documents that have been obtained in discovery but are not cited to in the FAC. (*See, e.g.*, Plaintiffs' Motion to Dismiss Slides at Slide 138; D.I. 178 at 4) The Court will not consider any such material in rendering its decision on the instant Motion.

that it was cutting off discussions regarding the supply of pens in August 2019, (D.I. 86 at 26; *see also* D.I. 16 at ¶¶ 58-59, 121, 134, 136, 288 & ex. E);

- SPI then acquired the United States rights to Apokyn and, with that, acquired the September 2019 Agreement. Its CEO made clear that it had joined in the conscious commitment to eliminate price-cutting competition by ensuring that the brand's pen—which would be required for the generic cartridge—would not be available for the generic. In 2022, SPI then coerced pharmacies to cancel orders for the generic cartridges in order to maintain its Apokyn monopoly. (D.I. 86 at 28; *see also* D.I. 16 at ¶¶ 152-54, 181-88, 209-10, 288); and

- Britannia and USWM have not exited the conspiracy; instead, they continue to profit from it. (D.I. 86 at 29; D.I. 16 at ¶¶ 22, 59)

Defendants' argument here is that Plaintiffs fail to allege facts demonstrating Defendants' "joint participation" in an overarching conspiracy to restrain the launch of Plaintiffs' generic cartridge. (D.I. 57 at 12-14 (emphasis omitted); *see also* D.I. 100 at 2-4) On that front, Defendants point out that: (1) there are no allegations that SPI was involved with Apokyn prior to its June 2020 acquisition of the Apokyn business; (2) there are no allegations that Britannia was involved in the filings of purported sham Citizen Petitions or with imposing restrictions on the sale of Apokyn samples; and (3) there are no allegations that US WorldMeds Partners, LLC, USWM, LLC, the Individual Defendants or Britannia were involved in SPI's alleged post-acquisition conduct in 2022 (i.e., coercing the specialty pharmacies to cancel orders for the generic cartridges). (D.I. 57 at 12-13; D.I. 100 at 2-3) As for the FAC's allegations that Britannia and certain US WorldMeds Defendants have continuing financial interests in SPI's sales of Apokyn (and that this interconnects the parties for purposes of an overarching conspiracy), Defendants contend that simply having a financial interest in Apokyn's success does not turn these defendants into co-conspirators. (D.I. 57 at 13)

The problem with Defendants' argument is that it seems to assume that to sufficiently allege a Section 1 agreement, all Defendants have to join the conspiracy at the same time, and that they must be equally involved in all of the activities that are said to further the conspiracy. But that is not the case. (Tr. at 118-19) Instead, "there is no requirement that allegations pertaining to one defendant mirror those against other defendants in terms of specific conduct or 'quantity' of alleged 'bad acts.' Indeed, a defendant need not be accused of having engaged in all activities alleged to have advanced the conspiracy." *In re Processed Egg Prods. Antitrust Litig.*, 821 F. Supp. 2d 709, 742 (E.D. Pa. 2011); *see also, e.g.*, *In re Zetia (Ezetimibe) Antitrust Litig.*, Mdl No. 2:18md2836, 2019 WL 6977405, at *4 (E.D. Va. Dec. 20, 2019) ("An antitrust conspirator need not be involved in all aspects of the conspiracy[.]") (citing cases). And a conspirator can join the conspiracy at any time, meaning you can have a defendant (like SPI here) that is alleged to have joined the conspiracy later in time than other defendants. *In re Zetia*, 2019 WL 6977405, at *4 ("[A] party can still be a proper antitrust defendant even if it joined the conspiracy later than its co-conspirators."); *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 689 (S.D.N.Y. 2012) ("[A] conspirator may join a conspiracy at any time that it is ongoing; there is no requirement that a conspirator join in a conspiracy from its inception."); *In re Processed Egg Prods.*, 821 F. Supp. 2d at 741 ("'[L]atecomer status' is not enough to undercut the SAC's overall allegations as to Rose Acre which plausibly suggest that it agreed to the overarching conspiracy.").

In the Court's view, the FAC's allegations sufficiently establish "plausible grounds" to infer an agreement among the groups of Defendants at issue here.[10] *See Bell Atl. Corp. v.*

[10] Herein, as noted above, the Court will sometimes group together certain entities under the name "US WorldMeds" or the "US WorldMeds Defendants." In doing so, and in concluding that the conspiracy allegations in Count 1 are plausible, the Court is simply

Twombly, 550 U.S. 544, 556 (2007) ("Asking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement."). It is important to note that when evaluating allegations regarding a defendant's participation in the context of a multi-defendant conspiracy, the "character and effect of [the] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." *In re Processed Egg Prods.*, 821 F. Supp. 2d at 718-19 (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 699 (1962)).

As described above, the FAC alleges that Britannia and US WorldMeds knew that FDA approval of a generic version of Apokyn would mean that the branded product would lose significant revenue—and that these Defendants and SPI joined a common scheme to delay such a generic entrant. (D.I. 16 at ¶¶ 16, 288) Britannia and the US WorldMeds Defendants then negotiated the September 2019 Agreement, which purportedly shut off Plaintiffs' access to Apokyn pens. Just a few months before that agreement was inked, US WorldMeds is alleged to have filed a sham Citizen Petition "arguing that a generic could not be approved without compatible pens and that the pens would not be available for use with generics"—timing that can suggest that "the agreement and petition are related as part of a broader, coordinated strategy to restrain generic entry." (*Id.* at ¶¶ 111-14, 134) SPI then acquired the Apokyn business and

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concluding that at least one or more US WorldMeds Defendant participated in the alleged conspiracy. In light of the nature of Defendants' arguments here, the Court need get no more specific than that. (*See, e.g.*, D.I. 17, ex. E (September 2019 Agreement signed by US WorldMeds, LLC); D.I. 58, exs. 3-5 (US WorldMeds, LLC submitting Citizen Petitions)) Certain of the US WorldMeds Defendants (i.e., US WorldMeds Partners, LLC and USWM, LLC) further assert in a separate motion to dismiss that there are not plausible allegations specific to them indicating that they participated in antitrust violations. (*See, e.g.*, D.I. 50 at 7-8) The Court does not address those specific arguments here, and will instead address them when it takes up that other motion.

joined the September 2019 Agreement (i.e., it joined in the alleged anti-competitive effort by assuming an agreement that had been entered into by other Defendants), and then it engaged in additional acts said to further the common objective of restraining generic entry. (*Id.* at ¶¶ 152-54, 181-87; Tr. at 111, 117) And additionally, Britannia and US WorldMeds thereafter continued to profit (along with SPI) from the maintenance of the Apokyn monopoly. (D.I. 16 at ¶¶ 22, 59-60; Tr. at 113, 115); *see, e.g.*, *Amphastar Pharms., Inc. v. Momenta Pharms., Inc.*, 297 F. Supp. 3d 222, 231 (D. Mass. 2018) (holding that the plaintiff in an antitrust action sufficiently pleaded the existence of a conspiracy, where the complaint "plausibly alleges that the collaboration agreement between Sandoz and Momenta created financial incentives for the companies to exclude other producers of generic enoxaparin from the marketplace" and it "purportedly documented specific milestone payments for maintaining their status as the sole providers").

The Court must draw all reasonable inferences in favor of Plaintiffs at this stage. Doing so here, the FAC's allegations plausibly demonstrate that the various Defendant groups executed a common scheme to delay and restrain the entry of a generic version of Apokyn. That is, the FAC's allegations allow the inference that Defendants here had a unity of purpose and a conscious commitment to a common scheme, whereby they all worked to help torpedo Sage's entry into the relevant markets.

2. Whether Plaintiffs have sufficiently alleged anticompetitive conduct

In order to establish an antitrust violation pursuant to Section 1 of the Sherman Act, a plaintiff must show that, *inter alia*, the defendant engaged in anticompetitive conduct. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir. 2016); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012). Anticompetitive conduct can take a variety of forms; it is

generally defined as "conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007); *see also Spectrum Sports, Inc. v. McQuillan,* 506 U.S. 447, 458 (1993) ("The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.").

Defendants argue that Plaintiffs fail to plead anticompetitive conduct because the conduct that the FAC points to in that regard—(1) Apokyn's "Restricted Distribution System"; (2) the September 2019 Agreement; and (3) SPI's 2022 conduct—is not plausibly anticompetitive. (D.I. 57 at 14-25; D.I. 100 at 5-13) The Court takes these different categories of conduct up in turn.

a. Apokyn's "Restricted Distribution System"

The FAC pleads that Sage "had difficulty obtaining samples" of Apokyn in 2018 and through the first half of 2019; this was because certain of the Defendants had entered into agreements with wholesalers and distributers, which prevented the sale of Apokyn to licensed pharmacies unless the pharmacy was on an approved buyer list and agreed to restrict distribution of the drug. (D.I. 16 at ¶¶ 99-110) As a result, Sage filed its ANDA before obtaining samples of the RLD, hoping to persuade the FDA that Sage should not be required to provide data on the RLD because: (1) RLD samples were not available to Sage; and (2) the FDA had access to data for the RLD in the New Drug Application. (*Id.* at ¶ 100)

However, in October 2018, the FDA requested samples of the proposed generic and of the RLD in order to complete a clinical review. (*Id.* at ¶ 102) Sage responded the next day that the RLD "'is not available'" and that "'Sage has been unable to procure this'"; Sage subsequently provided alternative information that the FDA had requested. (*Id.* at ¶ 104) In January 2019, the FDA requested RLD test results compared with ANDA drug product results.

(*Id.* at ¶ 105) This prompted Sage to "again reach[] out to sources seeking RLD samples" but Sage was told such samples were unavailable. (*Id.* at ¶ 106) One source told Sage that the wholesaler would not allow it to order the product because it was "only available through a limited distribution network of specialty pharmacies." (*Id.* (internal quotation marks omitted)) These specialty pharmacies would only supply the RLD product directly to patients. (*Id.*)

Sage explained all of this to the FDA in a February 11, 2019 response and was hopeful that a timely FDA approval would follow, but it did not; instead, in June 2019, the FDA reiterated its request for samples and compatibility data regarding the proposed generic cartridge's use with the Apokyn Pen. (*Id.* at ¶¶ 107-08) Sage contacted additional possible sources and received one offer to be supplied RLD cartridges for $30,000 per 5-pack (requiring a months-long lead time); this offer was more than five times the list price for Apokyn. (*Id.* at ¶ 110) Sage was not able to find a better source, so in July 2019 (one year after filing the ANDA) it placed an order for five packs of RLD cartridges as well as Apokyn Pens at a price of about $150,000. (*Id.*) The FAC identifies as anticompetitive conduct "Defendants' agreements prohibiting the resale" of Apokyn and their efforts to delay Sage's ability to obtain Apokyn samples—conduct that, in turn, is said to have impeded the review and approval of Sage's ANDA and therefore to have delayed generic competition. (*Id.* at ¶ 225; *see also id.* at ¶ 18 (noting the then-FDA Commissioner's May 2018 public statement that an "abuse" that he has often spoken about "is a practice by brand companies to create obstacles for generic developers in purchasing samples of their brand drugs" and asserting that Apokyn distribution restrictions made it "exceedingly difficult" for generic companies to obtain samples))

Defendants counter by arguing that the FAC's allegations regarding Apokyn's "Restricted Distribution System" fail to plausibly allege anticompetitive conduct. This is so,

they say, because Plaintiffs do not allege that Sage *asked* any Defendant for samples or that any Defendant *refused to sell* samples to Sage, and because Sage was ultimately successful in obtaining samples. (D.I. 57 at 14-17; D.I. 100 at 5-6; Tr. at 39, 46) Furthermore, Defendants say that there is nothing inherently unlawful about restricted distribution systems. They assert that in the case of Apokyn, such a system was in place so that patients could receive proper training (i.e., at a limited number of specialty pharmacies) regarding subcutaneous injection of the medication. (D.I. 57 at 15, 17)

Keeping in mind that the Court must assess the facts relating to Defendants' restriction of access to samples of Apokyn as one of a "series" of acts that allegedly restrained competition, (*see, e.g.*, D.I. 16 at ¶¶ 4-5), the Court concludes that the "Restricted Distribution System" allegations can amount to a relevant part of the actionable anticompetitive conduct at issue here. *See LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) ("[C]ourts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, MDL NO. 2445, 2017 WL 36371, at *8 (E.D. Pa. Jan. 4, 2017) ("[A] plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable.") (citing cases). It does so for a few reasons.

The Court starts by addressing Defendants' main point: that Plaintiffs' reliance on Apokyn's Restricted Distribution System is insufficient because there is no allegation that Plaintiffs actually *requested* samples from Defendants. The Court is not persuaded. Defendants have not pointed the Court to any case flatly stating that a failure to plead that samples were

requested from the defendant means that the existence of a restricted distribution system cannot amount to anticompetitive conduct. (Tr. at 42-43, 94)[11]

Both sides do, however, point to the decision in *F.T.C. v. Vyera Pharms., LLC*, 479 F. Supp. 3d 31 (S.D.N.Y. 2020) as supporting their position. (D.I. 86 at 32-33 n.28; D.I. 100 at 5; Tr. at 43) In *Vyera*, the operative complaint pleaded facts indicating that "[t]hrough a restricted distribution system, the defendants sought to impede access to Daraprim and thereby prevent generic drug manufacturers from obtaining sufficient quantities of Daraprim to conduct bioequivalence testing." 479 F. Supp. 3d at 39-40. The *Vyera* Court concluded that the complaint adequately alleged that the restricted distribution system was an unreasonable restraint of trade adversely affecting competition in the relevant market. *Id.* at 47. But the decision does not expressly state that the plaintiff had *requested* samples from the defendant and had been refused. (*See* D.I. 86 at 33 n.28) And so *Vyera* does not seem to support Defendants' argument that a sample request must always be made (and refused) before evidence of a restricted distribution system can be relevant to alleged antitrust violations like these.

Moreover, drawing all reasonable inferences in Plaintiffs' favor, the allegations suggest that had they asked for such samples, Defendants would have said "no." (Tr. at 40, 80-81) For example, Plaintiffs allege that:

> Defendants . . . had apparently entered into agreements with wholesalers and distributors preventing the sale of the Apokyn[] product to licensed pharmacies unless the pharmacy was on an approved buyer list and had agreed to restrict distribution of the

[11] The Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act was passed by Congress in December 2019; the Act created a private cause of action under which generic companies can sue branded companies that refused to sell them product samples required to support their ANDA applications. (D.I. 16 at ¶¶ 81-82) Defendants point out that to assert a claim under the CREATES Act, the generic must submit a written request before suing. (D.I. 57 at 16 n.10) Sage, however, filed its ANDA before the CREATES Act was enacted. (D.I. 16 at ¶¶ 96, 99)

> product. *Defendants sought to prevent sales to generic companies like Sage*.

(D.I. 16 at ¶ 103 (emphasis added); *see also id.* at ¶ 106 (alleging that the "[s]pecialty pharmacies would only supply the RLD product directly to patients"); *id.* at ¶ 18 (alleging that "Defendants created and maintained a limited distribution network and imposed restrictions prohibiting distributors and purchasers *from providing Apokyn[] to generic companies or their agents*") (emphasis added)) The FAC also alleges that the wholesaler's website would not let a Sage source order samples "'[d]ue to manufacturer limitations on distribution[.]'" (*Id.* at ¶ 106) And the FAC asserts that shortly after the FDA approved Sage's ANDA, Supernus' CEO told investors that Sage's generic cartridge would need to be paired with the Apokyn Pen, which "will not be available for the generics, obviously." (*Id.* at ¶¶ 209-10 (emphasis omitted)) So the thrust of Plaintiffs' allegations seems clearly to be that Defendants *were* intentionally trying to withhold from Plaintiffs any item that might make it easier for Plaintiffs to market their generic product. In light of this, Defendants' claim that "Plaintiffs [f]ail [t]o [p]lead Apokyn's 'Restricted Distribution System' [i]mpeded Sage's [e]fforts [t]o [o]btain [s]amples" is not correct. (D.I. 57 at 14)

Beyond this main argument, Defendants also contend that they cannot be liable for "simply implementing a limited distribution system for a drug with safety issues[,]" (D.I. 100 at 5; *see also* Tr. at 40), and that "Plaintiffs understandably do not allege that Apokyn's restricted distribution served no legitimate purpose, especially given the patient-vulnerability at issue[,]" (D.I. 57 at 15). But as Plaintiffs point out, Apokyn was not subject to an FDA risk evaluation and mitigation strategy ("REMS") program that would require a restricted distribution program[12]

[12] *See, e.g.*, *In re Thalomid & Revlimid Antitrust Litig.*, Civil No. 14-6997 (KSH) (CLW), 2015 WL 9589217, at *1, *3 (D.N.J. Oct. 29, 2015) (where the drugs at issue caused

(or at least, there are no allegations in the FAC indicating that it was). (D.I. 86 at 32-33; Tr. at 97) Indeed, the FDA rejected a request by the US WorldMeds Defendants to require generics to provide a "device-use training program" that the FDA had not required "as a condition of approval for Apokyn[.]" (D.I. 16 at ¶¶ 90, 93 (emphasis omitted)) And as Defendants ultimately acknowledged during oral argument, (Tr. at 44-45), Plaintiffs *did* allege that there was no legitimate procompetitive justification for Defendants' restricted distribution system, (D.I. 16 at ¶¶ 30, 202-03, 205, 289). Any argument to the contrary from Defendants is not one that should be considered at the motion to dismiss stage. (Tr. at 97); *see Roxul USA, Inc. v. Armstrong World Indus., Inc.*, Civil Action No. 17-1258, 2018 WL 810143, at *6 (D. Del. Feb. 9, 2018) ("Weighing pro-competitive and anti-competitive effects is best reserved for summary judgment or trial after the benefit of discovery.").

b. September 2019 Agreement

The next category of conduct at issue is the September 2019 Agreement. In that regard, exclusive dealing agreements may constitute anticompetitive conduct. *3Shape TRIOS A/S v. Align Tech., Inc.*, C.A. No. 18-1332-LPS, 2020 WL 2559777, at *5 (D. Del. May 20, 2020), *report and recommendation adopted*, 2020 WL 6938054 (D. Del. Nov. 25, 2020). In an exclusive dealing arrangement, "a buyer agrees to purchase certain goods or services only from a particular seller for a certain period of time." *ZF Meritor*, 696 F.3d at 270. The United States Court of Appeals for the Third Circuit has explained that "[t]he primary antitrust concern with exclusive dealing arrangements is that they may be used by a monopolist to strengthen its

serious birth defects, the FDA conditioned approval on the brand developing restricted distribution programs for the drugs); *Natco Pharma Ltd. v. Gilead Scis., Inc.*, Civil No. 14-3247 (DWF/JSM), 2015 WL 5718398, at *1-2, *5 (D. Minn. Sept. 29, 2015) (noting that distribution of a drug at issue "is normally restricted as part" of the branded company's REMS program).

position, which may ultimately harm competition." *Id*. At the same time, many exclusive dealing arrangements are entered into for "entirely procompetitive reasons" and "pose little threat to competition." *Id.* In that regard, from the buyer's perspective, exclusive dealing arrangements "may assure supply, afford protection against rises in price, enable long-term planning on the basis of known costs, [] and obviate the expense and risk of storage in the quantity necessary for a commodity having a fluctuating demand." *Standard Oil Co. v. United States*, 337 U.S. 293, 306 (1949). Meanwhile, from the seller's perspective, such arrangements may reduce expenses, provide protection against price fluctuations, and offer the possibility of a predicable market. *Id.* at 306-07.

Because exclusive dealing arrangements are not *per se* illegal (in light of their potential procompetitive benefits), the legality of such agreements are judged under the rule of reason. *ZF Meritor*, 696 F.3d at 271; *3Shape TRIOS A/S*, 2020 WL 2559777, at *6. Because of this, the analysis "usually requires some fairly detailed facts, the ascertainment of which is often beyond the scope of a Rule 12(b)(6) inquiry." *Regeneron Pharms., Inc. v. Amgen Inc.*, C.A. No. 22-697-RGA-JLH, 2023 WL 1927544, at *5 n.6 (D. Del. Feb. 10, 2023) (internal quotation marks and citations omitted). Pursuant to the rule of reason analysis, courts consider, *inter alia*, whether the exclusive dealing agreement at issue will "foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *ZF Meritor*, 696 F.3d at 271; *see also Int'l Constr. Prods. LLC v. Caterpillar Inc.*, Civil Action No. 15-108-RGA, 2016 WL 264909, at *4, *6 (D. Del. Jan. 21, 2016).[13] Thus, a plaintiff must plead facts supporting a plausible

[13] In evaluating the legality of an exclusive dealing arrangement, in addition to substantial foreclosure, courts also consider "the likely or actual anticompetitive effects of the exclusive dealing arrangement, including whether there was reduced output, increased price, or reduced quality in goods or services." *Eisai*, 821 F.3d at 403. To assess the "likely or actual anticompetitive effects[,]" courts employ a burden-shifting approach to determine whether the

inference that the exclusive dealing arrangement resulted in substantial foreclosure to the relevant market. *Roxul USA, Inc.*, 2018 WL 810143, at *4; *3Shape TRIOS A/S v. Align Tech., Inc.*, C.A. No. 18-1332-LPS, 2020 WL 6938054, *1-2 (D. Del. Nov. 25, 2020) (noting that the complaint must adequately allege substantial foreclosure, but need not prove it at the pleading stage); *see also Vázquez-Ramos v. Triple-S Salud, Inc.*, 55 F.4th 286, 301 (1st Cir. 2022) (affirming a district court's grant of a portion of a motion to dismiss in an antitrust case, with respect to an amended complaint that did not "allege facts plausibly pointing to any substantial degree of foreclosure in the alleged market"). The test with respect to substantial foreclosure "is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005). In the pharmaceutical context, "generics need not be barred from all means of distribution if they are barred from the cost-efficient ones." *FTC v. Shkreli*, 581 F. Supp. 3d 579, 627 (S.D.N.Y. 2022) (quoting *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015)).[14]

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exclusive dealing arrangement violates the rule of reason. *Id.* at 403, 407. The Supreme Court of the United States explained this approach as follows:

> [T]he plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. . . . If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. . . . If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.

Ohio v. Am. Express Co., 585 U.S. 529, 541-42 (2018) (internal citations omitted).

[14] In a footnote, Defendants argue that the same analysis applies to both Plaintiffs' Sherman and Clayton Act claims, and therefore that Plaintiffs' claims under these statutes should be dismissed for the same reasons. (D.I. 57 at 18 n.11) Exclusive dealing claims are cognizable

Here, Plaintiffs contend that the September 2019 Agreement constitutes anticompetitive conduct. The FAC alleges that in late 2018 and early 2019, with its ANDA then pending, Sage was negotiating an agreement for BD to supply the same model of reusable injector pens that BD supplied to Defendants for use with Apokyn Cartridges. (D.I. 16 at ¶ 118) During these discussions, BD told Sage that its standard practice was to not enter into exclusive arrangements. (*Id.* at ¶¶ 120, 133) Meanwhile, Britannia and the US WorldMeds Defendants had previously entered into a February 2019 agreement with BD, by which BD would supply Defendants with the pens on a non-exclusive basis (the "February 2019 Agreement"). (*Id.* at ¶¶ 21, 121 & ex. F) But thereafter, Defendants learned that Sage was in the process of securing a supply of pens from BD. (*Id*. at ¶ 20) And by September 2019, Britannia, the US WorldMeds Defendants and BD had renegotiated the February 2019 Agreement. (*Id*. at ¶ 121) In doing so, they added exclusionary terms requiring BD to: (1) "'terminate'" its negotiations with anyone other than Defendants regarding supplies of pens for the administration of apomorphine to treat symptoms of PD; and (2) refrain from future negotiations in that regard with anyone other than Defendants. (*Id.* at ¶¶ 20, 121, 123 & ex. E) The September 2019 Agreement also provides that Defendants can—simply by providing written notice of their intent and paying a fee—unilaterally decide to

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under Sections 1 and 2 of the Sherman Act as well as Section 3 of the Clayton Act, and all such claims are evaluated under the same rule of reason test. *ZF Meritor, LLC*, 696 F.3d at 281; *see also Int'l Constr. Prods.*, 2016 WL 264909, at *4. In one sentence of this footnote, Defendants provide another independent reason why Plaintiffs' Clayton Act claims should be dismissed as to the September 2019 Agreement: i.e., that the Clayton Act does not apply to situations where a buyer (here Defendants) is said to restrict a seller (here BD) from dealing with the buyer's competitors (here Plaintiffs)—instead, it just applies to exclusivity imposed by a seller restricting buyers from dealing with the seller's competitors. (D.I. 57 at 18 n.11) However, arguments raised solely in footnotes are considered waived. *See, e.g.*, *John Wyeth & Brother Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997); *Maugain v. FCA US LLC*, Civil Action No. 22-116-GBW, 2023 WL 1796113, at *18 n.9 (D. Del. Feb. 7, 2023) (citing cases). And so the Court will not consider this argument further here.

enter into exclusivity periods that extend the exclusionary restrictions. (*Id.* at ¶ 132) In light of the September 2019 Agreement, BD broke off negotiations with Sage and has subsequently refused to discuss supplying pens to Sage. (*Id.* at ¶ 131) The FAC alleges that the September 2019 Agreement blocked Sage's access to the only pens currently approved by the FDA for use with an apomorphine cartridge. (*Id.* at ¶¶ 116, 145, 170, 227) As an ANDA applicant, Sage was unable to modify its label to use its generic cartridge with a different pen. (*Id.* at ¶ 117)

For their part, Defendants contend that the September 2019 Agreement is not an unlawful exclusive agreement for two reasons: (1) Plaintiffs fail to allege substantial foreclosure; and (2) Plaintiffs' claim that the agreement harms competition is not plausible. (D.I. 57 at 17-21; D.I. 100 at 6-9) The Court assesses each argument in turn.

i. Substantial Foreclosure

Defendants' first argument seems to be that in order to plausibly plead substantial foreclosure here, Plaintiffs would have needed to allege that BD's Apokyn Pen "is, and could be, the only device compatible with Plaintiffs' cartridge"—in other words, that Plaintiffs would have had to allege facts demonstrating why they could never have sourced a pen from any other supplier. (D.I. 57 at 19; Tr. at 62) This the Plaintiffs could not do, according to Defendants, because Plaintiffs had alternative means to reach the market and compete with Defendants. (D.I. 57 at 17-20; D.I. 100 at 6-7) In support of that assertion, Defendants note that: (1) Plaintiffs do not allege that BD is the only *potential* supplier of compatible injectors; and (2) Plaintiffs do not plead any reason why they could not have commissioned and sought FDA approval of their own injector before, during or after the time period in which they sought FDA approval for their generic cartridge. (D.I. 57 at 19; D.I. 100 at 6-7; Tr. at 49-50)

At this stage of the case, these arguments are not persuasive. It is true that in determining whether a plaintiff has proven substantial foreclosure, courts consider whether alternative channels of distribution were viable. *Roxul USA, Inc. v. Armstrong World Indus., Inc.*, Civil Action No. 17-1258, 2019 WL 1109868, at *8 (D. Del. Mar. 8, 2019) (noting, in resolving a motion for summary judgment, that "[w]e also ask in determining substantial foreclosure whether Rockfon could sell its products through alternative channels"); *Methodist Health Servs. Corp v. OSF Healthcare Sys.*, No. 1:13-cv-01054-SLD-JEH, 2016 WL 5817176, at *8 (C.D. Ill. Sept. 30, 2016) (explaining in resolving a motion for summary judgment that in the substantial foreclosure analysis, one "factor[]" courts consider is "whether a firm can reach the market through alternative channels of distribution (existence of alternative means of distribution lessens any anticompetitive effect)"). This is because "[i]f competitors can reach the ultimate consumers of the product by employing existing or potential alternative channels of distribution, it is unclear whether such restrictions foreclose from competition *any* part of the relevant market." *Roxul USA, Inc.*, 2019 WL 1109868, at *8 (internal quotation marks and citations omitted) (emphasis in original).

At the same time, the Third Circuit has noted (in reviewing a post-trial decision) that the proper inquiry is not whether an alternative channel is viable only in the sense that it is *possible*; instead, courts must look at whether the alternative is *practical or feasible* in the market as it exists and functions. *Dentsply Int'l.*, 399 F.3d at 193; *see also GN Netcom, Inc. v. Plantronics, Inc.*, 278 F. Supp. 3d 824, 829 (D. Del. 2017) (making this inquiry at the summary judgment stage and explaining that "the mere existence of other avenues of distribution is not enough on its own. . . . Instead, there must be an assessment of [the alternative means'] overall significance to the market, and such alternative means must be practical or feasible in the market as it exists and

functions") (internal quotation marks and citation omitted). And at the pleading stage, a plaintiff is not required to *prove* that the exclusive dealing agreement at issue left open practical or feasible alternative channels of access to the market. *See, e.g.*, *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 236 n.28, 239 (S.D.N.Y. 2019) (stating that "[h]ere, at this [motion to dismiss] stage of the litigation, I need not consider whether or not the[re] might be alternative channels of access to the market by the Competitor Plaintiffs" and finding that the plaintiffs adequately alleged substantial foreclosure of distribution where they pleaded that no other viable means of distribution existed outside of those foreclosed by the defendant); *FTC v. Qualcomm Inc.*, Case No. 17-CV-00220-LHK, 2017 WL 2774406, at *24 (N.D. Cal. June 26, 2017) (concluding that the issue of whether agreements did in fact leave open alternative channels of distribution was premature on a motion to dismiss); *Com. Data Servers, Inc. v. Int'l Bus. Machs. Corp.*, No. 00CIV5008(CM)(LMS), 2002 WL 1205740, at *7 (S.D.N.Y. Mar. 15, 2002) (rejecting defendant's argument that the allegation that defendant threatened two value added resellers ("VARs") in an effort to prevent them from selling certain products was insufficient to allege substantial foreclosure, and concluding that plaintiff met its burden of alleging a substantial foreclosure of competition in the relevant market).[15]

In the few cases where courts have found that a *pleading* failed to plausibly allege that competition has been substantially foreclosed in a particular market because of alternative channels of distribution, it was very clear on the face of the pleading that such other viable

[15] In *Com. Data Servers, Inc. v. Int'l Bus. Machs. Corp.*, the last of these cited cases, the United States District Court for the Southern District of New York later concluded, at the *summary judgment* stage, that the plaintiff had not sufficiently demonstrated substantial foreclosure—where the evidence of record demonstrated that numerous alternative channels of distribution existed, and that there were an estimated 150 VARs. *Com. Data Servers, Inc. v. Int'l Bus. Machs. Corp.*, 262 F. Supp. 2d 50, 75-77 (S.D.N.Y. 2003).

channels actually existed. For example, in *Int'l Constr. Prods. LLC v. Caterpillar Inc.*, Civil Action No. 15-108-RGA, 2016 WL 264909 (D. Del. Jan. 21, 2016), the "factual allegations pertaining to exclusive dealing arrangements [were] sparse" and the complaint "repeatedly acknowledge[d] multiple alternative means of distribution" but "simply dismiss[ed] these alternatives as inferior[.]" 2016 WL 264909, at *5; (Tr. at 139). In finding that the plaintiff failed to adequately plead the lack of alternative channels of distribution, the *Int'l Constr. Prods.* Court also noted that the complaint failed to "lay out any facts that show that a dominant firm barred competitors from entire modes of distribution, or from nearly all cost-effective means of distribution"; instead the pleading facially suggested "that there are several viable alternative means of distribution." 2016 WL 264909, at *6; *see also, e.g.*, *Power Analytics Corp. v. Operation Tech., Inc.*, Case No. SA CV16-01955 JAK (FFMx), 2018 WL 10231437, at *20 (C.D. Cal. July 24, 2018) (finding that the complaint failed to plausibly allege that competition has been substantially foreclosed in a particular market, but where the complaint identified several other competitors and did not explain how the agreement at issue affected the plaintiff's ability to partner with those other competitors, such that those competitors did not represent a viable alternative for the plaintiff), *aff'd*, 820 F. App'x 1005 (Fed. Cir. 2020).

In contrast to those types of cases, here the FAC sufficiently alleges the lack of alternative channels of distribution by asserting that: (1) BD was the *only* supplier of the *unique* pens that were compatible with the apomorphine cartridges, (2) Sage was in negotiations for a supply of those pens from BD; and (3) with the September 2019 Agreement, Defendants cut off Sage's negotiations to obtain access to those pens—access that would have enabled Sage to obtain FDA approval more quickly and to launch a generic cartridge with an injection pen. (D.I.

16 at ¶¶ 20, 116-17, 124, 199, 200, 256; D.I. 86 at 33-34; Tr. at 58)[16] And it is not clear on the face of the FAC how "feasible" and cost-effective it would have been for another supplier's pen to be FDA approved during the relevant timeframe. Certainly, there are no allegations in the FAC that make clear that it would in fact have been *easy* or even *viable* to do so. (Tr. at 131) Any argument that instead of going to BD, Plaintiffs could have and should have "commissioned and sought FDA approval" of their own pen is one best reserved for later in the case after discovery has taken place. *See, e.g.*, *Roxul USA, Inc.*, 2018 WL 810143, at *6 ("Armstrong's factual defense regarding the availability and viability of alternative distribution channels is best reserved for summary judgment or trial."); *Pro Search Plus, LLC v. VFM Leonardo, Inc.*, No. SACV 12-2102-JLS (ANx), 2013 WL 6229141, at *7 (C.D. Cal. Dec. 2, 2013) (finding it "premature" on a motion to dismiss "to determine whether the agreements do in fact leave open alternative channels of distribution").[17]

[16] These allegations (i.e., that in the time period of the September 2019 Agreement there were no other feasible existing means of procuring a supply of pens, and that the agreement blocked Plaintiffs' ability to obtain such a supply) are in contrast to allegations like those in cases like *Int'l Constr. Prods.* This is sufficient to plausibly allege substantial foreclosure. *Cf. Microbix Biosys., Inc. v. BioWhittaker, Inc.*, 172 F. Supp. 2d 680, 692 (D. Md. 2000) (concluding, at the summary judgment stage, that if the plaintiff could establish that upon learning that it was a potential generic competitor in the urokinase market, a defendant entered into an exclusive supply agreement with another defendant ("BioWhittaker"), then this could suffice to establish anticompetitive conduct, where BioWhittaker was the only source of FDA-approved HNK cells, and noting that if "[t]he need to develop an alternative HNK cell source presented a significant entry barrier" to that market, then the "anti-competitive effects of the exclusive agreement would be obvious").

[17] Defendants make a few other brief arguments with respect to substantial foreclosure. For example, they assert that Plaintiffs' allegations rely on a faulty market that includes only the BD-supplied Apokyn pen, and that the inability to get a single product from a single manufacturer cannot amount to substantial foreclosure. (D.I. 57 at 20) The Court will take up Defendants' arguments regarding the market below.

Defendants also contend that Plaintiffs fail to allege that "BD is such a significant potential supplier that the September 2019 [] Agreement could result in substantial foreclosure."

ii. Harm to Competition

Next, Defendants argue that Plaintiffs' claim that the September 2019 Agreement harms competition is not plausible, because the FAC instead shows that that agreement actually had procompetitive purposes. (D.I. 57 at 20-21) According to Defendants, the FAC's "exhibits show that, as of early 2019, BD had terminated production of Apokyn Pens and was 'recommissioning' the line 'to produce additional inventory'"—and that the September 2019 Agreement was designed to "'maintain sufficient manufacturing capabilities to ensure commercial supply' to meet the needs of patients.'" (*Id.* (quoting D.I. 16, exs. E, F); *see also* D.I. 100 at 8) Because the September 2019 Agreement resulted in an increased output of Apokyn Pens that BD was otherwise discontinuing, Defendants seem to suggest that it is procompetitive as a matter of law (and thus any antitrust claim based on this agreement must fail). (D.I. 57 at 21)

Defendants' argument here, again, is premature. (D.I. 86 at 31-32; Tr. at 129) The Third Circuit has explained that whether an exclusive dealing arrangement is legal depends on, *inter alia*, "an analysis of likely anticompetitive effects considered in light of any procompetitive effects." *ZF Meritor*, 696 F.3d at 271. At the pleading stage, however, a plaintiff need only plead plausible allegations that, if true, would demonstrate that an agreement's anticompetitive effects outweigh its procompetitive virtues. *See FTC v. AbbVie Inc.*, 976 F.3d 327, 356 (3d Cir. 2020). If a plaintiff does so, then the district court must allow the plaintiff to take discovery; if

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(*Id*.) Defendants did not further explain this argument, aside from including a citation to *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 286 (3d Cir. 2012). In that *post-trial* decision, the Third Circuit found that evidence demonstrated that the extent of the market foreclosure at issue was significant. *ZF Meritor*, 696 F.3d at 286. As described above, the FAC's allegations state that BD was the *only* supplier of the unique pens that Sage needed, and the September 2019 Agreement blocked Sage from getting access to this supply. That is sufficient at this stage of the case.

genuine issues of fact remain thereafter, the factfinder (not the court) must engage in a rule of reason analysis. *Id.*

The FAC meets that test here. (D.I. 86 at 31-32 & n.25) The allegations demonstrating the anticompetitive purpose and effects of the September 2019 Agreement include that:

> (1) The focus of the September 2019 Agreement's restriction on pens used for the administration of apomorphine to treat PD shows that the purpose and effect of the agreement is to cut off generic competitors from the only source of compatible supplies of pens.;
>
> (2) The fact that the exclusionary provision was added after Britannia, the US WorldMeds Defendants and BD had agreed to a non-exclusive agreement for pen sales just seven months before shows that the exclusionary provision was not reasonably necessary.;
>
> (3) The fact that BD could sell an unlimited number of pens to other buyers as long as they were not used to treat PD, and the fact that the number of pens needed to treat PD is very small (with one pen suitable for reuse for a year) demonstrate that the exclusionary provision cannot legitimately be needed to ensure a supply of pens to Defendants.;
>
> (4) The February 2019 Agreement already contained a provision regarding the quantity of pens to be delivered to Defendants; this demonstrates that any argument that the restrictions in the September 2019 Agreement were needed to ensure a supply of pens to Defendants is pretextual.; and
>
> (5) As a result of the September 2019 Agreement, generic options have been excluded, output of generic apomorphine cartridges and compatible pens have been reduced and Defendants have continued to increase the price of Apokyn.

(D.I. 16 at ¶¶ 124-27, 220-21) Defendants' contrary assertions—i.e., that the September 2019 Agreement was entered into for the procompetitive purposes of recommissioning BD's line of injectors and ensuring a commercial supply of such injectors—are not clearly correct, in light of the materials of record at this stage. And they can be taken up later with the benefit of discovery on these issues. *See Roxul USA, Inc.*, 2018 WL 810143, at *6 (rejecting the defendant's

assertion on a motion to dismiss that the procompetitive effects of exclusivity arrangements outweighed any anticompetitive effects, where the plaintiff "allege[d] sufficient facts outlining the anti-competitive effects the exclusivity arrangements have on the ceiling tile market" and because "[w]eighing pro-competitive and anti-competitive effects is best reserved for summary judgment or trial after the benefit of discovery"); *see also In re Keurig*, 383 F. Supp. 3d at 239 (noting that "any procompetitive justification for such restrictions is not appropriately weighed on a motion to dismiss); *Cap. Radiology, PLLC v. St. Peter's Hosp.*, CV 07-17-H-DWM, 2008 WL 11415918, at *6 (D. Mont. Mar. 6, 2008) (explaining that at the motion to dismiss stage, the court is "deciding only whether harm to competition is alleged, not whether the agreement is illegal" and that it is only for that latter inquiry where "the harm to competition against the procompetitive effects of the agreement" is weighed); *cf. Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 509 (2d Cir. 2004) (noting, in reversing the district court's grant of summary judgment, that the evidence suggested that there was one sole available supplier and that if that was indeed the case, "then an exclusive dealing agreement that dedicated all that supply to one buyer could freeze out competition to an extent that greatly outweighed any pro-competitive effects").

c. SPI's 2022 Conduct

The final category of conduct at issue relates particularly to SPI. The FAC alleges that upon FDA approval in February 2022, Plaintiffs entered into contracts with the specialty pharmacies to supply them with generic cartridges, but SPI then "aggressively interfered" with these contracts and coerced the pharmacies to cancel orders for the generic cartridges—all to exclude generic competition and maintain its monopoly. (D.I. 16 at ¶ 181) Specifically, SPI threatened to sue the pharmacies and terminate its distribution agreements with one or more of

them if they supplied patients with a generic cartridge along with the Apokyn Pen ("SPI's 2022 conduct"). (*Id.* at ¶¶ 181-82) SPI's efforts were successful, as all three of the specialty pharmacies reneged on their contracts, canceled orders and returned generic cartridges. (*Id.* at ¶¶ 183-87) Plaintiffs allege that SPI's 2022 conduct amounts to entering into "exclusionary exclusive dealing agreements" with the pharmacies (the "2022 Pharmacy Agreements") that cannot be justified by any procompetitive purpose. (*Id.* at ¶¶ 202-03)

Defendants argue that the 2022 Pharmacy Agreements do not amount to unlawful exclusivity agreements, because Plaintiffs have failed to allege substantial foreclosure. (D.I. 57 at 21-25) Defendants say this is so because the FAC fails to plead any facts indicating that Plaintiffs were foreclosed from marketing or developing their own injector. (*Id.* at 23-25; D.I. 100 at 13 n.9 ("Plaintiffs simply fail to plead foreclosure because they fail to allege that they could not have commissioned their own injector.")) Instead, according to Defendants, Plaintiffs' allegations demonstrate that the specialty pharmacies canceled orders because they were unable "to dispense Plaintiffs' generic cartridges for use with the Apokyn[] pen"—in other words, it was Plaintiffs' strategy to "free-ride on Apokyn Pens" that led to the specialty pharmacies canceling orders. (D.I. 57 at 21)[18] Defendants continue that SPI did not anticompetitively block Plaintiffs' use of the Apokyn Pen, because distribution restrictions "aimed at preventing free-riding are legitimate and competition-enhancing." (*Id.*; *see also* D.I. 100 at 9)

Defendants' arguments relating to SPI's 2022 conduct are not winners here, for a few reasons.

[18] In antitrust law, "[f]ree-riding is the diversion of value from a business rival's efforts without payment." *Chi. Pro. Sports Ltd. P'ship v. Nat'l Basketball Ass'n*, 961 F.2d 667, 675 (7th Cir. 1992).

As an initial matter, as discussed above, any assertion that Plaintiffs could have and should have manufactured and launched their own generic pen instead of solely pursuing a generic cartridge is premature at the motion to dismiss stage. This is further demonstrated by Defendants' reliance on the decision in *Sandoz, Inc. v. United Therapeutics Corp.*, Case No. 2:19-cv-10170 (BRM) (JSA), 2022 WL 17335696 (D.N.J. Mar. 30, 2022). Defendants assert that the *Sandoz* Court rejected nearly identical claims "for reasons present on the face of the Complaint." (D.I. 57 at 22-23; *see also* D.I. 100 at 13 n.9)

In *Sandoz*, the generic company filed antitrust claims against the brand manufacturer. Administration of the drug at issue required a pump and cartridge; the brand manufacturer entered into an agreement with the supplier of the cartridges, by which it took title to all of the pump-compatible cartridges and became the sole distributer of these cartridges to the specialty pharmacies that provided the drug to patients. *Sandoz*, 2022 WL 17335696, at *1, *5-6. The defendant required the specialty pharmacies to supply cartridges only to patients who were dispensed the branded drug product. *Id.* at *6. The plaintiff alleged that the defendant "cornered the market for cartridges needed" for administration of the drug, "effectively blocking the entry of [its] generic product to the market." *Id.* at *2. The *Sandoz* Court ultimately agreed with the defendant that the plaintiff did not show substantial foreclosure of the relevant market. *Id.* at *15.

Importantly, however, this decision was rendered at the *summary judgment* stage of the case. The *Sandoz* Court explained there that the "record shows" that the plaintiff was "not foreclosed from contracting with other manufacturers to secure cartridges for its own use"; it pointed out, for example, how the record demonstrated that months before the plaintiff/generic's planned launch, it had "declined to pursue an arrangement" with the former supplier of the

cartridges. *Id.* at *14-15. This summary judgment decision, rendered after the benefit of discovery, does not compel the Court to find here—at the *pleading stage*—that Plaintiffs have failed to sufficiently plead substantial foreclosure. (D.I. 86 at 34 n.31) Indeed, the *Sandoz* Court had previously *denied* a motion to dismiss, *see Sandoz, Inc. v. United Therapeutics, Corp.*, Case No. 3:19-cv-10170-BRM-LHG, 2020 WL 697137, at *18-20 (D.N.J. Feb. 4, 2020), in which the defendants had made the same arguments that Defendants make here, *see* Case No. 19-10170-BRM-LHG, (D.I. 53-1 at 6-12) (D.N.J. May 24, 2019) (arguing that the plaintiffs "do not allege that they made any effort whatsoever to secure a supply of any pump or cartridge during the *eight-plus years* since Sandoz filed its treprostinil ANDA . . . . [n]or do they allege any reason they could not have invested time and money into securing an alternative pump at a much earlier point" and that plaintiffs' claims should therefore fail because they did not plead market foreclosure) (emphasis in original).[19]

As for Defendants' assertion that SPI's 2022 conduct was not unlawful because it was fairly aimed at preventing Plaintiffs from free-riding on Defendants' Apokyn Pens, this is also an argument for a different stage of the case. It is true that a firm "may seek to limit how

[19] While Defendants assert that the FAC pleads that Plaintiffs are "equally efficient competitors" with the capability of developing a pen, (D.I. 57 at 23 (citing D.I. 16 at ¶¶ 33-34, 145); *see also* Tr. at 65), the cited paragraphs of the FAC do not use that wording. Instead, the paragraphs simply note that: (1) Plaintiffs are pharmaceutical companies, with Sage dedicated to the development and commercialization of niche products; and (2) Sage understood the commercial challenges of sourcing a pen (in light of its work to reach agreement with BD, which was later cut short due to the September 2019 Agreement). (D.I. 16 at ¶¶ 33-34, 145)

Defendants also contend that Plaintiffs have not alleged any conduct by SPI or any other Defendant that blocked Plaintiffs from taking actions necessary to compete. (D.I. 57 at 24-25) That is not a persuasive argument, because the FAC pleads plenty of facts alleging that Defendants blocked Plaintiffs from competing, such as, for example, when Britannia and the US WorldMeds Defendants entered into the September 2019 Agreement with BD and required BD to terminate its negotiations with Sage, and when SPI coerced the specialty pharmacies to renege on their contracts with TruPharma. (D.I. 16 at ¶¶ 118, 121, 130-31, 183)

competitors or potential competitors might free-ride on its investments." *In re Keurig*, 383 F. Supp. 3d at 238; *see also, e.g.*, *N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, 883 F.3d 32, 43 (2d Cir. 2018) ("Eliminating free riders can be a procompetitive advantage of alleged restraints on competition like vertical price agreements."); *Picker Int'l, Inc. v. Leavitt*, 865 F. Supp. 951, 968 (D. Mass. 1994) ("It has generally been recognized that vertical agreements designed to prevent free-riding do not violate [Section] 1 of the Sherman Act because free-riding discourages capital investment and product innovation."). As the Supreme Court of the United States explained in *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004):

> 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, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities.

540 U.S. at 407-08 (*cited in* D.I. 57 at 22; D.I. 100 at 9).

In the Court's view, however, it is not clear that principle set out in *Trinko* spells doom for Plaintiffs' reliance on SPI's 2022 conduct. As Plaintiffs point out, in another case—*Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451 (1992)—the Supreme Court made statements that could suggest that Defendants' free-riding arguments are off base. In *Kodak*, the Supreme Court found that there was a triable issue at the summary judgment stage as to whether prevention of free-riding justified the defendant's conduct in restricting independent service organizations ("ISOs") from having access to replacement parts for the defendant's photocopiers and micrographic equipment. 504 U.S. at 456-58, 483, 485. Kodak's refusal to sell parts to the ISOs—parts that were not available from any other source—made it more difficult for the ISOs

to compete with Kodak in servicing Kodak's equipment. *Id.* at 457-58. Kodak had argued that the ISOs were free-riding because they had failed to enter the equipment and parts market (instead, the ISOs had only invested substantially in the service market), and that Kodak's policies were justified to prevent the ISOs from free-riding on Kodak's investment in product development and manufacturing. *Id.* at 485. The *Kodak* Court rejected this argument, however. It explained that "[t]his understanding of free-riding has no support in our case law.[] To the contrary . . . one of the evils proscribed by the antitrust laws is the creation of entry barriers to potential competitors by requiring them to enter two markets simultaneously." *Id.* The Supreme Court noted that Kodak's free-riding justification might have been more applicable if the ISOs were relying on Kodak's investment in the *service* market rather than the underlying equipment and parts market. *Id.* at 485 n.33.

Plaintiffs argue that Defendants' free-riding argument (i.e., that Plaintiffs are free-riding on the Apokyn Pen), (*see* D.I. 57 at 21-22), is premised on legal error in light of *Kodak*, (D.I. 86 at 34-35; Tr. at 98-99). According to Plaintiffs, *Kodak* dictates that in order for Defendants' free-riding argument to apply, Plaintiffs would have to be free-riding on Defendants' investment in the apomorphine *cartridge* market—i.e., Plaintiffs would have to be free-riding on the same kind of product that Defendants make and that Plaintiffs are trying to make (cartridges), instead of on a different, complementary product (injectors). (D.I. 86 at 35; Tr. at 98-99) As the FAC alleges, SPI's 2022 conduct "is not protecting against free-riding on *its* investments, but is rather blocking competitors from accessing compatible pens and distribution networks that *others* created in order to substantially foreclose access to resources and distribution channels needed to

compete" with SPI. (D.I. 16 at ¶ 203 (emphasis in original))[20] Defendants, for their part, retort that *Kodak* supports their view, in that Plaintiffs are seeking to "enter cartridges" to free-ride off "Defendants' investment in the injector and injector-cartridge combination, among other investments[.]" (D.I. 100 at 11)

Reading and harmonizing cases like *Trinko* and *Kodak* in this regard is not easy. But from what the Court can tell, at least based on the arguments that have been made at this stage, Plaintiffs' position seems to align nicely with what the Supreme Court was saying in *Kodak*. Plaintiffs have pleaded that the cartridge market and the injector market are two separate markets, *see infra* at 49, and that while they have entered the cartridge market, they have not done so in the injector market (and so in that sense, per *Kodak*, they were not engaged in prohibited free-riding via their interactions with BD). And Plaintiffs are asserting that SPI's 2022 conduct was wrongly forcing them to enter two markets simultaneously—including an injector market that (they allege) Defendants have *not* invested in. In the end, the FAC sufficiently alleges that SPI's conduct relating to the 2022 Pharmacy Agreements is anticompetitive; "any procompetitive justification [including the prevention of free-riding] for such restrictions is not appropriately weighed on a motion to dismiss." *In re Keurig*, 383 F. Supp. 3d at 238-39 (finding that a similar free-riding argument by defendant was premature at the motion to dismiss stage, where the complaint alleged that the defendant was not protecting against free-riding on its own investments, but instead was blocking competitors from accessing inputs and distribution networks created by others); *see also Roxul USA, Inc.*, 2018 WL 810143, at *6 (concluding that the defendant's assertion that the exclusivity agreement at issue prevented

[20] The FTC similarly argues that, based on *Kodak*, "it is not improper free-riding to market a product or service that is intended to be used in conjunction with a separate and distinct product sold by another company." (D.I. 93 at 12)

free-riding on its substantial investments was one best taken up on summary judgment or trial after the benefit of discovery, where the plaintiff alleged sufficient facts outlining the anti-competitive effects of the agreement).

d. Conclusion

For all of the reasons set out above, Plaintiffs have sufficiently alleged anticompetitive conduct as to Count 1.

3. Whether Plaintiffs have sufficiently alleged antitrust injury

Next, Defendants contend that Plaintiffs fail to allege antitrust injury. In order to establish an antitrust violation, in addition to showing that the defendant engaged in anticompetitive conduct, the plaintiff must also show that it suffered antitrust injury as a result. *Eisai, Inc.*, 821 F.3d at 402. Antitrust injury is an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164 (3d Cir. 2017) (internal quotation marks and citation omitted); *see also GN Netcom, Inc. v. Plantronics, Inc.*, 967 F. Supp. 2d 1082, 1085 (D. Del. 2013). While anticompetitive conduct must be a material or proximate cause of the antitrust injury, the competitive conduct need not be the *sole* cause of the injury; "[n]or must a plaintiff 'completely discredit in its initial pleadings all possible intervening causes' of its injury." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 13-MD-2445, 2017 WL 4910673, at *11 (E.D. Pa. Oct. 30, 2017) (citing *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 114 n.9 (1969)) (emphasis in original).

Defendants assert that Plaintiffs have not pleaded antitrust injury because the FAC shows that their own poor business decisions are what caused any harm they suffered. (D.I. 57 at 25-27; D.I. 100 at 13-16) More specifically, with respect to Apokyn's restricted distribution system,

Defendants argue that Plaintiffs' allegations fail because: (1) Sage knowingly chose to submit its ANDA to the FDA without first obtaining samples; and (2) Sage then "found samples within a month of earnestly seeking them." (D.I. 57 at 25 (emphasis omitted)) As for the September 2019 Agreement, Defendants argue that Plaintiffs fail to connect it to "any cognizable antitrust injury" because any complications with FDA approval were caused by: (1) Plaintiffs' own decision not to seek approval for both a cartridge and an injector; and (2) Plaintiffs' failure to access a compatible injector from any other manufacturer at any time. (*Id.* at 26) Similarly, with respect to the 2022 Pharmacy Agreements, Defendants assert that Plaintiffs have failed to allege cognizable antitrust injury because it was Plaintiffs' own decision not to develop an injector that is what caused pharmacies to terminate orders. (*Id.* at 26-27)

In the Court's view, the FAC plausibly alleges antitrust injury. (D.I. 86 at 41-42) With respect to the restricted distribution system, Defendants' position ignores the allegations, detailed above, that Sage had significant difficulty obtaining samples of the RLD both before it filed the ANDA and throughout the next year (and that it was only able to obtain such samples in July 2019 after paying an "exorbitant price"). (D.I. 16 at ¶¶ 100-106, 110) And more generally, as to all of the forms of alleged anticompetitive conduct at issue, Plaintiffs allege that it was this conduct that has delayed and restrained competition and that has deprived customers of the benefits of lower prices. (*Id.* at ¶¶ 29, 202, 206-08, 220-22, 224-37, 287-88) Below, the Court addresses both prongs of the antitrust injury analysis.

With regard to the first prong, acts that decrease competition in the relevant market (i.e., the types of acts pleaded here) are the type of wrongs targeted by antitrust laws. *GN Netcom, Inc.*, 967 F. Supp. 2d at 1085-86 (citing cases). The second prong of the analysis, which requires the plaintiff to plead an injury that flows from that which makes the defendant's acts unlawful,

"is generally met if the plaintiff is a competitor . . . in the relevant market." *Gulfstream III Assocs. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 429 (3d Cir. 1993) (internal quotation marks and citation omitted); *GN Netcom*, 967 F. Supp. 2d at 1087. Plaintiffs have pleaded that they compete with Defendants in the relevant market. (D.I. 16 at ¶¶ 33-36, 76, 88) This is sufficient to satisfy prong two. *See Nespresso USA, Inc v. Ethical Coffee Co. SA*, Civil Action No. 16-194-GMS, 2016 WL 11697058, at *1 n.2 (D. Del. Sept. 7, 2016); *GN Netcom*, 967 F. Supp. 2d at 1087.

The Third Circuit has stated that "the existence of antitrust injury is not typically resolved through motions to dismiss." *Schuykill Energy Res., Inc. v. Pa. Power & Light Co.,* 113 F.3d 405, 417 (3d Cir. 1997); *TransWeb, LLC v. 3M Innovative Props. Co.*, Civil Action No. 10-4413 (FSH), 2011 WL 2181189, at *18 (D.N.J. June 1, 2011) (noting the same, because "causes of an injury are inherently factual in nature"); *see also, e.g.*, *NRT Tech. Corp. v. Everi Holdings Inc.*, C.A. No. 19-804-MN-JLH, 2020 WL 3403091, at *8 (D. Del. June 19, 2020); *In re Suboxone*, 2017 WL 4910673, at *11, *14. At the appropriate stage of the case, after the benefit of discovery, Defendants may be able to prove that Plaintiffs' business choices (and not Defendants' alleged anticompetitive conduct) were the proximate cause of Plaintiffs' injuries. At present, however, the FAC's allegations permit the plausible inference that Defendants engaged in anticompetitive conduct that was a material cause of Plaintiffs' claimed injuries.[21]

[21] Defendants cite to *SEI Glob. Servs., Inc. v. SS&C Advent*, No. 20-3386, 2022 WL 2356730 (3d Cir. June 30, 2022) in support of their argument that Plaintiffs fail to allege antitrust injury because "Plaintiffs' poor business decisions do not suffice." (D.I. 57 at 25; Defendants' Slides at Slide 8) In the Court's view, the facts of that case are distinguishable. The *SEI Glob. Servs.* Court first found that the plaintiff's complaint failed to sufficiently plead the first prong of the antitrust injury analysis because the allegations focused on the injuries that the *plaintiff* would suffer should it lose access to the defendant's software, whereas a violation of antitrust laws will only be found when the challenged conduct harms the *market* and thus the *consumer*. *SEI Glob. Servs., Inc.*, 2022 WL 2356730, at *3. It then found that even assuming that the

B. Count 2: Tying

Count 2 relates to Plaintiffs' allegations regarding unlawful tying. "A tying arrangement is an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier." *Kodak*, 504 U.S. at 461 (internal quotation marks and citation omitted). "'[T]he essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms.'" *Thomson Reuters Enter. Centre GmbH v. Ross Intel. Inc.*, C.A. No. 20-613-LPS, 2022 WL 1224903, at *3 (D. Del. Apr. 26, 2022) (quoting *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 12 (1984)).

A plaintiff can establish antitrust liability for an unlawful tying arrangement with either a *per se* claim or a "rule of reason" claim. *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 511 (3d Cir. 1998); *NIBCO Inc. v. Viega LLC*, 354 F. Supp. 3d 566, 579 (M.D. Pa. 2018). To state a *per se* tying claim under the Sherman Act,[22] a plaintiff must establish that: "(1)

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plaintiff did plead harm sufficient for antitrust injury, the complaint failed to allege that that harm flowed from any purported anticompetitive conduct by the defendant—because the complaint made clear that 30 percent of service providers like the plaintiff did *not* use the defendant's software. *Id.* This facially demonstrated that the software was not indispensable to competing in the relevant market and that the plaintiff could have similarly decided not to use it. *Id.*

Here, in contrast, the FAC sufficiently pleads harm of the type antitrust laws are intended to prevent, and it pleads that the pens were unique and that BD was the sole supplier of them. (D.I. 16 at ¶¶ 20, 199, 200)

[22] As Defendants point out, (D.I. 57 at 28 n.13; D.I. 100 at 16 n.11), the Supreme Court has explained that "with respect to the definition of tying the standards used by" the Clayton Act and the Sherman Act are the same. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 23 n.39 (1984), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*,

a defendant seller ties two distinct products; (2) the seller possesses market power in the tying product market; and (3) a substantial amount of interstate commerce is affected[.]" *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 477 (3d Cir. 1992) (*en banc*); *Kickflip, Inc. v. Facebook, Inc.*, 999 F. Supp. 2d 677, 689 (D. Del. 2013). When a plaintiff satisfies these three elements, the tying practice is "automatically" unlawful and the plaintiff need not present further proof of anticompetitive effect. *Town Sound*, 959 F.2d at 477. The *per se* test is used in cases where "exploitation of leverage in the market for the tying product is 'probable.'" *Brokerage Concepts, Inc.*, 140 F.3d at 512. As for a rule of reason claim, unlike a *per se* case where a showing that the defendant had market power in the tying market leads to a presumption that it is using that power to expand into the tied market, there a plaintiff must prove that the alleged tie unreasonably restrained competition. *Id*. at 519.

Here, Plaintiffs allege that "Supernus's threats not to supply Apokyn[] pens unless pharmacy customers purchase branded cartridges and/or not generic apomorphine cartridges constitute" a tying claim under Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act. (D.I. 16 at ¶¶ 193, 302) And they allege that Defendants "have expressly conditioned the ability to purchase the tying product, i.e., the compatible pen, on the buyer's agreement to purchase a different, tied product, i.e. Apokyn[] cartridges, and/or *not* to purchase generic apomorphine cartridges, even for refill purchases." (*Id.* at ¶ 193 (emphasis in original))

547 U.S. 28 (2006). Plaintiffs contend that Defendants are incorrect in this regard, but they cite only to cases older than *Jefferson Parish* in support. (D.I. 86 at 19 & n.12); *see also Sheridan v. Marathon Petroleum Co. LLC*, 530 F.3d 590, 592 (7th Cir. 2008) ("Though some old cases say otherwise, the standards for adjudicating tying under the two statutes are now recognized to be the same.") (citing cases). The Court will thus assume *arguendo* that Defendants are correct here about the uniformity of the analysis as to the two Acts.

Defendants argue that Plaintiffs have failed to allege unlawful tying for four reasons. The Court will address each in turn.

First, Defendants contend that Plaintiffs failed to successfully plead the first element of a *per se* tying claim. They assert that the FAC's allegation that Supernus conditioned the pharmacies' purchase of Apokyn Pens on the purchase of *Apokyn Cartridges* is inconsistent with other allegations of the FAC, where Plaintiffs allege only that Supernus restricts pharmacies from dispensing *generic cartridges* for use with Apokyn Pens. (D.I. 57 at 28 (citing D.I. 16 at ¶¶ 184-87); D.I. 100 at 16) From there, Defendants assert that the FAC includes no allegations that Supernus "(1) refused or threatened to refuse to supply Apokyn Pens if a pharmacy *purchased* Plaintiffs' cartridges; or (2) secured any agreement from pharmacies not to *purchase* Plaintiffs' cartridges[,]" which is fatal to Plaintiffs' tying claim. (D.I. 100 at 16-17 (emphasis in original)) But this argument ignores the following allegations in the FAC, which plead exactly that:

> 23. . . . Supernus threatened these specialty pharmacies with . . . the discontinuation of access to the Apokyn[] pen to coerce them to only dispense the Apokyn[] cartridge and to refuse to purchase or dispense generic apomorphine cartridges, even for refills. . . .
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> 24. These threats were coercive and effective. The network pharmacies cancelled orders [and] returned previously purchased generic product . . . . The network pharmacies have accepted Defendants' conditions and have since ceased the planned purchases of the generic cartridge product. . . .
>
> 136. . . . [Defendants] condition[ed] access to [Apokyn] pens on the agreement not to purchase the generic once it was ultimately approved by the FDA. . . .
>
> 183. . . . Supernus successfully coerced all three of the network pharmacies to renege on their contracts with TruPharma, to cancel orders, and to return generic product received at their pharmacies or by their designated wholesaler. . . .

> 184. . . . According to an employee at CVS Caremark, Supernus informed CVS Caremark they would have a supply issue with the [Apokyn] pens if they dispensed the generic cartridge. A Red Oak employee, as agent for CVS Caremark, told TruPharma that CVS wants to dispense the generic, but that it had been blocked in that Supernus is aggressively threatening the pharmacy if they dispense the generic, "putting a vice grip around the product," and "doing everything they can to hold on to the business." . . . .
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> 185. . . . Supernus also told TruPharma's customers . . . that they would cut off Apokyn[] cartridge and pen supplies to any pharmacy that did in fact dispense [P]laintiffs' FDA approved apomorphine cartridge.
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> 195. . . . Supernus exploited control over the tying product (the Apokyn[] pen) to force the buyer into the purchase of a tied product (Apokyn[] cartridges) that the buyers might have preferred, and indeed tried to, purchase elsewhere on different terms.

(D.I. 16 at ¶¶ 23-24, 136, 183-85, 195 (*cited in* D.I. 86 at 20; Plaintiffs' Motion to Dismiss Slides ("Plaintiffs' Slides") at Slides 94-97)) These allegations (i.e., that Supernus conditioned access to Apokyn Pens on the pharmacies' agreement not to purchase generic cartridges from Plaintiffs) sufficiently plead the first necessary element of a tying claim. *See, e.g.*, *Crownalytics, LLC v. SPINS LLC*, Civil Action No. 22-cv-01275-NYW-SKC, 2023 WL 3071192, at *8-9 (D. Colo. Apr. 25, 2023) (finding that the plaintiff sufficiently pleaded a tying claim, where the complaint alleged that the defendants conditioned the sale of their data on their customers' agreement to not purchase or use the services of any third-party data analytics providers); *cf. Kodak*, 504 U.S. at 463-64 (finding sufficient evidence of a tying arrangement at the summary judgment stage of the case, where "[t]he record indicates that Kodak would sell parts to third parties only if they agreed not to buy service from ISO's").[23]

[23] Defendants also make a cursory argument that Plaintiffs' identification of the Apokyn Pen as the tying product is "economically irrational" because the tying prohibition "'strikes at the use of a dominant desired product to compel the purchase of a second undesired

Second, Defendants contend that the first element of a *per se* tying claim requires proof that the seller coerced a buyer to purchase the tied product; they assert that Plaintiffs do not allege that Supernus coerced pharmacies to purchase Apokyn Cartridges or not to purchase generic cartridges. (D.I. 57 at 29) Instead, according to Defendants, Plaintiffs' allegations show that the specialty pharmacies "want and need to purchase the combination Apokyn product[,]" which consists of both cartridges and pens. (*Id.*)

To state a claim for unlawful tying, there must be two separate products. *Kodak*, 504 U.S. at 462; *Jefferson Parish Hosp.*, 466 U.S. at 18. "[W]hether one or two products are involved turns not on the functional relation between them, but rather on the character of the demand for the two items." *Jefferson Parish Hosp.*, 466 U.S. at 19. Courts have "'often found arrangements involving functionally linked products at least one of which is useless without the other to be prohibited tying devices.'" *Kodak*, 504 U.S. at 463 (quoting *Jefferson Parish Hosp.*, 466 U.S. at 19 n.30).

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product.'" (D.I. 57 at 29 (quoting *T.A.M. Inc. v. Gulf Oil Corp.*, 553 F. Supp. 499, 507 (E.D. Pa. 1982)) Here, Defendants assert, the desired product is the Apokyn Cartridge that contains the apomorphine, whereas the Apokyn Pen is simply a product used to *administer* the apomorphine. (*Id.* (citing D.I. 16 at ¶¶ 121-24)) The Court is not persuaded that this argument requires dismissal of Plaintiffs' tying claim at this stage. For one thing, now does not seem to be the right stage to parse factual questions about the extent to which, in certain circumstances, Defendants' Apokyn Cartridge can be said to be a product that is "not otherwise desired from this seller on the offered terms[.]" 9 Phillip E. Areeda, *Antitrust Law* ¶ 1700a (1991). Moreover, the only case that Defendants cite in their opening brief in support of this argument was *T.A.M., Inc. v. Gulf Oil Corp.*, 553 F. Supp. 499, 507 (E.D. Pa. 1982). But *T.A.M*. was looking at an issue that is not at play here. In that case, after the defendant ("Gulf") refused to honor credit invoices from Gulf gas station franchisees for the sale of non-Gulf gasoline, the franchisees asserted, *inter alia*, a tying claim; they contended that the Gulf trademark and franchise was the tying product and that Gulf gasoline was the tied product. *T.A.M., Inc.*, 553 F. Supp. at 501, 506. At the *summary judgment* stage of the case, the court held that the plaintiffs could not make such a claim because in becoming franchisees, the plaintiffs had bargained for the attendant right to sell Gulf gasoline—such that Gulf was thus not imposing an unwanted commodity upon the franchisees by tying Gulf gasoline to the Gulf franchise. *Id.* at 507. Nothing like those facts is at issue here.

As explained above, the FAC *does* repeatedly allege that Supernus coerced pharmacies to purchase Apokyn Cartridges, when the pharmacies would have preferred to purchase generic cartridges instead. (D.I. 16 at ¶¶ 23-24, 136, 183, 195) And it facially alleges that the Apokyn Cartridge and the Apokyn Pen are understood to be two separate products. Indeed, while Defendants suggest that the Apokyn Cartridge and Pen amount to a single combination product, the FAC flatly pleads otherwise, alleging that they are "two distinct products" that are "distributed and packaged separately" and "sold separately[.]" (*Id.* at ¶¶ 196-97 (internal quotation marks and citation omitted)); *see, e.g.*, *Thomson Reuters*, 2022 WL 1224903, at *3-4 (finding that the plaintiff sufficiently alleged that public law databases and legal search tools may be two different products instead of one, where these products were separately developed, and where public law databases had been sold as discrete products).[24]

Third, Defendants contend that Plaintiffs fail to allege the second element of a *per se* tying claim: i.e., that Supernus possesses market power in the alleged tying product (i.e., the

[24] Defendants also argue that the FAC is devoid of any allegation that Supernus instructed pharmacies that they could not dispense generic Apokyn with both a generic cartridge and injector, and that Supernus' refusal to allow Plaintiffs to free-ride on Apokyn Pens cannot support a plausible tying claim. (D.I. 57 at 30; D.I. 100 at 17 n.12) Because Plaintiffs have sufficiently pleaded the elements of a tying claim, this argument does not win the day at this early stage of the case. In the only case that Defendants rely on here, *Medtronic Minimed Inc. v. Smiths Med. MD Inc.*, 371 F. Supp. 2d 578 (D. Del. 2005), the Court found at the *summary judgment* stage that the antitrust counterclaim defendant did not coerce customers to purchase the tied product because the customers were free to purchase any such product compatible with the tying product, and because the plaintiffs could have chosen to produce a compatible set to sell to customers. 371 F. Supp. 2d at 585-86. We are at the pleading stage here, however, not the summary judgment stage. And here, as was noted above, Plaintiffs have repeatedly alleged that Supernus coerced pharmacies to purchase Apokyn Cartridges or not to purchase generic cartridges. Additionally, as has been noted above, there are no indications in the FAC that Plaintiffs easily could have chosen to produce a compatible pen.

Apokyn Pen) market. (D.I. 57 at 30; D.I. 100 at 17 n.13)[25] According to Defendants, this is because Plaintiffs "fail to define a plausible injector market or substantial foreclosure preventing Plaintiffs from supplying their own injector." (D.I. 57 at 30-31) The Court will take up the substance of this (ultimately insufficient) argument below in its discussion of Count 3, where Defendants reiterate the argument.

Fourth, Defendants assert that Plaintiffs' allegations fail to support a tying claim under a rule of reason theory, because the FAC fails to allege that any tying arrangement harms competition in the tied product market (since any lack of competition in that market is the result of Plaintiffs' decision not to develop an injector for its generic cartridge). (D.I. 57 at 31; D.I. 100 at 18) As the Court explained above, however, consideration of defenses like these is not appropriate at the summary judgement stage of the case. (D.I. 86 at 21-22)

For all of these reasons, Plaintiffs have sufficiently alleged a tying claim in Count 2.

C. Count 3: Monopolization and Attempted Monopolization in the Alternative

The Court next turns to Count 3, which alleges monopolization and attempted monopolization. Under Section 2 of the Sherman Act ("Section 2"), it is unlawful to, *inter alia*, monopolize or attempt to monopolize interstate or international commerce. *Broadcom Corp.*, 501 F.3d at 306. Liability under a monopolization claim requires: "(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." *Id.* at 306-07 (internal quotation marks and citation

[25] One of Plaintiffs' retorts to this argument is that Defendants failed to challenge the market and the tying claim under the Clayton Act, and so, at most, "the only theory that could be rejected on market definition grounds is tying under the Sherman Act[.]" (D.I. 86 at 22) However, Defendants made clear that their arguments with regard to tying applied to both the Sherman Act and Clayton Act claims. (D.I. 57 at 28 & n.13; D.I. 100 at 16 n.11)

omitted). Monopoly power "is the ability to control prices and exclude competition in a given market." *Id.* at 307. A plaintiff pleading attempted monopolization 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." *Id.* at 317 (internal quotation marks and citation omitted).

Defendants argue that Plaintiffs fail to state a Section 2 claim for two reasons: (1) Plaintiffs fail to allege a plausible product market; and (2) Plaintiffs fail to allege anticompetitive conduct. (D.I. 57 at 32-42; D.I. 100 at 18-24) The Court will take up these arguments in turn.[26]

1. Whether Plaintiffs have properly defined an injector market

A plaintiff bears the burden of identifying the relevant market. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Id.* (internal quotation marks and citation omitted). The Third Circuit has explained that the relevant market is legally insufficient and a motion to dismiss may be granted where a plaintiff: (1) fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand;[27] or (2) alleges a proposed relevant market that clearly does not encompass all

[26] Defendants note that while Plaintiffs' responsive brief suggests that Britannia is subject to a Section 2 claim, the FAC references Supernus and US WorldMeds as the only defendants subject to that claim. (D.I. 100 at 18 n.16 (citing D.I. 86 at 25; D.I. 16 at ¶¶ 304-17)) To the extent Plaintiffs are trying (via their briefing) to assert a Section 2 claim against Britannia, the Court notes that they did not make such a claim in the FAC, and a party may not amend its complaint through argument in a brief responsive to a motion to dismiss. *Harmon v. Lawson*, Civil Action No. 21-1437-RGA, 2022 WL 2208906, at *4 (D. Del. June 21, 2022) (citation omitted).

[27] The Third Circuit has explained that:

interchangeable substitute products even when all factual inferences are granted in plaintiff's favor. *Id.* Absent these deficiencies, "courts are cautious" before dismissing for failure to define a relevant market. *Lifewatch Servs. Inc.*, 902 F.3d at 337. In most cases, proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers. *Id.*

Plaintiffs' FAC identifies two relevant product markets: (1) the market for "prescription-only, FDA-approved cartridges containing apomorphine hydrochloride for subcutaneous self-injection" indicated for the treatment of off episodes in patients with advanced PD (hereinafter, the "Cartridge Market"); and (2) the market for "FDA-approved, reusable self-injector pens that are compatible with, and used to administer, subcutaneous injections of apomorphine" (hereinafter, the "Injector Market"). (D.I. 16 at ¶ 254; *see also id.* at ¶ 256) With respect to the Injector Market, the FAC alleges that as a result of Defendants' exclusionary conduct, the Apokyn Pen is the only product currently in that market. (*Id.* at ¶ 256) The FAC pleads that Supernus (and the US WorldMeds Defendants before it) are liable under Section 2 for monopolizing the Cartridge Market and the Injector Market or by attempting to monopolize the Cartridge Market. (*Id.* at ¶¶ 258, 305, 316)

> When assessing reasonable interchangeability, [f]actors to be considered include price, use, and qualities. . . . Reasonable interchangeability is also indicated by cross-elasticity of demand between the product itself and substitutes for it. . . . [P]roducts in a relevant market [are] characterized by a cross-elasticity of demand, in other words, the rise in the price of a good within a relevant product market would tend to create a greater demand for other like goods in that market.

Queen City Pizza, 124 F.3d at 437-38 (internal quotation marks and citations omitted).

Defendants assert that Plaintiffs have failed to allege a plausible Injector Market and have thus failed to plead a Section 2 claim as to the cartridge or injector. (D.I. 57 at 32)[28] Plaintiffs' Injector Market requires existing FDA approval, which is why the Apokyn Pen is currently the only product in that market. (D.I. 16 at ¶¶ 254, 256) Defendants note that the FAC does not allege why any product *capable* of FDA approval for injecting apomorphine would not also be a part of the relevant market, nor does it describe "the contours and reach of the proposed Injector Market—what products are or would be interchangeable with the Apokyn Pen." (D.I. 57 at 32-33) They also assert that Plaintiffs "offer no reasons preventing any other manufacturer from supplying a compatible injector"; Defendants contend that it is impermissible to exclude such products from the relevant market just because they were not yet FDA approved for use with apomorphine. (*Id.* at 33; D.I. 100 at 18-19; Tr. at 32)

Plaintiffs first retort, citing to the Third Circuit's decision in *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007), that where a plaintiff relies on direct evidence of supra-competitive prices and restricted output, a definition of the relevant market is not required. (D.I. 86 at 22 (citing *Broadcom Corp.*, 501 F.3d at 307 & n.3); *see also* Plaintiffs' Slides at Slide 121) Plaintiffs note that the FAC pleads the existence of such direct evidence, in alleging that Defendants excluded competition, continued to increase prices, and restricted output of competing goods. (Plaintiffs' Slides at Slide 121 (citing D.I. 16 at ¶¶ 221-45, 255-74)); *see also In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 712 (E.D. Pa. 2014) (agreeing that the plaintiffs alleged direct evidence of supra-competitive prices and restricted output, where they alleged that the branded company impaired

[28] Defendants do not challenge Plaintiffs' allegations with respect to the Cartridge Market. (*See* D.I. 86 at 6, 16, 22; Tr. at 32)

and excluded generic competition which resulted in supra-competitive prices, no firm was able to respond to the high prices, and consumer welfare suffered from the lack of competing goods). Defendants do not respond to this particular argument. That said, some courts after *Broadcom Corp.* have found that even in cases involving direct evidence, "at least a rough identification of the relevant market is still required[.]" *Id.*; *see also In re Neurontin Antitrust Litig.*, MDL No. 1479, 2013 WL 4042460, at *3 (D.N.J. Aug. 8, 2013) (citing cases).

Even to the extent that Plaintiffs are required to define a relevant market, they have done so sufficiently at this stage. With respect to Defendants' criticism that Plaintiffs excluded non-FDA-approved pens from the Injector Market, Defendants cite to no cases stating that a product market must encompass products that are not yet FDA approved. To the contrary, the facts and the caselaw suggest that Plaintiffs have plausibly explained why the Injector Market is rightly confined to products that received FDA approval. (D.I. 86 at 24; Tr. at 137) The FAC alleges that prescription drugs must have FDA approval to be marketed and sold, that "[t]he FDA approval process creates significant barriers to entry for" the Injector Market and that "[o]btaining FDA approval for new apomorphine subcutaneous treatment is difficult and expensive" (so much so that to date, "no company other than Defendants has obtained FDA approval for an apomorphine self-injector pen"). (D.I. 16 at ¶¶ 279-80) And there are cases that have restricted the relevant market only to substitutes with FDA approval. *See, e.g.*, *Shkreli*, 581 F. Supp. 3d at 630 ("The Plaintiffs have proven that, by any established method, FDA-approved pyrimethamine is the relevant product market[.]"); *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, Civil Action No: 16-4544 (SDW) (LDW), 2017 WL 548944, at *1, *3-4 (D.N.J. Feb. 10, 2017) (noting that the undisputedly relevant product market was "IVI approved by the FDA for sale in the United States"); *see also Ethypharm S.A. Fr. v. Abbott Lab'ys*, 707 F.3d 223,

233, 237 (3d Cir. 2013) (concluding that the plaintiff did not have antitrust standing, which required it to be a competitor in the defined relevant market or to have suffered injuries that were the means by which the defendants sought to achieve their anticompetitive ends, where the plaintiff "did not suffer antitrust injury because it does not and indeed cannot compete in the United States fenofibrate market, unless and until it acquires the required FDA approval to do so").[29]

As for Defendants' criticism that the FAC fails to describe the "contours and reach" of the Injector Market, the FAC plausibly does so. It alleges that there are currently "no other reasonably interchangeable substitutes" for the pen because of "state generic substitution laws, FDA approval, and the unique characteristics of" the pen. (D.I. 16 at ¶ 257) Moreover, the FAC pleads that Defendants have "publicly recognized" that there is no alternative pen and that the "unique characteristics and distinct uses of the Apokyn[] pen preclude it from being reasonably

[29] Defendants' assertion that claims involving "single-brand or single-manufacturer product markets" are routinely rejected at the motion to dismiss stage is unpersuasive here, for at least three reasons. (D.I. 57 at 33 (quoting *Talley v. Christiana Care Health Sys.*, Civil Action No. 17-926-CJB, 2018 WL 4938566, at *7-8 n.8 (D. Del. Oct. 11, 2018)) For one, Plaintiffs' Injector Market would encompass any reusable self-injection pen that is FDA-approved to administer apomorphine hydrochloride doses from compatible cartridges. And so Plaintiffs and the FTC point out that while this market *currently* includes only one product due to Defendants' anticompetitive conduct, technically, this market is *not* a single-brand or single-manufacturer market since it "would include any other such pen that obtains FDA approval[.]" (D.I. 86 at 22 n.18; D.I. 93 at 16 n.26) Second, while courts may be generally skeptical of single-product market definitions, the Supreme Court has rejected the notion that "as a matter of law, a single brand of a product or service can never be a relevant market under the Sherman Act." *Kodak*, 504 U.S. at 481. Third, as even certain of Defendants' counsel have recognized in the past, "[t]here is nothing unusual in pharmaceutical cases about an antitrust market limited to a single class of drugs (as here), or even a single drug. Courts regularly find a single brand-name drug and its generics to be a relevant product market in cases where the challenged conduct involves a branded drug manufacturer's effort to exclude generic competition." (D.I. 87, ex. 2 at 25 (citing cases)); *see also FTC v. Syngenta Crop Prot. AG*, 1:22CV828, 2024 WL 149552, at *9 (M.D.N.C. Jan. 12, 2024) ("In the pharmaceutical context, lower courts have ruled that a brand-name drug and its generic analogs can comprise a relevant product market."). The Court does not see why this caselaw is not potentially analogous to the Injector Market at issue here.

interchangeable with any other type of injector pen[.]" (*Id.* at ¶ 275 (describing US WorldMeds Defendants' representation in a citizen's petition that "[n]or . . . is there any alternative auto-injector or injector pen separately approved or cleared by FDA with technical specifications and/or intended uses compatible with this use") (emphasis omitted); *see also id.* at ¶ 114); *Klein v. Facebook, Inc.*, 580 F. Supp. 3d 743, 781-82 (N.D. Cal. 2022) (rejecting the defendant's argument that the complaint failed to adequately allege the social advertising market because "markets limited to a single form of advertising are implausible and Advertisers have failed to define the 'contours'" of the social advertising market, where, *inter alia*, the defendants themselves touted social advertising as distinct from other forms of advertising). Moreover, the FAC references cross-elasticity of demand as to the market, alleging that "[a]s demonstrated by Defendants' successive, substantial, and profitable price increases, Apokyn[] does not exhibit significant positive cross-elasticity of demand with respect to price with any product other than A-rated versions of Apokyn[]" as administered through "self-injection." (D.I. 16 at ¶¶ 263-64; *see also id.* at ¶¶ 229, 259)

At this stage, then, Plaintiffs have sufficiently defined the Injector Market. *See, e.g.*, *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 246-47 (D. Conn. 2015) (finding that allegations that "there is no . . . cross-elasticity of demand between Aggrenox and other drugs sufficient to define any broader antitrust market, and that because Boehringer is able to charge supracompetitive prices for Aggrenox without losing sales, it does not share a market defined by interchangeability" plausibly pleaded monopoly power within a sufficiently defined market, and explaining that such allegations presented "clearly a fact-intensive inquiry" to be taken up at summary judgment or trial); *Mylan Pharms. v. Celgene Corp.*, Civil No. 14-2094 ES, 2014 WL 12810322, at *9-10 (D.N.J. Dec. 23, 2014) (declining to dismiss the plaintiff's claims based on a

failure to allege the relevant market, despite the defendant's assertion that single-market pleading was legally deficient and that the plaintiff had failed to explain why the market should be so limited, where the allegation was that the relevant market for Thalomid and Revlimid is the market for each product plus bioequivalent generic versions, which raised "factual questions[,]" such as whether other products would serve as adequate market substitutes).

2. Whether Plaintiffs have alleged anticompetitive conduct

Next, Defendants assert that Plaintiffs' Section 2 claims fail because Plaintiffs have not alleged anticompetitive conduct. They assert that this is so in part because USWMO's Citizen Petitions are immune from antitrust liability and did not delay approval of Sage's ANDA. (D.I. 57 at 33-41; Tr. at 68)[30]

Under the *Noerr-Pennington* doctrine, "[t]hose who petition [the] government for redress are generally immune from antitrust liability." *Pro. Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993). This doctrine is not absolute, however, and the sham exception applies where the petitioning at issue is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with business relationships of a competitor[.]" *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *FTC v. Shire ViroPharma Inc.*, Civil Action No. 17-131-RGA, 2018 WL 1401329, at *7 (D. Del. Mar. 20, 2018).

In deciding whether the sham exception applies, courts apply one of two standards, depending on whether there is a single petition or a series of petitions at issue. When there is

[30] Defendants also briefly rehash their above arguments by contending that "none of [Defendants'] alleged conduct was otherwise anticompetitive." (D.I. 57 at 34; *id.* at 41; D.I. 100 at 23-24) For the reasons discussed above, however, the Court concludes that the allegations regarding the anticompetitive nature of that conduct are sufficient. Here then, the Court need address only the Citizens Petitions in detail as to this issue.

only one alleged sham petition, a two-part test applies. *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015). First, the petition at issue must be objectively baseless, meaning no reasonable litigant could reasonably expect to succeed on the merits. *Id.* at 179. If the antitrust plaintiff fails to demonstrate this prong, the analysis ends; if the petition at issue is found to be objectively meritless, courts go on to assess the litigant's subjective motivations. *Id.* Under the second prong of the test, courts ask whether "the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor . . . through the use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *Id.* (internal quotation marks and citations omitted) (emphasis in original). In contrast, when a plaintiff alleges that a series of sham petitions were filed (as opposed to a single petition), a "more flexible" standard applies that "asks whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id.* at 180; *see also Shire ViroPharma, Inc.*, 2018 WL 1401329, at *7.

The parties did not engage in a meaningful back-and-forth as to which of those standards should apply here. Defendants suggest that the two-part test applies, and Plaintiffs do not expressly address which standard applies. (D.I. 57 at 34, 39 n.22; D.I. 86 at 35-36) The FAC makes reference to objective and subjective baselessness, (*see, e.g.*, D.I. 16 at ¶¶ 93, 112), which suggests that the two-part test applies. And so the Court will assume that it does here.

Defendants argue that the FAC fails to plausibly allege that: (1) the Citizen Petitions were shams; or (2) that they delayed approval of Sage's ANDA years later. (D.I. 57 at 35; D.I. 100 at 21-22; Tr. at 69) But Defendants' big hurdle is that the question of whether a petition meets the sham exception "is generally a question of fact for the jury." *In re Flonase Antitrust*

Litig., 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011) (internal quotation marks and citations omitted) (citing cases); *see also In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 154-55 (E.D.N.Y. 2018); *Shire ViroPharma*, 2018 WL 1401329, at *7 ("[W]hether ViroPharma's activity was in fact a sham under either standard is a factual inquiry, which cannot be resolved at the motion to dismiss stage.").

At this stage, Plaintiffs have sufficiently alleged both elements of the two-part sham litigation exception. The US WorldMeds Defendants filed an initial citizen petition in July 2015, three years before Sage filed its ANDA (the "first petition"). (D.I. 16 at ¶¶ 89-90) Plaintiffs are not claiming damages based on the first petition, but they allege that it is still relevant to demonstrate that subsequent petitions were filed in bad faith. (*Id.* at ¶ 95; D.I. 86 at 36 n.34) The FAC alleges that the first petition, which included 24 pages of "complicated analysis of data[,]" sought to persuade the FDA to implement requirements for generic competitors that exceeded what was required by Defendants when they obtained FDA approval for Apokyn, namely by requiring: (1) a device-using training program; and (2) a demonstration that the generic applicant's device is the same as the one used with the RLD cartridge in terms of key design attributes and performance. (D.I. 16 at ¶¶ 90-91) In January 2016, the FDA informed the US WorldMeds Defendants that the petition raised "complex issues." (*Id.* at ¶ 91) The FDA later fully denied the first petition in September 2017. (*Id.* at ¶ 92) The FAC alleges that the FDA's response highlights the objective baselessness of the first petition, in that the FDA explained that: (1) it "did not require the type of training program requested by the [first petition] as a condition of approval for Apokyn" and that, as a result, Apokyn's labeling does not reference a training program; and (2) it was "not aware of any information demonstrating that Apokyn[] is not safe or not effective as approved." (*Id.* at ¶ 93 (emphasis omitted)) The FAC

also alleges the subjective baselessness of the first petition is demonstrated by the FDA's observation that the US WorldMeds Defendants relied on data from studies that failed to support their assertions. (*Id.*) And it notes how the FDA also explained why it was denying the petition's second request that a generic applicant demonstrate that its device is the same as the one used with the RLD cartridge with respect to key design attributes and performance—i.e., that the FDA had already issued standards for reviewing proposed generic devices that have certain design differences as compared to an already-approved device, and that the FDA would simply follow those standards in the future if presented with a device like this. (*Id.* at ¶ 94)

One year after Sage filed its ANDA, the US WorldMeds Defendants filed a second citizen petition on July 1, 2019 (the "second petition"). (*Id.* at ¶ 112) This second petition requested that the FDA: (1) require that "'any ANDA referencing Apokyn[] seek approval of both the drug and device constituent parts of Apokyn'" and (2) establish "guidance" clarifying the circumstances under which the drug constituent part could be approved in an ANDA that did not also seek approval of the device constituent part." (*Id.*) The second petition acknowledged that there was no alternative injector pen that was FDA approved for use with apomorphine hydrochloride to treat advanced PD. (*Id.* at ¶ 114) Sage submitted a comment to the public docket in response to the second petition, asserting that the Apokyn Pen should be made available to patients regardless of whether they chose to use the branded or generic version of the cartridge. (*Id.* at ¶ 143) The FAC pleads that this second petition was objectively and subjectively baseless and filed in bad faith, as demonstrated by the fact that Defendants had already received a rejection of their previous attempt in the first petition to "create special rules for ANDAs referencing Apokyn[.]" (*Id.* at ¶ 112) In this vein, the FAC alleges that in filing the second petition, Defendants were subjectively motivated to delay the FDA's review process and

competition from generics instead of achieving real relief. (*Id.*) The FAC notes that the second petition was filed around the same time that the US WorldMeds Defendants were negotiating an exclusive agreement for pens with BD, and that this "close coordination" shows that the second petition was simply a tactic to delay Sage's market entry. (*Id.* at ¶ 113) The FDA denied the second petition's requests in November 2019 "'without comment'"; this made clear that it "would not address ANDA-specific matters outside the normal FDA review process for such applications." (*Id.* at ¶¶ 139-42)

On December 23, 2019, the US WorldMeds Defendants filed a third citizen's petition (the "third petition"), which raised the same arguments they had previously made; this petition was styled as an "appeal" of the earlier denials. (*Id.* at ¶ 143) The FAC alleges that the third petition was objectively baseless in part because no appeal process for Citizen Petitions exists under FDA regulations. The FDA denied the third petition on May 21, 2020, noting that the US WorldMeds Defendants had submitted a "substantially similar" petition in July 2019 that was denied in November 2019. (*Id.* at ¶ 150) The FAC alleges that because the third petition was a "retread" of the second petition, no reasonable petitioner, including the US WorldMeds Defendants, could have expected to prevail on the merits of the arguments. (*Id.*)

For a few reasons, the Court concludes that Plaintiffs' allegations about Defendants' Citizen Petitions are sufficient to plausibly allege a form of anticompetitive conduct:

> (1) Defendants argue that the petitions raised complex scientific and regulatory issues, which demonstrates that they were not objectively meritless. (D.I. 57 at 36, 38) However, the Third Circuit has instructed that a petition's "complexity" reflects little about its merits and does not itself immunize a petition. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 274 (3d Cir. 2017).
>
> (2) Defendants also suggest that the second petition raised an "unsettled" and "novel" regulatory issue, and that it cannot be meritless to request that the FDA consider such an issue as a matter

of law. (D.I. 57 at 37) The Court understands Defendants' argument, and perhaps it could be a winning one in the end. Yet, as was discussed above, the FAC does plausibly suggest that the temporal proximity between the filing of the second petition and the September 2019 Agreement could indicate that the petition was simply part of a bad-faith scheme to get the FDA to require that Plaintiffs must obtain FDA approval for their own injector device—all at the same time that Defendants were working to "cut Plaintiffs off from the 'sole supplier' of compatible pens [i.e., BD.]" (D.I. 86 at 37) This temporal proximity bolsters Plaintiffs' case for anticompetitive conduct. *Cf. Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 762 F.3d 1338, 1348 (Fed. Cir. 2014) (reversing a grant of summary judgment because disputed issues of fact remained with respect to whether a citizen petition filed by the plaintiff was baseless where, *inter alia*, the petition was filed just one day after the district court had granted the defendant summary judgment of non-infringement and just one week before the end of the 30-month stay period, and the allegation was that filing the petition at that late date caused the FDA to delay approval of the defendant's ANDA).

(3) Moreover, as was also noted above, the FAC alleges that the second petition amounted to a request that "the FDA ignore its prior procedures and instead adopt special standards" for ANDAs referencing Apokyn. (D.I. 16 at ¶ 112) Determining whether this is so (or not) may require one to learn and process a lot of additional information about the FDA's regulatory scheme regarding this type of petition. And now is not the time for the weighing of such fact-intensive matters. *Cf. Tyco Healthcare Grp.*, 762 F.3d at 1347 (noting that there was a dispute of fact as to whether a citizen petition was objectively baseless, and that one fact that could support such an assertion was that the FDA's denial noted that it had not required generic manufacturers to meet the standard requested in the petition except in very "rare" circumstances); *In re Prograf Antitrust Litig.*, No. 1:11-md-02242-RWZ, 2014 WL 4745954, at *9-11 (D. Mass. June 10, 2014) (denying the defendant's motion for summary judgment that its Citizen Petitions were not objectively baseless, where the defendant argued that the requests were reasonable because "they addressed unsettled issues of agency policy[,]" but where the plaintiffs had identified disputes of fact on the issue).[31]

[31] In support of their argument, Defendants cite to *ERBE Elecktromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1292 (Fed. Cir. 2010). (D.I. 57 at 37) *ERBE* does not compel a finding at the motion to dismiss stage that the petitions at issue are not objectively baseless as matter of law. In what can now be seen as a distinct pattern, in relying on *ERBE*,

> (4) Defendants suggest that they cannot be liable based on the third petition because that petition was merely a response to Sage's comment on the merit of the second petition, which is permitted by applicable regulations. (D.I. 57 at 38-39 (citing 21 C.F.R. § 10.33(e)) But the FAC alleges that this type of "appeal" did not fit within the boundaries of the FDA's regulations. (D.I. 16 at ¶ 143) And allegations that a "defendant advocated for relief in its citizen petition . . . that had been previously . . . rejected by the FDA" can be sufficient at this stage of the case to allege objective and subjective baselessness. *In re Prograf Antitrust Litig.*, No. 1:11-md-2242-RWZ, 2012 WL 293850, at *6-7 (D. Mass. Feb. 1, 2012); *see also In re Restasis*, 333 F. Supp. 3d at 156, 158 (finding that the plaintiffs' allegations of objective baselessness were plausible where, *inter alia*, Allergan's second and third petitions "largely rehash[ed] the claims of the first [petition] and were denied on the same grounds" and therefore "whether, on all of the evidence, a factfinder would find that the petitions were not baseless remains to be seen").

Defendants next argue that even if the FAC does plead facts plausibly suggesting that the Citizen Petitions were shams, Plaintiffs fail to plead that the second and third petitions—petitions resolved nearly two years before Sage's ANDA was approved—caused antitrust injury. (D.I. 57 at 39-41; D.I. 100 at 22-23) Here, Defendants point out that at the time the second petition was filed in July 2019, the FDA was still awaiting Sage's response to its June 3, 2019 complete response letter ("CRL"), in which the FDA had reiterated its request for samples of the Apokyn Pen and the generic cartridge—and that Sage responded just a few weeks before the FDA denied the second petition. (*See* D.I. 16 at ¶¶ 108, 137, 139) And Defendants assert that similarly, following Defendants' submission of the third petition in December 2019 and prior to the FDA's denial of the third petition on May 21, 2020, the FDA: (1) issued a further request to Sage in

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Defendants are again citing to a decision reviewing a *summary judgment* opinion. And the *ERBE* Court, in assessing whether a lawsuit was objectively baseless, simply noted that "[t]he existence of probable cause—e.g., where the law is unsettled, the action is arguably warranted by existing law, or there is an objectively good faith argument for extending existing law—precludes a sham litigation finding." *ERBE*, 629 F.3d at 1292.

January 2020 for samples of the RLD cartridge; (2) issued a March 2020 request noting that, *inter alia*, "the quality assessment for this ANDA requires an additional technical consultation[;]" and (3) issued a May 1, 2020 CRL determining that after Sage corrected some minor items, the ANDA had a goal approval date of August 25, 2020. (*See id.* at ¶¶ 146, 148-50) Defendants contend that these pleaded facts demonstrate that the FDA would not have approved Sage's ANDA more quickly had the second or third petitions never been filed. (D.I. 57 at 40-41)

Despite this, in the Court's view, the FAC sufficiently pleads that the Citizen Petitions caused antitrust injury. (D.I. 86 at 38-40) For example, the FAC alleges that collectively, the US WorldMeds Defendants' series of petitions "complicated" and "further delayed" the FDA's review of Sage's ANDA, by causing the FDA to have to: (1) spend additional time and resources responding to those petitions; and (2) prepare internal "'defensive'" documentation providing justification for FDA approval of Sage's ANDA, for use in the event of a further post-approval legal challenge. (D.I. 16 at ¶¶ 150-51, 164-67) With respect to the third petition, the FAC alleges that but for that petition (as well as the September 2019 Agreement), the FDA would not have required an additional technical consultation. (*Id.* at ¶ 148) Even if the FDA was also investigating other issues regarding Sage's ANDA during much of the time these petitions were pending, it does seem plausible that overall, the time and effort needed to review the petitions could have slowed down Sage's ultimate approval. In other words, it seems plausible that the FDA's ultimate approval might have come weeks or months faster if the agency did not have to engage in this petition-related work, or if it did not have to make petition-related follow up requests. (Tr. at 73-74) Whether this is what actually occurred is an issue best resolved after discovery. *See, e.g.*, *KPH Healthcare Servs., Inc. v. Mylan N.V.*, Case No. 20-

2065-DDC-TJJ, 2022 WL 3153687, at *37-38 (D. Kan. Aug. 8, 2022); *In re Suboxone*, 64 F. Supp. 3d at 690-91; *cf. In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 630 (E.D. Pa. 2011).[32]

D. Count 4: False, Deceptive and Misleading Promotion/Advertising Under the Lanham Act

In Count 4, the FAC alleges that Supernus violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). (D.I. 16 at 92) It asserts that Supernus did so by falsely advertising on its website (a website that is directed to Apokyn prescribers) that Apokyn "is the only FDA-approved therapy in the United States for the acute intermittent treatment of hypomobility—off episodes." (*Id.* at ¶¶ 26, 205, 212-19, 319-21 (emphasis omitted)) The Lanham Act provides that:

> Any person who [uses any] false or misleading description of fact, or false or misleading representation of fact . . . which . . . misrepresents the nature, characteristics, [or] qualities . . . of his or her or another person's goods . . . shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

In *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014), the Supreme Court determined that a statutory cause of action under the Lanham Act extends only to plaintiffs whose "injuries are proximately caused by violations of the statute." 572 U.S. at 132. To demonstrate proximate cause, a plaintiff "must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising[,]" which "occurs when

[32] The case that Defendants rely upon, *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, Nos. 5:03-00887-MRP (PLA), 5:04-00333-MRP (PLA), 2009 WL 8727693 (C.D. Cal. Feb. 17, 2009), is inapposite. (D.I. 57 at 40) In that case, the FDA had not yet taken final action on the citizen petition, the ANDA had not yet been approved, and the complaint did not allege that the citizen petition was a material cause of delay to FDA approval. *Aventis Pharma S.A.*, 2009 WL 8727693, at *4, *15.

deception of consumers causes them to withhold trade from the plaintiff." *Id.* at 134. The *Lexmark* Court instructed that "[i]f a plaintiff's allegations, taken as true, are insufficient to establish proximate causation, then the complaint must be dismissed; if they are sufficient, then the plaintiff is entitled to an opportunity to prove them. *Id.* at 134 n.6; *see also CareDx, Inc. v. Natera, Inc.*, Civil Action No. 19-662-CFC-CJB, 2019 WL 7037799, at *4 (D. Del. Dec. 20, 2019), *report and recommendation adopted*, 2020 WL 401773 (D. Del. Jan. 24, 2020).

Defendants' complaint with respect to Plaintiffs' Lanham Act claim is that Plaintiffs have not sufficiently established proximate causation. (D.I. 57 at 42; D.I. 100 at 24-25) According to Defendants, Plaintiffs' pleaded injury is based on "mere speculation[,]" as they "fail to allege *how* a single statement on one webpage 'artificially depressed demand.'" (D.I. 57 at 42-43 (emphasis in original); D.I. 100 at 25 ("Plaintiffs allege nowhere how a single statement . . . found on one webpage targeted at prescribers[] artificially depressed generic demand or otherwise proximately caused them an injury[.]"))

But the FAC *does* allege how the statement artificially depressed demand. The FAC first notes that the statement is found on a prominent place on Supernus' website (i.e., as the first sentence in the "About APOKYN" section of the website), "not in a footnote or someplace hidden deeply within the website[.]" (D.I. 16 at ¶ 215) And the FAC alleges that the statement "artificially depresses demand for generic apomorphine cartridges" because "[p]rescribers checking this web page would see this statement, be misinformed as a result, and then prescribe the branded drug without demanding that specialty pharmacies make the generic available to patients at more affordable costs." (*Id.* at ¶ 218; *see also id.* at ¶¶ 26, 321) This allegation tells us *how* the statement is alleged to artificially depress demand. (Plaintiffs' Slides at Slide 134) Plaintiffs also allege that the statement has "deprived Plaintiffs of substantial sales, threaten[ed]

the loss of substantial future sales, and ha[s] also caused significant harm to Plaintiffs' goodwill and reputation[.]" (D.I. 16 at ¶ 321)[33] So Plaintiffs have sufficiently pleaded proximate cause. *See Spanish Sports Network, LLC v. Spanish Football Prods., LLC*, No. CV 20-7354 (RBK/MJS), 2021 WL 2284260, at *8 (D.N.J. June 4, 2021) (finding that the complaint sufficiently established proximate cause as to a Lanham Act claim, where it alleged that "Mr. Sciore, as a direct competitor, is likely to be damaged by [d]efendants[']s misleading statement that it was the only source of coverage for Phillies and Eagles games because it will harm his business reputation and eventually lead to a decrease in revenue or profits"); *Steer Mach. Tool & Die Corp. v. SS Niles Bottle Stoppers, LLC*, 331 F. Supp. 3d 429, 434 (M.D. Pa. 2018) (finding that an allegation that as a direct and proximate cause of its direct competitor's conduct, "the plaintiff has been and is likely to continue to be injured in its business reputation and lose revenue and profits" was sufficient to satisfy the proximate cause requirement regarding a Lanham Act claim).[34]

[33] The cases that Defendants rely upon in support of their argument are not on all fours with our case here. (D.I. 57 at 43) For example, in *Millennium Access Control Tech., Inc. v. On the Gate, LLC*, 15-CV-6067(SJF)(AKT), 2017 WL 10445800 (E.D.N.Y. Feb. 14, 2017), the plaintiff's complaint was wholly conclusory in alleging that, as a direct and proximate cause of the defendants' unlawful act, the plaintiff had suffered damage to its business, reputation and goodwill. 2017 WL 10445800, at *11. And in *MiMedx Grp., Inc. v. DBW Partners LLC*, Civil Action No. 17-1925 (JDB), 2018 WL 4681005 (D.D.C. Sept. 28, 2018), the plaintiff failed to connect the allegedly false and misleading statements "to a competitive injury related to [the plaintiff's] commercial interests[,]" which compelled the court to find that proximate causation was not adequately pleaded. 2018 WL 4681005, at *8-9. Here, in contrast, the FAC pleads with specificity how the statement proximately caused injury to Plaintiffs.

[34] Defendants also argue that the FAC is insufficient because it does not specifically allege that the statement at issue caused prescribers to prescribe "Dispense as Written" for branded Apokyn; Defendants assert that in the absence of such an allegation, state substitution laws that require pharmacies to dispense a generic version instead of a branded version of a drug where possible would have kicked in—such that the statement at issue would have *increased* Plaintiffs' sales, not decreased them. (D.I. 57 at 43-44; D.I. 100 at 25) The Court does not agree. Defendants' argument assumes that the record indicates conclusively that all pharmacies

Therefore, the FAC sufficiently pleads the Lanham Act claim in Count 4.

E. Count 5: Tortious Interference With Contract and Count 6: Tortious Interference With Prospective Economic Advantage

Count 5 of the FAC alleges that Supernus interfered with the contracts that Plaintiffs had in place with the specialty pharmacies and their respective wholesalers to sell and distribute generic apomorphine cartridges, which caused the specialty pharmacies to back out of the contracts to buy large quantities of generic cartridges. (D.I. 16 at ¶¶ 323-27) Count 6 alleges that certain Defendants intentionally coerced the specialty pharmacies to cancel their orders and refrain from placing ongoing orders, and intentionally coerced BD to cut off discussions with Plaintiffs and violate its policy of not entering into exclusive agreements. (*Id.* at ¶¶ 329-35) Defendants assert that New Jersey law applies to these claims, and Plaintiffs do not dispute this. (D.I. 57 at 44 n.25; D.I. 86 at 42-43)

Under New Jersey law, malice is a required element of Plaintiffs' tortious interference claims. *Matrix Distribs., Inc. v. Nat'l Assoc. of Bds. of Pharmacy*, 34 F.4th 190, 200 (3d Cir. 2022). This element requires that "harm was inflicted intentionally and without justification or excuse." *Id.* (internal quotation marks and citation omitted). Defendants argue that the FAC fails to plead malice because "[w]here tortious interference is asserted on the same grounds as an

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must in all instances dispense a generic version of a drug unless "Dispense as Written" is specified on the prescription. But that is not the record before the Court. (*See* D.I. 16 at ¶ 77 ("When a pharmacist fills a prescription written for a branded drug, these laws allow (in *some states, require*) the pharmacist to dispense an A-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise.") (emphasis added)); *The Rsch. Found. of State Univ. of N.Y. v. Mylan Pharms. Inc.*, 723 F. Supp. 2d 638, 659 n.18 (D. Del. 2010) ("*[M]any* pharmacies will substitute the generic product for the branded product unless the physician specifies on the prescription form 'Dispense as Written.'") (emphasis added). At the pleading stage, where the Court must draw all reasonable inferences in favor of Plaintiffs, the FAC's explanation as to why the statement artificially depresses demand for generic cartridges is sufficient. Defendants can assert their defenses at the appropriate stage of the case.

implausible antitrust claim, malice is likewise implausible." (D.I. 57 at 44-45) According to Defendants, because Plaintiffs (1) failed to plead that Supernus's 2022 Pharmacy Agreements violated antitrust laws; and (2) failed to plead that the September 2019 Agreement substantially foreclosed competition; then (3) any allegation that Defendants' conduct with respect to these agreements constitutes malice must fail. (*Id.* at 45; D.I. 100 at 26)

As the Court has explained above, however, the FAC's allegations regarding the 2022 Pharmacy Agreements and the September 2019 Agreement do plausibly establish anticompetitive conduct. Thus, Defendants' argument as to why Plaintiffs' tortious interference claims must fail is not persuasive, and Defendants' Motion relating to Counts 5 and 6 is likewise denied. *See Fresenius Kabi USA, LLC*, 2017 WL 548944, at *5 (finding that the plaintiff's allegation that the defendant engaged in an "'extensive anticompetitive scheme' by entering into exclusive agreements to restrict entry of competitors" would constitute intentional illegal behavior (i.e., malice) if proven, and that the plaintiff's tortious interference claim was thus sufficiently pleaded).

IV. CONCLUSION

For the foregoing reasons, the Court DENIES the Motion.

Because this Memorandum Opinion may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Opinion. Any such redacted version shall be submitted no later than **May 16, 2024** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will

protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.