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

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION	:	**MDL NO. 2445** **13-MD-2445**
THIS DOCUMENT RELATES TO: *Wisconsin, et al. v. Indivior Inc. et al.* Case No. 16-cv-5073	:	
STATE OF WISCONSIN **By Attorney General Brad D. Schimel, *et al.*** **Plaintiffs,** **v.** **INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC., et al.** **Defendants.**	:	**CIV. A. NO. 16-5073**

Goldberg, J. **September 8, 2017**

MEMORANDUM OPINION

In this next installment of the ongoing antitrust litigation regarding the prescription drug Suboxone, a collection of states[1] (collectively, "Plaintiffs" or the "States"), have brought suit against Defendants Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) Ltd.; and Indivior PLC, f/k/a/ Reckitt Benckiser Group, plc; and MonoSol Rx, LLC (collectively "Defendants"). The States' lawsuit follows previously-filed

[1] Plaintiffs include the States of Wisconsin, Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Rhode Island, South Carolina, Tennessee, Utah, Vermont, and Washington; the Commonwealths of Kentucky, Massachusetts, Pennsylvania, and Virginia; and the District of Columbia, by their Attorneys General.

claims brought by several putative classes and a generic drug company. Similar to these prior claims, the States' Amended Complaint details antitrust allegations under §§ 1 and 2 of the Sherman Antitrust Act, allegations of an antitrust conspiracy between Indivior, Inc. ("Indivior")[2] and MonoSol Rx, LLC, and multiple state law claims in connection with Defendants' alleged use of a multi-pronged anticompetitive scheme. According to the States, this scheme was designed to prevent or delay less expensive generic versions of the Suboxone tablet from entering the market in order to preserve their profits from the sale of Suboxone. Currently pending is Defendant Indivior's ("Moving Defendant") Motion to Dismiss the Amended Complaint. For the following reasons, I will deny the motion in its entirety.

I. FACTS ALLEGED IN THE AMENDED COMPLAINT[3]

The following facts are set forth in the States Amended Complaint:

A. Generic Drug Approval Process

The federal Food and Drug Administration ("FDA") regulates the manufacture and commercial sale of pharmaceutical drugs under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. (Am. Compl. ¶ 26.) The manufacturer of a new drug must submit a new drug application ("NDA") that demonstrates, among other things, a drug's safety, clinically proven effectiveness, composition, and patent coverage. (Id.)

---

[2] Indivior, Inc. ("Indivior) was formerly incorporated under the name of Reckitt Benckiser Pharmaceuticals, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. (Am. Compl. ¶ 11.) Although the Amended Complaint used the name "Reckitt" throughout the document, Indivior is technically the named defendant in this case. To avoid confusion as to the appropriate defendant, I will refer only to Indivior as Moving Defendant.

[3] When determining whether to grant a motion to dismiss, a federal court must construe the complaint liberally, accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. Fowler v. UPMC Shadyside, 578 F.3d 203, 210–11 (3d Cir. 2009). In accordance with this principle, the recitation of the facts assumes the truth of the factual statements in the Amended Complaint.

In an effort to speed the entry of generic drugs into the market, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), under which generic drug manufacturers may receive FDA approval for generic drugs without replicating the clinical trials involved in an NDA. (Id. ¶ 27.) In lieu of an NDA, a generic drug manufacturer may submit an abbreviated new drug application ("ANDA") and incorporate data, such as clinical studies, that the NDA filer submitted to the FDA. (Id. ¶ 28.) To be approved, an ANDA must demonstrate that the generic drug (a) has the same active ingredients as; (b) is pharmaceutically equivalent to (same dosage form and strength); and (c) is bioequivalent to (exhibiting the same drug absorption characteristics) the previously approved drug. (Id. ¶ 29.)

Oral drugs proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category. (Id. ¶ 30.) In most cases, only oral drugs with an AB rating may be substituted by pharmacists for a physician's prescription of a brand-name drug without the physician's approval. (Id.) The FDA publishes a list of all approved drugs and therapeutic equivalents in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). (Id. ¶ 31.)

Once the FDA approves an ANDA and determines that the generic drug is AB-rated to the branded drug, state laws govern how the generic may be substituted for the brand name drug prescribed by physicians. (Id. ¶ 32.) In most states and under most health plans, a pharmacist may, and in many cases must, substitute an AB-rated generic drug for a prescribed brand-name drug. (Id. ¶ 32.)

B. Suboxone Tablet's Orphan Drug Designation

In 2002, Indivior introduced Suboxone, designed for the treatment of opioid addiction, as a sublingual tablet. (Id. ¶¶ 33, 37.) At that time, the two component ingredients of Suboxone—naloxone and buprenorphine—were not subject to any patent protection. (Id.) In 1994, and in lieu of exclusivity through patent protection, the FDA granted Indivior's Suboxone tablets a seven-year period of exclusivity as an "orphan drug"[4] based on Indivior's representation that it would be unlikely to recover the costs of developing and marketing the drug. (Id. ¶¶ 34, 36–37.) Nonetheless, Suboxone did not obtain actual marketing exclusivity until 2002, thus allowing Indivior to market the sublingual Suboxone tablet until October 8, 2009, without the threat of competition from any generic co-formulated buprenorphine/naloxone tablet. (Id. ¶ 37.) Indivior allegedly earned more than $2 billion on Suboxone tablets by 2010. (Id. ¶ 38.)

C. Indivior's Alleged Product-Hopping Scheme

1. Threat of Generic Entry in the Co-formulated Buprenorphine/ Naloxone Market

As a general rule, when AB-rated generic drugs become available, lower-priced generic competitors may be rapidly substituted for their brand-name counterparts because the Hatch-Waxman Act and state drug product selection laws permit, and in many cases require, pharmacists to substitute an AB-rated generic drug for the branded version unless the prescription specifically states otherwise. (Id. ¶ 40.) Soon after a generic competitor enters the

[4] The FDA may designate a drug as an "orphan drug" when it determines that either (a) the drug is intended for the safe and effective, treatment, diagnosis or prevention of a rare disease or disorder that affects fewer than 200,000 people in the United States; or (b) the disease or disorder affects greater than 200,000, but the manufacturer is not reasonably expected to recover the costs of developing and marketing the treatment drug from sales in the United States. (Id. ¶ 35.) After designation as an orphan drug, the FDA approves the drug for marketing. (Id. ¶ 36.) It then becomes eligible for a seven-year exclusivity period during which it may be marketed as a brand-name drug free from generic competition. (Id.)

market, manufacturers of brand-name drugs typically lose eighty percent or more of their sales to lower-priced generics. (Id. ¶ 41.)

As the orphan drug exclusivity period for Suboxone tablets neared expiration, Indivior became concerned that lower-priced generic versions of co-formulated buprenorphine/naloxone would enter the market and significantly reduce its sales and revenue of Suboxone tablets. (Id. ¶¶ 39, 42.) Faced with this impending loss of exclusivity, Indivior, in connection with a company named MonoSol Rx, LLC ("MonoSol"), began to formulate a "Buprenorphine Generic Offensive Strategy." (Id. ¶¶ 44–45.) This strategy relied on FDA regulations that allow branded manufacturers to seek FDA approval to modify the dosage form and strength of an existing product, which would in turn change its pharmaceutical equivalence and alter the AB-rating of any proposed or available generic substitutes. (Id. ¶ 43.) The first step of the plan was to develop a new version of Suboxone which could be used to secure patent protection, while the second step was to convert the market for co-formulated buprenorphine/naloxone from Suboxone tablets to the newly-developed version of Suboxone. (Id. ¶ 45.)

2. The Creation and Marketing of Suboxone Film

In a December 2006 meeting, MonoSol and Reckitt Benckiser Healthcare UK Ltd. signed an agreement to develop and market a sublingual film form of Suboxone for the purpose of extending Indivior's exclusivity in the co-formulated buprenorphine/naloxone market. (Id. ¶ 46.) According to the Amended Complaint, MonoSol originally proposed this idea and convinced Indivior to develop the film product in partnership with MonoSol. (Id. ¶ 47.) MonoSol also negotiated with Indivior to receive royalty payments on the sales of Suboxone film. (Id. ¶ 49.)

In April 2008, MonoSol applied for a patent, which was issued as patent number 8,017,150 entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made

Therefrom." (Id. ¶ 51.) Indivior listed the '150 patent, as well as patent numbers 8,475,832[5] and 8,603,514 in the FDA Orange Book, and alleged that they covered Suboxone film. (Id. ¶ 52.) The earliest patent expires in 2023. (Id.)

To speed up the approval process for the new film product, MonoSol suggested that Indivior have a pre-NDA filing guidance meeting with the FDA to request a priority review status. (Id. ¶ 53.) Both MonoSol and Indivior attended the FDA meeting. (Id.) On October 28, 2008, Reckitt submitted NDA 022410 to the FDA to market the sublingual film version of Suboxone. (Id. ¶ 55.) On August 21, 2009, the FDA rejected Indivior's application due to concerns that the film could be abused by patients and result in accidental exposure to children. (Id. ¶ 57.) In response, Indivior submitted a revised Risk Evaluation and Mitigation Strategy ("REMS")[6] to address the safety concerns related to the film form. (Id. ¶ 59.) Based on the REMS, the FDA approved Indivior's NDA for Suboxone film on August 30, 2010. (Id. ¶ 60.)

Because Suboxone film is in a different dosage form than Suboxone tablets, the two are not pharmaceutically equivalent. (Id. ¶ 56) Thus, any tablet form of generic co-formulated buprenorphine/naloxone would not be an AB-rated generic substitute for Suboxone film. (Id.) According to the Amended Complaint, however, the film offers no significant benefits for patients over the tablet and any differences between the two formulations are "clinically insignificant." (Id. ¶ 62.) Moreover, the FDA found that the film has no demonstrable safety advantage over Suboxone tablets and, in fact, expressed concerns that the film actually presents increased safety issues and potential for abuse. (Id. ¶¶ 65–67.)

---

[5] The United States District Court for the District of Delaware has invalidated the '832 patent. (Id. ¶ 52.)

[6] The REMS is a document provided by the manufacturer and contains a risk management plan or risk-minimization strategy that goes beyond the professional labeling to ensure that the benefits of a drug outweigh the risk. (Id. ¶ 58.)

According to Indivior's Suboxone Reformulation Development Plan, its "Priority I" goal was "to keep the target moving to reduce generic competition." (Id. ¶ 69.) In a March 2007 email, Indivior explained that "the current plan calls for the introduction of the film in June 2009, transitioning [patients] from the [sublingual] tabs to the film, and then withdrawing the [sublingual] tabs altogether prior to October 2009." (Id. ¶ 70.) MonoSol made the original suggestion that the withdrawal of Suboxone tablets could provide further protection from generic entry into the market, and this plan was discussed with employees of Reckitt Benckiser Healthcare, Ltd. (Id. ¶ 71.)

Subsequently, Indivior engaged in a multi-faceted campaign to convert the co-formulated buprenorphine/naloxone market to Suboxone film. (Id. ¶ 72.) First, Indivior communicated to the public and the medical community that single-dose or unit-dose packaging was necessary to prevent potential exposure to multiple doses in the case of accidental pediatric exposure, and it began marketing Suboxone film in unit-dose packaging. (Id. ¶ 74.) In connection with this message, it partnered with consulting firm Venebio Group, LLC to develop its "Film is safer" platform, which it acknowledged was due solely to "packaging type." (Id. ¶ 75.) Although Suboxone tablets had been sold in unit-dose packaging outside of the United States since 2005, Indivior did not make any attempt to convert its tablet packaging in the United States to unit-dose packaging, but rather continued to sell tablets in multi-unit bottles. (Id. ¶ 76.)

Second, Indivior began a "multi-front offensive" to get film into the market before the generics could enter with their version of the tablet, including (1) aggressively promoting the alleged superiority of the film to doctors, payors and pharmacists; (2) encouraging use of the film through a targeted and sustainable payor strategy by creating a patient subsidy program available only for Suboxone film; (3) pricing film to be less expensive than tablets despite the more

expensive production costs for film; (4) hiring and compensating its sales force so that it would earn bonuses for convincing health care providers to convert to film; and (5) coordinating efforts among field sales, marketing, and government to drive film's "stickiness" with targeted payors. (Id. ¶¶ 77–80, 83–86.)

In September 2012, Indivior issued a press release advising the public and prescribing physicians that it intended to withdraw the tablets from the market within the next six months due to a "pediatric exposure safety issue." (Id. ¶ 81.) Indivior also sought an FDA declaration that Suboxone tablets were being voluntarily pulled from the market for safety concerns. (Id. ¶ 82.) By mid-2012, the film accounted for over seventy percent of Suboxone prescriptions. (Id. ¶ 87.) By the time the generic tablets received FDA approval in February 2013, eighty-five percent of Suboxone prescriptions were written for the film. (Id.) Indivior withdrew Suboxone tablets from the market on March 18, 2013. (Id. ¶ 88.)

D. Indivior's Role in Delaying Generic Entry

The orphan drug exclusivity on branded Suboxone tablets expired on October 8, 2009, and ANDAs for approval to sell generic Suboxone tablets were filed in late 2009. (Id. ¶ 89.) Nevertheless, generic buprenorphine/naloxone tablets did not gain FDA approval until February 2013. (Id. ¶ 89.)

In late 2011, while certain potential generic competitors were awaiting FDA approval of their ANDAs, Indivior submitted a REMS for Suboxone tablets, which was approved by the FDA in December 2011. (Id. ¶ 90.) On January 6, 2012, the FDA ordered Indivior to cooperate with its potential competitors—including Actavis, Inc., Amneal Pharmaceutical LLC, Ethypharm USA Corp., Mylan Inc., Roxane Laboratories Inc., Sandoz Inc., Sun Pharmaceuticals Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, the "Buprenorphine Products

Manufacturers Group")—in a shared REMS. (Id. ¶ 91.) Shared REMS, like individual REMS, are used to address safety concerns of pharmaceutical products, but are designed to cover the situation where multiple manufacturers are marketing a generic product that is an AB-rated substitute product for a reference drug. (Id.)

Despite the fact that Indivior's Suboxone tablet REMS had just been approved by the FDA in December 2011, Indivior allegedly did not cooperate with the generic manufacturers in the finalization and submission of a shared REMS. (Id. ¶ 93.) While not explicitly refusing to participate, it engaged in multiple delay tactics to prolong the approval of the ANDA for the generics. (Id.) After the Buprenorphine Products Manufacturers Group met with Indivior for several months to negotiate a shared REMS, the Group ultimately reported to the FDA that Indivior had no desire to enter into a shared REMS, feigned cooperation with the shared REMS development process, refused to participate in meetings with the generic ANDA filers, refused to discuss any issues pertaining to the shared REMS with the generic ANDA filers, placed conditions on its cooperation with the shared REMS development process that it knew the ANDA filers could not agree to, refused to share information with the generic ANDA filers regarding the existing REMS, raised last-minute issues to cause further delay once a shared REMS was ready to be submitted in August 2012, and stopped participating altogether in September 2012. (Id. ¶ 94.) Indivior's refusal to cooperate successfully delayed submission of the shared REMS until August of 2012, when the generic ANDA filers obtained a waiver allowing them to submit a shared REMS program of their own without Indivior's cooperation. (Id. ¶ 97.)

In another purported delay tactic, Indivior filed a citizen petition[7] with the FDA on September 25, 2011. (Id. ¶ 98.) Indivior's citizen petition asked the FDA to withhold approval of the ANDAs for generic Suboxone tablets unless: (1) the ANDA contained a targeted pediatric exposure education program; (2) the ANDA product had child-resistant unit-dose packaging; and (3) the FDA had determined whether Indivior had discontinued Suboxone tablets for safety reasons. (Id. ¶ 102.)

In the same week it filed the citizen petition, Indivior announced its intent to permanently withdraw Suboxone tablets from the market for safety reasons. (Id. ¶ 103.) Indivior never disclosed these alleged safety concerns about Suboxone tablets to the generic manufacturers during the shared REMS negotiation process. (Id. ¶ 104.) Moreover, one month prior, on August 30, 2012, Indivior specifically represented to the FDA, in a combined REMS assessment, that its tablet was successful, it needed no further changes, and Indivior had considered and rejected converting its Suboxone tablets to unit-dose packaging for pediatric safety reasons. (Id. ¶ 105.)

The FDA denied Indivior's citizen petition on February 22, 2013, noting the petition was not supported by evidence and was inconsistent with Indivior's own behavior. (Id. ¶ 108.) The FDA further acknowledged that it had no authority to require Suboxone ANDAs to contain targeted pediatric exposure labeling because, pursuant to 21 U.S.C. § 355(j)(2)(A)(v) and 4(G), the labeling for an ANDA must be the same as the labeling for the approved listed drug. (Id.

[7] Under § 505 of the Food, Drug and Cosmetic Act, any individual may submit a "citizen petition" asking the FDA to take, or refrain from taking, certain administrative action. (Id. ¶ 99.) Such petitions are commonly used to express concerns about the safety or legality of a product. (Id.) Pursuant to 21 C.F.R. § 10.30, the FDA then has 150 days to respond to the citizen petition. (Id. ¶ 100.) During that period, FDA approval of any ANDA pending for the subject product is typically delayed, leading to some abuse by brand-name manufacturers in filing baseless citizen petitions in order to prolong their monopolies. (Id. ¶ 101.)

¶ 108.) The FDA also stated that the close proximity of Indivior's withdrawal of Suboxone tablets to the "period in which generic competition for this product was expected to begin cannot be ignored." (Id. ¶ 109.) In turn, the FDA referred Indivior's conduct to the Federal Trade Commission for antitrust investigation. (Id. ¶ 110.) Despite the denial, the citizen petition nonetheless had the effect of delaying FDA approval of the pending ANDAs. (Id. ¶¶ 111, 113.)

On February 22, 2013, the FDA granted the generics-only, waiver-based REMS and approved Amneal and Actavis' ANDAs for tablet sales. (Id. ¶ 114.) On March 6, 2013, generic co-formulated buprenorphine/naloxone tablets entered the market. (Id. ¶ 115.)

E. Procedural History

In June 2013, several putative classes initiated litigation against Indivior alleging anticompetitive behavior with respect to its marketing and sale of Suboxone. These cases were consolidated into a multi-district litigation ("MDL") in this Court. Among those cases were the class action complaint ("Class Action Complaint") brought by Direct Purchaser Plaintiffs and End-Payor Plaintiffs ("Class Plaintiffs") alleging that Defendants unlawfully delayed and impeded competition from generic versions of Suboxone tablets, resulting in ongoing overpayments by consumers. On December 3, 2014, I issued an opinion (the "Class Action Opinion") dismissing one of Direct Purchaser Plaintiffs' stand-alone antitrust claims, a variety of state law claims by the End-Payor Plaintiffs, and claims against several of the other Defendant entities. In re Suboxone, 64 F. Supp. 3d 665 (E.D. Pa. 2014). I left the remaining claims intact.

On December 23, 2015, Amneal Pharmaceuticals LLC ("Amneal"), a generic manufacturer and competitor of Indivior, filed a complaint regarding Indivior's alleged anticompetitive conduct surrounding Suboxone. That case was consolidated with the MDL currently before me. On January 4, 2017, I issued a decision dismissing part of Amneal's claims

that Indivior improperly delayed entry of generic tablets, all claims against Reckitt Benckiser Pharmaceuticals, Inc., and all claims against Indivior PLC. In re Suboxone, 13-MD-2445, 2017 WL 36371 (E.D. Pa. Jan. 4, 2017).

On September 22, 2016, the Plaintiff States initiated the current litigation against all Defendants. The States then filed a First Amended Complaint on November 23, 2016, setting forth five causes of action as follows: (1) monopolization under the Sherman Act § 2 against Indivior, Reckitt Benckiser Healthcare (UK) Ltd., and Indivior PLC (the "Reckitt Defendants"); (2) attempted monopolization under the Sherman Act § 2 against the Reckitt Defendants; (3) conspiracy to monopolize under the Sherman Act § 2 against all Defendants; (4) illegal restraint of trade under the Sherman Act § 1 against all Defendants; and (5) individual state law claims against all Defendants.

On December 12, 2016, Indivior filed a motion to dismiss the First Amended Complaint. The States responded on January 30, 2017, and Indivior filed a reply brief on February 21, 2017. Upon review, I find that the Amended Complaint properly pleads all alleged causes of action. As set forth in detail below, I will deny the motion to dismiss in its entirety.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" and "only a complaint that

states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 678 (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." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.

The Court of Appeals has detailed a three-step process to determine whether a complaint meets the pleadings standard. Bistrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for relief. Id. at 365. Next, the court must "peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." Id. Finally, the court "look[s] for well-pled factual allegations, assume[s] their veracity, and then 'determine[s] whether they plausibly give rise to an entitlement to relief.'" Id. (quoting Iqbal, 556 U.S. at 679). The last step is " 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.' " Id. (quoting Iqbal, 556 U.S. at 679).

III. DISCUSSION

Moving Defendant's Motion to Dismiss posits two broad challenges to the Amended Complaint. First, Moving Defendant argues that Plaintiffs' Sherman Act § 2 claims of monopolization and attempted monopolization cannot survive because Plaintiffs have not pled sufficient facts to support a finding of anticompetitive behavior. Second, Moving Defendant contends that Plaintiffs' conspiracy claims under §§ 1 and 2 of the Sherman Act fail to allege concerted action taken in restraint of trade. I address each argument separately.

A. Monopolization Under Section 2 of the Sherman Act

Section 2 of the Sherman Act "makes it unlawful to monopolize attempt to monopolize, or conspire to monopolize, interstate or international commerce." Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 306 (3d Cir. 2007) (citing 15 U.S.C. § 2). A monopolization claim requires proof of "a general intent to do the act, for no monopolist monopolizes unconscious of what he is doing." Times–Picayune Publ'g Co. v. United States, 345 U.S. 594, 626 (1953) (internal quotations and citations omitted). Nonetheless, "the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004). This is so because the Sherman Act "directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself." McQuillan v. Spectrum Sports, 506 U.S. 447, 458 (1993). Therefore, to succeed on a claim for actual monopolization under § 2, a party must prove: "(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 historical accident." Broadcom, 501 F.3d at 307 (quoting U.S. v. Grinnell Corp., 384 U.S. 563, 570–71 (1966)).[8]

[8] Notably, Plaintiffs also bring a claim for attempted monopolization under the Sherman Act § 2. "A claim of attempted monopolization under § 2 of the Sherman Act 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.'" Broadcom, 501 F.3d at 317 (quoting Crossroads Cogeneration Corp. v. Orange & Rockland Utils., Inc., 159 F.3d 129, 141 (3d Cir. 1998)). As the sole element at issue for both the monopolization and the attempted monopolization claims is whether Indivior engaged in anticompetitive conduct, I address both claims together.

In the present case, Moving Defendant does not deny that it possessed monopoly power in satisfaction of the first element,[9] but instead focuses on the sufficiency of the allegations regarding anticompetitive conduct. Given that concession, I will discuss only the second element of anticompetitive conduct.

Under the "rule of reason" burden-shifting framework set forth by the D.C. Circuit in United States v. Microsoft Corp., the party seeking to impose antitrust liability must initially provide evidence of the anticompetitive nature of a defendant's conduct. 253 F.3d 34, 58 (D.C. Cir. 2001). Once the plaintiff has met its burden of pleading or establishing the anticompetitive nature of a defendant's conduct, the burden shifts to the defendant to proffer a "nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for

---

[9] Monopoly power is "the ability to control prices and exclude competition in a given market." Broadcom Corp., 591 F.3d at 307. Although monopoly power can be demonstrated through direct evidence, id., the "more common way that a party may prove monopoly power is by providing indirect evidence, which includes 'structural evidence of a monopolized market.'" Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 435 (3d Cir. 2016) (quoting Harrison Aire, Inc. v. Aerostar Int'l, Inc., 423 F.3d 374, 381 (3d Cir. 2005)). To support a claim of monopoly power through indirect evidence, a plaintiff must show that (1) the defendant had market power in the relevant market and (2) that there were barriers to entry into the market. Id. The Third Circuit "generally require[s] a plaintiff alleging antitrust injury under Section 2 to show that [the] [d]efendant[] maintained a market share "significantly larger than 55%" to establish antitrust liability." Id. at 437 (citations omitted).

In the present case, Plaintiffs allege that the relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction, including both Suboxone film and Suboxone tablets together with any AB-rated generics, (Am. Compl. ¶ 19), and the relevant geographic market is the United States and its territories. (Id. ¶ 21.) Plaintiffs contend that before October 8, 2009, Suboxone was the only co-formulated buprenorphine/naloxone opioid treatment because of its orphan drug status, thus allowing Indivior to enjoy 100 percent of the market share in the United States and its territories. (Id. ¶ 22.) Even after the exclusivity period expired, Indivior's branded Suboxone products, including the film introduced in September 2010, remained the sole source of buprenorphine/naloxone until two generic manufacturers introduced generic tablets in March 2013. (Id.) After the generics were approved, Indivior's market share for co-formulated buprenorphine/naloxone dropped to sixty-eight percent. (Id.) These allegations suffice to satisfy the first element of section two Sherman Act claim.

example, greater efficiency or enhanced consumer appeal." Id. at 59; see also Mylan Pharms. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 431, 438 (3d Cir. 2016). The plaintiff may then " 'either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit.' " Id. (quoting Microsoft Corp., 253 F.3d at 58–59).

In general terms, "a firm engages in anticompetitive conduct when it attempts 'to exclude rivals on some basis other than efficiency' or when it competes 'on some basis other than the merits.'" W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 108 (3d Cir. 2010), (quoting Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605 (1985) and LePage's, Inc. v. 3M, 324 F.3d 141, 147 (3d Cir. 2003)). "Conduct that impairs the opportunities of rivals and either does not further competition on the merits or does so in an unnecessarily restrictive way may be deemed anticompetitive." Broadcom Corp., 501 F.3d at 308. Mere harm to competitors will not suffice; rather the alleged exclusionary acts must harm the competitive process and must actually have the requisite anticompetitive effect. Microsoft Corp., 253 F.3d at 58. Given the number of forms such conduct can take, a comprehensive enumeration of all the varieties of anti-competitive conduct is impossible. W. Penn Allegheny Health, 627 F.3d at 109. "The challenge for an antitrust court lies in stating a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it." Microsoft Corp., 253 F.3d at 58.

In the present matter, Plaintiffs' allegations of anti-competitive conduct fall into two broad categories: (1) product-hopping claims and (2) delay claims, each addressed separately below.[10]

[10] Plaintiffs argue that I must examine defendant's conduct as a whole, rather than as a set of isolated acts, while Defendant asserts that I must separately consider each individual theory. Notably, Plaintiffs' Sherman Act § 2 claim sets forth an overall scheme of anticompetitive

1. Product Hopping Claim

Plaintiffs' first theory alleges that Moving Defendant has engaged in anticompetitive "product hopping." Specifically, Plaintiffs claim that as the orphan drug exclusivity period for Suboxone tablets neared expiration, Moving Defendant sought to introduce Suboxone in a sublingual film form knowing that any generic tablets would not be AB-rated, *i.e.* not substitutable by a pharmacist, thereby converting the market to purely film. Plaintiffs contend that Moving Defendant did so solely to prolong its control over the buprenorphine/naloxone market without any concern for the fact that the film had substantial disadvantages in comparison to the tablet form. Moving Defendant now challenges the validity of this theory as a basis for a Sherman Act § 2 claim. I disagree with Moving Defendant and will allow this theory to proceed.

---

behavior rather than stating separate causes of action for each individual anticompetitive act. The Third Circuit has held that "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." LePage's Inc., 324 F.3d at 162; see also City of Anaheim v. S. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements."). Particularly at the motion to dismiss stage, allegations of multiple forms of anticompetitive conduct may be considered collectively to determine whether a plaintiff has plausibly pled a section 2 claim under the Sherman Act. See W. Penn Allegheny Health System, 627 F.3d at 109–10.

Nevertheless, the Third Circuit has clarified that "[t]he relevant inquiry is the anticompetitive effect of [a defendant's] *exclusionary* practices considered together." LePage's Inc., 324 F.3d at 162 (emphasis added). Logically, then, if none of the alleged conduct is exclusionary or anticompetitive, it cannot collectively violate section 2 of the Sherman Act. See Eatoni Ergonomics, Inc. v. Research in Motion Corp., 486 F. App'x 186, 191 (2d Cir. 2012) ("[When] alleged instances of misconduct are not independently anti-competitive . . . they are not cumulatively anticompetitive either."). Accordingly, I will separately consider the product hopping allegation and delay allegations to determine whether at least one of them can substantiate a claim of anticompetitive conduct.

When an alleged monopolist introduces a new product, the question is whether it is "engaging in exclusionary conduct 'as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" Microsoft, 253 F.3d at 58 (quoting Grinnell, 394 U.S. at 571). "As a general rule, 'any firm, even a monopolist, may . . . bring its products to market whenever and however it chooses.'" Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 925 n.7 (3d Cir. 1999) (quoting Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir. 1979)). The practice of "product hopping," however, "under certain circumstances may be viewed as anticompetitive conduct." Mylan Pharms. v. Warner Chilcott Public Ltd. Co., 838 F.3d 421, 438 (3d Cir. 2016). Product hopping occurs where "a pharmaceutical company makes modest reformulations to a brand name drug prior to the expiration of its market exclusivity for the purposes of stymieing generic competition and preserving monopoly profits." In re Suboxone Antitrust Litigation, No 13-2445, __ F.R.D. __, 2016 WL 3519618, at *1 (E.D. Pa. June 28, 2016). "Illegal product hopping—the introduction of a new product by a monopolist in combination with exclusionary conduct that either severely restricts the market's ambit or bars a substantial number of rivals—is anticompetitive." In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 256 (D. Mass. 2017).

In the Class Action Complaint by the direct purchasers and end-payors of Suboxone, I was presented with almost identical allegations of product hopping. Although I found that simply introducing a new product on the market, whether superior or not, does not by itself constitute exclusionary conduct, In re Suboxone, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014), I concluded that Indivior's other alleged wrongful conduct, taken in conjunction with the introduction of the new product, stated a plausible claim of anticompetitive activity. Id. This decision rested on the combination of Indivior's near simultaneous introduction of the Suboxone

film, removal of its own Suboxone tablets, and marketing campaign to disparage Suboxone tablets. Id. at 682–83. Plaintiffs had also plausibly alleged that "various market forces unique to the pharmaceutical industry ma[d]e generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals." Id. at 683–84. For example, plaintiffs asserted that a disconnect existed between the person paying for the prescription and the person selecting the appropriate treatment, meaning that "the ordinary market forces that would allow consumers to consider price when selecting a product [were] derailed." Id. at 684.

Since that decision in 2014, the soundness of product hopping as the basis for a Sherman Act § 2 claim has been the subject of several decisions both within and outside of the Third Circuit. First, the United States Court of Appeals for the Second Circuit, in New York ex rel Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) ("Namenda"), considered whether product hopping could violate the Sherman Act. The relevant market in that case involved the memantine drug used to treat Alzheimer's disease. Id. at 646–47. Defendants manufactured Namenda IR, a twice-daily immediate-release drug, and Namenda XR, a once-daily extended-release drug. Id. The only relevant medical difference between the two was that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day. Id. at 647. Patent exclusivity on Namenda IR was set to expire in July 2015 and, as a result, defendants brought Namenda XR to market in July 2013 to avoid the end of patent exclusivity, or the "patent cliff." Id. at 647–48. In conjunction with the introduction of the new product, the defendants stopped actively marketing IR; spent substantial sums of money promoting XR to doctors, caregivers, patients, and pharmacists; sold XR at a discounted rate; and issued rebates to health plans to ensure that XR co-payments remained lower than IR co-payments. Id. at 648. This was known as the "soft switch." Id. In early 2014,

prior to entry of generic IR, defendants publicly announced their plans to discontinue Namenda IR and began urging their customer base to make the switch to Namenda XR. Id. Eventually, the defendants withdrew IR entirely, thereby making the ultimate "hard switch" to XR. Id. The State of New York sued the defendants under antitrust laws and the district court granted the State a preliminary injunction. Id.

On appeal, the Second Circuit recognized that "neither product withdrawal nor product improvement alone is anticompetitive," but "when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act." Id. at 653–54 (emphasis in original) (internal citations omitted). On the facts of the case before it, the court held that "Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depended on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws." Id. at 654. In response to the defendants' claim that alternative means of marketing and selling the generics existed, the court noted that for there to be an antitrust violation, "generics need not be barred 'from all means of distribution' if they are 'bar[red] . . . from the cost-efficient ones.'" Id. at 656 (citing Microsoft, 253 F.3d at 64 and Dentsply Int'l, 399 F.3d at 191 ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.")). Considering the unique market characteristics of the pharmaceutical industry and the state substitution laws regarding AB-rated drugs, the Second Circuit affirmed the district court's

finding that antitrust law required the defendants to allow generic competitors a fair opportunity to compete using state substitution laws. Id. at 658.

Subsequent to that decision, the Third Circuit discussed product hopping in Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Company ("Doryx"), 838 F.3d 421 (3d Cir. 2016). In that matter, the plaintiff, a generic drug manufacturer, brought an action against name-brand drug manufacturers alleging that, in an effort to exclude generic competition, brand manufacturers made insignificant modifications to an oral tetracycline used to treat severe acne. Id. at 426. Although the case proceeded past the motion to dismiss stage, the trial court granted the defendants' motion for summary judgment. Id. at 431–32. On appeal, the Third Circuit found the plaintiff had failed to produce evidence that defendants' anticompetitive conduct foreclosed it from the relevant market. Distinguishing Namenda, the court remarked that defendants' reformulation was not an attempt to avoid a "patent cliff"—the end of patent exclusivity corresponding to the brand drug's loss of market share. Id. at 440. Rather, patent exclusivity on the brand-name oral tetracycline had long since expired and generic companies had been engineering and marketing their own versions of the drug during the lengthy ensuing time period. Id. at 438. The plaintiff delayed in developing its own generic version until significantly later and, at that time, received 180 days of exclusive marketing and sales rights, allowing it to sell its tablets at higher prices and reap generous profits. Id. at 438–39. The court ultimately determined that defendants' reformulation of their product was done in a further effort to compete with the multiple generic manufacturers already in the relevant market, and not to stymie competition. Id.

Despite affirming the district court's grant of summary judgment in favor of the defendants on the product-hopping claim, however, the Third Circuit offered guidance for cases

that present a "closer call." Id. at 440. Primarily, the Third Circuit distinguished the decision on the Suboxone Class Action Complaint, noting that it was decided at the motion-to-dismiss stage, whereas Doryx had already survived a motion to dismiss and proceeded through full discovery. Id. at 440. Moreover, the court emphasized the ongoing feasibility of a product-hopping claim, remarking that it did not "rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases." Id. It went on to explain that:

> [C]ourts may need to consider a number of additional, non-exhaustive factors. For instance, courts might need to balance the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers and to ensure fair competition under the antitrust laws. At the same time, courts should also be wary both of second-guessing Congress's legislative judgment and of turning courts into tribunals over innovation sufficiency. Moreover, courts may need to be cognizant of the unique separation between consumers and drug manufacturers in the pharmaceutical market, especially in cases where there is evidence of extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer's version of a drug.

Id. at 440–41 (footnotes omitted). It concluded that "even in more difficult cases, the disposition of each claim will necessarily turn on the facts and circumstances surrounding a company's alleged anticompetitive conduct." Id. at 441.

Most recently, the United States District Court for the District of Massachusetts had the opportunity to address the viability of a product hopping claim under section 2 of the Sherman Act. In re Asacol Antitrust Litig., 233. F. Supp. 3d 247 (D. Mass. 2017). At issue in that case were the drugs Asacol, used for the treatment of mild to moderately-active ulcerative colitis and approved by the FDA in 1992, and Asacol HD, a long-acting mesalamine tablet used to treat only moderately active ulcerative colitis and approved by the FDA in 2008. Id. at 255. The plaintiffs alleged that, with the patents for Asacol set to expire in July 2013, the defendant made

efforts to switch patients from Asacol to Asacol HD despite the fact that Asacol HD was only FDA–approved for treatment of moderately severe ulcerative colitis flares whereas the original Asacol treated three separate indications of ulcerative colitis. Id. at 256. The defendant's efforts of marketing Asacol HD from late 2009 into 2013 successfully moved sales from Asacol to Asacol HD. Id. During this effort, however, both Asacol and Asacol HD remained on the market, and sales of Asacol HD plateaued and remained at roughly one-fourth of the sales of Asacol by the end of 2012. Id. at 257. In mid-2012, the defendant began the design and launch of a new drug called Delzicol to replace its Asacol sales and, by April 1, 2013, the defendant discontinued selling Asacol altogether. Id. The plaintiffs alleged that this withdrawal of Asacol forced thousands of patients to switch to Asacol HD or Delzicol and eliminated the possibility that a generic product could be substituted automatically for an Asacol prescription. Id. The plaintiffs also alleged that the defendant raised concerns about an inactive ingredient in Asacol, while continuing to sell Asacol HD, which contained more than twice the amount of that same ingredient. Id.

The plaintiffs, direct purchasers of the drug, pled a product hop claim based on, among other things, a hard switch—"removing the original drug from the market entirely right before patent expiration to deprive potential generic manufacturers a prescription base for their generic version"—from Asacol to Asacol HD. Id. at 256. The court acknowledged that "conduct by a monopolist to perpetuate patent exclusivity through successive products" by means of "tweaking a brand-name drug to prevent pharmacists from substituting a generic equivalent" can constitute one form of anticompetitive product hopping. Id. (quoting In re Asacol Antitrust Litig., No. 15–12730, 2016 WL 4083333, at *8 (D. Mass. July 20, 2016)). The court noted, however, that " 'unless [a] plaintiff proves that some conduct of the monopolist associated with its introduction

of a new and improved product design constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market' there is no suspected anticompetitive conduct." Id. at 268 (quoting Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 1000 (9th Cir. 2010)) (additional internal quotation marks omitted). The plaintiffs in that case did not allege a hard switch from Asacol to Asacol HD, but rather asserted that the defendant acted over the course of an extended period to switch patients from Asacol to Asacol HD after its 2009 acquisition of both drugs. Id. at 268. Both Asacol and Asacol HD remained on the market throughout this period. Id. Although the plaintiffs claimed that the defendant's illegal attempts to market Asacol HD for off-label usage to reduce Asacol sales constituted a soft switch, the court remarked that soft switches "do not have the same anticompetitive result because 'the market can determine whether one product is superior to another . . . so long as the free choice of consumers is preserved.'" Id. at 269 (quoting Namenda, 787 F.3d at 654–55 (further quotations omitted)). In that case, the freedom of consumer choice existed because both products remained on the market contemporaneously for four years. Id.

Applying the cumulative lessons from these cases to the Amended Complaint before me, I find that this matter presents a "closer call" more akin to Namenda than to either Doryx or Asacol.

First, similar to Namenda and unlike in Doryx, the First Amended Complaint alleges the introduction of a new product, without any clinically significant benefits, in an attempt to avoid a "patent cliff"— or, in this case, the end of orphan drug exclusivity—before the entry of generic competitors into the relevant market. The Amended Complaint specifically alleges that in October 2008, as the orphan drug exclusivity period for Suboxone tablets neared its 2009

expiration, Moving Defendant submitted an NDA to the FDA to market a newly-developed sublingual film version of Suboxone, which is not an AB-rated generic substitute for Suboxone tablets. (Am. Compl. ¶ 55–56.) According to the Amended Complaint, the film offers no significant benefits for patients over the tablet and any differences between the two formulations were "clinically insignificant." (Id. ¶ 62.) After requiring Indivior to proceed through the REMS process, the FDA approved Indivior's NDA for Suboxone film on August 30, 2010, prior to the entry of any generics. (Id. ¶ 60.)

Second, Plaintiffs have alleged that, in connection with the introduction of the new but insignificant design changes, Moving Defendant engaged in the "extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer's version of a drug"—conduct identified as anticompetitive by the Third Circuit in Doryx. Doryx, 838 F.3d at 441. According to the Amended Complaint, Indivior allegedly engaged in a multi-faceted campaign to convert the co-formulated buprenorphine/naloxone market to Suboxone film by (a) communicating to the public and medical community that unit-dose packaging, as with the film was necessary to prevent accidental pediatric exposure; (b) aggressively promoting the alleged superiority of the film; (c) creating a patient subsidy program available only for Suboxone film; (d) pricing film to be less expensive than tablets despite the more expensive production costs for film; (e) hiring and compensating its sales force so that they would earn bonuses for convincing health care providers to convert to film; and (f) coordinating efforts among field sales, marketing, and government to drive film's "stickiness" with targeted payors. (Am. Compl. ¶¶ 77–80, 83–86.)

Finally, unlike in Asacol, Plaintiffs allege that Indivior effectuated a "hard switch" from Suboxone tablets to Suboxone film. Film was approved by the FDA on August 30, 2010 while

Suboxone tablets were still on the market, but prior to generic entry. Simultaneously with its introduction of film and its anti-tablet marketing campaign described above, Indivior, like the defendants in Namenda, issued a press release advising the public and prescribing physicians of its intent to withdraw tablets from the market in the next six months due to safety issues. These actions had the alleged purpose and effect of decreasing the prescription base for the tablet as physicians and users were forced to convert to the film, the only other co-formulated buprenorphine/naloxone on the market. As such, the press release signified the start of Indivior's "hard switch." On March 18, 2013, less than two weeks after generic entry, Indivior actually withdrew the tablets, thereby completing the hard switch and leaving generic manufacturers without a prescription base. Such actions "cross[] the line from persuasion to coercion" and, if proven, may rise to the level of anticompetitive conduct. Namenda, 787 F.3d at 654

Moving Defendant offers two additional arguments in support of its Motion to Dismiss. The first challenges Plaintiffs' failure to include allegations of actual foreclosure in the market, which Moving Defendant asserts is fatal to the claim. The second argument contends that Plaintiffs neglected to include crucial allegations of a price disconnect within the pharmaceutical market. Separately addressing each argument, I find them each meritless.

a. Allegations of Actual Foreclosure

Moving Defendant first contends that Plaintiffs have failed to include the allegations of "actual foreclosure" necessary to state a successful product-hop claim. Moving Defendant's argument relies heavily on the Doryx trial court's finding that the defendants did not exclude competition when they reformulated Doryx because (a) Doryx capsules had been available without patent protection for twenty years and had generic competition, (b) the plaintiff was able to introduce its own generic tablet and benefit from 180 days of exclusivity for the tablet, and

(c) the plaintiff was able to raise the price of two of its tablet dosages. Mylan Pharms., Inc. v. Warner Chilcott Public Ltd. Co., No. 12-3824, 2015 WL 1736957, at *12 (E.D. Pa. Apr. 16, 2015). The Doryx trial court remarked that "[t]hroughout this period, doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug." Id. at *13. The Third Circuit affirmed this conclusion and noted that the product hopping in this case was not anticompetitive conduct because the plaintiff "was not foreclosed from the market." Doryx, 838 F.3d at 438. Seizing on this language, Moving Defendant now argues that allegations of market foreclosure are a pleading requirement to establish anticompetitive behavior. Defendants urge that because the Amended Complaint pleads that generics entered the market and competed for sales notwithstanding the absence of automatic substitution, foreclosure may not be plausibly inferred.

Moving Defendant misapplies Doryx's holding and disregards several crucial distinctions from the present case. Primarily, Doryx was decided at the summary judgment stage, as opposed to the motion to dismiss stage. After a period of "exhaustive discovery," there was a "robust record void of any evidence of anticompetitive conduct." Id. at 440. Moreover, contrary to Moving Defendant's argument, the Third Circuit did not require allegations of total foreclosure in order for a product hopping claim to survive.[11] Rather, the Third Circuit's decision in Doryx was premised substantially on the fact that the expansive evidentiary record on summary judgment review showed that there were plenty of other competitors already in the relevant

[11] In fact, in another recent case, the Third Circuit reaffirmed the long-standing principle that "[t]he test is not total foreclosure," but whether the challenged practices "bar a substantial number of rivals or severely restrict the market's ambit," *i.e.* "substantial foreclosure." Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 403 (3d Cir. 2016) (quoting Dentsply Int'l, 399 F.3d at 191).

market and the defendants' market share was relatively small, never exceeding 18%. Id. at 437–38.

Finally, here, Plaintiffs plead sufficient facts to allow a plausible inference that the product hop substantially foreclosed competition. The Amended Complaint alleges that "[b]y causing a hard product switch, Indivior avoided, and continues to avoid, automatic substitution of AB-rated generics under state generic substitution laws and, therefore has limited . . . competition with generic substitutes for Suboxone Tablets." (Am. Compl. ¶ 120.) The Amended Complaint goes on to assert that by the time generic tablets received FDA approval in February 2013, 85% of Suboxone prescriptions were written for film instead of tablets. Id. ¶ 87. While the summary judgment record might be different, such allegations are sufficient at this juncture to allow a plausible inference that Moving Defendant's alleged anticompetitive conduct resulted in substantial foreclosure of competition. See Eisai, Inc. v. Sonofi Aventis U.S., LLC, 821 F.3d 394, 404 (3d Cir. 2016) (recognizing that even where competitors are not foreclosed from the market and consumers have a choice between products, if a defendant's conduct renders that choice meaningless, the defendant has acted in an anticompetitive fashion).

b. Allegations of a Price Disconnect

Moving Defendant's second and related argument for dismissal fares no better. Moving Defendant asserts that the Amended Complaint completely omits any of the "price-disconnect"[12] allegations that were central to the Class Action Plaintiffs' product hop claim. Moreover, Moving Defendant explains that the States' affirmative contentions are inconsistent with any

[12] A price disconnect is where a disconnect exists between the person paying for the prescription (the consumer) and the person selecting the appropriate treatment (the physician), thereby derailing the ordinary market forces that would allow consumers to consider price when selecting a product. In re Suboxone Antitrust Litig., __ F.R.D. __, 2016 WL 3519618, at *1 (E.D. Pa. June 28, 2016).

price disconnect since Plaintiffs assert that Indivior priced the film to be less expensive than tablets and raised the price of the tablets to induce the market to convert to film.

As a primary matter, allegations of a price disconnect in the pharmaceutical industry—while helpful in a complaint to explain why a product hop may be anticompetitive—are not essential to plausibly pleading an antitrust violation. In the class action portion of this case, the plaintiffs had emphasized the supposed price disconnect in the pharmaceutical industry and I specifically relied on these allegations when I found that Class Plaintiffs had plausibly alleged exclusionary conduct. In re Suboxone Antitrust Litig., __ F.R.D. __, 2016 WL 3519618, at *6 (E.D. Pa. June 28, 2016). I further concluded that "as a general evidentiary matter, it makes sense that evidence which disproves these allegations is also relevant." Id. Far from imposing an absolute requirement of price disconnect allegations in order to adequately plead antitrust injury, I simply noted that the Defendants were permitted to explore discovery regarding the Class Plaintiffs' ability to compete in the market despite the alleged product scheme. Id.

Here, the Amended Complaint relies on more than just the existence of a "price disconnect" and sufficiently pleads facts allowing a logical inference that Plaintiffs have been substantially foreclosed from the market. Plaintiffs explain that "only oral drugs that carry the FDA's AB generic rating in a particular category may be substituted by pharmacists for a physician's prescription for a brand-name drug without physician's approval." (Am. Compl. ¶ 30.) They go on to contend that "[b]y causing a hard product switch, [Indivior] avoided, and continues to avoid, automatic substitution of AB-rated generics under state generic substitution laws and, therefore, has limited, and continues to limit, competition with generic substitutes for Suboxone Tablets." (Id. ¶ 120.) This product hop scheme was combined with Indivior's plan to delay the entry of generic tablets, which enabled it "to sell Suboxone at supra-competitive

prices." (Id. ¶ 122.) Such allegations are sufficient to establish, at the motion to dismiss stage, substantial foreclosure of the generic tablets from the market.

Nor do I find any merit to Moving Defendant's argument that the Amended Complaint is starkly inconsistent with a "price disconnect" theory. Plaintiffs pled that "[Indivior] induced conversion of the market to the Film by raising the price of its Suboxone Tablets before the introduction of the AB-rated generic tablet product into the market. As a result, the Film was initially cheaper than the branded tablets." (Id. ¶ 84.) Such an allegation does not disprove a price disconnect, especially since, at the time Indivior dropped the price of the film, the only potential competitor was branded Suboxone tablets, without any threat of generic competition. This price adjustment was simply a small part of a larger campaign directed towards medical decisionmakers. (Id. ¶¶ 77–80, 83–86.) A reasonable inference remains that once generic tablets entered the market, the price disconnect between the prescribing doctor and the ultimate consumer would have prevented generic manufacturers from competing by pricing their tablets lower than Suboxone film.[13]

[13] Moving Defendant also contends that the requirement of foreclosure is not met by allegations that Indivior avoided state substitution laws by developing and marketing film. It again cites to the Doryx decision in which the Third Circuit found the record to be "void of any evidence of anticompetitive conduct" notwithstanding the plaintiffs' allegations that the defendants' product hops impaired the generics' ability to benefit from state substitution laws. Doryx, 838 F.3d at 430, 440.

The facts in Doryx are substantially distinguishable. In Doryx, the capsules were available for more than twenty years, and generic companies were free to engineer their own versions during that time. Id. at 438. When the plaintiff entered the market, it had 180 days of exclusive rights to market and sell its tablets, allowing it to set its tablet prices higher than the price of branded Doryx for at least some period of time and to reap generous profits from its sale of the generic tablet. Id. The Third Circuit did not find that reliance on state substitution laws to allege foreclosure was insufficient; rather it found that the plaintiff "failed to satisfy its burden of demonstrating that Defendants engaged in anticompetitive conduct prohibited by the Sherman Act." Id. at 439.

Taken together, Moving Defendant's "product-hopping" actions, as alleged in the Amended Complaint, constitute a combination of "product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition." Namenda, 787 F.3d at 654. Such actions are inherently anticompetitive in nature and, if substantiated by evidence, could rise to the level of monopolistic conduct in violation of § 2 of the Sherman Act.

2. The Delay Claims

The second broad category of anti-competitive behavior set forth in the Amended Complaint describes a two-part scheme by Indivior to delay generic entry into the market near the expiration of Indivior's orphan drug exclusivity period. First, despite a January 6, 2012 order by the FDA for Indivior to cooperate with potential generic competitors to the Suboxone tablet in the REMS process, Indivior feigned cooperation with the shared REMS development process, and ultimately refused to participate in any aspect of the shared REMS process. (Am. Compl. ¶¶ 91–94.) Second, Indivior allegedly filed a sham citizen petition with the FDA raising concerns about the safety of the tablet form of Suboxone and asking the FDA withhold approval of the ANDAs for generic Suboxone tablets unless: (a) the ANDA contained a targeted pediatric exposure education program; (b) the ANDA product had child-resistant unit-dose packaging; and (c) the FDA had determined whether Indivior had discontinued Suboxone tablets for safety reasons. (Id. ¶¶ 98–102.)

In the present case, Plaintiffs rely not only on the state substitution laws, but also on Moving Defendant's marketing campaign, misrepresentations about the safety of the tablet, and initiation of a "hard switch." They further allege resulting injury in the form of "paying more for co-formulated buprenorphine/naloxone than they would have paid in a competitive market." (Am. Compl. ¶ 124.) Thus, even if the state substitution laws are inconsistent among the various States or are insufficient to establish foreclosure, the totality of plaintiffs' allegations could allow a finding of anticompetitive behavior.

Moving Defendant challenges these allegations and argues that Plaintiffs' delay claim must be dismissed. Although I consider the entire delay scheme collectively, I address each component individually.

a. Refusal to Cooperate in Shared REMS

Moving Defendant first contends that any allegations relating to the shared REMS process cannot form the basis of an antitrust claim. In so arguing, Moving Defendant relies heavily on my Class Action Opinion, in which the plaintiffs claimed a Sherman Act § 2 violation based on Indivior's intentional delay of the SSRS process and disregard of the requirement that parties work together in good faith under 21 U.S.C. § 355-1(f)(8).[14] I concluded, in that Opinion, that even though the FDA ordered Moving Defendant to cooperate in the shared REMS process, Moving Defendant was under no antitrust duty to deal. Suboxone, 64 F. Supp. 3d at 687. I further noted that while the process would have moved more quickly had Indivior provided its REMS to its competitors, the generic drug manufacturers were free to, and ultimately did, submit an SSRS without Indivior's involvement. Id. at 688. As Indivior had no duty to deal under terms and conditions its rivals found commercially advantageous, I determined that Indivior's failure to cooperate could not constitute a valid form of anticompetitive action. Id.

While the claim in the States' Complaint rests on the identical behavior, that prior decision does not bind the outcome in this case due to one crucial distinction. In the Class Action Complaint, the plaintiffs premised an entirely separate count on Indivior's alleged refusal

[14] This provision states, "[n]o holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application." 21 U.S.C. § 355-1(f)(8).

to participate in the SSRS process. By contrast, in another Suboxone case by generic manufacturer Amneal (the "Amneal Complaint"), the plaintiff brought a similar cause of action alleging deception during the SSRS process, but also included that conduct as part of a cause of action alleging an overarching scheme of anticompetitive conduct. I determined that "to the extent that Amneal is attempting to bring a delay claim predicated on Indivior's conduct during the SSRS process alone," that claim failed and would be dismissed. Suboxone, 2017 WL 36371, at *8. To the extent, however, that Amneal alleged that the defendants' conduct during the SSRS process was part of a larger anticompetitive scheme alleged in the complaint, I noted that "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." Id.[15] As there had been no determination at that stage of the case that every aspect of the conduct alleged by Amneal—including the product hopping and sham citizen petition claims—failed under the antitrust laws, I concluded that the defendants' "conduct during the SSRS process may be considered as one aspect of the overarching scheme claim alleged by Amneal." Suboxone, 1017 WL 36371, at *9.

[15] See also Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962) (concluding that it is improper to treat antitrust claims as "separate and unrelated lawsuits" and that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each"); LePage's Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003) ("courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation"); In re Gabapentin Patent Litig., 649 F. Supp. 2d 340, 359 (D.N.J. 2009) ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability"); In re Neurontin Antitrust Litig., MDL No. 02-1390, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) ("[i]f an antitrust plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions may trigger antitrust liability as an overall scheme"); Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("[p]laintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not.").

The Amended Complaint in this case is far more akin to the Amneal complaint than the Class Action Complaint. Rather than separately challenging the delay in the SSRS process as anticompetitive, Plaintiffs aver that,

> Beginning in 2002, [Indivior] engaged in exclusionary conduct including, but not limited to: devising and implementing an anti-generic strategy by intentionally causing delays to FDA approval of ANDAs for generic co-formulated buprenorphine/naloxone, filing a baseless citizen petition to delay ANDA approval, and alleging unfounded concerns regarding the safety of the generic product while engaging in a campaign to convert the co-formulated buprenorphine/naloxone market from tablet formulations to their patent-protected Film.

(Am. Compl. ¶ 137.) In other words, the alleged SSRS delays are simply part of a broader, overarching scheme of anticompetitive conduct by Moving Defendant. Portions of this claim—specifically the product hopping and the citizen petition allegations[16]—likewise survive Rule 12(b)(6) review, meaning that the overall Sherman Act § 2 claim survives. To sever out the particular facts regarding the SSRS process from the claim would unfairly compartmentalize the underlying conduct into separate causes of action. Therefore, although Plaintiffs could not premise a Sherman § 2 claim on the SSRS delays alone, such activity may be considered as part of the broader scheme of anticompetitive conduct.

b. Citizen Petition

Moving Defendant also challenges the delay claim to the extent it is premised on Indivior's citizen petition. Although Moving Defendant concedes that my 2014 Class Action Opinion upheld the delay allegations based on the citizen petition, Moving Defendant contends that the intervening Second Circuit decision in Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51 (2d Cir. 2016) now requires a different result. I find Apotex distinguishable and

[16] I address the citizen petition claim in more detail below.

conclude that the allegations of delay based on the sham citizen petition properly state a claim for anticompetitive conduct.

In Apotex, plaintiff Apotex filed an ANDA for a generic drug to compete with defendant Acorda's branded drug. Id. at 57. Subsequently, Acorda filed a citizen petition with the FDA raising concerns with Apotex's ANDA and objecting to (1) Apotex's statement that its product was equivalent to Reference Listed Drugs and (2) allegedly misleading or untrue statements in the proposed label for the ANDA. Id. at 57–58. The FDA denied Acorda's citizen petition and, on the same day, approved Apotex's ANDA. Id. at 58. Apotex brought an antitrust claim alleging that Acorda's citizen petition was used to delay approval of the ANDA. Id. The district court granted a motion to dismiss that claim. Id.

On appeal, the Second Circuit expressly recognized that a single sham petition can violate antitrust law so long as it is both objectively baseless—in that no reasonable litigant could realistically expect success on the merits—and subjectively baseless—in that it conceals an attempt to interfere directly with the business relationships of a competitor. Id. at 59. The Second Circuit found, however, that Apotex failed to plead the objective baselessness of the citizen petition and, therefore, did not reach the question of whether it was subjectively baseless. Id. In so holding, the court acknowledged but rejected Apotex's argument that the timing of the petition's denial—which coincided exactly with the FDA's grant of the ANDA—conclusively established that the petition was objectively baseless. Id. at 59–60. The court discussed the FDA's new Guidance for Industry, which deals with the simultaneous pendency of an ANDA application and a citizen petition dealing with the same drug. Id. at 60. The Guidance states that it is preferable for the FDA not to issue a decision on a citizen petition until it issues a decision on the corresponding ANDA application. Id. The Second Circuit found that "[a]lthough it

remains conceivable, notwithstanding the Guidance, that a citizen petition might cause anticompetitive delay, the Guidance tends to undermine the inference . . . that when a citizen petition is denied simultaneously with the grant of an ANDA petition, the citizen petition was a sham and an anticompetitive weapon." Id.

Crucially, the Second Circuit directly addressed and distinguished my prior decision regarding the Class Action Complaint. Id. It noted that in the Suboxone Class Action Opinion, the Sherman Act § 2 claim based on the filing of a sham citizen petition survived dismissal "because of the many indicia that the petition was objectively baseless." Id. The Second Circuit therefore concurred that, in the Class Action Complaint, it was "plausibly pled" that the petition was objectively baseless. Id. at 62. In the case before it, however, Apotex had pled no other facts to suggest the petition was objectively baseless other than the timing of the FDA's decision. Id.

Unlike in Apotex, and similar to the Class Action Complaint here, the States' Amended Complaint does not simply rely on the timing of the FDA's denial of the citizen petition. Rather, it sets forth multiple facts which could create an inference that the petition was objectively baseless, including the following:

> 105. The same alleged safety concern raised in [Indivior's] citizen petition regarding the generic manufacturers' tablet product was dismissed by [Indivior] less than a month prior with regard to its own Suboxone Tablets. Specifically, on August 30, 2012 [Indivior] represented to the FDA in a combined REMS assessment that its tablet REMS was successful and needed no further changes. In fact, [Indivior] considered and rejected converting its Suboxone Tablets to unit-dose packaging for pediatric safety reasons as early as February 2008.
>
> . . .
>
> 108. The FDA ultimately denied [Indivior's] citizen petition on February 22, 2013, noting that it was not supported by evidence and was inconsistent with [Indivior's] own behavior. The FDA also said that it did not have the authority to issue some of the relief requested by [Indivior]. The FDA acknowledged in its ruling that it had no authority to grant [Indivior's] request to have

> Suboxone ANDAs contain targeted pediatric exposure program because the labeling for an ANDA must be the same as the labeling for the approved listed drug, pursuant to 21 U.S.C. § 355(j)(2)(A)(v) and 4(G).
>
> 109. The FDA further stated in its denial that the close proximity of [Indivior's] withdrawal of Suboxone Tablets to the "period in which generic competition for this product was expected to begin cannot be ignored."
>
> 110. The FDA referred [Indivior's] conduct to the FTC or antitrust investigation.

(Am. Compl. ¶¶ 105, 108–110.) Given these many indicia that Indivior's petition was baseless, Apotex supports a finding that the citizen petition delay claim should survive Rule 12(b)(6) review.

In an alternative interpretation of Apotex, Moving Defendant alleges that even assuming objective baselessness is satisfied, the principles in Apotex negate Plaintiffs' ability to show causation. Moving Defendant reasons that prior 2007, it was legal for the FDA to delay approval of a generic product pending the resolution of a related citizen petition. The state of that law led the Second Circuit in the case of In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009) to conclude that the simultaneous grant of an ANDA and denial of a citizen petition gave rise to the inference that the petition delayed the ANDA. Subsequently, Congress enacted 21 U.S.C. § 355(q),[17] which rendered such a delay illegal and caused the FDA to

[17] This provision states:

> The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42 because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

promulgate a new policy that citizen petitions should not be resolved until related ANDAs were ready for approval. Thereafter, in Apotex, the Second Circuit found, under this new policy, that its decision in DDAVP was no longer good law and that the simultaneous grant of an ANDA and denial of a citizen petition no longer creates an inference of delay. Based on that case, Moving Defendant now contends that the States have failed to allege any fact indicating that the filing of the citizen petition had any impact whatsoever on the timing of the approvals of the generic products. Indeed, it asserts that Plaintiffs have not alleged that the generic manufacturers had submitted fully approvable applications before Indivior filed its citizen petition. Therefore, it concludes that this claim should be dismissed for failure to plausibly plead causation.

This argument attempts to extend Apotex far too broadly. As set forth above, Apotex dealt only with what allegations were required to plausibly plead objective baselessness of a citizen petition. The Second Circuit did not touch on causation or conclusively hold that sham citizen petitions can never be the basis of a delay claim under the Sherman Act. Nor did the court require that in order to plead a delay claim, a plaintiff must set forth allegations that the ANDAs were fully-approvable at the time the citizen petition at issue was filed.[18] Given Moving

---

> (i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and
>
> (ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.
>
> Consideration of the petition shall be separate and apart from review and approval of any application.

21 U.S.C. § 355(q)(1)(A).

[18] In the 2017 Opinion on Moving Defendant's Motion to Dismiss the Amneal Complaint, I considered and rejected the identical argument that Amneal could not allege injury and causation because it had not properly alleged that its ANDA was fully approvable prior to the date on which the citizen petition was filed. In so holding, I relied on allegations that "Amneal has

Defendant's failure to identify any jurisprudence consistent with their argument, I decline to impose such a requirement here.

Moreover, even considering the causation element, I find that the Amended Complaint plausibly pleads that the citizen petition resulted in delay of the FDA's approval of the generic ANDAs. Specifically, the Amended Complaint states:

> During the 150-day period [in which the FDA must respond to each citizen petition under 21 C.F.R. § 10.30], FDA approval of any ANDA pending for a product that is the subject of the citizen petition is typically delayed. Although 21 U.S.C. § 355(q)(1)(A) provides that the Secretary "shall not delay approval" of a pending ANDA, subpart (ii) requires that "the Secretary, upon reviewing the petition," must determine whether a further delay is necessary to protect public health. Thus, the filing of a citizen petition in and of itself creates a delay insofar as the FDA must actually review the allegations made in the petition, enabling brand-name manufacturers to file a baseless citizen petition to prolong their monopoly on a particular branded drug. This abuse of the petition process has been repeatedly acknowledged by FDA officials.

(Am. Compl. ¶ 101.) Whether such a delay actually occurred in this case is a subject more properly left for resolution after discovery. For the present purposes, I find that Plaintiffs have adequately alleged causation.[19]

---

plausibly alleged that Indivior's misconduct in filing the citizen petition delayed approval of its ANDA and cost lost sales" and that but for the filing of the citizen petition, Amneal would have begun marketing the generic version of Suboxone well before it actually did. Suboxone, 2017 WL 36371, at *10. That reasoning is equally applicable to the present case.

[19] By way of a Notice of Supplemental Authority, Defendant has referred me to the Third Circuit's August 17, 2017 decision in In re Wellbutrin XL Antitrust Litigation, MDL Dkt. No. 305. In that case, the Third Circuit, in part, affirmed a grant of summary judgment in favor of a defendant pharmaceutical manufacturer on a claim that the defendant had, among other things, entered into a conspiracy to submit a "sham" citizen petition to the FDA. Defendant now contends that this ruling bolsters the Motion to Dismiss in three specific respects: (1) it establishes with certainty the proposition that a plaintiff must prove not only that a petition was a sham, but that it caused an antitrust injury by delaying generic competition; (2) it rejected a similar conspiracy theory and declined to find that joint conduct directed toward developing and

c. *Allegations of Delay Relating to the Years 2009–2011 and From February to March 2013*

Finally, Moving Defendant seeks dismissal of any delay claims (a) relating to the years 2009–2011 and (b) post-approval of Amneal and Actavis' ANDAs. It contends that the complaint is devoid of any allegations that Indivior did anything until the REMS negotiation began in 2012 to hinder the approval and launch of a generic alternative to Suboxone tablets. Moreover, Moving Defendant asserts that Plaintiffs set forth no facts that could attribute to Indivior any delay between the approval of the generic ANDAs on February 22, 2013 and the launch of generic tablet sales on March 6, 2013.

Moving Defendant's argument again attempts to improperly compartmentalize Plaintiffs' delay claim into separate causes of action. Plaintiffs assert an overall claim of monopolization, which requires that they allege anticompetitive conduct on the part of Moving Defendant. To do so, Plaintiffs set forth a broad scheme, which includes the product hop and the delay claims. The delay claims, in turn, are premised on Moving Defendant's allegedly deceptive refusal to

---

marketing new products is an unlawful conspiracy that violates the Sherman Act; and (3) it required a showing of actual foreclosure of generics in order to establish antitrust injury.

Moving Defendant's reading of Wellbutrin, however, ignores the crucial fact that this case was decided at the summary judgment stage. The Third Circuit specifically acknowledged that a sham lawsuit citizen petition which causes a delay in generic entry would not be entitled to immunity under the Noerr-Pennington doctrine and could give rise to an actionable antitrust violation. Slip. Op. at 27–28. The Court, however, affirmed the grant of summary judgment on the ground that the appellants had failed to produce evidence creating a genuine issue of material fact as to the questions of (a) whether the lawsuits/citizen petition caused an actual delay into the entry of generics into the market and (b) whether the appellees conspired to file the sham petition as opposed to acting independently. Slip Op. at 34, 37, 38, 42. Contrary to Moving Defendant's argument, nothing in Wellbutrin escalates the pleading burden on a plaintiff setting forth antitrust and conspiracy violations based on the filing of a sham petition. Nor does the Third Circuit ever suggest that product hop allegations must be dismissed for failure to allege foreclosure. As set forth in detail in this Memorandum, I have found that Plaintiffs in this case have sufficiently pled that the citizen petition was a sham, that it resulted in a delay in generic entry, and that Defendants Indivior and MonoSol conspired to file this petition for the precise purpose of delaying generic entry and avoiding competition with Suboxone.

cooperate in the shared REMS process and the filing of an allegedly sham citizen petition. Although Plaintiffs have not specifically alleged facts showing any delay caused by Indivior prior to 2011 and subsequent to February 22, 2013, the delay claim, as a whole, survives Rule 12(b)(6) scrutiny. The precise contours and impact of the delay cannot be accurately defined until after discovery on this claim. Accordingly, at this juncture, I decline to parse out specific timeframes to which the delay claim will not apply.

In sum, Plaintiffs' Amended Complaint pleads a plausible claim of anticompetitive delay by Moving Defendant. Given that the allegations of the Amended Complaint describe multiple actions comprising an overarching scheme, I shall not dismiss any part of this cause of action.

B. Conspiracy Claims

Counts III and IV of the Amended Complaint allege a conspiracy to monopolize under Sherman Act § 2 and a conspiracy to restrain trade under Sherman Act § 1 respectively. A Section 2 conspiracy claim has four elements: (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged. Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc., 602 F.3d 237, 253 (3d Cir. 2010) (citing United States v. Yellow Cab Co., 332 U.S. 218, 224–25 (1947); Am. Tobacco Co. v. United States, 328 U.S. 781, 788, 809 (1946)). "A plaintiff asserting a Section 1 claim also must allege four elements: '(1) concerted action by the defendants; [(2)] that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action.'" Id. (quoting Gordon v. Lewistown Hosp., 423 F.3d 184, 207 (3d Cir. 2005)).

Moving Defendant alleges that both claims fail because (a) Plaintiffs fail to allege concerted action among entities that, for antitrust purposes, do not represent a single enterprise; and (b) Plaintiffs fail to allege facts showing that any cooperative conduct was anticompetitive.[20] Considering each argument individually, I find them meritless.

1. Concerted Action

The Amended Complaint alleges that "[d]efendants Reckitt [consisting of all of the Defendant Reckitt entities] and MonoSol conspired to monopolize the relevant market for co-formulated buprenorphine/naloxone products." (Am. Compl. ¶ 149.) Reckitt Benckiser Healthcare UK, Ltd. and MonoSol "entered into a development agreement whereby MonoSol granted [Indivior] the right to use its patented sublingual film technology to manufacture Suboxone in a film version." (Id. ¶ 150.) According to the Amended Complaint, MonoSol actually convinced [Indivior] to introduce the Suboxone film as a means of preserving [Indivior's] market share and market exclusivity. (Id. ¶¶ 47–50.) Thereafter, MonoSol and Indivior worked jointly to develop the Suboxone film, obtain a patent, and bring the final product to market prior to the entry of generic co-formulated buprenorphine/naloxone tablets. (Id. ¶¶ 50–54.) MonoSol then made the initial suggestion that Indivior's withdrawal of Suboxone tablets from the market could provide "further protection from generic incursion." (Id. ¶ 71.) Finally, MonoSol "engaged in numerous conversations with [Indivior] about Film pricing" and "made adjustments to its own costs to ensure profitability to [Indivior] and MonoSol on Suboxone Film, despite the fact that it was launched at a lower price point to encourage the product switch." (Id. ¶ 85.) Ultimately, the Amended Complaint concludes that "[Indivior] and MonoSol entered into

[20] Moving Defendant also contends that these claims fail because the "product hop" claim itself is defective. As I have already found that the product hop claim survives Rule 12(b)(6) scrutiny, I need not consider this argument any further.

the agreement with the specific intent and for the purpose of extending [Indivior's] monopoly power, which was due to expire at the end of [Indivior's] FDA-granted 'orphan status' period, and for the purpose of preventing generic competition with its branded product." (Id. ¶ 152.)

Moving Defendant now contends that these allegations are insufficient to allege concerted action because Indivior and MonoSol share a "unity of interest" and the Sherman Act does not reach agreements between contracting parties who do not have independent competitive interests in the relevant market. (Defs.' Mem. Supp. Mot. to Dismiss 16.) Taking the factual allegations in the Amended Complaint as true, I disagree.

"To prevail on a section 1 claim or a section 2 conspiracy claim, a plaintiff must establish the existence of an agreement, sometimes also referred to as a 'conspiracy' or 'concerted action.'" W. Penn Allegheny Health System, Inc. v. UPMC, 627 F.3d 85, 99 (3d Cir. 2010) (quoting Twombly, 550 U.S. at 553; Gordon, 423 F.3d at 207 & n.16). "An agreement exists when there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme." Id. (citing Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 771 (1984); Howard Hess, 602 F.3d at 254; Gordon, 423 F.3d at 208). To plead an agreement, a plaintiff may allege direct or circumstantial evidence, or a combination of the two. Id. "If a complaint includes non-conclusory allegations of direct evidence of an agreement, a court need go no further on the question whether an agreement has been adequately pled." Id.

The United States Supreme Court has "long held that concerted action under § 1 does not turn simply on whether the parties involved are legally distinct entities," but rather has "eschewed such formalistic distinctions in favor of a functional consideration of how the parties involved in the alleged anticompetitive conduct actually operate." Am. Needle, Inc. v. Natl.

Football League, 560 U.S. 183, 191 (2010). Therefore, where members of a legally single entity are controlled by a group of a competitors and serve as a vehicle for concerted activity, a section 1 violation may exist. Id. at 192. Conversely, the mere fact that more than one legally distinct entity is involved does not necessarily establish concerted action. Id. "[S]ubstance, not form, should determine whether a[n] . . . entity is capable of conspiring under § 1." Copperweld, 467 U.S. at 773 n.21. "The relevant inquiry, therefore, is whether there is a 'contract, combination . . . or conspiracy' amongst 'separate economic actors pursuing separate economic interests,' . . . such that the agreement 'deprives the marketplace of independent centers of decisionmaking,' . . . and therefore of 'diversity of entrepreneurial interests,' . . . and thus of actual or potential competition." Am. Needle, 560 U.S. at 195 (internal quotations omitted).

Several key cases have helped define the contours of when entities engage in "concerted action." In Copperweld Corp. v. Independence Tube Corp., the Supreme Court held that a firm and its wholly-owned subsidiary are not capable of conspiring in violation of § 1 of the Sherman Act. 467 U.S. 752, 771 (1984). Subsequently, in Siegel Transfer, Inc. v. Carrier Exp., Inc., 54 F.3d 1125 (3d Cir. 1995), the Third Circuit extended Copperweld to the situation where two corporations with different ownership were so intertwined and had such unity of interest that they could not conspire. Id. at 1135. In that case, the plaintiff, a motor carrier, sued defendant Carrier Express, Inc., a shipper, and its subsidiaries under the Sherman Act. Id. at 1130. Carrier Express, a licensed common and contract carrier, did not hire employees, acquire equipment or engage its own drivers; rather it used commissioned, non-exclusive agents to make arrangements with owner-operators or with other carriers who had access to trucks and drivers to carry the freight. Id. at 1128. Carrier Express' operations were managed by Oak Management, who oversaw all of Carrier Express' day-to-day functions and received a percentage of Carrier

Express' revenues as payment for its services. Id. The plaintiff alleged a conspiracy among Carrier Express, its agents in the field, and Oak Management. Id. at 1134. The court found that the agents, whose only function was to make arrangements for the transport of Carrier Express freight with authorized carriers, were a single enterprise with Carrier Express. Id. at 1135. As to Carrier Express and Oak Management, the Third Circuit held that because Carrier Express did not have employees of its own, it used Oak Management to handle its day-to-day operations. Id. "Contractually obligated to manage Carrier Express affairs, Oak Management was, in effect, an inseparable part of Carrier Express' structure. Since its fee was a percentage of Carrier Express' revenue, Oak Management's economic well-being was directly tied to Carrier Express' success." Id. Therefore, the court held that "Oak Management and the Carrier Express agents could not conspire with Carrier Express or with each other under section 1." Id.

Moving Defendant asserts that Siegel Transfer is directly on point for three reasons. First, like Oak Management's role in Siegel Transfer, MonoSol was acting in partnership with Indivior in connection with a film joint venture and MonoSol, as the manufacturer of the film, was an inseparable part of the film joint venture. Second, just as Oak Management's economic well-being was directly tied to Carrier Express' revenue, MonoSol received royalty payments from the sale of Suboxone giving it financial incentive to contribute to "a long and vibrant life cycle for Suboxone film." (Am. Compl. ¶ 85.) Finally, as in Siegel Transfer, MonoSol and Indivior were not competitors and nothing in the Amended Complaint indicates that MonoSol would have been a participant in the relevant market in any capacity but for its "partnership" with Indivior. Overall, Moving Defendant concludes that Indivior and MonoSol constituted "one economic unit" and were unable to conspire with each other as a matter of law.

This argument disregards the distinction between two entities working under a completely intertwined "unity of interest" and two entities operating in a joint venture for a common purpose. It is well established that the reasoning of cases such as Copperweld and Siegel Transfer does not "extend[] to shelter independent actors having diverse economic interests acting jointly." Fishman v. Estate of Wirtz, 807 F.2d 520, 541 n.19 (7th Cir. 1986). As cogently stated by the United States Supreme Court:

> Any joint venture involves multiple sources of economic power cooperating to produce a product. And for many such ventures, the participation of others is necessary. But that does not mean that necessity of cooperation transforms concerted action into independent action; a nut and a bolt can only operate together, but an agreement between nut and bolt manufacturers is still subject to § 1 analysis. Nor does it mean that once a group of firms agree to produce a joint product, cooperation amongst those firms must be treated as independent conduct. The mere fact that the teams operate jointly in some sense does not mean that they are immune.

Am. Needle, 560 U.S. at 199.

Under this standard, the case before me aligns more closely to the joint venture defined in American Needle than to the intertwined entities in Siegel Transfer. The Third Circuit in Siegel Transfer relied heavily on the fact that Oak Management constituted "an inseparable part of Carrier Express' structure" because it handled all of Carrier Express' day-to-day operations, its economic success was tied to Carrier Express' success because it received a percentage of Carrier Express' revenue, and it did not compete with Carrier Express. In stark contrast, MonoSol is a separate corporation engaged in the development, manufacture and sale of pharmaceuticals throughout the United States. (Am. Compl. ¶ 14.) Neither Indivior nor MonoSol were responsible for the other corporation's day-to-day operations. Moreover, although Indivior contracted for MonoSol to receive royalty fees on sales of Suboxone film, nothing in the complaint suggests that this was MonoSol's sole form of income or that its

economic success was tied fully to Indivior's economic success. Rather, the reasonable inference is that the particular agreement between the two parties created economic incentives for the parties to put forth their best faith efforts in carrying out their joint venture related to Suboxone film. On a broader scale, the two parties were acting for their own financial interests. See Am Needle, 560 U.S. at 201 ("If the fact that potential competitors shared in profits or losses from a venture meant that the venture was immune from § 1, then any cartel 'could evade the antitrust law simply by creating a "joint venture" to serve as the exclusive seller of their competing products.'") (citations omitted).

Finally, the Amended Complaint allows the reasonable inference that MonoSol could have competed in the relevant market outside of its agreement with Indivior. MonoSol purportedly encouraged Indivior "and other pharmaceutical companies" to partner with MonoSol and use its "PharmFilm formulations" to "introduce products that are highly differentiated from other dosage forms, both in performance and marketability, creating fresh, dynamic revenue-creating opportunities." (Id. ¶ 48.) Indivior was but one of the companies to enter into such an agreement with MonoSol. (Id. ¶ 49.) In short, the relationship between Indivior and MonoSol "is one of competitive reality" lacking "complete unity of interest," and does "not possess either the unitary decisionmaking quality or the single aggregation of economic power characteristic of independent action." Am. Needle, 560 U.S. at 195.

For purposes of the motion to dismiss, I find that the Amended Complaint sufficiently pleads facts to support an inference of concerted action. Therefore, I will deny the motion on this ground.

2. Purpose of the Conspiracy

Moving Defendant's second and final challenge to the conspiracy claim asserts that a "conspiracy" to innovate is not anticompetitive. Moving Defendant reasons that marketing a new product is encouraged by both the antitrust laws and the Hatch-Waxman Act. According to Moving Defendant, Plaintiffs seek to penalize that precise conduct: MonoSol and Indivior's agreement to develop a new product and bring that product to the market—an act that has been deemed entirely procompetitive. Doryx, 838 F.3d at 440; Namenda, 787 F.3d at 653–54.

As previously explained, "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit." Suboxone, 64 F. Supp. 3d at 682. "Product innovation generally benefits consumers and inflicts harm on competitors, so courts look for evidence of 'exclusionary or anticompetitive effects' in order to 'distinguish "between conduct that defeats a competitor because of efficiency and consumer satisfaction"' and conduct that impedes competition through means other than competition on the merits." Namenda, 787 F.3d at 652. As noted above, although neither product withdrawal nor product improvement alone is anticompetitive, when a monopolist combines product improvement with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, the conduct is anticompetitive under the Sherman Act. Id. at 653–54.

Had Plaintiffs limited their allegations regarding the conspiracy between Indivior and MonoSol to mere product innovation and introduction of the Suboxone film, Plaintiffs would have been hard-pressed to establish that the conspiracy acted in restraint of trade or for a

noncompetitive purpose. Contrary to Moving Defendant's arguments, however, the Amended Complaint goes far beyond allegations that the "conspiracy" was intended only to introduce a new product into the market; rather it combines allegations of product improvement with product withdrawal and other anticompetitive conduct as follows:

> MonoSol encouraged [Indivior] and other pharmaceutical companies to engage in illegal and anticompetitive product-hopping on its website [through the use of PharmFilm for their patented drugs]. (Am. Compl. ¶ 48.)
>
> . . .
>
> [Indivior] and MonoSol's development of the new sublingual Film was intended to thwart generic entry, and to maintain Suboxone's market share by extending [Indivior's] exclusivity on a co-formulated buprenorphine/naloxone product. (Id. ¶ 50.)
>
> . . .
>
> Throughout the Suboxone Film development process, MonoSol was aware that the timing of both FDA approval and final product development was crucial to bring the Suboxone Film to market prior to the entry of generic co-formulated buprenorphine/naloxone tablets. MonoSol actively strategized with [Indivior] to minimize various manufacturing delays to beat the generic tablets to market. (Id. ¶ 54.)
>
> . . .
>
> MonoSol made the initial suggestion that [Indivior's] withdrawal of Suboxone Tablets from the market could provide further protection from generic incursion, and that employees of Reckitt Benckiser Healthcare (UK), Ltd. participated in discussions regarding the plans to remove the Tablets from the market. (Id. ¶ 71.)
>
> To complete their plan to extend Suboxone's exclusivity by the patent protection claimed for the Film, [Indivior] then engaged in a multi-faceted campaign to convert the co-formulated buprenorphine/naloxone market to Suboxone Film. (Id. ¶ 72.)
>
> . . .
>
> MonoSol engaged in numerous conversations with [Indivior] about Film pricing. MonoSol made adjustments to its own costs to ensure profitability to [Indivior] and MonoSol on Suboxone Film, despite the fact that it was launched at a lower price point to

> encourage the product switch. Cost and pricing decisions, along with MonoSol's royalty payments, were part of ongoing negotiations between MonoSol and [Indivior] with MonoSol pledging to do all that it can to contribute to a long and vibrant product life cycle for Suboxone Film. (Id. ¶ 85.)
>
> . . .
>
> As early as 2011, MonoSol actively participated in [Indivior's] plan to delay generic entry through its abuse of the citizen petition process. MonoSol participated in meetings regarding the citizen petition with Indivior, which were described as "urgent" to "explore what [citizen petition] opportunities may exist" regarding Suboxone Tablets. (Id. ¶ 112.)
>
> . . .
>
> Indivior's conspiracy with MonoSol and its acts, practices, and scheme described herein were for the purposes of, and had the effect of, restraining competition unreasonably by preventing the entry of generic co-formulated buprenorphine/naloxone and destroying the market for tablet formulation by the time the generic competitors gained FDA approval. (Id. ¶ 118.)

Considered collectively, these allegations plausibly plead that the conspiracy between MonoSol and Indivior was designed squarely to "stymie competition, prevent consumer choice and reduce the market's ambit." Suboxone, 64 F. Supp. 3d at 682.

To the extent Moving Defendant intends to argue that the true purpose of the joint venture was for procompetitive innovation, resolution of that inquiry is premature. In addressing allegations of anticompetitive conduct based on product hops, the "rule of reason" burden-shifting framework set forth by the D.C. Circuit in United States v. Microsoft Corp. applies. Under that framework, the party seeking to impose liability must initially provide evidence of the anticompetitive nature of a defendant's conduct. 253 F.3d at 58. Once established, the defendant then has the burden of "proffer[ing] 'nonpretextual' procompetitive justifications for its conduct," and "[t]he plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." Id. at 58–59. Such questions may

only be fairly addressed after full discovery on the merits. Accordingly, I decline to dismiss the conspiracy claims on this ground.

IV. CONCLUSION

Having thoroughly considered Moving Defendant's arguments, I find that Plaintiffs' claims survive Rule 12(b)(6) review.[21] For all of the foregoing reasons, Indivior's Motion to Dismiss the States' Amended Complaint will be denied in its entirety.

An appropriate Order follows.

[21] In an effort to dismiss Plaintiffs' Count V state law claims, Defendant presents a cursory two-sentence argument, as follows:

> The States' state-law claims fail for the same reasons as their federal-law claims. As discussed in more detail in Section IV of Reckitt Benckiser Healthcare (UK) Limited's brief, since Plaintiffs fail to state a claim under the Sherman Act and since the state law claims are based on the same allegations, those claims [should] also [b]e dismissed.

(Def.'s Mem. Supp. Mot. to Dismiss 4). As I do not find that the Sherman Act claims fail, I likewise do not find that the state law claims fail. To the extent Reckitt Benckiser Healthcare (UK) Limited raises additional reasons to dismiss the state law claims, I will address them in the context of deciding that motion.