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 APPLIES TO:	:	
Amneal Pharmaceuticals LLC v. Indivior Inc. et al., 16-cv-563	:	

Goldberg, J. **January 4, 2017**

MEMORANDUM OPINION

This antitrust litigation involves allegations regarding the sale of Suboxone, a drug used to treat opioid dependence. During the infancy of this case, Direct Purchaser Plaintiffs and End-Payor Plaintiffs ("Class Plaintiffs") filed consolidated class action complaints alleging that Indivior Inc.,[1] the manufacturer of brand name Suboxone, unlawfully delayed and impeded competition from generic versions of Suboxone tablets. Class Plaintiffs claimed that Indivior's conduct negatively affected competition and resulted in ongoing overpayments by consumers.

On December 3, 2014, I issued an opinion dismissing one of Direct Purchaser Plaintiffs' stand-alone claims, a variety of state law claims brought by End-Payor Plaintiffs as well as the claims against several of the Defendant entities. Thereafter, Class Plaintiffs filed amended complaints, answers were filed, and a discovery scheduling order was entered.

[1] Reckitt Benckiser Pharmaceuticals, Inc. is the former corporate name of Indivior, Inc. (Amneal Compl. ¶ 21.)

On December 23, 2015, Amneal Pharmaceuticals LLC, a generic manufacturer and competitor of Indivior,[2] filed a Complaint in the District of New Jersey regarding Indivior's alleged anticompetitive conduct surrounding Suboxone. That action was transferred to the Eastern District of Pennsylvania in February of this year and consolidated with the MDL currently before me.

The allegations contained in Amneal's Complaint are similar to those contained in the Direct Purchaser Plaintiffs' Complaint. Amneal's Complaint consists of the following claims: (1) monopolization in violation of 15 U.S.C. § 2; (2) attempted monopolization in violation of 15 U.S.C. § 2; and (3) false advertising in violation of the Lanham Act, 15 U.S.C. § 1152(a). Indivior has filed a partial motion to dismiss Amneal's Complaint.[3] For the reasons that follow, Indivior's motion will be granted in part and denied in part.

I. LEGISLATIVE FRAMEWORK

As it is necessary to understand Amneal's claims, the relevant statutory and regulatory frameworks are set forth below.

A. NDA, ANDA and A/B Rating

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq., a manufacturer who creates a new drug must obtain approval from the Food and Drug Administration ("FDA") to sell the drug through the filing of a New Drug Application ("NDA"). (Amneal Compl. at ¶ 27.) As part of a NDA filing, applicants are required to submit any patents

[2] Amneal develops, manufactures, and distributes generic pharmaceutical products. (Amneal Compl. ¶ 20.)

[3] As noted below, Indivior has not moved to dismiss Amneal's product hop claim. As part of its product hop claim, Amneal alleges that as the period of exclusivity on brand-name Suboxone expired and generic versions of that drug were to become available, Indivior effectuated inconsequential changes to the Suboxone dosage form to prevent competition from generic formulations.

that claim the drug or a method of using the drug and also to demonstrate the drug's efficacy and safety. (Id. at ¶ 27.)

The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417 (1984), commonly referred to as the Hatch-Waxman Act, was designed to lower the costs of prescription drugs and encourage generic drug competition. The Hatch-Waxman Act amended the FDA's approval process to allow generic manufacturers to file Abbreviated New Drug Applications ("ANDA"). (Id. at ¶ 28.)

In order to gain FDA approval of an ANDA, a generic drug manufacturer must demonstrate that its generic version is "bioequivalent" to the NDA brand name drug. In order for a drug to be found to be bioequivalent, the generic product must deliver the same amount of active ingredient for the same amount of time as the brand name drug. The Hatch-Waxman Act allows generic manufacturers seeking ANDA approval to rely on data and clinical studies supporting a brand manufacturer's NDA. (Id. at ¶¶ 33, 34.)

Approval of ANDAs are subject to statutory delays based on exclusivities awarded to the corresponding NDA reference drugs. One such exclusivity is a seven year "orphan drug exclusivity," 21 U.S.C. 360bb(a)(2)(A-B), which is awarded to drugs intended to "treat a disease or condition for which there is (a) a U.S. prevalence of less than 200,000 persons; or (b) no reasonable expectation that the costs of developing and making the drug available will be recovered from U.S. Sales." (Id. at ¶¶ 29, 31.)

ANDA filers demonstrating bioequivalence also generally seek to have their product deemed "AB-rated" to the brand name drug, meaning that in addition to being bioequivalent, the two drugs are also pharmaceutically equivalent—which includes such considerations as having the same active ingredient, the same strength, the same route of administration and the same

dosage form. Under the generic substitution laws in effect in all fifty states and the District of Columbia, a pharmacy may not substitute a generic drug for a brand name drug unless the generic is AB-rated. (Id. at ¶¶ 35-37, 47.)

B. REMS/SSRS

Under the FDA Amendments Act of 2007, the FDA has the authority to require drug manufacturers to conduct a Risk Evaluation and Mitigation Strategy ("REMS"). 21 U.S.C. § 355-1. REMS is a process by which a drug's manufacturer demonstrates to the FDA that the drug's benefits outweigh its risks. A REMS may include a "medication guide, communication plans, patient package inserts, potential restrictions regarding individuals or entities that may dispense the drug, and other similar illustrations." (Id. at ¶ 38.)

If the FDA requires a REMS for a brand name drug, any subsequent generic manufacturer who files an ANDA must join with the brand manufacturer to create a "single, shared" REMS ("SSRS"). The SSRS process is intended to minimize the burden on the healthcare delivery system of having multiple REMS programs. (Id.)

The statute also authorizes the Secretary of the Department of Health and Human Services to allow a waiver from the SSRS requirement and allow a generic applicant to create a "waiver-based" REMS in certain circumstances, including when "the burden of creating a single, shared system outweighs the benefit of a single, system. . . ." 21 U.S.C. 355-1(i)(1)(B)(i). An ANDA will not be approved until the SSRS process has been approved or a waiver request has been granted and a waiver-based REMS has been approved. (Id.)

C. Citizen Petitions

FDA regulations allow anyone to file a "Citizen Petition" requesting that the FDA take some form of administrative action. 21 U.S.C. § 355(q) addresses Citizen Petitions that request

any action related to an ANDA – these petitions are commonly referred to as "505(q) petitions." The FDA must take final agency action on a 505(q) petition within 180 days of the petition's submission date. (Id. at ¶¶ 39, 41.)

21 U.S.C. § 355(q)(1)(E) provides that "[i]f the Secretary determines that a [Citizen] [P]etition . . . was submitted with the primary purpose of delaying the approval of an [ANDA] and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination." The FDA, however, has never summarily denied a Citizen Petition under this provision. (Id. at ¶ 41.)

II. ALLEGATIONS CONTAINED IN AMNEAL'S COMPLAINT[4]

The facts alleged in the Complaint are as follows: Suboxone, which contains the active ingredients Buprenorphine and Naloxone "BPN/NLX," is used for the treatment of opioid dependence. (Id. at ¶ 2.) Suboxone was the first opioid dependence treatment on the market that could be prescribed by a doctor for use in a patient's home. (Id. at ¶ 50.)

The FDA approved Indivior's NDA for Suboxone tablets in 2002. Although Indivior did not hold a patent for Suboxone tablets, it was able to obtain a seven-year period of exclusivity from the FDA because Suboxone was found to be an orphan drug.[5] Indivior's period of exclusivity for Suboxone tablets was scheduled to expire on October 8, 2009. (Id. at ¶ 56.)

[4] In reviewing Indivior's motion to dismiss, I assume that all facts found in Amneal's Complaint are true and view them in the light most favorable to Amneal, the non-moving party. To the extent any facts from outside the Complaint are recited, they are referenced for informational purposes only. See Ethypharm S.A. France v. Abbott Labs., 707 F.3d 223, 225 n.1 (3d Cir. 2013).

[5] The FDA found that Indivior demonstrated "that there is no reasonable expectation that the costs of developing and making available [Suboxone] will be recovered from U.S. sales, despite the fact that the product treats a disease or condition that has a U.S. prevalence of 200,000 or more individuals." (Id. at ¶ 79.)

Shortly before the expiration of Suboxone tablets' orphan drug exclusivity, Indivior filed an NDA for the film dosage form of Suboxone, which is a strip that dissolves under a patient's tongue. The FDA approved the NDA on August 30, 2010. Indivior holds several patents purportedly covering Suboxone film which do not expire until 2030. (Id. at ¶¶ 57, 3.)

Amneal contends that Indivior successfully pursued a scheme to avoid competition with generic Suboxone by delaying generic entry and hindering the ability of generic manufacturers to compete after entry. Specifically, Amneal alleges that Indivior took several actions to delay generic entry, including the following which are relevant to the instant motion: (a) deceptive conduct which thwarted the development of a SSRS for generic Suboxone and delayed the issuance of a waiver based REMS; and (b) submission of a sham Citizen Petition on the eve of the SSRS waiver request that had the intended effect of further stalling generic entry. (Id. at ¶¶ 4-13, 64-65.)[6]

A. REMS/SSRS

When the FDA approved Indivior's ANDA in October of 2002, it required Indivior to implement a "comprehensive risk management program, or RiskMAP. The RiskMAP, a precursor to the REMS program, was designed to "deter abuse and diversion from [Suboxone's] legitimate use, develop instructions to physicians regarding proper use of these drugs, require close monitoring of drug distribution channels, and require child-resistant packaging." Indivior implemented and administered the RISKMAP. (Id. at ¶¶ 66-67.)

[6] Like the Class Plaintiffs, Amneal also alleges that Indivior's switch from tablets to film was anticompetitive. Indivior, however, has not challenged the sufficiency of Amneal's product hop allegations. Indivior has also not challenged Amneal's allegations which pertain to the relevant market or monopoly power. As such, I have not set forth those aspects of Amneal's Complaint in this opinion.

In August of 2009, the FDA ordered Indivior to replace the RiskMAP with a REMS for its Suboxone tablet and film products. On August 30, 2010, the FDA approved the REMS Indivior submitted for Suboxone film. On December 22, 2011, the FDA approved the REMS Indivior submitted for Suboxone tablets. (Id. at ¶ 68.)

On January 6, 2012, the FDA issued a letter to Amneal and all other sponsors of pending ANDAs related to generic Suboxone tablets. Therein, the FDA stated that before the "FDA can continue review of your ANDA you must submit a proposed REMS as an amendment to your ANDA." The FDA further stated that a "single, shared system to implement the REMS program is needed" and directed the generic sponsors to contact Indivior regarding the development of the SSRS. The FDA indicated that it "expected the SSRS to be completed by May 6, 2012." (Id. at ¶¶ 70-71.)

Over the next six months, the generic sponsors, including Amneal, attempted to collaborate with Indivior. Despite its representation to the FDA and the generic sponsors that it was willing to cooperate with the SSRS process, Indivior never complied with the SSRS mandate. (Id. at ¶ 73.) Initially, Indivior denied that it received any correspondence from the FDA regarding the SSRS and also refused to cooperate with the process until "instructed to do so by the FDA." Indivior also declined to participate in weekly meetings held by the generic sponsors. On March 9, 2012, Indivior entered into a confidentiality agreement with the generic sponsors, "falsely leading them to believe that [Indivior] would cooperate in the development of the SSRS." (Id. at ¶¶ 74-76.)

On March 19, 2012, Indivior's counsel sent the generic sponsors a list of "legal and governance" issues that had to be resolved before Indivior would be willing to engage in any substantive conversations regarding the SSRS. One such demand was that the generic sponsors

agree to share the cost of any future product liability costs incurred by Indivior in connection with the SSRS. (Id. at ¶¶ 77-78.)

On April 2, 2012, Indivior finally agreed to meet in person with the generic sponsors "but only through its lawyers." However, once at the meeting, Indivior's representative refused to engage in any substantive conversations or share any non-public information or even a description of its REMS program until all legal and governance issues were resolved. (Id. at ¶ 79.)

In May of 2012, after months of unsuccessful discussions with Indivior, the generic sponsors requested a meeting with the FDA to discuss the delays and impasse caused by Indivior's conduct. On June 18, 2012, the FDA met with the generic sponsors and Indivior. The FDA agreed to a compromise that would allow the generic sponsors and Indivior to develop an entirely new SSRS comparable to Indivior's existing REMS, but which would not use or rely upon Indivior's allegedly proprietary information contained in that REMS. At this meeting, Indivior represented that it would cooperate with the generic sponsors to develop this new "compromise" SSRS. The FDA stated that it expected the new SSRS to be "up and running . . . by August 17, 2012." (Id. at ¶ 80.)

Despite renewing its professed commitment to cooperate, Indivior continued to develop "new excuses" to delay the development of the SSRS. For example, Indivior refused to sign a "governing program agreement" unless Indivior was given veto authority or a super-majority vote for all issues relating to the SSRS administration process. Indivior also demanded that all generic sponsors agree to share a pre-specified percentage of all future product liability claims, regardless of fault. (Id. at ¶ 82.)

Two days before the scheduled submission of the proposed new SSRS, Indivior announced that it would not join the SSRS submission without a "prescriber outreach component," which was not part of Indivior's existing REMS program. Based on the timing and magnitude of Indivior's demand, the generic sponsors suggested that the parties explore the issue after they received comments from the FDA on the SSRS that was about to be submitted. Despite this proposal, Indivior refused to submit the new SSRS. (Id. at ¶ 83.)

In light of Indivior's refusal to cooperate, on October 3, 2012, the generic sponsors filed a request that the FDA waive the SSRS requirement and allow a "separate, waiver-granted REMS." Indivior's conduct made the development of an "SSRS impossible and delayed the development and implementation of a waiver-granted REMS for many months." If Indivior had not falsely represented its intention to cooperate in good-faith, the generic sponsors would have sought a waiver of the SSRS requirement sooner. (Id. at ¶¶ 84, 86-87.)

On February 22, 2013, approximately nine months after the SSRS was to have been completed and simultaneous with the denial of Indivior's Citizen Petition, the FDA approved the generic sponsors' waiver-granted REMS as well as Amneal's ANDA. (Id. at ¶¶ 13, 89.)

B. Citizen Petition

On September 25, 2012, Indivior filed a Citizen Petition requesting that the FDA impose new conditions on generic Suboxone that had not been imposed on Indivior during its ten years of exclusive sales of Suboxone. In its petition, Indivior requested that (1) the FDA require educational programs and unit-dose packaging for generic Suboxone tablets to address purported pediatric exposure issues, and (2) determine that Indivior had withdrawn Suboxone tablets for safety reasons. The Citizen Petition requested that the FDA refrain from approving any Suboxone tablet ANDAs until after the FDA resolved these requests in Indivior's favor. "As a

result of the sham Petition, generic entry was delayed by another five months as the FDA was forced to consider the Petition, which further delayed consideration and approval of a waiver-based REMS." (Id. at ¶¶ 90-92.)

Amneal contends that Indivior's request that the FDA determine that the future withdrawal of Suboxone tablets was done for safety reasons was objectively baseless as Indivior had not, at the time of filing, withdrawn Suboxone tablets and would not do so for months. (Id. at ¶ 93.)

Amneal also contends that Indivior's other requests were also objectively baseless because the FDA lacked authority to grant the relief requested. For example, regarding the request for a pediatric educational program, no such program was part of Indivior's existing REMS for Suboxone tablets and the FDA has no authority to require ANDA filers to include materials that are not part of the brand name drug's REMS. Additionally, Amneal alleges that the FDA lacks the authority to require unit-dose packaging because, as Indivior was aware, the Consumer Products Safety Commission has exclusive jurisdiction to regulate packaging standards. (Id. at ¶¶ 94-95.)

On February 22, 2013, the FDA issued a decision denying Indivior's Citizen Petition in its entirety, concluding that: (1) Indivior did not provide sufficient evidence to support its assertions that the educational programs and unit-dose packaging would cause a decline in pediatric exposure, and (2) Indivior's withdrawal of Suboxone tablets was not necessary for safety reasons. The FDA also noted that it referred the matter to the Federal Trade Commission for an investigation into the question of Indivior's "anticompetitive conduct." (Id. at ¶¶ 98, 101.)

C. Lanham Act

The Complaint also alleges that Indivior's advertising materials include "numerous false claims" which have been displayed on Indivior's website and distributed throughout the country. (Id. at ¶ 115.) For example, Indivior has claimed that the film provides "benefits" over tablets such as "favorable taste rating," "faster dissolve time," and "child-resistant" packaging, "[f]ewer partial doses left in open pouches where children might access them" and "patient preferred." (Id. at ¶¶ 115-9.) Amneal contends that each of the foregoing statements is false or, "at best, devoid of reliable supporting evidence." (Id. at ¶ 115.)

III. PRIOR MOTION TO DISMISS RULING

Indivior primarily argues that Amneal's Complaint is similar to and shares the same deficiencies as the Complaints filed by the Class Plaintiffs. Indivior relies upon my December 3, 2014 ruling granting certain portions of its motion to dismiss the Class Plaintiffs' Complaints to argue that similar claims brought by Amneal should also be dismissed. Relevant portions of that Opinion are summarized below.

A. SSRS/REMS

Similar to Amneal, the Direct Purchasers alleged that Indivior violated § 2 of the Sherman Act by failing to cooperate during the SSRS process. Indivior moved to dismiss the Direct Purchasers' standalone SSRS claim on the basis that the antitrust laws generally do not impose a duty to deal with competitors.

In granting that portion of Indivior's motion to dismiss, I noted that precedent from the United States Supreme Court "instructs[s] that the antitrust laws do not create a duty for competitors to work together. Statutes and regulations requiring cooperation between rivals do not alter this analysis; in fact, regulation indicates that antitrust scrutiny is not necessary or

prudent." In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 686 (E.D. Pa. 2014) (citing Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004)). I further noted that, although the Supreme Court has recognized "that the right for a monopolist to refuse to deal with its competitors is not unqualified," the Supreme Court has "been very cautious in recognizing such exceptions, because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm." Id.

In light of this precedent, I concluded that "[t]he antitrust laws do not impose a duty on [Indivior] to aid the Generics in obtaining expeditious approval of an ANDA. While other courts have indicated that antitrust liability may attach where the SSRS process is manipulated to completely preclude a generic from filing an ANDA, that is not the situation presently before me. . ." Id. at 688. Accordingly, I granted Indivior's motion to dismiss the standalone SSRS claim contained in the Direct Purchasers' Complaint. Id.

B. Citizen Petition

I, however, denied Indivior's motion to dismiss Direct Purchasers' claim that Indivior violated § 2 of the Sherman Act by filing a sham Citizen Petition. Of particular relevance to the motion currently pending before me, I rejected Indivior's argument that the Direct Purchaser Plaintiffs failed to adequately allege that Indivior's conduct in filing a Citizen Petition caused antitrust injury. In rejecting this argument, I found:

> that the complaints plausibly allege that the Citizen Petition caused antitrust injury by delaying Generic entry into the market. The complaints state that Reckitt filed the Citizen Petition for the purpose of delaying Generic competition, and but for the filing of the Citizen Petition, "competitors would have begun marketing generic version of Suboxone well before they actually did." (DP Compl. ¶¶ 189–90.) They further allege that, despite the enactment of § 355(q)(1)(A), "a branded firm may still be able to delay generic approval while the FDA considers whether the relevant Citizen Petition implicates issues of

> public health, regardless of whether the petition actually does or not, and regardless of whether the petition is [a] sham or not." (Id. at ¶ 72.) The combination of these two allegations indicates that the FDA violated 21 U.S.C. § 355(q)(1)(A). To dismiss a claim for not using that exact language would be to place form over substance.

In re Suboxone, 64 F. Supp. 3d at 690–91.

IV. LEGAL STANDARD

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." Id.

To determine the sufficiency of a complaint under Twombly and Iqbal, a court must take the following three steps: (1) the court must "tak[e] note of the elements a plaintiff must plead to state a claim;" (2) the court should identify the allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth;" and (3) "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011) (citations omitted).

V. INDIVIOR'S PARTIAL MOTION TO DISMISS AMNEAL'S COMPLAINT

Indivior has moved to dismiss Amneal's "delay" claims predicated on Indivior's conduct during the SSRS and the Citizen Petition processes as well as Amneal's Lanham Act claims. I will first address the challenges Indivior brings in connection with Amneal's SSRS allegations.

A. SSRS Allegations

Indivior argues that Amneal's claim regarding Indivior's alleged failure to cooperate with generic sponsors during the SSRS process are "substantively identical" to the Class Plaintiffs'

allegations regarding the SSRS process, which did not survive the motion to dismiss stage. (Def.'s Mot. p. 9.)

Amneal responds that its Complaint states an actionable claim for anticompetitive deception which was not the subject of the prior motion to dismiss ruling regarding the Supreme Court's duty-to-deal precedent. In support of its anticompetitive deception theory, Amneal primarily relies upon Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297 (3d Cir. 2007).

In Broadcom, the plaintiff alleged that the defendant, Qualcomm Inc., falsely represented that it would license its patented mobile wireless technology to competitors on "fair, reasonable, and non-discriminatory" ("FRAND") terms. Qualcomm allegedly made this representation to a private industry group known as a "standards-determining organization" ("SDO") which in turn included Qualcomm's technology in an industry wide standard on the basis of this representation. Qualcomm, however, then licensed the technology on non-FRAND terms, locking-in its competitors at monopoly prices. Id. at 314.

The United States Court of Appeals for the Third Circuit held that the plaintiff had alleged sufficient facts to state a claim for monopolization under § 2 of the Sherman Act. In reaching this conclusion, the Third Circuit stated: "[w]e hold that (1) in a consensus-oriented private standard-setting environment, (2) a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, (3) coupled with an SDO's reliance on that promise when including the technology in a standard, and (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive conduct." Id. at 314.

I conclude that Broadcom was decidedly narrow and its applicability is confined to its unique factual circumstances. I do not find Amneal's reliance on Broadcom to be persuasive as that case was fact specific and the Court's holding so explicitly limited. Amneal is simply

recasting the Direct Purchasers' duty to deal claim, which I rejected, as a "deception" claim.[7] Changing the name of the theory does not change its substance nor does it render it cognizable under antitrust precedent. Therefore, to the extent that Amneal is attempting to bring a delay claim predicated on Indivior's conduct during the SSRS process alone, that claim fails and will be dismissed.

Alternatively, Amneal urges that, even if not actionable standing alone, Indivior's conduct during the SSRS process is part of a larger anticompetitive scheme alleged in the Complaint. In support, Amneal notes that the first claim of their Complaint alleges that Indivior engaged in an overarching exclusionary scheme which included, but was not limited to, Indivior's conduct during the SSRS process. During oral argument, counsel for Amneal characterized this overarching exclusionary scheme as a "tapestry." (Oral Arg. Tr. pp. 11-12.)

In response, Indivior contends that Amneal must show that "each type of conduct it alleges is independently anticompetitive" because conduct does not become actionable merely because a plaintiff alleges an overarching scheme. (Def.'s Reply. p. 10-11.) In support, Indivior points to Pacific Bell Telephone Co. v. Linkline Communications, Inc., 555 U.S. 438 (2009). In that case, internet service providers ("ISPs") which sold digital subscriber ("DSL") internet to retail customers sued a telephone company that owned much of the infrastructure necessary to provide DSL. Id. at 442-443. The ISPs alleged that the telephone company (1) charged high

[7] "[D]eception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." Santana Prod., Inc. v. Bobrick Washroom Equip., Inc., 401 F.3d 123, 132 (3d Cir. 2005) (citing E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 145 (1961); Schachar v. Am. Acad. of Ophthalmology, Inc., 870 F.2d 397, 399 (7th Cir. 1989) ("antitrust law does not compel your competitor to praise your product or sponsor your work")). The Third Circuit recently reaffirmed this proposition and held that "deceptive statements may violate the antitrust laws" only in "rare circumstances." Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 407 n.40 (3d Cir. 2016). Nothing about the nature of the SSRS process or the Complaint's allegations warrant deviating from the general rule that deception is not actionable as an antitrust violation.

wholesale prices to the ISPs for access to the DSL infrastructure but (2) low prices to telephone company's DSL retail customers, thereby squeezing the ISPs' profit margins. Id. at 449.

The Supreme Court concluded that the ISPs' wholesale claim was not actionable under the Court's duty-to-deal precedent and the retail level predatory pricing claim failed because the telephone company's prices remained above cost. Id. at 449-451. The Supreme Court then rejected the ISPs' "price squeezing" claim as an attempt to join the two failed claims and "alchemize them into a new form of antitrust liability never before recognized by this Court." Id. at 457. The Court concluded by explaining that "[t]wo wrong claims do not make one that is right." Id.

Despite the holding in Linkline, in certain circumstances, 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. See 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., 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").

Linkline does not undermine the general principles set forth above. See In re Neurontin Antitrust Litig., 2009 WL 2751029, at *16 ("[nothing] in the Linkline decision indicate[s] an intention on the part of the Court to overrule long-established principles concerning the viability of claims alleging an overall scheme.") Rather, Linkline demarcates the outer limits of a plaintiff's ability to allege an overall scheme or what Amneal has termed its "tapestry" theory. Linkline does so by prohibiting a plaintiff from creating a new theory of antitrust liability by joining multiple claims, all of which are specifically foreclosed by existing antitrust precedent.

Here, unlike Linkline, there has been no determination at this stage of the case that every aspect of the conduct alleged by Amneal fails under the antitrust laws. In fact, Indivior has not challenged Amneal's product hop claim. As such, I conclude that Indivior's conduct during the SSRS process may be considered as one aspect of the overarching scheme claim alleged by Amneal. Discovery will determine whether Amneal can succeed on its overarching scheme theory and whether Indivior's conduct during the SSRS process is properly considered as part of that overall scheme.

B. Citizen Petition

Indivior next argues that Amneal's claim predicated on the Citizen Petition process should be dismissed because Amneal fails to allege that: (1) its ANDA was otherwise approvable prior to the denial of Indivior's Citizen Petition and that the FDA delayed approval solely

because of Indivior's Citizen Petition, and (2) the FDA violated its statutory duty not to delay approval of Amneal's ANDA.

i. Failure to allege that its own ANDA was "approvable"

According to Indivior, in order to plead actionable antitrust delay, Amneal must plausibly allege that its ANDA was complete and ready for approval prior to February 22, 2013 –the date on which the Citizen Petition was denied – and that the FDA delayed approval because of the Citizen Petition. Indivior contends that these crucial allegations are not present in Amneal's Complaint.[8] As such, Indivior urges that Amneal has not alleged that it has suffered an injury or that Indivior's alleged antitrust violation caused any such injury.

Indivior goes one step further and also argues that Amneal does not and cannot allege injury and causation because documents produced in discovery prove that there were problems with Amneal's ANDA and the FDA was requiring remedial measures from Amneal up until February 12, 2013 – just ten days prior to the denial of Indivior's Citizen Petition – and additional REMS compliance measures until March 5, 2013 – two weeks after the denial of Indivior's Citizen Petition.[9]

[8] In support of this argument, Indivior emphasizes that the Complaint does not allege that, prior to February 22, 2013, Amneal had received "tentative approval" of its ANDA indicating that the FDA had determined that Amneal's generic product had met the requirements for bio-equivalency. Amneal objects to Indivior's suggestion that it must allege that it had obtained tentative approval from the FDA in order to state an actionable delay claim.

Amneal correctly notes that tentative approval letters are only issued where the ANDA is premised on a brand name drug protected by a patent and/or other legal exclusivities. At the time Amneal filed its ANDA, Indivior's orphan drug exclusivity had already expired and, therefore, the FDA would not have issued a tentative approval letter for Amneal's ANDA. As such, Indivior's argument premised on the absence of allegations regarding tentative approval fails.

[9] Indivior attached these documents to its motion to dismiss and states that they "are not here offered in support of this motion to dismiss, nor are they necessary for dismissal. They are cited only to demonstrate why the necessary allegations regarding Amneal's ANDA have not been

Amneal presents multiple arguments in response. First, Amneal urges that other courts have "repeatedly found facts similar to those alleged by Amneal, such as where an ANDA was approved on the same day the FDA denied an alleged sham citizen petition, sufficient under Rule 12." Second, Amneal points out that I have already determined that "Class Plaintiffs' nearly identical allegations stated an actionable claim of delay." Third, Amneal contends that Indivior's argument raises factual issues which are improper at this stage in the litigation. (Pl.'s Resp. p. 16-17.)

Although Amneal has not explicitly alleged that their ANDA was "approvable" prior to the date on which the Citizen Petition was denied, Amneal has plausibly alleged that Indivior's misconduct in filing the Citizen Petition delayed approval of its ANDA and caused lost sales. Other courts have found allegations that a plaintiffs' ANDA was approved on the same day the FDA denied an alleged sham citizen petition sufficient. See, e.g., In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009). Contrary to Indivior's argument, there is no authority requiring plaintiffs to plead antitrust delay by using a particular phraseology.

Furthermore, in ruling on Indivior's motion to dismiss the Class Plaintiffs' Complaints, I found that those Complaints "plausibly allege that the Citizen Petition caused antitrust injury by delaying Generic entry into the market. The complaints state that Indivior filed the Citizen Petition for the purpose of delaying Generic competition, and but for the filing of the Citizen Petition, 'competitors would have begun marketing generic version of Suboxone well before they actually did.'" In re Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 690–91 (E.D. Pa. 2014).

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made: Amneal knows that such allegations would be untrue." (Def.'s Mot. p. 14.) I have not considered the substance of these documents when reviewing the sufficiency of Amneal's Complaint.

The delay allegations contained in Amneal's Complaint and the Class Plaintiffs' Complaints are similar and the reasoning set forth in my prior ruling applies with equal force here.

Additionally, Indivior's reliance on documents produced in discovery is inappropriate. The significance of these documents presents factual issues which cannot and should not be resolved at this stage of the litigation. See In re Suboxone, 64 F. Supp. 3d at 691 ("[a]s to Reckitt's argument that any delays in approval of the ANDA were due to amendments made by the Generics themselves, this is a classic factual issue that is properly determined by a fact finder.")

ii. Failure to Allege that the FDA Violated 21 U.S.C. § 355(q)(1)

Relatedly, Indivior next argues that, even if Amneal's ANDA was approvable before February 22, 2013, the Complaint fails to allege that any supposed delay in approval was caused by Indivior's Citizen Petition. Indivior urges that, unlike the Class Plaintiffs' Complaint, Amneal's Complaint does not address the FDA's obligation under 21 U.S.C. § 355(q)(1)(A) to prevent such a delay nor does it allege facts which plausibly suggest that the FDA violated its statutory duty.

Amneal responds that I previously rejected the same argument made by Indivior in its motion to dismiss the Class Plaintiffs' complaints. I agree. In ruling on that argument, I previously held:

> The complaints state that Reckitt filed the Citizen Petition for the purpose of delaying Generic competition, and but for the filing of the Citizen Petition, "competitors would have begun marketing generic version of Suboxone well before they actually did." (DP Compl. ¶¶ 189–90.) They further allege that, despite the enactment of § 355(q)(1)(A), "a branded firm may still be able to delay generic approval while the FDA considers whether the relevant Citizen Petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition is [a] sham or not." (Id. at ¶ 72.) The combination of these two allegations indicates that the FDA

> violated 21 U.S.C. § 355(q)(1)(A). To dismiss a claim for not using that exact language would be to place form over substance.

In re Suboxone Antitrust Litig., 64 F. Supp. 3d at 690–91.

Here, Amneal alleges that the Citizen Petition delayed the FDA's approval of both its ANDA and waiver-based REMS. (Compl. ¶¶ 7, 92, 97.) In arguing that Amneal's claim is deficient for failure to expressly allege that the FDA violated is statutory duty, Indivior again places form over substance. I do not think Indivior has offered a sound basis for departing from my previous conclusion that the plaintiffs need not explicitly state that the delay they alleged violated the FDA's statutory duties under 21 U.S.C. § 355(q)(1)(A).

C. Lanham Act Claim

The Lanham Act states, in relevant part, that:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). To state a claim for false advertising under the Lanham Act, a plaintiff must allege the following five elements:

> 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014) (citing Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc., 653 F.3d 241, 248 (3d Cir. 2011) (alterations in original).

Liability attaches if the advertisement is either "(1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers." Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharm. Co., 290 F.3d 578, 586 (3d Cir. 2002).

Indivior argues that Amneal's Lanham Act claim must be dismissed for three reasons: (1) Amneal has failed to clearly identify which statements it is challenging; (2) the Complaint fails to set forth facts to support the conclusory assertion that the challenged statements are false or misleading; (3) the Complaint's alternative allegations that the statements are unsubstantiated are inadequate to state a claim for false advertising.

According to Indivior, the Complaint specifically identifies the following five statements as the allegedly "false advertising claims" attributed to Indivior: "favorable taste rating," "faster dissolve time," "child-resistant" packaging, "fewer partial doses left in open pouches where children might access them," and "patient preferred." (Def.'s Mot. p. 15.)

Rather than defending its allegations regarding the five above-referenced statements, Amneal responds that the Complaint "properly pleads facts showing that [Indivior] engaged in false advertising by claiming, both explicitly and implicitly that (a) Suboxone film is safer than Bu-Na tablets, and (b) Bu-Na tablets are, standing alone, unsafe." (Pl.'s Resp. p. 20.) These phrases do not appear in the Complaint.

At oral argument, Amneal's counsel conceded that the statements – "favorable taste rating, child[] resistant packaging, [and] patient preferred" – were not actionable as Lanham Act claims in and of themselves. Counsel further clarified that they were still pursuing the other two statements "fewer partial doses and faster dissolve time" as actionable Lanham Act claims. (Oral Arg. Tr. pp. 35-6.) Based on the pleadings and counsel's explanation at oral argument, it appears that Amneal contends that the statements "fewer partial doses and faster dissolve time" are

examples of Indivior's allegedly false advertising claims that Suboxone film is safer than Suboxone tablets and Suboxone tablets are, standing alone, unsafe.

Amneal has offered shifting accounts of what particular statements form the basis of its Lanham Act claim. Given this ambiguity, I conclude dismissal of Amneal's Lanham Act claim is warranted. See Binsack v. Lackawanna Cnty. Prison, 438 Fed. Appx. 158, 160 (3d Cir.2 011) (dismissal is proper when a complaint "left the defendants having to guess what of the many things discussed constituted [a cause of action]." Amneal, however, will be given leave to file an amended complaint which more clearly identifies the particular statements that it contends constitute false advertising in violation of the Lanham Act.[10]

D. Claims against Reckitt Benckiser Pharmaceuticals Inc. and Indivior PLC

Lastly, Indivior moves to dismiss Reckitt Benckiser Pharmaceuticals Inc. and Indivior PLC because Amneal has failed to serve those two entities. Additionally, Indivior urges that Reckitt Benckiser Pharmaceuticals Inc. should be dismissed because it is merely Indivior's former corporate name. Amneal responds that it does not oppose the dismissal of its claims against Reckitt Benckiser Pharmaceuticals Inc. Amneal, however, does not respond to Indivior's arguments regarding Indivior PLC.

The motion to dismiss Reckitt Benckiser Pharmaceuticals Inc. will be granted as unopposed. Indivior PLC was not served and Amneal has not responded to the argument to dismiss Indivior PLC. As such, Indivior PLC will also be dismissed.

[10] In its motion, Indivior also argued that Amneal's claim fails because it relies entirely on "selective snippets of alleged marketing materials statements [sic] without any context." (Def.'s Mot. p. 22.) Indivior urges that these isolated excerpts do not provide notice as to which statements are from which marketing materials at issue. Regardless of which phrases Amneal intends to challenge in the context of its Lanham Act claims, I agree. If Amneal chooses to amend its Lanham Act claim, it should endeavor to provide additional allegations regarding the context in which the challenged statements were made.

VI. CONCLUSION

For the foregoing reasons, Indivior's motion to dismiss will be granted in part and denied in part. An appropriate order follows.