IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Docket No. 20-1076-CFC
This Document Relates to: All Actions	

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MEMORANDUM OPINION

July 5, 2022
Wilmington, Delaware

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COLM F. CONNOLLY
CHIEF JUDGE

These three separately consolidated antitrust actions have been coordinated for discovery and pretrial proceedings pursuant to a stipulated order. D.I. 134 at 3.[1] The actions arise out of agreements to settle patent litigation over extended-release quetiapine fumarate, an anti-psychotic drug sold by Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively, AstraZeneca) under the brand-name Seroquel XR®. Two of the consolidated actions are class actions brought by pharmaceutical wholesalers (the Direct Purchasers)[2] and by union health and welfare funds and municipalities (the End-Payors).[3] The third consolidated action consists of three cases filed by pharmaceutical retailers (the

[1] Unless otherwise indicated, citations to docket items refer to filings in Civil Action No. 1:20-cv-1076.

[2] J M Smith Corporation d/b/a Smith Drug Company and KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. filed the operative Consolidated Amended Complaint on behalf of the Direct Purchasers. D.I. 135.

[3] The operative complaint in the End-Payors' action is the Second Consolidated Amended Complaint filed by Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Law Enforcement Health Benefits, Inc.; The Mayor and City Council of Baltimore; Pipe Trades Services MN Welfare Fund; Sergeants Benevolent Association Health & Welfare Fund; Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C, and 137R; and The Uniformed Firefighters' Association of Greater New York Security Benefit Fund and The Retired Firefighters' Security Benefit Fund of the Uniformed Firefighters' Association. D.I. 136.

Retailers).[4] All the operative complaints allege that AstraZeneca, Handa Pharmaceuticals LLC, Par Pharmaceuticals, Inc., and Accord Pharmaceuticals, Inc. were original or successor parties to unlawful noncash "reverse payment" agreements that settled certain patent lawsuits and delayed and suppressed competition among sellers of generic versions of Seroquel XR®. Plaintiffs claim that, as a result of these agreements, they paid directly or indirectly supracompetitive prices for branded and/or generic versions of Seroquel XR®.[5]

The operative complaints in the Direct Purchasers' and Retailers' actions each allege five counts under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. *See* D.I. 135 ¶¶ 180–87, 197–203 (alleging violations of § 1 in Counts 1 and 3); D.I. 135 ¶¶ 188–96, 204–11, 212–17 (alleging violations of § 2 in Counts 2, 4, and 5); 20-1086, D.I. 1 ¶¶ 159–65, 175–80 (alleging violations of § 1 in Counts 1 and 3); 20-1087, D.I. 1 ¶¶ 161–67, 177–82 (same); 20-1089, D.I. 1 ¶¶ 158–64, 174–79

[4] Although the Retailers' actions have been consolidated, the Retailers have not filed a consolidated complaint. There are three operative complaints in the Retailers' action: No. 1:20-cv-1086, D.I. 1, filed by CVS Pharmacy, Inc., Rite Aid Corp., and Rite Aid Hdqtrs. Corp.; No. 1:20-cv-1087, D.I. 1, filed by Walgreen Co., The Kroger Co., Albertsons Companies, Inc., and H-E-B, L.P.; and No. 1:20-cv-1089, D.I. 1 filed by Hy-Vee Inc.

[5] To be precise, certain Plaintiffs claim that they are in certain instances the assignee of claims based on purchases made by various assignors. *See, e.g.*, 20-1087, D.I. 1 ¶¶ 28–31. The fact that a purchase was made by a Plaintiff or its assignor has no bearing on the pending motions and, accordingly, for ease of discussion, I refer only to Plaintiffs in this Memorandum Opinion.

(same); 20-1086, D.I. 1 ¶¶ 166–74, 181–89, 190–95 (alleging violations of § 2 in Counts 2, 4, and 5); 20-1087, D.I. 1 ¶¶ 168–76, 183–90, 191–96 (same); 20-1089, D.I. 1 ¶¶ 165–73, 180–87, 188–93 (same). The operative complaint in the End-Payors' action alleges a series of state law antitrust, consumer protection, and unjust enrichment claims. D.I. 136 ¶¶ 233–95.

All the operative complaints name AstraZeneca, Handa, and Par as defendants; the operative complaints in the Retailers' actions also name Accord as a defendant in two counts. For ease of reference, I will refer at times to AstraZeneca, Handa, Par, and Accord collectively as "Defendants."

Pending before me are (1) AstraZeneca, Handa, and Par's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) the Consolidated Amended Complaint filed by the Direct Purchaser Plaintiffs, D.I. 137; (2) AstraZeneca, Handa, Par, and Accord's motion to dismiss pursuant to Rule 12(b)(6) the three complaints filed by the Retailer Plaintiffs, D.I. 141; and (3) AstraZeneca, Handa, and Par's motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) the Second Consolidated Amended Complaint filed by the End-Payor Plaintiffs, D.I. 139. (Accord states in its briefing that it joins the first motion. D.I. 144 at 1. AstraZeneca UK Ltd. is named as a movant in all three motions, but it is not a named defendant in the Direct Purchasers' complaint. D.I. 135 at 1.)

I. BACKGROUND

A. Legal Framework

The antitrust claims in this case arise out of Abbreviated New Drug Application or "ANDA" litigation and implicate patent law and the so-called Hatch-Waxman Act amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. Judge Sirica helpfully summarized in *King Drug Company of Florence v. Smithkline Beecham Corporation*, 791 F.3d 388 (3d Cir. 2015), how patent law intersects with the Hatch-Waxman amendments to create ANDA litigation:

> A patent . . . is an exception to the general rule against monopolies and to the right to access to a free and open market. The Constitution's Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the "Progress of Science and useful Arts." [U.S. Const. art. I, § 8, cl.8.] In turn, from their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy. A patent, consequently, is a special privilege designed to serve the public purpose of promoting the "Progress of Science and useful Arts." [*Id.*]
>
> With the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch–Waxman Act, Congress attempted to balance the goal of making available more low[-]cost generic drugs with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement. The Act seeks to

accomplish this purpose, in part, by encouraging manufacturers of generic drugs to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices. The resulting regulatory framework has the following four relevant features identified by the Supreme Court in [*Federal Trade Commission v.*] *Actavis*, [570 U.S. 136, 140–44 (2013)].

First, a new drug—that is, a pioneer, "brand-name" drug—cannot be introduced until it is approved by the Food and Drug Administration ("FDA"). A New Drug Application ("NDA") requires the applicant to submit, among other things, full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use, as well as comprehensive information about the drug. This reporting requirement entails "a long, comprehensive, and costly testing process." [*Id.* at 142].

Second, the Hatch-Waxman Act facilitates the development of generic drugs by allowing an applicant to file, for new drugs shown to be "bioequivalent" to a drug previously approved by the FDA, 21 U.S.C. § 355(j)(2)(A)(iv), a less onerous and less costly "Abbreviated New Drug Application" ("ANDA") in lieu of an NDA. The ANDA process "allow[s] the generic to piggy-back on the pioneer's approval efforts . . . , thereby furthering drug competition." *Actavis*, [570 U.S. at 142] (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* [566 U.S. 399, 405] (2012)).

Third, Hatch–Waxman "sets forth special procedures for identifying, and resolving, related patent disputes." *Id.* [at 143]. A new drug applicant must list information on any patents issued on the drug's composition or methods of use. If the FDA approves the new drug, it publishes this information, without verification, in its *Orange Book.* In turn, any manufacturer filing an ANDA to produce a generic version of that pioneer drug must consult the

> *Orange Book* and "assure the FDA that [the] proposed generic drug will not infringe the brand's patents." [*Caraco*, 566 U.S. at 406]. As relevant here, the manufacturer may tender that assurance with a "paragraph IV" certification that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). But filing a paragraph IV certification means provoking litigation, because the patent statute treats paragraph IV certification as a per se act of infringement, *see* 35 U.S.C. § 271(e)(2)(A). The patentee then has an incentive to sue within 45 days in order to trigger a 30–month stay of the FDA's potential approval of the generic "while the parties litigate patent validity (or infringement) in court. If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product." *Actavis*, [570 U.S. at 143] (citing 21 U.S.C. § 355(j)(5)(B)(iii)).
>
> "Fourth, Hatch–Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route." [*Id.*] From when it first begins marketing its drug or when a court enters judgment finding the challenged patent invalid or unenforceable, the first-filing generic enjoys a 180-day period of exclusivity during which no other generic manufacturer can enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (iv). This exclusivity period belongs to first-filing ANDA applicants alone and is nontransferable. *See id.* § 355(j)(5)(D); *Actavis*, [570 U.S. at 143–44]. The period does not, however, prevent the brand-patentee from marketing its own "authorized generic."

Id. at 394–96 (footnotes, most citations, and most internal quotation marks omitted). (An "authorized generic"—often referred to as "AG"—is simply the term used to describe an approved brand name drug that is marketed without the

brand name on its label. *See* FDA List of Authorized Generic Drugs, Food & Drug Admin. (Apr. 1, 2022), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs.)

In *Actavis*, the Supreme Court held that agreements between first-filer generics and brand manufacturers to settle ANDA cases may in certain circumstances give rise to antitrust claims. In reaching this conclusion, the Court rejected the Eleventh Circuit's so-called "scope of the patent" rule that immunized such agreements "'from antitrust attack so long as [their] anticompetitive effects fall within the scope of the exclusionary potential of the patent.'" 570 U.S. at 141 (quoting *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)). The Court held specifically in *Actavis* that a settlement agreement pursuant to which a brand manufacturer pays a first-filer generic manufacturer a "large and unjustified" sum in exchange for the generic's agreement to relinquish its patent invalidity and noninfringement claims and delay its entry into the market "can sometimes violate the antitrust laws." 570 U.S. at 141, 158. Such agreements are referred to as "reverse payment" agreements because they require the patentee to pay the alleged infringer, and not the other way around. They raise antitrust concerns because they remove from the market the risk of competition that arises from expected litigation outcomes. The Court explained in *Actavis* that an

"unexplained large reverse payment" that is inconsistent with traditional settlement considerations, such as avoided litigation costs,

> would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.

570 U.S. at 157.

In *King Drug*, the Third Circuit held that *Actavis*'s holding is not "limited to reverse payments of cash." 791 F.3d at 403. At issue in *King Drug* was a "no-AG" settlement agreement whereby a brand manufacturer agreed to relinquish its right to produce an AG drug to compete with a first-filer generic's drug during the 180 days of first-filer market exclusivity. The Court explained that the 180–day exclusivity period was "possibly worth several hundred million dollars" and "where the bulk of the first-filer's profits lie." *Id.* at 404 (internal quotation marks omitted). It held accordingly that "no-AG" agreements can "fall[] under *Actavis*'s rule because [they] may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that [they are] a payment to eliminate the risk of competition." *Id.* at 394.

B. Facts

Because I am assessing the merits of motions to dismiss under Rule 12(b)(6) for failure to state a claim and a motion to dismiss under Rule 12(b)(1) for lack of jurisdiction based on an alleged failure to plead facts necessary to support constitutional standing, I accept as true all factual allegations in the operative complaints and in documents explicitly relied upon in the operative complaints. *See Mgmt. Sci. Assocs., Inc. v. Datavant, Inc.*, 510 F. Supp. 3d 238, 244 (D. Del. 2020) ("When assessing the merits of a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and in documents explicitly relied upon in the complaint, and it must view those facts in the light most favorable to the plaintiff."); *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017) (holding that courts should apply Rule 12(b)(6) standard of review to "facial" challenges under Rule 12(b)(1) that the pleaded facts did not establish constitutional standing). The following background information is based on those allegations.[6]

AstraZeneca makes and sells brand and AG versions of Seroquel XR®. Before generic versions of Seroquel XR® were made available on the market,

[6] The allegations in the five operative complaints are largely the same and, therefore, following the parties' lead, I refer only to the Direct Purchasers' operative complaint unless a difference of significance among the complaints exists.

AstraZeneca's annual sales of brand Seroquel XR® in the United States exceeded $1 billion. D.I. 135 ¶ 2. AstraZeneca listed U.S. Patent No. 5,948,437 (the #437 patent) in the *Orange Book* for Seroquel XR®. The #437 patent's expiration date was May 28, 2017. D.I. 135 ¶ 5.

In 2008, Handa filed with the FDA the first ANDA for approval to sell generic Seroquel XR® in four dosages: 50 mg, 150 mg, 200 mg, and 300 mg. D.I. 135 ¶ 3. Handa also filed an ANDA for a 400 mg dosage of Seroquel XR® in 2008, but Accord had filed earlier in the year the first ANDA for that dosage. D.I. 135 ¶ 3. At least four other manufacturers filed ANDAs for at least one dosage, and at least one of those ANDAs covered all five dosages. *AstraZeneca Pharms. LP v. Anchen Pharms., Inc.*, 2012 WL 1065458, at *5, *8 (D.N.J. Mar. 29, 2012), *aff'd*, 498 F. App'x 999 (Fed. Cir. 2013).

Both Handa and Accord filed paragraph IV certifications asserting that the #437 patent was invalid, unenforceable, or would not be infringed by their respective generic products. D.I. 135 ¶¶ 3–4. In response, AstraZeneca filed patent infringement suits against Handa and Accord in 2008 and 2009. D.I. 135 ¶¶ 7–10.

Over the course of AstraZeneca's litigation with Handa, based in part on the court's claim construction rulings, "it became clear that Handa's proposed generic version[s] of Seroquel XR[®] would not infringe the [#]437 [p]atent." D.I. 135 ¶

11. Almost two years into the litigation, in December 2010, the FDA granted tentative approval of Handa's ANDA, having "determin[ed] that Handa's ANDA for generic Seroquel XR[®] was approvable and satisfied all bioequivalence; chemistry, manufacturing, and controls ('CMC'); and labeling requirements." D.I. 135 ¶ 13. The FDA was unable to give final approval of Handa's ANDA because of the 30-month stay that was triggered when AstraZeneca sued Handa for infringement. D.I. 135 ¶ 13.

In September 2011, "[r]ather than face the risk that Handa's proposed generic versions of Seroquel XR[®] would be found not to infringe the [#]437 [p]atent, AstraZeneca [decided to] induce[] Handa with a large 'reverse payment' (i.e., a payment from the patent holder, AstraZeneca, to the alleged infringer, Handa), to quit the patent fight and not compete with AstraZeneca for up to five years." D.I. 135 ¶ 14. The reverse payment came in the form of (1) a promise by AstraZeneca not to sell its 50 mg, 150 mg, 200 mg, and 300 mg AG versions of Seroquel XR® during Handa's 180-day first-filer exclusivity period (i.e., from November 1, 2016 through April 30, 2017) and (2) the right to buy generic product from AstraZeneca to sell as Handa's own product during its first-filer exclusivity period. D.I. 135 ¶ 15; D.I. 136 ¶ 15.[7] The Direct Purchasers and the End-Payors

[7] The Retailers do not allege Handa's right to buy generic product from AstraZeneca. 20-1086, D.I. 1 ¶ 15; 20-1087, D.I. 1 ¶ 15; 20-1089, D.I. 1 ¶ 15.

allege that AstraZeneca's "no-AG" promise to Handa was worth more than $233 million—i.e., the difference, according to Plaintiffs, between what Handa would reasonably have expected to earn as the only generic seller on the market for the 180 days after November 1, 2016 and what it would reasonably have expected to earn if it faced competition from an AG during that period. D.I. 135 ¶¶ 21, 139. The Retailers allege the no-AG promise was worth more than $163 million. 20-1086, D.I. 1 ¶ 114; 20-1087, D.I. 1 ¶ 116; 20-1089, D.I. 1 ¶ 113. In exchange for the "reverse payment" and the right to buy AG from AstraZeneca to sell as its own generic, Handa agreed to "quit" its patent fight and delay the launch of its generic Seroquel XR® products until November 1, 2016.

The purpose and effect of the Handa/AstraZeneca settlement agreement was to (1) delay until November 1, 2016 the availability of generic Seroquel XR® in the four Handa first-filer dosages, (2) allocate to AstraZeneca through November 1, 2016 100% of the U.S. sales of Seroquel XR® in those dosages, (3) delay the entry of AstraZeneca's AG for those dosages until May 1, 2017 and thereby allocate to Handa 100% of U.S. sales of generic Seroquel XR® between November 1, 2016 and May 1, 2017, and (4) enable AstraZeneca and Handa to sell at supracompetitive prices, respectively, brand and generic Seroquel XR® in the four Handa first-filer dosages. D.I. 135 ¶¶ 123, 182.

In 2012, Par acquired Handa's ANDA and an assignment of the Handa/AstraZeneca settlement agreement. Under the terms of that acquisition, Par and Handa share any profits obtained from sales of generic Seroquel XR® products made pursuant to the settlement agreement. D.I. 135 ¶ 17–18.

AstraZeneca reached a similar agreement with Accord. Like Handa, Accord received tentative approval of its ANDA from the FDA in December 2010. D.I. 135 ¶ 126. But unlike Handa, Accord conceded in its litigation with AstraZeneca that its product infringed the #437 patent. *See* D.I. 144-2 ¶ 77 (incorporated by reference in the Direct Purchasers' operative complaint, D.I. 135 ¶¶ 4–10, nn.5–10). In October 2011, Accord executed a settlement agreement with AstraZeneca pursuant to which Accord agreed to "quit" its "patent fight" with AstraZeneca and delay its launch of generic 400 mg Seroquel XR® tablets until November 1, 2016. D.I. 135 ¶ 19. For its part, AstraZeneca agreed not to sell AG 400 mg tablets until after Accord's 180-day first-filer exclusivity period ended on April 30, 2017. D.I. 135 ¶ 19. The Direct Purchasers and the End-Payors allege that the "no-AG" promise was worth more than $107 million to Accord. D.I. 135 ¶ 140; D.I. 136 ¶ 175. The Retailers allege it was worth more than $75 million. 20-1086, D.I. 1 ¶ 115; 20-1087, D.I. 1 ¶ 117; 20-1089, D.I. 1 ¶ 114.

Plaintiffs allege that the purpose and effect of the Accord/AstraZeneca settlement agreement was to (1) delay until November 1, 2016 the availability of

generic 400 mg Seroquel XR®, (2) allocate to AstraZeneca through November 1, 2016 100% of the U.S. sales of 400 mg Seroquel XR®, (3) delay the entry of AstraZeneca's 400 mg AG until May 1, 2017 and thereby allocate to Accord 100% of U.S. sales of 400 mg generic Seroquel XR® between November 1, 2016 and May 1, 2017, and (4) enable AstraZeneca and Accord to sell at supracompetitive prices, respectively, brand and generic 400 mg Seroquel XR®. D.I. 135 ¶ 199.

On November 1, 2016, Par began selling 50 mg, 150 mg, 200 mg, and 300 mg generic Seroquel XR® and Accord began selling 400 mg generic Seroquel XR®. D.I. 135 ¶¶ 19, 21. AstraZeneca launched AG versions of Seroquel XR® in 50 mg, 150 mg, 200 mg, 300 mg, and 400 mg dosages on May 1, 2017. D.I. 135 ¶ 22. Also in May 2017, other competitors launched their own generic versions of Seroquel XR® in all dosage strengths. D.I. 135 ¶ 23.

Had Handa/Par and Accord not entered into their settlement agreements with AstraZeneca, they would have obtained final FDA approval for and sold their respective dosages of generic Seroquel XR® before November 1, 2016. D.I. 135 ¶ 128. Thus, but for the settlement agreements, AstraZeneca's brand Seroquel XR® would have faced competition from generics before November 1, 2016 and the price of brand Seroquel XR® would have been lower.

Also, but for those agreements, AstraZeneca would have sold AG versions of Seroquel XR® contemporaneously with the market entry by Handa/Par and

Accord instead of after Handa/Par's and Accord's 180-day exclusivity periods. D.I. 135 ¶ 144. Thus, but for the settlement agreements, there would have been competition in the market between generic versions of Seroquel XR® and the price of generic Seroquel XR® would have been lower.

Beginning on August 2, 2015, the Direct Purchasers and the Retailers purchased branded Seroquel XR® from AstraZeneca and generic Seroquel XR® from Par or Accord at supracompetitive prices. D.I. 135 ¶ 35–36; 20-1086, D.I. 1 ¶ 27–29; 20-1087, D.I. 1 ¶ 27–31; 20-1089, D.I. 1 ¶ 27–28.[8] Beginning on September 5, 2013, the End-Payors, who operate employee and retiree health benefits plans, "indirectly purchased, paid and/or [provided reimbursement or reimbursed] for some or all of the purchase price of brand or generic Seroquel XR[®]" at supracompetitive prices. D.I. 136 ¶¶ 32–38, 166, 223. The End-Payors bring their claims on behalf of a class of "persons and entities" located in 35 states

[8] The Direct Purchasers define their Class Period as being from August 2, 2015 "until the effects of Defendants' conduct ceases." D.I. 135 ¶ 43. The Retailers allege that they are "absent class members" of the Direct Purchasers' putative class "[b]y virtue of their assignments [from various drug wholesalers]," and they base their claims on purchases they made during the same time span covered by the Direct Purchasers' Class Period. *See* 20-1086, D.I. 1 ¶ 129; 20-1087, D.I. 1 ¶ 131; 20-1089, D.I. 1 ¶ 128. The End-Payors allege that their Class Period started on September 5, 2013 and continues "until the anticompetitive effects of Defendants' challenged conduct cease." D.I. 136 ¶ 223. The starting dates of the Class Periods have no bearing on the resolution of the pending motions.

and the District of Columbia who, similarly, indirectly purchased or reimbursed the purchase of brand or generic Seroquel XR®. D.I. 136 ¶ 223.

II. LEGAL STANDARDS

A. Rule 12(b)(6)

"A district court may grant a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6) if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to the plaintiff, plaintiff is not entitled to relief." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007) (internal quotation marks and citation omitted). To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Detailed factual allegations are not required, but the complaint must include more than mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must set forth enough facts, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 570. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Deciding whether a claim is plausible is a "context-specific task that requires the reviewing

court to draw on its judicial experience and common sense." *Id.* at 679 (citation omitted).

B. Rule 12(b)(1)

A party may file under Rule 12(b)(1) a motion to dismiss for lack of subject-matter jurisdiction. A plaintiff's standing to bring suit is a jurisdictional matter properly asserted under Rule 12(b)(1). *Ballentine*, 486 F.3d at 810. "On a motion to dismiss for lack of standing, the plaintiff bears the burden of establishing the elements of standing, and each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Id.* (internal quotation marks and citations omitted). "At the pleadings stage, general factual allegations of injury resulting from the defendant's conduct may suffice" to defeat a motion to dismiss for lack of standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

III. DISCUSSION

Defendants argue that dismissal of the Direct Purchasers' operative complaint is required for two reasons: First, the antitrust claims alleged in the complaint are barred by the statute of limitations set forth in 15 U.S.C. § 15b; and second, Plaintiffs have failed to plead an antitrust injury. D.I. 138 at 2–3. Defendants contend that the Retailers' operative complaints should be dismissed

"for the same reasons set forth in Defendants' motion to dismiss [the Direct Purchasers'] claims." D.I. 142 at 2.

Defendants argue that the End-Payors' claims "suffer from myriad and substantive deficiencies" that include alleged failures to satisfy state-specific pleading requirements. D.I. 140 at 2–3. Although the End-Payors have not alleged federal antitrust claims, Defendants argue that the End-Payors' state law claims "amount[] to 'a Frankensteinian equivalent' of federal antitrust law" and that the state law claims therefore "should be dismissed for the same reasons that the [Direct Purchasers'] claims should be dismissed." D.I. 140 at 1–2. Defendants argue, and the End-Payors do not dispute, that "[i]f [I] conclude[] that the [Direct Purchasers'] [federal antitrust] claims should be dismissed, the [End-Payors'] claims should also be dismissed, and there is no need to reach the remaining state law-specific issues." D.I. 140 at 2. For that reason, I begin my analysis by considering Defendants' arguments with respect to the adequacy of the Direct Purchasers' federal antitrust claims.

A. The Direct Purchasers' Federal Antitrust Claims

1. Whether the Direct Purchasers' Claims are Barred by § 15b

The parties agree that under § 15b the statute of limitations for federal antitrust claims is four years. They also agree that the claims alleged in the Direct Purchasers' operative complaint were first brought when Smith Drug Company

filed the first complaint in the Direct Purchasers' action—that is, August 2, 2019. D.I. 138 at 4; D.I. 147 at 4; D.I. 148 at 2.[9] And finally, they agree that the Direct Purchasers' antitrust claims that accrued more than four years before that date are barred by the statute of limitations. D.I. 138 at 4; D.I. 147 at 4; D.I. 148 at 2. The parties dispute, however, when the Direct Purchasers' claims accrued.

Defendants argue that the claims accrued when the settlement agreements were executed and publicly announced in October 2011. D.I. 138 at 4. Plaintiffs argue, and I agree, that under *Zenith Radio Corp. v. Hazeltine Research., Inc.*, 401 U.S. 321 (1971), the claims accrued when Defendants sold the Direct Purchasers Seroquel XR® at supracompetitive prices. D.I. 148 at 4–5.[10]

In *Zenith*, the Court held:

> The basic rule is that damages are recoverable under the federal antitrust acts only if suit therefor is 'commenced within four years after the cause of action accrued,' 15 U.S.C. § 15b, plus any additional number of years during

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[9] The Retailers state in their brief that Smith Drug filed its complaint on August 3, 2019. D.I. 147 at 4. The complaint, however, was filed on August 2, 2019. *See* D.I. 1 at 67.

[10] The Retailers had alleged in their operative complaints that Defendants fraudulently concealed the Handa/AstraZeneca and Accord/AstraZeneca agreements and that this concealment should permit Plaintiffs to recover for the supracompetitve purchases of Seroquel XR® they made before August 2, 2015. 20-1086, D.I. 1 ¶ 130; 20-1087, D.I. 1 ¶ 132; 20-1089, D.I. 1 ¶ 129. The Retailers, however, have withdrawn their fraudulent concealment allegations, *see* D.I. 147 at 4, and therefore I do not address Defendants' arguments regarding fraudulent concealment.

> which the statute of limitations was tolled. Generally, a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business. This much is plain from the treble-damage statute itself. 15 U.S.C. § 15. *In the context of a continuing conspiracy to violate the antitrust laws, . . . this has usually been understood to mean that each time a plaintiff is injured by an act of the defendants a cause of action accrues to him to recover the damages caused by that act and that, as to those damages, the statute of limitations runs from the commission of the act.*

401 U.S. at 338–39 (citations omitted) (emphasis added). Applying this basic rule to the continuing antitrust conspiracies alleged in the operative complaint, each time Defendants sold Seroquel XR® at a supracompetitive price to a Direct Purchaser, Defendants committed an overt act that injured that Direct Purchaser and triggered a new limitations period. Accordingly, since August 2, 2015 is the beginning of both the Class Period and the limitations period, each sale of supracompetitive-priced Seroquel XR® by Defendants during the Class Period gives rise to a timely federal antitrust claim.

Defendants insist that their sales of Seroquel XR® during the limitations period were "by no stretch . . . ***new*** overt acts," D.I. 138 at 9 (emphasis in the original), but instead were simply "a manifestation of the prior overt act of entering into [the settlement agreements]," D.I. 138 at 10 (internal quotation marks and citation omitted). According to Defendants, "[l]ater performance (or

consequences) of allegedly anticompetitive contracts does not keep the limitations period running." D.I. 138 at 10 (footnote omitted).

Courts have held that performance of an anticompetitive contract does not restart the limitations period. *See, e.g., US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 68–69 (2d Cir. 2019); *Varner v. Peterson Farms*, 371 F.3d 1011, 1019–20 (8th Cir. 2004). But Defendants' sales to the Direct Purchasers did not constitute performance of the settlement agreements. The Direct Purchasers were not parties to the agreements. Nor were they third-party beneficiaries of the agreements; on the contrary, they are alleged victims of the agreements. The agreements gave the Direct Purchasers no right to purchase Seroquel XR®, nor did they obligate Defendants to sell Seroquel XR® to the Direct Purchasers. Thus, Defendants' sales to the Direct Purchasers at supracompetitive prices were independent acts that caused the Direct Purchasers' injuries and started new limitations periods.

Courts have also held that consequences that necessarily flow from an anticompetitive agreement do not restart the limitations period. *See, e.g., DXS, Inc. v. Siemens Medical Systems, Inc.*, 100 F.3d 462, 467–68 (6th Cir. 1996) ("[A]cts that are merely 'unabated inertial consequences' . . . do not restart the statute of limitations."); *Poster Exch., Inc. v. Nat'l Screen Serv. Corp.*, 517 F.2d 117, 128 (5th Cir. 1975) ("[A] newly accruing claim for [antitrust] damages must be based

on some injurious act actually occurring during the limitations period, not merely the abatable but unabated inertial consequences of some pre-limitations action."). But since the agreements here did not require the Direct Purchasers to buy or Defendants to sell Seroquel XR®, Defendants' sales of Seroquel XR® to the Direct Purchasers after August 2, 2015, D.I. 135 ¶ 43, did not necessarily flow from (and were not the "unabated inertial consequences of") the agreements. Defendants are correct that, under the operative complaint's theories of liability, the agreements were necessary for the sales to occur—that is, they were "but for" causes of the sales; but the agreements alone were not sufficient to bring about the sales. For the sales to take place, Defendants had to engage in separate overt acts independent of their obligations under the agreements. At a minimum, Defendants had to negotiate and agree on the terms of the sales and then carry them out.

Confirmation that under *Zenith*'s basic rule Defendants' sales of Seroquel XR® to the Direct Purchasers constituted overt acts that restarted the limitations period comes from *Klehr v. A.O. Smith Corp.*, 521 U.S. 179 (1997). Citing *Zenith* among other authorities, the Supreme Court stated in *Klehr* that

> [a]ntitrust law provides that, in the case of a "continuing violation," say, a price-fixing conspiracy that brings about a series of unlawfully high priced sales over a period of years, "each overt act that is part of the violation and that injures the plaintiff," *e.g.*, each sale to the plaintiff, "starts the statutory period running again,

> regardless of the plaintiff's knowledge of the alleged illegality at much earlier times."

521 U.S. at 189 (citations omitted).

Defendants argue that this statement from *Klehr* "has no bearing here because Plaintiffs do not allege price-fixing." D.I. 154 at 4. But Plaintiffs do allege price fixing. *See* D.I. 135 ¶¶ 182 ("The purpose and effect of the Handa Non-Compete Agreement was to: . . . fix and maintain, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate in the Handa/Par Strengths."), 191 ("The Handa Non-Compete Agreement . . . fixed and maintained, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate in the Handa/Par Strengths."), 214 ("AstraZeneca . . . fixed and maintained, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate."); *see also* D.I. 135 ¶¶ 27, 154, 199, 207 (also alleging price-fixing). And, in any event, even though the quoted language from *Klehr* uses price-fixing as an example of a continuing antitrust violation, the Court did not limit its summary of antitrust statute of limitations law to price-fixing conspiracies. Defendants have offered, and I can think of, no reason to distinguish the alleged conspiracy here from a price-fixing conspiracy for statute of limitations purposes. Defendants say that price-fixing conspiracies "are fundamentally different than

other types of antitrust violations," because they "confer 'unlawfully acquired market power,'" and therefore "each time the conspirators 'use[] that power (*i.e.*, each sale), they commit[] an overt act.'" D.I. 154 at 5 (alterations in the original) (quoting *In re Propane Tank*, 860 F.3d 1059, 1067 (8th Cir. 2017)). But the operative complaint alleges that AstraZeneca "possessed substantial market power (*i.e.*, monopoly power)" "[a]t all relevant times prior to November 1, 2016," D.I. 135 ¶ 189, and the challenged agreements gave Par and Accord 100% of the U.S. sales respectively for their generic dosages during the 180-day exclusivity period beginning November 1, 2016, D.I. 135 ¶ 154.

Defendants also argue that applying the "continuing violation" doctrine set forth in *Zenith* and *Klehr* to this case will "render the limitation[s] period never-ending." D.I. 138 at 10. But the doctrine is "subject to the separate accrual rule, where each violation 'starts the statutory period running again' and 'the commission of a separate new overt act [within the limitations period] generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period.'" *Heraeus Med. GmbH v. Esschem, Inc.*, 927 F.3d 727, 740 (3d Cir. 2019) (quoting *Klehr*, 521 U.S. at 189) (alterations in original). In other words, the doctrine merely allows a plaintiff to claim as separate antitrust violations those acts that occurred within four years of the complaint's filing and

that caused the plaintiff to suffer an injury. The four-year statute of limitations "thus remains in full force under the separate accrual rule . . . ." *Id.* at 741.

Defendants argue that the continuing violation doctrine in *Zenith* and *Klehr* should not apply here because Plaintiffs have admitted that they were aware of all material provisions in the challenged settlement agreements as of October 2011, when the agreements were publicly announced. D.I. 138 at 6, 11. But the Court in *Klehr* expressly rejected the notion that knowledge of the anticompetitive conduct had any bearing on the continuing violation analysis. As the Court stated in *Klehr*, "each sale to the plaintiff[] starts the statutory period running again, *regardless of the plaintiff's knowledge of the alleged illegality at much earlier times*." 521 U.S. at 189 (emphasis added) (internal quotation marks and citation omitted).

I also reject Defendants' theory of the statutory limitations on policy grounds. Under their theory, parties could agree to divvy up a market for the purpose of raising prices but evade antitrust liability simply by waiting four years to raise prices and reap the profits of their illegal agreement. For good reason, "[t]hat is not the law." *In re Wholesale Grocery Prod. Antitrust Litig.*, 752 F.3d 728, 736 (8th Cir. 2014). Rather, "[u]nder *Klehr*, a monopolist commits an overt act each time [it] uses unlawfully acquired market power to charge an elevated price." *Id.*

Finally, I note that in reaching this conclusion, I join the majority of courts that have ruled on the issue. Since *Actavis*, courts have reliably concluded that each overpriced sale of a drug resulting from a reverse payment agreement gives rise to a new cause of action. *See, e.g.*, *Mayor of Baltimore v. Actelion Pharms. Ltd.*, 995 F.3d 123, 132 (4th Cir. 2021) ("Virtually every court faced with similar allegations has held, citing the continuing-violation doctrine, that a new cause of action accrues to purchasers upon each overpriced sale of the drug." (internal quotation marks and citation omitted)); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1329 (D. Kan. 2018) ("[D]efendants engaged in new and additional acts each time they charged the allegedly inflated prices for the EpiPen. And each of those acts inflicted a new and accumulating injury on the class plaintiffs . . . ."); *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 385 (D.N.J. 2018) ("'[E]very court to have considered [the applicability of the continuing violation doctrine] in the pay-for-delay context has held that a new cause of action accrues to purchasers upon each overpriced sale of the drug.'" (quoting *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 746–747 (E.D. Pa. 2014)); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 400 (D. Mass. 2013) (holding that "every time the Direct Purchasers were overcharged for [the branded drug], they suffered a cognizable injury" that gave rise to a new cause of action); *see also* 6 Louis Altman & Malla Pollack, Statutes

of limitations—Accrual of Cause of Action, *Callmann on Unfair Competition, Trade & Monopolies* § 23:32 (4th ed. 2021) ("Every court to have considered [the continuing tort rule] in the pharmaceutical patent settlement, pay-for-delay context has held that a new cause of action accrues to purchasers upon each overpriced sale of the drug.").

In sum, I find that the Direct Purchasers' federal antitrust claims are not barred by the statute of limitations.

2. Whether the Direct Purchasers Have Pleaded Antitrust Standing

"In order to maintain an antitrust suit, a plaintiff must establish antitrust standing, which is distinct from Article III standing." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 163 (3d Cir. 2017) (footnote and citations omitted). The requirement of antitrust standing exists for prudential reasons. *Id.* Antitrust violations can "cause ripples of harm to flow through the Nation's economy" but "Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action" under the Sherman Act. *Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 534–35 (1983) (internal quotation marks and citations omitted). Accordingly, district courts must consider as a threshold matter "whether the plaintiff is a proper party to bring [the] private antitrust action." *Id.* at 535 n.31.

"To establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury—that is, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful.'" *Wellbutrin*, 868 F.3d at 164 (citation and footnotes omitted) (alterations in original). Defendants argue that Plaintiffs have failed to meet this standard because they have not alleged facts that plausibly imply that the harm they say the Direct Purchasers suffered—being forced to pay supracompetitive prices for Seroquel XR® because of Handa/Par's and Accord's delayed entry into the generic market—flowed from (i.e., was caused by) the settlement agreements they say were unlawful.

a. The Handa/AstraZeneca Settlement Agreement

Defendants argue that the Handa/AstraZeneca settlement agreement "did not injure Plaintiffs because Handa's product lacked FDA approval until May 2017—long after the period when Plaintiffs claim they should have been able to buy it—and so the launch was blocked by [the] FDA, not Defendants." D.I. 138 at 15. But the Direct Purchasers allege in the operative complaint that the FDA had tentatively approved Handa's ANDA in 2010 after "determining that Handa's ANDA for generic Seroquel XR[®] was approvable and satisfied all bioequivalence; chemistry, manufacturing, and controls ('CMC'); and labeling requirements," D.I. 135 ¶ 13; that the FDA was unable to give final approval of

Handa's ANDA at that time because of the 30-month stay that was triggered when AstraZeneca sued Handa for infringement, D.I. 135 ¶ 13; and that, but for Handa's settlement agreement with AstraZeneca, Handa/Par would have obtained final FDA approval for and sold Handa/Par's dosages of generic Seroquel XR® before November 1, 2016, D.I. 135 ¶¶ 16, 86, 126.

Defendants argue that this latter allegation—that Handa/Par would have obtained final FDA approval before November 1, 2016—"is belied by FDA record, which is incorporated into the [operative] [c]omplaint[s]." D.I. 138 at 18. In support of this assertion, they point to a sentence in the FDA's May 2017 final approval letter for Handa/Par's ANDA. D.I. 138 at 19. That sentence reads: "Reference is also made to the tentative approval letter issued by this office on December 9, 2010, the complete response letter issued by this office on January 27, 2014, and to your amendments dated January 31, 2014; December 21, 2016; and January 12 (two amendments), March 15, and May 5, 2017." D.I. 143, Ex. 10, at 1. According to Defendants,

> a [complete response letter] signifies that FDA will "not approve the [ANDA] in its present form." 21 C.F.R. § 314.110(a). The [complete response letter] required additional information as a prerequisite for approval, and Handa/Par had to amend the ANDA five separate times (a total of six amendments) between January 31, 2014 and May 5, 2017 before receiving final approval on May 9, 2017.

D.I. 138 at 19 (second alteration in original).

But neither the FDA's issuance of the complete response letter in 2014 nor the fact that Handa/Par amended its ANDA between that time and when it received final approval in May 2017 contradict Plaintiffs' allegation that, but for the Handa/AstraZeneca settlement agreement, Handa/Par would have received final approval of its ANDA before November 1, 2016. Nothing in the FDA's final approval letter suggests that the FDA rescinded its December 2010 tentative approval or revoked its "determin[ation]" that Handa's ANDA as of that date "was approvable and satisfied all bioequivalence; chemistry, manufacturing, and controls ('CMC'); and labeling requirements." D.I. 135 ¶ 13. The final approval letter does not state why the FDA sent Handa/Par the 2014 complete response letter or why Handa/Par amended its ANDA; it does not identify the issues raised in the complete response letter or when or how Handa/Par resolved those issues to the FDA's satisfaction; and it does not say that Handa/Par's amendments to its ANDA were made in response to issues raised in the complete response letter.

Defendants in effect ask me to extrapolate from the issuance of the 2014 complete response letter and Handa/Par's subsequent ANDA amendments only inferences unfavorable to Plaintiffs. But there are plausible explanations for the letter and the ANDA amendments that are consistent with Plaintiffs' allegation that, but for the Handa/AstraZeneca settlement agreement, Handa/Par would have

obtained final FDA approval before November 1, 2016. For example, in light of the substantial reverse payment Handa/Par received and its decision to exercise its option to launch sales in November 2016 using AG product supplied by AstraZeneca, it is plausible to infer from the issuance of the complete response letter and ANDA amendments that Handa/Par decided sometime between 2011 and 2014 not to launch its own product until May 2017 and to make in the interim voluntary changes to its product or manufacturing processes that required later interaction with the FDA. As the Direct Purchasers allege in the operative complaint,

> [i]t is . . . not unusual for generic companies that have entered into pay-for-delay agreements with brand companies to use the interim period of time between the agreement and the delayed entry date to make adjustments to certain aspects of their ANDA that would otherwise not be made or would ordinarily be made post-approval and post-commercial launch.
>
> It is also often the case that FDA is made aware of Paragraph IV patent litigation settlements between brand and generic companies, as well as the agreed upon entry date. Given the limited resources of FDA, it has no interest in working to grant immediate final approval to ANDAs for generic drugs that are not slated, because of an agreement between the generic and brand companies, to enter the market for several years. Most often, and regardless of its knowledge or lack of knowledge about patent litigation settlements, FDA will simply wait, or even require that generic companies initiate additional, final approval activities nearer in time to the date that the

generics know they are eligible or desire to enter the market with their ANDA-based products.

In the context of the facts at issue here, after settling with AstraZeneca in 2011 with a generic entry date years ahead in exchange for a reverse payment, Handa (and eventually Par) . . . had no interest in obtaining, and no need to obtain, final approval of [its] respective generic Seroquel XR[®] ANDAs in the near term, and the FDA, likewise, had no interest or need to grant such final approval until the agreed generic launch date was nearing.

. . . AstraZeneca and Handa/Par delayed the launch of Handa's generic Seroquel XR[®] 50, 150, 200 and 300 mg products until November 1, 2016, and Handa/Par had the additional contractual right and economic incentive to launch and sell generic product as supplied to it by AstraZeneca for at least 180 days at least in part because Handa/Par could avoid manufacturing responsibilities and costs by distributing product supplied by AstraZeneca. Thus Handa (and Par) had no incentive to seek final approval for its ANDA versions of these milligram strengths until approximately 180 days after November 1, 2016. Handa (and eventually Par) and FDA geared their respective resources towards final approval of their ANDA-based products for May 2017. Par launched less expensive generic versions of 50, 150, 200 and 300 mg Seroquel XR[®] on November 1, 2016 with product as supplied by AstraZeneca, and thereafter obtained final ANDA approval from FDA for those same milligram strengths in early May 2017. Again, this sequence of events was no coincidence, but a direct result of the agreed entry date that AstraZeneca had purchased with its large reverse payment to Handa.

D.I. 135 ¶¶ 82–86.

Although evidence produced during discovery may ultimately show that Handa/Par would not have obtained final FDA approval before November 1, 2016, for the purposes of the pending motions, I am required to accept the operative complaints' allegations as true and construe them in the light most favorable to Plaintiffs. Adopting Defendants' arguments would require me to draw from the alleged facts only negative inferences against the Plaintiffs. Viewed in the light most favorable to Plaintiffs, the Handa/AstraZeneca agreement forced the Direct Purchasers to pay supracompetitive prices and therefore caused them to suffer antitrust injury.

b. The Accord/AstraZeneca Settlement Agreement

Defendants argue that the Accord/AstraZeneca agreement "did not injure Plaintiffs because Accord's generic infringed a valid patent, and so its launch was blocked by the patent laws." D.I. 138 at 15. As noted above, unlike Handa/Par, Accord conceded in its ANDA litigation with AstraZeneca that it infringed the #437 patent. *See* D.I. 144-2 ¶ 77. Thus, at the time they struck their settlement agreement, both Accord and AstraZeneca knew that without such an agreement, Accord could not lawfully enter the market before May 28, 2017 unless it won at trial on its invalidity defenses. D.I. 135 ¶ 5 (noting the expiration date of the #437 patent); D.I. 144-2 ¶ 6 (same).

The Direct Purchasers, however, do not allege in the operative complaint any facts that plausibly imply that the #437 patent had weaknesses that would have enabled Accord to prevail at trial on its invalidity defenses; nor do they allege any facts that plausibly imply that AstraZeneca or Accord believed that Accord could prevail at trial. According to Defendants, these failures are "no accident" because the four generics that proceeded to trial after the Accord/AstraZeneca settlement was reached lost their invalidity challenges both at trial and then on appeal before the Federal Circuit. D.I. 138 at 16. Thus, in Defendants' view of things, the Direct Purchasers "are unable to muster any allegation that Accord could have launched its generic without infringing AstraZeneca's valid patent," and this inability precludes the Direct Purchasers from alleging antitrust injury. D.I. 138 at 16.

Plaintiffs do not address the merits of this argument in their briefing. Instead, they say that the operative complaint alleges "that earlier generic entry [by Accord] would have occurred . . . through [a] settlement[] without an unlawful 'pay-for-delay' term and concomitant earlier generic entry date, *i.e.*, a 'Lawful Settlement[.]'" D.I. 148 at 9; *see also* D.I. 147 at 12 (arguing that "Accord would have entered . . . via an alternative settlement with earlier entry and no reverse payment"). And, they argue, this "theory" of liability "moots" Defendants' argument that the #437 patent's validity precludes the Direct Purchasers from alleging antitrust injury. D.I. 148 at 10; *see also* D.I. 147 at 14 (arguing that "entry

. . . pursuant to a license from the patent holder necessarily constitutes lawful entry").

Plaintiffs are correct insofar as the operative complaint makes the conclusory allegations that "it would have been economically rational for AstraZeneca to have launched authorized generic Seroquel XR[®] contemporaneously with market entry by Handa/Par and Accord instead of after Handa/Par's and Accord's 180-day exclusivity periods" and that, "[a]bsent the Accord Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR[®] in the 400 mg strength contemporaneous with Accord's launch of generic Seroquel XR[®] in the 400 mg strength." D.I. 135 ¶ 144 (emphasis omitted). And the complaint also alleges that "AstraZeneca often competes with first-filers by launching authorized generics," D.I. 135 ¶ 141, and that "[i]t is economically rational for a brand manufacturer that intends to compete for generic sales by launching an authorized generic to do so contemporaneously with the first ANDA filer's launch" because, "during the first-filer's 180-day exclusivity, the only possible competitors for generic sales are the first-filer and the brand's authorized generic," D.I. 135 ¶ 143.

But there are no non-conclusory factual allegations in the operative complaint that plausibly imply that it would have been economically rational for AstraZeneca to enter into an alternative settlement agreement with Accord under

the circumstances presented by the operative complaint—i.e., where Accord conceded that it infringed the #437 patent and in the absence of any allegation that the #437 patent was invalid or weak such that Accord could have prevailed or believed that it could have prevailed at trial on its invalidity defenses. At oral argument, Plaintiffs argued that the $107 million value of the reverse payment is sufficiently large that, under *Actavis*, it "can serve as a proxy for patent weakness." D.I. 175 at 88:1–5. But the operative complaint has no allegations that allow for plausible inferences to be drawn about whether $107 million is sufficiently "large" or "unjustified" under *Actavis* to sustain a reverse payment antitrust claim. Although the average citizen views $107 million as a huge sum, that is not the case for large pharmaceutical companies engaged in patent litigation. As alleged in the operative complaint, AstraZeneca's *annual* sales of brand Seroquel XR® in the United States exceeded $1 billion, D.I. 135 ¶ 2; and it has been on the market since 2007, *see AstraZeneca Pharms.*, 2012 WL 1065458, at *4 (noting that the "FDA approved sustained release quetiapine fumarate tablets for the treatment of schizophrenia in May 2007"). Those kinds of revenue figures breed patent litigation, and multi-billion dollar jury awards in pharmaceutical patent cases are not uncommon. *See, e.g.*, *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1332 (Fed. Cir. 2021) (reviewing $1.2 billion verdict); *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys*, 636 F.3d 1341, 1343–44 (Fed. Cir. 2011)

(reviewing $1.67 billion verdict); *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 2018 WL 922125, at *1 (D. Del. Feb. 16, 2018) (reviewing $2.54 billion verdict). Thus, the allegation that the reverse payment was worth $107 million is by itself insufficient to support a plausible inference that AstraZeneca made a large and unjustified payment because it had serious doubts about the patent's validity. *See Actavis*, 570 U.S. at 157.

Plaintiffs argue that "[n]umerous courts have . . . recognized that a plaintiff can prove earlier generic entry 'but-for' a reverse payment by proving that rational, profit-maximizing companies still would have settled, but without a reverse payment and with earlier generic entry." D.I. 148 at 10–11 (collecting cases). But in four of the five cases they cite in support of this assertion, the plaintiffs alleged that the patent at issue was or was likely to be found infringed, invalid, and/or unenforceable. *See In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 298 (D.R.I. 2019) (noting that the "Defendants' allegedly anticompetitive conduct[] includ[ed] protecting Loestrin with a patent Warner Chilcott knew was invalid"); *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *16 (N.D. Ga. June 14, 2018) (explaining that part of the plaintiffs' evidence was expert testimony that "[the brand manufacturer] likely viewed its chances of winning [the patent infringement case] to be at about 33%"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *14 (D. Mass. Jan. 25, 2018)

(noting that the "[p]laintiffs argue[d] that their evidence demonstrates that the [#]838 patent was invalid for obviousness"); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1151 (N.D. Cal. 2017) (noting that the "[p]laintiffs counter[ed] that . . . [they] ha[d] ample evidence from which a reasonable juror could determine that [the ANDA filer] would have prevailed in the patent litigation"). And, in the fifth case, the plaintiffs defeated summary judgment by providing evidence that the brand's settlement offer far exceeded both the brand's expected litigation expenses and the generic's likely profits if the generic succeeded in an ANDA trial. *See In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 196, 199 (S.D.N.Y. 2018). Thus, none of the cited cases support Plaintiffs' position that, to sustain an antitrust claim under *Actavis*, a plaintiff need only make the conclusory assertion that it would have been rational for the defendants to have settled their ANDA litigation without a reverse payment and with earlier generic entry.

Plaintiffs also argue that "causation is rarely an appropriate basis for dismissal on the pleadings." D.I. 147 at 11. I do not dispute that observation as a general matter, but it has no application here. Under *Iqbal*, the Direct Purchasers were required to plead factual content that allows for a plausible inference that the Accord/AstraZeneca settlement agreement unlawfully caused the delay of

Accord's entry into the generic market under *Actavis*. But the Direct Purchasers alleged no facts from which it can be plausibly inferred that the $107 million non-cash reverse payment AstraZeneca made to Accord was an "unexplained large reverse payment" inconsistent with traditional settlement considerations and suggestive of serious doubts by AstraZeneca about the survival of the #437 patent. *See Actavis*, 570 U.S. at 157.

Finally, Plaintiffs make passing reference to two alternative theories of antitrust injury. Without any elaboration, they say that but for the settlement agreement Accord would have "entered [the market] (1) at risk[] [and] (2) following a patent litigation victory . . . ." D.I. 147 at 12; *see also* D.I. 148 at 9–10. They allege no facts in support of these conclusory allegations, and therefore they are inadequate to sustain a claim under *Iqbal*. 556 U.S. at 663 ("[T]he tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements."). Plaintiffs also intimate in a single sentence in the Retailers' briefing that a no-AG agreement is per se anticompetitive and injurious. *See* D.I. 147 at 17 ("Retailer Plaintiffs can recover overcharges merely by showing that AstraZeneca delayed the launch of an AG for six months . . . ."); D.I. 148 at 19 (similar). But they cite no caselaw in support of this bare assertion and make no attempt to justify or explain the assertion. This "passing reference to an issue will not suffice to

bring that issue before this court." *Skretvedt v. E.I. DuPont De Nemours*, 372 F.3d 193, 202–03 (3d Cir. 2004) (internal quotation marks and citation omitted); *see also John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997) ("[A]rguments raised in passing (such as, in a footnote), but not squarely argued, are considered waived." (citation omitted)).

For these reasons, I find that the Direct Purchasers failed to adequately plead antitrust injury caused by the Accord/AstraZeneca settlement agreement. I will therefore dismiss the federal antitrust claims that are based on that agreement; but I will deny the motion to dismiss the federal antitrust claims that are based on the Handa/AstraZeneca settlement agreement. In addition, because the End-Payors do not dispute Defendants' contention that, if the Direct Purchasers' federal antitrust claims should be dismissed, the End-Payors' state law claims should also be dismissed, D.I. 140 at 2, I will also dismiss the End-Payors' claims to the extent that they are based on the Accord/AstraZeneca settlement agreement.

B. The End-Payors' State Law Claims

I turn then to the End-Payors' state law claims that are based on the Handa/AstraZeneca settlement agreement.

As noted above, the End-Payors did not purchase Seroquel XR® from AstraZeneca or Handa/Par. Rather, they reimbursed others who made such purchases and thus were so-called indirect purchasers. Consistent with its antitrust

standing requirement, the Supreme Court held in *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 730, 735 (1977), that indirect purchasers cannot bring federal antitrust claims. Indirect purchasers, however, can assert antitrust claims under various state laws; and the End-Payors have alleged here various state law antitrust claims under the laws of 35 states and the District of Columbia. The End-Payors have also alleged statute-based consumer protection[11] claims and common law unjust enrichment claims. D.I. 136 ¶¶ 233–95. Defendants have moved to dismiss some of the End-Payors' state law claims for lack of standing, inadequate pleadings, and substantive deficiencies.

1. Antitrust Claims

Defendants argue that the End-Payors' antitrust claims under the laws of 15 states should be dismissed for lack of Article III standing, that their claims under the laws of five states should be dismissed for lack of antitrust injury, and that the claims brought under the laws of four states should be dismissed for failure to allege intra-state effects.

[11] I use "consumer protection" throughout as shorthand for the set of state statutes under which the End-Payors bring their "Fourth Claim for Relief" titled "Unfair or Deceptive Trade Practices." D.I. 136 ¶¶ 277–79.

a. Article III Standing

Defendants argue first that the End-Payors lack Article III standing to assert claims brought under the laws of 15 jurisdictions—Alabama, Arkansas, District of Columbia, Hawaii, Iowa, Mississippi, Montana, Nebraska, New Mexico, North Dakota, Rhode Island, South Dakota, Utah, West Virginia, and Wisconsin—because no named End-Payor is alleged to have "'paid and/or reimbursed' for Seroquel XR® 'in' [those] states[.]" D.I. 140 at 9. Neither the Supreme Court nor the Third Circuit has addressed whether named plaintiffs in a class action have standing to assert on behalf of others claims under the laws of states in which no jurisdiction lies over the named plaintiffs.

The courts that have addressed whether a named plaintiff has standing to assert claims that only putative class members may advance are split. The Supreme Court has acknowledged that there is "tension" in its own caselaw about whether "variation" between a named plaintiff's claims and the claims of putative class members "is a matter of Article III standing . . . or . . . goes to the propriety of class certification pursuant to Federal Rule of Civil Procedure 23(a)." *Gratz v. Bollinger*, 539 U.S. 244, 263 & n.15 (2003).

Although I see merit in Defendants' position on this interesting issue, for pragmatic reasons I will defer the standing analysis required by Article III until after class certification has been resolved under Rule 23. This decision is

consistent with the Third Circuit's approach in *Georgine v. Amchem Prod., Inc.*, 83 F.3d 610, 623 (3d Cir. 1996), *aff'd sub nom. Amchem Prod., Inc. v. Windsor*, 521 U.S. 591 (1997). At issue in *Georgine* was the legitimacy of a district court's class-action certification that sought to achieve a settlement of asbestos-related claims. The Third Circuit vacated the class certification without resolving difficult Article III standing issues raised in the case. The Court explained:

> Although the existence of justiciability and subject matter jurisdiction are not free from doubt, . . . we decline to reach these issues, and pass on to the class certification issues. The class certification issues are dispositive, and we believe it prudent not to decide issues unnecessary to the disposition of the case, especially when many of these issues implicate constitutional questions. In doing so, we offend no principle of constitutional law, for the jurisdictional issues in this case would not exist but for the certification of this class action. . . . Moreover, a court need not reach difficult questions of jurisdiction when the case can be resolved on some other ground in favor of the same party.

Georgine, 83 F.3d at 623. In upholding the Third Circuit's decision, the Supreme Court "agree[d]" that the class certification issues were dispositive and that, "because their resolution here is logically antecedent to the existence of any Article III issues, it is appropriate to reach them first." *Amchem*, 521 U.S. at 612 (citation omitted).

I recognize that my holding here reaches beyond *Georgine* and *Amchem* in that the Rule 23 issues there *were* dispositive, whereas the Rule 23 issues here *may*

be dispositive. But the same prudential considerations that drove the Third Circuit in *Georgine* and the Supreme Court in *Amchem* drive my decision. I see no reason to wade through complex issues of jurisdiction and constitutional law when determinations of fact and interpretation of Rule 23 could well resolve the issue. Treatment of Rule 23 issues first will not result in the End-Payors' evading their obligation to demonstrate standing.

My conclusion is also consistent with the decisions of the two courts of appeals that have addressed the issue. *See Langan v. Johnson & Johnson Consumer Cos.*, 897 F.3d 88, 95 (2d Cir. 2018) ("[C]onsidering variation[] in state law[] as [a] question[] of predominance under Rule 23(b)(3), rather than standing under Article III, makes sense [because] . . . it acknowledges the obvious truth that class actions necessarily involve plaintiffs litigating injuries that they themselves would not have standing to litigate."); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 49 (1st Cir. 2018) ("Our conclusion is in line with our prior precedent . . . requir[ing] only that a plaintiff make a single purchase in order to satisfy standing for a claim brought under multiple state laws."); *see also Mayor of Baltimore*, 995 F.3d at 133–34 (permitting consideration of Rule 23 issues prior to issues of statutory standing). Defendants contend that my deferral of the standing analysis here "overlook[s]" *Neale v. Volvo Cars of North America*, 794 F.3d 353 (3d Cir. 2015). D.I. 140 at 10. District courts in this Circuit are split with respect to

Neale's import when courts evaluate whether a named plaintiff may represent the claims of putative class members. *Compare, e.g.*, *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, 2022 WL 736250, at *17 (D. Del. Mar. 11, 2022) (dismissing claims in states without named class members for lack of standing and finding *Neale* dispositive), *with In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 829 (E.D. Pa. 2019) (finding *Neale* did not affect whether a district court could defer the standing analysis). But Defendants nowhere argue in their briefing that *Neale* is dispositive binding precedent. And the express holding of the Court in *Neale*—"We now squarely hold that unnamed, putative class members need not establish Article III standing. Instead, the 'cases or controversies' requirement is satisfied so long as a class representative has standing," 794 F.3d at 362—does not speak directly to the question before me. Thus, deferring standing analysis here does not "overlook[]" *Neale*.

b. Antitrust Standing

Defendants next contend that the End-Payors lack standing to assert claims under the laws of Florida, Illinois, Maryland, and Massachusetts because these states "have not enacted statutes that circumvent *Illinois Brick*'s holding that only direct purchasers have standing to sue for damages . . . ." D.I. 140 at 10.

1) Florida (Counts II and III)

Defendants argue that "[i]ndirect purchasers do not suffer cognizable injury under the Florida Antitrust Act." D.I. 140 at 10 (internal quotation marks and citations omitted). But the End-Payor Plaintiffs seek relief under the Florida Deceptive and Unfair Trade Practice Act (FDUTPA), not the Florida Antitrust Act. D.I. 136 ¶¶ 257(d), 274(d) (citing Fla. Stat. §§ 501.201–501.213); D.I. 150 at 12 & n.10. And the FDUPTA permits indirect purchasers to bring claims. *See Mack v. Bristol-Myers Squibb Co.*, 673 So. 2d 100, 110–11 (Fla. Dist. Ct. App. 1996) ("[T]he Florida DTPA clearly expresses the legislative policy to authorize consumers (that is, indirect purchasers) to bring actions under the Florida DTPA for price-fixing conduct."); *see also Generic Pharms.*, 368 F. Supp. 3d at 840 & n.114 (*citing In re Fla. Microsoft Antitrust Litig.*, 2002 WL 31423620, at *2 (Fla. Cir. Ct. Aug. 26, 2002) ("Indirect purchasers of a monopolist's or price fixer's products, such as Plaintiffs here, may bring suit under the [FDUTPA].")).

2) Illinois (Counts I–III)

Defendants' standing argument with respect to the End-Payors' Illinois antitrust claims comprises three sentences:

> [Section 7(2) of] [t]he Illinois Antitrust Act provides: "no person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General." 740 Ill. Comp. Stat. Ann. 10/7. A "majority of courts," including courts in the

> Third Circuit, have held that this statute is "substantive" in nature because, among other things, it is "intertwined with Illinois substantive rights and remedies." *See, e.g.*, *In re Lipitor*, 336 F. Supp. 3d 395, 414-18 (D.N.J. 2018) (collecting cases; discussing and applying *Shady Grove Orthopedic Assocs. v. Allstate Ins. Co.*, 559 U.S. 393 (2010)); *see also In re Novartis & Par*, 2019 WL 3841711, at *7 (S.D.N.Y. Aug. 15, 2019). Because federal district courts "must utilize . . . state substantive law," [the End-Payors'] Illinois claims are barred. *Lipitor*, 336 F. Supp. 3d at 414.

D.I. 140 at 11 (ellipses in original).

The End-Payors counter in their answering brief that the express language of section 7(2) prohibits class actions only in Illinois state courts. D.I. 140 at 12–13. They also note that two federal district courts applied *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393 (2010), in holding that section 7(2) is a procedural limitation and, consistent with Federal Rule of Civil Procedure 23, does not preclude a plaintiff from bringing Illinois antitrust claims in a class action filed in federal court. D.I. 150 at 13 (citing *In re Broiler Chicken*, 290 F. Supp. 3d 772, 817–18 (N.D. Ill. 2017), and *In re Liquid Aluminum Sulfate Antitrust Litig.*, 2017 WL 3131977, *18–19 (D.N.J. July 20, 2017)).

In their reply brief, Defendants write: "[The End-Payors] assert that *Shady Grove* . . . saves their Illinois claims. Wrong. Post-*Shady Grove*, courts in this Circuit continue to hold that the Illinois Antitrust Act prohibits class actions." D.I. 155 at 6 (citations omitted). Defendants did not address in their reply brief the

End-Payors' argument that the express language of section 7(2) prohibits class actions only in Illinois state courts.

"[A]s a practical matter, when, as in this case, a party merely states an argument in conclusory fashion in its opening brief and then files a reply brief but does not contest in that brief the specific rebuttal points made in the answering brief, a court may rightly conclude that the party implicitly conceded those points. Failure to contest the rebuttal points in such circumstances is 'not necessarily a waiver, but it is a risky tactic, and sometimes fatal.'" *Progressive Sterilization, LLC v. Turbett Surgical LLC*, 2020 WL 3071951, at *2 (D. Del. June 10, 2020) (quoting *Law v. Medco Research, Inc.*, 113 F.3d 781, 787 (7th Cir. 1997)); *see also Hardy v. City Optical Inc.*, 39 F.3d 765, 771 (7th Cir. 1994) (stating that the failure to respond in a reply brief to a point made in an answering brief "waives, as a practical matter anyway, any objections not obvious to the court to specific points urged" in the answering brief). As the Court noted in *Hardy*, "[i]n an adversary system, in which by its nature judges are heavily dependent on the lawyers to establish the facts upon which decision will be based, the failure to reply to an adversary's point can have serious consequences." 39 F.3d at 771.

Under the circumstances present here, I will treat Defendants' failure to address whether the express language of section 7(2) prohibits indirect purchaser class actions only in Illinois state courts as implicitly conceding the point for the

purposes of the pending motion; and I will therefore allow the End-Payors' Illinois antitrust claims to proceed. On its face, the language quoted by the parties from the Illinois Antitrust Act appears to concern only Illinois state courts. Nothing in the quoted text says or implies that the limitation prohibits a plaintiff from asserting Illinois antitrust claims in class actions filed in federal courts. It would also be imprudent to interpret *Shady Grove* without the benefit of fulsome briefing by the parties. It can be safely said that a majority of the Court in *Shady Grove* held that a New York statute prohibiting class actions "in suits seeking penalties or statutory minimum damages" did not bar a class action for claims under New York law in federal court. 559 U.S. at 411 (plurality). But Justice Scalia in his plurality opinion and Justice Stevens in his concurring opinion reached that holding by very different routes. *Id.* ("The concurrence would decide this case on the basis, not that Rule 23 is procedural [as the plurality does], but that the state law it displaces is procedural . . . ."). Courts are understandably divided on the question of whether Justice Stevens's concurring opinion is controlling. *See Knepper v. Rite Aid Corp.*, 675 F.3d 249, 265 (3d Cir. 2012) (conducting analysis under both the Scalia and Stevens frameworks); *Lisk v. Lumber One Wood Preserving, LLC*, 792 F.3d 1331, 1335–37 (11th Cir. 2015) (leaving "unresolved" whether the Scalia or the Stevens opinion controls because of the "uncertainty" presented); *In re Aggrenox Antitrust Litig.*, 2016 WL 4204478, at *5 (D. Conn. Aug. 9, 2016) (expressing "some doubt"

that the Stevens concurrence controls); *3M Co. v. Boulter*, 842 F. Supp. 2d 85, 95 (D.D.C. 2012) (finding Justice Scalia's opinion controlling as to one question); *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 675 (E.D. Pa. 2010) (collecting cases and finding that "[l]ower courts have also concluded that Justice Stevens'[s] Rules Enabling Analysis in Shady Grove is controlling"). Courts are similarly divided on the specific question posed here of whether *Shady Grove* allows for Illinois antitrust claims to be brought in a federal class action suit. *Compare In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 418 (D.N.J. 2018) ("The language of the [Illinois Antitrust] Act presents a substantive conflict with Rule 23 . . . ."), *with Broiler Chicken*, 290 F. Supp. 3d at 817 ("*Shady Grove*'s reasoning with respect to New York's class action ban is equally applicable to Illinois's requirement . . . .").

Accordingly, I will deny Defendants' request to dismiss the End-Payors' Illinois antitrust claims for lack of standing.

3) Maryland (Counts I–III)

Maryland amended its Antitrust Act on October 1, 2017 to allow for claims by indirect purchasers. Md. Code Ann., Com. Law § 11-209(b)(2)(ii). Defendants argue that the amendment does not apply retroactively and that the End-Payors' Maryland claims should therefore be dismissed since the alleged harms occurred before October 1, 2017. D.I. 140 11–12.

Under Maryland law, statutes that affect substantive rights are presumed to operate prospectively only. *Landsman v. Md. Home Improvement Comm'n*, 839 A.2d 743, 749 (Md. 2003). Nothing in the Maryland Antirust Act states or suggests that the 2017 amendment applies retroactively. *See* Md. Code Ann., Com. Law §§ 11-201–213. Accordingly, since the amendment created a substantive right on the part of indirect purchasers to bring suit on claims they had no right to bring prior to the amendment, it applies only prospectively. *In re Hard Disk Drive Suspension Assemblies Antitrust Litig.*, 2021 WL 4306018, at *7 (N.D. Cal. Sept. 22, 2021) (citing *State Comm'n on Hum. Rels. v. Amecom Div. of Litton Sys., Inc.*, 360 A.2d 1, 5 (1976)).

The pre-2017 version of the Maryland Antitrust Act, however, permitted political subdivisions of the state to pursue actions "regardless of whether [the political subdivision] dealt directly or indirectly with the person who has committed the violation." Md. Code Ann., Com. Law § 11-209(b)(2)(ii) (West 2017); 2017 Maryland Laws Ch. 842 (S.B. 858). One of the named End-Payors is the Mayor and City Council of Baltimore, and the operative complaint alleges that this Plaintiff is a "municipality." D.I. 136 ¶ 34. Accordingly, the Mayor and City Council of Baltimore and any putative Maryland political subdivision are not precluded from asserting claims under the Maryland Antitrust Act. I will, however, dismiss counts I–III of the End-Payors' operative complaint to the extent

that the claims are asserted under Maryland law by any other Plaintiff based on purchases made before October 1, 2017.

4) Massachusetts (Counts III and IV)

The End-Payors bring their Massachusetts antitrust and consumer protection claims under the Massachusetts General Laws Chapter 93A, titled "Regulation of Business Practices for Consumers Protection." *See* D.I. 136 ¶¶ 274k, 278d; *see also* D.I. 150 at 14. Section 11 of Chapter 93A provides a right of action to sue for unfair practices to "[a]ny person who engages in the conduct of any trade or commerce . . . ." Mass. Gen. Laws ch. 93A § 11. Section 9 of Chapter 93A provides the same right to "[a]ny person, other than a person entitled to bring action under section eleven . . . ." *Id.* § 9. Chapter 93A thus "distinguishes between 'consumer' and 'business' claims, the former actionable under § 9, the latter actionable under § 11." *Frullo v. Landenberger*, 61 Mass. App. Ct. 814, 821 (2004). Massachusetts courts apply the *Illinois Brick* rule to claims brought under section 11, but not to claims brought under section 9. *See In re Asacol Antitrust Litig.*, 2016 WL 4083333, at *13 (D. Mass. July 20, 2016); *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53, 62–63 (2002) (noting that, in section 11, but not section 9, actions, "the court shall be guided in its interpretation of unfair methods of competition by the provisions of the [Massachusetts] Antitrust Act," which bar indirect-purchaser suits pursuant to *Illinois Brick*).

Defendants argue that the End-Payors lack standing to bring Chapter 93A claims because they were indirect purchasers engaged in commerce. I agree. The distinction between a business claim and a consumer claim under Chapter 93A "[u]ltimately . . . turn[s] on whether a given party has undertaken the transaction in question for business reasons, or has engaged in it for purely personal reasons (such as the purchase of an item for personal use)." *Frullo*, 61 Mass. App. Ct. at 821. "[A]ny transaction in which the plaintiff is motivated by business considerations gives rise to claims only under the statute's business section." *Id.* Here, the named End-Payors are organizations that indirectly purchased or made reimbursements for Seroquel XR® in the course of their business or institutional practices. D.I. 136 ¶¶ 32–38. In their briefing, the End-Payors point to no allegations that plausibly imply that the End-Payors were motivated by anything other than business considerations. *See* D.I. 150 at 14, 17. Accordingly, the End-Payors lack antitrust standing to assert claims under Massachusetts law and I will dismiss those claims.

5) Utah (Counts I–III)

The Utah Antitrust Act authorizes suits by "a person who is a citizen of [Utah] or a resident of [Utah]." Utah Code Ann. § 76-10-3109(1)(a). Defendants argue that the Utah claims must be dismissed because no named End-Payor is a citizen or resident of Utah. There are no allegations in the operative complaint that

a named plaintiff is a Utah citizen or resident. Plaintiffs insist that "[t]here is no statutory requirement that the named plaintiffs be citizens or residents of Utah," D.I. 150 at 14; but that assertion is belied by the express language of the Utah statute. To the extent the End-Payors seek to assert claims on behalf of putative class members, the End-Payors allege only that class members "purchased, paid and/or provided reimbursement for" brand or generic Seroquel XR® "in [Utah,]" not that putative class members are citizens or residents of Utah. D.I. 136 ¶¶ 223, 243w. Accordingly, I will dismiss the End-Payors' Utah claims.

c. Intra-State Effects

Defendants say, and the End-Payors' do not dispute, that the antitrust laws of New York, Mississippi, Tennessee, and Wisconsin require proof of substantial intra-state effects. Defendants argue that the End-Payors' claims brought under these laws must be dismissed because the operative complaint makes no non-conclusory allegations that commerce within these four states was affected by Defendants' anticompetitive conduct. D.I. 140 at 13. The complaint, however, identifies the four states, D.I. 136 ¶ 257, and alleges that brand and generic Seroquel XR® were "shipped into each state and [were] sold to or paid for by [the] End-Payors," D.I. 136 ¶ 218; that "in connection with the purchase and sale of branded Seroquel XR[®], money exchanged hands and business communications and transactions occurred in each state," D.I. 136 ¶ 219; and that "retailers within

each state were foreclosed from offering cheaper Seroquel XR[®] and generic extended-release quetiapine fumarate to the End-Payors purchasing inside each respective state," D.I. 136 ¶ 220. *See also* D.I. 136 ¶¶ 33, 37 (alleging conduct in New York and Tennessee). These allegations are sufficient to plausibly imply intra-state commerce effects in New York, Mississippi, Tennessee, and Wisconsin.

2. Consumer Protection Claims

The End-Payors bring claims under the consumer protection statutes of 15 states. D.I. 136 ¶¶ 277–82. Defendants move to dismiss on the grounds that the claims are inadequately pleaded and that the alleged conduct is not actionable under the requirements of the laws of Illinois, New York, Minnesota, Missouri, Nevada, and North Carolina.

a. Adequacy of Pleadings

Defendants argue that the End-Payors' allegations of state consumer protection law violations are inadequately pleaded because the End-Payors rely on the same factual allegations as they do for their alleged antitrust violations, only provide conclusory recitations of the elements of consumer protection violations, and list relevant state statutes without explaining their applicability. D.I. 140 at 14.

But Defendants do not explain why the alleged facts are inadequate to support consumer protection claims under the laws of all the relevant states. If the End-Payors failed to plead required elements of the claims, Defendants were free

to point out those deficiencies—and indeed they did so for certain states. Defendants' suggestion that the End-Payors must list the elements of every asserted state consumer protection statute and connect the pleaded facts to those elements goes too far. *See Generic Pharms.*, 368 F. Supp. 3d at 840 ("[Plaintiffs] need not reiterate these facts [supporting federal antitrust claims] in their consumer protection law counts." (footnote omitted)). *But see Avenarius v. Eaton Corp.*, 898 F. Supp. 2d 729, 739 (D. Del. 2012) (dismissing a "formulaic recitation" of consumer protection complaints that "do not clearly relate back" to more detailed supporting allegations). Here, the operative complaint alleges anticompetitive conduct that plausibly deprived consumers of the benefits of competition. D.I. 136 ¶¶ 108, 166–67, 174–75, 199–200. And it provides the relevant statute for each state consumer protection claim. D.I. 136 ¶ 278. Barring a specific deficiency raised by Defendants, these allegations are sufficient to state claims for unfair competition. I turn then to the specific deficiencies identified by Defendants.

b. State-Specific Requirements

1) Illinois

Defendants argue that "[i]nsofar" as the End-Payors cannot bring an antitrust claim under the Illinois Antitrust Act, they cannot bring antitrust claims under the Illinois Consumer Fraud and Deceptive Business Practices Act (ICFDBPA), 815 Ill. Comp. Stat. 510, as an end-run to that prohibition. *See* D.I. 140 at 15–16; D.I.

155 at 8. As I have already found that the End-Payors *can* bring their claims under the Illinois Antitrust Act, this argument fails, and I will allow the End-Payors' ICFDBPA claims to move forward.

2) New York

Defendants argue that New York's consumer protection law, N.Y. Gen. Bus. § 349, requires plaintiffs to allege deception directed towards consumers and that the End-Payors have not alleged any such deception. D.I. 140 at 16. The End-Payors respond that they have adequately pleaded deception "by alleging that Defendants engaged in anticompetitive conduct" to inflate prices. D.I. 150 at 16. Federal courts are split as to what facts are sufficient to plead deception under New York law. *Compare Effexor*, 337 F. Supp. 3d at 466 (holding that "prevent[ing] the earlier market entry of [a] generic [drug]" and "caus[ing] individuals to pay a premium" is sufficient to sustain a claim under New York's consumer protection law), *with In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 410 (S.D.N.Y. 2011) (dismissing "antitrust allegations that were [not] imbued with a degree of subterfuge" (internal citation and quotation marks omitted)). New York's statute is modeled on the Federal Trade Commission Act (FTC Act), and the federal "government may use the FTC Act to enforce antitrust laws." *New York v. Feldman*, 210 F. Supp. 2d 294, 302 (S.D.N.Y. 2002) (citing *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 609 (1953)). But New York's statute "does not

include the FTC Act's prohibition on unfair methods of competition and unfair acts and practices." *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 197 (D. Me. 2004) (citing N.Y. Gen. Bus. Law § 349(a) and 15 U.S.C. § 45(a)(1)).

Here, the End-Payors have not explained what makes the alleged unlawful agreements deceptive as required by New York Law. *See Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*, 3 N.Y.3d 200, 205–06 (2004) ("In order to make out a valid [New York consumer protection] claim, a plaintiff must allege both a deceptive act or practice directed toward consumers and that such act or practice resulted in actual injury to a plaintiff." (citations omitted)); *see also City of New York v. Smokes-Spirits.Com, Inc.*, 12 N.Y.3d 616, 623 (2009) ("[P]laintiffs must also plead that they have suffered actual injury caused by a materially misleading or deceptive act or practice." (citations omitted)); *N. State Autobahn, Inc. v. Progressive Ins. Grp. Co.*, 102 A.D.3d 5, 13 (N.Y. App. Div. 2012) ("[T]he deception itself is the harm that the statute seeks to remedy . . . ." (citations omitted)). The End-Payors allege anticompetitive conduct, *see, e.g.*, D.I. 136 ¶¶ 25, 32, 179, but not deceptive conduct, save in conclusory allegations attached to their deceptive trade practices count, *see* D.I. 136 ¶¶ 278–79. I am convinced by the reasoning of the *New Motor Vehicles* court that the End-Payors must plead conduct that is both anticompetitive and deceptive to make out a case

under New York's consumer protection law. Accordingly, because the End-Payors have not alleged facts that suggest consumer deception, I will dismiss their claims brought under New York's consumer protection law.

3) Minnesota

Minnesota's Consumer Fraud Act also requires deception. Minn. Stat. Ann. § 325F.69; *Grp. Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2, 12 (Minn. 2001) ("Minnesota Statutes § 325F.69, subdivision 1, defines the conduct proscribed essentially as any misrepresentation made with the intent that others rely on it in connection with the sale of any merchandise."); *Ly v. Nystrom*, 615 N.W.2d 302, 310 (Minn. 2000) (explaining that under the MCFA, "fraudulent conduct must not have been committed in a vacuum–it must have been intended to deceive someone"); *Alsides v. Brown Inst., Ltd.*, 592 N.W.2d 468, 474 (Minn. Ct. App. 1999) ("[A] [consumer fraud] plaintiff must demonstrate that the defendant made a false promise or misrepresentation with the intent that others rely thereon . . . ."); *Arrowhead Bluffs, Inc. v. Blackburn*, 2003 WL 22778336, at *2 (Minn. Ct. App. Nov. 25, 2003) (citing *Alsides*, 592 N.W.2d at 474). Defendants argue that the End-Payors fail to plead factual allegations of "fraud" or "deception." D.I. 140 at 16–17. The End-Payors respond only with reference to their arguments under the New York consumer protection law. D.I. 150 at 17.

Since, as discussed above, the End-Payors have not alleged facts suggesting any intent to deceive, I will dismiss their Minnesota consumer protection claim.

4) Missouri

The Missouri consumer protection law only provides a private cause of action for purchases made primarily for "personal, family, or household purposes." Mo. Rev. Stat. § 407.025; *Hess v. Chase Manhattan Bank, USA, N.A.*, 220 S.W.3d 758, 773–74 (Mo. 2007) (en banc) (citing Mo. Stat. § 407.025) (explaining that a purchase "primarily for personal, family or household purposes" is a required element of a claim under Section 407); *Cupit v. Dry Basement, Inc.*, 592 S.W.3d 417, 423 (Mo. Ct. App. 2020) ("To plead a violation of the [Missouri Merchandising Practices Act], the plaintiff must plead that he or she (1) purchased merchandise . . . from the defendant, (2) for personal, family, or household purposes . . . ." (citation omitted)).

Defendants argue that I must dismiss the End-Payors' Missouri claims "[b]ecause [the End-Payors] made no purchases for personal, family, or household purposes . . . ." D.I. 140 at 18. The End-Payors respond only with the non sequitur that their "class includes individual consumers as well as end-payors, who participate in consumer transactions . . . ." D.I. 150 at 18. Their failure to identify any allegation in the operative complaints that a putative member of the End-Payors' class made purchases for "personal, family, or household purposes" dooms

their Missouri claims. For that reason, I will dismiss the End-Payors' claims brought under the Missouri consumer protection law.

5) Nevada

Plaintiffs assert claims under the Nevada Deceptive Trade Practices Act (NDTPA). D.I. 136 ¶ 278(i) (citing Nev. Rev. Stat. § 598.0903–993). Chapter 41 of Title 3 of that Act provides that "any person" who is a victim of "consumer fraud" may bring an action and includes the conduct prohibited by the NDTPA within the scope of "consumer fraud." Nev. Rev. Stat. Ann. §§ 41.600(1), (2)(e). Defendants argued for the first time in their reply brief that "any person" is limited to natural persons. D.I. 155 at 10. The argument is therefore waived for the purposes of the pending motion. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig (No. II)*, 751 F.3d 150, 157 (3d Cir. 2014) ("We have consistently held that [a]n issue is waived unless a party raises it in its opening brief . . . ." (first alteration in original) (internal quotation marks and citation omitted)).

6) North Carolina

Defendants argue that the End-Payors do not allege "a substantial effect" on intrastate commerce as required by North Carolina's consumer protection law. D.I. 140 at 18. But for the reasons discussed above, *see infra* at Section III(B)(1)(c), the operative complaint alleges that Defendants' conduct had significant in-state effects in each of the states identified in the complaint. That

allegation is sufficient for the North Carolina claim to proceed at this stage of the case. *See Am. Rockwool, Inc. v. Owens-Corning Fiberglas Corp.*, 640 F. Supp. 1411, 1427 (E.D.N.C. 1986) (relying in part on plaintiff's presence in North Carolina to exercise jurisdiction under North Carolina's consumer protection law); *Hometown Pub., LLC v. Kidsville NewsA, Inc.*, 2014 WL 7499450, at *5 (E.D.N.C. Oct. 3, 2014) (quoting *American Rockwool*).

3. Unjust Enrichment Claims

Defendants argue that (1) all the End-Payors' unjust enrichment claims are inadequately pleaded and therefore should be dismissed, D.I. 140 at 19; (2) the unjust enrichment claims brought under the laws of states that follow *Illinois Brick* should be dismissed "as such claims contravene th[ose] states' express policy decisions," D.I. 140 at 18; (3) the unjust enrichment claims brought under the laws of the states that allow for indirect purchaser antitrust claims should be dismissed as "duplicative," D.I. 140 at 21; and (4) the End-Payors' unjust enrichment claims asserted under Georgia, Kentucky, Pennsylvania, and West Virginia laws should be dismissed for state-specific reasons, D.I. 140 at 21–22.

a. Adequacy of Pleadings

Defendants argue that the End-Payors' claims for unjust enrichment are inadequately pleaded, because they incorporate the rest of the allegations in the

operative complaint and neither provide the relevant law nor connect the pleaded facts to that law. D.I. 140 at 19.

To state an unjust enrichment claim in most states, a plaintiff must allege that the defendant received a benefit at the plaintiff's expense under circumstances that would make it unjust for the defendant to retain the benefit without paying for it where there is not an adequate remedy at law. *See* 66 Am. Jur. 2d *Restitution and Implied Contracts* § 11 (2021); Restatement (First) of Restitution § 1 (1937). Here, the End-Payors allege that they paid for brand and generic Seroquel XR® at supracompetitive prices. D.I. 136 ¶¶ 203–206, 286–287; D.I. 150 at 18–19. In other words, Defendants received excess profits at the End-Payors' expense on account of Defendants' alleged anticompetitive conduct. These facts are sufficient to plausibly state prima facie unjust enrichment claims.

b. Claims under Laws of States that Follow *Illinois Brick*

Defendants argue that the End-Payors "cannot sidestep *Illinois Brick*'s prohibition on indirect-purchaser suits by bringing unjust enrichment claims in states that explicitly disallow indirect purchasers from pursuing antitrust and consumer protection claims." D.I. 140 at 19 (internal citation, alterations, and quotation marks omitted). I agree. As another district court in this circuit explained, "the vast majority of courts have held that indirect purchasers may not bring state claims for unjust enrichment if they otherwise would be barred from

bringing a claim under that state's antitrust and consumer-protection statutes, absent a showing that the common law of the state in question expressly allows for such recovery. . . . [A]llowing . . . [such] unjust enrichment claims . . . would result in circumvention of the policies expressed by state legislatures through limitations inherent in those laws." *Niaspan*, 42 F. Supp. 3d at 763; *see In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *6 (S.D.N.Y. Aug. 15, 2019) (quoting *Niaspan*); *In re Packaged Seafood Prod. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1088–89 (S.D. Cal. 2017) ("[T]he vast majority of courts rightly hold that unjust enrichment may not supply a valid cause of action in states where plaintiffs are otherwise barred from recovery under relevant antitrust and consumer protection statutes. This makes sense. The crux of a plaintiff's claim will be the same, and, after all, unjust enrichment is an equitable remedy, and it would be inequitable to permit relief where the state has clearly made a policy determination that no such relief should lie." (citations omitted)); *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1175 (N.D. Cal. 2015) ("[Plaintiff] cannot make an 'end run' around *Illinois Brick* by relying on [plaintiff's] unjust enrichment claim for states that have not enacted an *Illinois Brick* repealer statute . . . ."); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 232 (S.D.N.Y. 2012) (similar).

Accordingly, I will dismiss the unjust enrichment claims in states that have not repealed the *Illinois Brick* rule (i.e., Florida, Illinois, Maryland, Massachusetts, Alabama, Georgia, Kentucky, and Pennsylvania). D.I. 140 at 20.

c. Unjust Enrichment Claims in States with an Adequate Statutory Remedy

The End-Payors plead their unjust enrichment claims "in the alternative to [their] other claims . . . ." D.I. 136 ¶ 284. Defendants argue that I should dismiss the End-Payors' unjust enrichment claims as duplicative of their state-law antitrust and consumer protection claims because the unjust enrichment claims will only succeed where those statutory claims succeed. D.I. 140 at 21 (citing *Novartis & Par*, 2019 WL 3841711, at *7 ("I nevertheless conclude that plaintiffs' unjust enrichment claims are unnecessary and duplicative of their statutory claims. . . . Dismissing these claims serves an important function in streamlining the litigation proceedings of a complex case.")). But if the unjust enrichment claims prove to be duplicative, the End-Payors will have an adequate remedy at law and, presumably, will not be able to recover for unjust enrichment. The End-Payors pleaded these claims in the alternative, as permitted under Federal Rule of Civil Procedure 8(d)(2), and Defendants have not explained why the relevant state laws render these claims duplicative.

d. State-Specific Requirements

1) Georgia, Kentucky, and Pennsylvania

Defendants argue that Georgia, Kentucky, and Pennsylvania do not permit unjust enrichment claims by indirect purchasers. D.I. 140 at 21. Since I will dismiss the unjust enrichment claims in these states for the reasons stated above, *see supra* at Section III(B)(3)(b), I need not consider Defendants' state-specific arguments.

2) West Virginia

West Virginia state law bars unjust enrichment claims on laches grounds if there is "a delay in the assertion of a known right which works to the disadvantage of another." *Dunn v. Rockwell*, 689 S.E.2d 255, 267 n.11 (W. Va. 2009) (citation and internal quotation marks omitted). Defendants argue that the End-Payors delayed in asserting "a known right for nearly a decade." D.I. 140 at 22 (internal quotation marks and alterations omitted). But, because Defendants have not explained why the alleged delay prejudiced them, I will not dismiss the West Virginia unjust enrichment claims based on laches. *See Dunn*, 689 S.E.2d at 267 n.11 (explaining that the Supreme Court of Appeals of West Virginia "has consistently emphasized the necessity of a showing that there has been a detrimental change of position in order to prove laches" (citation and internal quotation marks omitted)); *Hess v. Radford*, 2011 WL 8193594, at *1 (W. Va.

Dec. 2, 2011) ("Laches is a delay in the assertion of a known right which works to the disadvantage of another . . . ." (internal quotation marks and citation omitted)); *Shuff v. Bank of Am.*, 2021 WL 219105, at *4 (S.D.W. Va. Jan. 21, 2021) (citing and quoting *Dunn*).

IV. CONCLUSION

For the reasons stated above, I will grant in part and deny in part the pending motions to dismiss. I will dismiss:

- Plaintiffs' claims in all the operative complaints to the extent they are based on the Accord/AstraZeneca agreement.
- Counts I, II, and III of the End-Payors' Second Consolidated Amended Complaint to the extent they include claims brought under Utah or Maryland law, except for the claims brought by the Mayor and City Council of Baltimore and any other unnamed political subdivisions of Maryland that may be in the proposed class.
- Counts III and IV of the End-Payors' Second Consolidated Amended Complaint to the extent they include claims brought under Massachusetts law.
- Count IV of the End-Payors' Second Consolidated Amended Complaint to the extent it includes claims brought under New York, Minnesota, or Missouri law.

- Count V of the End-Payors' Second Consolidated Amended Complaint to the extent it includes claims brought under Florida, Illinois, Maryland, Massachusetts, Alabama, Georgia, Kentucky, or Pennsylvania law.

I will deny the motions to dismiss in all other respects.[12]

The Court will enter an Order consistent with this Memorandum Opinion.

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[12] Defendants also argue in their briefing that "[i]f this case is to proceed past Rule 12(b)(6), the *per se* allegations should be dismissed, and rule of reason applied." D.I. 138 at 21. As an initial matter, Plaintiffs do not bring any per se antitrust *claim*, so there is no claim to dismiss under Rule 12(b)(6). With regards to the "*per se* allegations" made in the operative complaints, "[*p*]*er se* and rule-of-reason analysis are but two methods of determining whether a restraint is 'unreasonable,' *i.e.*, whether its anticompetitive effects outweigh its procompetitive effects." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342 (1990) (footnote omitted); *see Eichorn v. AT & T Corp.*, 248 F.3d 131, 138 (3d Cir. 2001), as amended (June 12, 2001) ("Once there is the finding of antitrust injury, courts examine the alleged illegal conduct under one of two distinct tests: per se violation or rule of reason."). The Third Circuit has explained that "[t]he Federal Rules do not require a plaintiff to set out a legal theory at the pleadings stage, and courts have upheld a complaint against a Rule 12(b)(6) motion to dismiss even though the plaintiff appeared to rely on an inappropriate theory." *Andrews v. Monroe Cnty. Transit Auth.*, 523 F. App'x 889, 891 (3d Cir. 2013) (citations omitted). Thus, even if Defendants are correct that Plaintiffs are attempting to invoke improperly an antitrust theory, I need not address this potential error now. *See Bartholet v. Reishauer A.G. (Zurich)*, 953 F.2d 1073, 1078 (7th Cir. 1992) ("[A] complaint need not identify a legal theory, and specifying an incorrect theory is not fatal.").