IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: SENSIPAR (CINACALCET HYDROCHLORIDE TABLETS) ANTITRUST LITIGATION	MDL No. 2895
THIS DOCUMENT RELATES TO:	C.A. No. 19-md-2895-LPS
ALL DIRECT PURCHASER ACTIONS	C.A. No. 19-396-LPS C.A. No. 19-1460-LPS
ALL INDIRECT PURCHASER ACTIONS	C.A. No. 19-369-LPS C.A. No. 19-1461-LPS

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OPINION

March 11, 2022
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court are: (1) Defendant Amgen Inc.'s ("Amgen") motion (D.I. 209)[1] to dismiss the End Payor Plaintiffs' ("EPPs")[2] second amended consolidated class action complaint (D.I. 202), filed pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6); (2) Amgen's motion (D.I. 211) to dismiss the Direct Purchaser Plaintiffs' ("DPPs")[3] second amended consolidated class action complaint (D.I. 195), filed pursuant to Rule 12(b)(6); and (3) Defendants Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Actavis Pharma, Inc.'s (collectively, "Teva") motion (D.I. 213) to dismiss both the DPPs' second amended consolidated class action complaint and the EPPs' second amended consolidated class action complaint, filed pursuant to Rules 12(b)(1) and 12(b)(6).[4]

I. BACKGROUND

This multi-district litigation ("MDL") relates to a drug with the active ingredient cinacalcet hydrochloride. Cinacalcet hydrochloride is used to treat secondary hyperparathyroidism and hypercalcemia in patients with certain medical conditions. (D.I. 195 ¶ 64; D.I. 202 ¶ 64) Amgen has marketed cinacalcet under the brand name "Sensipar" since 2004. (D.I. 195 ¶ 65; D.I. 202 ¶ 65) Sensipar has earned Amgen sales of over $1 billion annually since 2015. (D.I. 195 ¶ 85; D.I. 202 ¶ 69)

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[1] Unless otherwise specified, all citations to the docket index refer to C.A. No. 19-md-2895.

[2] The End Payor Plaintiffs are also referred to as the Indirect Purchaser Plaintiffs. They include: UFCW Local 1500 Welfare Fund, Teamsters Local 237 Welfare Fund, Teamsters Local 237 Retirees' Benefit Fund, and Teamster Western Region & Local 177 Health Care Plan. (*See* D.I. 202 ¶¶ 19-21)

[3] The Direct Purchaser Plaintiffs include: César Castillo, LLC and KPH Healthcare Services, Inc., a.k.a. Kinney Drugs, Inc. (*See* D.I. 195 ¶¶ 16, 17)

[4] Teva also joins both of Amgen's motions to dismiss. (*See* D.I. 216)

Amgen held an exclusive license to now-expired U.S. Patent No. 6,011,068 (the "'068 patent"), which was listed in the Orange Book[5] in connection with Sensipar and covered the cinacalcet drug substance. (D.I. 195 ¶¶ 66-69; D.I. 202 ¶¶ 66, 67, 70) As early as March 2008, generic manufacturers began filing abbreviated new drug applications ("ANDAs") to market generic versions of Sensipar. (D.I. 195 ¶ 84; D.I. 202 ¶ 76) Several of these early ANDA filers received tentative approvals from the U.S. Food and Drug Administration ("FDA") before the March 8, 2018 expiration date of the '068 patent. (D.I. 195 ¶¶ 95-98; D.I. 202 ¶¶ 92-95) Because these early filers' challenges to the '068 patent were unsuccessful, they were prohibited from entering the generic cinacalcet market until after the expiration of that patent. (D.I. 195 ¶ 73; D.I. 202 ¶ 79)

On June 28, 2016, Amgen obtained U.S. Patent No. 9,375,405 (the "'405 patent"), which covers formulations of cinacalcet. (D.I. 195 ¶¶ 74, 75; D.I. 202 ¶ 74) The '405 patent expires on September 22, 2026. (D.I. 195 ¶ 66; D.I. 202 ¶ 70) Amgen added the '405 patent to the Orange Book listing for Sensipar; almost as soon as it did, generic manufacturers began to challenge it. By June 2017, more than 20 generic manufacturers had filed ANDAs containing paragraph IV certifications, representing to the FDA that the '405 patent was invalid, unenforceable, or would not be infringed by their generic products. (D.I. 195 ¶¶ 83, 86, 87; D.I. 202 ¶¶ 76, 77) Under the circumstances, none of the ANDA filers would have been entitled to 180-day first-filer

[5] A drug manufacturer holding an approved new drug application ("NDA") is required to notify the FDA of certain categories of drug-related patents "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1)(A)(viii) and (c)(2). The FDA lists such patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book." *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

exclusivity.[6] (D.I. 195 ¶ 132; D.I. 202 ¶ 122) Between September 2016 and June 2017, Amgen brought a series of lawsuits in this Court against these ANDA filers, alleging that the proposed generic products would infringe the '405 patent. (D.I. 195 ¶¶ 89, 93; D.I. 202 ¶¶ 86, 90)

Beginning in September 2017, Amgen settled most of these suits asserting the '405 patent, starting with the ANDA filers who had the weakest cases (i.e., those filers who were least likely to prove non-infringement, invalidity, or unenforceability of the '405 patent). (D.I. 195 ¶¶ 100, 109-16; D.I. 202 ¶¶ 97, 104-11) The agreements pursuant to which these cases were settled required that the settling defendants (1) admit to infringement of the '405 patent and (2) promise not to launch their generic versions of Sensipar before a specified and agreed entry date (which was a date prior to the expiration of the '405 patent). (D.I. 195 ¶ 101; D.I. 202 ¶ 98) The agreed entry dates varied among the settling defendants. (*See, e.g.*, D.I. 195 ¶¶ 109, 113, 135; D.I. 202 ¶¶ 107, 109, 131)

Each of the settlement agreements also included an "acceleration" clause that would allow the settling defendants to enter the cinacalcet market before their agreed entry dates if another generic manufacturer entered the cinacalcet market without authorization from Amgen; that is, if another generic manufacturer launched its generic version of Sensipar "at risk" of being liable for patent infringement. (D.I. 195 ¶¶ 101-03; D.I. 202 ¶¶ 98-100) Each of the acceleration provisions also included a 10-day "grace" period, during which Amgen could avoid triggering the acceleration clauses – in other words, Amgen could prevent the settling generic manufacturers from having their agreed entry dates accelerated – by either seeking a preliminary

[6] As an incentive for generic pharmaceutical companies to challenge the Orange Book-listed patents, the first company to submit an ANDA with a paragraph IV certification may be granted a 180-day period of generic marketing exclusivity, during which time the FDA will not approve a later-filed ANDA based on the same NDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv); *see also Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008).

injunction against the at-risk launcher or by reaching an agreement with the at-risk launcher to take its generic cinacalcet product off the market. (D.I. 195 ¶ 103; D.I. 202 ¶ 100)

In March 2018, as the '068 patent expired, and the FDA granted final approval to several ANDAs – but none of the generic manufacturers holding an approved ANDA launched its cinacalcet product at that time. (D.I. 195 ¶¶ 178-82; D.I. 202 ¶¶ 134, 135, 163) Meanwhile, also in March 2018, the non-settled lawsuits asserting the '405 patent went to trial before the Honorable Mitchell S. Goldberg, sitting by designation here in the District of Delaware. Specifically, Amgen's cases were tried against four ANDA filers: Watson Laboratories, Inc. ("Watson"), Piramal Healthcare UK Ltd. ("Piramal"), Amneal Pharmaceuticals LLC ("Amneal"), and Zydus Pharmaceuticals (USA) Inc. ("Zydus"). (D.I. 195 ¶ 171; D.I. 202 ¶ 158) Following a four-day bench trial, Judge Goldberg issued an opinion on July 27, 2018, finding that the ANDAs of Watson, Piramal, and Amneal did not infringe any of the asserted claims of the '405 patent while Zydus' ANDA did infringe some of the asserted claims. (D.I. 195 ¶¶ 172, 173; D.I. 202 ¶¶ 161, 162; *see also Amgen Inc. v. Amneal Pharms. LLC*, 328 F. Supp. 3d 373 (D. Del. 2018)) The Court entered final judgment on August 24, 2018. (D.I. 195 ¶ 174; D.I. 202 ¶ 164) Amgen and Zydus appealed the judgments to the Court of Appeals for the Federal Circuit. (D.I. 195 ¶ 177; D.I. 202 ¶ 166)

On December 27, 2018, while these appeals were pending, the FDA approved Watson's ANDA. (D.I. 195 ¶ 183; D.I. 202 ¶ 170) The next day, Teva – which owns Watson's ANDA[7] – launched Watson's approved generic cinacalcet product at risk. (D.I. 195 ¶ 184; D.I. 202 ¶ 170) Over the next several days, Teva sold and shipped more than 409,000 bottles of the product to

[7] Hence, any reference in this Opinion to "Teva's" product is a reference to Watson's product as approved by the FDA.

wholesalers, which was sufficient supply to satisfy 1.6 to 3.6 months of the entire U.S. market demand. These several days of sales generated revenues of approximately $393 million, netting approximately $213 million in profits. (D.I. 195 ¶¶ 184, 187; D.I. 202 ¶¶ 170, 171)

Within less than a week, on January 2, 2019, Amgen and Teva reached a settlement (the "Amgen-Teva Agreement"). (D.I. 195 ¶ 189; D.I. 202 ¶ 180) Pursuant to the Amgen-Teva Agreement, Teva agreed to immediately cease sales of its generic cinacalcet product and not to resume sales until June 30, 2021 (five years before the '405 patent was set to expire) – all subject to the operation of an acceleration clause that would permit Teva to reenter the market sooner than the agreed-upon date if another generic manufacturer launched at risk. (D.I. 195 ¶ 190; D.I. 202 ¶ 193)

Under the Amgen-Teva Agreement, Teva was not required to remove from the market any of the product it had distributed during the at-risk launch. It was, however, required to pay Amgen an initial payment of $10 million followed by additional payments that might bring the total amount paid by Teva to Amgen to as much as $40 million. Teva's additional payments would not be required if another generic cinacalcet product entered the market. (D.I. 195 ¶ 190; D.I. 202 ¶¶ 180-82, 193)

Amgen and Teva also agreed to jointly request that Judge Goldberg issue an indicative ruling vacating the non-infringement finding with respect to the Watson generic cinacalcet product and enter the parties' proposed consent judgment – including Teva's admission of infringement – if the Federal Circuit, upon the parties' notification that Judge Goldberg would grant their request for an indicative ruling, would remand the case for that purpose. (D.I. 195 ¶¶ 192, 193; D.I. 202 ¶¶ 194, 195) Judge Goldberg later denied Amgen and Teva's request. (D.I. 195 ¶ 196; D.I. 202 ¶ 216)

On January 4, 2019, two days after execution of the Amgen-Teva Agreement, counsel for Amgen wrote a letter to counsel for Cipla Ltd. ("Cipla") – another ANDA filer seeking approval to market a generic cinacalcet product – asking Cipla to confirm that it would not engage in an at-risk launch based on Teva's launch. (D.I. 195 ¶ 207; D.I. 202 ¶ 204) Amgen also notified Cipla that, if Cipla launched its product at risk, Amgen would exercise its rights and pursue the remedies available to it under their settlement agreement (the "Amgen-Cipla Agreement"). (D.I. 195 ¶ 207; D.I. 202 ¶ 204)

On January 8, 2019, Cipla filed a lawsuit against Amgen (the "*Cipla* action," C.A. No. 19-44-LPS) in this Court, seeking a declaratory judgment that it was entitled to launch its generic cinacalcet product under the terms the "Amgen-Cipla Agreement." (D.I. 195 ¶ 210; D.I. 202 ¶ 211) The *Cipla* action also alleged antitrust violations and patent misuse. (D.I. 195 ¶¶ 210-11; D.I. 202 ¶¶ 211-12) After Cipla obtained a copy of the Amgen-Teva Agreement through expedited discovery, Cipla amended its complaint to add Teva as a co-defendant. (D.I. 195 ¶ 213; D.I. 202 ¶ 214)

On March 6, 2019, while the *Cipla* action was pending, Cipla launched at risk, although "not selling in anything like the volume it would sell if it did not have this threat [from the lawsuit by Amgen] hanging over it." (D.I. 195 ¶¶ 214, 220; D.I. 202 ¶¶ 215, 221) On March 11, 2019, Amgen moved in the *Cipla* action for a preliminary injunction, seeking to restrain Cipla's sales of its generic cinacalcet product. (D.I. 195 ¶ 216; D.I. 202 ¶ 217) On May 2, 2019, the Court denied Amgen's motion, finding Amgen was not likely to succeed on the merits of its breach of contract claim because the Amgen-Cipla Agreement did not entitle Amgen to any relief against Cipla's launch of generic cinacalcet. *See Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 400 (D. Del. 2019). On appeal the Third Circuit affirmed. *See Cipla Ltd. v. Amgen Inc.*,

778 F. App'x 135 (3d Cir. 2019). Following the Court's denial of Amgen's motion for a preliminary injunction in the *Cipla* action, several other manufacturers launched their generic cinacalcet products. (D.I. 195 ¶¶ 227-30, 232; D.I. 202 ¶¶ 226-29, 231)

In the meantime, between February 2019 and April 2019, the DPPs and the EPPs (collectively, "Plaintiffs") filed four class action antitrust lawsuits against Amgen and Teva (collectively, "Defendants") in the Eastern District of Pennsylvania, the District of New Jersey, and the District of Delaware.[8] On July 31, 2019, the Judicial Panel on Multidistrict Litigation ("JPML") centralized the *Cipla* action and the four class actions for coordinated pretrial proceedings in this Court. (*See* D.I. 1; *see also In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, 412 F. Supp. 3d 1344 (J.P.M.L. 2019))

On September 13, 2019, the DPPs and the EPPs filed consolidated class action complaints on behalf of direct purchasers and indirect purchasers, respectively. (*See generally* D.I. 12, 13) On October 15, 2019, Amgen and Teva moved to dismiss both complaints. (*See* D.I. 27, 30, 31) On July 22, 2020, Magistrate Judge Hall issued a Report and Recommendation, in which she recommended that the Court dismiss all of Plaintiffs' federal and state law claims without prejudice and with leave to amend. (*See* D.I. 157 at 25) On November 30, 2020, the undersigned Judge adopted in part Judge Hall's Report and Recommendation, finding that Plaintiffs' claims based on the theory of an unlawful reverse payment from Amgen to Teva did

[8] On February 21, 2019, UFCW Local 1500 Welfare Fund filed a class action antitrust complaint in this District on behalf of entities that indirectly purchased or provided reimbursement for the purchase of cinacalcet. (*See* C.A. No. 19-369 D.I. 1) On February 26, 2019, César Castillo, Inc. filed a class action antitrust complaint in this District on behalf of direct purchasers of cinacalcet. (*See* C.A. No. 19-396 D.I. 1) On March 14, 2019, Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund filed an indirect-purchaser class action in the District of New Jersey. (*See* C.A. No. 19-1461 D.I. 1) On April 9, 2019, KPH Healthcare Services, Inc. filed a direct-purchaser class action complaint in the Eastern District of Pennsylvania. (*See* C.A. No. 19-1460 D.I. 1)

not warrant dismissal. (D.I. 177 at 9-12) The Court agreed with Judge Hall that Plaintiffs' claims based on two other theories did not survive the motions to dismiss: (1) that the Amgen-Teva Agreement delayed the entry of generic manufacturers other than Teva (*see id.* at 6); and (2) that the use of acceleration clauses deterred generic manufacturers from marketing generic cinacalcet (*see id.* at 7). The Court granted Plaintiffs leave to amend the consolidated class action complaints to include "only those claims and theories that remain[ed] in the case." (*Id.* at 17; *see also id.* at 3 ("Plaintiffs are granted leave to file amended complaints, consistent with the Report and this Order, provided that any such amended complaint must be filed no later than December 30, 2020 . . . .") (internal emphasis omitted)) The Court also denied Amgen's motion directed solely to the EPPs' state law claims, without prejudice to renew after the filing of any amended complaint. (*Id.* at 3)

On February 16, 2021 and March 5, 2021, the DPPs and the EPPs filed their respective amended consolidated class action complaints.[9] (*See generally* D.I. 195, 202) The DPPs' amended consolidated class action complaint includes four counts under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. (*See* D.I. 195 ¶¶ 281-319) The EPPs' amended consolidated class action complaint includes three claims for injunctive and other equitable relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, as well as a series of state law antitrust, unfair trade, consumer protection, and unjust enrichment claims. (*See* D.I. 202 ¶¶ 276-427)

[9] The EPPs filed their amended consolidated class action complaints on February 16, 2021. (D.I. 196) The parties then stipulated to allow the EPPs to file the second amended consolidated class action complaint to include another end-payor plaintiff, Teamsters Western Region & Local 177 Health Care Fund ("TWR"). (*See* D.I. 199) To avoid confusion, the Court will refer to the Plaintiffs' second amended consolidated class action complaints (D.I. 195, 202) as their "amended consolidated class action complaints."

On March 30, 2021, Amgen and Teva filed the pending motions to dismiss. (*See* D.I. 209, 211, 213) The motions are fully and extensively briefed. (*See, e.g.*, D.I. 210, 212, 214, 215, 222-24, 228, 232, 233, 243, 245, 246) The Court heard oral argument on the motions, using videoconference technology, on July 13, 2021. (*See* D.I. 244) ("Tr.")

II. LEGAL STANDARDS

A. Motion to Dismiss Under Federal Rule of Civil Procedure 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of an action for "lack of subject matter jurisdiction." A Rule 12(b)(1) motion may present either a facial or factual challenge to the Court's subject matter jurisdiction. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *See Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). When considering a facial attack, the Court accepts the plaintiff's well-pleaded factual allegations as true and draws all reasonable inferences from those allegations in the plaintiff's favor. *See In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017). When reviewing a factual attack, the Court may weigh and consider evidence outside the pleadings. *See Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

B. Motion to Dismiss Under Federal Rule of Civil Procedure 12(b)(6)

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted).

Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, "[t]o survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). 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). At bottom, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

III. DISCUSSION

A. Plaintiffs' Federal Antitrust Claims

1. Reverse Payment Under Section 1 of the Sherman Act (DPPs' Count IV and EPPs' Second Claim for Relief)

In the amended complaints, Plaintiffs allege that, under the Amgen-Teva Agreement, Amgen provided a "large and unjustified payment" to Teva in exchange for delay of generic entry into the cinacalcet market. (D.I. 195 ¶ 312; D.I. 202 ¶ 285) According to Plaintiffs, the "large and unjustified" reverse payment included:

> (1) Teva's retained revenue from its generic product launch,
>
> (2) an agreed entry date that provides Teva with exclusive market entry before other generic entrants, and
>
> (3) an acceleration provision, assuring Teva an ability to resume sales of its generic product if another generic launched before Teva's entry date.

(D.I. 195 ¶ 312; D.I. 202 ¶ 285) Plaintiffs allege that the reverse payment scheme under the Amgen-Teva Agreement "substantially, unreasonably, and unduly restrained trade in the [cinacalcet] market." (D.I. 195 ¶ 313; D.I. 202 ¶ 286) Specifically, Plaintiffs allege that the Amgen-Teva Agreement had the "purpose and effect" to:

> a. eliminate existing competition between Amgen and Teva and to prevent Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021;
>
> b. delay entry of generic versions of Sensipar by companies other than Teva in order to maintain the period in which Amgen brand Sensipar monopolizes the relevant market; and
>
> c. raise and maintain the prices that Plaintiffs and the class would pay for Sensipar and Teva's generic Sensipar to and at supra-competitive levels.

(D.I. 195 ¶ 313; D.I. 202 ¶ 286)

The Court already considered the plausibility of Plaintiffs' reverse payment claim in connection with Defendants' motions (D.I. 27, 31) to dismiss Plaintiffs' original complaints (D.I. 12, 13). The Court concluded then that "a portion of Plaintiff's Section 1 claims survive the motions to dismiss, specifically the theories embodied in statements a and c above (but not b)." (D.I. 177 at 6) In the amended complaints, Plaintiffs have re-pled all the key facts supporting the reverse payment claim. (*See, e.g.*, D.I. 222 at 32-33) The Court finds no persuasive reason to depart from its previous conclusion.[10]

In support of their motions now directed at the amended complaints, and notwithstanding the Court's earlier analysis, Defendants contend that the payments Teva received from Amgen do not qualify as "large and unjustified," as required to state a reverse payments claim under *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013). (*See* D.I. 212 at 8) Defendants first argue that the Amgen-Teva Agreement "function[ed] like the early entry compromise explicitly blessed by *Actavis*" because it allowed Teva to sell its generic drug product prior to the expiration of the '405 patent. (*See id.* at 9) However, as the Court has explained:

> [W]hile one might view as pro-competitive Amgen's agreement that Teva could enter the market five years before Amgen's patent would otherwise exclude Teva, one might alternatively view Amgen's inducement of Teva to ***leave the market*** after just a week of sales . . . approximately 2 ½ years ***before the agreed-upon re-entry date*** (June 2021), as anti-competitive.

[10] Also consistent with its previous decision, the Court finds that the reverse payment included (1) the release of Amgen's infringement claim for damages against Teva, thus allowing Teva to retain most of the revenues from its at-risk sales, and (2) the acceleration clause provided to Teva in the Amgen-Teva Agreement. Plaintiffs' allegation that the payment included "an agreed entry date that provides Teva with exclusive market entry before other generic entrants" is implausible, as the operative complaints allege that at least seven other generic manufacturers obtained the same entry date as Teva, leaving Teva with no "exclusive market entry." (*See* D.I. 195 ¶¶ 139-46; D.I. 202 ¶¶ 135-42)

(D.I. 177 at 13-14) Determining which of these competing inferences is correct (and supported by a preponderance of the evidence) is not possible at this stage of the case. Accordingly, the Court cannot conclude at this stage that the Amgen-Teva Agreement is consistent with those agreements "blessed by *Actavis*."

Defendants also take issue with Plaintiffs' allegations regarding the weakness of Amgen's patent infringement claims, contending that these allegations "***flatly contradict*** any theory that Amgen's release was disproportionately valuable compared to the up-to-$40 million that Teva agreed to pay for it." (D.I. 212 at 9-10) Defendants specifically point to the allegation that Amgen had no "reasonable expectation of prevailing on its patent merits" (D.I. 195 ¶ 201; D.I. 202 ¶ 186; *see also* D.I. 212 at 9-10; Tr. at 10-11), arguing that Plaintiffs effectively "abandoned" the reverse payment theory, as "[u]nder the facts pled, Amgen's release was worthless, and no meaningful consideration flowed from Amgen to Teva from the granting of that release." (D.I. 232 at 9 n.11) Defendants' argument is based on the common-sense notion that if Plaintiffs are correct that Amgen's patent claims were weak, then when Amgen released Teva from liability on those patent claims, Amgen was giving close to nothing of value to Teva. The Court, however, is not persuaded that Plaintiffs have effectively pled themselves out of a reverse payments claim.

As an initial matter, Amgen's purported assessment of the merits of its patent infringement claims is not necessarily indicative of the value of its release ***as perceived by Teva***. At this early stage, in connection with a motion to dismiss and without any evidence, it would be improper to infer from the allegation that ***Amgen*** had no "reasonable expectation of prevailing on its patent merits" that ***Teva*** also believed Amgen had no real case against Teva. It would be

improper, then, to draw the inference – against Plaintiffs – that "Amgen's release was worthless."

Moreover, a motion to dismiss in an antitrust case does not present an opportunity for the Court to accurately assess the strength of a party's patent claims. Without evidence in the record, the Court is not in a position to determine the value of Amgen's patent infringement claims relative to, among other things, (i) the value of Teva's retained revenue, (ii) the value of the payment made by Teva to Amgen, or (iii) the litigation costs each party saved by settling. Thus, the impact of the purported weakness of Amgen's infringement claims against Teva on Amgen's release of those claims is not a question the Court is in a position to resolve at this point.[11]

This conclusion is consistent with the Third Circuit's guidance that a plaintiff can satisfy the pleading standard for a reverse payments claim "without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or preempting every possible explanation for it." *Fed. Trade Comm'n v. AbbVie Inc.*, 976 F.3d 327, 356 (3d Cir. 2020). Even assuming Defendants are correct that the value of Amgen's release depends, to some extent, on the strength of Amgen's infringement claims (*see* D.I. 212 at 9), Plaintiffs are not required, at the pleading stage, to account for the precise impact of the weakness of Amgen's infringement claims on the value of the release. In addition, "even if there is an explanation for a reverse payment, that possibility [does] not justify dismissing the antitrust plaintiff's

[11] Defendants' reliance on *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017), is misplaced. (*See* D.I. 212 at 9) In *Lipitor*, the release of an infringement claim that had a "high likelihood of success" was found to support the allegation of a reverse payment. *See* 868 F.3d at 253. *Lipitor* did not, however, hold that the release of an infringement claim that was purportedly "weak" could not also constitute a reverse payment (particularly in combination with other value given from the patentee to the alleged infringer).

complaint." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 257 (3d Cir. 2017) (internal quotation marks omitted). Instead, Defendants will have an opportunity, as this case proceeds, to attempt to show that "legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Actavis*, 570 U.S. at 156.

Plaintiffs have plausibly stated a Section 1 claim under the reverse payment theory. Teva generated revenues of $393 million and made over $200 million in profits from its at-risk sales. (*See* D.I. 195 ¶¶ 184, 187; D.I. 202 ¶¶ 170, 171) The Amgen-Teva Agreement only required that Teva pay Amgen no more than $40 million in damages, thus allowing Teva to retain nearly 90% of its revenues and nearly 80% of its profits. (*See* D.I. 195 ¶ 190; D.I. 202 ¶¶ 180-82, 193) Teva's retention of revenue (notwithstanding Amgen's allegations of patent infringement), in an amount of no less than $353 million, in combination with an acceleration clause (allowing Teva to immediately re-enter the cinacalcet market should other generic manufacturers launch their cinacalcet products),[12] plausibly amounted to a "large and unjustified" transfer of value from Amgen to Teva, as alleged by Plaintiffs. (*See, e.g.*, D.I. 195 ¶ 312; D.I. 202 ¶ 285)

As the Court previously explained, and continues to hold:

> [T]he Amgen-Teva revenue retention provisions were, in fact, a brand providing a generic with a share of monopoly profits the brand would otherwise have earned over the few days of seeming competition, before the brand induced the generic to exit the

[12] The value to Teva of the acceleration clause in the Amgen-Teva Agreement is that it allows Teva to re-enter the generic cinacalcet market ahead of their agreed-upon entry date, if another generic launches. Combined with the revenues and profits Teva was permitted to retain, the Court concludes – under the required "holistic analysis" (D.I. 177 at 11) – that Plaintiffs have sufficiently alleged a plausible "large and unjustified" payment from Amgen to Teva. The Court need not decide whether the acceleration clause on its own would satisfy the pleading standard. (*See* D.I. 212 at 11 n.7) Further, as the Court has previously concluded (and now adheres to), Plaintiffs' theory that the acceleration clause deterred other generics is not plausible. (*See* D.I. 177 at 15-16)

> market in exchange for (among other things) keeping most of the profits the generic earned over those few days.

(D.I. 177 at 10) In other words, the consideration that allegedly flowed from Amgen to Teva pursuant to the Amgen-Teva Agreement – which, for purposes of illustration, the Court will refer to collectively as "A" – consisted primarily of the $393 million of revenues Amgen permitted Teva to earn through its at-risk launch, the release of Amgen's patent infringement claims against Teva (which protected Teva's retention of revenue), and the acceleration clause. In turn, the consideration that allegedly flowed from Teva to Amgen pursuant to their agreement – which, for purposes of illustration, the Court will refer to collectively as "B" – consisted primarily of Teva paying Amgen up to $40 million.[13] The issues as this case proceeds will include: (1) is the value of A greater than the value of B, such that net value flowed from Amgen, the patentee, to Teva, the alleged infringer (i.e., a reverse payment); and (2) if so, is the net value (i.e., A minus B) large and unjustified? These are, as the Court has explained, simply not questions that can be decided (at least in this case) on the pleadings.

Defendants next contend that Plaintiffs' reverse payment, or pay-for-delay, theory fails "not only for lack of an unjustified payment, but also due to lack of any 'delay.'" (D.I. 212 at 11) According to Defendants, because the amended complaints allege that Teva sold "its entire inventory" before execution of the Amgen-Teva Agreement (*see* D.I. 195 ¶ 184; D.I. 202 ¶ 170), and include "no fact indicating Teva would or could have continued selling at risk," there is no

[13] Of course, Teva's cessation of sales of its generic cinacalcet product (i.e., exiting the market) also had significant value to Amgen. In evaluating the consideration flowing to Amgen, however, this value is not included in "B" because it is (allegedly, and plausibly so) the prohibited "delay" in Plaintiffs' "reverse payment for delay" claim. That is, in assessing whether the amounts Amgen paid to Teva to "delay" Teva's entry (or delay Teva's "permanent entry" or "re-entry") into the market are "large and unjustified," it does not matter what that delay was worth to Amgen.

allegation that could plausibly support the theory that the Amgen-Teva Agreement caused any delay in Teva's sales. (*See* D.I. 212 at 11-12) This argument is unpersuasive. Instead, the Court agrees with Plaintiffs it is plausible that "absent the [Amgen-Teva A]greement, Teva would have obtained and produced more cinacalcet, as any rational economic actor would have done." (D.I. 222 at 37) While it is also plausible that "Teva took a unilateral risk and timed its launch (and voluntary exit)" and was never, under any circumstances, going to market any more of its generic product (at least not at-risk) (*see* D.I. 212 at 12), the Court must draw all reasonable inferences in Plaintiffs' favor on a motion to dismiss. It is reasonable to infer – from, at minimum, Teva's large and quick sales as well its negotiation of an acceleration provision that could permit it to reenter the market quickly – that Teva had both the capacity and willingness to remain on the generic cinacalcet market, had it not been for the Amgen-Teva Agreement.

Defendants advocate for a general principle that "settling damages from at-risk sales of the same drug as the disputed patent is not an antitrust violation under *Actavis*." (*Id.*) Defendants contend that "releasing a claim for at-risk damages – if it relates to the same patent being litigated – provides the generic with nothing more than a compromise of the enforcement of claims tied to the disputed patent." (*Id.*) In these circumstances, according to Defendants, "there is no reason to believe the generic agreed to an entry date not driven by the strength of the patent case." (*Id.*) The Court declines to adopt this approach, for which Defendants have not cited persuasive authority.[14] Even when a claim for at-risk damages relates to the same patent being litigated, it is possible the patentee may offer to accept an unreasonably low damages

[14] While Defendants are correct (*see, e.g.*, D.I. 212 at 13) that *Lipitor*, 868 F.3d at 253, involved a brand company delaying the generic entry of one drug by releasing infringement claims covering a different drug, there is no suggestion in *Lipitor* that settling patent infringement claims for the same drug would be immune from antitrust scrutiny.

payment in exchange for the generic manufacturer's agreement to a later re-entry date. This is not necessarily a "traditional" settlement, in which "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim," to account for "avoided litigation costs or fair value for [the generic's] services." *Actavis*, 570 U.S. at 152, 156. Instead, it may be a settlement in which the generic "pays" the branded company far less than the value the generic earned and, thus, retains great value from its at-risk launch, thereby effectively receiving large payments from the branded company, all in exchange for removing its product; that is, "walk[ing] away with money simply so it will stay away from the patentee's market." *Id.* at 152. As the Supreme Court instructed, "settlements taking this form tend to have significant adverse effects on competition." *Id.* at 148.

Finally, Defendants insist that permitting Plaintiffs' antitrust claims to proceed will have a chilling effect on generic competition because any generic settling patent litigation after an at-risk launch would have to choose between "either repay[ing] the entire value of the at-risk infringement claim or settl[ing] on reasonable terms but fac[ing] the near-certain prospect of expensive class action antitrust litigation." (D.I. 212 at 14; *see also* D.I. 214 at 19-20) The Court cannot, however, ground its conclusion in Defendants' policy argument, no matter how persuasive. The Court's understanding of the law leads it to conclude, instead, that damages settlements arising from at-risk sales of the same drug as the disputed patent are not exempt from antitrust liability.[15]

For all the foregoing reasons, the Court continues to conclude that Plaintiffs have plausibly stated a Section 1 claim under the reverse payment theory.

[15] Defendants' references to a California statute and an FTC decision (*see* D.I. 212 at 14), while helpful to the Court's analysis, are not dispositive here, for reasons including that they are not binding authority.

2. Market Allocation Under Section 1 of the Sherman Act (DPPs' Count III and EPPs' First Claim for Relief)

In the amended complaints, Plaintiffs also allege that the Amgen-Teva Agreement violated Section 1 of the Sherman Act under a market allocation theory. Specifically, Plaintiffs allege that the Amgen-Teva Agreement was "preceded by, and built upon, Amgen's numerous patent infringement settlements with other generic Sensipar manufacturers." (D.I. 195 ¶ 303; D.I. 202 ¶ 278) The settlement agreements at issue included "acceleration" clauses – which allowed the settling generics to immediately enter the generic cinacalcet market after a third-party at-risk launch – and "grace" periods within which Amgen could act to avoid triggering these "acceleration" clauses, either by seeking a preliminary injunction or reaching an agreement with the at-risk launcher. (*See, e.g.*, D.I. 195 ¶¶ 101-03, 303, 308; D.I. 202 ¶¶ 98-100, 278, 279) Plaintiffs further allege:

> When Teva launched its generic Sensipar at-risk, Teva and Amgen became horizontal market competitors. By then entering the Amgen-Teva Agreement on January 2, 2020, Amgen and Teva utilized the "grace" period that Amgen had also inserted into each of its prior settlement agreements with generic Sensipar ANDA holders, thwarting market entry by those other generics. Amgen and Teva agreed to divide up the market for Sensipar and its generic equivalent, sharing hundreds of millions in profits from sales at supra-competitive prices.

(D.I. 195 ¶ 304; D.I. 202 ¶ 279) By this theory, Plaintiffs allege that the Amgen-Teva Agreement caused the same antitrust effects as those resulting from their reverse payment theory, including both "eliminat[ing] existing competition between Amgen and Teva" and "delay[ing] entry of generic versions of Sensipar by companies other than Teva." (D.I. 195 ¶ 313; D.I. 202 ¶ 277)

To the extent Plaintiffs are alleging that the Amgen-Teva Agreement reduced competition by removing ***Teva*** from the cinacalcet market, the Court agrees with Defendants that Plaintiffs' market allocation theory is effectively a pay-for-delay theory and, hence, "depends upon an allegation of an unlawful 'reverse payment'" governed by the rule of reason test under *Actavis*. (*See* D.I. 212 at 15 n.10) The Court sees no good reason to treat this part of Plaintiffs' market allocation theory as a standalone claim; all of the allegations (and, eventually, evidence) supporting this theory can be included as part of the reverse payment theory the Court has already held will proceed.

With respect to Plaintiffs' market allocation theory alleging that the Amgen-Teva Agreement delayed the entry of generic cinacalcet manufacturers ***other than Teva***, the Court concludes that Plaintiffs have failed to state a claim. The Court previously held that the market allocation theory alleged in the original complaints was deficient because Plaintiffs had failed to plead facts as to whether "Teva had any involvement in Amgen's settlements with the other generic manufacturers or that Teva's decision to launch at risk was made with Amgen's knowledge, authorization, or agreement." (D.I. 177 at 7) Nor had Plaintiffs alleged that "Defendants agreed prior to Teva's launch that Teva could enter the market and they would share monopoly profits." (*Id.*) In the amended complaints, Plaintiffs have still failed to plead these such facts that might support a plausible theory of a conspiracy between Amgen and Teva to exclude other generic cinacalcet manufacturers from the market.

At points it appears that Plaintiffs now contend that since Amgen and Teva entered into an "actual agreement" purportedly restricting market competition, no allegation of any prior collusion to allocate the market is required. (*See* D.I. 222 at 25-26) Such a contention, however, is contradicted by Plaintiffs' representation during oral argument that their market allocation

theory is "based entirely [on] the settlements ***before Teva's launch***." (Tr. at 72) (emphasis added) Without any allegation of "some form of concerted action" or facts indicating "conscious commitment to a common scheme" by Amgen and Teva before Teva's at-risk launch, Plaintiffs' "delaying other generics" market allocation theory fails to meet the requirements for a Section 1 claim. *See In re Baby Food Antitrust Litig.*, 166 F.3d 112, 117 (3d Cir. 1999).

Even assuming it is plausible that Amgen and Teva participated in a "common scheme" ***after*** Teva's at-risk launch, by conspiring to exploit the grace period provided in the settlement agreements of other generic cinacalcet manufacturers and reaching a quick deal before the acceleration clauses in those agreements could be triggered (*see* D.I. 222 at 25-26, 29), their conduct still would not amount to an actionable antitrust violation. In this case, the earlier settling generic cinacalcet manufacturers could not enter the market freely; instead, they had already contractually agreed, ***before*** the Amgen-Teva Agreement, that they would not enter the generic cinacalcet market until long after the time period at issue here. The inclusion of the grace period provisions in the settlement agreements – although allegedly at Amgen's insistence (*see* D.I. 195 ¶ 5; D.I. 202 ¶ 6) – was "the consequence of those generics' voluntary decisions to negotiate terms in their settlements that they, at arm's length, believed were fair." (D.I. 212 at 16) Under these circumstances, the Court agrees with Defendants that "[t]he earlier settlers had no contractual expectation or right requiring Amgen to settle its other pending infringement claims in a way that allowed those earlier settlers' acceleration . . . clauses to take effect" (D.I. 232 at 3), a proposition that Plaintiffs also "agree completely with" (Tr. at 72-73).[16]

[16] The case relied on by Plaintiffs, *LePages' Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003), is inapposite. (*See* D.I. 222 at 27-28) *LePages'* does not concern a market allocation theory and does not involve market competition that had been restrained by existing contracts before the alleged antitrust conduct at issue took place. *See also generally King Drug Co. of Florence, Inc.*

Additionally, even further assuming that Amgen and Teva could have theoretically violated antitrust law by avoiding triggering the acceleration clauses in the settlement agreements of other generic cinacalcet manufacturers, the Amgen-Teva Agreement did not, in fact, have that effect. As the Court found in the *Cipla* action, because Teva was "not found to have infringed the '405 patent" by Judge Goldberg, Amgen was likely "precluded from seeking (and precluded from recovering) preliminary and permanent relief in relation to Cipla's At Risk Launch of the Cipla Product." *Cipla*, 386 F. Supp. 3d at 400. The same provision that the Court found dispositive in reaching its conclusion with respect to Cipla was included in the settlement agreements of at least five other generic manufacturers (*see* D.I. 195 ¶ 104 n.22); thus, Cipla's at-risk launch would have further "opened the door to everyone else." (Tr. at 29-30)

Alternatively, Plaintiffs ask the Court to apply the *per se* test to their market allocation claim. (*see* D.I. 195 ¶ 305; D.I. 202 ¶ 280) This test is reserved, however, for agreements "whose nature and necessary effect are so plainly anti-competitive that no elaborate study of the industry is needed to establish their illegality." *Eichorn v. AT&T Corp.*, 248 F.3d 131, 138 (3d Cir. 2001). That situation does not pertain to Plaintiffs' claim. Instead, for antitrust claims alleging defendants have allocated a market for a patented drug, "case law uniformly supports the application of *Actavis* and the rule of reason approach." *In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *4 (S.D.N.Y. Aug. 15, 2019) (collecting cases); *see also In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 2021 WL 3612497, at *31 (N.D. Cal. Aug. 13, 2021).

Finally, since Plaintiffs concede that they are only challenging the Amgen-Teva Agreement the parties "reached in January [2019]" (*id.* at 62), the Court need not address

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v. Smithkline Beecham Corp., 791 F.3d 388, 408-09 (3d Cir. 2015) ("*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible.").

Plaintiffs' arguments about Amgen's "later on enforcement of the agreement."[17] (*Id.*) Relatedly, Plaintiffs also agree that the threatening signals Defendants sent to the marketplace, which purportedly impacted Cipla's decision regarding the timing and volume of its at-risk launch, were "background but . . . not actionable." (*Id.*)

For the foregoing reasons, then, the Court concludes that Plaintiffs' Section 1 claim based on the theory that the Amgen-Teva Agreement delayed the entry of generic cinacalcet manufacturers ***other than Teva*** must be dismissed.

3. Monopolization Claims Under Section 2 of the Sherman Act (DPPs' Counts I and II and EPPs' Third Claim for Relief)

Plaintiffs' Section 2 claims in the amended complaints are an amalgamation of the "deterrence by acceleration clauses" theory, which was pled in the original complaints and dismissed by the Court (*see* D.I. 177 at 7), and a repackaged market allocation theory based on the grace period, which was not pled as part of the Section 2 claims in the original complaints (*see* D.I. 12 ¶¶ 113-22; D.I. 13 ¶¶ 242-48). The Court permitted the amended complaints to include "***only those claims and theories that remain[ed] in the case.***" (D.I. 177 at 17) (emphasis added) Hence, Plaintiffs were not granted leave to re-plead the "deterrence by acceleration clauses" theory or market allocation theory based on the grace period in their

[17] Given Plaintiffs' concession, the positions Amgen took during the *Cipla* action are not relevant to the Court's analysis. In any event, it appears that Amgen's advocacy of its interpretation of the Amgen-Cipla Agreement is subject to the *Noerr-Pennington* doctrine; the anticompetitive effects deriving from good-faith legal advocacy are not subject to antitrust liability. *See Prof'l Real Estate Inv'rs v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) ("If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail."). Plaintiffs do not allege that the legal arguments Amgen made about the interpretation of the Amgen-Cipla Agreement were made in bad faith or were objectively unreasonable.

Section 2 claims. These portions of Plaintiffs' Section 2 claims are dismissed (or dismissed again), as further explained below.

On *de novo* review of Judge Hall's decision recommending dismissal of all claims in the original complaints, the Court concluded that "a portion of Plaintiffs' Section 2 claims survive[d] the motions to dismiss." (*Id.* at 7) Specifically, all that survived was the theory that Amgen's purported exclusionary scheme involved "paying Teva to remove its generic product from the market and delay its entry." (*Id.* at 6-7) While Judge Hall had recommended that Plaintiffs be granted leave to amend their complaints (*see* D.I. 157 at 25-26), the Court instructed that "[b]ecause the Court [had] concluded that some but not all of Plaintiffs' federal antitrust claims survive . . . , it [would] promote the efficient management of these cases for the operative complaints to be re-pled to include ***only*** those claims and theories that remain in the case." (D.I. 177 at 17) (emphasis added) Thus, Plaintiffs were granted leave to re-plead only the portion of their Section 2 claims that survived the motions to dismiss: that Amgen paid Teva to induce Teva to remove Teva's generic product from the market and delay its entry. (*Id.* at 6-7) In the operative amended complaints, it appears that Plaintiffs no longer pursue this theory as part of their Section 2 claims. (*Compare* D.I. 13 ¶ 244 *with* D.I. 195 ¶¶ 281-98) Therefore, Plaintiffs have pled no Section 2 claim on which they may proceed.

Plaintiffs' arguments to the contrary are unpersuasive. Relying on Judge Hall's recommendation that "Plaintiff's complaints be dismissed without prejudice to amend" (D.I. 157 at 25), Plaintiffs somehow read the Court's order that their objections were "overruled in part and sustained in part" (D.I. 177 at 2) as meaning that "the part of the report that [the Court] sustained was the dismissal without prejudice of the monopolization claim" (Tr. at 120). Plaintiffs also point to a statement in the Court's order in which the Court agreed with Judge Hall

that "the market allocation theory ***as pled*** contains insufficient specificity to survive the motions to dismiss" (D.I. 177 at 15), finding in this sentence a suggestion that Plaintiffs could try again to plead this theory more successfully (*see* D.I. 222 at 2 n.5; *see also* Tr. at 121). These understandings, however, are inconsistent with the explicit instructions in the Court's order that Plaintiffs were not permitted to re-plead the claims and theories in the original complaints that did not survive the motions to dismiss.[18]

In any event, even if the Court were to consider the merits of Plaintiffs' Section 2 claims in the amended complaints, it would still find that these claims do not survive the motions to dismiss. Plaintiffs' theory is that the acceleration clauses in the settlement agreements with the generic cinacalcet manufacturers who had the weakest non-infringement positions "disincentivize[d] other would-be generic Sensipar competitors that held stronger patent positions and greater resources from launching at-risk because once they did, other generics would immediately accelerate to market as well, cannibalizing the profits the early-launching generic would otherwise have enjoyed." (D.I. 195 ¶ 303; D.I. 202 ¶ 278)

The parties fiercely dispute whether the acceleration clauses in the settlement agreements are procompetitive or anticompetitive. (*See* D.I. 212 at 18-19; D.I. 222 at 16-19; D.I. 232 at 13-17) Both sides cite cases seeming to side with them on this issue. *See, e.g.*, *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 2021 WL 3612497, at *24 (N.D. Cal. Aug. 13, 2021) (finding acceleration clauses "at least plausibly deterred some generics"); *In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727, at *27 (S.D.N.Y. June 11, 2021) (finding

[18] In addition, contrary to Plaintiffs' argument that "if there is an absence of saying with prejudice, then it would be without prejudice" (Tr. at 41), a dismissal under Rule 12(b)(6) that is silent as to prejudice is presumed to be with prejudice. *See In re PHP Healthcare Corp.*, 128 F. App'x 839, 842 (3d Cir. 2005) ("[I]n the absence of a clear statement to the contrary, a dismissal pursuant to Rule 12(b)(6) should be presumed to be made with prejudice.").

argument that "acceleration clauses did not change the generic market at all, and arguably increased competition" is "rather appealing"); *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 612 (N.D. Cal. 2020) (finding that "most-favored entry plus" clause is "significant deterrent to second filers" but "most-favored entry" clause is "not as clear a deterrent"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 334 (D.R.I. 2017) ("EPPs have plausibly alleged that the acceleration clause had anticompetitive effects."); *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015) ("[A]s to the acceleration clauses, Plaintiffs have failed to set forth any plausible basis for viewing them as anticompetitive."))

The Court, however, need not address this difficult question because, in this case, the operative clauses governing a third-party at-risk launch (Section 5.5), at least on their face, only prevented Amgen from seeking a preliminary injunction to enjoin the at-risk launch; they did not prevent Amgen from seeking infringement damages from the at-risk sales – an interpretation that Plaintiffs do not appear to challenge. (*See* D.I. 212 at 20-21; *see also e.g.*, D.I. 243 Exs. 1-6) In other words, under the settlement agreements, a third-party at-risk launch would not permit ***riskless*** entry by other settling generics. Instead, the settling generic manufacturers would only have had the opportunity to launch ***at risk***, facing potential patent infringement damages. (*See* D.I. 212 at 20) This severely undermines any plausibility that Plaintiffs' theory might otherwise have.

Plaintiffs' reference to Section 5.6 of the settlement agreements – which, according to Plaintiffs (*see* D.I. 222 at 20-21), purportedly prevented Amgen from seeking any relief against a generic manufacturer who has launched at risk following a third-party at-risk launch – does not change the Court's conclusion. Section 5.6 is present in the settlement agreements of only a minority of settling generic manufacturers, among whom only two had approved ANDAs prior

to 2019. (*See* D.I. 195 ¶¶ 104 n.22, 178, 182) It is, thus, implausible that the alleged "immediate and complete genericization" of the cinacalcet market would occur (or that any generic contemplating an at-risk launch would assume this as an inevitability). (*See* D.I. 195 ¶ 107; D.I. 202 ¶ 102) Moreover, the amended complaints have no allegations regarding how Section 5.6 would impact other generic manufacturers' launch decisions.

Plaintiffs' theory that the acceleration clauses deterred the entry of generic cinacalcet products is further undermined by the lack of actual anticompetitive effects in the marketplace.[19] Plaintiffs allege in the amended complaints that the acceleration clauses were "intended to, and did, ensure that no other generic drug manufacturer – no matter how much time and resources it spent in its litigation against Amgen and no matter how successful it was in that litigation – could enter the market without other generics likewise entering the market." (D.I. 195 ¶ 149) It is undisputed that this alleged deterrence did not actually occur. Instead, four non-settling generic manufacturers continued to challenge Amgen's patent through trial, even though many other manufacturers had previously settled their patent litigation with Amgen. (D.I. 195 ¶¶ 148, 171; D.I. 202 ¶¶ 144, 158) Moreover, besides Teva's launch, at least six generics – Cipla, Piramal, Mylan, Alkem, Aurobindo, and Strides – entered the market prior to their agreed entry dates. (D.I. 195 ¶¶ 214, 228-30, 232; D.I. 202 ¶¶ 215, 227-29, 231) The lack of deterrence observed in the generic cinacalcet market is consistent with the Court's prior conclusion that "ANDA filers understand that other manufacturers of generic drugs may also file ANDAs

[19] In their brief, Plaintiffs contend that the continued litigation and the subsequent at-risk launches by multiple generic manufacturers "are factually irrelevant and cannot defeat the plaintiffs' monopolization claims." (D.I. 222 at 21) However, during oral argument, Plaintiffs conceded that "they are relevant." (Tr. at 71-72) ("If we said something how they're irrelevant, then somebody got excited when typing something . . . .") The Court finds relevance in these real-world events.

seeking to market their own generic versions of branded drugs, which (after FDA approval) compete not only with the branded drug but also with any ANDA filer's generic product." (D.I. 177 at 15) Again, Plaintiffs' theory lacks plausibility.

Plaintiffs also allege that Amgen's purported monopolization scheme "included Amgen's injection of 'grace' provisions into the dozen-plus agreements with generics, giving it the opportunity to quickly pay off any generic that decided to launch" and thereby prevent the acceleration clauses from being triggered. (D.I. 222 at 14; *see also* D.I. 195 ¶¶ 8, 9, 103; D.I. 202 ¶¶ 9, 100) The Court has considered this issue in connection with Plaintiffs' Section 1 market allocation claim and concludes that the utilization of grace periods to avoid the triggering of acceleration clauses did not amount to an antitrust violation. (*See supra* III.A.2.)

For the foregoing reasons, the Court will dismiss Plaintiffs' Section 2 claims.

4. Teva's Challenge to Plaintiffs' Article III and Antitrust Standing

Teva (but not Amgen) contends that Plaintiffs lack both Article III and antitrust standing to maintain their Section 1 claims that are based on the Amgen-Teva Agreement. Specifically, Teva argues that (1) since Plaintiffs have failed to allege that the Amgen-Teva Agreement delayed generic cinacalcet manufacturers (other than Teva) from entering the market, Plaintiffs cannot plausibly establish that the Amgen-Teva Agreement caused Plaintiffs' purported overcharge injury – that is, the higher prices Plaintiffs paid and reimbursed for the branded and generic Sensipar products (*see* D.I. 214 at 13-14); and (2) Plaintiffs have also failed to plausibly allege any overcharge injury caused by Teva's exit from the generic cinacalcet market under the Amgen-Teva Agreement (*see id.* at 15-19). The Court need not address Teva's first argument, because it goes to Plaintiffs' market allocation theory, which the Court has decided to dismiss. (*See supra* III.A.2.) Even assuming Plaintiffs have established both Article III and antitrust

standings, they have failed to state a market allocation claim under the "delay other generics" theory. The Court will address Teva's second argument, to explain why it is not persuaded by it.

To establish Article III standing, a plaintiff "must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Causation in the context of Article III standing is "akin to 'but for' causation in tort and may be satisfied even where the conduct in question might not have been a proximate cause of the harm." *Finkelman v. Nat'l Football League*, 877 F.3d 504, 510 (3d Cir. 2017) (internal quotation marks omitted).

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." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 164 (3d Cir. 2017). Unlike the causation requirement for Article III standing, "[a]ntitrust standing requires proximate causation between defendant's conduct and the injury to plaintiff." *Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 430 (3d Cir. 1993).

Teva argues that the overcharge injury Plaintiffs allege in the amended complaints "largely, if not exclusively, assumes the continued viability of their 'delay of other generics' theory." (D.I. 214 at 15) The Court does not agree. Plaintiffs have alleged that the Amgen-Teva Agreement "eliminate[d] existing competition between Amgen and Teva and . . . prevent[ed] Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021." (D.I. 195 ¶ 313; D.I. 202 ¶ 286) Plaintiffs have further alleged that competition by generic drug manufacturers "enables all purchasers of the drug to: (a) purchase generic versions of a drug at

substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price." (D.I. 195 ¶ 272; D.I. 202 ¶ 245) Nothing in the amended complaints indicates that Plaintiffs' overcharge injury is attributable exclusively to the delay of entry by generic manufacturers other than Teva.

Teva next contends that Plaintiffs fail to allege an injury caused by Teva's exit from the generic cinacalcet market, because the allegation that "Teva sold its entire inventory of product forecloses any inference that there was anything Teva could have done to bring that price down any further." (D.I. 214 at 17) The Court has addressed this issue in connection with Amgen's contention that the Amgen-Teva Agreement did not cause any delay of Teva's entry. (*See supra* III.A.1) It is plausible at this stage to infer that Teva would have remained in the generic cinacalcet market absent the Amgen-Teva Agreement.[20]

Teva's argument that "even if Teva did have additional product to sell, neither class of Plaintiffs alleges that it could or would have had an ability to purchase it" is also unpersuasive. (*See* D.I. 214 at 17-18) The fact that Plaintiffs have not alleged that they made any purchases from Teva is not a dispositive failing here.[21] Plaintiffs have alleged that, but for Defendants'

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[20] The situation in this case is readily distinguishable from that in the case cited by Teva. (*See* D.I. 214 at 17; *see also* Tr. at 34-35) In *Cottrell v. Alcon Labs.*, 874 F.3d 154, 168 (3d Cir. 2017), the Third Circuit reversed a district court decision but added it "might be inclined to agree with the District Court that the pricing theory was too speculative if it, in fact, had depended on these [drug pricing] presumptions." In the district court litigation, the plaintiffs based their injury theory, in part, on the presumption that "Defendants would have reduced the price of a bottle of medication in accordance with the reduction in volume." *Id.* The district court had rejected this premise, because it had "no way of knowing whether Defendants would price their products [based on volume], particularly since the pricing of pharmaceuticals is complex." *Id.* Here, by contrast, it is far less speculative to infer – on the bases of Teva's past sales and its bargaining for future sales – that Teva would have continued producing and selling its generic cinacalcet product in the absence of the Amgen-Teva Agreement.

[21] Teva's reliance on *Marian Bank v. Elec. Payment Servs., Inc.*, 1997 WL 367332 at *4 (D. Del. Feb. 5, 1997), is misplaced. (*See* D.I. 214 at 18) There the court dismissed the plaintiff's claim

anticompetitive conduct, they "would have paid less for oral tablets comprised of cinacalcet hydrochloride by: (a) substituting purchases of less-expensive AB-rated generic Sensipar for their purchases of more expensive branded Sensipar; (b) receiving discounts on their remaining branded Sensipar purchases; and (c) purchasing generic cinacalcet hydrochloride at lower prices sooner." (D.I. 195 ¶ 273; D.I. 202 ¶ 245) There is no requirement that an antitrust plaintiff must make purchases from a co-conspirator to sue for that co-conspirator's contribution to the antitrust injury allegedly suffered by the plaintiff. *See Bogosian v. Gulf Oil Co.*, 561 F.2d 434, 448 (3d Cir. 1977) ("The fact that a customer has not made purchases from every co-conspirator does not prevent him from suing all for each co-conspirator contributed to the charging of the supracompetitive price paid by the purchaser.").

Finally, Teva contends that any injury Plaintiffs suffered as a result of Teva's exit from the generic cinacalcet market was "completely" remedied or "minimized" by the entry of other generic cinacalcet products. (*See* D.I. 214 at 18-19) The Court agrees with Plaintiffs that this contention presents an issue of damages, not standing. (*See* D.I. 222 at 40) Plaintiffs have sufficiently alleged that "although other generic manufacturers have since launched generic versions of Sensipar, competition in the market remains impaired as a result of the Amgen-Teva Agreement due to the fact that Teva is no longer selling generic Sensipar." (D.I. 202 ¶ 13)

For the foregoing reasons, the Court finds that Plaintiffs have alleged an overcharge injury that was proximately caused by Teva's exit from the generic cinacalcet market as the result of the Amgen-Teva Agreement. Thus, Plaintiffs have established both Article III standing and antitrust standing for their Section 1 claims against Teva.

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as to one defendant because that defendant's participation in the conspiracy post-dated the period relevant to the plaintiff's claim.

B. EPPs' State Law Claims

In addition to their federal antitrust claims, the EPPs attempt to assert various state law claims under the laws of the District of Columbia, Puerto Rico, and all states except Indiana and Ohio. Defendants have sought to dismiss most of these state law claims on various grounds.[22]

1. Article III Standing

Defendants contend that the EPPs only have Article III standing to pursue state law claims in 15 states because the EPPs' amended complaint lacks allegations that the named plaintiffs were injured outside of those 15 states.[23] (*See* D.I. 210 at 5) The EPPs counter that they have Article III standing to pursue their claims and those of absent class members, because "all claims arise from the same alleged misconduct." (D.I. 224 at 3) In the EPPs' view, "a plaintiff's ability to represent the claims held by absent class members is not" an Article III jurisdictional issue. (*Id.* at 5)

On this dispute, the Court agrees with Defendants.[24] The EPPs may only proceed with their state law claims in the 15 states where at least one named plaintiff was injured by allegedly overpaying for branded and generic Sensipar. (*See* D.I. 202 ¶¶ 19-21)

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[22] According to Defendants, the only state law claims that are not subject to the motion to dismiss are: the Florida consumer protection claim; the California consumer protection claim and antitrust claims as to concerted conduct; New York and Tennessee antitrust claims as to concerted conduct; and the Arizona, Maryland, and Oregon claims. (*See* D.I. 210 at 3 n.1)

[23] The 15 states are: Alaska, Arizona, California, Florida, Hawaii, Indiana, Maryland, Missouri, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, and Utah.

[24] The issue of Article III standing in class action lawsuits presents an unsettled question on which courts, including in the Third Circuit, are split. *See, e.g.*, *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2021 WL 100204, at *14 (D.N.J. Jan. 12, 2021) (finding no standing in states where named plaintiffs "do not reside and were not injured"); *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 223 (D.N.J. 2020) ("Plaintiffs lack standing to assert claims on behalf of unnamed plaintiffs in jurisdictions where Plaintiffs have suffered no alleged injury."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 758 (E.D. Pa. 2014)

Under Third Circuit law, "[s]tanding requires that the party seeking to invoke federal jurisdiction 'demonstrate standing for ***each claim*** he seeks to press.'" *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 359 (3d Cir. 2015) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006)) (emphasis added). "The requirements for standing do not change in the class action context." *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 634 (3d Cir. 2017). In class actions, Article III standing "must be satisfied by at least one named plaintiff," while "unnamed, putative class members need not establish Article III standing." *Neale*, 794 F.3d at 359, 362 (internal quotation marks omitted). "[N]amed plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." *Lewis v. Casey*, 518 U.S. 343, 357 (1996) (internal quotation marks omitted); *see also Long v. Se. Pa. Transp. Auth.*, 903 F.3d 312, 325 (3d Cir. 2018) ("[A]ny harm to unnamed class members cannot constitute injury in fact.").

Applying these principles here is fairly straightforward, especially considering that the EPPs have conceded: (i) the named plaintiffs only have suffered injuries in the 15 states, and (ii) the fact that the named plaintiffs incurred injuries in those 15 states does not confer on them Article III standing in states beyond the 15 (*see* Tr. at 104-05). The EPPs cannot premise Article III standing for claims outside of the 15 states on the injuries allegedly suffered by putative,

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("[N]amed plaintiffs lack standing to assert claims under the laws of the states in which they do not reside or in which they suffered no injury."); *but see, e.g.*, *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 831 (E.D. Pa. 2019) (declining to dismiss case because "state law claims of the named [plaintiffs] largely parallel those of the putative class members"); *Gress v. Freedom Mortg. Corp.*, 386 F. Supp. 3d 455, 462 (M.D. Pa. 2019) ("Plaintiffs' capacity to state claims under the laws of other states on behalf of putative class members . . . is a matter to be decided under the rubric of Rule 23" and is not issue of standing).

unnamed class members in other states. Accordingly, the EPPs have Article III standing only for claims in the 15 states. *See Neale*, 794 F.3d at 359.

The EPPs' reliance on non-Third Circuit cases is misplaced; at least some of those cases are inconsistent with binding Third Circuit law. For example, the Second Circuit held that "[named] class action plaintiffs are not required to have individual standing to press any of the claims belonging to their unnamed class members." *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 95 (2d Cir. 2018). This conclusion is at odds with *Neale*'s holding that Article III standing "must be satisfied by at least one named plaintiff" in class actions. *See Neale*, 794 F.3d at 359. The First Circuit found that named plaintiffs have Article III standing to assert claims held by absent class members where the claims of the named plaintiffs "parallel" those of the putative unnamed class members. *See In re Asacol Antitrust Litig.*, 907 F.3d 42, 49 (1st Cir. 2018). Under Third Circuit law, however, courts "do not exercise jurisdiction over one claim simply because it arose from the same nucleus of operative fact as another claim." *Neale*, 794 F.3d at 359 (internal quotation marks omitted).[25]

The Court finds no need to defer addressing the Article III standing issue until after class certification, an approach adopted in some cases cited by the EPPs (*see* D.I. 224 at 5-6), cases that relied on the reasoning of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), in which the Supreme Court was asked to review both class certification issues and the Article III standing of some, but not all, class members. In that case, the Supreme Court agreed with the Court of

[25] The other appellate court cases cited by the EPPs do not address the disputed issue here. The Fourth Circuit decision in *Mayor of Baltimore v. Actelion Pharmaceuticals Ltd.*, 995 F.3d 123, 131 (4th Cir. 2021), addressed statutory standing, not Article III standing. The Sixth Circuit and Seventh Circuit decisions allowed named plaintiffs to assert the ***same*** federal law claims as the putative class members. *See Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 423 (6th Cir. 1998); *Arreola v. Godinez*, 546 F.3d 788, 790, 795 (7th Cir. 2008).

Appeals that the class certification issues were dispositive and the other issues "would not exist but for the class-action certification." *Amchem*, 521 U.S. at 612. Thus, the Supreme Court found that it was appropriate in *Amchem* to reach the class certification issues first, "because their resolution here is logically antecedent to the existence of any Article III issues." *Id. Amchem* did not, however, require that courts always address class certification before standing. Here, since the Court is only confronted with a challenge to Article III standing, and has not yet reached the stage of considering class certification, there would be no practical benefit to waiting to decide standing until after a decision on class certification. *See generally Flecha v. Medicredit, Inc.*, 946 F.3d 762, 769 (5th Cir. 2020) ("[I]f it is the ***class representative*** who presents a standing problem, then ***that*** standing issue must be addressed first, prior to deciding class certification. After all, if the class representative lacks standing, then there is no Article III suit to begin with – class certification or otherwise.").

For these reasons, the Court agrees with Defendants that the EPPs lack Article III standing to press their state law claims except in the following 15 states: Alaska, Arizona, California, Florida, Hawaii, Indiana, Maryland, Missouri, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, and Utah. Their state law claims in all other jurisdictions will be dismissed without prejudice.

2. Antitrust and Consumer Protection Statutes

Defendants contend that several of the EPPs' state-law antitrust and consumer protection claims should be dismissed because these claims are not allowed under relevant state statutes. Specifically, Defendants argue that (1) the EPPs' Sixth Claim for Relief against Amgen should be dismissed under California, New York, and Tennessee law, because these state statutes do not prohibit unilateral conduct (*see* D.I. 210 at 10); (2) the EPPs' claims under Hawaii law should be

dismissed for failure to comply with the statutory notice requirement (*see id.* at 11); (3) the EPPs' claims under Missouri consumer protection law should be dismissed because the named plaintiffs are not "consumers" (*see id.* at 12); and (4) the EPPs' claims under Utah law should be dismissed because none of the named plaintiffs is a citizen or resident of Utah (*see id.* at 12). The Court addresses each of Defendants' challenges below.

a. California, New York, and Tennessee

Defendants contend that the EPPs' monopolization claims "against Amgen alone" (D.I. 202 ¶¶ 324-32) fail as a matter of law because the statutes of California, New York, and Tennessee "prohibit only concerted conduct, not unilateral conduct."[26] (D.I. 210 at 10) The EPPs do not dispute Defendants' interpretation of the law. Instead, they point out that they have pled concerted conduct, including Amgen's conspiracy with Teva and its settlements with other generic manufacturers. (*See* D.I. 224 at 10)

The Court agrees with the EPPs. The statutes at issue do not prohibit claims against one co-conspirator who participated in a concerted scheme. Thus, the mere fact that the claims are directed "against Amgen alone" does not form a basis for dismissal.

The concerted conduct alleged in the EPPs' amended complaint is readily distinguishable from the conduct that courts have found to be unilateral in nature. *See, e.g.*, *Commonwealth*

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[26] California's Cartwright Act, Cal. Bus. & Prof. Code § 16720, "applies only to a 'combination' involving 'two or more persons,' not to ***unilateral*** conduct." *Flagship Theatres of Palm Desert, LLC v. Century Theatres, Inc.*, 198 Cal. App. 4th 1366, 1386 (Cal. Ct. App. 2011). New York's Donnelly Act prohibits "[e]very contract, agreement, arrangement or combination" that creates a monopoly or restrains competition. N.Y. Gen. Bus. Law § 340(1). An antitrust claim under the Donnelly Act "must allege . . . concerted action by two or more entities." *Global Reinsurance Corp. U.S. Branch v. Equitas Ltd.*, 969 N.E.2d 187, 192 (N.Y. 2012). The Tennessee Trade Practices Act declares unlawful "[a]ll arrangements, contracts, agreements, trusts, or combinations between persons or corporations" that suppress competition or control price. Tenn. Code § 47-25-101.

Elec. Inspection Servs. v. Town of Clarence, 776 N.Y.S.2d 687, 688-89 (N.Y. App. Div. 2004) (municipalities enacting particular ordinance); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1109 (N.D. Cal. 2007) (wrongfully filing patent lawsuits); *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 420-21 (D.N.J. 2018) (fraudulently obtaining patent, listing fraudulently obtained patent in Orange Book, filing sham citizen petition, and engaging in sham litigation).

Thus, the Court will not dismiss the EPPs' Sixth Claim for Relief against Amgen under California, New York, and Tennessee statutes.[27]

b. Hawaii

Defendants contend that the antitrust claims brought under Haw. Rev. Stat. §§ 480, *et seq.* should be dismissed because the EPPs failed to comply with the statutory notice requirement. (*See* D.I. 210 at 11) Section 480-13.3 of the Hawaii statute sets forth detailed procedural requirements for maintaining a class action for trade violation claims on behalf of indirect purchasers by a person other than the state's attorney general. The statute requires that the proposed class representative file a complaint under seal and serve, among other things, a filed copy of the complaint upon the attorney general, "not later than seven days after filing of the complaint." Haw. Rev. Stat. § 480-13.3(a)(1). The attorney general then has the discretion to take over the class action, or to file its own action on the same or similar claims, and in the latter case the proposed class representative's complaint "shall be dismissed." Haw. Rev. Stat. §§ 480-13.3(a)(4), (a)(5)(A) and (a)(5)(B). If the attorney general declines or fails to timely take

[27] *See In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 395 (D.N.J. 2018) (upholding New York and Tennessee claims based on reverse settlement agreement); *Lipitor*, 336 F. Supp. 3d at 421 (same).

over the action or to file its own action, the proposed class representative "shall have the right" to proceed with its class action. Haw. Rev. Stat. § 480-13.3(a)(5)(C).

While the EPPs assert that they have provided notice to the Hawaii attorney general (*see* D.I. 224 at 11), they failed to do so in compliance with the statutory requirements.[28] *See* Haw. Rev. Stat. § 480-13.3(a)(1). The EPPs contend, nonetheless, that their claims should not be dismissed because, following Justice Scalia's plurality opinion in *Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co.*, 559 U.S. 393 (2010), "Rule 23 preempts state laws restricting class actions." (D.I. 224 at 11) Defendants counter that Justice Stevens' concurrence, rather than Justice Scalia's plurality opinion, is the controlling analysis in *Shady Grove*. (*See* D.I. 233 at 5) Under that analysis, Hawaii's notice requirement governing indirect purchasers' antitrust class action lawsuits – which, according to Defendants, are "part of a State's framework of substantive rights or remedies," *Shady Grove*, 559 U.S. at 419 (Stevens, J., concurring in part and concurring in the judgment) – should apply in federal court. (*See* D.I. 233 at 5) The Court agrees with Defendants.

In *Shady Grove*, 559 U.S. at 398-401, a majority of the Supreme Court agreed that Rule 23 directly conflicts with New York's statute precluding class actions seeking penalties or statutory minimum damages. The Supreme Court, however, was split on the issue of when Rule 23 preempts a conflicting state class action statute. In the plurality opinion, Justice Scalia concluded that Rule 23 preempts all state class action statutes, regardless of the "substantive nature" or "substantive purpose" of the state law. *Id.* at 409. By contrast, Justice Stevens, in his

[28] The EPPs filed their original complaint on February 21, 2019 (*see* C.A. No. 19-369, D.I. 1) and "enclose[d]" a copy of the complaint in letters sent to the attorney general "on or about April 30, 2019." (*See* D.I. 202 ¶ 274) The EPPs also provided a notice to the Hawaii attorney general ten days after filing their second amended complaint. (*See* D.I. 224 Ex. A)

opinion concurring in the judgment, espoused the view that when a federal rule and a state statute directly conflict, the federal rule "cannot govern a particular case in which the rule would displace a state law that is . . . so intertwined with a state right or remedy that it functions to define the scope of the state-created right." *Id.* at 423. Although the Third Circuit has not addressed the issue, the Court finds that the opinion of Justice Stevens, who "concurred in the judgments on the narrowest grounds," provides the controlling analysis of *Shady Grove*. *See Marks v. United States*, 430 U.S. 188, 193 (1977). This is the same conclusion reached by a majority of courts that have addressed the same issue. *See, e.g.*, *Albright v. Christensen*, 24 F.4th 1039, 1044 n.1 (6th Cir. 2022) ("[W]e restate our conclusion . . . that Justice Stevens's concurrence in *Shady Grove* controls the test governing the [Rule Enabling Act] and constitutional standards."); *James River Ins. Co. v. Rapid Funding, LLC*, 658 F.3d 1207, 1217 (10th Cir. 2011) ("The Tenth Circuit has understood [Justice Stevens'] concurrence to be the controlling opinion in *Shady Grove*."); *Greene v. Gerber Prods. Co.*, 262 F. Supp. 3d 38, 60 (E.D.N.Y. 2017) (collecting cases and agreeing with "the majority of district and circuit courts that have found Justice Stevens' concurring opinion controls because it provides the 'narrowest grounds' or the 'common denominator' of the majority position); *Phillips v. Philip Morris Co.*, 290 F.R.D. 476, 480-81 (N.D. Ohio 2013) (collecting cases and concluding "[i]n the wake of *Shady Grove*, a clear majority of courts have applied Stevens's narrower holding as the controlling opinion for use in determining whether a federal rule may displace a conflicting state law").

The Court finds that Hawaii's notice requirement "functions to define the scope of the state-created right" and is not, therefore, preempted. *Shady Grove*, 559 U.S. at 423. First, unlike the New York statute at issue in *Shady Grove*, which "applies not only to claims based on New

York law but also to claims on federal law or the law of any other State," *id.* at 432, the notice requirement in the Hawaii statute applies only to "[a] class action for claims for a violation of this chapter [i.e., Haw. Rev. Stat. §§ 480, *et seq.*]." Haw. Rev. Stat. § 480-13.3. The specific applicability of the notice requirement suggests that it is "bound up" with the substantive right created by Hawaii law. *See Greene v. Gerber Prods. Co.*, 262 F. Supp. 3d 38, 61 (E.D.N.Y. 2017) (finding that notice prerequisite applying only to "a violation of Chapter 1345 of the [Ohio Revised Code]" indicates "its substantive nature"); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 408-09 (D. Mass. 2013) (finding Illinois' requirement that all indirect purchaser class actions be brought by attorney general is substantive, as it is "contained in the state's antitrust statute").

The text of the Hawaii statute further indicates that the notice requirement defines the scope of a state-created right. The statute states that the notice requirement "shall not ***limit the rights of consumers*** to bring class actions," suggesting that the notice requirement ***is*** intended to limit indirect purchasers' rights to bring class actions. (*See* D.I. 210 at 11 n.4; *see also* Haw. Rev. Stat. § 480-13.3(b) (emphasis added)) The statute also specifies that the proposed class representative "***shall have the right***" to conduct the class action if the state does not take it over, further suggesting that the right to conduct class actions does not vest until after the state has exercised its right of first refusal. *See* Haw. Rev. Stat. § 480-13.3(a)(5)(C) (emphasis added). Hence, disregarding the notice requirement would impermissibly "abridge, enlarge or modify" the substantive right granted by the Hawaii statute.[29] *See* 28 U.S.C. § 2072(b).

[29] *But see In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 253-54 (D. Conn. 2015) (finding that Hawaii's procedural requirements are not sufficiently part of its framework of substantive rights or remedies).

For these reasons, since the EPPs failed to comply with the statutory notice requirement, their antitrust claims brought under the Hawaii statute will be dismissed.[30]

c. Missouri

Defendants contend that the EPPs' claims under the Missouri Merchandising Practices Act (MMPA), Mo. Rev. Stat. § 407.025(1), should be dismissed because that statute authorizes "only claims by consumers who pay for a product for their ***own*** use." (D.I. 210 at 12) (emphasis added) The EPPs respond that their proposed class includes both benefit plan plaintiffs and consumers who paid for Sensipar indirectly. (*See* D.I. 224 at 12; *see also* D.I. 202 ¶ 264) As to the benefit plan plaintiffs, the EPPs argue that they paid for the "personal and/or household use" of the individual consumers in the plans. (*See* D.I. 224 at 12)

The Missouri statute provides a private cause of action for "[a]ny person who purchases or leases merchandise primarily for personal, family or household purposes."[31] Mo. Rev. Stat. § 407.025(1). Like many district courts that have considered the same issue,[32] this Court

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[30] Several courts have found that the Hawaii statute does not require dismissal for failure to comply with procedural requirements. *See, e.g.*, *In re Aftermarket Filters Antitrust Litig.*, 2009 WL 3754041, at *6 (N.D. Ill. Nov. 5, 2009); *In re Propranolol Antitrust Litig.*, 249 F. Supp 3d 712, 728 n.14 (S.D.N.Y. 2017); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, 2018 WL 7197233, at *25 (S.D.N.Y. Dec. 26, 2018). While the statute is silent on the proper remedy for non-compliance with its procedural requirements, the Court concludes that the EPPs have acquired no right to conduct class actions without affording the state attorney general the right of first refusal. It follows that their antitrust claims should be dismissed. *See, e.g.*, *Asacol*, 2016 WL 4083333, at *15; *Lipitor*, 336 F. Supp. 3d at 416; *In re Chocolate Confectionary Antitrust Litig.*, 749 F. Supp. 2d 224, 232-33 (M.D. Pa. 2010); *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1158 (N.D. Cal. 2009).

[31] The Missouri statute defines "person" to include business entities. *See* Mo. Rev. Stat. § 407.010(5).

[32] A Missouri state court has held that plaintiffs who purchase merchandise ***indirectly*** from defendants can seek damages under this statute, but has not addressed the issue of whether the statute authorizes claims of plaintiffs who purchase – directly or indirectly – merchandise for someone else's personal use. *See State v. Polley*, 2 S.W.3d 887, 891-92 (Mo. Ct. App. 1999)

concludes that the statute should be construed to authorize only claims brought by persons who have purchased merchandise for their own – but not someone else's – "personal, family or household purposes." *See, e.g.*, *In re Express Scripts, Inc.*, 2006 WL 2632328, at *10 (E.D. Mo. Sept. 13, 2006); *Asacol*, 2016 WL 4083333, at *12; *Los Gatos Mercantile, Inc., v. E.I. DuPont De Nemours & Co.*, 2015 WL 4755335, at *23 (N.D. Cal. Aug. 11, 2015); *In re Actimmune Mktg. Litig.*, 2010 WL 3463491, at *12 (N.D. Cal. Sept. 1, 2010); *In re Pharm. Indus. Average Wholesale Price Litig.*, 252 F.R.D. 83, 97 n.13 (D. Mass. 2008). A contrary interpretation would be at odds with the "fundamental purpose of the Act: the protection of consumers." *Gibbons v. J. Nuckolls, Inc.*, 216 S.W.3d 667, 669 (Mo. 2007).

Here, since the benefit plan plaintiffs did not purchase Sensipar for their own use, the MMPA does not authorize their claims. However, individual consumers who indirectly purchased Sensipar for their own personal use may press claims under the MMPA. *See In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 847 (E.D. Pa. 2019).

Defendants contend that the Court can only consider whether "the ***named plaintiffs*** have plausible claims." (D.I. 233 at 5) While only named plaintiffs are considered for Article III standing purposes (as the Court has held elsewhere in this Opinion (*see supra* III.B.1.)), Defendants cite no authority to support their contention that the Court must do the same with respect to the merits elements of a claim. Hence, since the MMPA authorizes claims for at least

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(consumer's home-repair materials and services purchased indirectly from construction business); *Gibbons v. J. Nuckolls, Inc.*, 216 S.W.3d 667, 669-70 (Mo. 2007) (consumer's automobile purchased indirectly from automobile wholesaler). Consistent with the Court's interpretation of the statute, these state court cases permit consumer-plaintiffs to proceed with claims if they have purchased (albeit indirectly) merchandise for their own personal use, not for someone else's personal use.

some putative class members, the Court will not dismiss the EPPs' claims under this statute, and will deny this portion of the Defendants' motion.

d. Utah

Defendants contend that the EPPs' claims under the Utah statute should be dismissed because the statute provides that "[a] person who is a citizen of [Utah] or a resident of [Utah] . . . may bring an action." Utah Code 76-10-3109(1)(a). According to Defendants, none of the named plaintiffs allege that they are citizens or residents of Utah. (*See* D.I. 210 at 12-13) In response, the EPPs argue that the unnamed plaintiffs in the putative class may satisfy this statutory requirement. (*See* D.I. 224 at 13) Although the EPPs do not explicitly allege that any putative class member is a citizen or resident of Utah, they do, however, allege that the putative classes include persons and entities that "indirectly purchased, paid, and/or provided reimbursement" in Utah. (D.I. 202 ¶ 264) It is, thus, not implausible to infer that some of those putative class members may be citizens or residents of Utah. Thus, the Court will not dismiss the EPPs' claims brought under the Utah statute.

C. Unjust Enrichment Claims

1. Alaska, New Jersey, Pennsylvania, and South Carolina

Defendants seek dismissal of the EPPs' state law unjust enrichment claims in the listed "non-*Illinois Brick* repealer" states because these claims attempt to circumvent the prohibition on indirect purchasers' antitrust damages claims.[33] (*See* D.I. 210 at 13) The Court agrees with

[33] Defendants also include Florida in this category. However, the *Illinois Brick* doctrine does not prevent the EPPs from bringing claims under the Florida Deceptive & Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201, *et seq.* *See Mack v. Bristol-Myers Squibb Co.*, 673 So. 2d 100, 110-11 (Fla. Dist. Ct. App. 1996); *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 819-20 (N.D. Ill. 2017). Thus, *Illinois Brick* does not provide a basis for dismissing the EPPs' unjust enrichment claim under Florida law.

Defendants and will dismiss the EPPs' unjust enrichment claims as pled under Alaska,[34] New Jersey, Pennsylvania, and South Carolina law.

Under the *Illinois Brick* doctrine, indirect purchasers may not recover damages from an antitrust defendant. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 730 (1977). However, many states have enacted statutes that do authorize indirect purchasers to bring antitrust claims seeking monetary damages, effectively "repealing" the effect of *Illinois Brick* (for purposes of state law claims). Other states, however, have not attempted to "repeal" *Illinois Brick* by statute. In these "non-repealer" states, "it would be inequitable to permit relief where the state has clearly made a policy determination that no such relief should lie." *In re Packaged Seafood Prods. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1088-89 (S.D. Cal. 2017).

Notwithstanding the several cases cited by the EPPs holding the contrary (*see, e.g.*, D.I. 224 at 15-16), the weight of authority supports the proposition that indirect purchasers may not bring state law claims for unjust enrichment if that state's antitrust and consumer protection statutes do not otherwise provide a private cause of action for damages. *See, e.g.*, *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 542 (E.D. Pa. 2010) ("[W]here an antitrust defendant's conduct cannot give rise to liability under state antitrust and consumer protection laws, Plaintiffs should be prohibited from recovery under a claim for unjust enrichment."); *In re K-Dur Antitrust Litig.*, 2008 WL 2660780, at *5 (D.N.J. Feb. 28, 2008) ("[A] plaintiff cannot circumvent the statutory framework by recasting an antitrust claim as one for unjust enrichment."); *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1380 (S.D. Fla. 2001) ("State

[34] Alaska allows only the state attorney general to bring antitrust claims on behalf of those indirectly harmed. *See* Alaska Stat. Ann. § 45.50.577(i).

legislatures and courts that adopted the *Illinois Brick* rule against indirect purchaser antitrust suits did not allow 'an end run around the policies allowing only direct purchasers to recover.'").

Accordingly, the Court will dismiss the EPPs' unjust enrichment claims in Alaska, New Jersey, Pennsylvania, and South Carolina.

2. Hawaii, Missouri, and Utah

Defendants contend that in these states – all of which provide statutory remedies for indirect purchasers – the EPPs' unjust enrichment claims should be dismissed because their statutory claims fail. (*See* D.I. 210 at 13) Having concluded that the EPPs' statutory claims in Missouri and Utah survive the motion to dismiss, the Court only needs to address the EPPs' unjust enrichment claim in Hawaii.

The Court does not find that Hawaii's antitrust statutes provide the exclusive remedies for antitrust claims brought by indirect purchasers. *See generally Miller v. French*, 530 U.S. 327, 340-41 (2000) (stating courts "should not construe a statute to displace courts' traditional equitable authority absent the clearest command") (internal quotation marks omitted). Defendants fail to show such a "clear[] command" here. It follows, then, that the EPPs' right to recover an equitable remedy is not entirely dependent on the success of their statutory antitrust claims. (*See* D.I. 224 at 15) Moreover, as the EPPs rightly argue, under Federal Rule of Civil Procedure 8(d), the EPPs are permitted to plead causes of action in the alternative, even if they are premised on the same factual basis. (*See id.* at 14-15) Thus, the dismissal of EPP's statutory antitrust claims does not necessarily require the dismissal of their unjust enrichment claims, which may proceed as an alternative cause of action.

Thus, the Court will not dismiss the EPPs' unjust enrichment claims under Hawaii, Missouri, and Utah law.[35]

3. Florida, New Jersey, New York, and Pennsylvania

Defendants contend that the EPPs' unjust enrichment claims in these states should be dismissed because the law of these states requires a benefit that is conveyed from a plaintiff to a defendant directly. (*See* D.I. 210 at 14) Since the Court will dismiss the EPPs' unjust enrichment claims in New Jersey and Pennsylvania based on the continued viability of *Illinois Brick* in these states (see above), the Court will only address this additional argument in connection with the EPPs' unjust enrichment claims under Florida and New York law.

The Court will dismiss the EPPs' unjust enrichment claim under Florida law. The Florida Supreme Court has held that "to prevail on an unjust enrichment claim, the plaintiff must directly confer a benefit to the defendant." *Kopel v. Kopel*, 229 So. 3d 812, 818 (Fla. 2017). For example, a party to a contract cannot assert an unjust enrichment claim against another party to a different contract even if a benefit can arguably flow through a third party common to both contracts. *See, e.g., Peoples Nat'l Bank of Commerce v. First Union Nat'l Bank of Fla., N.A.*, 667 So. 2d 876, 878-79 (Fla. Dist. Ct. App. 1996). The Court must apply this definitive construction of Florida law by the Florida Supreme Court. The EPPs, representing the indirect purchasers, have not alleged that any putative class member directly conferred a benefit to any Defendant. The cases cited by the EPPs (*see, e.g.*, D.I. 224 at 17) all predated *Kopel*. The Court will follow *Kopel* and, hence, dismiss this claim.

[35] For the same reasons, the Court will not dismiss the unjust enrichment claims as duplicative where the EPPs have plausibly pled any statutory claim in a particular state. (*See* D.I. 210 at 19)

Under New York law, "a plaintiff need not be in privity with the defendant to state a claim for unjust enrichment." *Sperry v. Crompton Corp.*, 863 N.E.2d 1012, 1018 (N.Y. 2007). However, such a claim is not permitted when the relationship between the plaintiff and the defendant is "too attenuated." *Id.* New York courts have found, for example, that end users cannot assert an unjust enrichment claim against the manufacturer of an ***ingredient*** of the product they purchased. *See id.* (dismissing claim by purchasers of tires against defendants who fixed prices for chemical additives in tires); *see also State ex. rel. Spitzer v. Daicel Chem Indus., Ltd.*, 840 N.Y.S.2d 8, 12 (N.Y. App. Div. 2007) (dismissing claim by consumers of food products against defendants who fixed prices of additives used to extend food's shelf life). Here, the EPPs indirectly purchase the product at issue: Sensipar or generic cinacalcet; they are not trying to sue, for example, a company that provides ingredients that Defendants put into Sensipar or generic cinacalcet. Hence, the relationship between the EPPs and Defendants is not "too attenuated." *See, e.g., In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 234 (S.D.N.Y. 2012) (denying motion to dismiss because "Plaintiffs plausibly conferred some benefit on Defendants, albeit indirectly, by purchasing DDAVP at elevated prices"); *Waldman v. New Chapter, Inc.*, 714 F. Supp. 2d 398, 403-04 (E.D.N.Y. 2010) (holding that indirect purchaser can assert unjust enrichment claim "against the manufacturer of the ***product*** itself"). The Court will not dismiss EPPs' unjust enrichment claim based on New York law.

4. California

Defendants contend that California does not recognize unjust enrichment as a standalone claim. (*See* D.I. 210 at 14) While some courts have agreed with this position, *see, e.g., Melchior v. New Line Prods, Inc.*, 106 Cal. App. 4th 779, 793 (Cal. Ct. App. 2003) ("The phrase 'unjust enrichment' does not describe a theory of recovery."), other courts, including the Supreme Court

of California, appear to acknowledge that parties may pursue unjust enrichment claims under California law. *See, e.g.*, *Ghirardo v. Antonioli*, 924 P.2d 996, 1002 (Cal. 1996) (holding that plaintiff can assert unjust enrichment claim where his claim seeks restitution and other remedies are inadequate); *Fed. Deposit Ins. Corp. v. Dintino*, 167 Cal. App. 4th 333, 346 (Cal. Ct. App. 2008) ("[U]njust enrichment is a common law obligation implied by law based on the equities of a particular case."). The California courts have not definitively prohibited an independent cause of action for unjust enrichment. Thus, the Court will not dismiss the EPPs' unjust enrichment claim brought under California law.

IV. Conclusion

An appropriate Order follows.