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-02895
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

MEMORANDUM ORDER

WHEREAS, on July 22, 2020, Magistrate Judge Hall issued a Report & Recommendation ("Report") (D.I. 157),[1] recommending that the Court grant Defendant Amgen Inc.'s ("Amgen") motion to dismiss the Direct Purchaser Plaintiffs'[2] Consolidated Complaint (D.I. 27), Amgen's motion to dismiss the End Payor Plaintiffs'[3] Consolidated Complaint (D.I. 30), and Defendants Teva Pharmaceuticals USA Inc., Watson Laboratories, Inc., and Actavis Pharma, Inc.'s (collectively "Teva") motion to dismiss Direct Purchaser Plaintiffs' and End Payor Plaintiffs' (collectively "Plaintiffs") Consolidated Complaints (D.I. 31);[4]

[1] All citations are to the record in action No. 19-md-2895, except where otherwise noted.

[2] Cesar Castillo, LLC (C.A. No. 19-396-LPS) and KPH Healthcare Services, Inc. (C.A. No. 19-1460-LPS).

[3] UFCW Local 1500 Welfare Fund (C.A. No. 19-369-LPS) and Teamsters Local 237 Welfare Fund (C.A. No. 19-1461-LPS).

[4] The pending motions were all filed pursuant to Federal Rule of Civil Procedure 12(b)(6). The Court adopts the Report's recitation of the legal standards applicable to review of such a motion, which standards are not disputed by the parties. (*See* Report at 10)

WHEREAS, on August 5, 2020, the Direct Purchaser Plaintiffs and End Payor Plaintiffs jointly filed Objections to Judge Hall's Report ("Objections") (D.I. 167, 168), specifically objecting that Judge Hall erred in finding that *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013), governed the action and erred in finding that *Actavis* foreclosed Plaintiffs' claims;

WHEREAS, on August 19, 2020, Defendants Amgen and Teva filed a response to Plaintiffs' Objections ("Response") (D.I. 174);

WHEREAS, the motions to dismiss present case-dispositive issues and, accordingly, the Court has considered the motions and the parties' objections and responses to the Report *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); *see also* 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that, for the reasons more fully articulated herein,

1. Plaintiffs' Objections (D.I. 167, 168) are **OVERRULED IN PART** and **SUSTAINED IN PART**, and the Report (19-md-2895 D.I. 157; C.A. No. 19-369 D.I. 91; C.A. No. 19-396 D.I. 120; C.A. No. 19-1460 D.I. 86; C.A. No. 19-1461 D.I. 71) is **ADOPTED IN PART**;

2. Amgen's motion to dismiss the Direct Purchaser Plaintiffs' Consolidated Complaint (19-md-2895 D.I. 27; C.A. No. 19-396 D.I. 57; C.A. No. 19-1460 D.I. 24) is **DENIED**;

3. Teva's motion to dismiss the Direct Purchaser Plaintiffs' and End Payor Plaintiffs' Consolidated Complaints (19-md-2895 D.I. 31; C.A. No. 19-369 D.I. 42; C.A. No. 19-396 D.I. 60; C.A. No. 19-1460 D.I. 27; C.A. No. 19-1461 D.I. 23) is **DENIED**;

4. Amgen's motion to dismiss End Payor Plaintiffs' Complaint (19-md-2895 D.I. 30; C.A. No. 19-369 D.I. 39; C.A. No. 19-1461 D.I. 21) – a motion directed solely to state law claims – is **DENIED WITHOUT PREJUDICE** to renew after the filing of any amended complaint;

5. 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**; and

6. The following motions are **DENIED AS MOOT**:

a. Teva's motion to dismiss for failure to state a claim and lack of subject matter jurisdiction (19-md-2895 D.I. 25), which relates solely to the now-settled litigation among Cipla Ltd., Amgen, and Teva (C.A. No. 19-44)

b. UFCW Local 1500 Welfare Fund's Motion for Transfer and Consolidation of Proceedings (C.A. No. 19-1460 D.I. 2) (a motion granted at C.A. No. 19-1460 D.I. 7).

Background

As the Report explains, "Direct Purchaser and End Payor Plaintiffs allege that they paid too much for cinacalcet drugs because Amgen entered into anticompetitive settlement agreements with generic manufacturers that kept cheaper versions off the market." (Report at 2-3) The litigation between the branded pharmaceutical company, Amgen, and various companies seeking to market generic versions of Amgen's Sensipar®, is well encapsulated in the Report. (*See id.* at 3-7) In short, Teva obtained a district court judgment finding that Teva's cinacalcet hydrochloride ANDA[5] product did not infringe Amgen's patents. (*Id.*) While Amgen appealed

[5] Abbreviated New Drug Application ("ANDA").

that decision, Teva launched its ANDA product at-risk. (*Id.*)[6] After Teva sold $393 million of its ANDA product in just seven days, Amgen and Teva entered into a settlement agreement. (*See id.* at 6-7)

The terms of the Amgen-Teva settlement agreement included a payment from Teva to Amgen of $40 million and Teva's cessation of sales of its ANDA product. (*See id.* at 6) In turn, Amgen gave up any right to seek damages (beyond the $40 million) for the completed sales of Teva's ANDA product and allowed Teva to re-enter the market and again sell its ANDA product in June 2021, approximately five years before the 2026 expiration of Amgen's applicable patent. (*See id.* at 20) The Amgen-Teva agreement also contained an acceleration provision, which allowed Teva to reenter the market with its ANDA product if another generic competitor enters the market at-risk before Amgen and Teva's agreed-upon reentry date. (*See id.*)

Both the Direct Purchaser Plaintiffs and the End Payor Plaintiffs allege that the Amgen-Teva settlement agreement violates antitrust law. The Report determined that because Plaintiffs' antitrust causes of action are inextricably bound up with patent law, they are governed by the Supreme Court's decision in *Actavis*. There the Supreme Court held that an antitrust claim involving a "reverse payment" settlement – that is, where a patentee pays an alleged infringer,

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[6] As Plaintiffs correctly explain:

> [T]he post-launch patent litigation settlement here [between Amgen and Teva] occurred after a non-infringement ruling in Teva's favor, significantly reducing Teva's risk of paying damages and incentivizing Amgen to pay Teva in order to maintain its monopoly.
>
> The non-infringement finding was not, however, without its risk. Amgen could, and did, appeal.

(Objections at 3 & n.13) (internal footnote omitted)

"rather than the other way around" – that "unreasonably diminish[es] competition in violation of the antitrust laws" will constitute an antitrust violation. *Actavis*, 570 U.S. at 141. After finding that *Actavis* governs the analysis, the Report concluded that Plaintiffs did not plausibly allege the existence of a reverse payment and, therefore, recommended dismissal of the complaints. (Report at 20, 22)

Plaintiffs' Objections rest on multiple grounds. Plaintiffs' principal contention is that *Actavis* does not even apply to their claims. Instead, in Plaintiffs' view, this case does not involve a reverse payment but a "rank allocation agreement between Teva and Amgen" which is *per se* unlawful. (Objections at 3) In the alternative, if the Court finds that that *Actavis* governs, then Plaintiffs' position is that they have adequately pled a plausible claim of an unreasonable reverse payment. (*See id.* at 3-4) That is, Plaintiffs contend that they have "sufficiently pled that Teva received a large and unjustified payment under *Actavis*" and its rule of reason. (*Id.* at 3-4)

In reviewing these matters *de novo*, the Court has concluded, consistent with the Report, that *Actavis* and the rule of reason apply. But the Court has also concluded that, under the *Actavis* standard, Plaintiffs have pled plausible antitrust claims (although not all of what Plaintiffs plead is plausible). On this latter point, then, the Court has reached a different conclusion than the Report.

Plaintiffs' Sherman Act Claims and Theories of Antitrust Violations

Count One of both the Direct Purchaser Plaintiffs' and End Payor Plaintiffs' Consolidated Complaints allege a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, which prohibits agreements in restraint of trade. (*See* Report at 8-9) "To establish a violation of Section 1, a plaintiff must prove: (1) concerted action by the defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted

actions were illegal; and (4) that it was injured as a proximate result of the concerted action." *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005). In support of their Section 1 claims, Plaintiffs specifically contend that the Amgen-Teva agreement was

> an unlawful market division agreement . . . . the purpose and effect of which was 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 to and at supra-competitive levels.

(D.I. 13 ("DPP Compl.") ¶ 233; *see also* D.I. 12 ("EPP Compl.") ¶¶ 105-12)

The Report recommended that the Section 1 claims be dismissed, finding that none of the theories as to how the Amgen-Teva agreement is allegedly unlawful state a claim on which relief may be granted. On *de novo* review, as explained further below, the Court concludes that a portion of Plaintiffs' Section 1 claims survive the motions to dismiss, specifically the theories embodied in statements a and c above (but not b).

Count Two of both the Direct Purchaser Plaintiffs' and End Payor Plaintiffs' Consolidated Complaints allege a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, which prohibits monopolization. (*See* Report at 9) To succeed on a Section 2 monopolization claim, the plaintiff must demonstrate (1) the defendant's possession of monopoly power in a relevant market and (2) anticompetitive conduct. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). In support of their Section 2 claims, Plaintiffs allege that Amgen:

> engaged in an exclusionary conduct scheme that involved (i) paying Teva to remove its generic product from the market and

> delay its entry; and (ii) deterring all generic manufacturers from marketing generic cinacalcet hydrochloride before the expiration of the [Amgen] patent or another agreed to delayed date, through use of anticompetitive acceleration clauses.

(DPP Compl. ¶ 244; *see also* EPP Compl. ¶¶ 113-22)

The Report recommended that the Section 2 claims be dismissed, finding that none of the theories as to how the Amgen-Teva agreement is allegedly unlawful state a claim on which relief may be granted. On *de novo* review, as explained further below, the Court concludes that a portion of Plaintiffs' Section 2 claims survive the motions to dismiss, specifically the theories embodied in statement i above (but not ii).

***Actavis* and the Rule of Reason Govern the Analysis of the Sufficiency of Plaintiffs' Claims**

Judge Hall found that Plaintiffs' "market allocation" theory was not supported in detail. (*See* Report at 15) No allegation exists "that 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. The Court is thus not confronted with an allegation, for example, that Defendants agreed prior to Teva's launch that Teva could enter the market and they would share monopoly profits." (*Id.*) Instead, Plaintiffs' claims put before the Court a challenge to a "settlement agreement between Teva and Amgen, under which (Plaintiffs allege) Teva agreed to exit the market. That makes this case governed by *Actavis*" and its rule of reason, rather than presenting an allegation of a *per se* unlawful market allocation. (*Id.*) The Court agrees with and adopts this portion of the Report.

In *Actavis*, the Supreme Court "recognize[d] the value of settlements." 570 U.S. at 153. In seeking to balance promotion of settlement of litigation with patent and antitrust doctrines, the Court held that a quick-look, *per se* antitrust review of patent settlements is not appropriate, "because the likelihood of a reverse payment bringing about anticompetitive effects depends

upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 159. Thus, a reverse payment settlement of a patent dispute is governed by a rule of reason analysis. *See id.* at 159-60; *see also* Report at 12-14.[7]

With respect to the applicability of *Actavis* to the allegations here, Judge Hall put it well:

> *Actavis* . . . considered the relationship between the antitrust laws and patent settlements. And it stated the standard to be applied where the particular restraint being challenged is an agreement by a generic drug manufacturer to stay off the market. That is the case here.

(Report at 14-15) The Court agrees and, accordingly, will apply *Actavis* and the rule of reason to assess the sufficiency of Plaintiffs' claims.

Plaintiffs Adequately Allege Reverse Payment Claims

Plaintiffs "allege that Teva agreed to stay out of the cinacalcet market in exchange for two forms of value from Amgen: (1) 'Teva's retained revenue' from its at-risk cinacalcet launch; and (2) an acceleration provision allowing Teva to resume sales of its generic product if another generic launched before Teva's agreed-upon entry date." (Report at 17) Judge Hall found that

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[7] Antitrust scholar Herbert Hovenkamp has explained how a patent settlement does not present a typical *per se* antitrust violation. *See* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F.L.R. 11, 19-20 (2004). The *per se* rule "is reserved for a small subset of offenses that have been found to be clearly anticompetitive on a number of occasions. . . . [When a type of challenged restraint] is virtually always anticompetitive, from that point on the restraint can be condemned simply upon proof that is has occurred." *Id.* "By contrast, the 'rule of reason' is reserved for types of practices that are facially ambiguous. . . . The practice might be anticompetitive under some circumstances but not others. . . . Or a practice, while *prima facie* anticompetitive, may have perfectly innocent or procompetitive explanations that can be raised as defenses." *Id.* at 20. In the patent context, settlements "should be subject to" a rule of reason analysis. *Id.* at 22. "[T]here are good reasons for courts to encourage good faith settlements," even though such settlements "may not be as competitive as [an outcome] where the patent is declared invalid and the infringement defendant plus anyone else who wants to may now enter competition with the patentee." *Id.* at 23.

neither constituted a reverse payment but, instead, a payment from the accused infringer to the patentee; i.e., a "commonplace form of settlement" with a "compromise damages amount." (Report at 17-18) Plaintiffs object to these conclusions, claiming that the Report "ignores the[] allegations and economic realities" and wrongly "exalts form over substance." (Objections at 6)

The Third Circuit, in applying *Actavis*, has stated that an actionable reverse payment occurs when there is "an unexplained large transfer of value from the patent holder to the alleged infringer." *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015). The Third Circuit has further instructed that the simple inclusion of "a token payment by the purportedly infringing generic manufacturer" does not "shield [patent] settlements from antitrust review." *F.T.C. v. AbbVie Inc.*, 976 F.3d 327, 355 (3d Cir. 2020). To hold otherwise would mean that "unlawful reverse payment settlement agreements attempting to eliminate the risk of competition would escape review." *Id.* What matters, then, are two principles: "First, a reverse payment's legality depends mainly on its economic substance, not its form." *Id.* at 356. Second, a plaintiff can meet the antitrust pleading standard for reverse payments "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." *Id.*

Applying the Third Circuit's guidance to Plaintiffs' "retained value" allegations, the Court concludes that Plaintiffs have adequately pled the existence of an unlawful reverse payment. Although Teva paid Amgen $40 million as part of the Amgen-Teva settlement of Amgen's patent infringement claims against Teva, that "forward" payment cannot be divorced from what Teva did ***not*** pay Amgen. Teva's launch of its generic product was at risk. Were Amgen to have prevailed in its then-ongoing appeal of the district court's finding of non-infringement by Teva, Amgen would have been entitled to seek the entire value of Amgen's lost

profits (an amount which likely exceeded the at-risk profits Teva earned). By dropping that appeal, and thereby giving up its claim to all but $40 million (and not even the full $393 million of revenues Teva had earned from its at-risk launch), Amgen was permitting Teva to retain at least some of the profits Teva had earned at Amgen's expense. That retention constitutes a "transfer of value" to Teva that may be proven, under a rule of reason analysis (considering all the pertinent factors) to be unlawful (i.e., "large and unjustified") under *Actavis* and its Third Circuit progeny.

Defendants observe that "[a]n essential characteristic of an improper reverse payment is the brand providing the generic with 'a share of its monopoly profits' that the brand earns from the generic's agreement not to compete." (Response at 5-6) (quoting *King Drug*, 791 F.3d at 405) While Defendants deny that this is what occurred here, insisting instead Teva earned its revenue from the marketplace by competing with Amgen (*id.* at 6) (citing Report at 18), Plaintiffs plausibly allege that the 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 market in exchange for (among other things) keeping most of the profits the generic earned over those few days. (*See, e.g.*, EPP Compl. ¶ 63 ("Teva still realized over $170 million in net revenues, which . . . is far more than it could have retained absent the unlawful agreement."); *id.* ¶ 68 ("[B]y entering its illicit agreement with Amgen, Teva ensured that the enormous profits it reaped from its one-week of sales would not be significantly reduced by price competition from rival Sensipar generics."); DPP Compl. ¶¶ 72-78 (describing economics of generic pricing); *id.* ¶ 90 (alleging Teva agreement ensured no additional generics would erode de facto-exclusivity pricing)) The Court cannot credit Defendants' denial of these facts on a motion to dismiss.

Plaintiffs also challenge the Amgen-Teva agreement's "acceleration provision," by which Amgen agreed that Teva would be permitted to reenter the market with its ANDA product earlier than the otherwise agreed-to reentry date upon market entry by another generic competitor. (Objections at 4, 8-9) The Court agrees with Plaintiffs that the acceleration provision, too, could be proven to constitute value transferred from Amgen to Teva. As the Report (at 20) observes, "[n]o one disputes that such a clause had value to Teva." Consistent with *AbbVie*, 976 F.3d at 358-59, which provides that a transfer of value need not be a cash payment, this additional transfer of value must also be factored into the rule of reason analysis of Plaintiffs' challenge to the Amgen-Teva settlement agreement.[8]

Further, where, as here, there is an allegation that multiple settlement terms are linked, the Court must (on a motion to dismiss) accept that allegation as true. *See AbbVie*, 976 F.3d at 358. Because Plaintiffs allege that the acceleration provision is related to (and indeed part of) the Amgen-Teva settlement, it must be considered as part of the required holistic analysis.[9] Because that acceleration provision has independent value to Teva, and because the "retention of value" (i.e., the $353 million of revenues Teva retained) also has value to Teva, it follows that

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[8] *See also generally* Response at 3 (Defendants stating *Actavis* "endorses compromise entry dates and puts them to antitrust scrutiny, under the rule of reason, only when they are accompanied by some 'reverse payment,'" thereby effectively acknowledging that where – as here – Court has found plausible allegations of reverse payment as well as agreed-upon early entry date and acceleration of such date upon third-party generic entry, rule of reason antitrust scrutiny is required by *Actavis*) (internal emphasis omitted).

[9] The Court does not agree with Plaintiffs' unwarranted assertion that Judge Hall "improperly atomized the components" of the challenged settlement agreement, considering them in a "piecemeal" fashion rather than "holistically." (Objections at 1, 5 & n.20, 8) The Report expressly and repeatedly stated that it was evaluating Plaintiffs' challenges as a whole, finding them deficient whether viewed "alone or viewed together." (Report at 22; *see also id.* at 17) Plaintiffs provide no support for their suggestion that the Court should reject Judge Hall's statement that she followed the appropriate holistic approach. *See generally In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 322 (D.R.I. 2019) (stating that reverse payment claims must "be considered holistically to determine [their] alleged effect[s] on competition").

both in combination also constitute "value" to Teva; more pertinently, they together constitute value transferred to Teva as a result of Amgen's actions. That, combined with the allegation that such value is "large and unjustified," is sufficient to state a claim for purposes of Section 1 of the Sherman Act.

Given these conclusions, the Court also finds plausible (and sufficiently alleged) Plaintiffs' allegations that Amgen and Teva agreed that Teva would leave the market and delay its reentry into the market until the agreed-upon date in 2021, for the purpose and effect of raising and maintaining the supra-competitive prices Plaintiffs would have to pay for Sensipar®. Plaintiffs' related allegations that these same actions promoted Amgen's monopoly in the relevant market are likewise adequate to state a plausible claim for relief under Section 2 of the Sherman Act.

Accordingly, at this stage of the proceedings, taking the well-pled factual allegations of the Complaints as true, Plaintiffs have stated plausible claims of violations of Sections 1 and 2 of the Sherman Act. The motions to dismiss must, therefore, be denied. *See generally AbbVie*, 976 F.3d at 356 ("If a plaintiff plausibly alleges that an agreement's anticompetitive effects outweigh its procompetitive virtues, the district court must accept that allegation and allow the plaintiff to take discovery. If genuine issues of material fact remain, the rule-of-reason analysis is for the factfinder, not the court.").

Defendants' Criticisms

The Court is not persuaded by Defendants' criticisms (many of which have been addressed above) of the conclusions the Court has now reached. Defendants write:

> Plaintiffs' theory contradicts the core principles of the Supreme Court's decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), and ignores two inescapable facts: *first*, Teva earned money from its at-risk sales by competing ***against*** Amgen with lower prices, not

> from restricting competition; and *second*, Teva's compromise entry date is a *pro-competitive* settlement that allows early entry before patent expiration.

(Response at 1-2)

The Court disagrees with Defendants' analysis. As has been stated repeatedly, the Court views its decision as entirely consistent with (and not contradicting) *Actavis*. And Defendants' purported "two inescapable facts" cannot be taken as true at this stage of these cases.

Teva earned money from competing against Amgen for one week in a market that Amgen had already monopolized (based on patents) and in which Amgen quickly reestablished its monopoly precisely by executing the settlement agreement with Teva. One might view this as Teva earning money from briefly competing in the marketplace. Alternatively, one might view it as Teva taking a small, temporary slice of Amgen's monopoly profits for only so long as benefited Amgen and Teva, who ceased their ostensible "competition" before their actions would harm both of them by opening the floodgates to additional generic competition (by operation of the acceleration clauses in settlement agreements Amgen had executed with other manufacturers of generic cinacalcet).[10] On a motion to dismiss, the Court must credit the latter view, which might well support a conclusion that Defendants' actions were, under a rule of reason analysis and considering the totality of circumstances, anti-competitive rather than pro-competitive.

Similarly, while 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

[10] *See Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 396 n.25 (D. Del. 2019) (describing allegation that Amgen-Teva settlement agreement constituted patent misuse because of, *inter alia*, "the fact that Amgen and Teva structured their agreement so that both make more money the longer the market remains free of other generic competition"), *aff'd*, 778 Fed. App'x 135 (3d Cir. 2019).

(despite a non-infringement finding in Teva's favor) and approximately 2 ½ years ***before the agreed-upon re-entry date*** (June 2021), as anti-competitive. Discovery and further proceedings will be needed before it will be begin to be possible to discern which of these competing plausible inferences is correct.

One additional criticism merits discussion. Defendants, echoing the Report, suggest that a conclusion there is plausibility to any portion of Plaintiffs' claims will deter patent settlements (and not just in the Hatch-Waxman context) by raising the specter of antitrust challenges to nearly all such settlements and, hence, the prospect of having to litigate patent infringement and validity issues (in the context of defending antitrust claims by third parties) that the settling parties were seeking to avoid. (*See, e.g.*, Response at 7 (decrying "terrible competition policy"); *see also* Report at 17-20) Regardless of whatever empirical or predictive accuracy these contentions may have, the Court has concluded that the result it reaches today is compelled by *Actavis* and the Third Circuit cases that have applied it. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 253-54 (3d Cir. 2017) (holding that forgiveness of damages claim may constitute actionable reverse payment where it is large and unjustified); *King Drug*, 791 F.3d at 403 ("*Actavis*'s holding can[not] be limited to reverse payments of cash" as any "unexplained large transfer of value from the patent holder to the alleged infringer" may state antitrust claim). Defendants' policy concerns (no matter how well-founded) do not alter the outcome.

Plaintiffs' Theories That Amgen and Teva Deterred Other Generics Will Be Dismissed

The Court does not find plausible the allegations that the Amgen-Teva agreement constitutes an unlawful effort to "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." (*E.g.*, DPP Compl. ¶ 233) (emphasis added) As an initial (and dispositive)

matter, the Court has already stated that it agrees with the Report that the market allocation theory ***as pled*** contains insufficient specificity to survive the motions to dismiss. (*See supra* at 7) (quoting Report at 15)[11]

The Court also agrees with Defendants that if their agreement was lawful when they executed it, that same agreement could not later become unlawful solely due to the actions of other parties, e.g., other generic competitors of Teva. (*See* Response at 7-8) ("The agreements and actions of third parties cannot possibly be the basis for a plausible claim that the Amgen-Teva settlement contains a 'reverse payment' and violates the antitrust laws.") Further, the allegations on which these claims rest are not plausible. ANDA filers understand that other manufacturers of generic drugs may also file ANDAs 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. *See, e.g., Belcher Pharm., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331 n.4 (D. Del. 2019) ("[I]t is not uncommon for multiple ANDAs to be filed on the same patent at the same time . . . .").[12] Because ANDA filers

[11] The Court recognizes that in connection with denying Amgen's motion for a preliminary injunction to enjoin Cipla from launching its generic product at risk, the Court stated: "it seems plausible that Amgen and Teva may have colluded to divide up the market for cinacalcet, in order to share supracompetitive profits and deter true generic competition. This collusion, if proven, could be an antitrust violation under a rule of reason analysis." *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 396 (D. Del. 2019), *aff'd*, 778 Fed. App'x 135 (3d Cir. 2019) (internal footnote omitted). The Court believes today's decision is not inconsistent with its earlier statement. As an initial matter, the statement in the preliminary injunction opinion was dicta. More importantly, the Court's speculation that a plausible claim might be stated has now run into the actual claims Plaintiffs have attempted to state and Plaintiffs' efforts to do so are deficient, as explained in this Order. Furthermore, events that post-date the Court's preliminary injunction ruling (e.g., Cipla's at-risk launch and that of yet another generic competitor) detract even more from the plausibility of Plaintiffs' claims. (*See* Response at 2 n.3)

[12] *See also Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356-57 (Fed. Cir. 2008) (describing Hatch-Waxman Act provisions creating potential 180-day period of exclusivity as incentive for first generic manufacturer to file ANDA).

understand the nature of competition in the pharmaceutical market, Plaintiffs have not plausibly alleged that other manufacturers of generic cinacalcet hydrochloride would be deterred from launching their generic product just because Amgen agreed to allow Teva also to re-launch upon any third-party launch.[13]

End Payor Plaintiffs' State Law Claims

The End Payor Plaintiffs also allege violations of various state laws. (*See* Report at 9-10) The End Payor Plaintiffs agreed that if all federal antitrust claims are dismissed, then their state law claims should be dismissed as well. (*See, e.g.*, Report at 25) Because Judge Hall recommended dismissal of all federal antitrust claims, she understandably and appropriately did not address the sufficiency of the state law claims. (*See id.*) Therefore, no party had any basis to object to the Report's treatment of the state law claims.

Now, however, the Court has decided Plaintiffs have stated federal antitrust claims that survive the motions to dismiss. If the End Payor Plaintiffs still intend to press their state law claims, Defendants will have an opportunity to renew their challenges to them, and Judge Hall will in that event evaluate their legal sufficiency. Because the motions were referred to Judge Hall and because she has not yet had occasion to analyze the merits of the state law claims, the Court will leave it to her to do so in the first instance (if necessary).

[13] The Court notes the fact (which was litigated extensively in this Court, including in the Cipla action (C.A. No. 19-44) that was part of this multi-district litigation) that other generic drug companies, including Cipla and Aurobindo, did in fact launch their generic cinacalcet hydrochloride products, further demonstrating the implausibility of Plaintiffs' allegations on this point. (*See, e.g.*, DPP Compl. ¶¶ 195-96) (Cipla and Aurobindo launches) These undisputed realities corroborate the Court's conclusions, although they are not necessary to the Court's ruling. Even if ignored, the Court would reach the same conclusion as it does in this Order.

Amendment

The Report (at 25-26) recommends that Plaintiffs be provided an opportunity to file amended complaints. Defendants did not file an objection to this recommendation. Because the Court has concluded that some but not all of Plaintiffs' federal antitrust claims survive (e.g., Plaintiffs have plausibly alleged unreasonably large and unjustified reverse payments were made by Amgen to Teva but have not stated a *per se* unlawful market allocation claim), it will 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. Additionally, given the Court's analysis of the federal claims, the End Payor Plaintiffs should now evaluate whether they wish to continue to pursue their state law claims – and, if they do, Defendants shall have an opportunity to (if they wish) again press their challenges to the state law claims by again moving to dismiss. For all of these reasons, Plaintiffs are directed to file amended complaints within the next 30 days.

November 30, 2020
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT COURT