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:	)	Civil Action No. 19-md-02895-LPS
ALL DIRECT PURCHASER ACTIONS	)	Civil Action No. 19-396-LPS
	)	Civil Action No. 19-1460-LPS
ALL INDIRECT PURCHASER ACTIONS	)	Civil Action No. 19-369-LPS
	)	Civil Action No. 19-1461-LPS
	)	**FILED UNDER SEAL**

REPORT AND RECOMMENDATION

This multidistrict antitrust litigation consists of four putative class actions and one individual action. The operative complaints differ in certain respects, but they all contain allegations of anticompetitive conduct in connection with patent litigation settlements between a brand drug manufacturer and generic manufacturers. Each complaint names two sets of defendants: (1) Amgen Inc. ("Amgen"), the brand manufacturer of Sensipar® (cinacalcet), a drug used to treat secondary hyperparathyroidism and hypercalcemia in certain patients; and (2) Teva Pharmaceuticals USA Inc. and related entities (collectively, "Teva"), a manufacturer of a generic cinacalcet product. There are three categories of plaintiffs: (1) a putative class of those who purchased cinacalcet directly from the manufacturers (the "Direct Purchaser Plaintiffs"); (2) a putative class of those who provided reimbursement for the purchase of cinacalcet (the "End Payor Plaintiffs"); and (3) Cipla Ltd. and Cipla USA, Inc. ("Cipla"), a manufacturer of generic cinacalcet. Each category of plaintiffs is proceeding under its own complaint.

Defendants Amgen and Teva each filed motions to dismiss each of the operative complaints. Each motion was filed on the master multidistrict docket and on the docket(s) of the individual action(s) to which it pertains. I heard argument on all of those motions on April 28, 2020.[1]

This Report and Recommendation relates solely to Defendants' motions to dismiss the Direct Purchaser Plaintiffs' Consolidated Complaint and the End Payor Plaintiffs' Consolidated Complaint. (No. 19-md-2895, D.I. 27; No. 19-396-LPS, D.I. 57; and No. 19-1460-LPS, D.I. 24 (Amgen's motion to dismiss Direct Purchaser Plaintiffs' Consolidated Complaint); No. 19-md-2895, D.I. 30; No. 19-369-LPS, D.I. 39; and No. 19-1461-LPS, D.I. 21 (Amgen's motion to dismiss End Payor Plaintiffs' Consolidated Complaint); No. 19-md-2895, D.I. 31; No. 19-369, D.I. 42; No. 19-396-LPS, D.I. 60; No. 19-LPS-1460, D.I. 27; No. 19-1461-LPS, D.I. 23 (Teva's motion to dismiss Direct Purchaser Plaintiffs' and End Payor Plaintiffs' Consolidated Complaints).)

At bottom, Direct Purchaser and End Payor Plaintiffs allege that they paid too much for cinacalcet drugs because Amgen entered into anticompetitive settlement agreements with generic

[1] The motions currently pending before the Court are

- No. 19-md-2895, D.I. 25 and No. 19-44-LPS, D.I. 238 (Teva's motion to dismiss Cipla's Complaint);
- No. 19-md-2895, D.I. 27; No. 19-396-LPS, D.I. 57; and No. 19-1460-LPS, D.I. 24 (Amgen's motion to dismiss the Direct Purchaser Plaintiffs' Consolidated Complaint);
- No. 19-md-2895, D.I. 30; No. 19-369-LPS, D.I. 39; and No. 19-1461-LPS, D.I. 21 (Amgen's motion to dismiss the End Payor Plaintiffs' Consolidated Complaint); and
- No. 19-md-2895, D.I. 31; No. 19-369-LPS, D.I. 42; No. 19-396-LPS, D.I. 60; No. 19-LPS-1460, D.I. 27; No. 19-1461-LPS, D.I. 23 (Teva's motions to dismiss the Direct Purchaser Plaintiffs' Consolidated Complaint and the End Payor Plaintiffs' Consolidated Complaint).

manufacturers that kept cheaper versions off the market. I conclude that their complaints fail to plausibly allege that those agreements included "large and unjustified" reverse payments to the generic manufacturers, as required to state a federal antitrust claim. *F.T.C. v. Actavis*, 570 U.S. 136, 158 (2013). Accordingly, I recommend that the Court dismiss the federal antitrust claims. End Payor Plaintiffs also assert a number of state law claims based on the same conduct. They do not oppose dismissal of those claims if the Court concludes that the complaints fail to state federal antitrust claims—which I do. Accordingly, I recommend that the Court dismiss the state law claims as well.

I. BACKGROUND[2]

A. Sensipar Patent Litigation

To fully understand Direct Purchaser Plaintiffs' and End Payor Plaintiffs' (together, "Plaintiffs") allegations, it is necessary to be familiar with the applicable framework for drug approval and infringement litigation—commonly known as the Hatch-Waxman Act. The Hatch-Waxman Act has been well explained in numerous cases,[3] and I could describe it no better here. Accordingly, this Report and Recommendation assumes familiarity with the key features of the Hatch-Waxman drug approval process and associated infringement litigation.

Cinacalcet hydrochloride is used to treat secondary hyperparathyroidism and hypercalcemia in certain patients. (No. 19-md-2895, D.I. 13 ("DPP Compl.") ¶ 3; No. 19-md-2895, D.I. 12 ("EPP Compl.") ¶¶ 1, 29.) Amgen has marketed Sensipar, a branded cinacalcet

[2] I assume the facts alleged in Direct Purchaser Plaintiffs' Consolidated Complaint and End Payor Plaintiffs' Consolidated Complaint to be true for purposes of resolving the motions to dismiss for failure to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[3] *See, e.g.*, *Actavis*, 570 U.S. at 142–44 (describing "key features" of the Hatch-Waxman Act); *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 240–41 (3d Cir. 2017) (describing the Hatch-Waxman Act and explaining "at-risk" launches and "authorized generics"); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394–396 (3d Cir. 2015).

formulation, since 2004. According to the complaints, Sensipar is a top-selling drug in the United States, earning Amgen sales of over $1 billion annually since 2015. (DPP Compl. ¶¶ 4–5, 110; EPP Compl. ¶¶ 2, 30.)

The patent covering the cinacalcet drug substance, U.S. Patent No. 6,011,068 ("'068 patent"), expired on March 8, 2018. (DPP Compl. ¶¶ 6, 110; EPP Compl. ¶ 4.) However, Amgen also owns U.S. Patent No. 9,375,405 ("'405 patent"), which is listed in the Orange Book in connection with Sensipar and covers cinacalcet formulations. (DPP Compl. ¶¶ 8, 95, 103, 106; EPP Compl. ¶¶ 4, 31.) The '405 patent does not expire until September 22, 2026. (DPP Compl. ¶ 8; EPP Compl. ¶ 4.[4])

Pursuant to the Hatch-Waxman scheme, numerous generic manufacturers filed Abbreviated New Drug Applications (ANDAs) with the FDA seeking to market their generic versions of Sensipar upon expiry of the '068 (drug substance) patent. (DPP Compl. ¶¶ 7–9, 111; EPP Compl. ¶¶ 3–4, 32.) By June 2017, twenty generic manufacturers had filed ANDAs containing "paragraph IV" certifications as to the '405 (formulation) patent, *i.e.*, the generic manufacturers asserted that the patent was invalid, unenforceable, or would not be infringed by their generic products. (DPP Compl. ¶¶ 9, 111–113; EPP Compl. ¶¶ 3–4, 33.) Amgen, in turn, filed infringement lawsuits against each of them.[5] (DPP Compl. ¶¶ 115, 119–121; EPP Compl. ¶ 34.) Under the particular circumstances, none of the potential generic manufacturers would have been entitled to 180-day first-filer exclusivity. (DPP Compl. ¶¶ 12, 67; EPP Compl. ¶¶ 5, 34.)

[4] End Payor Plaintiffs inadvertently listed the expiration date as September 22, 2016 in their complaint but do not dispute that the correct date is September 22, 2026.

[5] The submission of an ANDA containing a paragraph IV certification is "an act of infringement." 35 U.S.C. § 271(e)(2)(A).

Most of the generic manufacturers settled with Amgen before trial. (DPP Compl. ¶¶ 13, 122, 133–38, 143–45; EPP Compl. ¶¶ 5, 35.) The terms of those settlements included an agreement that the generic could enter the market at a specified date (license date) prior to the expiration of the '405 patent; the date of entry varied among the settling defendants. Each of the settlement agreements also included an "acceleration clause" that allowed the settling generic to enter the market before its agreed entry date if a certain triggering event occurred. (DPP Compl. ¶¶ 13–16, 19, 122–24, 128; EPP Compl. ¶¶ 5, 36–37.) The triggering event involves several conditional contract provisions,[6] but roughly speaking, the acceleration clauses would be triggered if another generic manufacturer entered the market without authorization from Amgen (launched "at risk") and did not agree with Amgen within a certain period of time to cease selling. (DPP Compl. ¶¶ 16, 124–125; EPP Compl. ¶¶ 5, 37–39.)

By the time the infringement cases got to trial before the Honorable Mitchell S. Goldberg in March 2018, there were only four generic manufacturers still litigating: Teva, Piramal Healthcare UK Ltd., Amneal Pharmaceuticals LLC, and Zydus Pharmaceuticals (USA) Inc. After a bench trial, the Court found on August 24, 2018 that Teva, Piramal, and Amneal did not infringe any of the asserted claims of the '405 patent, but Zydus did. *Amgen Inc. v. Amneal Pharm. LLC*, 328 F. Supp. 3d 373 (D. Del. 2018). (DPP Compl. ¶¶ 21, 161–70; EPP Compl. ¶¶ 6, 48.) Amgen and Zydus appealed. *Amgen Inc. v. Amneal Pharm. LLC*, 945 F.3d 1368 (Fed. Cir. 2020).[7] (DPP Compl. ¶ 173; EPP Compl. ¶¶ 6, 48.)

[6] For a full discussion of those provisions as they appear in the settlement agreement between Amgen and Cipla, *see Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 394 (D. Del. 2019) and *Cipla Ltd. v. Amgen Inc*, 778 F. App'x 135, 139–41 (3d Cir. 2019).

[7] For additional history regarding that dispute, *see Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. at 389–93; and *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x at 137–38.

On December 27, 2018, during the pendency of the appeals, Teva received FDA approval to sell its generic product. Teva launched at risk that same day. (DPP Compl. ¶¶ 22–23, 175–77; EPP Compl. ¶¶ 7, 49.) During the next week, Teva "flooded the market with eight to nine months-worth of product sales, reaping over $393 million in revenue in just seven days." (DPP Compl. ¶ 24; EPP Compl. ¶¶ 7, 50.)

B. Amgen-Teva Settlement

A week after Teva's launch, and while Amgen's appeal was still pending, Amgen and Teva reached a settlement (the "Amgen-Teva agreement"). (DPP Compl. ¶¶ 24–25, 181; EPP Compl. ¶¶ 8, 57.) Pursuant to that agreement, Teva was to stop selling its generic product until a compromise entry date of June 30, 2021 (five years before the '405 patent was set to expire), subject to the operation of an acceleration clause. (DPP Compl. ¶¶ 25, 185, 236; EPP Compl. ¶¶ 8, 57–58.) Teva was not required to "pull . . . off the market" any of the generic product it had already sold, but it was required to pay Amgen up to $40 million.[8] (DPP Compl. ¶¶ 183, 185–188; EPP Compl. ¶¶ 8, 57–58.) According to Direct Purchaser Plaintiffs' Consolidated Complaint, Teva's payment to Amgen "represented only a fraction of the hundreds of millions of dollars Teva actually made launching at risk for just six days." (DPP Compl. ¶¶ 26, 183, 185–186; EPP Compl. ¶¶ 8, 61.) Plaintiffs do not allege that Amgen authorized or had prior knowledge of Teva's at-risk launch.

Pursuant to the Amgen-Teva agreement, the parties were also required to, and did, jointly move the district court for an "indicative ruling"[9] that it would vacate its finding of non-

[8] The amount Teva had to pay depended (in part) on whether other generics entered the market during a certain period. (*Id.*)

[9] *See* Fed. R. Civ. P. 62.1 (permitting parties to move the district court for an "indicative ruling" on a motion that the court then lacks authority to grant because the case is on appeal).

infringement as to Teva and enter a consent judgment of infringement. (DPP Compl. ¶¶ 182, 184; EPP Compl. ¶¶ 10, 64.) Judge Goldberg denied that motion. *Amgen Inc. v. Amneal Pharms. LLC*, C.A. No. 16-853, D.I. 439 (D. Del. Mar. 26, 2019). (DPP Compl. ¶ 184; EPP Compl. ¶¶ 10, 69.)

According to Plaintiffs, Amgen's "quick" settlement with Teva on January 2, 2019 (one week after Teva's at-risk launch) prevented "triggering" of the acceleration clauses in Amgen's agreements with the other settling generic manufacturers. (DPP Compl. ¶ 189; EPP Compl. ¶¶ 9, 58.) Notwithstanding, Cipla launched on March 6, 2019, and another settling generic manufacturer launched on July 15, 2019. (DPP Compl. ¶¶ 195–196; EPP Compl. ¶ 11.)

C. Multidistrict Antitrust Litigation

Pending in this multidistrict litigation are four class actions and one individual action.

On January 8, 2019, a few days after the Amgen-Teva agreement was announced, Cipla filed suit in this court seeking a declaratory judgment that it is entitled to launch its generic product under the terms of its settlement with Amgen. Cipla also alleged that Amgen's conduct violated federal and state antitrust laws. (No. 19-44, D.I. 2.) Cipla later amended its complaint to (among other things) add a fraud claim and add Teva as a defendant. (*Id.*, D.I. 73 ("Cipla Complaint").) On July 16, 2020, Cipla and Amgen filed a stipulation of dismissal as to the claims against Amgen. (*Id.*, D.I. 285.)

On February 26, 2019, César Castillo, Inc. filed a class action antitrust complaint in this district on behalf of direct purchasers of cinacalcet. (No. 19-396, D.I. 1.) On April 9, 2019, KPH Healthcare Services, Inc. filed a direct-purchaser class action complaint in the Eastern District of Pennsylvania. (No. 19-1460, D.I. 1.)

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. (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. (No. 19-1461, D.I. 1.)

On July 31, 2019, the United States Judicial Panel on Multidistrict Litigation transferred all five actions to this district for coordinated pretrial proceedings. (No. 19-md-2895, D.I. 1.) *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, 412 F. Supp. 3d 1344 (U.S. Jud. Pan. Mult. Lit. 2019). On September 13, 2019, César Castillo, Inc. (now César Castillo, LLC) and KPH Healthcare Services, Inc. (together, "Direct Purchaser Plaintiffs") filed a Consolidated Class Action Complaint on behalf of direct purchasers. (No. 19-md-2895, D.I. 13.) On September 13, 2019, UFCW Local 1500 Welfare Fund, Teamsters Local 237 Welfare Fund, and Teamsters Local 237 Retirees' Benefit Fund (together, "End Payor Plaintiffs") filed a Consolidated Class Action Complaint on behalf of indirect purchasers. (No. 19-md-2895, D.I. 12.)

D. Current Motion

This Report and Recommendation relates solely to Amgen's and Teva's motions to dismiss Direct Purchaser Plaintiffs' Consolidated Complaint and End Payor Plaintiffs' Consolidated Complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. (No. 19-md-2895, D.I. 27, 30, 31; No. 19-369-LPS, D.I. 39, 42; No. 19-396-LPS, D.I. 57, 60; No. 19-1460-LPS, D.I. 24, 27; and No. 19-1461-LPS, D.I. 21, 23.)

Direct Purchaser Plaintiffs' Consolidated Complaint includes two claims for relief under the federal antitrust laws. Count One alleges that Amgen and Teva violated Section 1 of the Sherman Act, 15 U.S.C. § 1, which prohibits agreements in restraint of trade. (DPP Compl. ¶¶ 232–241.) In particular, it alleges 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.

(*Id.* ¶ 233.) Count One of End Payor Plaintiffs' Consolidated Complaint contains near-identical allegations. (EPP Compl. ¶¶ 105–112.)

Count Two of Direct Purchaser Plaintiffs' Consolidated Complaint alleges that Amgen violated Section 2 of the Sherman Act, 15 U.S.C. § 2, which prohibits monopolization. (DPP Compl. ¶¶ 242–248.) In support of that count, 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 '405 patent or another agreed to delayed date, through use of anticompetitive acceleration clauses." (*Id.* ¶ 244.) Count Two of End Payor Plaintiffs' Consolidated Complaint contains near-identical allegations. (EPP Compl. ¶¶ 113–122.)

End Payor Plaintiffs also allege violations of the laws of all fifty states, the District of Columbia, and Puerto Rico. Count Three of End Payor Plaintiffs' Consolidated Complaint alleges "Conspiracy and Combination in Restraint of Trade" under the laws of twenty-seven states, and it contains similar allegations as Count One. (EPP Compl. ¶¶ 123–131.) Count Four alleges "Monopolization and Monopolistic Scheme" under the laws of twenty-seven states, and it contains similar allegations as Count Two. (*Id.* ¶¶ 132–138.) Count Five is styled "State Consumer Protection Violations" and alleges violations of three states' consumer protection statutes. (*Id.*

¶¶ 139–158.) Count Six alleges unjust enrichment under the laws of forty-eight states, the District of Columbia, and Puerto Rico. (*Id.* ¶¶ 159–222.) The state law claims are all premised on the contention that Amgen's patent settlement agreements unlawfully restrained the market for generic cinacalcet drugs and that consumers paid higher prices as a result.

II. LEGAL STANDARDS

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

In determining the sufficiency of the complaint under the plausibility standard, all "well-pleaded facts" are assumed to be true, but legal conclusions are not. *Id.* at 679. "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (internal marks omitted).

III. DISCUSSION

A. Plaintiffs' Federal Antitrust Claims

Plaintiffs allege that Amgen's settlement agreements with generic manufacturers, including Teva, violated the federal antitrust laws. The Supreme Court discussed the circumstances under which Hatch-Waxman settlements can violate the antitrust laws in *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013).

The particular issue before the Court in *Actavis* was whether so-called "reverse-payment"—aka "pay for delay"—settlements are subject to antitrust scrutiny. Prior to that case, manufacturers seeking to market generic versions of the brand-name drug AndroGel had filed ANDAs containing certifications that the relevant patent owned by the brand, Solvay Pharmaceuticals, was invalid and not infringed. Solvay filed patent infringement lawsuits against the generic manufacturers, but it ultimately settled with each of them. Under the terms of each settlement, the generic manufacturer agreed not to bring its generic version to market for approximately nine years ("unless someone else marketed a generic sooner"), and Solvay agreed to pay the generic manufacturer millions of dollars ("12 million in total to Paddock; $60 million in total to Par; and an estimated $19-$30 million annually, for nine years, to Actavis"). *Id.* at 145.

The FTC filed suit against the settling parties, alleging that they violated the antitrust laws "by unlawfully agreeing to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years." *Id.* The district court dismissed the FTC's complaint, and the Eleventh Circuit affirmed, holding that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the

exclusionary potential of the patent." *F.T.C. v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

The Supreme Court reversed. *Actavis*, 570 U.S. at 158–60. The Court assumed that the "anticompetitive effects fall within the exclusionary potential of the patent" but found that it did not immunize the challenged settlement agreements because what the holder of a valid and infringed patent could do "does not by itself answer the antitrust question." *Id.* at 147. The Court thus found it improper to "determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Id.* at 148.

The Court identified "five sets of considerations" leading to its conclusion that reverse payment settlements are subject to antitrust scrutiny under the rule of reason. Among them was its recognition that a reverse payment has "the potential for genuine adverse effects on competition" because it "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* at 153–54 (quoting *F.T.C. v. Indiana Federation of Dentists*, 476 U.S. 447, 460–61 (2009)). The Court also stated that the "anticompetitive consequences" of exclusion payment settlements would "sometimes prove unjustified." *Id.* at 156. And it stated that "where a reverse payment threatens to work unjustified anticompetitive harm," the patentee likely possesses market power to bring about that harm. *Id.* at 157.

The Court also discounted the Eleventh Circuit's concerns about the feasibility of litigating patent validity in the context of the antitrust case. The Supreme Court held that it will "normally" not be necessary "to litigate patent validity" because the size of an "unexplained large reverse

payment can provide a workable surrogate for a patent's weakness." *Id.* at 157–58. The Court further stated that "the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit." *Id.* at 158. Rather, the parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* The Court concluded that those considerations "taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements." *Id.*

The *Actavis* majority also responded to the dissent's concern that permitting antitrust scrutiny of patent litigation settlements could not logically be limited to reverse-payment agreements in the Hatch-Waxman context. *Id.* at 168–73 (Roberts, J. (dissenting)). The majority stated that its holding did not extend to the "commonplace" form of settlement where "Company A sues Company B for patent infringement and demands, say, $100 million in damages," but the parties settle the case, and as part of the settlement, "B (the defendant) . . . pay[s] A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example." *Id.* at 151 (citing Marc G. Schildkraut, *Patent–Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1046 (2004)); *see* Schildkraut, 71 Antitrust L.J. at 1046 (suggesting that the hypothetical includes "an implicit net payment" from A to B of $60 million—*i.e.*, the amount of the settlement discount). The Court stated that a patentee's agreement to accept a fraction of its total claim was not subject to antitrust liability "for that reason alone." *Actavis*, 570 U.S. at 152.

In sum, the Supreme Court held that a reverse payment settlement in the Hatch-Waxman context may be challenged under the antitrust laws where the payment is "large and unjustified."

Id. at 158. But the Court indicated that it did not intend to subject patent settlements to antitrust liability merely because the patentee settled for a fraction of its claim.

1. *Actavis* applies to Plaintiffs' antitrust claims.

The parties first dispute whether *Actavis* has any application to this case at all. According to Plaintiffs, the complaints allege a "rank agreement to allocate the U.S. market for cinacalcet hydrochloride tablets," which is *per se* unlawful under the antitrust laws. (No. 19-md-2895, D.I. 72 at 7–8; DPP Compl. ¶ 234; EPP Compl. ¶ 107.) Plaintiffs assert that "*Actavis* did not . . . insulate all schemes involving settlements of patent infringement cases from *per se* or 'quick look' scrutiny," and that "[h]orizontal market allocation agreements remain *per se* unlawful." (No. 19-md-2895, D.I. 72 at 7–8.) In support, Plaintiffs cite *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972), where the Supreme Court applied a *per se* rule of illegality to an agreement between grocers to sell a certain brand of product only in each grocer's assigned geographic territory.

Defendants Amgen and Teva contend that because this case involves the settlement of patent litigation between a generic and a brand that involves an agreement by the generic to exit the market, it should be analyzed under the framework set forth in *Actavis*. Under that framework, "plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251–52 (3d Cir. 2017) (quoting *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016)). If Plaintiffs do so (and Defendants say they haven't), the challenged settlement is subject to antitrust scrutiny under the rule of reason. *Id.*

I agree with Defendants. Plaintiffs are surely correct that *Actavis* did not insulate "all schemes" that "involve" patents from *per se* scrutiny. But the *Topco* case cited by Plaintiffs did not involve the assertion of patent rights or the settlement of patent ligation. *Actavis*, in contrast,

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.

Plaintiffs' brief does not explain their "market allocation" theory in any detail. Their request for the Court to find the Amgen-Teva agreement *per se* unlawful suggests that they may view the issues of patent infringement and validity as irrelevant to the analysis, but they cite no authority in support of that proposition. Nor do Plaintiffs allege 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. Rather, the "agreement" being challenged under Section 1 of the Sherman Act is the settlement agreement between Teva and Amgen, under which (Plaintiffs allege) Teva agreed to exit the market. That makes this case governed by *Actavis*.

2. Plaintiffs do not plausibly allege a "large and unjustified" reverse payment to Teva.

Defendants allege that Plaintiffs' complaints fail to plausibly allege a "large and unjustified" reverse payment in accordance with *Actavis*, necessitating dismissal of the Section 1 claims.[10] I agree.

As alleged, the cash payments under the Amgen-Teva agreement go from Teva (the generic) to Amgen (the brand). They flow in the forward direction, not in reverse. But it is not

[10] "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).

enough to look at the monetary payments. The Third Circuit has explained that "*Actavis*'s holding can[not] be limited to reverse payments of cash" and that a complaint states a claim under the Sherman Act if it alleges "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).

In *King Drug*, the Third Circuit analyzed a settlement agreement in which a brand manufacturer agreed not to produce an "authorized generic" version of its drug (a so called "no-AG agreement") in return for a generic manufacturer abandoning its patent fight and delaying its entry into the market. The Court noted that "a brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits" by competing with the settling generic once it entered the market. *Id.* at 405. The no-AG agreement essentially transferred those potential profits to the settling generic. Such transfers, the Court stated, "are likely to present the same types of problems as reverse payments of cash." *Id.* at 404. Because such an agreement may "represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer," the Court held that it was subject to challenge under the antitrust laws. *Id.* at 394.

The Court's opinion in *In re Lipitor Antitrust Litigation*, 868 F.3d 231 (3d Cir. 2017) likewise considered an allegation that a Hatch-Waxman settlement agreement violated the antitrust laws because it transferred "value" from the brand to the generic. Prior to that case, Pfizer sued a generic company for infringement of a patent covering Pfizer's drug Lipitor. While that case was pending, Pfizer was also involved in a litigation with the generic company over another drug, Accupril. *In re Lipitor*, 868 F.3d 231, 242–46. After the generic launched its version of Accupril at risk, the parties settled both cases. In connection with the settlements, the generic agreed to a

delayed entry date for its generic version of Lipitor, and it agreed to pay $1 million to Pfizer in connection with the Accupril litigation. In the subsequent antitrust case, direct purchasers of Lipitor alleged that Pfizer's Accupril infringement claims were likely to succeed and worth way more than $1 million, and, thus, Pfizer's agreement to release them for a fraction of their value amounted to a "large and unjustified" payment to the generic manufacturer. The Third Circuit agreed, holding that the plaintiffs had plausibly alleged that generic company's $1 million payment was a smokescreen for the real deal between the settling parties: the release of Pfizer's valuable Accupril damages claim in exchange for the generic's delayed entry in the Lipitor market. *Id.* at 253–54.

In this case, 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. (No. 19-md-2895, D.I. 72 at 9.) I disagree that either is properly viewed a "reverse payment," alone or together.

a. Teva's retention of at-risk profits

With respect to the former, Plaintiffs point to their allegation that Teva's brief at-risk launch generated over $400 million in revenue for Teva, yet the Amgen-Teva agreement only required Teva to pay $40 million to Amgen. According to Plaintiffs, "[b]y allowing . . . Teva to keep virtually all of the revenue generated [from its at-risk launch], Amgen—in substance—paid Teva upwards of $350 million." (No. 19-md-2895, D.I. 72 at 12.)

The main problem with Plaintiffs' "implicit net payment" theory is that it was specifically disavowed in *Actavis*, as explained above. 570 U.S. at 151–52 (distinguishing such settlements as "commonplace forms of settlement," which the Supreme Court "d[id] not intend" to be "subject to antitrust liability"). And for good reason. If resolving a damages claim for less than the claimed

amount could constitute a "reverse payment" under *Actavis*, all patent litigation settlements that include a compromise damages amount and an agreement to stop infringing would invite antitrust scrutiny.[11]

The second problem I see with Plaintiffs' theory is that the alleged $350 million "payment" did not come from Amgen. The money Teva made from its at-risk launch was earned from the marketplace, by competing with Amgen. Plaintiffs have not alleged that Amgen authorized or agreed to Teva's at-risk launch or that Amgen was otherwise "in on" a scheme with Teva to launch. Nor do Plaintiffs allege that Amgen and Teva had a no-AG agreement during the period that Teva was on the market.

Plaintiffs argue that this case falls under *Lipitor*, where the Third Circuit held that a patentee's forgiveness of a damages claim could constitute a reverse payment where it is large and unjustified. But *Lipitor* is inapposite because the damages claim there related to a different drug than the market alleged to be restrained. The challenged restraint in *Lipitor* was the generic's agreement to stay out of the Lipitor market. There, the antitrust plaintiffs alleged that Pfizer had

[11] Plaintiffs might point to the fact that the Supreme Court stated that a patentee's agreement to accept a fraction of its total claim was not subject to antitrust liability "for that reason alone," which suggests that compromised patent settlements may still be scrutinized if there are other aspects of the agreement that raise antitrust concerns. *Id.* at 152. Indeed, the *Actavis* decision discusses prior cases in which agreements that provided for entry before patent expiration and involved no cash payment were found to violate the Sherman Act. *Id.* at 149–51.

But I do not read *Actavis* to permit an antitrust suit to proceed merely because the patentee accepted a compromise damages amount and the alleged infringer agreed to stop selling, even if the antitrust plaintiff alleges that the patentee would have lost if the litigation had proceeded. Such a reading would permit antitrust scrutiny of "commonplace" patent settlements, and would presumably require litigation of the same patent issues the parties agreed to settle, a result I do not believe the Court intended. *See In re Actos End Payor Antitrust Litigation*, No. 13-9244, 2015 WL 5610752, at *14 (S.D.N.Y. Sept. 22, 2015), *aff'd in part, vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017). Indeed, in concluding that large reverse-payment settlements should be subject to antitrust scrutiny, the Court relied on its determination that courts would usually *not* need to litigate the underlying patent issues. *Actavis*, 570 U.S. at 157–58.

a damages claim arising from the generic company's at-risk launch of generic Accupril that was "worth hundreds of millions of dollars" and "had a high likelihood of success." *In re Lipitor Antitrust Litigation*, 868 F.3d at 253–58; *see id.*, 868 F.3d at 255 (noting that Pfizer posted a $200 million bond to seek an injunction and that "Pfizer itself told shareholders that it was likely to succeed on the merits of the case"). In other words, the antitrust plaintiffs alleged that the generic company owed Pfizer hundreds of millions of dollars in connection with Accupril because Pfizer had a good infringement claim with respect to Accupril. Forgiveness of that enormous debt was alleged to be worth a lot of money to the generic manufacturer, and the surrounding circumstances permitted an inference that Pfizer offered that forgiveness in exchange for the generic's promise to stay out of the Lipitor market.

The reasoning of *Lipitor* does not apply here. Plaintiffs contend that Amgen's compromise of its damages claim for Teva's at-risk launch in the cinacalcet market was "payment" for Teva staying out of that same market. But, unlike *Lipitor*, Plaintiffs here do not allege that Amgen had (or believed it had) a good infringement claim against Teva. Indeed, Plaintiffs' antitrust case is premised on the opposite conclusion: that Teva's generic product did not infringe and that Amgen thus had no right to keep it out of the market. If Plaintiffs are correct about that, Amgen did not have a valuable damages claim against Teva, so compromise of its claim was not a "payment" from Amgen to Teva. The money Teva kept was money it earned from competing against Amgen in the market.

In other words, the reason that the payment in *Lipitor* did not fall within *Actavis*'s exemption of "commonplace" settlements from antitrust scrutiny is because Lipitor involved consideration *in addition to* the damages compromise on the drug that was the subject of the challenged restraint. That is not the case here. And Plaintiffs have cited no authority extending

the reasoning of *Lipitor* to these circumstances. Rather, the allegations here describe the kind of payment that the Supreme Court said was not subject to antitrust liability: "Company A sues Company B for patent infringement and demands, say, $100 million in damages," but the parties settle the case, and as part of the settlement, "B (the defendant) . . . pay[s] A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example." *Actavis*, 570 U.S. at 151. I conclude that the settlement of the cinacalcet damages claim does not qualify as a reverse payment under *Actavis*.

b. Teva's acceleration clause

Under the Amgen-Teva agreement, Teva agreed to leave the cinacalcet market until June 30, 2021 (five years before the '405 patent was set to expire), but it was allowed to enter earlier if another generic launched at risk. Plaintiffs assert that the acceleration clause constituted a reverse payment to Teva. I disagree.

No one disputes that such a clause had value to Teva. But settlement terms always have value to the parties that enter into them—otherwise they wouldn't settle. *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.) ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."). The question is whether an "acceleration clause" is properly viewed as a "payment" from Amgen.

The district court's opinion in *In re Actos End Payor Antitrust Litigation* is instructive. 13-9244, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015), *aff'd in part, vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017). In that case, the court considered the legality of Hatch-Waxman settlements that provided for a specified early entry date that would be accelerated if another generic entered the market. The court considered the two possible outcomes of such clauses: (1) if triggered, the generic would be permitted to launch earlier than it otherwise would have been

based on its compromise entry date, or (2) if not triggered, the generic would be restricted from entry until the compromise entry date it agreed to at the time of settlement. *Id.* at *15. The court remarked that "it is difficult to view the provisions as 'payments' from [the brand] to the [generics] to retain monopoly pricing power" since the generics "received no compensation from [the brand], but rather were compensated only through the market when they began selling their generic product." *Id.* at *15; *see also In re Humira (Adalimumab) Antitrust Litig.*, No. 19-1873, 2020 WL 3051309, at *19–20 (N.D. Ill. June 8, 2020); *Asahi Glass*, 289 F. Supp. 2d at 994 (rejecting argument that a settlement term allowing early entry constituted a "payment" because its value to the generic company came from increased competition).

The court further concluded that an acceleration clause was not the type of settlement term made unlawful by *Actavis*, since "[a]n acceleration clause by its plain terms merely affects the date of entry into the market—a date that can be lawfully agreed upon by the parties settling a patent infringement suit." *Actos*, 2015 WL 5610752 at *16; *see also Actavis*, 570 U.S. at 158 (stating that parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point"). I agree with the *Actos* court's reasoning.

Plaintiffs cite *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307 (D.R.I. 2017) for the proposition that "courts analyzing acceleration clauses as parts of reverse payments have held that the clauses may be considered 'as a component in the greater calculus' of the reverse payment." (No. 19-md-2895, D.I. 72 at 12–13.) But the *Loestrin* court was facing allegations of a multi-faceted deal that included, among other things, a no-AG agreement and "promotional deals" alleged to be worth "tens of millions" to the generic manufacturer that, "taken as a whole, amounted to a large and unjustified reverse payment." 261 F. Supp. 3d at 321, 332–36. In contrast,

Plaintiffs here point to two facets of a deal (an early entry date and a damages compromise) that *Actavis* says are permissible.

Plaintiffs also cite *Staley v. Gilead Sci., Inc.*, but the district court in that case explicitly did "not address the question of whether a[n acceleration clause] by itself can constitute anticompetitive conduct." No. 19-2597, 2020 WL 1032320, at *25 (N.D. Cal. Mar. 3, 2020). Here, although Plaintiffs argue that the acceleration clause "along with the other benefits granted Teva under the agreement, amount to a reverse payment" (No. 19-md-2895, D.I. 72 at 12), I have already concluded that the only "other" alleged benefit—the compromise of Amgen's damages claim—is not subject to scrutiny under *Actavis*.

I conclude that the acceleration clause does not qualify as a reverse payment under *Actavis* either alone or viewed together with Amgen's agreement to compromise its damages claim for Teva's at-risk launch. Accordingly, I recommend that the Court grant Defendants' motions to dismiss Plaintiffs' claims under Section 1 of the Sherman Act.

3. Plaintiffs do not plausibly allege a "large and unjustified" reverse payment to other generic manufacturers.

Plaintiffs' monopolization claims under Section 2 of the Sherman Act rely on the same types of conduct as their Section 1 claims.[12] (*See* EPP Compl. ¶¶ 113, 115 (listing as "exclusionary and anticompetitive conduct . . . (i) paying Teva to remove its generic product from the market and delay its entry; and (ii) deterring all generic manufacturers . . . through the use of anticompetitive acceleration clauses"); DPP Compl. ¶¶ 242, 244 (same).) For the reasons explained above, I am not persuaded that there has been an unlawful "reverse payment" from (1)

[12] 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. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007).

Teva's retention of revenue from its at-risk launch, or (2) the acceleration clause in the Amgen-Teva agreement. For the same reason that I conclude that Teva's acceleration clause does not constitute a reverse payment under *Actavis*, I also conclude that the acceleration clauses in the settlement agreements with other generic manufacturers do not constitute reverse payments. As Plaintiffs challenge no other aspects of Amgen's settlement agreements, I conclude that they are not subject to scrutiny under the antitrust laws.

Plaintiffs nevertheless argue that Amgen's "web of poison pill 'acceleration' clauses" with multiple settling generic manufacturers constituted anticompetitive conduct. (No. 19-md-2985, D.I. 72 at 14.) According to Plaintiffs, Amgen's use of such clauses was intended to and did have an anticompetitive effect because they eliminated the incentive of non-settling generic manufacturers to continue to litigate against Amgen. In particular, Plaintiffs allege that "[a]ny non-settling generic knew that if it litigated, won, and entered the market, the acceleration clauses previously granted to the settling generics would mean that the other generic manufacturers would share in the fruits of the win . . . . Absent the acceleration clauses, the other generics would be bound by their agreed entry dates and would not share in the earlier entry." (DPP Compl. ¶ 157; *see also* EPP Compl. ¶¶ 43–46.) Stated another way, Plaintiffs contend that a non-settling generic manufacturer's incentive to continue to litigate was reduced because its entry meant that "all others could as well, depriving the stronger generics of the real benefit of that position: entry during a time of reduced competition." (No. 19-md-2895, D.I. 72 at 18.)

Plaintiffs, however, cite no case endorsing the position that an antitrust claim can be pursued solely based on the alleged inclusion of acceleration clauses in Hatch-Waxman settlement agreements in the absence of a reverse payment allegation. And I decline to endorse it here. Plaintiffs' theory is inconsistent with the principles of *Actavis*. *Actavis* is clear that parties are

permitted to settle Hatch-Waxman suits by "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration" so long as there is no reverse payment. 570 U.S. at 158. An acceleration clause is simply an agreement that a generic manufacturer can enter the market early. *See Actos*, 2015 WL 5610752, at *16.

The parties vigorously dispute whether acceleration clauses are anticompetitive or procompetitive, either in general or under the particular circumstances of this case.[13] And for purposes of the argument, I accept Plaintiffs' contention that a non-settling generic has less incentive to continue to litigate if settling generics entered into agreements with acceleration clauses. But that does not mean that Amgen's inclusion of such clauses in the settlement agreements violates the law. I am unaware of no legal requirement that parties reach the most procompetitive settlements possible, either generally or in the patent context. As the *Actos* court put it, "*Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *Actos*, 2015 WL 5610752, at *16.

Plaintiffs' argument is based on its assertion that providing generic challengers with an incentive—in the form of a period of *de facto* generic exclusivity if they win—will encourage them to stay in the patent fight in situations where no generic is entitled to first-filer exclusivity. But Plaintiffs have not explained why Amgen (as opposed to Congress) should be the one to provide that incentive, nor am I persuaded that Amgen was required under the antitrust laws to do so. I recommend that the Court dismiss Plaintiffs' Section 2 claims.[14]

[13] For example, Amgen points out that four of the generic companies were apparently not deterred by the acceleration clauses because they litigated all the way through a Hatch-Waxman infringement trial.

[14] Because I conclude that dismissal is appropriate under *Actavis*, I do not reach Defendants' alternative arguments.

B. End Payor Plaintiffs' State Law Claims

End Payor Plaintiffs agree that if the federal antitrust claims are dismissed without prejudice for failure to state a claim, the state law claims may also be dismissed. (No. 19-md-2895, D.I. 152 ("[W]ere the Court to dismiss the federal claims because the complaint did not state plausible Sherman Act claims, we would not oppose dismissal—without prejudice to further amendment—of the state antitrust and consumer law claims based on the current motions and allegations in [EPP]s' complaint."). Accordingly, I recommend that the Court dismiss End Payor Plaintiffs' state law claims.

IV. CONCLUSION

Plaintiffs argue that Amgen's agreements with generic drug manufacturers reduced competition for cinacalcet drugs, and that consumers paid higher prices as a result. For purposes of the argument, I assume that Plaintiffs are right. But Amgen has a patent covering cinacalcet formulations, and a patent is an "exception" to the general rules against monopolies and restraints of trade. *King Drug*, 791 F.3d at 394. The particular restraint challenged here is the type that *Actavis* exempted from antitrust scrutiny, notwithstanding its potential effects on the market.

Accordingly, for the reasons set forth above, I recommend that Amgen's and Teva's motions to dismiss be GRANTED and that Plaintiffs' complaints be DISMISSED without prejudice to amend. (No. 19-md-2895, D.I. 27; No. 19-396-LPS, D.I. 57; and No. 19-1460-LPS, D.I. 24 (Amgen's motion to dismiss Direct Purchaser Plaintiffs' Consolidated Complaint); No. 19-md-2895, D.I. 30; No. 19-369-LPS, D.I. 39; and No. 19-1461-LPS, D.I. 21 (Amgen's motion to dismiss End Payor Plaintiffs' Consolidated Complaint); No. 19-md-2895, D.I. 31; No. 19-369, D.I. 42; No. 19-396-LPS, D.I. 60; No. 19-LPS-1460, D.I. 27; No. 19-1461-LPS, D.I. 23 (Teva's motion to dismiss Direct Purchaser Plaintiffs' and End Payor Plaintiffs' Consolidated

Complaints).) I further recommend that Plaintiffs be granted leave to amend their complaints within thirty days.[15]

This Report and Recommendation relies on material set forth in filings that remain under seal. Accordingly, I am issuing this Report and Recommendation under seal, pending review by the parties. However, I am aware that much (if not all) of the information under seal has already been disclosed as a result of this Court's prior rulings and opinions. In the extremely unlikely event that any party contends that portions of this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version no later than 4:00 p.m. on July 23, 2020, for review by the undersigned, along with a motion supported by a declaration that includes a detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). The Court intends to issue a public version of this Report and Recommendation no later than July 24, 2020.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B),(C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

[15] Teva apparently opposes the opportunity to amend (*see* No. 19-md-2985, D.I. 31, Att. 1 (requesting dismissal with prejudice)), but it is not clear from this limited record that amendment would necessarily be futile. *See Alston v. Parker*, 363 F.3d 229, 235-36 (3d Cir. 2004) (holding that leave to amend should be granted "unless a curative amendment would be inequitable, futile, or untimely").

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

Dated: July 22, 2020

Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE