IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: SENSIPAR (CINACALCET HYDROCHLORIDE TABLETS) ANTITRUST LITIGATION	)	MDL No. 19-2895-LPS
CIPLA LTD. and CIPLA USA, INC., Plaintiffs,	)	Civil Action No. 19-44-LPS
v.	)	
TEVA PHARMACEUTICALS USA, INC. Defendant.	)	

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 as well as 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] Cipla and Amgen subsequently filed a stipulation of dismissal of Cipla's claims against Amgen. This Report and Recommendation relates solely to Teva's Motion to Dismiss Cipla's First Amended Complaint. (No. 19-md-2895, D.I. 25; No. 19-44-LPS, D.I. 238.)

Cipla contends that a settlement agreement between Amgen and Teva (regarding Teva's proposed generic cinacalcet product) violates Section 1 of the Sherman Act because it affects Cipla's ability to enter the generic cinacalcet market pursuant to its own prior settlement agreement with Amgen. For the reasons stated below, I conclude that Cipla fails to state an antitrust claim against Teva. I also conclude that Cipla's related state-law claims should be dismissed.

[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).

I. BACKGROUND[2]

A. Sensipar® Patent Litigation and Amgen-Cipla Settlement

To fully understand Cipla's 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. Amgen has marketed Sensipar, a branded cinacalcet formulation, since 2004. Amgen 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. The '405 patent does not expire until September 22, 2026.

Pursuant to the Hatch-Waxman scheme, numerous generic manufacturers, including Cipla, filed Abbreviated New Drug Applications (ANDAs) with the FDA seeking to market their generic versions of Sensipar. Amgen, in turn, filed infringement lawsuits against each of them in this

[2] I assume the facts alleged in Cipla's First Amended Complaint ("FAC") to be true for purposes of resolving the motion to dismiss for failure to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). I also take judicial notice of the contents of proceedings in related cases. In particular, I take notice that those proceedings occurred and that the courts made certain findings in them, but I do not assume the truth of those findings. *See S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999) (holding that courts may take judicial notice of other courts' proceedings "not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity").

Certain background facts also appear to be undisputed. I relay them for reader interest and for ease of understanding, but they do not affect the outcome of the motion.

[3] *See, e.g., F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (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).

district. Under the particular circumstances, none of the potential generic manufacturers would have been entitled to 180-day first-filer exclusivity.

Most of the generic manufacturers settled with Amgen before trial. Cipla was among them. On February 26, 2018, Amgen and Cipla executed a settlement agreement (the "Amgen-Cipla agreement"). (C.A. No. 19-44, D.I. 73 ("FAC") ¶ 8, Ex. 1.) Pursuant to the agreement, Cipla "acknowledge[d] and agree[d] that [the '405 patent is] valid and enforceable . . . and would be infringed" by Cipla's generic product. (*Id.*, Ex. 1 § 4.1.)

The agreement also grants Cipla a license to sell its generic product no later than 97 days before expiration of the '405 patent, and it was permitted to launch earlier under certain circumstances. (FAC ¶¶ 9-10, 15, Ex. 1 §§ 5.1, 5.2, 5.3, 5.5.) Under one scenario, Cipla's ability to launch would be triggered if a third party engaged in an at-risk launch, and Amgen did not within a certain period of time either (i) move for a temporary restraining order or preliminary injunction against the third party, or (ii) enter into an agreement requiring the third party to stop selling its product within thirty days. (*Id.*, Ex. 1 § 5.5(a).) The Amgen-Cipla agreement also sets forth the circumstances under which Amgen can seek relief against Cipla for an at-risk launch following a third party's at-risk launch. (*Id.*, Ex. 1 § 5.6.) However, Amgen is not entitled under the agreement to seek or recover relief from Cipla if the third-party launcher "is not found to have infringed" or "has not ceased or agreed to cease selling."[4] (*Id.*) On March 5, 2018, the Honorable Mitchell S. Goldberg (who was presiding over the patent infringement actions) entered the parties' jointly-proposed consent judgment, in which Cipla agreed that the '405 patent was valid and enforceable and would be infringed by Cipla's product. *Cipla Ltd.*, 386 F. Supp. 3d at 391.

[4] For a full discussion of those provisions in the Amgen-Cipla agreement, *see Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 395-405 (D. Del. 2019) and *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 139–41 (3d Cir. 2019).

By the time the remaining Hatch-Waxman infringement cases got to trial before Judge Goldberg in March 2018, there were only four ANDA filers 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). (FAC ¶ 13.) Amgen and Zydus appealed. *Amgen Inc. v. Amneal Pharm. LLC*, 945 F.3d 1368 (Fed. Cir. 2020).[5]

On or about December 28, 2018, while Amgen's appeal of the district court's finding of non-infringement by Teva was pending, Teva launched its generic product at risk. (FAC ¶ 12.)

B. Amgen-Teva Settlement and Public Statements

On January 2, 2019, five days after Teva's launch, Amgen and Teva entered into a settlement agreement (the "Amgen-Teva agreement"), which resolved Amgen's infringement claims against Teva. (FAC ¶ 17, Ex. 3.) Pursuant to the agreement, and despite having prevailed at trial on the issue of non-infringement, Teva "acknowledge[d] and agree[d] that [the '405 patent is] valid and enforceable . . . and would be infringed" by Teva's generic product. (*Id.*, Ex. 3 § 4.1.) The agreement contemplated that Amgen would withdraw its pending Federal Circuit appeal and that the parties would seek entry of a consent judgment of Teva's infringement in the district court. (*Id.*, Ex. 3 §§ 2.1-3.)

Pursuant to the Amgen-Teva agreement, Amgen released any claims that could be made against Teva for its at-risk launch, and Teva agreed to pay Amgen up to $40 million depending, in part, on how long the cinacalcet market remained free of generic products. (*Id.*, Ex. 3 § 3.1.) According to the FAC, the "up to $40 million" payment from Teva to Amgen did not represent all

[5] For additional details about that dispute, *see Cipla Ltd.*, 386 F. Supp. 3d at 389–93; and *Cipla Ltd.*, 778 F. App'x at 137–38.

of Teva's profits for its at-risk launch. Rather, Teva was allowed to retain "up to hundreds of millions of dollars in profits on sales of Cinacalcet Products." (*Id.* ¶ 32.) The Amgen-Teva agreement also grants Teva a license to sell its generic product beginning on June 30, 2021, or earlier under certain circumstances. (*Id.*, Ex. 3 § 5.1.)

On January 2, 2019, Teva and Amgen each issued public statements about the settlement. (*Id.* ¶¶ 18-19.) Amgen's statement stated, in part, that "Teva has agreed to stop selling its generic product until its license date in mid-year 2021 or sooner depending on certain occurrences." (*Id.* ¶ 18.) Teva's statement stated, in part, that "Teva has agreed to stop selling its generic product until its license date in mid-year 2021, or sooner depending on certain circumstances." (*Id.* ¶ 19.) According to the FAC, those statements were false because, pursuant to the Amgen-Teva agreement, Teva was not required to stop selling its generic product unless and until the district court entered the consent judgment against Teva, which had not happened at that point (and never did happen).[6] (*Id.* ¶¶ 22-23, 30.) *Amgen Inc. v. Amneal Pharm. LLC*, C.A. No. 16-853, D.I. 439 (D. Del. Mar. 26, 2019).

After Amgen and Teva settled, Cipla sent Amgen a letter concerning its right to launch under the Amgen-Cipla agreement, and Amgen responded on January 4, 2019. (FAC ¶ 20, Ex. 6.) In the letter, Amgen contended that Cipla's right to launch had not been triggered by Teva's at-risk launch and subsequent settlement because Teva had agreed to stop selling its generic product within the time period specified in the Amgen-Cipla agreement. (*Id.*) The letter asked Cipla to "confirm immediately that Cipla has not and will not engage in an at risk launch based on [Teva's] at risk launch," and it threatened litigation against Cipla. (*Id.* ¶¶ 20, 39, Ex. 6.) According to the

[6] On January 9, 2019, Amgen and Teva moved Judge Goldberg for an "indicative ruling" that the court would vacate its finding of non-infringement as to Teva and enter the consent judgment of infringement. Judge Goldberg denied that motion on March 26, 2019. *Amgen Inc. v. Amneal Pharm. LLC*, C.A. No. 16-853, D.I. 439 (D. Del. Mar. 26, 2019).

FAC, "Cipla was prepared to begin selling its own generic version of Sensipar in the United States immediately after January 16, 2019 and would have done so but for the January 4, 2019, letter from Amgen with its threat of further litigation." (*Id.* ¶ 68.)

C. The Cipla Action

On January 8, 2019, Cipla filed a declaratory judgment action in this Court against Amgen, seeking a ruling that Cipla was allowed to launch under the terms of the Amgen-Cipla agreement. (No. 19-44, D.I. 2.) Cipla also alleged that Amgen's conduct violated federal and state antitrust laws. (*Id.*, D.I. 2.) On February 25, 2019, Cipla amended its complaint to (among other things) add a fraud claim and add Teva as a defendant. (*Id.*, D.I. 73.)

Cipla launched its generic product in early March 2019. (*Id.*, D.I. 101 (letter to Court from Cipla's counsel advising that it "commenced sales of SENSIPAR®-equivalent cinacalcet hydrochloride tablets" on March 2, 2019).) Amgen responded on March 11, 2019 by filing a motion for a preliminary injunction to stop Cipla's sales as being in breach of the Amgen-Cipla agreement. (*Id.*, D.I. 121.) This Court denied the motion for preliminary injunction on May 2, 2019, holding that Amgen could not seek relief against Cipla for its at-risk launch—irrespective of whether Teva had ceased selling—because Teva was "not found to have infringed" within the meaning of the Amgen-Cipla agreement. *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 399-400 (D. Del. 2019) (No. 19-44, D.I. 187). Amgen filed an interlocutory appeal of that ruling, but the Third Circuit affirmed on July 16, 2019. *Cipla Ltd. v. Amgen Inc*, 778 F. App'x 135 (3d Cir. 2019).

D. Multidistrict Antitrust Litigation

Currently pending in this multidistrict litigation are four class actions and Cipla's individual action. 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 the class actions to this district for coordination with Cipla's action. (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). The direct purchasers and the indirect purchasers thereafter filed amended consolidated class action complaints. On July 22, 2020, I issued a Report and Recommendation in which I recommended that the Court dismiss the consolidated class action complaints for failure to state a claim. (No. 19-md-2895, D.I. 160.)

E. Current Motion

This Report and Recommendation relates solely to Teva's motion to dismiss Cipla's claims against it. (No. 19-md-2895, D.I. 25; No. 19-44-LPS, D.I. 238.) Cipla's FAC contains five counts. Count One was asserted against Amgen and sought a Declaratory Judgment that Cipla is licensed under the Amgen-Cipla agreement as a result of Teva's at-risk launch. Cipla and Amgen have now settled, so that count is out of the case. (No. 19-44, D.I. 285.) Count Two alleges that Amgen and Teva violated Section 1 of the Sherman Act, 15 U.S.C. § 1, which prohibits agreements in restraint of trade. (FAC ¶¶ 41–71.) Counts Three and Four also name both Amgen and Teva and allege violations of California Business and Professional Code § 16720 (Cartwright Act) and

§ 17200 (Unfair Competition Law). (*Id.* ¶¶ 72–79.) Count Five alleges fraud.[7] (*Id.* ¶¶ 80–81.) The state-law counts refer to the same conduct underlying Cipla's Sherman Act claim.

Teva argues that Cipla's remaining claims should be dismissed under Federal Rule of Civil Procedure 12(b)(1) for lack of standing because Cipla has not plausibly alleged an injury in fact. Teva alternatively argues that the Sherman Act claim (Count Two) should be dismissed under Rule 12(b)(6) because (i) Cipla lacks antitrust standing and (ii) the FAC fails to state a Section 1 violation. Teva argues that Cipla's California statutory claims (Counts Three and Four) should also be dismissed because they rise and fall with Cipla's federal claim. Finally, Teva argues that the FAC fails to state a claim for fraud (Count Five).

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

[7] Count Five alleges that "[t]he conduct of Amgen and *Cipla* constitutes fraud." (FAC ¶ 81.) I assume, as do the parties, that it meant "Amgen and *Teva*."

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. Cipla's Antitrust Claim

Cipla alleges that the Amgen-Teva agreement violates Section 1 of the Sherman Act.[8] 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

[8] "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).

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 Fed'n 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. Cipla is required to plead more than Teva's agreement to exit the market.

In this case, Cipla alleges that the Amgen-Teva agreement violates Section 1 of the Sherman Act. (No. 19-44, D.I. 252 at 8 ("The FAC Alleges That the Amgen-Teva Agreement and Its Implementation Were Anticompetitive in Purpose and Effect.").) As an initial matter, the parties dispute how *Actavis* applies to this case, including whether it has any effect on the pleading standard for a Section 1 violation.

Teva argues that because the restraint being challenged is an agreement by a generic to exit the market, it should be analyzed under the framework set forth in *Actavis*, and Cipla must plead a reverse payment. Cipla, on the other hand, suggests that it need only plead that Teva agreed to cease selling when it did not infringe. For support, Cipla cites *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma.*, 468 U.S. 85 (1984), in which the Supreme Court remarked that "[r]estrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit." *Id.* at 107-08. In Cipla's view, that Amgen has a patent that might preclude antitrust liability is a "patent-based defense" that does not affect what Cipla must allege to state an antitrust claim.

I disagree with Cipla to the extent it suggests that it need only plead an agreement under which one party was required to exit the market. Cipla is correct that *Actavis* rejected the "scope of the patent" test for determining when patent settlements are subject to antitrust scrutiny. But I do not understand *Actavis* to have opened the door to antitrust challenges of all patent settlements

in which the alleged infringer exits the market. The *NCAA* case cited by Cipla did not involve the assertion of patent rights or the settlement of patent ligation.

Such a position would also be inconsistent with Third Circuit case law. In *In re Lipitor*, the Third Circuit stated that, "to survive a motion to dismiss when raising an antitrust violation under *Actavis*, 'plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*.'" *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)). Only if "plaintiffs do so [may they] proceed to prove their allegations under the traditional rule-of-reason analysis." *Id.* In other words, to state an antitrust claim, it is not enough to allege that a patent settlement involved an agreement to exit the market. There must be something more.

2. *Actavis* requires more than an allegation that the exiting generic does not infringe.

But requiring an antitrust plaintiff who seeks to challenge a patent settlement to plead more than the alleged infringer's agreement to exit the market does not answer the question of what more must be pleaded. Cipla points out that *Actavis* cited and followed earlier Supreme Court cases, including *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963), that permitted antitrust scrutiny of patent-related settlement agreements. According to Cipla, those cases stand for the proposition that settlement agreements that attempt to "expand the scope" of the patent can be challenged under the antitrust laws. Cipla points to the FAC's allegations that Teva's generic products do not infringe the '405 patent and that, notwithstanding, Teva agreed to exit the market and seek a consent judgment of infringement. (FAC ¶¶ 29-35; Tr. 68:18-22.)

Teva contends that because Cipla is challenging the settlement of patent litigation between a generic and a brand in which the restraint being challenged is an agreement by the generic to exit

the market, it should be analyzed under the framework set forth in *Actavis*. That is, Cipla must plead that the Amgen-Teva agreement involved a large and unjustified reverse payment.

I agree with Teva. In *Actavis*, the Supreme Court discussed prior cases, including *Singer*, in which patent-related settlement agreements that involved no cash payment were found to violate the antitrust laws. *Id.* at 149–51. But I do not read *Actavis* to permit an antitrust suit to proceed merely because the alleged infringer agreed to stop selling and the antitrust plaintiff alleges (and wants to prove) that the patentee would have lost if the litigation had proceeded. Such a reading would permit antitrust scrutiny of "commonplace" patent settlements, which the Court exempted from antitrust scrutiny.[9] *Id.* at 152. It would also require litigation of the same patent issues the parties agreed to settle, a result I do not believe the Court intended. 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.

Cipla stresses the fact that Judge Goldberg found that Teva's generic product did not infringe. (Tr. 68:18-69:13.) But, of course, a district court judge's finding is not the last word. Amgen appealed that decision. The parties were entitled to weigh the risks and benefits of continuing to litigate while the appeal was pending, and they decided to settle. That, without more, does not open the door to antitrust scrutiny.

Cipla also refers to Teva's admission of infringement in the Amgen-Teva agreement as a "sham." Cipla likewise refers to Amgen's and Teva's joint request for a consent judgment of infringement as a "sham." By "sham," Cipla means that Teva's admission was erroneous because

[9] At oral argument, Cipla's counsel pointed out that the Supreme Court's remarks about "commonplace" settlements were dicta. I don't disagree with that. But I will take the Supreme Court at its word.

Teva did not infringe—either because Judge Goldberg found that Teva did not infringe (D.I. 19-44, D.I. 252 at 11; Tr. 68:18-69:13; FAC ¶¶ 13, 33), or because Cipla intends to prove Teva's non-infringement in this case (D.I. 19-44, D.I. 252 at 8-9; Tr. 68:18-69:13, 79:21-80:6), or even perhaps because Teva allegedly didn't believe it infringed (Tr. 70:15-71:11). But Cipla does not mean "sham" in the way it is usually used in the antitrust context, *i.e.*, Cipla does not allege that the infringement allegations against Teva were so baseless that no reasonable litigant could have thought Teva infringed.[10] (Tr. 69:19-70:14.) In other words, Cipla does not allege facts demonstrating that Teva lacked litigation risk. Teva's elimination of that risk via settlement does not violate the antitrust laws in the absence of a reverse payment.[11]

To be clear, I do not read *Actavis* as preventing an antitrust plaintiff from challenging a no-

[10] Similarly, Cipla does not challenge Teva's assertion that the act of filing the joint consent motion is immunized from scrutiny under the *Noerr-Pennington* doctrine. Regardless, Judge Goldberg denied the motion, so the judgment was never entered.

[11] Cipla also contends that it was "misled and deceived" into delaying its launch by Teva's "sham public 'admission'" of patent infringement. But I don't take Cipla to be saying that Teva lied about the fact that it admitted to infringement. Rather, Cipla appears to be saying that it was tricked into not entering the market sooner because Teva did not in fact infringe.

Either way, that sounds like a fraud argument. But fraud requires reliance (among other things), and the facts pleaded in the FAC demonstrate the opposite. In particular, the FAC alleges that Cipla would have launched its generic product on January 16, 2019 "but for the January 4, 2019, letter from Amgen with its threat of further litigation." (FAC ¶ 68.) That letter says nothing about an "admission" of infringement by Teva. I cannot conclude, therefore, that Cipla delayed its launch because it relied on Teva's statement that it infringed the '405 patent.

Moreover, while it is true that Cipla did not launch as it was prepared to on January 16, 2019, Cipla did file suit on January 8 to obtain a declaratory judgment that it was entitled to launch. (No. 19-44, D.I. 2.) In other words, Cipla did not refrain from acting in reliance on either Teva's statements or Amgen's letter, but rather, it acted through litigation. Cipla's action to seek a declaration that it was free to launch rather than just simply launching was a tactical decision, not reliance.

The FAC also alleges that Teva did not, in fact, agree to stop selling its generic product, and that Cipla relied on false statements to the contrary. (FAC ¶¶ 18-24.) However, Cipla does not address those specific allegations in its brief (which focuses on the allegation that Teva's infringement admission was a sham (*see* D.I. 252 at 1-6, 8-10, 14-15)). Nor does Cipla explain how a generic company's alleged secret deal to remain *on* the market amounts to an antitrust problem.

reverse payment patent settlement agreement if there is some other aspect of the agreement that raises antitrust concerns. But Cipla has not alleged other concerns that might justify antitrust scrutiny. To the extent that Cipla was at all restricted from entering the cinacalcet market, it was the result of its own contract with Amgen, and there is no allegation that Teva had anything to do with the Amgen-Cipla agreement.

There is also no allegation that Amgen knew about or consented to Teva's December 2018 launch prior to its occurrence. There is no allegation that Amgen agreed to forgo launching an authorized generic while Teva was on the market. There is no allegation that Amgen's infringement suit against Teva was a sham, nor does the FAC assert that Amgen's allegations of infringement against Teva or the parties' proposed consent judgment of infringement were objectively baseless. There is no allegation that Teva knew the terms of the Amgen-Cipla settlement agreement or how its own settlement (including the consent judgment) would affect Cipla's right to launch. There is no allegation that Teva had any prior knowledge or involvement with Amgen's January 4, 2019 letter that threatened Cipla with litigation or Amgen's attempt to obtain a preliminary injunction against Cipla.

I make no comment about the antitrust implications of any of those allegations, had they been raised. The allegations before me are that Teva launched at risk, made a lot of money selling its generic product, and then settled with Amgen for a fraction of those profits, even though the Federal Circuit might later have concluded that Teva's product did not infringe. The "agreement" being challenged under Section 1 of the Sherman Act is Amgen's and Teva's agreement to settle their patent dispute, under which Teva agreed to exit the market. That makes this case governed by *Actavis*.

3. Cipla does not plausibly allege a "large and unjustified" reverse payment from Amgen to Teva.

Teva argues that Cipla fails to plausibly allege a "large and unjustified" reverse payment in accordance with *Actavis*, necessitating dismissal of the Section 1 claim. I agree.

As I discussed in my earlier Report and Recommendation, the flow of value under the Amgen-Teva agreement goes from Teva to Amgen, not in the reverse direction. Nor does Amgen's compromise of its damages claim for Teva's at-risk launch—which Cipla characterizes as a "cession of $200 million to Teva"—count as a reverse payment. As I explained in my prior Report, the money Teva made selling its generic product did not come from Amgen; it came from the market. (No. 19-md-2895, D.I. 160 at 18.) Moreover, the Supreme Court in *Actavis* rejected the idea that a compromise damages settlement amounted to an "implicit net payment."[12] 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"); *see also* No. 19-md-2895, D.I. 160 at 17-18.

The FAC alleges that the Amgen-Teva agreement violates Section 1 the Sherman Act. However, it fails to allege that the settlement involved a large and unjustified reverse payment or that some other aspect of the agreement raises antitrust concerns. Accordingly, I conclude that the FAC fails to state a claim under the Section 1.

[12] As explained in my prior Report, the Third Circuit's opinion in *Lipitor* does not change the result. That case involved a settlement where the patentee conferred value unrelated to the patent at issue. *In re Lipitor Antitrust Litigation*, 868 F.3d at 253–58; No. 19-md-2895, D.I. 160 at 18-19.

4. Cipla fails to plead antitrust standing.

Teva also argues that the Section 1 claim should be dismissed for the alternative reason that Cipla lacks antitrust standing. I agree.[13]

To plead antitrust standing, a plaintiff must plead 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.'" *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 233 (3d Cir. 2013) (alteration in original) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). "The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-reducing aspect or effect of the defendant's behavior." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990). Antitrust standing is a prudential limitation rather than a jurisdictional requirement. *Ethypharm*, 707 F.3d at 232. As such, it is properly viewed as an element of an antitrust claim. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164 (3d Cir. 2017).

Cipla's alleged injury is that it was delayed from entering the generic cinacalcet market for a period of several weeks. (FAC ¶ 67.) However, that injury did not stem from a competition-reducing aspect of the Amgen-Teva agreement. The reason why Hatch-Waxman settlements implicate the antitrust laws is because they keep the settling generic's product off the market, which restricts the supply of drugs and keeps prices high. Cipla's alleged injury does not "flow" from restricted cinacalcet output and higher prices caused by Teva's exit from the market. Any delay Cipla suffered was the result of the choices it made in view of its own agreement with Amgen, and not the result of an adverse impact on competition as a whole stemming from the

[13] I am unpersuaded by Teva's argument that Cipla lacks constitutional standing. I find its arguments more applicable to the questions of whether Cipla states a cognizable antitrust violation or has antitrust standing.

Amgen-Teva agreement. And none of the cases cited by Cipla stand for the proposition that a plaintiff has antitrust standing when its alleged exclusion from the market results from the effect of the challenged conduct on the terms of a contract that the plaintiff agreed to.[14]

What's more, the FAC does not plausibly allege that the Amgen-Teva agreement, or Teva's admission of infringement pursuant to that agreement, caused Cipla's delayed entry. Rather, the FAC alleges that "Cipla was prepared to begin selling its own generic version of Sensipar in the United States immediately after January 16, 2019 and would have done so but for the January 4, 2019 letter from Amgen with its threat of further litigation." (FAC ¶ 68.) In other words, it was Amgen's threat to sue Cipla under the Amgen-Cipla agreement that caused Cipla to choose to delay its launch, not the anticompetitive effects of the Amgen-Teva agreement. *See also* n.11, *supra.*

I conclude that Cipla's Section 1 claim should also be dismissed for failure to plead antitrust standing.[15]

B. Cipla's State Law Claims

Teva argues that Cipla's California statutory claims rely on the same allegations supporting its Sherman Act claim, and that they fail for the same reasons. Cipla responds that its California claims are actionable for "substantially the same reasons" as its Sherman Act claim, but Cipla does not explain why or how the California claims survive dismissal of federal claim. Accordingly, I recommend that the California statutory claims (Counts Three and Four) be dismissed.

[14] *See Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982); *Radiant Burners, Inc. v. Peoples Gas Light & Coke Co.*, 364 U.S. 656 (1961); *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85 (3d Cir. 2010).

[15] Because I conclude that dismissal of the Section 1 claim is appropriate for the reasons stated above, I do not reach Teva's alternative arguments.

Teva also argues that Cipla's fraud claim should be dismissed because Cipla fails to plausibly plead a "misrepresentation" or "reliance."[16] Cipla responds that it delayed its launch in reliance on Teva's false admission of infringement. I agree with Teva. The FAC alleges that Cipla would have launched "but for" Amgen's January 4, 2019 letter threatening litigation. There is no allegation that Teva had anything to do with the letter, and the letter does not say anything about Teva's admission of infringement. In short, the FAC disclaims reliance on any statement made by Teva. I recommend that the fraud claim (Count Five) be dismissed.

IV. CONCLUSION

Cipla argues that Amgen and Teva entered into an agreement that had the effect of delaying Cipla's entry into the cinacalcet market. However, Cipla's ability to compete in that market was restricted by its own agreement with Amgen. To the extent that Amgen took actions in breach of that agreement, Cipla's remedy is under contract law, not the antitrust laws. That is not to say that a breach of contract may not coincide with an antitrust violation or that deception and fraud, particularly when used to mislead a competitor, cannot form the basis of an antitrust claim. But where the alleged harm results from breach of contract or fraud, courts must carefully consider whether antitrust law is the appropriate vehicle to award relief. And courts must not expand antitrust law to encompass breach of contract claims merely because a savvy plaintiff has artfully plead them under the guise of antitrust. *Cf. Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 526–27 (1983); *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417–18 (3d Cir. 1997); Erik Hovenkamp, *Tying, Exclusivity, and Standard-Essential Patents*, 19 Colum. Sci. & Tech. L. Rev. 79, 122–23 (2017)

[16] The parties dispute whether Delaware or California law applies to Cipla's fraud claim. I don't need to resolve that dispute because both states require, among other things, a misrepresentation and reliance.

("As a general principle, a breach of contract is not an antitrust violation; it is simply a breach of contract. That is not to say that a breach may not *coincide* with an antitrust violation; but the point is that it does not *create* one. Rather, to find an antitrust violation, the conduct effecting the breach must offend the antitrust laws on their own terms.").

For the reasons set forth above, I recommend that Teva's motion to dismiss be GRANTED. I further recommend that Cipla be granted leave to amend its complaint within thirty days.[17]

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 by no later than 4 p.m. on August 3, 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. Indiana 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 on August 4, 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

[17] Teva apparently opposes the opportunity to amend (*see* No. 19-44, D.I. 238, 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").

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.

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 31, 2020

Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE