United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JACKSONVILLE POLICE OFFICERS AND FIRE FIGHTERS HEALTH INSURANCE TRUST,

Plaintiff,

v.

GILEAD SCIENCES, INC., et al.,

Defendants.

Case No. 20-cv-06522-JSW

ORDER GRANTING, IN PART, AND DENYING, IN PART, MOTION TO DISMISS FIRST AMENDED COMPLAINT AND SETTING CASE MANAGEMENT CONFERENCE

Re: Dkt. No. 47

This matter comes before the Court upon consideration of the motion to dismiss filed by Gilead Sciences, Inc. ("Gilead") and by Cipla, Ltd. ("Cipla") and Cipla USA, Inc. ("Cipla USA") (collectively "Cipla").[1] The Court has considered the parties' papers, relevant legal authority, and the record in this case, and it HEREBY GRANTS, IN PART, AND DENIES, IN PART, Defendants' motion.

BACKGROUND

The Jacksonville Police Officers and Fire Fighters Health Insurance Trust ("Trust"), alleges Defendants violated the Sherman Act, 15 U.S.C. section 1 (the "Sherman Act Claim"), California's Cartwright Act, Business and Professions Code sections 16700, *et seq.* (the "Cartwright Act Claim"), and California's Unfair Competition Law, Business and Professions Code sections 17200, *et seq.* (the "UCL Claim"). The Trust also asserts a claim for equitable monetary relief ("Count IV") and asserts 27 "sister state" anti-trust claims ("Count V" or the "Sister State Claims") "[t]o the extent the Cartwright Act is found not to apply to the claims of

[1] The Court refers to Gilead and the Cipla entities collectively as "Defendants."

Class members located outside of the state of California[.]".[2] (First Amended Class Action Complaint ("FACC") ¶ 158.)

This litigation presents the tension that may arise "between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act." *United States v. Line Material Co.*, 333 U.S. 287, 310 (1948). In brief, the Trust's theory is that Defendants settled patent litigation through a "reverse payment settlement," *i.e.* a settlement where "a party with no claim for damages … walks away with money simply so it will stay away from the patentee's market." *FTC v. Activis, Inc.*, 570 U.S. 136, 152 (2013) ("*Activis*"). In *Activis,* the Supreme Court rejected the proposition that reverse payment settlements were immune from antitrust scrutiny and held "large and unjustified" reverse payments "can bring with [them] the risk of significant anticompetitive effects" subject to a rule of reason analysis. *Id.* at 159; *see also In Re Cipro Cases I & II*, 16 Cal. 4th 116, 130 (2015) (holding that reverse payment settlements can violate the Cartwright Act).

The Court summarized the considerations that led to its holding as follows:

> [O]ne who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.

Activis, 570 U.S. at 158; *see also id.* at 154-58 (discussing these considerations in detail). If, however, a patent holder "does not have the power to charge supracompetitive prices, 'it is unlikely to pay large sums to induce others to stay out of its market.'" *United Food & Com. Workers v. Teikoku Pharma USA*, 74 F. Supp. 3d 1052, 1065 (N.D. Cal. 2014) ("*United Food*") (quoting *Activis*, 570 U.S. at 157).

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[2] "'Sister state' is a term courts have coined to describe class actions raising multiple similar state law causes of action." *Jones v. Micron Tech., Inc.*, 400 F. Supp. 3d 897, 908 n.3 (N.D. Cal. 2019).

A. The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") and Food and Drug Administration ("FDA") Approval of New Drugs.

"[M]ost, if not all, reverse payment settlement agreements arise in the context pharmaceutical drug regulation, and specifically in the context of suits brought" pursuant to the provisions of the Hatch-Waxman Act. *Activis*, 570 U.S. at 141. When a drug manufacturer wants to market a new drug, it must submit a New Drug Application ("NDA") to the FDA and then "undergo a long, comprehensive, and costly testing process[.]" *Id.* If a manufacturer wants to market a generic version of an FDA approved new drug, it can file an Abbreviated New Drug Application ("ANDA") and "piggy-back" on the brand-name manufacturer's NDA by "show[ing] that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). "'[T]his process is designed to speed the introduction of low-cost generic drugs to market," furthering competition. *Id.*

The Hatch-Waxman Act created procedures to resolve patent disputes between a brand-name drug manufacturer and a manufacturer seeking to market a generic version of a drug. When a brand-name manufacturer files an NDA, it must list the number of and expiration date of any relevant patents. *Activis*, 570 U.S. at 143; *see also* 21 U.S.C. § 355(b)(1). In turn, when a generic manufacturer files its ANDA, it must include assurances that its generic drug will not infringe the brand-name manufacturer's patents. *Activis*, 570 U.S. at 143. One way to do that is by filing what is known as a "paragraph IV certification," which certifies that a relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the new generic. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Filing a paragraph IV certification "automatically counts as patent infringement" and triggers deadlines for the brand-name manufacturer to file suit. *Activis*, 570 U.S. at 143. If the patent holder files a timely lawsuit, the FDA "must withhold approving the generic" for approximately 30 months while the parties litigate the matter. That gives a patent holder an incentive to initiate litigation when a generic manufacturer files a paragraph IV certification.

Activis, 570 U.S. at 143 (citing 21 U.S.C. § 355(j)(5)(B)(iv)). The Hatch-Waxman Act also incentivizes generic manufacturers to file paragraph IV certifications because it provides the first ANDA applicant to use that route

> a period of 180 days of exclusivity (from the first commercial marketing of its drug). … During that period of exclusivity no other generic drug can compete with the brand-name drug. If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars.

Id. at 143-44; *see also In re Cipro*, 16 Cal. 4th at 135 ("This legal regime means that, regardless of the likely degree of validity of a patent, the brand and first-filing generic have an incentive to effectively establish a cartel through a reverse payment settlement.").

B. Factual Background of this Dispute.

Gilead manufactures a number of drugs to treat the human immunodeficiency virus ("HIV"), which include tenofovir disproxil fumarate ("TDF"), emtricitabine[3] and/or efavirenz as ingredients. These drugs are "typically prescribed in combination with each other or with other drugs." (FACC ¶¶ 1, 18-19.) Gilead markets these drugs under the following brand-names:

- Viread, a tablet containing 300 mg of TDF
- Emtriva, a tablet containing 200 mg of emtricitabine
- Truvada, a tablet containing 200 mg of emtricitabine and 300 mg of TDF, and
- Atripla, a tablet containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of TDF.[4]

(FACC ¶ 19.)

In 2012, the FDA approved Truvada for pre-exposure prophylaxis ("PrEP") as a means to

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[3] "Gilad did not invent emtricitabine. It was patented by researchers at Emory University, who assigned the patents to Gilead." (FACC ¶ 19.b.) Emtricitabine, in turn, "is one of two enantiomers of a compound whose name is abbreviated as ß-FTC, specifically the enantiomer called "(-)-ß-FTC[;]" the other enantiomer is called "(+)-ß=FTC. An enantiomer is a term used to describe a situation where a "compound's 3-dimensional structure is not superimposable on a compound that is its mirror image[.]" (*Id.* ¶¶ 24, 26.)

[4] Atripla was formulated by a joint venture between Bristol-Meyers Squibb ("Bristol-Meyers") and Gilead. Bristol-Meyers has a license for efavirenz from Merck Sharp & Dohme ("Merck"), which holds patents covering that drug. (FACC ¶ 19.d.)

reduce the risk of HIV infection in high risk adults. In 2016 the FDA approved a modified dosage of Truvada to be used in pediatric patients. At the time the Trust filed the FACC, Truvada was the only drug approved for PrEP in the United States. Truvada, which is relatively inexpensive to make, has been very profitable for Gilead: in 2018, for example, sales from Truvada totaled $2.6 billion.[5] Atripla also has been extremely profitable for Gilead. In 2018, its sales in the United States totaled $967 million. (*Id.* ¶¶ 20-24.)

Gilead held rights in a patent claiming the compound ß-FTC (U.S. Patent No. 5,814,639 ("'639 Patent")) and in a patent claiming the use of ß-FTC to treat HIV (U.S. Patent No. 5,210,085 ("'085 Patent")). These patents expired in 2010 and 2015, respectively. (*Id.* ¶ 27.) Gilead also holds patent rights in emtricitabine (*i.e.* (-)-ß-FTC) (U.S. Patent 6,703,396 (the "'396 Patent")) and in the use of emtricitabine to treat HIV (U.S. Patent No. 6,642,245 (the "'245 Patent")). The '396 Patent expired on March 21, 2021, subject to a pediatric exclusivity period that expired on September 9, 2021. The '245 Patent expired on November 4, 2020, subject to a pediatric exclusivity period that expired on May 4, 2021. (*Id.* ¶ 28.)

Gilead also holds patent rights claiming the combination of TDF and emtricitabine in a single dosage, which it markets as Truvada, and has patent rights claiming the combination of TDF, emtricitabine, and efavirenz in a single dosage that forms Atripla. (*Id.* ¶ 29.) The Trust alleges that Gilead's rights in these patents have been challenged in the United States for decades by companies seeking to manufacture generic versions of the drugs. (*Id.* ¶ 30.) "While the patents suffer from glaring weaknesses, no case has ever been fully litigated" in the United States. (*Id.* ¶¶ 29-30.) The Trust claims this is because Gilead has settled these cases through reverse payment settlements.

1. Gilead Litigation Against Teva.

As one example, the Trust describes litigation between Gilead and Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (collectively "Teva"). In 2008, Teva filed an

[5] The Trust has spent $15,000 on Truvada for its members since the beginning of 2020. (FACC ¶ 2.)

ANDA for approval to manufacture and sell a generic version of Truvada, which included paragraph IV certifications relating to the patents covering efavirenz, emtricitabine, and TDF. In 2009, Teva filed ANDAs for approval to manufacture and sell generic versions of Atripla and Viread, which also contained paragraph IV certifications for the patents covering efavirenz, emtricitabine, and TDF. Merck and Bristol-Meyers filed suit regarding the efavirenz patents ("Teva efavirenz litigation"), and the parties settled that case before trial on terms that have not been disclosed. According to the Trust, Teva did not make any drugs containing efavirenz before the last of the patents at issue expired in 2018. (*Id.*, ¶¶ 31-33.)

Gilead filed suit regarding the TDF patents ("Teva TDF litigation"), and that case also ended with a confidential settlement. However, Teva announced that it would launch an exclusive generic version of Viread on December 15, 2017, which was shortly before the last of the relevant patents and exclusivity periods expired on January 25, 2018. The Trust alleges that six-week period of exclusivity was worth approximately $106 million to Teva and alleges it would not have been rational for Gilead to provide Teva with such a valuable benefit unless it believed Teva could have prevailed in the Teva TDF suit. (*Id.* ¶¶ 32, 34.)

Finally, Teva filed suit on the emtricitabine patents ("Teva emtricitabine litigation"), which would have proceeded as a bench trial. However the parties settled shortly before presenting closing arguments in February 2014.[6] (*Id.* ¶¶ 32, 35, 43.) The primary issue in that case was whether the '396 and '245 Patents covering emtricitabine were invalid for obviousness or for anticipation in light of the '639 and '085 Patents. (*Id.* ¶¶ 36-37.) The Trust alleges that Teva's anticipation theory "gave [it] a clear path to a verdict in its favor." (*Id.* ¶ 38.) The Trust also alleges that the record in that case suggested the judge was not persuaded by many of Gilead's arguments on why the '396 and '245 Patents were valid. (*Id.* ¶¶ 39-42.) The case was dismissed on April 30, 2014. (*Id.* ¶ 43.)

According to the Trust, the settlement in the Teva emtricitabine litigation provided that Teva would stay out of the Truvada market. In return, Gilead would grant it an exclusive license

[6] Emory University was a co-plaintiff in the Teva emtricitabine litigation.

to market a generic version of Truvada, starting on September 30, 2020, with a right to accelerate if any other company entered the market ("most-favored entry (MFE)" or "most-favored entry plus (MFEP)" clauses). (*Id.* ¶ 44.)[7]

2. Gilead Litigation Against Cipla.

In 2007, Cipla Ltd. submitted an ANDA seeking approval to market a generic version of Viread, which did not contain a paragraph IV certification. Instead, Cipla Ltd. certified that it would wait to market a generic version until the patents expired. The FDA tentatively approved that ANDA in 2009. In 2009, Cipla, Ltd., through Cipla USA, submitted ANDAs to market generic versions of Emtriva, Truvada, and Atripla, which also did not include paragraph IV certifications and certified that Cipla Ltd. would wait until relevant patents expired. The FDA approved those ANDAs in March 2011, February 2014, and February 2012. (*Id.* ¶ 45.)

On July 18, 2012, Cipla notified Gilead that it amended: (1) its ANDA relating to Emtriva to include paragraph IV certifications regarding the '245 and '395 Patents, *i.e.* the emtricitabine patents at issue in the Teva emtricitabine litigation. On July 30, 2012, Cipla notified Gilead it amended its ANDA for Viread to include paragraph IV certifications for four patents claiming TDF. Gilead filed a lawsuit asserting infringement of the emtricitabine patents (the "Cipla emtricitabine litigation") and filed a separate lawsuit asserting infringement of the TDF patents (the "Cipla TDF litigation,") which were assigned to the same judge as the Teva emtricitabine litigation (collectively, the "Cipla Litigation"). (*Id.* ¶ 46.) The parties settled the Cipla Litigation in July 2014. With the exception of a license agreement, the parties did not disclose the terms the settlement. (*Id.* ¶ 47.)

The Court will address additional facts as necessary in its analysis.

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[7] "An agreement with an MFE clause arises when the brand manufacturer and" the first generic manufacturer to file an ANDA "settle the patent litigation, with the generic manufacturer agreeing to delay entering the market until a specified date." *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 590 (N.D. Cal. 2020). An MFE clause generally "provides that if any other generic manufacturer (a 'second-filer') succeeds in entering the market before that date, the first-filer may enter the market at the same time." *Id.* An MFEP clause "provides that the brand manufacturer will not grant a license to any second-filer to enter the market until a defined period of time after the first-filer enters." *Id.*

ANALYSIS

A. Legal Standard on Motion to Dismiss.

Defendants move to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). In general, the Court's "inquiry is limited to the allegations in the complaint, which are accepted as true and construed in the light most favorable to the plaintiff." *Lazy Y Ranch Ltd. v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008). Even under the liberal pleading standard of Federal Rule of Civil Procedure 8(a)(2), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). If the allegations are insufficient to state a claim, a court should grant leave to amend, unless amendment would be futile. *See, e.g., Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 246-47 (9th Cir. 1990). If a plaintiff has previously amended a complaint, a court has "broad" discretion to deny leave to amend. *Allen v. City of Beverly Hills*, 911 F.2d 367, 373 (9th Cir. 1990) (quoting *Ascon Props., Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1160 (9th Cir. 1989).

B. The Court Grants, in part, the Requests for Judicial Notice and Denies the Trust's Request to File a Sur-Reply.

Each party filed requests for judicial notice, which include some argument that goes beyond what is necessary to show a particular document can be judicially noticed. The Court has not considered that argument. Defendants request judicial notice of documents from various FDA databases. (Dkt. No. 50, "Def. RJN"; Dkt. Nos. 50-1 to 50-4, Declaration of Peter Giunta ("Giunta Decl.") & Exs. A-C.) The Trust objects and argues these documents, and the facts on

which Defendants rely, could have and should have been submitted with Defendants' motion. The Court agrees, but because the Trust does not dispute the authenticity of the documents, which are publicly available, it grants Defendants' request but denies the Trust's motion to file the proposed sur-reply. The Court will take judicial notice of the existence of the documents and of the fact that statements were made about the dates on which Cipla began to market these drugs. *See, e.g., Lee v. City of Los Angeles*, 250 F.3d 668, 688-90 (9th Cir. 2001).

After briefing on the motions closed, the Trust filed a request for judicial notice. (Dkt. No. 55, "Trust RJN".) The Trust asks the Court to take judicial notice of a document from the FDA's National Drug Code Directory Database that shows Cipla's "start marketing date" for the generic version of Atripla was March 30, 2021. (*Id.*, Ex. 1.) Defendants do not object. Accordingly, the Court grants that request and takes judicial notice of the existence of the document and the fact that statements are contained therein about the start date. *Lee*, 250 F.3d at 688-90.

C. The Court Concludes the Trust States a Claim.

In order to state a claim based on an alleged reverse payment settlement, the Trust must be able to allege facts that suggest any "payment" in the Cipla litigation flowed from Gilead to Cipla, *i.e.* that it is a reverse payment. The Trust also must include "information that is "sufficient to estimate the value of the" reverse payment settlement, "at least to the extent of determining whether it is large and unjustified." *In re Loestrin 24 FE Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016) ("*In re Loestrin*") (internal quotations and citation omitted); *United Food*, 74 F. Supp. 3d at 1065 (to warrant scrutiny under *Activis,* plaintiff must allege a payment, that is reverse, large, and unexplained).[8]

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[8] Under the Cartwright Act, a plaintiff must show "(1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic manufacture; and the consideration exceeds (3) the value of goods and services *other* than delay in market entry provided by the generic challenger to the brand, as well as (4) the brand's expected remaining litigation costs absent settlement." *In re Cipro*, 16 Cal. 4th at 151 (emphasis in original).

1. Reverse Payment.

Defendants argue Plaintiffs merely speculate that the Cipla litigation was settled by a reverse payment.[9] Although the Trust uses language that would be considered speculative in other contexts, the Court concludes that is not fatal to its claim. "A plaintiff can meet [the] pleading standard without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or preempting every possible explanation for it." *FTC v. Abbvie Inc.*, 976 F.3d 327, 356 (3rd Cir. 2020); *see also In re Epipen (Epinephrine Injection, USP) Mktg., Sales Practices and Antitrust Litig.*, 336 F. Supp. 3d 1257, 1302-05 (D. Kan. 2018) (although plaintiffs were unable to plead the exact terms of settlements, court found the allegations were sufficient to allege each settlement was anticompetitive).

In *Activis*, the FTC alleged the settlement provided that the generic manufacturers would not bring their products to market until 65 months before the brand-name manufacturer's patent expired and would promote the brand-name product in the interim. In exchange, the brand-name manufacturer paid each of the generic manufacturers "millions of dollars." 570 U.S. at 145. The defendants claimed the payments were for services to be rendered to the patent holder, but the FTC alleged the "true point of the payments was to compensate the generic manufacturers for agreeing not to compete" against the patent holder's brand-name drug. *Id.* The Supreme Court did not expressly address pleading standards, but it found the FTC's allegations were sufficient to permit the case to proceed to a rule-of-reason analysis.

Similarly, the Third Circuit concluded the plaintiffs sufficiently alleged a reverse payment where a settlement provided that the defendant would end its challenge to the patent in exchange for an early entry into the market. In return, the patent holder gave up its right to manufacturer an

[9] Defendants state that the settlement has been submitted to the FTC in accordance with requirements of the Hatch-Waxman Act and notes the FTC has not raised any objections. The Court has considered that fact but finds it does not undermine the plausibility of the Trust's allegations. *See, e.g., In re Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3rd Cir. 2017) (stating "it is erroneous to conclude that the FTC's inaction equates to a determination that the settlement agreement does not run afoul of the Sherman Act" and finding plaintiffs sufficiently alleged a reverse payment settlement).

"authorized generic" ("no AG agreement") that would otherwise compete with the generic drug during the Hatch-Waxman Act's 180-day exclusivity period. *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 397 (3rd Cir. 2015). The court reasoned that such an agreement would be valuable to a first-filer because it would benefit from the exclusivity period provided by the Hatch-Waxman Act and would not face competition from the patent holder.[10] *Id.* at 404, 407. That conclusion was bolstered by public records, which showed the generic sales of the drug in one year totaled $671 million. *Id.* at 404; *see also In re Lipitor*, 868 F.3d at 253-58 (finding allegations about settlement involving patentee's release of claims in a lawsuit that had a high chance of success and was worth "hundreds of millions of dollars" in exchange for delay in release of generic were sufficient to show reverse payment); *United Food*, 74 F. Supp. 3d at 1070 (concluding no-AG agreement qualified as reverse payment).

The Trust also relies on *Staley*, where the court concluded the plaintiffs included sufficient facts to allege Gilead's settlement with Teva, in the Teva litigation described above, was a reverse payment settlement. 446 F. Supp. 3d at 610-12. In *Staley*, the plaintiffs alleged the MFE and MFEP clauses in the settlement were anticompetitive because they delayed the first-filer's entry into the market and "reduc[ed] a second-filer's incentive to try and enter the market before the first-filer." *Id.* at 590 (citing complaint). The defendants argued that there was no cash-payment involved and that the agreements were not anti-competitive. *Id.* at 610-12. The court rejected both arguments.

The court interpreted *Activis* to allow challenges to settlements even in the absence of a reverse payment "if there were other circumstances that posed potential anti-competitive concern" and determined the plaintiffs alleged such circumstances. *Id.* at 611 (citing *Activis*, 570 U.S. at 158). For example, it cited to the fact that Teva's entry date into the market was close to the date Gilead's patents would expire, from which it could be inferred that Teva gave up its right to

[10] The first-filer's exclusivity period applies only to other generic manufacturers. Under the Hatch-Waxman Act, the brand-name manufacturer is permitted to market and sell an authorized generic, which allows "the brand-name drug manufacturer to recover some of the sales and profits it would otherwise lose when an ANDA applicant begins to sell the generic drug." *United Food*, 74 F. Supp. 3d at 1061.

challenge the patents and obtain earlier entry into the market "in return for a significant benefit, -- even if that benefit did not come at Gilead's expense." *Id.* at 612. The court also concluded the MFEP provision raised a "yellow flag" because Teva had already forfeited its first-to-file exclusivity period. Thus, the provision worked to resurrect "ANDA exclusivity or at least some kind of exclusivity where it no longer applied," which could deter second filers. *Id.* & n.28.

Because the terms of the settlement are not part of the record, the Trust *and* the Court necessarily must rely on allegations about the Defendants' conduct to determine whether the existence of a reverse payment is plausible. The Trust posits the payment could consist of: (1) a license to market a generic version of Atripla before Gilead's patents on that drug expire; (2) a license to manufacture drugs for hepatitis C; and/or (3) the right to supply Teva with the active pharmaceutical ingredients (APIs) for Truvada and Atripla. (FACC ¶¶ 1, 50, 57.)

Although the Trust relied on an allegation that Cipla received approval to market emtricitabine in 2018 but had not done so, the record now includes information showing Cipla stated it began to sell emtricitabine on August 30, 2020. Defendants argue that Cipla "obtained [the Hatch-Waxman Act] 180-day period of exclusivity … in its settlement with Gilead." (Reply at 4:2-3; Def. RJN, Giunta Decl., ¶ 4, Ex. B.) Those facts could signal the type of early entry settlement that would not warrant antitrust scrutiny. *See Activis*, 570 U.S. at 158. The Trust also alleges that Gilead had an incentive to avoid competition from co-packaged versions of Truvada until 2021 and, if the emtricitabine patents were found to be invalid, Cipla could have begun to market a co-packaged version of emtricitabine and TDF as early as 2018. (FACC ¶¶ 88-93.) Those allegations show that Gilead may have had an incentive to settle, but they also rest on assumptions and speculations about whether the FDA would have approved co-packaged drugs, rather than allegations that the FDA had approved co-packaged versions.

However, the Trust also alleges that Gilead has a history of filing paragraph IV litigation relating to Emtriva, Truvada, and Atripla and of settling those cases before trial. The Trust also alleges that the "sheer number of companies that submitted Paragraph IV certifications" for those drugs implies that generic manufacturers saw Gilead's patents as weak. (*Id.* ¶¶ 58-86.) That is a plausible inference. *See, e.g., Staley*, 446 F. Supp. 3d at 612 n.29 (noting that although there were

no facts to explain why Gilead patents were weak, concluding it was plausible to infer "that there were problems with the patents" based on multiple challenges by generics). In addition, despite its history of litigation, Gilead did not sue Cipla when Cipla amended its ANDAs on Atripla to include paragraph IV certifications. However, it did file suit against at least one other generic manufacturer who filed a paragraph IV certification on Atripla but who had not settled litigation relating to Gilead's HIV medications. (*Id.* ¶¶ 57.c, 57.e.) The Trust also alleges that as part of the Teva emtricitabine litigation, Gilead gave Teva a period of exclusivity to market Atripla and includes facts about why it would be irrational for Cipla to stay out of the Atripla market absent significant compensation from Gilead, even if one takes into account the potential competition from Teva. (*Id.* ¶ 57.d; *see also id.* ¶ 48 & Trust RJN, Ex. 1 (alleging Cipla received approval to market generic Atripla in June 2019 but did not do so until March 30, 2021).)

Defendants argue there is nothing unusual about the parties attempting to reach a global settlement involving multiple patents and multiple drugs and that it is equally plausible that the Cipla settlement was a routine early entry settlement. The Court is not persuaded. The Trust also alleges that the patents that would have been at issue in litigation over Atripla were not the same patents at issue in the Cipla Litigation and are not due to expire until 2026. Because the Court must construe the facts and all reasonable inferences in the Trust's favor, the Court concludes these allegations are sufficient to show that even if emtricitabine is taken out of the equation, it is plausible the Cipla settlement involves a reverse payment settlement. *See, e.g., See, e.g., Abbvie*, 976 F.3d at 345, 357-58 (finding plaintiff stated claim where it alleged that, on the day the parties settled infringement regarding one drug, defendants announced a deal relating to a separate drug, which protected "billions of dollars" in revenue for the patent holder); *In re Lipitor*, 868 F.3d at 256-57 (finding allegations regarding release relating to separate drug in exchange for delaying entry into Lipitor market sufficient to state a claim, despite defendants' arguments that global settlement was involved).

In addition, approximately two-months after Gilead and Cipla settled the Cipla Litigation, Gilead publicly announced that it was licensing seven generic manufacturers, including Cipla, to sell generic versions of two of Gilead's hepatitis C drugs in 91 developing countries. Reports

indicated that one of the drugs "could potentially be worth US$300-US$500m, and offer a $100-$185m formulation and active pharmaceutical ingredient (API) opportunity" and that Cipla was likely to earn the API rights to the drug. (FACC ¶ 57.g.) In light of that timing and the Trust's allegations that many other companies had the capability to manufacture the APIs, the Court concludes it is reasonable to infer that Cipla obtained those rights as part of the settlement with Gilead. *Cf. In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752-53 (E.D. Pa. 2014) (concluding plaintiffs sufficiently alleged existence of reverse payment where allegations included facts that defendants "cloaked reverse payments behind two spurious contracts").

The Court concludes the Trust sufficiently alleges the existence of a reverse payment.

2. Large and Unjustified.

The Court now turns to whether the allegations are sufficient to plausibly allege the payment was large and unjustified. The Supreme Court did not clearly define either term in *Activis*. A settlement may be justified where a payment "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services" *Activis*, 570 U.S. at 156. In *United Food*, the plaintiffs alleged that a $266 million payment had "no rational connection to, and far exceed[ed], any approximation of the costs of continuing the patent litigation." 74 F. Supp. 3d at 1072. The plaintiffs also alleged that the presence of an authorized generic would have caused the price of the generic to drop from 90% of the brand name's price to 52% of that price. *Id.* at 1069. The court concluded that the status of the underlying patent litigation, one case had settled and one case had proceeded past the pleadings phase, made plaintiffs' allegations plausible. *Id.* at 1072.

The Third Circuit reached a similar conclusion in *In re Lipitor*, based on allegations that the patent holder released claims worth hundreds of millions of dollars. The generic manufacturer released its drug "at risk" and was subsequently preliminarily enjoined from distributing the generic. As part of the settlement, the generic agreed to delay its entry into the market for the brand-name drug and paid the patent holder $1 million. The plaintiffs alleged that the value of the release was well in excess of any litigation costs. 868 F.3d at 253-56. In *In re Epipen*, the plaintiffs alleged that the trial court made rulings favorable to the generic manufacturer and

alleged that the parties had completed trial, so that it was likely the parties "would incur marginal litigation expenses going forward, as compared to the expenses already incurred at settlement." 336 F. Supp. 3d at 1303. The court found those allegations, among others, plausibly suggested that the "consideration provided as part of the … settlement constituted a substantial reverse payment." *Id.*

Here, the parties reached a settlement shortly before the Cipla cases were set to go to trial, when weaknesses in Gilead's patents allegedly were exposed by the Teva litigation and when future litigation costs had diminished. The Trust also alleges that when the parties settled the Cipla emtricitabine suit, Gilead's most recent 10-K showed it had $27.4 million sales in Emtriva. Although the FDA had approved other ANDAs for generic Emtriva, Cipla was the first-to-file. (FACC ¶¶ 53-54, 57.d.) According to the Trust, if Cipla had prevailed at trial, the exclusivity period "would have been worth millions" to Cipla. *See Activis*, 570 U.S. at 144. The Trust also alleges that the value of the API manufacturing rights for the hepatitis C drugs was approximately $185 million and provides estimates of the value to Cipla of a co-packaged drug even in a competitive market. (*See, e.g.,* FACC ¶¶ 55-56, 57.g.)

The Court concludes that the Trust alleges facts that plausibly suggests the payment was large and unjustified. Accordingly, the Court DENIES Defendants' motion to dismiss the Sherman Act claim.

D. Standing to Assert California and Sister State Claims.

Defendants move to dismiss all of the claims asserted under California law (the Cartwright Act claim, the UCL claim, and Count IV), as well as most of the Sister State claims contained in Count V on the basis on the basis that the Trust lacks standing to assert these claims because it fails to allege a purchase in California or allege that it suffered an injury in California. The Trust concedes it fails to allege sufficient conduct occurring in California to support the claims against Cipla under the Cartwright Act and the UCL. Accordingly, the Court GRANTS Cipla's motion to dismiss those claims.

Standing is not dispensed "in gross", *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996), and the Trust must show it has standing for each claim it raises, *Town of Chester, N.Y v. Laroe Estates,*

Inc., 137 S. Ct 1645, 1650 (2017). With respect to the Sister State claims, this Court has previously joined courts within the Ninth Circuit that have held that a plaintiff in a putative class action lacks standing to assert claims under the laws of states other than those where the plaintiff resides or was injured. *See, e.g., Jones,* 400 F. Supp. 3d at 910-11 (citing cases).[11] The Trust acknowledges the Court's holding in *Jones*. It urges the Court to revisit that decision and to follow *Staley* by addressing the issue at the class certification stage. *See Staley*, 446 F. Supp. 3d at 622 (citing *Melendres v. Arpaio*, 784 F.3d 1254 (9th Cir. 2015)).

The Court finds no basis to revisit its prior analysis of this issue. The Trust is a resident of Florida. It fails to include *any* allegations about where it purchased Truvada for its members, but based on the allegations that its principal place of business is located in Jacksonville, Florida the Court concludes it is reasonable to infer the purchases were made in Florida. For the reasons set forth in *Jones*, which are incorporated herein, the Court concludes the Trust lacks standing to pursue the Sister State claims in Count V, with the exception of the claim under Florida law. *Jones*, 400 F. Supp. 3d at 408-11.[12] This ruling is without prejudice to the Trust filing an amended complaint that includes additional class representatives.

CONCLUSION

For the foregoing reasons, the Court GRANTS, IN PART, AND DENIES, IN PART, Defendants motion. The Trust shall either file an amended complaint or statement that it does not intend to amend by no later than September 9, 2022. The Court tolls Defendants' time to respond until the Trust has amended or filed a notice that it will stand on the FACC. Defendants shall then have 21 days to answer or otherwise respond.

Finally, the Court ORDERS the parties to appear for a case management conference on November 4, 2022 at 11:00 a.m. The parties shall file a joint case management conference

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[11] In *In re Big Heart Pet Brands*, the Court distinguished its holding in *Jones* on the basis that the named plaintiffs in that case had not attempted to bring based on the laws of "jurisdictions in which they do not reside or where they did not purchase the" product at issue. No. 18-cv-861-JSW, 2019 WL8266869, at *12 (N.D. Cal. Oct. 4, 2019). This case is analogous to *Jones*.

[12] In light of this ruling, the Court does not reach Defendants' alternative arguments about why the Trust's state law claims, including the Cartwright Act claim, fail.

statement by October 28, 2022.

IT IS SO ORDERED.

Dated: August 19, 2022

JEFFREY S. WHITE
United States District Judge