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 MOTION TO DISMISS SECOND AMENDED CLASS ACTION COMPLAINT, WITH FINAL LEAVE TO AMEND

Re: Dkt. Nos. 77, 108, 119

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, the record in this case, and oral argument For the reasons that follow, the Court HEREBY GRANTS Defendants' motion. The Court will give Plaintiffs one final opportunity to amend.

BACKGROUND

The Court set forth the facts underlying this dispute in its Order granting, in part, and denying, in part Defendants' motion to dismiss the first amended complaint, and the Court will not repeat them in detail. *See Jacksonville Police Officers and Fire Fighters Health Insurance Trust v. Gilead Sciences, Inc.*, No. 20-cv-6522-JSW, 2022 WL 3579881, at *1-*4 (N.D. Cal. Aug. 19, 2022) ("*Jacksonville*").

In brief, Gilead manufactures a number of drugs used to treat HIV, including Viread (a tablet containing 300 mg of tenofovir disproxil fumarate ("TDF")), Emtriva (a tablet containing

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

200 mg of emtricitabine), and Truvada (a tablet containing 200 mg of emtricitabine and 300 mg of TDF). *Id.* at *2. The Jacksonville Police Officers and Fire Fighters Health Insurance Trust ("Trust") and John Doe ("Doe") (collectively, "Plaintiffs") allege Defendants entered into anti-competitive reverse-payment settlement agreements to protect Gilead's patents on its brand name drugs. *See, e.g., FTC v. Activis, Inc.*, 570 U.S. 136, 152 (2013) ("*Activis*"); *In Re Cipro Cases I & II*, 16 Cal. 4th 116, 130 (2015). Plaintiffs' theory is that Cipla agreed not to produce a co-packaged, generic version of Truvada, in return for: (1) a license to produce Atripla, another HIV medication manufactured by Gilead; and/or (2) a license to produce drugs for Hepatitis C in India ("Access Agreement"); and/or (3) the right to provide Teva Pharmaceuticals USA, Inc. ("Teva") with TDF for Teva's generic version of Truvada ("Supply Agreement"). (*See* Second Amended Class Action Complaint ("SACC") ¶ 59.)

Doe asserts three claims for relief. First, he asserts a claim on behalf of himself and a putative class for violations of the Cartwright Act.[2] Second, he a UCL claim on behalf of himself and a putative class of individuals and entities in California. Third, he asserts a claim against Gilead under common law for "restitution, money had and received, unjust enrichment, [and/or] quasi-contract/assumpsit," on behalf of himself and a nationwide class.[3] The Trust asserts a claim for violations of Florida's Deceptive and Unfair Trade Practices Act (the "FDUPTA Claim").

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

ANALYSIS

A. The Court Will Not Deny the Motion on Procedural Grounds.

Plaintiffs argue that the Court should deny Defendants' motion pursuant to Federal Rule of

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[2] The Trust originally alleged Defendants' conduct violated the Sherman Act, and the Court concluded the allegations were sufficient to allege a reverse payment settlement. However, the Court dismissed the claims for violations of California's Cartwright Act, California's Unfair Competition Law ("UCL"), and all but the Florida sister state claim, because the Trust failed to allege facts that it purchased Truvada in California.

The Trust has dropped the Sherman Act claim, and Doe now asserts the Cartwright Act claim on behalf of a putative class that consists of individuals in California, the District of Columbia, and 26 other states.

[3] In the alternative, Doe asserts this claim on behalf of himself and a California class.

Civil Procedure 12(g)(2), which provides that if a party omits a defense from a motion to dismiss under Rule 12(b), it cannot raise that defense in a subsequent Rule 12(b) motion.[4] If, as is the case here, a defendant "omits a defense under Rule 12(b)(6)", the defense is not waived. Instead, the defense may be raised in an answer, a motion for judgment on the pleadings, or at trial. Fed. R. Civ. P. 12(h)(2). Because strict adherence to Rule 12(g)(2) "can produce unnecessary and costly delays," the Ninth Circuit has been "forgiving" when a district court rules "on the merits of a late-filed Rule 12(b)(6) motion." *In re Apple iPhone Antitrust Litig.*, 846 F.3d 313, 317-18 (9th Cir. 2017).

Defendants do not dispute that the arguments they raise, including the argument about antitrust injury and standing, and the supporting evidence could have been presented with their first motion. They state that if the Court denies their motion under Rule 12(g), they simply will file a Rule 12(c) motion. Accordingly, in the interest of judicial efficiency and economy, the Court will address the merits of their arguments. *See, e.g., Davidson v. Sprout Foods, Inc.*, No. 22-cv-1050-RS, 2022 WL 13801090, at *4 (N.D. Cal. Oct. 21, 2022); *see also DeSoto Cab Co., Inc. v. Uber Techs., Inc.*, No. 16-cv-6385-JSW, 2020 WL 10575294, at *2 (N.D. Cal. Mar. 25, 2020) ("[C]ourts have discretion to consider a successive motion under Rule 12(g) if to do so would facilitate judicial economy and efficiency.") (citation omitted).

B. Applicable Legal Standard and Evidentiary Issues.

Defendants move to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Unless otherwise noted, the Court has accepted the allegations in the SAC as true, has construed those allegations in the light most favorable Plaintiffs, and has examined those allegations to determine if Plaintiffs "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Lazy Y Ranch Ltd. v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008). Although the Court's evaluation of a motion to dismiss generally is limited to the allegations in a complaint, it may consider "documents incorporated into the complaint by reference, and matters of which [the Court] may take judicial notice." *Tellabs, Inc.*

[4] Rule 12(g)(2) includes exceptions that are not applicable here.

v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-23 (2007) ("Tellabs"); *see also Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999-1001 (9th Cir. 2018).

Defendants ask the Court to consider portions of the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book") (exhibits 1-7, 11-16, 36-37), court filings (exhibits 8-10, 15, 34), patents (exhibits 17-24), the Settlement Agreements between Gilead and Cipla (exhibits 23-24), and seven "Access Agreements" Gilead entered into with Cipla (exhibit 26) and six other companies (exhibits 27-32), and supply agreements Cipla entered into with Teva (exhibits 33, 35). (Dkt. No. 78, Defendants' Request for Judicial Notice.) Because the Court did not rely on the majority of these exhibits to resolve the motion, the Court denies the request as moot, except as noted. The Court has considered exhibits 23-24 under the incorporation by reference doctrine, subject to the limitations set forth in *Khoja*. *See* 899 F.3d at 1003 ("[I]t is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint.").

Defendants also ask the Court to consider a "Patent Certification and Exclusivity Statement" from Cipla dated March 25, 2014, which contains a paragraph IV certification regarding a generic version of Atripla. (Dkt. Nos. 107-1, 107-2, Declaration of Nicholas Wasdin, ¶ 3, Ex. 38.) Plaintiffs object and ask for leave to file a sur-reply. The Court did not rely on that exhibit to resolve the motion. Accordingly, the Court denies both requests as moot.

After briefing was closed, Plaintiffs asked the Court to take judicial notice of excerpts of briefs filed by Gilead and Teva in *In re HIV Antitrust Litigation*, No. 19-cv-02573-EMC, which include statements about Teva's views about its litigation position with Gilead. (Dkt. No. 112, Plaintiffs' Request for Judicial Notice, Exs. 1-2.) Defendants do not oppose Plaintiffs' request. The Court takes judicial notice of the existence of the briefs and the statements made therein.

C. Antitrust Standing and Injury.

Defendants move to dismiss on the basis that Plaintiffs fail to allege facts to show antitrust injury. Plaintiffs assert they were injured because the Defendants' conduct allegedly kept a co-packaged, generic version of Truvada off the market. (*See* SAC ¶¶ 94-99; Dkt. No. 124 (Transcript of Hearing ("Tr.") at 6:16-19, 7:5-18 (explaining theory of antitrust injury).)

Defendants argue that Plaintiffs' allegations are still speculative. *See Jacksonville*, 2022 WL 3579881, at *7.

Plaintiffs also allege that Cipla never sought approval from the FDA to market a co-packaged emtricitabine/TDF product "despite strong indications from the FDA that such an application would be approved." Plaintiffs allege those facts are that the FDA "encourage[d] sponsors to submit applications … for approval of fixed dose combination … and copackaged version of previously approved" HIV drugs, that those products would be eligible for priority review, and that even if individual drugs were still protected by a patent, the FDA could "grant tentative approval so that [a] fixed-dose combination or copackaged configuration could be marketed as soon as" a patent expired. Plaintiffs allege that is the route Gilead used to obtain the FDA's approval of Truvada and allege the FDA guidance noted that approval for the drug combination used in Truvada would not require clinical studies. (*Id.* ¶¶ 59(b), 92, 95.)

Plaintiffs allege Cipla filed ANDAs for Viread and Emtriva but did not file an ANDA on Truvada. (SAC ¶¶ 57, 59(b).) According to Plaintiffs, that fact "would have indicated to Gilead that Cipla intended to sell copackaged TDF and emtricitabine to compete with Truvada." (*Id.* ¶ 57.) Plaintiffs also allege that "even if the Viread patents were ultimately held to be valid, Cipla could still have marketed a copackaged TDF/emtricitabine product as early as January 2018, when the patents on TDF expired, *if* it could successfully challenge the patents on emtricitabine[.]" (*Id.*; *see also id.* ¶ 90.) Plaintiffs allege this posed a threat to Gilead because of a settlement with Teva: "If Cipla were to produce its own generic copackaged drug, Teva's right to immediately sell generic Truvada *likely* would have been triggered, costing Gilead significant revenue, potentially in the billions of dollars." (*Id.* ¶ 57; *see also id.* ¶ 58.)

Although Plaintiffs have provided greater factual support for the allegation that FDA approval of a co-packaged version of Truvada was a "virtual certainty," the Court concludes their allegations about whether Cipla, or any other generic manufacturer, intended to seek approval for a co-packaged version of Truvada are based on speculation and conjecture and are insufficient to plausibly allege their theory of injury.

CONCLUSION

For the foregoing reasons, the Court GRANTS Defendants' motion to dismiss. The SAC constitutes the third iteration of Plaintiffs' complaint. However, because the Court cannot say it would be futile, the Court will give Plaintiffs' one final opportunity to amend. If Plaintiffs choose to amend, they shall file an amended complaint by no later than September 26, 2023. If Plaintiffs choose not to amend, they shall file a notice of that intent, and the Court will enter a dismissal and judgment. If Plaintiffs amend, Defendants shall answer or otherwise respond within 21 days thereafter. The Court will defer setting a case management conference until Defendants have answered.

IT IS SO ORDERED.

Dated: August 28, 2023

JEFFREY S. WHITE
United States District Judge

United States District Court
Northern District of California