United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STALEY, et al.,

Plaintiffs,

v.

GILEAD SCIENCES, INC., et al.,

Defendants.

Case No. 19-cv-02573-EMC

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS

Docket Nos. 143, 149, 158, 159

Plaintiffs in this putative class action are:

(1) individuals who purchased and/or paid for some or all of the purchase price for certain HIV medications and

(2) health and welfare trust funds/plans that purchased or provided reimbursement for some or all of the purchase price for certain HIV medications.

Plaintiffs have filed suit against companies that are the new drug application holders[1] for, or otherwise manufacture, sell, and/or distribute, those HIV medications, namely:

(1) Gilead[2];

(2) Bristol-Myers Squibb ("BMS")[3];

(3) Japan Tobacco; and

[1] Before a drug manufacturer can sell a drug on the market, it must get approval from the Food and Drug Administration ("FDA"). It does so by submitting a new drug application. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).

[2] Plaintiffs have formally sued multiple Gilead entities: Gilead Sciences, Inc.; Gilead Holdings, LLC; Gilead Sciences, LLC; and Gilead Sciences Ireland UC.

[3] Plaintiffs have formally sued multiple BMS entities: Bristol-Myers Squibb Company and E.R. Squibb & Sons, L.L.C.

(4) Janssen.[4]

The bulk of Plaintiffs' claims against Defendants are antitrust claims, both federal and state (Counts 1-6 and 8-13). Plaintiffs have also asserted a claim based on violation of state consumer protection laws (Count 7). Currently pending before the Court are four motions to dismiss, one filed by each defendant named above. Two amicus briefs have also been submitted: one from the Federal Trade Commission ("FTC") and one from a group of nonprofit organizations that do HIV-related work.

Having considered the parties' briefs and accompanying submissions, as well as the oral argument of counsel, the Court hereby **GRANTS** in part and **DENIES** in part the motions to dismiss.

I. FACTUAL & PROCEDURAL BACKGROUND

The operative complaint is the corrected consolidated class action complaint ("CAC"). In that pleading, Plaintiffs allege as follows.

A. Regulatory Background

1. New Drugs and Generic Drugs

Drug manufacturers must obtain approval from the Food and Drug Administration ("FDA") before they can market and sell their drugs. If a drug manufacturer wants to sell a new drug, it must file a New Drug Application ("NDA") with the FDA. *See* CAC ¶ 68. Another process applies to generic drugs.

> [O]nce the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures. The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application ["ANDA"] specifying that the generic has the "same active ingredients as," and is "biologically equivalent" to the already-approved brand-name drug." In this way the generic manufacturer can obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval "for a pioneer drug." The Hatch-Waxman process, by allowing the generic to piggyback on the pioneer's approval efforts, "speed[s] the introduction of low-cost generic drugs to market."

[4] Plaintiffs have formally sued multiple Janssen entities: Johnson & Johnson and Janssen R&D Ireland.

FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013).

"The FDA assigns generic drugs that are pharmaceutical equivalents of branded drugs an 'AB' rating." CAC ¶ 71. State laws "either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing doctor has specifically ordered otherwise)." CAC ¶ 91.

2. Generic Manufacturers and Paragraph IV Certifications

New drugs, of course, are often protected by patents which, in theory, prevent the sale of generic versions of the new drugs – at least until the patents expire. Those patents, however, like any patents, may be challenged before their expiration dates.

A generic manufacturer may effectively raise a challenge to a patent by including in its ANDA what is known as a Paragraph IV certification – *i.e.*, a statement that the brand drug is covered by a patent but that the patent is invalid or will not be infringed by the generic drug. *See* CAC ¶ 75. A generic manufacturer has an incentive to include a Paragraph IV certification so that it can sell the generic drug before the patent on the brand drug expires on its own terms.

In addition, the *first* generic manufacturer to file an ANDA with a Paragraph IV certification gets an added benefit: it is "entitled to 180 days of ANDA Exclusivity," meaning that the FDA cannot approve any other generic version of the drug "until 180 days after the first-filer enters the market." CAC ¶ 77 (emphasis added). As the Supreme Court has noted, ANDA Exclusivity "can prove valuable, possibly worth several hundred million dollars. Indeed, the Generic Pharmaceutical Association said in 2006 that the vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Actavis*, 570 U.S. at 144. (ANDA Exclusivity can be forfeited under certain circumstances.[5]) "The first-filing generic manufacturer is guaranteed [the] exclusivity period even if it settles litigation with a patent owner without resolving the invalidity or noninfringement issues." *AIDS Healthcare Foundation, Inc. v. Gilead Sciences, Inc.*, No. C 16-00443 WHA, 2016 U.S. Dist. LEXIS 87578, at *4-5 (N.D.

[5] For example, it the first filer does not get tentative approval of the generic drug within 30 months, the ANDA Exclusivity is forfeited. *See* CAC ¶ 78. The first filer also forfeits if "it fails to market its generic drug within 75 days after another manufacturer obtains a final decision that the brand manufacturer's patents are invalid or not infringed." CAC ¶ 78.

Cal. July 6, 2016).

In turn, when a Paragraph IV certification is made, a brand manufacturer has an incentive to sue the generic manufacturer for patent infringement because, if it does so within 45 days of receiving the Paragraph IV certification, it may delay approval of the ANDA. More specifically, if the brand manufacturer files suit within 45 days, then the FDA is automatically barred from granting approval to the generic manufacturer's ANDA "until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed." CAC ¶ 76.

Notably, even if a generic manufacturer wants to file an ANDA with a Paragraph IV certification as soon as possible (given the above), it cannot do so in all circumstances. In particular, "where the FDA has approved a new chemical entity ['NCE'] (a drug substance that the FDA has not previously approved), no other manufacturer may seek FDA approval for a product containing that drug substance until five years after the FDA first approved it." CAC ¶ 86. Thus, the FDA cannot accept an ANDA from a generic manufacturer if the generic drug contains a NCE until the five-year "NCE Exclusivity" period has expired. *See* CAC ¶ 87. NCE Exclusivity thus "operates independent of any patent protection." *AIDS Healthcare*, 2016 U.S. Dist. LEXIS 87578, at *7.

B. Science Background

1. cART Regimen

The modern HIV treatment regimen is known as cART, which stands for combination antiretroviral therapy. *See* CAC ¶ 1. A combination – or "cocktail" – is usually made up of:

(1) Two NRTIs (nucleotide/nucleoside analogue reverse transcriptase inhibitors); and

(2) A third agent (also known as a core agent).

See CAC ¶¶ 2, 56. A cocktail may also include a third class of drug – namely, a booster. Boosters not taken for any anti-HIV property in the drug but rather for their ability to inhibit the breakdown of some third agents. *See* CAC ¶¶ 64-65.

"The need to use multiple drugs in cART regimens can be a barrier to patient compliance." CAC ¶ 63. Thus, to reduce the burden on the patient, multiple drugs are often coformulated

together into a single pill known as an FDC, which stands for fixed-dose combination. *See* CAC ¶ 63. An FDC can be made up of drugs made by one manufacturer or by more than one manufacturer, if the manufacturers can reach agreement.

2. Gilead's Drugs

Gilead makes various drugs that are used in cART regimens. The main ones at issue in the instant case are as follows:

- TDF and TAF (NRTIs). Tenofovir is one of the principal NRTIs used in cART regimens. It is one of the principal NRTIs because it has medical benefits over other NRTIs. *See* CAC ¶¶ 58, 382 (alleging that other NRTIs need to be triple phosphorylated for the drug to be activated, but Tenofovir only needs to be phosphorylated twice); CAC ¶¶ 383-90 (discussing additional problems with other NRTIs, *e.g.*, side effects). Because Tenofovir cannot be administered orally by itself, Gilead developed two different "prodrugs" of Tenofovir that allow it to be swallowed: TDF and TAF. *See* CAC ¶¶ 57, 59 (alleging that "[p]rodrugs are pharmacologically inactive compounds that can be more efficiently absorbed and then converted into the active form of the drug within the body"). TAF is essentially the successor drug to TDF and is superior to TDF (*e.g.*, fewer side effects). A generic version of TDF became available in December 2017. *See* CAC ¶ 98. There is no generic TAF available yet. "Tenofovir is almost always used alongside another NRTI" because, when an HIV virus becomes resistant to the other NRTI, "the virus's susceptibility to Tenofovir increases." CAC ¶ 60 (emphasis omitted).
- FTC (an NRTI). FTC is one of the NRTIs commonly used with Tenofovir in cART regimens. *See* CAC ¶ 60. Generic FTC will become available in September 2020. *See* Opp'n at 9; CAC ¶ 357.
    - Even though there is no generic FTC available yet, there is another drug – 3TC – that Gilead does not manufacture and that may be used as a substitute for FTC. *See* CAC ¶ 61 (alleging that "[b]oth the United States

Department of Health and Human Services . . . and the World Health Organization . . . guidelines stipulate that the drugs, when used for HIV treatment, can be used interchangeably"). Generic 3TC has been available since 2012. *See* CAC ¶¶ 62, 97-98.

- TDF/FTC (an FDC). Gilead makes an FDC made up of two of the above NRTIs – *i.e.*, TDF/FTC. It appears that generic TDF/FTC will become available in September 2020. *See* Opp'n at 9, 51; CAC ¶ 357.
- COBI (a booster). There is no generic COBI available yet. *See* CAC ¶¶ 64-65.
    - Even though there is no generic COBI available yet, there is another drug – RTV – that Gilead does not manufacture and that may be used as a substitute for COBI. Generic RTV has been available since March 2018. *See* CAC ¶¶ 65, 112.

C. Anticompetitive Conduct

The anticompetitive conduct identified in Plaintiffs' CAC falls into the following three categories:

(1) Agreements between Gilead and one of the other defendants that contain "No-Generics Restraints."

(2) Patent settlement agreements between Gilead and a generic manufacturer, Teva, under which Teva agreed to delay entry into the market in exchange for certain benefits.

(3) Gilead's commercialization of one of its drugs known as TAF.

1. Agreements with No-Generics Restraints

TDF, FTC, and TDF/FTC were critical drugs for Gilead's business because of the medical benefits of Tenofovir over other NRTIs. By their terms, the patents protecting TDF were not due to expire until January 2018. As for the patents protecting FTC and TDF/FTC, they were not due to expire until September 2021 and January 2024, respectively. *See* CAC ¶ 96. However, Gilead expected to face generic competition for TDF, FTC, and TDF/FTC far earlier – *i.e.*, in 2009, 2011, and 2011 – because the patents protecting the drugs were weak and thus generic manufacturers

would challenge the patents. *See, e.g.*, CAC ¶ 96 (indicating, *e.g.*, that the NCE Exclusivity for TDF expired in October 2006, so if a generic manufacturer thereafter filed an ANDA with a Paragraph IV certification, then Gilead would bring a patent infringement suit which would delay the ANDA process for about 30 months – *i.e.*, until 2009).

To protect its vulnerable NRTIs, Gilead began – starting in December 2004 – to enter into agreements with other drug manufacturers, in particular, those who made third agents (instead of NRTIs).[6] Under a typical agreement, Gilead and the other drug manufacturer would agree to coformulate a FDC made up of (1) Gilead's vulnerable NRTIs and (2) the other drug manufacturer's third agent, which had a longer patent life (assuming that Gilead's NRTIs would face generic competition in 2009, 2011, and 2011, respectively). The agreement would also contain a provision that, even when generic versions of Gilead's NRTIs became available (*e.g.*, if the patents were successfully challenged), the other drug manufacturer would not, on its own, offer a competing FDC made of (1) generic versions of Gilead's NRTIs and (2) the other drug manufacturer's third agent. Plaintiffs call this provision a "No-Generics Restraint" and, for ease of reference, the Court shall do the same.

According to Plaintiffs, they are not claiming as anticompetitive conduct any agreement to coformulate a FDC. Indeed, they concede that the FDCs benefit people with HIV, making available to them products that would not otherwise exist.[7] What Plaintiffs do contest are the No-

[6] The rough timeline is as follows:

- December 2004: Gilead entered into an agreement with BMS (the Atripla Agreement).
- March 2005: Gilead entered into an agreement with Japan Tobacco.
- July 2009: Gilead entered into an agreement with Janssen (the Complera Agreement).
- June 2011: Gilead entered into another agreement with Janssen (the Prezcobix Agreement). This agreement allegedly protected one of Janssen's vulnerable drugs, not Gilead's.
- October 2011: Gilead entered into a second agreement with BMS (the Evotaz Agreement). This agreement allegedly protected one of BMS's vulnerable drugs, not Gilead's.
- December 2014: Gilead entered into more agreements with Janssen (the Odefsey Agreement and the Symtuza Agreements). The Symtuza Agreement allegedly protected one of Janssen's vulnerable drug, not Gilead's.

[7] And Defendants point out that the federal government has applauded some of the business collaborations. *See* Gilead Mot. at 9 (citing to comments made by the Secretary of Health & Human Services with respect to business collaboration between Gilead and BMS on a FDC commercially known as Atripla).

Generics Restraints in the agreements because, as alleged, the restraints effectively protect Gilead's NRTIs by precluding the other drug manufacturer from selling FDCs that incorporate generic versions of Gilead's NRTIs *even after the patents protecting the NRTIs expire*. (According to Plaintiffs, Gilead entered into "reciprocal" agreements with BMS and Janssen wherein Gilead and the other company agreed to pair in a FDC one of Gilead's drugs (the booster known as COBI) with one of the other company's vulnerable drugs.)

The agreements with the No-Generics Restraints – by themselves – only provided limited protection for Gilead's NRTIs. When generic versions of the NRTIs became available, individuals with HIV could, at least in theory, buy generic TDF, generic FTC, and/or generic TDF/FTC as "standalones" – *i.e.*, instead of as part of a FDC. But, as Plaintiffs allege, there are benefits to purchasing and using a FDC over purchasing and using standalone components to that FDC. *See* CAC ¶ 63 (alleging that "[t]he need to use multiple drugs in cART regimens can be a barrier to patient compliance"). Moreover, according to Plaintiffs, Gilead also took affirmative steps to move its customer base from standalone TDF, FTC, and/or TDF/FTC to the FDCs, as the FDCs would be protected by the No-Generics Restraints.[8] *See, e.g.*, CAC ¶ 4 (alleging that the No-Generics Restraints "gave Gilead an enormous financial incentive to move prescriptions from its standalone version of TDF to the FDCs, which would be insulated from generic competition even after the TDF[] patents expired"). According to Plaintiffs, once individuals with HIV have moved over to the FDCs, they are not likely to move back "to the original product or regimen, even if a generic version of the original product becomes available at a much lower price" for various reasons – *e.g.*, "[d]octors who have switched patients from one HIV product or HIV drug regimen to another are very reluctant to switch patients back." CAC ¶ 181. Also, "[s]witching costs (e.g., the need for another visit to the doctor for a new prescription) impair a move back," and "pharmaceuticals are 'experience' goods that consumers and physicians are hesitant to change if they are working."[9] CAC ¶ 181.

[8] Plaintiffs suggest that Gilead was able to do this through use of "large sales forces that visit doctors' offices and persuade them to prescribe" certain products. *See* CAC ¶ 368.

[9] Plaintiffs also allege that "doctors typically are not aware of the relative costs of brand

Plaintiffs further note that, once a person is prescribed an FDC, it is not possible for the pharmacist to fill the prescription with standalone components for the FDC (*i.e.*, standalone generic TDF, FTC, and/or TDF/FTC along with standalone of the other company's drug). This is because standalone components of an FDC are not AB-rated to the FDC. *See* CAC ¶ 183 (alleging that "[g]eneric versions of TDF and/or FTC are not AB-rated to, and therefore not automatically substitutable for, the TDF-based FDCs"); *see also* Opp'n at 3(asserting that, "[u]nder state drug-substitution laws, pharmacists receiving a prescription for the FDC cannot dispense generic versions of the standalone components").

According to Plaintiffs, one effect of the No-Generics Restraints was that Gilead decided to shelve further development of TAF (the superior successor drug to TDF) – *i.e.*, Gilead no longer had to roll out TAF in order to be competitive in the market but rather could "make more profits by defeating generic competition to TDF and then rolling out TAF much later as part of a line extension." CAC ¶ 214; *see also* CAC ¶ 202 *et seq.* (explaining that TAF is a superior product compared to TDF because the former has significantly less risk of side effects).

Plaintiffs add that, although Gilead has now rolled out TAF, it has done so in an anticompetitive way, including, *e.g.*, by making agreements with the other defendants to protect TAF, *even after the patents on that drug expire*, through No-Generics Restraints. *See* CAC ¶ 192 (alleging that "Defendants are *repeating this anticompetitive cycle again* with respect to the TAF-based FDCs") (emphasis added); CAC ¶ 428 (alleging that, "[u]nless enjoined by this Court, Defendants' unlawful conduct will have additional and intensified anticompetitive effects once generic versions of [*inter alia*] TAF . . . become available").

2. Patent Settlement Agreements with Teva

The prospect of generic competition for Gilead's vulnerable NRTIs (*i.e.*, TDF, FTC, and/or TDF/FTC) became a concrete reality by 2008 when Teva began to challenge the patents protecting the drugs through Paragraph IV certifications. Other generic manufacturers followed suit. *See* CAC ¶ 313. According to Plaintiffs, these challenges to TDF, FTC, and/or TDF/FTC prompted

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pharmaceuticals and, even when they are aware of costs, are largely insensitive to price differences because they do not pay for the products." CAC ¶ 368.

Gilead to get moving with TAF – in particular, moving its customer base over from TDF-based FDCs to TAF-based FDCs, which would also be protected by No-Generics Restraints. *See* CAC ¶ 314.

Gilead was able to settle its patent infringement lawsuits with Teva and get Teva to agree to delay entry into the market for the above drugs (a benefit for Gilead); in exchange, Gilead gave Teva Most-Favored Entry ("MFE") and Most-Favored Entry Plus ("MFEP") clauses in the settlement agreements, a benefit over *other* generic manufacturers. As described in the complaint:

> An agreement with an MFE clause arises when the brand manufacturer and the "first-filer" – the generic manufacturer that filed the first ANDA with a Paragraph IV certification – settle the patent litigation, with the generic manufacturer agreeing to delay entering the market until a specified date. The MFE clause provides that if any other generic manufacturer (a "second-filer") succeeds in entering the market before that date, the first-filer may enter at the same time.

CAC ¶ 317. According to Plaintiffs, a MFE is anticompetitive in nature not only because it delays the first filer's entry into the market but also because it "delay[s] generic entry by reducing a second-filer's incentive to try to enter the market before the first-filer." CAC ¶ 317; *see also* CAC ¶ 319 (alleging that a MFE eliminates the possibility that a second filer could enter the market before the first filer).

As for a MFEP clause, it

> 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. The clause might provide, for example, that the brand manufacturer will not grant a license to any second-filer to enter the market until 180 days after the first-filer enters.

CAC ¶ 320 (emphasis in original). It thus affirmatively favors the first filer with whom the manufacturer has negotiated. According to Plaintiffs, a MFEP delays generic entry both by delaying the entry of the first filer and "dramatically reduc[ing] a second-filer's incentive to try to enter the market before the first-filer." CAC ¶ 320.

Gilead ultimately entered into two different settlement agreements with Teva.

- The first agreement (dated April 2013) applied to TDF. *See* CAC ¶ 340. Gilead's patents protecting TDF were to expire, by their own terms, in January 2018. *See*

CAC ¶ 96. "Under the agreement, Teva agreed to delay marketing its generic [TDF] and any TDF-containing product until December 15, 2017" – *i.e.*, just a few weeks before the TDF patents were due to expire. CAC ¶ 342. Teva was willing to put off its entry date until such a late date because it received, in exchange, the MFE and MFEP clauses in the settlement agreement. The MFEP clause "provided that Gilead would not grant any other manufacturer a license to enter the market with generic [TDF] until at least *six weeks* after Teva's agreed entry date." CAC ¶ 343 (emphasis added).

- The second agreement (dated February 2014) applied to TDF/FTC and a drug that Gilead coformulated with BMS that contains TDF/FTC. (The commercial name for that drug is Atripla.) The agreement was reached after the parties had tried the patent infringement case and were awaiting certain decisions from the trial court. *See* CAC ¶ 354. Under the agreement, Teva agreed not to launch generics for TDF/FTC and the other drug until September 2020 – "just one year before the end of the patent term" for FTC. CAC ¶ 357. In exchange, Teva was given MFE and MFEP clauses in the settlement agreement. "The MFEP provided that Gilead would not grant a license to any other manufacturer to enter the market . . . until at least *six months* after Teva's agreed entry date." CAC ¶ 357 (emphasis in original).

3. Commercialization of TAF

As noted above, Plaintiffs maintain that one effect of the No-Generics Restraints was that Gilead could shelve TAF (the successor drug to TDF) – *i.e.*, Gilead no longer had to roll out TAF in order to be competitive in the market but rather could "make more profits by defeating generic competition to TDF and then rolling out TAF much later as part of a line extension." CAC ¶ 214; *see also* CAC ¶ 202 *et seq.* (explaining that TAF is a superior product compared to TDF because the former has significantly less risk of side effects). Plaintiffs also maintain that, although Gilead has now rolled out TAF, it has done so in an anticompetitive way – for instance, by making agreements with the other defendants to protect TAF, even after the patents on the drug expire, through No-Generics Restraints.

According to Plaintiffs, however, this was not the only way that Gilead commercialized TAF in an anticompetitive way. Plaintiffs assert that Gilead had the goal of moving over prescriptions from TDF-based FDCs to TAF-based FDCs precisely because the FDCs (unlike any standalone drugs) would be protected by the No-Generics Restraints. To move over to TAF-based FDCs, Gilead took steps to: (1) make the TDF-based FDCs less desirable, and (2) ensure that TAF standalone could or would not be used in conjunction with other standalone drugs in place of a TAF-based FDC. For example:

- Gilead intentionally degraded the safety of one of its TDF-based FDCs, commercially known as Stribild (*i.e.*, by keeping the strength of TDF at a certain level when a lower level would produce fewer side effects), and further artificially raised the price of the drug. *See generally* CAC ¶ 242 *et seq.*
- When Gilead released TAF standalone (after withholding it from the market from about 2015-2016), Gilead labeled the drug as a treatment for chronic Hepatitis B only (and not HIV as well)[10] and further intentionally degraded the drug (*i.e.*, by selling it at a strength that produced more side effects instead of a lower strength). *See generally* CAC ¶ 250 *et seq.*

II. PLAINTIFFS' CAUSES OF ACTION

Based on, *inter alia*, the above allegations, Plaintiffs have asserted the following causes of action:

(1) Conspiracy to monopolize in violation of §§ 1 and 2 of the Sherman Act (against all Defendants and implicating all three categories of anticompetitive conduct). *See* 15 U.S.C. §§ 1-2.

(2) Conspiracy to monopolize in violation of state antitrust laws (against all Defendants and implicating all three categories of anticompetitive conduct).

(3) Monopolization in violation of § 2 of the Sherman Act (against Gilead only and

[10] According to Plaintiffs, theoretically, doctors could prescribe TAF for an off-label use – *i.e.*, to treat HIV. "But, in fact, substantial numbers of doctors will not do so. And federal law (21 C.F.R. § 202.1) makes it unlawful for a pharmaceutical manufacturer to actively encourage doctors to prescribe the product for off-label use." CAC ¶ 307.

implicating all three categories of anticompetitive conduct). *See id.* § 2.

(4) Monopolization in violation of state antitrust laws (against Gilead only and implicating all three categories of anticompetitive conduct).

(5) Attempted monopolization in violation of § 2 of the Sherman Act (against Gilead only and implicating all three categories of anticompetitive conduct). *See id.*

(6) Attempted monopolization in violation of state antitrust laws (against Gilead only and implicating all three categories of anticompetitive conduct).

(7) Violation of state consumer protection laws (against all Defendants and implicating all three categories of anticompetitive conduct).

(8) Conspiracy in violation of § 1 of the Sherman Act (against Gilead and Janssen only and implicating the No-Generics Restraints only). *See id.* § 1.

(9) Conspiracy in violation of state antitrust laws (against Gilead and Janssen only and implicating the No-Generics Restraints only).

(10) Conspiracy in violation of § 1 of the Sherman Act (against Gilead and Japan Tobacco only and implicating the No-Generics Restraints only). *See id.*

(11) Conspiracy in violation of state antitrust laws (against Gilead and Japan Tobacco only and implicating the No-Generics Restraints only).

(12) Conspiracy in violation of § 1 of the Sherman Act (against Gilead and BMS only and implicating the No-Generics Restraints only).

(13) Conspiracy in violation of state antitrust laws (against Gilead and BMS only and implicating the No-Generics Restraints only).

III. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint that fails to meet this standard may be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6). To overcome a Rule 12(b)(6) motion to dismiss after the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), a plaintiff's "factual allegations [in the complaint] 'must .

. . suggest that the claim has at least a plausible chance of success.'" *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1135 (9th Cir. 2014). The court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But "allegations in a complaint . . . may not simply recite the elements of a cause of action [and] must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Levitt*, 765 F.3d at 1135 (internal quotation marks omitted). "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." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal quotation marks omitted).

IV. ANTITRUST CLAIMS BASED ON OVERARCHING CONSPIRACY – COUNTS ONE AND TWO

In Counts One and Two of the CAC, Plaintiffs allege an overarching conspiracy involving all Defendants and implicating all three categories of anticompetitive conduct. Defendants move to dismiss the causes of action on the basis that Plaintiffs have failed to adequately allege all Defendants were involved in one overarching conspiracy. Defendants underscore that nowhere in the CAC do Plaintiffs suggest that there was any collective agreement among BMS, Japan Tobacco, and Janssen to assist Gilead. *See, e.g.*, BMS Mot. at 12-13 (asserting that "[n]ot a single factual allegation supports the theory that all defendants knowingly and willfully joined together" to assist Gilead in protecting its drugs from competition; adding that "Plaintiffs here allege only that Gilead over the course of a decade, entered into separate, bilateral agreements with BMS, Janssen, and Japan Tobacco").

In response, Plaintiffs admit that BMS, Japan Tobacco, and Janssen were each acting separately, and not acting collectively, with Gilead. *See, e.g.*, Opp'n at 44 (asserting that "[e]ach of BMS, Janssen, and Japan Tobacco separately, not acting collectively, conspired with Gilead"). And consistent with this admission, Plaintiffs do not make any claim that, *e.g.*, BMS or Japan Tobacco could be held liable for the alleged conspiracy between Janssen and Gilead to restrain

trade in or monopolize the market for the Janssen/Gilead coformulated FDCs and their generic equivalents.

Plaintiffs, however, do argue that there is a viable overarching conspiracy claim based on a broader product market – *i.e.*, the market for cART drugs. *See* Opp'n at 42 (arguing that each non-Gilead defendant conspired with Gilead to maintain its cART monopoly); *see also* CAC ¶¶ 442, 451 (for Counts One and Two, referring to "monopoly power in the cART Market"). That is, Plaintiffs contend that there was a conspiracy to restrain trade in or monopolize the market for cART drugs; that each non-Gilead defendant knew of and contributed to that conspiracy by separately conspiring with Gilead; and that each non-Gilead defendant is therefore liable for the conspiracy "even if the defendant did not know all the conspirators [*i.e.*, the other non-Gilead defendants], did not participate in the conspiracy from its beginning or participate in all its enterprises, or otherwise know all its details." *United States v. Grasso*, 724 F.3d 1077, 1086 (9th Cir. 2013) (addressing criminal case involving conspiracy to defraud); *cf. United States v. Friedman*, 593 F.2d 109, 117 (9th Cir. 1979) (in criminal case involving drug conspiracy, stating that "[t]he standard for determining the existence of a single conspiracy is whether there was a single overall agreement among the co-conspirators to perform various functions to carry out the objectives of the conspiracy"; "the performance by a conspirator of separate and independent acts in furtherance of the conspiracy is not inconsistent with the existence of a single overall agreement").

The Court dismisses Plaintiffs' overarching conspiracy claim because, as discussed below, Plaintiffs have not adequately alleged a cART product market. *See* Part VIII, *infra*. In addition, Plaintiffs have failed to adequately allege that each non-Gilead defendant knew of its connection to a conspiracy to restrain trade in or monopolize that broader product market (as opposed to the narrower product markets consisting of each FDC coformulated by a non-Gilead defendant and Gilead, and its generic equivalent).[11] *Cf. Grasso*, 724 F.3d at 1086 (9th Cir. 2013) (stating that,

[11] Notably, Plaintiffs do not allege that a non-Gilead defendant got any benefit out of the agreements that Gilead had with the other non-Gilead defendants. It is not obvious why knowledge of a conspiracy should be inferred under these circumstances absent specific supporting facts.

"[w]here the defendant has a connection (even if slight) to the conspiracy, the government must also show that the defendant's connection to the conspiracy is knowledgeable; 'that is, the government must prove beyond a reasonable doubt that the defendant knew of his connection to the charged conspiracy'" – *i.e.*, that "the defendant was aware of 'the unlawful object toward which the agreement [was] directed'"). Plaintiffs have leave to amend.

V. ANTITRUST CLAIMS BASED ON NO-GENERICS RESTRAINTS – COUNTS THREE THROUGH SIX AND COUNTS EIGHT THROUGH THIRTEEN

In the remaining antitrust claims – Counts Three through Six and Counts Eight through Thirteen – Plaintiffs claim anticompetitive conduct based on one or more of the three categories identified above. Here, the Court addresses the first category of anticompetitive conduct, *i.e.*, the No-Generics Restraints contained in the agreements that Gilead entered into with the other defendants. As noted above, Plaintiffs maintain that they are not challenging Defendants' agreements to create FDCs (which are beneficial to individuals with HIV). Rather, Plaintiffs contest only the No-Generics Restraints in the agreements.

A. Ancillary Restraints Doctrine

According to Defendants, even if the agreements did contain No-Generics Restraints (as discussed below, not all defendants agree that there are, in fact, such restraints in the contracts at issue), the No-Generics Restraints are, effectively, per se valid under the ancillary restraints doctrine. The gist of Defendants' ancillary restraints argument is that, where competitors enter into a joint venture (or other business collaboration), it is reasonable to have a provision barring members of the joint venture from competing with the joint venture – or else there would be no incentive to enter into the joint venture in the first place. In other words, here, where Gilead and another defendant entered into agreement to create an FDC made up of Gilead's drugs and the other defendant's drug, it was reasonable to include a provision that would keep the contracting parties from creating a competing FDC using generic versions of those drugs. Defendants underscore that this prevented competition only with respect to the *specific* FDC at issue; it would not bar the contracting parties from using their drugs in other ways, including as standalones or in combination with different drugs to create different FDCs.

In evaluating this argument, the Court begins with the principle that, as a general matter, agreements between competitors – what are known as "horizontal agreements" – are suspect from an antitrust perspective. *See Betkerur v. Aultman Hosp. Ass'n*, 78 F.3d 1079, 1092 (6th Cir. 1996) (stating that "'horizontal' restraints – that is, agreements among competitors at the same level of the market structure – are particularly suspect because they typically serve no purpose other than to stifle competition"); *cf. Republic Tobacco Co. v. N. Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) (noting that "horizontal agreements are generally more suspect than vertical agreements"). That being said, not all horizontal agreements are antitrust violations. Joint ventures or other business collaborations between competitors can actually be procompetitive – offering to the market a product that could not otherwise be offered in the absence of the joint undertaking.[12] *Cf. NCAA v. Board of Regents*, 468 U.S. 85, 102 (1984) (noting that "the NCAA plays a vital role in enabling college football to preserve its character, and as a result enables a product to be marketed which might otherwise be unavailable[;] [i]n performing this role, its actions widen consumer choice – not only the choices available to sports fans but also those available to athletes – and hence can be viewed as procompetitive"); *Addamax Corp. v. Open Software Found, Inc.*, 152 F.3d 48, 52 (1st Cir. 1998) (noting that "[j]oint venture enterprises . . . , unless they amount to complete shams, are rarely susceptible to per se treatment"; in fact, "[w]here the venture is producing a new product . . . there is patently a potential for a productive contribution to the economy").

Consistent with the above, the Supreme Court has held that the creation of a joint venture is not deemed invalid per se but rather is evaluated under the rule of reason.[13] *See Texaco Inc. v.*

[12] Although the Court shall hereinafter refer to "joint ventures" only, it notes that it is not limiting its discussion to joint ventures alone – *i.e.*, the ancillary restraints doctrine also has application to other business forms or structures such as business collaborations. *See Texaco Inc. v. Dagher*, 547 U.S. 1, 7 (2006) (noting that the ancillary restraints doctrine "governs the validity of restrictions imposed by a legitimate business collaboration, such as a business association or joint venture, on nonventure activities").

[13] Cases often address joint ventures in the context of § 1 of the Sherman Act since § 1 covers agreements to restrain trade. There is no reason not to apply a similar analysis to § 2 claims for conspiracy to monopolize as such claims require a showing of anticompetitive conduct. Furthermore, the parties have not made any argument that the § 1 and § 2 conspiracy claims should be treated differently in this regard.

Dagher, 547 U.S. 1, 6 n.1 (2006) (indicating that the creation of a joint venture can be anticompetitive; whether it is anticompetitive must be assessed "under the rule of reason"); *see also Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 885-86 (2007) (stating that, under the rule of reason, "'the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition'"; in contrast, where the per se illegality rule applies, there is no "need to study the reasonableness of an individual restraint in light of the real market forces at work"). In contrast, where there is, in fact, a legitimate joint venture, and the only issue is whether specific conduct of the joint venture violates antitrust law, then a court must decide what mode of analysis to apply: the rule of per se illegality or the rule of reason. *See In re ATM Fee Antitrust Litig.*, 554 F. Supp. 2d 1003, 1012 (N.D. Cal. 2008).

In their opposition, Plaintiffs contend that they are challenging to whether joint ventures were, in fact, created. That is, Plaintiffs assert that, as a factual matter, not all of the agreements at issue actually create joint ventures, and, at the very least, it is a factual question whether the joint ventures are legitimate – both of which thereby make dismissal at the 12(b)(6) phase of proceedings improper. For purposes of this order, the Court assumes the agreements constituted joint ventures and that the only issue for the Court to resolve is whether the specific conduct of the joint ventures – *i.e.*, the No-Generics Restraints – plausibly constitutes anticompetitive conduct.

Here, there is no dispute that Plaintiffs have adequately alleged that the No-Generics Restraints are *some* kind of restraint on trade. Plaintiffs have alleged that the non-Gilead defendants are not able to offer certain FDCs that compete with the joint venture FDCs – *i.e.*, the same FDCs except using generic versions of Gilead's drugs after the patents on Gilead's drugs expire. The only question is, as noted above, whether the restraints are valid or invalid under antitrust law.

In addressing this specific issue, the Court would ordinarily be confronted with the question of whether to apply the rule of per se illegality or instead the rule of reason. *See ATM Fee*, 554 F. Supp. 2d at 1010 (noting that "the decision of what mode of analysis to apply . . . is entirely a question of law for the Court," although that legal question "might involve factual

disputes"); *accord Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 61 (1st Cir. 2004). Defendants argue, however, that the Court need not apply even the rule of reason because the No-Generics Restraints may, in effect, be deemed per se *valid* under the ancillary restraints doctrine. According to Defendants, under this doctrine, so long as a restraint supports or benefits the (legitimate) joint venture,[14] then it is deemed per se valid under the Supreme Court's decision in *Dagher*; the restraint is not even subject to a rule-of-reason analysis. Defendants rely on the following language from *Dagher*: "Under the [ancillary restraints] doctrine, courts must determine whether the nonventure restriction is a naked restraint on trade, and thus invalid, or one that is ancillary to the legitimate and competitive purposes of the business association, and thus valid." *Dagher*, 547 U.S. at 7.

The Court rejects Defendants' argument. The above language, taken in isolation, might suggest that once a restriction supports or benefits the joint venture, it is deemed per se valid. However, as Plaintiffs point out, the context of *Dagher* must be taken into account. In *Dagher*, the plaintiffs simply claimed that a pricing policy of a joint venture was per se illegal; they did *not*

[14] Lower courts have varied somewhat as to how they define "ancillary restraint." *See, e.g.*, *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 345-46 (3d Cir. 2010) ("Ancillary restraints are 'those that are part of a larger endeavor whose success they promote.'"); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005) ("Ancillary restraints are generally permitted if they are 'reasonably necessary' toward the contract's objective of utility and efficiency."); *Sullivan v. NFL*, 34 F.3d 1091, 1102 (1st Cir. 1994) ("[A] 'restraint' that is ancillary to the functioning of . . . a joint activity [is] one that is required to make the joint activity more efficient . . . ."); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986) ("To be ancillary, . . . an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction. The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose."); *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 188-89 (7th Cir. 1985) ("'[A]ncillary restraints . . . are part of a larger endeavor whose success they promote.'"); *L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 726 F.2d 1381, 1395 (9th Cir. 1984) ("[T]he ancillary restraints doctrine teaches that some agreements which restrain competition may be valid if they are 'subordinate and collateral to another legitimate transaction and necessary to make that transaction effective.'"); *see also Major League Baseball Props., Inc. v. Salvino*, 542 F.3d 290, 339 (2d Cir. 2008) (Sotomayor, J., concurring) ("The [ancillary restraints] doctrine recognizes that a restraint that is unnecessary to achieve a joint venture's efficiency-enhancing benefits may not be justified based on those benefits. Accordingly, a challenged restraint must have a reasonable procompetitive justification, related to the efficiency-enhancing purposes of the joint venture, before that restraint will be analyzed as part of the venture.").

The Supreme Court has noted that "[t]he classic 'ancillary' restraint is an agreement by the seller of a business not to compete within the market." *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 729 n.3 (1988).

"put forth a rule of reason claim." *Id.* at 7 n.2. Because they did not assert a rule-of-reason claim, a conclusion that the pricing policy was not per se illegal meant, by default, that it was valid. *See also id.* at 7 ("If [the joint venture's] price unification policy is anticompetitive, then respondents should have challenged it pursuant to the rule of reason. But it would be inconsistent with this Court's antitrust precedents to condemn the internal pricing decisions of a legitimate joint venture as *per se* unlawful.").

Moreover, the Court does not view *Dagher* as some kind of sea change that displaced the prior law – as articulated by both the Supreme Court and the lower courts – that the rule of reason applies to ancillary restraints. *See, e.g.*, *Nat'l Soc'y of Prof. Eng'rs v. United States*, 435 U.S. 679, 689 (1978) (stating that the rule of reason "has been regarded as a standard for testing the enforceability of covenants in restraint of trade which are ancillary to a legitimate transaction, such as an employment contract or the sale of a going business"); *Addamax*, 152 F.3d at 52 (in a pre-*Dagher* case, stating that "conduct that is strictly ancillary to [the joint venture's] productive effort . . . is evaluated under the rule of reason"); *Polk Bros.*, 776 F.2d at 188-89 (in a pre-*Dagher* case, stating that "[a] court must distinguish between 'naked' restraints, those in which the restriction on competition is unaccompanied by new production or products, and 'ancillary' restraints, those that are part of a larger endeavor whose success they promote"; ancillary restraints are evaluated under the rule of reason); *L.A. Mem'l*, 726 F.2d at 1395 (in a pre-*Dagher* case, stating that "[t]he ancillary restraint must . . . be tested under the rule of reason, the relevance of ancillarity being it 'increases the probability that the restraint will be found reasonable'"); *Aydin Corp. v. Loral Corp.*, 718 F.2d 897, 901 (9th Cir. 1983) (in a pre-*Dagher* case, stating that "[t]he proper function of ancillarity in antitrust analysis 'is to remove [in some instances] the per se label from restraints otherwise falling within the category'[;] [w]hether a restraint that does not fall within a per se category is ancillary to a valid agreement is relevant only in the sense that ancillarity increases the probability that the restraint will be found reasonable"). If the Supreme Court had intended to overturn both its and the lower courts' approach to the ancillary restraints doctrine, *i.e.*, replacing the rule of reason with a per se valid rule, it would have made that ruling more clearly. Furthermore, post-*Dagher*, the Supreme Court has indicated that the rule of reason

continues to apply to ancillary restraints. *See Am. Needle v. NFL*, 560 U.S. 183, 203 (2010) (stating that, "[w]hen 'restraints on competition are essential if the product is to be available at all,' *per se* rules of illegality are inapplicable, and instead the restraint must be judged according to the flexible Rule of Reason"); Areeda & Hovenkamp, Antitrust Law ¶ 1906 (noting that, in *American Needle, Inc.*, the Supreme Court applied the rule of reason in assessing a restraint in a license agreement that restricted NFL team members' ability to license their own individually owned intellectual property separately). Similarly, lower courts have continued to apply the rule of reason to such restraints. This includes the Federal Circuit as reflected in its decision *Princo Corp. v. ITC*, 616 F.3d 1318 (Fed. Cir. 2010), a case on which Defendants heavily rely. *See id.* at 1336 (stating that "[t]he 'ancillary restraints' that are often important to collaborative ventures, such as agreements between the collaborators not to compete against their joint venture, are also assessed under the rule of reason). *See also Major League Baseball*, 542 F.3d at 339 n.7 (Sotomayor, J., concurring) (stating that "an ancillary restraint is not necessarily lawful[;] [i]ts competitive benefits and harms must still be weighed, as part of the joint venture, under a rule-of-reason analysis").

Ultimately, the Court understands *Dagher* as the Sixth Circuit has – *i.e.*, with pre-*Dagher* law distinguishing between "naked" and "ancillary" restraints, and with *Dagher* adding a third category of restraint to the mix, namely, "restraints that are *core* to the joint venture's efficiency enhancing purpose." *Med. Ctr. at Elizabeth Place, LLC v. Atrium Health Sys.*, 922 F.3d 713, 724-25 (6th Cir. 2019) (emphasis added). Per *Dagher*, where a core restraint is at issue, the ancillary restraints doctrine is entirely inapplicable. *See Dagher*, 547 U.S. at 7-8 ("agree[ing] . . . that the ancillary restraints doctrine *has no application here*, where the business practice being challenged involves the core activity of the joint venture itself – namely, the pricing of the very goods produced and sold by [the joint venture]") (emphasis added). The Sixth Circuit has indicated that core restraints are those that are "'integral to the running of the joint venture'" whereas "[a] restraint is ancillary if it bears a reasonable relationship to the joint venture's success." *Med. Ctr.*, 922 F.3d at 725. Defendants do not, in their papers, claim that the No-Generics Restraints are core restraints that fall outside the application of the ancillary restraints doctrine. Furthermore, even if

they had, the Court concludes that that position lacks merit.

In *Dagher*, the challenged pricing policy was a core restraint because it was required "in order to make the venture work" and the restraint "did not impose any limitations on nonventure activities" – *i.e.*, "setting a common price for commonly produced gasoline placed no limits on the *separate* activities of the joint venturers." Areeda & Hovenkamp, Antitrust Law ¶ 1906 (emphasis added); *see also Dagher*, 547 U.S. at 7 (2006) (noting that the ancillary restraints doctrine "governs the validity of restrictions imposed by a legitimate business collaboration, such as a business association or joint venture, *on nonventure activities*" – activities outside of the joint venture) (emphasis added).

The situation in the instant case is different. Plaintiffs have put at issue a restraint on nonventure activities of the non-Gilead defendants – activities outside the joint production of their FDCs. Furthermore, it is far from clear that the No-Generics Restraints were required to make the joint ventures between Gilead and the non-Gilead defendants work. Whereas the pricing policy in *Dagher* "was very likely unavoidable" because "once the [joint venture] was found to be lawful, common pricing of a commonly produced product followed as a matter of course," Areeda & Hovenkamp, Antitrust Law ¶ 1906, the same cannot be said for the No-Generics Restraints because they prevented the non-Gilead defendants from using generic versions of Gilead's drugs *even after the patents protecting those drugs expired*.

Accordingly, the Court denies Defendants' motions to dismiss the antitrust claims based on the ancillary restraints doctrine. The No-Generics Restraints are not *per se* legal. They are subject to review under, at the very least, the rule of reason.

Because the Court rejects Defendants' ancillary restraints *per se* argument, it now turns to the specific agreements that Gilead entered into with BMS, Japan Tobacco, and Janssen.

B. Agreements with BMS

The Court first addresses the agreements between Gilead and BMS.

There are two agreements between Gilead and BMS:

(1) The Atripla Agreement (December 2004). Atripla is the commercial name for the FDC that Gilead and BMS coformulated. Atripla is made of (1) TDF/FTC (Gilead's drugs)

and (2) EFV (BMS's drug).

(2) The Evotaz Agreement (October 2011). Evotaz is the commercial name for another FDC that Gilead and BMS coformulated. Evotaz is made up of (1) COBI (Gilead's drug) and (2) ATV (BMS's drug).

1. Atripla Agreement

The Atripla Agreement was purportedly for the benefit of Gilead – *i.e.*, to protect its vulnerable NRTIs. Gilead and BMS make several arguments as to why the Atripla Agreement cannot plausibly be seen as anticompetitive.

First, Gilead and BMS assert that it makes no sense that they entered into the agreement to protect Gilead's drugs (TDF, FTC, and TDF/FTC), because Gilead's drugs actually had longer patent lives compared to BMS's drug (EFV). *See* BMS Reply at 1 (noting that "[t]he patents covering the BMS components for Atripla expired before Gilead's, not after") (emphasis omitted); *see also* CAC ¶ 127 (alleging that "[t]he principal patents that protected BMS's EFV . . . were not scheduled to expire until 2018"); CAC ¶ 96 (alleging that the patents for TDF would expire "by their own terms" in January 2018; the patents for FTC in January 2021; and the patents for the combination drug TDF/FTC in January 2024). Although this is technically true (at least for FTC and TDF/FTC), Plaintiffs have alleged that Gilead expected to encounter generic competition to TDF, FTC, and TDF/FTC "as early as 2009, 2011, and 2011, respectively, if generic manufacturers successfully challenged the patents." CAC ¶ 96.

Second, Gilead and BMS seem to argue that the Atripla Agreement does not actually contain a No-Generics Restraint. But Plaintiffs have pointed to a provision in the agreement that is plausibly a No-Generics Restraint. That provision is § 2.9(a) of the Atripla Agreement. It provides in relevant part as follows:

> For the avoidance of doubt, nothing in this Agreement . . . shall be deemed to restrict or prohibit either Member Party or any of its Affiliates from . . . developing, manufacturing and commercializing combination products (**other than the Combination Product**) for the treatment of HIV infection or otherwise, including, without limitation, any product containing such Party's Single Agent Product(s) and/or Double Agent Product.

Ostrander Decl., Ex. A (Atripla Agreement § 2.9(a)) (emphasis added). In other words, under §

2.9(a), both Gilead and BMS were free to make FDCs "other than the Combination Product," and, according to Plaintiffs, "[t]he 'Combination Product' that the conspirators are prohibited from making outside their collaboration is a product comprising the pharmaceutical ingredients (brand *or generic*) TDF/FTC/EFV." Opp'n at 30 (emphasis in original). "Combination Product" is not clearly defined in the agreement as brand or generic TDF/FTC/EFV. *See* Ostrander Decl., Ex. A (Atripla Agreement § 1.50) (emphasis added) (defining "Combination Product" as "the fixed-dose co-formulated product developed pursuant to this Agreement containing, as its only active pharmaceutical ingredients per single daily dose, 300 mg TDF, 200 mg FTC and 600 mg EFV"). However, to the extent "Combination Product" has any ambiguity, that ambiguity cannot be resolved at the 12(b)(6) phase of proceedings.

Third, Gilead and BMS argue that, even if § 2.9(a) is considered some kind of No-Generics Restraint, there are additional provisions in the Atripla Agreement that effectively temper the restraint and render it valid from an antitrust perspective. *See* BMS Reply at 2. In particular, Gilead and BMS point out:

- That the Atripla Agreement expressly contemplates that generic versions of the parties' drugs will become available and that either party is allowed to terminate because of the availability of a generic version of the other party's drug(s). *See, e.g.*, Ostrander Decl., Ex. A (Atripla Agreement § 14.5) (providing that "[e]ither Member Party (the 'Continuing Member Party') may terminate this Agreement by notice to the other member Party (the 'Terminated Member Party') in the event that there is the Launch in the Territory of at least one (1) Generic Version of all of the Single Agent Products (or the Double Agent Product[15]) of the Terminated Member Party (a 'Generic Version Launch') and the Continuing Member Party delivers notice of termination within thirty (30) days after the Generic Version Launch").

[15] "'Single Agent Product' shall mean each of Viread [TDF], Emtriva [FTC], and Sustiva [EFV]." Ostrander Decl., Ex. A (Atripla Agreement § 1.196). "'Double Agent Product' shall mean Truvada, the co-formulated product developed by Gilead containing, as its only active pharmaceutical ingredients, TDF and FTC." Ostrander Decl., Ex. A (Atripla Agreement § 1.77).

- That, even if the No-Generics Restraint does not allow a party to create a competing FDC using generic versions of the other party's drugs, a party is still allowed to create a competing FDC that is *comparable* in nature. *See* CAC ¶ 140 (alleging that the Atripla Agreement "prohibited BMS from making a *generic* version of Atripla when generic TDF and generic FTC became available, but did *not* prohibit BMS from making a *comparable* version comprising generic TDF, 3TC (instead of Gilead's FTC), and EFV") (emphasis in original).

While Gilead and BMS's first point above is fair, the Court finds that there is nevertheless a factual question as to whether the specific No-Generics Restraint is anticompetitive under, at the very least, the rule of reason. As Plaintiffs point out, even though the Atripla Agreement has a termination provision, arguably, there was an incentive *not* to terminate because the terminating party would have to pay the terminated party royalty payments for three years. *See* CAC ¶ 124 (alleging that, "if BMS elected to terminate Gilead's interest [because generic versions of both TDF and FTC were available], BMS would be required to pay a substantial penalty to Gilead, comprising three years of additional royalty payments, at declining percentages over the three years[;] [t]he purpose and effect of the penalty provision was to dissuade BMS from terminating Gilead's participation in the joint venture even after its patents on TDF and/or FTC expired"); *see also* Ostrander Decl., Ex. A (Atripla Agreement § 14.6(b)(i)-(ii)) (providing, *inter alia*, that "[t]he Continuing Member Party shall pay or cause the JV to pay to the Terminated Party" royalty payments).

Gilead and BMS question how much of an incentive there actually was because the termination provision in the Atripla Agreement was actually invoked – and by Gilead, not BMS (even though the agreement was supposedly to protect Gilead's vulnerable drugs). *See* CAC ¶ 141 (alleging that "Gilead recently terminated BMS's participation in the Atripla joint venture, triggering Gilead's obligation to make the penalty payments described above"). Although this is a fair point, the Court still cannot say, at this early juncture in proceedings, that the No-Generics Restraint, as tempered by the termination provision, is valid as a matter of law. As alleged by Plaintiffs, the point of the Atripla Agreement was to protect Gilead's drugs; thus, even if Gilead

ultimately decided to terminate because of a turn of events (*i.e.*, the TDF patents having longer lives than anticipated such that the EFV patents would expire first), that does not mean that there was not a substantial incentive on the part of BMS not to terminate.

As for the second point made by Gilead and BMS, here, it is a closer call. Plausibly, the No-Generics Restraint in the Atripla Agreement provided that the parties could not offer any FDC made up of brand or generic TDF, FTC, and EFV specifically. But the restraint did not prevent the parties from offering a *comparable* FDC. Accordingly, once the TDF patents were to expire (whether by their own terms or based on a successful challenge to them), BMS could sell an FDC made up of generic TDF, 3TC (a comparable to FTC), and EFV. And that is what seems to have happened. As Plaintiffs allege in the CAC, when generic TDF became available (in December 2017), BMS licensed Mylan Pharmaceuticals to produce a comparable FDC that competed with Atripla – formulated with generic TDF, 3TC, and EFV. *See* CAC ¶ 140. Thus, the No-Generics Restraint did not restrict all competition after the patents on TDF expired. Nonetheless, it still is a factual question as to whether the restriction on generics alone (as opposed to comparables) had enough anticompetitive effects to be deemed an antitrust violation.

2. Evotaz Agreement

Gilead and BMS entered into the Evotaz Agreement some seven years after the Atripla Agreement. Plaintiffs maintain that, while the Atripla Agreement was designed to protect Gilead's vulnerable drugs (TDF, FTC, and TDF/FTC), the Evotaz Agreement was designed to protect BMS's vulnerable drug (ATV).[16] Plaintiffs cite to the following provision as the No-Generics Restraint: "During the Term, without the prior written consent of BMS, (i) Gilead shall not . . . make, use, sell, [etc.] . . . in the Field in the Territory, the Combination Product (including

[16] As alleged by Plaintiffs, BMS expected generic competition for ATV as early as 2012, if generic manufacturers were successful in challenging the patents protecting the drug. *See* CAC ¶ 132. This date was earlier than the date that Gilead's patents protecting COBI would expire (*i.e.*, 2029). *See* CAC ¶ 133.

any Generic Combination Product)."[17] Ostrander Decl., Ex. C (Evotaz Agreement § 14.2(a)).[18]

Unlike the Atripla Agreement, which the parties expressly labeled a "Collaboration Agreement," the Evotaz Agreement was expressly characterized as a "License Agreement." According to Gilead and BMS, the Evotaz Agreement is, as a matter of law, a lawful agreement because (1) a patent is a lawful monopoly and (2) the Evotaz Agreement simply reflects Gilead's right to grant to BMS an exclusive license to use the COBI patents in certain ways. *See* Ostrander Decl., Ex. C (Evotaz Agreement § 8.1(a)) (providing that "Gilead hereby grants to BMS an exclusive (even as to Gilead and its Affiliates and except as provided in Section 8.4), royalty-bearing license . . . under the Gilead Technology" to develop and commercialize the Licensed Combination Product (*i.e.*, COBI + ATV) and "not to Exploit the COBI API individually or in combination with any other API other than in the Licensed Combination Product"). The defendants cite to *Rail-Trailer Co. v. ACF Industries, Inc.*, 358 F.2d 15, 16-17 (7th Cir. 1966), where the court stated:

> [A] patentee may . . . grant an exclusive license for the manufacture of the patented device, which license serves to exclude the patentee himself from engaging in the manufacture of the device, and which action, *without more*, does not constitute an illegal restraint of trade or violation of the anti-trust laws. This is so because the restraint arises from the patent grant and a lawful transfer of a part of the rights to which that grant attached.

Id. at 16-17 (emphasis added).

Plaintiffs argue that the "without more" language is significant and that "exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 393, 407 (3d Cir. 2015); *cf.* 35 U.S.C.

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[17] "'Combination Product' shall mean a fixed-dose co-formulated product in oral dosage form containing, as its only APIs, [ATV] and COBI . . . ." Ex. C (Evotaz Agreement § 1.48). "'Generic Combination Product' shall mean a generic version of the Combination Product that is approved for marketing in the Field under an [ANDA] . . . ." Ex. C (Evotaz Agreement § 1.90).

[18] The Evotaz Agreement also contains a similar No-Generics Restraint that restricts BMS: "During the Term, without the prior written consent of Gilead (i) BMS shall not . . . make, use, sell, [etc.] . . . in the Field in the Territory, the Combination Product (including any Generic Combination Product)." Ostrander Decl., Ex. C (Evotaz Agreement § 14.3(a)). However, for purposes of the instant case, the relevant No-Generics Restraint is § 14.2(a) given Plaintiffs' theory that the Evotaz Agreement was designed to protect BMS's vulnerable drug.

§ 209(a)(4) (providing that "[a] Federal agency may grant an exclusive or partially exclusive license on a federally owned invention . . . only if . . . granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws").

For example, in *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990), two companies that offered bar review courses were in competition with each other in Georgia.

> In early 1980, they entered into an agreement that gave [the Georgia company] an exclusive license to market [the Delaware company's] material in Georgia and to use its trade name . . . . The parties agreed that [the Delaware company] would not compete with [the Georgia company] in Georgia and that [the Georgia company] would not compete with [the Delaware company] outside of Georgia.

Id. at 47. The Supreme Court held that "agreements between competitors to allocate territories to minimize competition are illegal." *Id.* at 49 (further stating that agreements "not to compete in the other's territories . . . are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other").

According to Plaintiffs, here, the exclusive license in the Evotaz Agreement has been also been used in an anticompetitive way – *i.e.*, through the No-Generics Restraint that is contained in the agreement. As noted above, the relevant No-Generics Restraint in the Evotaz Agreement prohibited Gilead from making, using or selling the "Combination Product (including any Generic Combination Product)." Ostrander Decl., Ex. C (Evotaz Agreement § 14.2(a)). In effect, Gilead promised not to sell a competing FDC using generics even after the vulnerable ATV patents expired. This would give BMS's ATV extended protection even after the patents on the drug would have expired.

Gilead and BMS suggest that this is necessarily a consequence of an exclusive license – *i.e.*, with an *exclusive* license, the patent holder is not just giving someone else the right to use the patent but also giving up the patent holder's own right to use the patent (in effect, not to "compete"). *Cf.* 35 U.S.C. § 271(d)(4) (providing that a patent owner is not guilty of patent misuse because it has, *e.g.*, "refused to . . . use any rights to the patent"). But what patent law

permits (*i.e.*, exclusive licenses) is not dispositive of legality for antitrust purposes.[19] A patent license may be impermissibly anti-competitive.

For example, in *Actavis*, 570 U.S. at 136, the Supreme Court was asked to consider a settlement in a patent infringement case where the patentee paid the alleged infringer instead of the other way around – what is known as a reverse payment settlement agreement. More specifically, the Supreme Court had to determine whether a reverse payment settlement agreement "can sometimes unreasonably diminish competition in violation of antitrust laws." *Id.* at 141. During proceedings below, the Eleventh Circuit had held that

> a reverse payment settlement agreement generally is "immune from antitrust attack so long as its anticompetitive effects fall *within the scope* of the exclusionary potential of the patent." And since the alleged infringer's promise not to enter the patentee's market expired before the patent's term ended, the Circuit found the agreement legal and dismissed the FTC complaint.

Id. The Supreme Court rejected the proposition that, so long as the anticompetitive effects were within the scope of the exclusionary potential of the patent, there could be no antitrust violation. *See id.* at 147 (stating that, just because anticompetitive effects fall within the scope of the exclusionary potential of the patent, that does not "immunize the agreement from antitrust attack"); *see also King Drug*, 791 F.3d at 399 (noting that, "in *Actavis*, the Supreme Court rejected the 'scope of the patent' test, a categorical rule that reverse payment patent settlements in the Hatch-Waxman context were immune from antitrust scrutiny so long as the asserted anticompetitive effects fell within the scope of the patent"). "[T]his Court has indicated that patent and antitrust policies are *both* relevant in determining the 'scope of the patent monopoly' – and consequently antitrust immunity – that is conferred by a patent." *Actavis*, 570 U.S. at 147 (emphasis added); *see also id.* at 151 (discussing precedent and holding that these cases "seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition").

The Third Circuit's decision in *King Drug* also illustrates that an exclusive license

[19] Indeed, as noted above, Defendants have taken the position that what constitutes patent misuse under patent law does not establish what is per se illegal under antitrust law.

permissible under patent law is not necessarily immune from scrutiny under antitrust law. In *King Drug*, defendants were (1) GSK, the manufacturer of a brand drug (Lamictal), and (2) Teva, the manufacturer of a generic version of that drug.

> In earlier litigation, Teva had challenged the validity and enforceability of GSK's patents on lamotrigine, Lamictal's active ingredient. Teva was also the first to file an application with the FDA alleging patent invalidity or nonenforceability and seeking approval to produce generic lamotrigine tablets and chewable tablets for markets alleged to be annually worth $2 billion and $50 million, respectively. If the patent suit resulted in a judicial determination of invalidity or nonenforceability – or a settlement incorporating such terms – Teva would be statutorily entitled to a valuable 180-day period of market exclusivity, during which time only it and GSK could produce generic lamotrigine tablets. (The relevant statute permits the brand to produce an "authorized generic" during the exclusivity period.)
>
> After the judge presiding over the patent litigation ruled the patent's main claim invalid, GSK and Teva settled. They agreed Teva would end its challenge to GSK's patent in exchange for early entry into the $50 million annual lamotrigine chewables market and GSK's commitment not to produce its own, "authorized generic" version of Lamictal tablets for the market alleged to be worth $2 billion annually.

King Drug, 791 F.3d at 393-94.[20] The plaintiffs in *King Drug* filed suit against both GSK and Teva, asserting that the no authorized generics agreement ("no-AG agreement") violated antitrust law.

In response, GSK and Teva argued, *inter alia*, that the no-AG agreements "are in essence 'exclusive licenses' and patent law expressly contemplates exclusive licenses." *Id.* at 406. The Third Circuit rejected the companies' position, stating as follows:

> [T]he "right" defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise. Instead, it is a right to use valuable licensing in such a way as to induce a patent challenger's delay. . . . [In *Actavis*, where the Supreme Court held that reverse-payment settlements can sometimes violate antitrust law], the patentee gave the challenger a license to enter 65 months before patent expiration, *plus* a reverse payment of "millions of dollars." This reverse payment was not immunized, of course, simply because of that early-entry "license." Similarly, the fact that a patent holder may generally have the right to grant licenses, exclusive or not, does not

[20] *See also In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 U.S. Dist. LEXIS 127748, at *15 (S.D.N.Y. Sept. 22, 2015) (noting that an authorized generic is one sold by the brand or through a licensed third-party generic manufacturer).

> mean it also has the right to give a challenger a license along with a promise not to produce an authorized generic – i.e., a promise not to compete – *in order to induce the challenger "to respect its patent and quit [the competitor's] patent invalidity or noninfringement claim without any antitrust scrutiny*." In the *Actavis* Court's review, the question is not one of patent law, but of antitrust law, the latter of which invalidates "the improper use of [a patent] monopoly." And as we read the Court's opinion, even exclusive license cannot avoid antitrust scrutiny where they are used in anticompetitive ways.

King Drug, 791 F.3d at 406-07 (emphasis in original and added).

To be sure, *Actavis* and *King Drug* are not on all fours with the instant case. For example, in both *Actavis* and *King Drug*, the patent holder gave a license (on certain terms) to protect its own patents; here, Gilead (the patent holder) allegedly gave BMS a license to protect BMS (not Gilead itself) after the patent protections for the BMS drug expired. But there is no material distinction. In both situations, a patent right (*i.e.*, to give an exclusive license) has been used to restrain competition in an allegedly anticompetitive way. That is, Gilead agreed not to sell a competing FDC *even after the patents on BMS's drugs expired*. The alleged restraint on trade is not Gilead's giving BMS an exclusive license to make and use COBI + ATV; it is that Gilead is giving up the right to make COBI + ATV generic *even after the patents on ATV expire*. Such a restraint is not *per se* immune from review under rule of reason analysis simply because it is framed as an exclusive license.[21]

3. Summary

For the foregoing reasons, the Court denies Gilead and BMS's motions to dismiss the antitrust claims based on the Atripla and Evotaz Agreements.

C. Agreement with Japan Tobacco

Gilead and Japan Tobacco entered into one agreement only. That agreement, dated March 2015, is titled a "License Agreement" and concerns one of Japan Tobacco's drugs, EVG (also

[21] This is not to say that every exclusive license may be subject to antitrust scrutiny. In many cases, such as where a manufacturer grants an exclusive license to one distributor, the licensor does not ordinarily compete with the licensee. The license in that context facilitates competition. In contrast, here, the licensor would ordinarily compete in the same market as the licensee but agrees as part of the license to withdraw from competition; thus, arguably there is at least an cognizable restraint of trade. Such a restraint may nonetheless be lawful under, *e.g.*, rule of reason, but it is not automatically immune from scrutiny.

referred to as JTK-303 in the agreement). Gilead and Japan Tobacco entered into the agreement because "JT [had] developed a proprietary anti-viral compound designated as JTK-303 [*i.e.*, EVG], to be used in a product or products for the treatment of HIV" and "Gilead desire[d] to obtain the exclusive right to develop and commercialize, for itself and its Affiliates such formulations and dosages of [EVG] outside of Japan, and JT desire[d] to grant Gilead such rights." Ostrander Decl., Ex. D (EVG Agreement, Recitals). Gilead eventually developed and commercialized two drugs containing EVG: (1) Stribild (combining EVG with Gilead's drugs TDF, FTC, and COBI) and (2) Genvoya (combining EVG with Gilead's drugs TAF, FTC, and COBI). As noted above, Gilead expected to face generic competition for TDF, FTC, and TDF/FTC in 2009, 2011, and 2011, respectively. The main patents protecting Japan Tobacco's drug EVG are not scheduled to expire until 2026.[22] *See* CAC ¶ 108.

Similar to above, Gilead and Japan Tobacco argue that the antitrust claims predicated on this agreement should be dismissed because the agreement simply conveys an exclusive license, which is permissible under patent law. Gilead and Japan Tobacco add that Plaintiffs have not even been able to point to any actual provision in the license agreement that is a No-Generics Restraint.[23]

As discussed above, an exclusive license without more is not an antitrust violation, but an exclusive license may be used in anticompetitive ways. Here, the problem for Plaintiffs is that there is no indication that Gilead and Japan Tobacco agreed that the exclusive license would be used in an anticompetitive way. As Gilead and Japan Tobacco point out, the agreement between the companies did not contain an express provision containing a No-Generics Restraint. Plaintiffs contend that there is no dispute that the agreement implicitly barred Japan Tobacco from selling competing FDCs using generics. But *Twombly* and *Iqbal* require specific allegations plausibly

[22] Although Gilead's COBI patents have a longer maximum patent life – until 2029 – Plaintiffs indicate that the inclusion of COBI in Stribild and Genvoya was not that significant because Japan Tobacco could have used an available substitute for COBI (*i.e.*, RTV or generic RTV) in a competing FDC. *See, e.g.*, CAC ¶ 112 (noting that generic RTV became available in March 2018).

[23] Gilead and Japan Tobacco raise additional arguments in their papers but, for the reasons discussed below, it is not necessary to address them.

suggesting a conspiracy (or anti-competitive agreement). *See Twombly*, 550 U.S. at 556-57 (stating that, "[w]ithout more, parallel conduct does not suggest conspiracy"; at the pleading stage, there must be "allegations plausibly suggesting (not merely consistent with) agreement"); *Iqbal*, 556 U.S. at 678 (stating that, "[w]here 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"'"). Plaintiffs have failed to do so here.

Accordingly, the Court grants Gilead and Japan Tobacco's motions to dismiss the antitrust claims based on the agreement between the two companies. The dismissal is with prejudice because Plaintiffs have not suggested that they could amend to cure this deficiency.

D. Agreements with Janssen

There are four agreements between Gilead and Janssen:

(1) The Complera Agreement (July 2009). Complera is the commercial name for the FDC that Gilead and Janssen coformulated. Complera is made of (1) TDF/FTC (Gilead's drugs) and (2) RPV (Janssen's drug).

(2) The Odefsey Agreement (December 2014). Odefsey is the commercial name for another FDC that Gilead and Janssen coformulated – essentially the successor FDC to Complera. Odefsey is made up of (1) *TAF* and FTC (Gilead's drugs) and (2) RPV (Janssen's drug).

(3) The Prezcobix Agreement (June 2011). Prezcobix is the commercial name for an FDC that Gilead and Janssen coformulated. Prezcobix is made up of: (1) COBI (Gilead's drug) and (2) DRV (Janssen's drug).

(4) The Symtuza Agreement (December 2014). Symtuza is the commercial name for another FDC that Gilead and Janssen coformulated – essentially the successor FDC to Prezcobix. Symtuza is made up of (1) *TAF*, FTC, and COBI (Gilead's drugs) and (2) DRV (Janssen's drug).

The No-Generics Restraints for the above agreements are found at: § 17.2 in the Complera Agreement and § 17.2.1 in the Odefsey Agreement, and § 14.2(a) in the Prezcobix Agreement and § 14.3.2 in the Symtuza Agreement. At least some of the No-Generics Restraints seem to bar not

only competing FDCs using generics but also comparable FDCs.[24]

Plaintiffs have characterized the Complera and Odefsey Agreements as agreements intended to protect Gilead's vulnerable drugs (TDF and FTC), *see* CAC ¶¶ 96, 150 (alleging that Janssen's RPV patents are not scheduled to expire until 2019 to 2025 whereas the Gilead expected to face generic competition for TDF and FTC in 2009 and 2011 if generic manufacturers successfully challenged the patents protecting the drugs), whereas the Prezcobix and Symtuza Agreements were agreements intended to protect Janssen's vulnerable drug (DRV). *See* CAC ¶¶ 133, 163 (alleging that Janssen expected generic competition for DRV as early as 2013, if generic manufacturers were successful in challenging the patents protecting the drug; in contrast, Gilead's patents protecting COBI would not expire until 2029).

With respect to the above agreements, Gilead and Janssen have essentially made only the ancillary restraints argument discussed above. Janssen also makes one additional argument –

[24]

- Ostrander Decl., Ex. E (Complera Agreement § 17.2(a)) ("During the term of this Agreement, without the prior written consent of Gilead (i) [Janssen] will not import, sell or offer to sell . . . (A) the Combination Product other than pursuant to this Agreement, or (B) any other combination product that is a Derivative Combination Product . . . .").
- Ostrander Decl., Ex. G (Odefsey Agreement § 17.2.1) ("Without the prior written consent of Gilead: (i) Janssen shall not . . . make, have made, use, sell, have sold, offer for sale, or import . . . (A) a Combination Product other than pursuant to this Agreement or (B) any Other Combination Product . . . ."); Ostrander Decl., Ex. G (Odefsey Agreement § 1.265) ("'Other Combination Product' shall mean any fixed-dose, co-formulated combination product (other than a Combination Product) in oral dosage form that contains, as its sole APIs, all three (3) of (a) TAF or TDF, (b) FTC or 3TC, and (c) RPV.").
- Ostrander Decl., Ex. F (Prezcobix Agreement § 14.2(a)) ("During the term of this Agreement, without the prior written consent of [Janssen]: (i) Gilead shall not . . . make, use, sell, have sold, offer for sale, or import . . . (A) the Combination Product, or (B) any Other Combination Product . . . .").
- Ostrander Decl., Ex. H (Symtuza Agreement § 14.3.2) ("Without the prior written consent of Janssen, . . . Gilead shall not . . . make, have made, use, sell, have sold, offer for sale, or import . . . (A) the STR other than pursuant to this Agreement, (B) any Other STR, or (C) any Other Restricted Product . . . ."); Ostrander Decl., Ex. H (Symtuza Agreement § 1.299) ("'Other STR' shall mean any fixed-dose, co-formulated combination product in oral dosage form (other than the STR) that contains, as its only four (4) APIs, (a) COBI or RTV, (b) TAF or TDF, (c) FTC or 3TC and (d) DRV or a version of ATV sold by a Person other than BMS or any of its Affiliates or third party distributors."); Ostrander Decl., Ex. H (Symutza Agreement § 1.298) ("'Other Restricted Product' shall mean any fixed-dose, co-formulated combination product in oral dosage form that contains, as its only three (3) APIs, (a) DRV or a generic version of ATV and (b) any two of the following: (i) COBI or RTV and (b) any two of the following: (i) COBI or RTV, (ii) TAF or TDF or (iii) FTC or 3TC.").

namely, that Plaintiffs have improperly named as a defendant one of the Janssen entities, Johnson & Johnson ("J&J"). According to Janssen, Plaintiffs have not adequately alleged that J&J was involved in any conspiracy – indeed, J&J was not a party to any of the collaboration agreements identified above. Although J&J is Janssen's corporate parent, Janssen maintains that "a corporate parent cannot be held liable merely because a Sherman Act claim has been asserted against its subsidiary." Janssen Mot. at 13.

In response, Plaintiffs argue that Janssen has glossed over the fact that Plaintiff has used the term "Janssen" in the CAC to refer to both the parent and the subsidiary – thus, "both defendants [parent J&J included] negotiated and abided by the No-Generics Restraints; both defendants encouraged doctors to switch prescriptions to the FDCs insulated form generic competition; and both defendants shared in the monopoly profits that the unlawful agreements generated." Opp'n at 35. Plaintiffs add that they have a factual basis for asserting that J&J was involved in the conspiracy:

> [First,] the Complera/Odefsey Agreement indicates that a Johnson & Johnson "Executive" has a significant management and oversight role with respect to Janssen and Gilead's collaboration, including patent matters and the development of marketing materials [citing, *inter alia*, the Odefsey Agreement §§ 1.103 and 6.7.1.2]. [Second,] [t]he agreement also requires the parties to send copies of all collaboration-related reports and communications to Johnson & Johnson's General Counsel [citing the Odefsey Agreement § 20.2]. Finally, in a press release attached to the agreement, Johnson & Johnson's Worldwide Chairman for Pharmaceuticals extols the company's agreement with Gilead.

Opp'n at 36.

The Court agrees that Plaintiffs have a factual basis for alleging that J&J was involved. In particular, § 6.7.1.2 of the Odefsey Agreement addresses marketing materials that Gilead shall develop and propose to Janssen (the subsidiary). If the parties are unable to reach agreement, they "may refer any disputed issues to the Executives for resolution pursuant to Section 20.6. If the Executives are unable to reach agreement with respect thereto within the Executives Review Period, Gilead shall have final decision-making authority with respect to such matter." Ostrander Decl., Ex. G (Odefsey Agreement § 6.7.1.2). "Executives" is defined in the agreement as follows: "(a) in the case of Gilead, the President and Chief Operating Officer of Gilead Parent, and (b) in

the case of Janssen, a Worldwide Chairman of Janssen Parent's pharmaceutical group." Ostrander Decl., Ex. G (Odefsey Agreement § 1.103). Given the factual basis articulated by Plaintiffs, the Court does not dismiss at this time J&J from the proceedings. The Court cannot say, as a matter of law, that J&J did not play a role in the No-Generics Restraint scheme.

Accordingly, the Court denies Gilead and Janssen's motions to dismiss the antitrust claims based on the No-Generics Restraints in the Complera, Odefsey, Prezcobix, and Symtuza Agreements.

With respect to the antitrust claims based on the No-Generics Restraints, the Court rejects Defendants' ancillary restraints argument. However, the Court grants Gilead and Japan Tobacco's motions to dismiss the antitrust claims based on the specific agreement entered into by these two companies.

E. Antitrust Injury

The final issue for the Court to address is whether the remaining claims against Gilead, BMS, and Janssen should be dismissed for failure to allege antitrust injury. "[A]ntitrust injury consists of four elements: '(1) unlawful conduct, (2) causing an injury to the plaintiff, (3) that flows from that which makes the conduct unlawful, and (4) that is of the type the antitrust laws were intended to prevent.'" *Somers v. Apple, Inc.*, 729 F.3d 953, 963 (9th Cir. 2013). The main antitrust injury arguments are addressed below.

1. Standalone Components of FDC

Defendants argue first that Plaintiffs have failed to adequately allege any anticompetitive injury because, even if the joint venture members could not make a competing FDC using generics, nothing prevented patients from buying the standalone components to the FDCs (*i.e.*, a patient could buy generic TDF and/or FTC and then, separately, the other defendant's drug). *See, e.g.*, Gilead Mot. at 21; BMS Mot. at 11-12. But even if a patient could buy the standalone components of the joint venture FDC, that does not necessarily mean that the No-Generics Restraint did or does not have any anticompetitive effects. Plaintiffs have alleged that doctors

were likely to prescribe brand FDCs[25] and that individuals who were prescribed such FDCs could not get their prescriptions filled with generic standalone components: "[u]nder state drug-substitution laws, pharmacists receiving a prescription for [an] FDC cannot dispense [in its place] generic versions of the standalone component[]" drugs, Opp'n at 3, because "[g]eneric versions of TDF and/or FTC are not AB-rated to, and therefore not automatically substitutable for, the TDF-based FDCs." CAC ¶ 183. Furthermore, getting standalone components would be contrary to the whole point of an FDC – *i.e.*, to get better patient compliance. *See* CAC ¶ 63 (alleging that "[t]he need to use multiple drugs in cART regimens can be a barrier to patient compliance" and "[t]o reduce this possible burden, multiple antiretroviral drugs are often coformulated together into a single pill," *i.e.*, FDC").[26]

2. Untainted Competitor

Second, Defendants argue that the antitrust injury claimed by Plaintiffs is too speculative. But a reasonable jury could infer that, absent the No-Generics Restraints, the other defendants would want to make competing FDCs once the generic versions of Gilead's vulnerable drugs became available (*i.e.*, once the patents protecting the drugs expired); that would be in their own self-interest. *Cf. King Drug*, 791 F.3d at 405 (noting that, "[a]bsent a no-AG [authorized generics] promise, launching an authorized generic would seem to be economically rational for the brand [manufacturer]"). In this regard, it is notable that, when generic TDF became available in December 2017 (generic FTC will not become available until September 2020), BMS *did* come up with a competing FDC because its No-Generics Restraint with Gilead did not bar it from making a competing FDC that was *comparable* to the FDC covered by the joint venture agreement. *See* CAC ¶ 140 (alleging that, "[w]hen generic TDF became available, BMS licensed Mylan

[25] As noted above, Plaintiffs suggest that Gilead was able to do this through use of "large sales forces that visit doctors' offices and persuade them to prescribe" certain products. *See* CAC ¶ 368.

[26] In its motion, BMS argues that "having to take two pills a day instead of one is not the type of interest protected by the antitrust laws, which concern quantifiable *economic* injury." BMS Mot. at 12 (emphasis in original). But Plaintiffs are claiming an economic injury – the inability to purchase a competing FDC made up (at least in part) of generics. The reason why Plaintiffs want to buy the competing FDC (*e.g.*, for convenience) should not mean there is not an economic injury.

Pharmaceuticals to product [the] comparable version [to Atripla]" – *i.e.*, generic TDF, 3TC (instead of FTC), and EFV). Furthermore, Plaintiffs fairly make the point that, "if the conspirators were not likely to have marketed competing versions of the products, Defendants would have had no reason to include the No-Generics Restraint." Opp'n at 36.

Defendants make one additional argument on antitrust injury – *i.e.*, that it is speculative for Plaintiffs to assert that untainted competitors in BMS, Japan Tobacco, and Janssen's positions would actually have challenged Gilead's patents prior to their expiration dates (*e.g.*, instead of waiting for the TDF patents to expire in December 2017). *See, e.g.*, CAC ¶¶ 114, 130, 158. Defendants' contention is not without force. However, that asserted injury appears to be Plaintiffs' alternative position on antitrust injury and thus, even if credited, would not result in dismissal. Plaintiffs, however, have leave to provide a more definite statement regarding this antitrust injury theory.

VI. ANTITRUST CLAIMS BASED ON TEVA PATENT SETTLEMENT AGREEMENTS – COUNTS THREE THROUGH SIX AND COUNTS EIGHT THROUGH THIRTEEN

In Counts Three through Six and Counts Eight through Thirteen, Plaintiffs also claim anticompetitive conduct based on patent settlement agreements between Gilead and Teva. As noted above, the agreements contained MFE and MFEP clauses, which are what allegedly induced Teva to delay its entry into the market.

> The MFE provided that, if any second filer entered the market before the agreed-upon date, Teva's entry date would be moved up accordingly. . . . The MFEP provided that Gilead would not grant a license for a second filer to enter the market any earlier than six weeks [in one case or six months in another] after Teva entered.

Opp'n at 8. Thus, according to Plaintiffs, the two clauses "insulated Teva from the . . . risk that one or more of the several subsequent filers lined up behind it would enter on or before the agreed-upon entry dates, either by succeeding in their own lawsuits or by using the leverage of their patent challenges to negotiate an entry date equal to or earlier than Teva's licensed entry date." Opp'n at 51.

As indicated above, Plaintiffs assert that the agreements are anticompetitive because (1)

Teva agreed to delay its entry into the market in exchange for being given MFE and MFEP provisions and (2) the MFE and MFEP provisions also served as a "disincentive" for second filers to try to enter the market before Teva.

In its motion to dismiss, Gilead argues first that MFEs and MFEPs are basically most-favored nation ("MFN") clauses, and it is not uncommon to find MFN clauses in settlement agreements. While this may be true, it that does not mean MFN clauses are automatically free from antitrust scrutiny, and Gilead concedes as much. *See* Gilead Mot. at 10 (arguing that, "at most, . . . MFNs can be anticompetitive in rare circumstances") (emphasis omitted). That a MFE and/or MFEP is deserving of antitrust scrutiny – especially compared to other kinds of MFN clauses – is underscored by the fact that the whole point of a MFE and/or MFEP is about *entry*, *i.e.*, when competition is allowed into a market.

Gilead argues next that the MFE and MFEP at issue here are not enough to constitute anticompetitive conduct because they are actually procompetitive in nature. Gilead focuses on the MFE in particular: under the MFE, if a generic manufacturer obtains an earlier entry date than Teva does (*e.g.*, by prevailing in a patent infringement lawsuit initiated by Gilead), then Teva gets its entry date advanced; thus, that means *more* competition – *i.e.*, from both the generic manufacturer and Teva. This argument is problematic for at least three reasons: (1) it addresses only the MFE, and not the MFEP (which gives Teva a preferential entry date compared to other generic manufacturers); (2) it ignores Plaintiffs' theory that Teva agreed to a delayed entry date – *i.e.*, a later date than it otherwise would have – because it was given, in exchange, the benefits afforded by both the MFE and MFEP; and (3) it ignores Plaintiffs' theory that the MFE/MFEP combination deterred second filers from trying to get an earlier entry date.

To the extent Gilead relies on the Supreme Court's *Actavis* decision, *Actavis* does not hold that an early entry date (relative to the patent expiration date) is *automatically* procompetitive. In *Actavis*, the Supreme Court simply acknowledged that, as a general matter, "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring

about competition, again to the consumer's benefit." *Actavis*, 570 U.S. at 154.[27] To the extent the New York district court in *Actos* suggested otherwise, *see Actos*, 2015 U.S. Dist. LEXIS 127748, at *45 (addressing a MFE which the court denominated an "acceleration clause"; stating that, "[a]t their core, the settlements at issue simply granted the Generic Defendants a compromise date of generic entry – the very type of settlement sanctioned by the *Actavis* Court"), the Court is not persuaded. Furthermore, the *Actos* court acknowledged that "another case may present circumstances" where it would be plausible that a MFE could deter a second filer from challenging a patent because, even if the second filer won, "it would be deprived of any period of market exclusivity" because the first filer could "also enter the market immediately thereafter." *Id.* at *48-49. The *Actos* court simply held that, in the case before it, a deterrent effect was not plausible. *See id.* at *49 (noting, *inter alia*, that, even after the patent holder and certain generic manufacturers settled, another generic manufacturer continued to challenge the patent at issue). Finally, the court in *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307 (D.R.I. 2017), did in fact hold that a plaintiff had plausibly alleged anticompetitive effects from a MFE. *See id.* at 333-34 (taking note of plaintiff's allegations that, "with the acceleration clause in place, other generics did not have the opportunity, and thus the incentive to try, to enter the market before Watson's scheduled entry"; adding that "[i]t may be that with more factual and expert discovery, the . . . Defendants can establish that there were no anticompetitive effects, or that . . . the 'challenged payment was justified by some precompetitive objective[,]' [b]ut at this juncture, the Court is not prepared to hold that an acceleration clause like the one [here] may never be cognizable as a component of a complex settlement agreement amounting to a large and unjustified reverse payment").

[27] As noted above, the *Actavis* Court ultimately held that a reverse payment settlement agreement could be anticompetitive in nature, even if the alleged infringer simply made the promise not to enter the patentee's market before the patent term ended. *See Actavis*, 570 U.S. at 141.

The Court notes that, although there appears to have been a MFE in *Actavis*, the MFE was not substantively discussed in the opinion. *See id.* at 145 (noting that "Actavis [the generic manufacturer] agreed that it would not bring its generic to market until August 31, 65 months [more than 5 years] before Solvay's patent expired (unless someone else marketed a generic sooner)").

Gilead protests still that the MFE and/or MFEP cannot be deemed anticompetitive when they do not represent "reverse payments" (from Gilead to Teva) in the first place; more specifically, they do not represent payments at all because "[Teva] received no compensation from [Gilead], but rather, [was] compensated only through the market when [it] began selling [its] generic product." *Actos*, 2015 U.S. Dist. LEXIS 127748, at *48. It is true that the MFE and/or MFEP may not be a "payment" from Gilead to Teva in the sense that cash was not being taken out of Gilead's pocket and being given to Teva – or even in the sense that Gilead was giving up a benefit that it otherwise would have had for Teva's benefit. *See, e.g.*, *King Drug*, 791 F.3d at 404-05 (stating that "no-AG [authorized generic] agreements are likely to present the same types of problems as reverse payments of cash" – *e.g.*, they "may be of great monetary value [to] the first-filing generic [manufacturer]" and "a brand[] [manufacturer's] commitment not to produce an authorized generic means that it must give up the valuable right to capture profits").

But *Actavis* did not preclude a patent settlement agreement from being anticompetitive in the absence of a reverse payment *if there were other circumstances* that posed potential anti-competitive concern. *See Actavis*, 570 U.S. at 158 (suggesting that patent litigation could be settled "by allowing the generic manufacturer to enter the patentee's market prior to the patent expiration, without the patentee paying the challenger to stay out prior to that point"). In the instant case, Plaintiffs have pointed to indicators of anti-competitiveness. For instance, even though Teva was allowed to enter the market prior to the patent expiration dates, the entry date was, relatively speaking, quite late – *i.e.*, close in time to the patent expiration dates (in one case, only six weeks before the patent expiration date and, in the other case, only a year before the patent expiration date). Thus, this gives rise to a concern that Teva was induced to accept a late entry date (*i.e.*, giving up the right to pursue its challenge to the patent and earlier entry) in return for a significant benefit – even if that benefit did not come at Gilead's expense.

Another yellow flag is with respect to the MFEP clause specifically. The MFEP clause, in effect, gave Teva exclusivity for a period time (six weeks in one case and six months in another), but Plaintiffs have alleged that, "in the case of Truvada [TDF/FTC] (and possibly Atripla as well), . . . Teva had [already] forfeited" the 180-day ANDA Exclusivity "by filing to gain timely

tentative approval from the FDA." Opp'n at 51. Thus, the MFEP clause was essentially "resurrect[ing]" ANDA Exclusivity or at least some kind of exclusivity where it no longer applied. Opp'n at 51. Resurrection of exclusivity could arguably be a significant deterrent to second filers.[28]

The Court acknowledges that the antitrust claims here would arguably be a closer call if the Court was dealing with just a MFE clause and not, in addition, a MFEP clause. A MFE clause is not as clear a deterrent to a second filer (as compared to a first filer) because a second filer is simply prevented from doing better than the first filer but is nevertheless guaranteed *equality* (although Plaintiffs argue that it is a factual question as to whether a MFE is enough of a deterrent). *See, e.g.*, Opp'n at 52 (noting that a former executive of Apotex, "one of the largest generic manufacturers in the world," testified before Congress that MFEs are "'poison pill' provisions" and "represent 'the primary anticompetitive aspects of settlements' insofar as they 'eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry'"). In contrast, a MFEP clause guarantees a second filer that it will be in a *worse* position compared to the first filer even where there is no ANDA Exclusivity. Since the instant case presents a situation where there is both a MFE and a MFEP, it is different from those cited by Gilead, and the Court need not address the question of whether a MFE by itself can constitute anticompetitive conduct.

Accordingly, for the antitrust claims based on the MFE and MFEP clauses, Gilead's motion to dismiss is denied.[29]

[28] As noted above, a "first-filing generic manufacturer is guaranteed [the ANDA] exclusivity period [of 180 days] even if it settles litigation with a patent owner without resolving the invalidity or noninfringement issues" – which serves as a disincentive for a second filer to press a patent challenge – *AIDS Healthcare*, 2016 U.S. Dist. LEXIS 87578, at *4-5, but resurrection of ANDA Exclusivity is a different matter.

[29] Gilead suggests that the antitrust claims are predicated on Plaintiffs' position that the patents protecting TDF, FTC, and/or TDF/FTC are weak, but there are no factual allegations to explain why the patents are weak. *See* Gilead Mot. at 30-31. While this argument is not without some merit, it is reasonable to infer that there were problems with the patents as Teva and the multiple other generic manufacturers levied patent challenges. This is not a matter that can be determined as a matter of law at this juncture.

VII. ANTITRUST CLAIMS BASED ON GILEAD'S COMMERCIALIZATION OF TAF – COUNTS THREE THROUGH SIX AND COUNTS EIGHT THROUGH THIRTEEN

Finally, in Counts Three through Six and Counts Eight through Thirteen, Plaintiffs claim anticompetitive conduct based on the way that Gilead commercialized TAF. As indicated above, Plaintiffs assert that Gilead commercialized TAF in a particular manner with the goal of moving over prescriptions from TDF-based FDCs to TAF-based FDCs because the FDCs (unlike any standalone drugs) would be protected by the No-Generics Restraints. According to Plaintiffs, to move over to TAF-based FDCs, Gilead took steps to make the TDF-based FDCs less desirable and further took purposeful steps to ensure that TAF standalone could or would not be used in conjunction with other standalone drugs in place of a TAF-based FDC. For example:

- Gilead intentionally degraded the safety of one of its TDF-based FDCs, commercially known as Stribild (*i.e.*, by keeping the strength of TDF at a certain level when a lower level would produce fewer side effects), and further artificially raised the price of the drug. *See generally* CAC ¶ 242 *et seq.*
- Gilead withheld standalone TAF from the market in or about the time period from 2015-2016 and then, when it released TAF standalone, labeled the drug as a treatment for chronic Hepatitis B only (and not HIV as well) and further intentionally degraded the drug (*i.e.*, by selling it at a strength that produced more side effects instead of a lower strength). *See generally* Opp'n at 47; CAC ¶ 250 *et seq.*

Gilead argues that the antitrust claims based on the commercialization of TAF should be dismissed because the same or similar types of claims were already dismissed in a case before Judge Alsup, *i.e.*, *AIDS Healthcare*, 2016 U.S. Dist. LEXIS 87578. Because Gilead's argument largely depends on *AIDS Healthcare*, the Court briefly discusses the case below.

In *AIDS Healthcare*, the plaintiff brought a § 1 tying claim and a § 2 monopolization claim, both related to TAF. In the tying claim, the plaintiff alleged that "Gilead entered into agreements with Janssen and Japan Tobacco to tie sales of TAF to sales of [the other companies']

respective drugs by combining them into [FDCs]." *Id.* at *19. Judge Alsup noted that one element of a tying claim is that there be "'two distinct products . . . in different markets whose sales are tied together.'" *Id.* But here, TAF was not available as a standalone product as the FDA had not yet approved it. *See id.* at *20 (stating that "[t]he extent of consumer demand for standalone TAF is irrelevant because TAF *cannot* be sold as a standalone product as a matter of law"). Judge Alsup added that Gilead "had no duty to pursue FDA approval of the standalone version. To hold otherwise would require manufacturers to seek approval of each component of the drug before seeking approval of the combination drug. This could entirely undermine the FDA's policy of encouraging the development of combination drugs." *Id.* at *21.

As for the § 2 claim, there, the plaintiff alleged that "Gilead improperly bundled TAF" with Janssen and Japan Tobacco's drugs to make certain FDCs

> as a means of maintaining its dominance in the TAF market. Specifically, it alleges that by bundling TAF with the other ingredients, it insulated the allegedly weak patents covering TAF from challenges, because any generic manufacturer seeking to produce a TAF product would need to invalidate all the patents [for the drugs making up the FDCs] before it could win FDA approval, rather than just the TAF patents.

Id. at *22-23. Judge Alsup dismissed the § 2 claim for several reasons. One of the reasons was that the plaintiff had failed to allege any anticompetitive conduct. Judge Alsup acknowledged that Gilead had chosen to release TAF as part of a FDC before seeking approval for TAF as a standalone; but,

> "[a]s a general rule, any firm, even a monopolist . . . [,] may bring its products to market whenever and however it chooses." *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983). There is no legal basis for concluding that Gilead had a *duty* to release TAF as a standalone product. *See Allied Orthopedic*, 592 F.3d at 1002 ("[A] monopolist has no duty to help its competitors survive or expand when introducing an improved product design.").

Id. at *23-24 (emphasis added).

The above language from *AIDS Healthcare* lends some support to Gilead's position that it was free to withhold TAF as well as free to shape the product as it saw fit. But, as indicated above, Plaintiffs' antitrust claims here are not based on what Gilead did with TAF *alone*; they are also based on what Gilead did with TDF (*i.e.*, intentionally degrading Stribild and artificially

raising its price).

Putting aside that point, Judge Alsup's concern in *AIDS Healthcare* seemed to be that Gilead should have been free to decide how to market TAF – *i.e.*, it was not unreasonable for Gilead to market the drug as part of a FDC first and put off selling the drug as a standalone. But here Plaintiffs are not just alleging that TAF standalone was put off for some time; rather, Plaintiffs are alleging that there was a deliberate choice to withhold TAF in order to get consumers to move over from TDF-based products to TAF-based products and to do so in a particular manner. Plaintiffs allege that, when TAF standalone was eventually released, it was in too high a strength, and it was not given with an indication that it could be used for treatment of HIV.

Finally, the Court notes that the following language from *AIDS Healthcare* – "'[a]s a general rule, any firm, even a monopolist . . . [,] may bring its products to market whenever and however it chooses,'" *id.* – comes from a Ninth Circuit opinion *Foremost*. *Foremost*, in turn, took this language from another Ninth Circuit case, *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979). In *Berkey*, the court immediately followed the statement above with the following footnote:

> This is not to say, of course, that new product introductions are Ipso facto immune from antitrust scrutiny, and we do not agree with Kodak's argument that they are, *See, e. g.*, *Sargent-Welch Scientific Co. v. Ventron Corp.*, 567 F.2d 701 (7th Cir. 1977), *Cert. denied*, 439 U.S. 822 (1978) (use of power over old product to promote sale of new); in all such cases, however, *it is not the product introduction itself, but some associated conduct, that supplies the violation*.

Id. at 286 n.30 (emphasis added).

That statement in *Berkey* is consistent with later Ninth Circuit law, including *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991 (9th Cir. 2010). In *Allied*, the Ninth Circuit noted that § 2 law does not condemn the success of a monopolist where it is based on invention and innovation. *See id.* at 998. Thus, "'[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes.'" *Id.* But, the court added, "changes in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2." *Id.* Thus, for example, when Microsoft integrated its web browser

into its operating system, an antitrust violation was found, particularly as Microsoft gave no procompetitive justification for that conduct. *See id.* The *Allied Orthopedic* court added that, where a design change does "improve[] a product by providing a new benefit to consumers," it "does not violate Section 2 *absent* some associated anticompetitive conduct." *Id.* at 998-99 (emphasis added); *see also id.* at 999-1000 (noting that "*CalComp* and *Foremost* . . . stand for the uncontroversial proposition that product improvement *by itself* does not violate Section 2, even if it is performed by a monopolist and harms competitors as a result") (emphasis added).

With respect to the instant case, Plaintiffs are not contesting per se Gilead's introduction of the TAF-based FDCs – *i.e.*, the product introduction, improvement, and/or innovation. Rather, Plaintiffs are challenging Gilead's purposeful conduct – namely, moving consumers over to the TAF-based FDC (instead of letting the superiority of the products drive that change). For this conduct, Plaintiffs have a plausible argument that there is no procompetitive justification for the action. For instance, what purpose is served by Gilead degrading Stribild and/or standalone TAF? What purpose is served by Gilead not putting a HIV indication on TAF? Whether this was an unlawful restraint cannot be determined on this motion to dismiss.

The Court therefore denies Gilead's motion to dismiss the antitrust claims based on the commercialization of TAF.

VIII. ALL ANTITRUST CLAIMS – RELEVANT MARKET AND MARKET POWER

Generally speaking, all of Plaintiffs' antitrust claims (whether based on an unreasonable restraint of trade under § 1 or monopolization under § 2, and whether based on federal or state law) require the definition of a product market. *See, e.g.*, *Big Bear Lodging Ass'n v. Snow Summit, Inc.*, 182 F.3d 1096, 1104-05 (9th Cir. 1999) ("Except when alleging a *per se* antitrust violation, Plaintiffs must identify the relevant geographic and product markets in which Plaintiffs and Defendants compete and allege facts demonstrating that Defendants' conduct has an anticompetitive effect on those markets. Market definition is also essential to establish a monopolization claim.").[30]

[30] As indicated above, if the Court were to find per se illegality under § 1, then Plaintiffs would not need to worry about market definition. But at this juncture of the proceedings, the Court has

A product market "encompass[es] the product at issue as well as all economic substitutes for the product." *Newcal Indus. v. Ikon Office Sol.*, 513 F.3d 1038, 1045 (9th Cir. 2008). "'The outer boundaries of a product market are determined by the reasonable interchangeability of use *or* the cross-elasticity of demand between the product itself and substitutes for it.'" *Id.* (emphasis added). "Elasticity of demand is a concept used to signify the relationship between changes in price and responsive changes in demand." *United States v. LSL Biotechnologies*, 379 F.3d 672, 697 (9th Cir. 2004); *see also Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 469 (1992) (indicating that cross-elasticity of demand refers to "the extent to which consumers will change their consumption of one product in response to a price change in another."). In the instant case, Plaintiffs have pointed to two product markets: (1) the broader market for cART drugs generally and (2) the narrower market for each brand drug (standalone or FDC) and its AB-rated generic equivalent. *See* CAC ¶ 376.

To the extent Defendants suggest it is not permissible for Plaintiffs to base their antitrust claims on two different product markets, the Court does not agree. As both Plaintiffs and the FTC explain in their respective briefs, what the appropriate product market is depends on what anticompetitive harm is being claimed. *Cf. U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) (indicating that one must "remember[] to ask, in defining the market, *why* we are doing so: that is, what is the antitrust question in this case that market definition aims to answer?"; adding that "the nature of the claim can affect the proper market definition") (emphasis added). Defining a product market is simply a way to determine whether a defendant has market power. *See, e.g., Todd v. Exxon Corp.*, 275 F.3d 191, 199 (2d Cir. 2001) (stating that "[o]ne traditional way to demonstrate market power is by defining the relevant product market and showing defendants' percentage share of that market"); *Bhan v. NME Hosps., Inc.*, 669 F. Supp. 998, 1018 (E.D. Cal. 1987) (noting that, "[s]ince market power can only be measured in relationship to a particular product market, the market definition bears directly upon the degree of market power a firm has[;] [t]hus, to prove that a defendant has market power, the first crucial step

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not made any conclusion as to whether the per se illegal rule applies.

is to establish the bounds of the relevant market"). Market power, in turn, is simply a way to assess whether the defendant's conduct has anticompetitive effects. *See, e.g.*, *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (in discussing § 2 claim, stating that "[e]valuating market power begins with defining the relevant market[;] [t]his inquiry will also prove useful for analyzing the § 1 allegations because a market definition provides the context against which to measure the competitive effects of an agreement"); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 668 (D. Conn. 2016) (stating that "articulating a relevant market definition is not an end in itself, but is in the service of answering the question of market power, which in turn 'is but a surrogate for detrimental effects'").

In the instant case, it is not unreasonable for Plaintiffs to have identified two different product markets because they have claimed harm to competition in two different ways. More specifically, Plaintiffs allege that (1) one "purpose and effect of Defendants' unlawful conduct was to impair competition among drugs used in the cART regimen," Opp'n at 65, and (2) another "purpose and effect of Defendants' . . . unlawful conduct was to impair competition from generic versions of each of the brand name drugs at issue." Opp'n at 63.

Defendants contend still that there are insufficient factual allegations to support each asserted product market. For the narrower market, the Court disagrees. For example, it is plausible each brand drug and its AB-rated generic version is not reasonably interchangeable with other drugs because, as Plaintiffs allege, "once the physician and patient find that one of these drugs is well tolerated, at competitive prices the doctor and patient are very unlikely to switch to a different HIV drug based on variations of price of 10% or less." CAC ¶ 364; *see also* CAC ¶ 181 (alleging that "pharmaceuticals are 'experience' goods that consumers and physicians are hesitant to change if they are working"). Plaintiffs also suggest that there is not reasonable interchangeability because each brand drug (and its AB-rated generic version), compared to other drugs, has "varying ability to treat the conditions for which it is prescribed" and a different "side-effects profile." CAC ¶ 363.

However, Defendants' position has merit on the broader market. That is, it is not clear from the CAC what exactly the cART product market is. Although the Court understands from

the CAC that cART stands for combination antiretroviral therapy, that it is the modern means of treating HIV, and that it often consists of two NRTIs and a third agent, Plaintiffs have not explained, *e.g.*, how there is reasonable interchangeability of use with respect to different cART drugs.[31]

Because the Court concludes that Plaintiffs have not adequately alleged a cART market, it does not address Defendants' contention that the broader and narrower product markets contradict one another. However, the Court does note that, under Ninth Circuit law, "it is legally permissible to premise antitrust allegations on a submarket." *Newcal*, 513 F.3d at 1045.

In sum, because Plaintiffs have not adequately alleged a cART market, its antitrust claims based on that market (as opposed to the narrower market for each brand drug) are dismissed but with leave to amend.

IX. STATE LAW CLAIMS – ANTITRUST AND CONSUMER PROTECTION – COUNTS TWO, FOUR, SIX, SEVEN, NINE, ELEVEN, AND THIRTEEN

As noted above, Plaintiffs bring two kinds of state law claims: state antitrust claims and state consumer protection claims. With respect to the state antitrust claims, Defendants argue that their arguments on the federal antitrust claims are also applicable. Defendants also make several other independent arguments in favor of dismissal of the state law claims, whether based on antitrust law or consumer protection law. Because most of these independent arguments are expressly made by Gilead, the Court largely refers to Gilead hereinafter.

A. Antitrust and Consumer Protection Claims: Application of California Law to Nationwide Purchases

For the most part, Plaintiffs claim violation of a particular state's law (whether antitrust or consumer protection) based on a purchase made in that state. The one exception is with respect to California law. Plaintiffs maintain that California law can apply to purchases made anywhere in the nation because Gilead is based in California. In its motion to dismiss, Gilead argues that it is a violation of due process to apply California law (antitrust or consumer protection) nationwide.

[31] For instance, which cART drugs are included and which are not? Is that market limited to those which contain a Gilead product or does it extend to all cART drugs?

As an initial matter, Plaintiffs suggest that the Court should not rule on this issue in the context of a 12(b)(6) motion; rather, Plaintiffs assert, the issue should be reserved for class certification. *See, e.g.*, *Bias v. Wells Fargo & Co.*, 942 F. Supp. 2d 915, 928 (N.D. Cal. 2013) (Gonzalez-Rogers, J.) ("find[ing] that the choice of law determination in this case is better suited for the class certification stage because the record with respect to balancing the competing states' interests is not sufficiently developed"); *Khoa Nguyen v. Barnes & Noble, Inc.*, No. SACV 12-812-JLS (RNBx), 2015 U.S. Dist. LEXIS 187099, at *11 (C.D. Cal. Nov. 23, 2015) (noting that, "[a]lthough there is some disagreement, most courts in this circuit hold that a claim should not be dismissed on a conflict of law analysis at the pleading stage, especially 'when dealing with a potential nationwide class action'"; therefore, "declin[ing] to engage in a choice of law analysis based solely on the pleadings"); *Andriesian v. Cosmetic Dermatology, Inc.*, No. 3:14-cv-01600-ST, 2015 U.S. Dist. LEXIS 50502, at *28 (D. Or. Mar. 3, 2015) (citing cases in support of the proposition that "a case should not be dismissed based on a conflict of law analysis prior to class certification" – *i.e.*, a choice-of-law analysis at the pleading phase is "'premature'"). But Plaintiffs' position seems problematic, especially as the cases on which they rely hold that it is premature to make a choice-of-law decision prior to class certification. Here, Gilead is not really asking the Court to make a choice-of-law decision per se. Rather, Gilead is asking the Court to make a due process determination – *i.e.*, even though Plaintiffs claim that California law can be applied to purchases made outside the state ("extraterritorial" purchases), would application of California law violate Gilead's due process rights?[32]

The Court therefore addresses the due process argument now, leaving for another day the issue of whether California law is the correct choice of law. As to the due process argument, the parties essentially agree that the governing authority is *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985). There, the defendant was an oil company that produced or purchased natural gas from leased land located in eleven different states, and that sold most of the gas in interstate commerce. The plaintiffs were the royalty owners possessing rights to the leases from which the defendant

[32] To be sure, it may be argued that Gilead is asserting choice of law dressed up as a due process claim. But as noted herein, case law has established a distinct due process analytical framework.

produced gas. *See id.* at 799. The plaintiffs brought a class action against the defendant in Kansas state court, "seeking to recover interest on royalty payments which had been delayed by [the defendant." *Id.* The trial court certified a class action under Kansas law. *See id.* at 801. The final certified class "contained 28,100 members" of which "[l]ess than 1,000 . . . resided in Kansas. [In addition,] [o]nly a miniscule amount, approximately one quarter of one percent, of the gas leases involved in the lawsuit were on Kansas land." *Id.* at 801.

One of the issues before the Supreme Court was whether it was appropriate to apply Kansas law to all of the class members' claims. *See id.* at 802 (noting argument that "Kansas courts could not apply Kansas law to every claim in the dispute"); *see also id.* at 814-15 (noting that "[t]he Kansas courts applied Kansas contract law and Kansas equity law to every claim in this case, notwithstanding that over 99% of the gas leases and some 97% of the plaintiffs in the case had no apparent connection to the State of Kansas except for this lawsuit"). According to the defendant, "total application of Kansas substantive law violated the constitutional limitations on choice of law mandated by the Due Process Clause of the Fourteenth Amendment and the Full Faith and Credit Clause of Article IV, § 1." *Id.* at 816.

The Supreme Court noted that it first had to "determine whether Kansas law conflicts in any material way with any other law which could apply. There can be no injury in applying Kansas law if it is not in conflict with that of any other jurisdiction connected to this suit." *Id.* Because there were at least some conflicts, the Court then asked whether Kansas had "'a significant contact or significant aggregation of contacts' to the claims asserted by each member of the plaintiff class, contacts 'creating state interests,' in order to ensure that the choice of Kansas law is not arbitrary or unfair.'" *Id.* at 821-22. It concluded that, "[g]iven Kansas' lack of 'interest' in claims unrelated to that State, and the substantive conflict with jurisdictions such as Texas, we conclude that application of Kansas law to every claim in this case is sufficiently arbitrary and unfair as to exceed constitutional limits." *Id.* at 822.

Accordingly, under *Phillips*,

> the law of any particular state may not be applied to a nationwide class unless (1) the chosen state's law does not conflict with the law of another jurisdiction that has an interest in the case, and (2) the

> chosen state has a significant contact or significant aggregation of contacts to claims asserted by each member of the plaintiff class such that the choice of that state's law is not arbitrary or unfair.

In re Capacitors Antitrust Litig., 106 F. Supp. 3d 1051, 1073 (N.D. Cal. 2015) (Donato, J.).

1. Conflict Between California Law and Law of Other States

According to Gilead, there is, in fact, a conflict between California law and the laws of other states. More specifically, Gilead argues that, under California antitrust law, indirect purchasers may obtain damages but, under the laws of at least five states/jurisdictions whose laws have been implicated by the CAC, the opposite is true. *See* Gilead Mot. at 47-48 (citing Illinois, Puerto Rico, Rhode Island, Utah, and Maryland antitrust law[33]); *see also Capacitors Antitrust*, 106 F. Supp. 3d at 1073-74 ("find[ing] [a] potential conflict" because "'some states allow their citizens to sue for antitrust injuries as indirect purchasers (like California) and some do not'").[34]

Whether the antitrust law of the five states/jurisdictions at issue bar indirect purchasers from getting damages is addressed below. *See* Part IX.D, *infra*.

For the time being, however, the Court notes that Gilead has pointed to a conflict in *antitrust* law only, and not to any conflict in *consumer protection* law. In its motion to dismiss, Gilead does suggest that Plaintiffs cannot avoid the rule of no damages for indirect purchasers by recasting their state antitrust claims as state consumer protection claims. *See* Gilead Mot. at 37. However, in making this argument, Gilead addresses the laws of nine states/jurisdictions – of which only four overlap with the states/jurisdictions identified above (*i.e.*, Illinois, Puerto Rico, Rhode Island, and Utah).

Accordingly, at most, Gilead has pointed to a conflict with the antitrust laws of five states/jurisdictions and a conflict with the consumer protection laws of four states/jurisdictions.

2. Significant Contacts with California

If there are no conflicts between California antitrust or consumer protection law and the

[33] Gilead also discusses Massachusetts law but based on a consumer protection statute, not antitrust law.

[34] There is no dispute that, under federal antitrust law, indirect purchasers are not entitled to damages. *See generally Ill. Brick Co. v. Ill.*, 431 U.S. 720 (1977).

laws of other states/jurisdictions, then California law can be applied on a nationwide scale – *i.e.*, to purchases made in other states – without there being a due process problem.

If, however, there are conflicts, that does not mean that California law cannot apply. Rather, under *Phillips,* the question is whether California has a significant contact, or significant aggregation of contacts, to the claims asserted by each member of the plaintiff class; if so, there is no due process concern. In the instant case, Plaintiffs argue that there are significant contacts with California because Gilead is "headquartered in-state and the challenged conduct occurred within the state." *In re Charles Schwab Corp. Sec. Litig.*, 264 F.R.D. 531, 538 (N.D. Cal. 2009) (Alsup, J.). That is, at least a part of the challenged conduct (whether based on the No-Generics Restraints, the Teva patent settlement agreements, or the commercialization of TAF) occurred within the state because Gilead's decisionmaking emanated from California.

Plaintiffs' position has merit. And although Gilead does have arguments to the contrary, they are not convincing. For example, Gilead argues that "the focus of the analysis is on the nexus between plaintiffs' claims and California, *not* defendants' contacts." Gilead Reply at 17 (emphasis in original). This is only partly true. It is correct that the Court must evaluate whether Plaintiffs' claims have a significant contact with California, but that does not mean that Gilead's contacts are thereby irrelevant. Plaintiffs' claims are based on wrongdoing committed by Gilead. Thus, where Gilead committed the wrongdoing is clearly significant. This case differs from *Phillips*.

The Ninth Circuit confirmed as much in *AT&T Mobility LLC v. AU Optronics Corp.*, 707 F.3d 1106 (9th Cir. 2013). There, the court held that

> anticompetitive conduct by a defendant within a state that is related to a plaintiff's alleged injuries and is not "slight and casual" establishes a "significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." Specifically, we hold in this case that [California's] Cartwright Act can be lawfully applied without violating a defendant's due process rights when more than a *de minimis* amount of that defendant's alleged conspiratorial activity leading to the sale of price-fixed goods to plaintiffs took place in California. Such a defendant cannot reasonably complain that the application of California law is arbitrary or unfair when its alleged conspiracy took place, at least in part, in California.

Id. at 1113; *see also id.* at 1111-12 (criticizing the district court for "mak[ing] a single contact – the location of Plaintiffs' injury – dispositive"; "the relevant 'occurrence or transaction' in this case includes not only the sale of price-fixed goods, but Defendants' alleged agreements and conspiracies to fix LCD prices").

Admittedly, Gilead has cited some authority in support of its position, but that authority was issued before *AT&T*, is not binding, and is not persuasive. For instance, in *In re Relafen Antitrust Litigation*, 221 F.R.D. 260 (D. Mass. 2004), the district court declined to apply Pennsylvania law to a nationwide class even though the company producing the drug was headquartered in the state and the product was sold and distributed from the state. Its rationale was that

> the primary aim of antitrust and consumer protection laws generally – and those of indirect purchaser states particularly – is compensating consumers, not policing corporate conduct. Accordingly, the Court considers the more significant contact in this context to be the location of the injury – that is, the location of the sales to the end payor plaintiffs.

Id. at 277. But even if the district court was correct in elevating injury to the end payor over the policing of corporate conduct, that does not mean that the policing of corporate conduct is not an important part of antitrust and consumer protection law – such that the location of the corporate conduct could not be a significant contact for purposes of due process analysis.

Gilead also relies on *In re Graphics Processing Units Antitrust Litigation*, 527 F. Supp. 2d 1011 (N.D. Cal. 2007) (hereinafter "*GPU*"), another decision that pre-dates *AT&T*. There, Judge Alsup held that there was no significant contact with California based on the specific allegations in the complaint. The plaintiffs in *GPU* had alleged that "secret meetings between defendants' representatives took place in California," that one defendant is "headquartered in California," and that another defendant had "at least some business operations . . . in California." *Id.* at 1028. According to Judge Alsup, these allegations were insufficient to establish significant contacts because "plaintiffs have never alleged the specific locations of any of the meetings between defendants" and one of the defendants "is organized in Canada and has its headquarters there." *Id.* Arguably, Judge Alsup's conclusion is problematic; it seems a fair inference that at least a fair

amount of the alleged conspiracy between the defendants (*e.g.*, to fix prices) took place in California given that one defendant was based in the state and thus decisionmaking emanated from there. But, in any event, *GPU* is distinguishable from the instant case because, even if two of Plaintiffs' theories turn on Gilead's actions with other companies (*i.e.*, the claims based on the No-Generics Restraints and the Teva patent settlement agreements), one theory (*i.e.*, the claims based on the commercialization of TAF) does not.

Accordingly, the Court holds that it would not be a due process violation for California law to apply nationwide, *i.e.*, to purchases made outside the state. This ruling, however, is not dispositive of whether California law should in fact be the choice of law. The Court leaves that decision for another day, *see AT&T*, 707 F.3d at 1113 (noting that "the Due Process Clause does nothing but circumscribe the universe of state laws that can be constitutionally applied to a given case, [and so] we 'need not . . . balance the competing interests of California and [other states]';] [o]bjections based on the interests of other states are more properly raised under a choice of law analysis") – especially since the main authority on which Plaintiffs rely, *In re Qualcomm Antitrust Litig.*, 328 F.R.D. 280 (N.D. Cal. 2018) (Koh, J.), is currently on appeal. *See id.* at 312 (conducting a choice-of-law analysis and concluding that California law – which permits damages for indirect purchasers – could apply to a nationwide class of consumers "because other states do not have an interest in barring their own citizens from recovering damages for a California-based corporation's anticompetitive conduct that took place almost entirely in California").

B. Antitrust and Consumer Protection Claims: Standing for 25 States/Jurisdictions

According to Gilead, Plaintiffs' state law claims implicate the laws of 36 different states; however, they have alleged that purchases were made in only 11 of those 36 states. "No purchase by any Plaintiff is alleged in the other 25 states." Gilead Mot. at 35. Gilead contends that, because Plaintiffs have not alleged purchases made in those 25 states, they lack standing to bring state law claims based on the laws of those 25 states. In response, Plaintiffs argue that any standing issue is, in effect, more appropriately addressed at the class certification stage, rather than the 12(b)(6) stage.

Plaintiffs have the better argument. This Court recently addressed the same basic issue in

In re Chrysler-Dodge-Jeep EcoDiesel Mktg., Sales Practices & Products Liability Litigation, 295 F. Supp. 3d 927 (N.D. Cal. 2018) (hereinafter, "*FCA*"). In *FCA*, the Court explained that, in 2015, it held in a different case (*In re Carrier IQ, Inc. Consumer Privacy Litigation*, 78 F. Supp. 3d 1051 (N.D. Cal. 2015)), that it had discretion as to whether to defer questions of standing until class certification; however, just a few months later, the Ninth Circuit decided *Melendres v. Arpaio*, 784 F.3d 1254 (9th Cir. 2015), holding that, once a named plaintiff demonstrates individual standing for a claim, the standing inquiry is satisfied and any issue regarding the relationship between the named plaintiff and the members of the putative class is relevant only to class certification, not standing. *See FCA*, 295 F. Supp. 3d at 954-55. This Court expressly found that *Melendres* was controlling, establishing a per se rule.

Gilead points out that the Court made an alternative holding in *FCA* – *i.e.*, "[e]ven if *Melendres* does not sweep so broadly as to impose a per se rule," a court should exercise its discretion to address standing *before* class certification where the named plaintiffs have ties to only a limited number of states on whose laws they have sued. *Id.* at 956 (noting that, in *Carrier IQ*, "[t]he named plaintiffs came from 13 states, and there were no named plaintiffs from 35 other states," whereas, in *FCA*, "the named Plaintiffs reside in or purchased or leased Class Vehicles in 43 states, and there are no named Plaintiffs for only seven states and the District of Columbia"). However, this Court still found as an initial matter that *Melendres* was dispositive.

C. Antitrust and Consumer Protection Claims: Pre-Filing Requirement

Gilead argues that (1) the antitrust laws of Arizona, Hawaii, Nevada, and Utah and (2) the consumer protection laws of Alabama, Massachusetts, and West Virginia have pre-filing notice requirements that have not been met. *See* Gilead Mot. at 40.

- Ariz. Rev. Stat. § 44-1415(A): "A person filing a complaint . . . for any violation of the provisions of this article [the Antitrust Act] shall simultaneously with the filing of the pleading in the superior court or, in the case of pendent state law claims in the federal court, serve a copy of the complaint . . . on the attorney general."
- Haw. Rev. Stat. § 480-13.3(a)(1): "A class action for claims for a violation of this chapter [monopolies and restraint of trade] other than claims for unfair or deceptive

acts or practices may be filed, and may be prosecuted on behalf of indirect purchasers by a person other than the attorney general as follows: (1) A filed copy of the complaint . . . shall be served on the attorney general not later than seven days after filing of the complaint." *See also id.* § 480.13.3(a)(5)(B) ("If the State files its own action involving the same or similar claim or claims set forth in the complaint filed by the proposed class representative, then the complaint filed by the proposed class representative shall be dismissed.").

- Nev. Rev. Stat. § 598A.210(3): "Any person commencing an action for any violation of the provisions of this chapter shall, simultaneously with the filing of the complaint with the court, mail a copy of the complaint to the Attorney General."
- Utah Code Ann. § 76-10-3109(9): "The attorney general shall be notified by the plaintiff about the filing of any class action involving antitrust violations that includes plaintiffs from this state."
- Ala. Code § 8-19-10(e): "At least 15 days prior to the filing of any action under this section [deceptive trade practices], a written demand for relief, identifying the claimant and reasonably describing the unfair or deceptive act or practice relied upon and the injury suffered, shall be communicated to any prospective respondent by placing in the United States mail or otherwise. Any person receiving such a demand for relief who, within 15 days of the delivering of the demand for relief, makes a written tender of settlement which is rejected by the claimant may, in any subsequent action, file the written tender and an affidavit concerning this rejection. If the court finds that the relief tendered was sufficient to compensate the petitioner for his or her actual damages, the court shall not award any additional damages or attorney's fees or costs to the petitioner."
- Mass. G.L. ch. 93A, § 9(3): "At least thirty days prior to the filing of any such action, a written demand for relief, identifying the claimant and reasonably describing the unfair or deceptive act or practice relied upon and the injury

suffered, shall be mailed or delivered to any prospective respondent. Any person receiving such a demand for relief who, within thirty days of the mailing or delivery of the demand for relief, makes a written tender of settlement which is rejected by the claimant may, in any subsequent action, file the written tender and an affidavit concerning its rejection and thereby limit any recovery to the relief tendered if the court finds that the relief tendered was reasonable in relation to the injury actually suffered by the petitioner."

- W. Va. Code § 46A-6-106(c): "[N]o action . . . may be brought pursuant to the provisions of this section [consumer protection] until the person has informed the seller or lessor in writing and by certified mail, return receipt requested, of the alleged violation and provided the seller or lessor twenty days from receipt of the notice of violation but ten days in the case a cause of action has already been filed to make a cure offer: Provided, That the person shall have ten days from receipt of the cure offer to accept the cure offer or it is deemed refused and withdrawn."

In response, Plaintiffs maintain that they "are not required to plead compliance with [the notice] requirements to state a claim under the relevant statutes." Opp'n at 80. Plaintiffs add that, in any event, "on May 14, 2019, Plaintiffs notified the attorneys general of Arizona, Hawaii, Nevada, and Utah regarding the Complaint and the claims pursuant to the respective state antitrust statutes." Opp'n at 80; *see also* Goldstein Decl., Exs. P, Q, U, and W (letters to attorneys general of Nevada, Hawaii, Arizona, and Utah). In addition, on May 14, 2019, "Plaintiffs notified Defendants that the filed Complaint contained claims brought pursuant to the Massachusetts Consumer Protection Act and the West Virginia Consumer Credit and Protection Act." Opp'n at 80; Goldstein Decl., Exs. A-O (letters to Defendants). As for the only remaining state, Alabama, Plaintiffs assert that no demand letter on Defendants was necessary because "that provision 'shall not apply if the prospective respondent does not maintain a place of business or does not keep assets within the state.'" Opp'n at 80 (quoting Ala. Code § 8-19-10(e)).

Gilead does not challenge the above in its reply brief. Accordingly, the Court rejects Gilead's argument for dismissal based on the pre-filing notice requirements.

D. Antitrust and Consumer Protection Claims: *Illinois Brick* Rule

As indicated above, there is no dispute that, under federal antitrust law, indirect purchasers are not entitled to damages. *See generally Ill. Brick Co.*, 431 U.S. at 720 (decided in 1977). According to Gilead, several states/jurisdictions have the same or similar *Illinois Brick* rule, barring indirect purchasers from getting damages.

1. Illinois Antitrust Act

Illinois's Antitrust Act contains the following provision:

> No provision of this Act shall deny any person who is an indirect purchaser the right to sue for damages. Provided, however, that in any case in which claims are asserted against a defendant by both direct and indirect purchasers, the court shall take all steps necessary to avoid duplicate liability for the same injury including transfer and consolidation of all actions. *Provided further* that no person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General, who may maintain an action parens patriae as provided in this subsection.

740 Ill. Comp. Stat. § 10/7 (emphasis added).

As reflected the language of the statute, an indirect purchaser *may* sue for damages for a violation of the Illinois Antitrust Act – thus making Illinois an "*Illinois Brick* repealer state" for purposes of state antitrust law – *except* that "no person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act." *Id.* Here, Plaintiffs have brought a class action. Thus, Gilead argues that Plaintiffs – as indirect purchasers – cannot assert any claim for damages.

"District courts are divided on whether the Illinois Antitrust Act precludes indirect purchasers from filing class actions [in federal court]." *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 391 (D.N.J. 2018). *Compare, e.g.*, *In re Opana Er Antritrust Litigation*, 162 F. Supp. 3d 704, 723 (N.D. Ill. 2016) ("dismiss[ing] with prejudice [the] indirect purchaser antitrust claim brought under Illinois law"), *with In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 817-18 (N.D. Ill. 2017) (refusing to dismiss "the Illinois antitrust claim on the basis of the Illinois[] class action bar").

It appears that the majority of cases are in line with *Opana*. *See Effexor*, 357 F. Supp. 3d

at 391. Representative of these cases is a decision issued by Judge Orrick in 2014.

> The EPPs [end purchaser plaintiffs] contend that the Supreme Court decision in *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 396 (2010), holding that a New York law prohibiting class actions in suits seeking penalties or statutory minimum damages did not prevent a federal district court sitting in diversity from entertaining a class action under Rule 23, allows the Illinois claim here. Oppo. 31-32. The *In re Wellbutrin XL Antitrust Litig.* Court [from the Eastern District of Pennsylvania], in a very detailed analysis, rejected that very argument explaining "The Illinois restrictions on indirect purchaser actions are intertwined with Illinois substantive rights and remedies because (1) the restrictions apply only to the IAA [Illinois Antitrust Act], (2) they are incorporated in the same statutory provision as the underlying right, not a separate procedural rule, and (3) the restrictions appear to reflect a policy judgment about managing the danger of duplicative recoveries. Because the indirect purchaser restrictions of the IAA are 'intertwined' with the underlying substantive right, application of Rule 23 would 'abridge, enlarge or modify' Illinois' substantive rights, and therefore Illinois' restrictions on indirect purchaser actions must be applied in federal court." *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d at 677. I agree with Judge McLaughlin's analysis, *especially as the no indirect purchaser class action rule was expressly adopted as an integral part of the Illinois Antitrust Act's repeal of* Illinois Brick. As such, I conclude that the Illinois antitrust claims must be DISMISSED with prejudice.

United Food & Commer. Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1084 (N.D. Cal. 2014) (emphasis added).

The rationale provided by courts who have reached the opposite conclusion is typically as follows:

> The Court finds that *Shady Grove*'s reasoning with respect to New York's class action ban is equally applicable to Illinois's requirement that class actions be brought by the Attorney General. It is true that the Seventh Circuit has noted that Illinois's decision to repeal *Illinois Brick* and allow indirect purchaser lawsuits "reflects different judgments about the feasibility of trying such claims and the potential danger of duplicative recoveries." *Ill., ex rel. Burris v. Panhandle E. Pipe Line Co.*, 935 F.2d 1469, 1480 (7th Cir.1991). And some district courts have identified this statement as an indication that the Seventh Circuit considers decisions about the "feasibility" of indirect purchaser suits to be a substantive, not procedural, issue. *See In re Opana ER Antritrust Litig.*, 162 F. Supp. 3d at 723 (citing *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 677 (E.D. Pa. 2010)). Moreover, the *Illinois Brick* issue – whether indirect purchasers can bring suit at all, even individually – is certainly substantive in that it affects the "rights and remedies" of indirect purchasers. But whether such plaintiffs may bring a class action does not affect their substantive rights. The availability of the class action procedure does not change the

> substantive rights or remedies available to them under Illinois law. *See In re Lithium Ion Batteries Antitrust Litig.*, 2014 U.S. Dist. LEXIS 141358, 2014 WL 4955377, at *21 (N.D. Cal. Oct. 2, 2014) [Gonzalez-Rogers, J.]; *In re Aggrenox Antitrust Litig.*, 2016 U.S. Dist. LEXIS 104647, 2016 WL 4204478, at *6 (D. Conn. Aug. 9, 2016).

Broiler Chicken Antitrust, 290 F. Supp. 3d at 817-18.

The Court finds Judge Orrick's analysis in *United Food* more persuasive than the analysis in *Broiled Chicken Antitrust*. This is especially true given this Court's take on *Shady Grove* as articulated in *In re MyFord Touch Consumer Litigation*, No. 13-cv-03072-EMC, 2016 U.S. Dist. LEXIS 179487 (N.D. Cal. Sep. 14, 2016). The Court noted as follows:

> While the Ninth Circuit has not expressly recognized this, it has relied on Justice Stevens's concurrence for the proposition that "there are some state procedural rules that federal courts must apply in diversity cases because they function as part of the State's definition of the substantive rights and remedies." *Makaeff v. Trump Univ., LLC*, 736 F.3d 1180, 1187 (9th Cir. 2013). Under Justice Stevens's analysis, Rule 23 will not govern here if the Colorado and Virginia statutes are "procedural in the ordinary use of the term but [are] so intertwined with a state right or remedy that it functions to define the scope of the state-created right." *Shady Grove*, 559 U.S. 393, 423 (2010) (Stevens, J., concurring)."

Id. at *77-78. Here, the Illinois prohibition on class actions is deeply intertwined with the rights under the *Illinois Brick* repealer.

Accordingly, the Court grants Gilead's motion to dismiss on the Illinois Antitrust Act – more specifically, to the extent Plaintiffs seek damages as indirect purchasers for a violation of the state statute, such is not permissible.

2. Puerto Rico Antitrust Act

Title 10 of the Puerto Rico code deals with commerce, and Chapter 13 within that title deals with monopolies and restraint of trade. *See generally* 10 L.P.R.A. §§ 251-276. Unlike Illinois, Puerto Rico does not have an *Illinois Brick* repealer statute. Section 268 of the code simply provides: "Any person who shall be injured in his business or property by any other person, by reason of acts or intended acts, forbidden or declared to be unlawful by the provisions of this chapter, except § 259 and 261 of this title, may sue therefor . . . ." *Id.* § 268.

Similar to above, there is conflicting authority as to whether Puerto Rico allows for damages for indirect purchasers under Puerto Rico law.

For example, in *United Food*, Judge Orrick took note that, in *Rivera-Muniz v. Horizon Lines Inc.*, 737 F. Supp. 2d 57, 61 (D.P.R. 2010), a district court from Puerto Rico held that, "'[b]ecause Puerto Rico liberally construes its standing requirements in private antitrust cases . . . it is immaterial whether Plaintiffs are direct or indirect purchasers of cabotage services.'" *United Food*, 74 F. Supp. 3d at 1086 (quoting *Rivera-Muniz*). On the other hand, there were two decisions from the Northern District of California that favored the antitrust defendants.

> In the first, *In re TFT-LCD Antitrust Litig.*, Case No. 07-mdl-1827 SI, 599 F. Supp. 2d 1179 (N.D. Cal. 2009) the court dismissed the claims under Puerto Rico law because it was "reluctant to find standing in the absence of an explicit *Illinois Brick* repealer, either by statute or case law." *Id.* at 1188. . . . In the second, *In re Static Random Access Memory (SRAM) Antitrust Litig.*, Case No. 07-mdl-01819 CW, 2010 U.S. Dist. LEXIS 131002, (N.D. Cal. Dec. 8, 2010), the court dismissed the indirect purchaser claims because "IP Plaintiffs point to no authority that suggests that *Illinois Brick*'s interpretation of federal antitrust law would not be applied to Puerto Rico law" and because of the ruling in *In re TFT-LCD Antitrust Litig.*, 2010 U.S. Dist. LEXIS 131002.

United Food, 74 F. Supp. 3d at 1086-87. Finally, Judge Orrick acknowledged that, in a district court case from Massachusetts, the court considered each of the three cases identified above and held that "'in light of the fact that Puerto Rico antitrust law has been interpreted in accordance with federal antitrust law, which does not allow claims from indirect purchasers following *Illinois Brick* – this Court dismisses the claims arising under the Puerto Rico law.'" *Id.* at 1087 (quoting *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 410 (D. Mass. 2013)).

After surveying this authority, Judge Orrick ultimately came down on the side of the antitrust defendant, particularly because he did not find *Rivera-Muniz* persuasive.

> I realize that the court in *Rivera-Muniz* first noted that the "[Puerto Rico Antitrust Act] is modeled after federal antitrust statutes" and then relied solely on *Pressure Vessels of P.R., Inc. v. Empire Gas de P.R.*, 137 P.R. Dec. 497, 509-18, 1994 Juris P.R. 144 (1994) as authority that Puerto Rico nevertheless "explicitly rejects" the indirect purchaser standing limitations imposed under the federal statutes. *Id.* at 737 F. Supp. 2d at 61. However, the *Pressure Vehicles* court did not address the standing of indirect purchasers under the PRAA and did not discuss *Illinois Brick* or whether it had been repealed by Puerto Rico. Instead, the *Pressure Vehicles* court relied on cases recognizing the "liberal standing theory under Clayton Act sec. 4" and concluded that "plaintiff need not establish anything beyond a factual causal relation between the injury and the

> violation to meet the" pleading requirements under the PRAA; "it suffices that the plaintiff has been injured as a result of the statutory violation." *Pressure Vessels of Puerto v. Empire Gas P.R.*, 137 D.P.R. 497, 1994 Juris P.R. No. 144, 1994 WL 909547 (P.R. 1994).
>
> Because neither *Rivera-Muniz* nor *Pressure Vehicles* addressed *Illinois Brick*, I agree with the weight of authority and find that the claims under Puerto Rico's statute must be DISMISSED with prejudice.

Id. at 1087; *see also In re Loestrin 24 FE Antitrust Litig.*, No. 1:13-MD-2472-WES-PAS, 2019 WL 5406077, at *7 (D.R.I. Oct. 17, 2019) ("join[ing] the majority of courts in concluding that the EPPs do not have standing to bring antitrust claims under Puerto Rico law"); *Opana*, 162 F. Supp. 3d at 723 (finding *Rivera-Muniz* unpersuasive for similar reasons; stating that "[a]bsent an interpretation by the courts of Puerto Rico allowing antitrust recovery by indirect purchasers or an express *Illinois Brick* repealer statute enacted by the legislature, the Court concludes that EPPs' indirect purchaser antitrust claim is barred in Puerto Rico and must be dismissed with prejudice"); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 251 (D. Conn. 2015) (noting that "*Pressure Vessels* did not address indirect-purchaser standing or the rule of *Illinois Brick*[,] [a]nd though I agree with the indirect purchasers' contention that the courts of a particular jurisdiction can authoritatively interpret their laws as allowing antitrust recovery by indirect purchasers even in the absence of an express *Illinois Brick* repealer by the legislature, I cannot conclude that *Pressure Vessels* is such an authoritative statement").

In contrast, a New York district court has found in favor of the antitrust plaintiff.

> The Court recognizes that many district courts in the continental United States have dismissed indirect purchaser claims under the PRAA for lack of standing, based on the idea that the PRAA is modeled on federal statutes that do not extend standing to indirect purchasers. *See, e.g.*, Opana ER, 162 F.Supp.3d at 723 (collecting cases); *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 413 (S.D.N.Y. 2011).
>
> Nonetheless, this Court finds that the U.S. District Court for the District of Puerto Rico has more faithfully interpreted the standing requirements of the PRAA, in light of how the Supreme Court of Puerto Rico reads that statute. *Rivera-Muniz*, 737 F. Supp. 2d at 61 (citing *Pressure Vessels P.R. v. Empire Gas P.R.*, 137 D.P.R. 497, 520 (P.R. 1994)).
>
> In *Pressure Vessels*, the Supreme Court of Puerto Rico interpreted the private damages section of the PRAA to hold that private

> remedies were available to any plaintiff who met the following conditions: (1) the person was harmed in his business or property (2) by reason of (3) actions prohibited by law. 137 D.P.R. at 518. The Supreme Court of Puerto Rico reasoned that, in order to satisfy this second prong, a plaintiff need only allege that "as a consequence of the legal violation, he has been injured." *Id.* at 520. Based on this interpretation of the PRAA in *Pressure Vessels*, the Court in *Rivera-Muniz* held, "Because Puerto Rico liberally construes its standing requirements in private antitrust cases, it is immaterial whether Plaintiffs are direct or indirect purchasers." *Rivera-Muniz*, 737 F. Supp. 2d at 61 (internal citation omitted).
>
> Defendants' motion to dismiss this claim is, therefore, DENIED.

Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc, No. 15 CIV. 6549 (CM), 2018 WL 7197233, at *23 (S.D.N.Y. Dec. 26, 2018).

As above, the Court finds Judge Orrick's *United Food* decision more persuasive. The Court therefore grants Gilead's motion to dismiss on the Puerto Rico Act, in particular, to the extent Plaintiffs seek damages as indirect purchasers.

3. Rhode Island Antitrust Act

For the Rhode Island Antitrust Act, Gilead argues that Rhode Island did not adopt an *Illinois Brick* repealer statute until July 15, 2013, *see* R.I. Gen. Laws § 6-36-7(d) (providing that, "[i]n any action under this chapter, the fact that a person or public body has not dealt directly with the defendant shall not bar or otherwise limit recovery[,] [p]rovided, however, that courts shall exclude from the amount of monetary relief awarded in the action any amount of monetary relief which duplicates amounts which have been awarded for the same injury"); 2013 R.I. SB 840 (July 15, 2013) (adding § 6-36-7(d)); "[t]hus, any Rhode Island Antitrust Act claim for damages based on conduct prior to July 15, 2013 must be dismissed." Gilead Mot. at 36.

In response, Plaintiffs argue that "[t]he repealer provision should be applied retroactively." Opp'n at 72. But the cases on which Plaintiffs rely are not persuasive. For example, in *Landgraf v. Usi Film Products*, 511 U.S. 244 (1994), the Supreme Court stated that there is a "traditional presumption against truly 'retrospective' application of a statute." *Id.* at 279. And with respect to *Pion v. Bess Eaton Donuts Flour Co.*, 637 A.2d 367 (R.I. 1994), Plaintiffs have taken a select quotation. The full context for the quotation is as follows:

> Generally, it is presumed that statutes and their amendments are "to

> operate prospectively unless it appears by clear, strong language or by necessary implication that the Legislature intended to give the statute retroactive effect." *VanMarter v. Royal Indemnity Co.*, 556 A.2d 41, 44 (R.I. 1989). If a statute lacks clear direction or necessary implication concerning its retroactive application, the difference between a substantive statute and a remedial or procedural statute becomes relevant. *See Lawrence v. Anheuser-Busch, Inc.*, 523 A.2d 864, 869 (R.I. 1987). Substantive statutes, which create, define, or regulate substantive legal rights, must be applied prospectively. *See id.* In contrast, remedial and procedural statutes, which do not impair or increase substantive rights but rather prescribe methods for enforcing such rights, may be construed to operate retroactively. *See id.*

Id. at 371.

There is no clear and strong language directing that the Rhode Island repealer statute be given retroactive effort. Accordingly, the Court concludes that there is no retroactive application for the Rhode Island *Illinois Brick* repealer statute and, to that extent, Gilead's motion to dismiss is granted.

4. Utah Antitrust Act

The Utah code provides in relevant part that "[a] person who is a citizen of this state or a resident of this state and who is injured or is threatened with injury in his business or property by a violation of the Utah Antitrust Act may bring an action for injunctive relief and damages, regardless of whether the person dealt directly or indirectly with the defendant." Utah Code Ann. § 76-10-3109(1)(a). Gilead underscores that "[t]he Utah Antitrust Act permits damages claims by indirect purchasers only if they are citizens or residents of the state," but here "[n]o Plaintiffs are alleged to meet this description." Gilead Mot. at 36. Gilead adds that "Plaintiffs cannot rely on absent class members to meet the . . . citizenship/residence requirement." Gilead Reply at 18.

The Court rejects Gilead's argument. This is essentially the *Melendres* issue discussed above. *See also In re Generic Pharm. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 838 (E.D. Pa. 2019) (noting that "'[a]llegations that members of the putative class presumably include Utah . . . citizens and residents are sufficient to overcome a motion to dismiss'"). Therefore, the motion to dismiss the damages claim under the Utah statute is denied without prejudice. The remedy is, however, restricted to citizens and residents of Utah.

5. Maryland Antitrust Act

In 1993, the Maryland code was amended to include the following provision: "A person whose business or property has been injured or threatened with injury by a violation of § 11-204 may maintain an action for damages or for an injunction or both against any person who has committed the violation." Md. Code Ann. § 11-209(b)(2)(i) (1993); *see also* 1993 MD. SB 196 (May 27, 1993). In 2002, a state appellate court held that § 11-209(b)(2)(i) follows the *Illinois Brick* rule, particularly because "section 11-202(a)(1)[] states the purpose of [the Maryland Antitrust Act] is 'to complement the body of federal law governing restraints of trade, unfair competition, and unfair, deceptive, and fraudulent acts or practices.'" *Davidson v. Microsoft Corp.*, 143 Md. App. 43, 50 (2002). The appellate court also cited legislative history in support. *See id.* at 51 (noting, *inter alia*, that a bill from 2001 which "would have amended 11-209(b) to permit suits by private parties who dealt indirectly with the violator . . . was defeated in committee").

In 2017, however, § 11-209(b)(b)(i) was amended and now reads as follows: "A person whose business or property has been injured or threatened with injury by a violation of Section 11-204 of this subtitle may maintain an action for damages or for an injunction or both against any person who has committed the violation *regardless of whether the person maintaining the action dealt directly or indirectly with the person who has committed the violation*." Md. Code Ann. § 11-209(b)(2)(i) (2017) (emphasis added); *see also* 2017 Md. HB 1415 (May 27, 2017); 2017 Md. SB 858 (May 27, 2017).

Based on the above, Gilead argues that, up until the 2017 *Illinois Brick* repealer statute, indirect purchasers could not get damages under Maryland law. *See* Gilead Reply at 18. ("Maryland's 2017 *Illinois Brick* repealer does not apply retroactively."). Plaintiffs do not appear to substantively dispute such – they do not, *e.g.*, argue for retroactive application. Hence, the antitrust claim based on Maryland law is dismissed to the extent damages to indirect purchasers are claimed prior to May 27, 2017.

6. Massachusetts Consumer Protection Act

Title XV of the Massachusetts code concerns the regulation of trade. The antitrust

provisions in the Massachusetts code can be found in chapter 93. In turn, the regulation of business practices for the protection of consumers can be found in chapter 93A.

In chapter 93A, governing consumer protection, there are two different provisions giving rise to a private right of action for unfair methods of competition or deceptive acts or practices.

- Section 9 of chapter 93A provides: "Any person, other than a person entitled to bring action under section 11 of this chapter, who has been injured by another person's use or employment of any method, act or practice declared to be unlawful by section two or any rule or regulation issued thereunder . . . may bring an action in the superior court . . . for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper." Mass. G.L. ch. 93A, § 9.
- Section 11 of chapter 93 in turn provides: "Any person who engages in the conduct of any trade or commerce and who suffers any loss of money or property, real or personal, as a result of the use or employment by another person who engaged in any trade or commerce of any unfair method of competition or an unfair or deceptive act or practice declared unlawful by section two or by any rule or regulation issued under paragraph (c) of section two may, as hereinafter provided, bring an action in the superior court . . . for damages and such equitable relief, including an injunction, as the court deems to be proper and necessary." Mass. G.L. ch. 93A, § 11.

Massachusetts courts have indicated that the difference between § 9 and § 11 is that § 9 makes "consumer claims" actionable while § 11 makes "business claims" actionable. *See Lantner v. Carson*, 374 Mass. 606, 610 (1978) (noting that, "where § 9 affords a private remedy to the individual consumer . . . , an entirely different section, § 11, extends the same remedy to 'any person who engages in the conduct of any trade or commerce'"); *Frullo v. Landenberger*, 61 Mass. App. Ct. 814, 821 (2004) (stating that "General Laws c. 93A distinguishes between 'consumer' and 'business' claims, the former actionable under § 9, the latter actionable under § 11"); *see also Cont'l Ins. Co. v. Bahnan*, 216 F.3d 150, 156 (1st Cir. 2000) (noting that "section 11 affords no

relief to consumers and, conversely, section 9 affords no relief to persons engaged in trade or commerce"). Although "[t]he dividing line between a consumer claim and a business claim for purposes of G.L. c. 93, §§ 9 and 11[] is not always clear," "the choice appears to turn on whether a given party has undertaken the transaction in question for business reasons, or has engaged in it for purely personal reasons (such as the purchase of an item for personal use)." *Id.* "[A]ny transaction in which the plaintiff is motivated by business considerations gives rise to claims under the statute's business section," and the fact "[t]hat a transaction may be an isolated one not in the normal course of business does not insulate it from the reach of . . . § 11." *Id.*

In the instant case, Gilead contends that "five of the Plaintiffs . . . are union insurers, not consumers," Gilead Mot. at 36, and thus they can only bring § 11 claims. The Massachusetts Supreme Court has held that, under § 11, claims by indirect purchasers are not permissible – in contrast to § 9 consumer claims which do allow for claims by indirect purchasers. This issue was addressed by the Massachusetts Supreme Court in *Ciardi v. F. Hoffman La Roche, Ltd.*, 436 Mass. 53 (2002).

There, the state Supreme Court began by noting that the Massachusetts Antitrust Act – covered by chapter 93 of the code as opposed to chapter 93A – was to be construed in harmony with federal antitrust law. "Because the [Massachusetts] Antitrust Act is to be construed in harmony with judicial interpretations of comparable Federal antitrust statutes, the rule of law established in *Illinois Brick* . . . would apply with equal force to preclude claims brought under G.L. c. 93 by indirect purchasers in Massachusetts. *Id.* at 57-58. The plaintiff in *Ciardi*, however, was not bringing a claim under chapter 93 but rather under chapter 93A. "In analyzing what constitutes unfair methods of competition and unfair or deceptive acts or practices, which are not defined in G. L. c. 93A, this court looks to interpretations by the Federal Trade Commission and Federal courts of § 45(a)(1) of the Federal Trade Commission Act (FTC Act)." *Id.* at 59. The FTC "may . . . enforce the antitrust laws." *Id.* Moreover,

> [t]he plain and unambiguous language of G.L. c. 93A reveals no legislative intent to limit lawsuits for price-fixing to direct purchasers. To the contrary, because the language of G.L. c 93A, §§ 1, 9(1), allows *any* person who has been injured by trade or commerce *indirectly* affecting the people of this Commonwealth to

> bring a cause of action, the plaintiff is the type of consumer the Legislature intended to protect.

Id. (emphasis in original). Finally, the state Supreme Court pointed out that "the language of the [Massachusetts] Antitrust Act unambiguously states that 'it shall have no effect upon the provisions of [c. 9A], except as *explicitly provided in said* [c. 93A].'" *Id.* at 62 (emphasis in original). In contrast to § 9, § 11 – *i.e.*, the provision giving rise to business claims instead of consumer claims – "*includes a specific provision that in any action brought under that section, the court shall be guided in its interpretation of unfair methods of competition by the provisions of the [Massachusetts] Antitrust Act*. [Section] 9[] contains no such explicit provision." *Id.* at 62-63 (emphasis added); *see also United Food*, 74 F. Supp. 3d at 1086 (noting that "indirect purchaser claims cannot be asserted under Section 11"); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, No. C 07-5944 SC, 2014 U.S. Dist. LEXIS 35387, at *66 (N.D. Cal. Mar. 13, 2014) (stating that, "while corporations engaged in commerce can bring suits under Section 11 and potentially win them, a corporation engaged in commerce whose suit is based on indirect purchases will not have standing under Section 11"). Accordingly, as a general matter, § 9 consumer claims may be brought by indirect purchasers, but not § 11 business claims.

In the instant case, Gilead asserts that the union plaintiffs can bring only § 11 claims. As Gilead points out, two district courts have held that health and welfare funds have only § 11 claims when they purchase products not for their own personal use but rather for the use of their members. *See United Food*, 74 F. Supp. 3d at 1085 (noting that, "according to their own complaint, the EPPs did not purchase the products (and/or provide reimbursement for those products) for their personal use, but for the use of their members[;] [t]he Plan and the City appear to be engaged in the 'trade or commerce' of providing health and welfare benefits"); *In re Asacol Antitrust Litig.*, No. 15-cv-12730-DJC, 2016 U.S. Dist. LEXIS 94605, at *43-44 (D. Mass. July 20, 2016) (stating that health fund plaintiffs – *i.e.*, organizations – "cannot bring a claim under § 9 as they cannot show that they undertook the relevant transactions 'for purely personal reasons (such as the purchase of an item for personal use'").

On the other hand, as Plaintiffs note, the union insurers are nonprofit entities, and there is case law indicating that "a party's status as a non-profit influences [the] analysis"; "'[i]n most

circumstances, a charitable institution will not be engaged in trade or commerce *when it undertakes activities in furtherance of its core mission*.'" *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 20, 81 (D. Mass. 2007) (emphasis added; quoting *Linkage Corp. v. Trs. of Bos. Univ.*, 425 Mass. 1, 26 (1997)). For example, in *In re Lorazepam & Clorazepate Antitrust Litigation*, 295 F. Supp. 2d 30 (D.D.C. 2003), the plaintiff was Blue Cross Blue Shield of Massachusetts ("BCBS"). It brought an unfair competition claim against several pharmaceutical companies on its own behalf as a third-party payor of prescription drugs for its insureds. The court held that BCBS's claim fell under § 9 (instead of § 11), explaining as follows:

> BCBS Massachusetts's charitable mission is set forth in its enabling statute, Mass. Gen Laws ch. 176B ("ch. 176B"). Further, BCBS Massachusetts has alleged that it is a medical service corporation under ch. 176B, and operates as a "nonprofit medical service plan" pursuant to which it provides "health services," including prescription drug benefits, to its members. *See* Complaint ¶ 14; *see also* generally ch. 176B. BCBS Massachusetts's core mission has been recognized by the First Circuit as well:
>
> > Blue Shield of Massachusetts, Inc. and Blue Cross of Massachusetts, Inc. are nonprofit, tax exempt medical service and hospital service corporations, organized to provide "for the preservation of the public health by furnishing medical services at low cost to members of the public who become subscribers. . . ." 1941 Mass. Acts c. 306, preamble. Mass. G.L. c. 176B (Blue Shield); c. 176A (Blue Cross).
>
> *Kartell v. Blue Shield of Massachusetts, Inc.*, 592 F.2d 1191, 1191 (1st Cir. 1979). The transactions identified by Plaintiff here – payment for members' prescription drug claims, *see, e.g.*, Complaint ¶¶ 1-8 – are clearly at the core of BCBS Massachusetts's charitable mission. Further, while the Court has not found cause to review any of Plaintiff's financial statements, the Court must construe the complaint in the light most favorable to the Plaintiff and accepts as true for purposes of the instant motion BCBS Massachusetts's allegation that it does not "profit" under the specific transactions at issue (i.e., payment for its members' prescription drug claims).

Id. at 45-46. The court added that "an absence of legislative mandate tend[s] to indicate the presence of Section 11 'trade or commerce,'" but here "BCBS Massachusetts is a creation of statutory law that [is] subject to both legislative mandate and constraint. For example, pursuant to Mass. Gen. Laws ch. 176, § 23 and ch. 176B, § 13, the state commissioner of the Division of Insurance is responsible for ascertaining, *inter alia*, that BCBS Massachusetts is 'not being

operated for profit' and is maintaining sufficient reserves." *Id.* at 46. *Compare S. Shore Hellenic Church, Inc. v. Artech Church Interiors, Inc.*, 183 F. Supp. 3d 197, 202 (D. Mass. 2016) (noting that, *in Linkage* – where the plaintiff-company sued Boston University, a nonprofit entity, for unlawfully terminating an agreement under which the plaintiff provided educational, training, and other programs of a technical nature at a satellite facility owned by the university – the court held that the university had engaged in trade or commerce because "it [had] cut a private company out of a lucrative market").

Because a party's status as a nonprofit affects the analysis as to whether it has a § 9 or § 11 claim, the Court shall allow the union insurers' claims based on the Massachusetts Consumer Protection Act to proceed. The union insurers' role arguably is akin to that of consumers; the factual record must be developed in order for the Court or the trier of fact to make an informed determination as to whether the union insurers profit from paying its insureds' prescription drug claims.

7. Summary

Gilead's motion to dismiss the indirect purchaser claims for damages is granted as to the Illinois Antitrust Act and the Puerto Rico Antitrust Act. On the Rhode Island Antitrust Act and the Maryland Antitrust Act, Rhode Island and Maryland each has an *Illinois Brick* repealer statute but indirect purchaser claims for damages prior to the effective date of that statute are not viable. The motion to dismiss the indirect purchaser claims for damages under the Utah Antitrust Act and the Massachusetts Consumer Protection Act is denied without prejudice.

E. Consumer Protection Claims: Circumvention of the *Illinois Brick* Rule

Gilead notes that Plaintiffs have brought not only antitrust claims under state law but also state law consumer protection claims. According to Gilead, certain states have an *Illinois Brick* rule for their antitrust laws; to the extent they do, Plaintiffs cannot try to "end run" the *Illinois Brick* rule by recasting the antitrust claims as consumer protection claims. *See* Gilead Mot. at 37 (arguing that the "consumer-protection claims under the laws of Arkansas, Connecticut, Illinois, Idaho, Missouri, Montana, Puerto Rico, Rhode Island, and Utah must fail").

Gilead's argument is problematic. In support, Gilead cites *In re DDAVP Indirect*

Purchaser Antitrust Litig. v. Ferring Pharms. Inc., 903 F. Supp. 2d 198 (S.D.N.Y. 2012). But there the court simply agreed with other courts holding that, "'where the applicable state law bars antitrust actions for damages by indirect purchasers . . . a plaintiff cannot circumvent the statutory framework by recasting an antitrust claim as *one for unjust enrichment*.'" *Id.* at 232. Here, Plaintiffs are not bringing a claim for unjust enrichment but rather a statutory claim for consumer protection. Furthermore, as Plaintiffs note in their papers, "[m]any of the [the] statutes . . . contain 'harmonization' provisions providing a legislative mandate that the statutes be interpreted in accordance with the Federal Trade Commission ('FTC') Act." Opp'n at 75. Finally, the consumer protection statutes cover more than just anticompetitive conduct – typically covering unfair, unconscionable, or deceptive conduct. *See* Opp'n at 75.

Accordingly, the Court denies Gilead's motion to dismiss based on the "end run" argument (as applied to state consumer protection laws).

F. Consumer Protection Claims: Conclusorily Pled

Gilead argues, in effect, that the consumer protection claims have been conclusorily pled – "providing no information on how the claims at issue satisfy the particular requirements of each state's individual consumer-protection statutes." Gilead Mot. at 37; *see also* Gilead Reply at 19 (arguing that Plaintiffs "ignore the differences among state consumer-protection laws").

This argument has no merit. Plaintiffs have been clear about what wrongdoing has allegedly been committed by Gilead. If Gilead believes that specific elements of consumer protection claims have not been met, that is their obligation to identify those specific elements.

G. Consumer Protection Claims: Deceptive Conduct

According to Gilead, fifteen states require deceptive conduct, or at least conduct directed to and relied upon by a consumer, in order to state a consumer protection claim, but, here, "the Complaint alleges no such conduct." Gilead Mot. at 15. Gilead cites to the laws of Arizona, California, District of Columbia, Idaho, Illinois, Kansas, Maine, Michigan, New York, Nevada, New Mexico, Rhode Island, Tennessee, Utah, and West Virginia. Following are the specific state laws identified by Gilead:

- Arizona. "The act, use or employment by any person of any deception, deceptive

or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice." Ariz. Rev. Stat. § 44-1522(A); *see also id.* § 44-1522(C) (providing that "[i]t is the intent of the legislature, in construing subsection A, that the courts may use as a guide interpretations given by the federal trade commission and the federal courts to 15 United States Code sections 45, 52 and 55(a)(1)").

- California. "[U]nfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code." Cal. Bus. & Prof. Code § 17200.
- District of Columbia. "It shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby, including to: [*inter alia*] (f) fail to state a material fact is such failure tends to mislead." D.C. Code § 28-3904(f); *see also id.* § 28-3901(d) (providing that, "[i]n construing the term 'unfair or deceptive trade practice' due consideration and weight shall be given to the interpretation by the Federal Trade Commission and the federal courts of the term 'unfair or deceptive act or practice,' as employed in section 5(a) of An Act to create a Federal Trade Commission, to define its powers and duties, and for other purposes, approved September 26, 1914").
- Idaho. "The following unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared to be unlawful, whether a person knows, or in the exercise of due care should know, that he has in the past, or is: [*inter alia*] (17) Engaging in any act or practice which is

otherwise misleading, false, or deceptive to the consumer." Idaho Code § 48-603(17).

- Illinois. "Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' [815 ILCS 510/2], approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby." 815 Ill. Comp. Stat. § 505/2.[35]
- Kansas. "No supplier shall engage in any deceptive act or practice in connection with a consumer transaction." Kan. Ann. Stat. § 50-626(a). "Deceptive acts and practices include, but are not limited to the following, each of which is hereby declared to be a violation of this act, whether or not any consumer has in fact been misled: [*inter alia*] (3) the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact." *Id.* § 50-626(b)(3).
- Maine. "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." 5 Me. Rev. Stat. § 207; *see also id.* § 207(1) (providing that "[i]t is the intent of the Legislature that in construing this section the courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to Section 45(a)(1) of the Federal Trade Commission Act (15 United States Code 45(a)(1)), as from time to time amended").

[35] Regarding a claim of deception based on concealment or suppression, an Illinois state court has noted that "sellers have a duty not to conceal or suppress known material facts regarding products from potential buyers" and that, for liability to attach, "a plaintiff must establish that defendants intended that [the consumers] rely on the suppression in making their choice to buy." *Jensen v. Bayer AG*, 371 Ill. App. 3d 682, 689 (2007).

- Michigan. "Unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful and are defined as follows: [*inter alia*] (s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer." Mich. Comp. Laws § 445.903(1)(s).
- New York. "Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful." N.Y. Gen. Bus. Law § 349(a).
- Nevada. "A person engages in a 'deceptive trade practice' if, in the course of his or her business or occupation, he or she: [*inter alia*] (15) Knowingly makes any other false representation in a transaction." Nev. Rev. Stat. § 598.0915(15).
- New Mexico. "Unfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce are unlawful." N.M. Stat. Ann. § 57-12-3. "'[U]nfair or deceptive trade practice' means an act specifically declared unlawful pursuant to the Unfair Practices Act, a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services . . . that may, tends to or does deceive or mislead any person . . . ." *Id.* § 57-12-2(D).
- Rhode Island. "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." R.I. Gen. Laws § 6-13.1-2. "'Unfair methods of competition and unfair or deceptive acts or practices' means any one or more of the following: [*inter alia*] (xiii) Engaging in any act or practice that is unfair or deceptive to the consumer." *Id.* § 6-13.1-1(6)(xiii):
- Tennessee. "Unfair or deceptive acts or practices affecting the conduct of any trade or commerce constitute unlawful acts or practices . . . ." Tenn. Code § 47-18-104(a). "The following unfair or deceptive acts or practices affecting the conduct of any trade or commerce are declared to be unlawful and in violation of this part . .

. ." *Id.* at 47-18-104(b); *see also id.* § 47-18-115 (providing that "[i]t is the intent of the general assembly that this part shall be interpreted and construed consistently with the interpretations given by the federal trade commission and the federal courts pursuant to § 5(A)(1) of the Federal Trade Commission Act, codified in 15 U.S.C. § 45(a)(1)").[36]

- Utah. "A deceptive act or practice by a supplier in connection with a consumer transaction violates this chapter . . . ." Utah Code § 13-11-4(1). In addition, "[a]n unconscionable act or practice by a supplier in connection with a consumer transaction violates this act . . . ." *Id.* § 13-11-5(1).
- West Virginia. "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." W. Va. Code § 46A-6-104. "'Unfair methods of competition and unfair or deceptive acts or practices' means and includes, but is not limited to, any one or more of the following: [*inter alia*] (M) The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby." *Id.* § 46A-6-102(7)(M).[37]

As an initial matter, Gilead's position is questionable because it is not clear that all of the states identified condemn deceptive conduct only – *e.g.*, on their face, some of the statutes seem to implicate unfair conduct as well. *Compare In re Dynamic Random Access Memory (DRAM)*

[36] *See also In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 203 (D. Me. 2004) (acknowledging that the Tennessee statute directs a court to look to federal interpretation of the FTC Act for guidance but nevertheless "follow[ing] the narrower interpretation of the Tennessee courts" – *i.e.*, "deception is required for a TCPA claim").

[37] Regarding a claim of deception based on concealment or suppression, a West Virginia state court has noted as follows: "Where concealment, suppression or omission is alleged, and proving reliance is an impossibility, the causal connection between the deceptive act and the ascertainable loss is established by presentation of facts showing that the deceptive conduct was the proximate cause of the loss." *White v. Wyeth*, 227 W. Va. 131, 140 (2010).

Antitrust Litig., 516 F. Supp. 2d 1072, 1117 (N.D. Cal. 2007) (Hamilton, J.) (noting that the Utah statute – unlike the FTC Act – does *not* refer to unfair competition, and therefore "the FTCA's prohibition on antitrust price-fixing should not be read into the CSPA here") (emphasis omitted).

But putting aside that point, Plaintiffs fairly point out that they have claimed deception, more specifically in the form of concealment: "Plaintiffs have . . . alleg[ed] a conspiracy between Gilead and its coconspirators to monopolize the cART market and maintain artificially high prices, a fact that Defendants *concealed* from Plaintiffs." Opp'n at 77 (emphasis added). At least some courts have found this a plausible claim of deception. *See, e.g.*, *GPU*, 527 F. Supp. 2d at 1030 (Alsup, J.) (concluding that plaintiffs made sufficient allegations to state a claim under state consumer protection law because plaintiffs "contend that defendants have engaged in deceptive acts to conceal the alleged agreement to fix prices" – *i.e.*, "[d]efendants hid the alleged conspiracy from plaintiffs, resulting in plaintiffs paying higher prices"); *see also In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, 172 F. Supp. 3d 724, 752-53 (D.N.J. 2016) (stating that "anticompetitive conduct can violate § 349 [of New York law] if it is deceptive in nature" – *e.g.*, if defendants made efforts to conceal an anticompetitive agreement, if defendants secretly agreed to raise prices, or if defendants entered into secret anticompetitive agreements). *Compare Leider v. Ralfe*, 387 F. Supp. 2d 283, 295-97 (S.D.N.Y. 2005) (noting that § 349 refers to deceptive, but not unfair, practices; manipulation of a market is a generic antitrust scheme and not deception).

However, if the claim is based on such deception, it is not clear what relief Plaintiffs seek as a result of Defendants' deception. Arguably, Plaintiffs' cannot conflate harm from Defendants' deception with harm from Defendants' anticompetitive conduct. *Cf. Motor Vehicles Canadian*, 350 F. Supp. 2d at 176-77, 189 (rejecting argument that there was actionable deception under, *inter alia*, Michigan law, because defendants failed to inform consumers about conspiracy to keep out Canadian cars, which inflated new car prices in the United States; price differential was not hidden from or unknown to consumers – thus, "if United States consumers failed to acquire the cheaper Canadian vehicles, it was because they did not care to, or because the alleged conspiracy prevented Canadian dealers from selling to them . . . , not because the conspiracy was unknown"). The Court therefore orders Plaintiffs to provide a more definite statement as to what relief is

sought for any deceptive conduct.

H. Consumer Protection Claims: Consumer Requirement

Gilead argues that ten states/jurisdictions "allow a plaintiff to sue only in its capacity' as a consumer," and, here, five of the plaintiffs are union insurers – who are not consumers but rather third-party payors. Gilead Mot. at 38 (citing to the laws of the District of Columbia, Hawaii, Kansas, Maine, Missouri, Montana, North Carolina, Rhode Island, Utah, and Vermont).

In response, Plaintiffs argue that the union insurers do constitute "consumers" because "third-party payor Plaintiffs participate in consumer transactions by paying some or all of the prices charged to individual consumers and, as a result, pay a portion of any overcharges. These purchases are made for the personal purposes of the patient." Opp'n at 77. Plaintiffs admit that the union insurers "do not personally use the products, [but] they nonetheless purchase them for others' personal use." Opp'n at 78.

The states at issue are addressed below.

1. District of Columbia

Under D.C. law, "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived or damaged thereby . . . ." D.C. Code § 28-3904. "A consumer may bring an action seeking relief from the use of a trade practice in violation of a law of the District." *Id.* § 28-3905(k)(1). When used as a noun, "consumer" means "a person who, other than for purposes of resale, does or would purchase, lease (as lessee), or receive consumer goods or services, including as a co-obligor or surety, or does or would otherwise provide the economic demand for a trade practice." *Id.* § 28-3901(a)(2)(A). When used as an adjective, "consumer" "describes anything, without exception, that: (i) A person does or would purchase, lease (as lessee), or receive and normally use for personal, household, or family purposes."

In *Lidoderm,* Judge Orrick evaluated the above statutes and found in favor of the defendants. *See Lidoderm,* 103 F. Supp. 3d at 1155 (Orrick, J.). His reasoning was as follows:

> As explained by the District of Columbia Court of Appeals, "the relevant distinction is one between retail and wholesale transactions. Transactions along the distribution chain that do not involve the

> ultimate retail consumer are not 'consumer transactions' that the Act seeks to reach. Rather, it is the ultimate retail transaction between the final distributor and the individual member of the consuming public that the Act covers. Accordingly, it is not the use to which the purchaser ultimately puts the goods or services, but rather the nature of the purchaser that determines the nature of the transaction."
>
> Here the purchase at issue – the one trying to secure a recovery for its indirect purchase – is GEHA [Government Employees Health Organization]. It is true that GEHA has pled it is a joint "end payor" for the Lidoderm patches, and that it has paid retail and mail order pharmacies in the District of Columbia $13,432.85 for Lidoderm patches during the relevant period. However, GEHA was not part of the "retail" transaction, in terms of deciding to purchase the product or actually purchasing it. It, instead, was required to pay the pharmacies for a portion of the expenses for the patches because its members filled personal prescriptions for Lidoderm patches. Although GEHA played a role in the retail transaction, its own transactions with the pharmacies were more akin to "wholesale" than retail transactions.

Id.

Respectfully, the Court disagrees with Judge Orrick's analysis. Although an insurer who purchases a pharmaceutical product does not make that purchase for its own use, its role is located on the retail side of the transaction given that it is essentially acting as a proxy for its insured. Absent legislative history indicating that "consumer" as used in the statutes means an individual or business purchasing for his, her, or its use only, the Court does not limit application of the statutes as argued by Gilead.

2. Hawaii

Under Hawaii law, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful." Haw. Rev. Stat. § 480-2(a). "No person other than a consumer, the attorney general or the director of the office of consumer protection may bring an action based upon unfair or deceptive acts or practices declared unlawful by this section." *Id.* § 480-2(d). "'Consumer' means a natural person who, primarily for personal, family, or household purposes, purchases, attempts to purchase, or is solicited to purchase goods or services or who commits money, property, or services in a personal investment." *Id.* § 480-1(d).

Because the Hawaii code refers specifically to a suit being brought by a consumer and then

defines consumer as a "natural person," Gilead has the better position. *See also Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15 Civ. 6549, 2018 U.S. Dist. LEXIS 220574, at *109-10 (S.D.N.Y. Dec. 26, 2018) (holding in favor of defendants on Hawaii code).

3. Kansas

Under Kansas law, "[n]o supplier shall engage in any deceptive act or practice in connection with a consumer transaction." Kan. Stat. Ann. § 50-626(a). "'Consumer transaction' means a sale, lease, assignment or other disposition for value of property or services within this state . . . to a consumer." *Id.* § 50-624(c). "'Consumer' means an individual, husband and wife, sole proprietor, or family partnership who seeks or acquires property or services for personal, family, household, business or agricultural purposes." *Id.* § 50-624(b). "Whether a consumer seeks or is entitled to damages or otherwise has an adequate remedy at law or in equity, a consumer aggrieved by an alleged violation of this act may bring an action . . . ." *Id.* § 50-634(a).

Because the Kansas code specifically refers to a consumer bringing suit and defines "consumer" as it does above (excluding, *e.g.*, entities such as insurers), Gilead has the better position.

4. Maine

Under Maine law, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." 5 Me. Rev. Stat. § 207.

> Any person who purchases or leases goods, services or property, real or personal, primarily for personal, family, or household purposes and thereby suffers any loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful by section 207 . . . may bring an action . . . .

Id. § 213(1).

Although arguably a close call, the Court finds in Plaintiffs' favor. Defendants have not cited any legislative history or case law indicating that a person must purchase a good for his, her, or its *own* personal, family, or household purpose. As discussed above in conjunction with D.C. law, an insurer who purchases a pharmaceutical product essentially acts as a proxy for its insured,

who clearly falls within the common understanding of a "consumer."

5. Missouri

Under Missouri law,

> [t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the state of Missouri, is declared to be an unlawful practice.

Mo. Rev. Stat. § 407.020(1). Furthermore,

> [a]ny person who purchases or leases merchandise primarily for personal, family or household purposes and thereby suffers an ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful by section 407.020, may bring a private civil action . . . .

Id. § 407.025(1).

As above, although arguably a close call, Plaintiffs have the better position, particularly in the absence of legislative history indicating that a consumer is restricted to one who purchases for his, her, or its own use. *But see In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2010 U.S. Dist. LEXIS 90480, at *37 (N.D. Cal. Aug. 31, 2010) (in discussing Missouri law, stating that, "[a]lthough the term 'person' explicitly includes corporations like GEHA, the statute has been interpreted as requiring that a person purchase the property for his, her or its own 'personal, family or household purposes'" and, "[a]ccordingly, the claims of health care plans and third-party payors have been dismissed for lack of standing").

6. Montana

Under Montana law, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful." Mont. Code § 30-14-103. "A consumer who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act, or practice declared unlawful by 30-14-103 may bring an individual but not a class action." *Id.* § 30-14-133(1). "'Consumer' means a person who purchases or leases goods, services, real property, or information primarily for

personal, family, or household purposes." *Id.* § 30-14-102(1).

As above, although arguably a close call, Plaintiffs have the better position, particularly in the absence of legislative history indicating otherwise. *But see Lidoderm*, 103 F. Supp. 3d at 1165 (Orrick, J.) (dismissing the Montana claim because the statute "defines a 'consumer' as 'a person who purchases or leases goods, services, real property, or information primarily for personal, family, or household purposes'" and "[t]he statute excludes persons who buy goods for resale").

7. North Carolina

Under North Carolina law, "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful." N.C. Gen. Stat. § 75-1.1(a).

> If any person shall be injured or the business of any person, firm or corporation shall be broken up, destroyed, or injured by reason of any act or thing done by any other person, firm or corporation in violation of the provisions of this Chapter, such person, firm or corporation so injured shall have a right of action on account of such injury done . . . .

Id. § 75-16. Given the broad language used in the statutes, the Court finds in favor of Plaintiffs. Gilead relies on *Food Lion, Inc. v. Capital Cities/ABC, Inc.*, 194 F.3d 505 (4th Cir. 1999), presumably because, there, the court noted that North Carolina "gives a private cause of action to consumers aggrieved by unfair or deceptive business practices." *Id.* at 519; *see also id.* at 519-20 (adding that "businesses are sometimes allowed to assert UTPA claims against other businesses because 'unfair trade practices involving only businesses' can 'affect the consumer as well'"; however, "one business is permitted to assert an UTPA claim against another business only when the businesses are competitors (or potential competitors) or are engaged in commercial dealings with each other"). But the Fourth Circuit did not foreclose the possibility that a party involved in a consumer transaction, other than the consumer him/herself – such as a union insurer – could bring suit under the state consumer protection law.

8. Rhode Island

Under Rhode Island law, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." R.I. Gen. Laws § 6-

13.1-2.

> Any person who purchases or leases goods or services primarily for personal, family, or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act, or practice declared unlawful by Section 6-13.1-2, may bring an action . . . .

Id. § 6-13.1-5.2(a). As above, although arguably a close call, Plaintiffs have the stronger position, particularly in the absence of any legislative history to the contrary.

9. Utah

Under Utah law, "[a] deceptive act or practice by a supplier in connection with a consumer transaction violates this chapter whether it occurs before, during, or after the transaction." Utah. Code Ann. § 13-11-4(1). "'Consumer transaction' means a sale, lease, assignment, award by chance, or other written or oral transfer or disposition of goods, services, or other property, both tangible and intangible (except securities and insurance) to, or apparently to, a person for: (i) primarily personal, family, or household purposes." *Id.* § 13-11-3(2)(a). "Whether he seeks or is entitled to damages or otherwise has an adequate remedy at law, a consumer may bring an action" for certain relief. *Id.* § 13-11-19(1).

Whether a union insurer could be a "consumer" under Utah law is a close call. In *Sergeants Benevolent*, 2018 U.S. Dist. LEXIS 220574, at *135-38, the court found in favor of the plaintiffs and against the defendants. The court noted first that the Utah code does not define "consumer" but does define "consumer transaction" – covering not just a sale to a person for, *e.g.*, personal purposes but also *apparently to* a person for personal purposes. The court found that "apparently to" language critical. *See id.* at *137 ("[U]nlike other consumer protection statutes reviewed by this Court, the UCSPA contemplates sales made both 'to' and 'apparently to' a person for personal, family, or household purposes."). "Construing the allegations in the Complaint in the light most favorable to the IPP [indirect purchaser plaintiff], . . . the Court finds that sales of Namenda were made either to or 'apparently to' consumers primarily for their personal, family, or household purposes. Therefore, the Complaint states a claim." *Id.* at *138. Because of the unique language in the Utah statute, the Court denies the motion to dismiss the

union insurers' claims based on Utah law.

10. Vermont

Under Vermont law, "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce are hereby declared unlawful." 9 Vt. Stat. Ann. § 2453(a).

> Any consumer who contracts for goods or services in reliance upon false or fraudulent representations or practices prohibited by section 2453 of this title, or who sustains damages or injury as a result of any false or fraudulent representations or practices prohibited by section 2453 of this title, or prohibited by any rule or regulation made pursuant to section 2453 of this title may sue . . . .

Id. § 2461(b)1.

> "Consumer" means any person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of his or her trade or business but for his or her use or benefit or the use or benefit of a member of his or her household . . . or a person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of his or her trade or business but for the use or benefit of his or her business or in connection with the operation of his or her business.

Id. § 2451a(a). Given that the Vermont code specifies that it is only a consumer who may bring suit and the specific definition of "consumer" above, Gilead has the better position.

11. Summary

In summary, the Court grants the motion to dismiss the union insurers' claims based on the consumer protection laws of the following states/jurisdictions: Hawaii, Kansas, and Vermont.

I. Antitrust Claims: Concerted Action Requirement

Counts 4 and 6 of the CAC are the state law causes of action for monopolization and attempted monopolization (as opposed to, *e.g.*, conspiracy to monopolize or conspiracy to restrain trade). These claims are pled against Gilead only. Gilead argues that certain states – namely, Kansas, New York, and Tennessee – only allow for antitrust claims where there is concerted action, *see* Gilead Mot. at 37 (arguing that "[t]he antitrust laws of Kansas, New York, and Tennessee apply only to agreements between two or more parties"),[38] and therefore Counts 4 and

[38] *See also* Kan. Stat. § 50-101 (providing that "a trust is a combination of capital, skill, or acts, by

6 based on these states' laws must be dismissed. In response, Plaintiffs do not dispute that the above states' laws require concerted action. They point out, however, that Counts 4 and 6 are still based – at least in part – on concerted action, namely, the No-Generics Restraints and the Teva patent settlement agreements. In reply, Gilead asserts: "Counts 4 and 6 should be dismissed *to the extent* they claim unilateral conduct." Gilead Reply at 19 (emphasis omitted). Implicitly, Gilead is referring to the antitrust claims based on its commercialization of TAF. Because this appears to be unilateral action on the part of Gilead, the Court dismisses the above state law claims to this extent.

X. CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss are granted in part and denied in part.

- The overarching conspiracy claims are dismissed with leave to amend.
- The motions to dismiss the antitrust claims based on the No-Generics Restraints are granted in part and denied in part. The claims based on the No-Generics Restraints in the Gilead/Japan Tobacco agreement are dismissed with prejudice. The claims based on the No-Generics Restraints in the Gilead/BMS agreements and the Gilead/Janssen agreements are allowed to proceed. Plaintiffs have leave to provide a more definite statement regarding their antitrust injury theory that untainted competitors in BMS, Japan Tobacco, and Janssen's positions would actually have challenged Gilead's patents prior to their expiration dates (*e.g.*, instead of waiting for the TDF patents to expire in December 2017).
- The motion to dismiss the antitrust claims based on the Teva settlement agreements is denied.
- The motion to dismiss the antitrust claims based on Gilead's commercialization of

two or more persons" for the purpose of, *e.g.*, creating or carrying out restrictions in trade or commerce); N.Y. Gen. Bus. Law § 340(1) (declaring as illegal and void contracts, agreements, arrangements, or combinations for monopoly or in restraint of trade); Tenn. Code §§ 47-25-101 to -112 (addressing arrangements, contracts, agreements, trusts, or combinations between persons or corporations).

TAF is denied.

- The motion to dismiss based on a failure to adequately plead the relevant market is granted in part and denied in part. The motion is granted to the extent Plaintiffs have not adequately alleged a cART market. Plaintiffs have leave to amend.
- The motion to dismiss the state law claims (antitrust and consumer) is granted in part and denied in part.
    - Applying California law to nationwide purchases is not a due process violation.
    - The Court shall address at the class certification stage Gilead's argument that Plaintiffs cannot proceed with their state law claims for 25 states (*i.e.*, because "[n]o purchase by any Plaintiff is alleged in the . . . 25 states"). Gilead Mot. at 35.
    - The motion to dismiss based on failure to satisfy pre-filing requirements is denied.
    - The motion to dismiss the indirect purchaser claims for damages is granted as to the Illinois Antitrust Act and the Puerto Rico Antitrust Act. On the Rhode Island Antitrust Act and the Maryland Antitrust Act, Rhode Island and Maryland each has an *Illinois Brick* repealer statute but indirect purchaser claims for damages prior to the effective date of that statute are not viable. The motion to dismiss the indirect purchaser claims for damages under the Utah Antitrust Act and the Massachusetts Consumer Protection Act is denied without prejudice.
    - The motion to dismiss certain consumer protection claims based on an "end run" argument (*i.e.*, around *Illinois Brick*) is denied.
    - The motion to dismiss the consumer protection claims as conclusorily pled is denied.
    - The motion to dismiss the consumer protection claims to the extent based on deceptive conduct is denied. However, the Court orders Plaintiffs to

provide a more definite statement as to what relief is sought for any deceptive conduct.

- The motion to dismiss is granted with respect to the union insurers' claims based on the consumer protection laws of the following states/jurisdictions: Hawaii, Kansas, and Vermont.
- The motion to dismiss the monopolization and attempted monopolization claims under Kansas, New York, and Tennessee law is granted in part – *i.e.*, to the extent the claims are based on the unilateral conduct of Gilead in commercializing TAF.

To the extent the Court has allows Plaintiffs leave to amend, Plaintiffs' amended complaint shall be filed within 30 days from the date of this order. Thereafter, Defendants shall have 30 days to respond. If Defendants respond with another motion to dismiss, the Court strongly encourages Defendants (as before) to coordinate. Ideally, Defendants would be able to file a joint motion to dismiss, and the Court would extend page limitations to reflect the joint nature of the motion.

This order disposes of Docket Nos. 143, 149, 158, and 159.

IT IS SO ORDERED.

Dated: March 3, 2020

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California