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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

PETER STALEY, et al.,

Plaintiffs,

v.

GILEAD SCIENCES, INC., et al.

Defendants.

Case No. 3:19-cv-02573-EMC

PLAINTIFFS' OMNIBUS MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

Date: January 16, 2020
Time: 1:30 p.m.
Ctrm: 5–17th Floor
Judge: Honorable Edward M. Chen

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I. INTRODUCTION

Plaintiffs' Complaint alleges in exhaustive detail a multi-part scheme by Gilead and its coconspirators to dominate the market for modern HIV treatment regimens, a conspiracy that has delayed more efficient treatment and prevention for HIV patients and cost consumers billions of dollars. The Complaint explains that Gilead agreed with its erstwhile competitors that they would not compete with it by using generic substitutes even after Gilead's patents expired. In return, Gilead agreed to share its extended monopoly profits. The Complaint also details numerous other acts by Gilead in furtherance of this anticompetitive scheme, including buying off generic challengers to Gilead's patents, degrading its own products, and sacrificing profits in order to switch patients to new drugs with patents that expire later.

Defendants' efforts to explain away this conduct ring hollow. They attempt to characterize their naked agreements to extend the life of Gilead's patents as legitimate joint ventures despite the fact that virtually none of them are even structured as joint ventures and there is no reason why any legitimate joint venture would need to agree to unlawfully extend the term of a patent. At times, they deny that their agreements say what they expressly say. Remarkably, they sometimes even deny that they are separate companies at all, arguing that Gilead and Japan Tobacco—two publicly traded companies with no relationship—are really the same entity for antitrust purposes and therefore cannot have conspired with each other. Finally, and most tellingly, Defendants argue that their agreements not to compete are necessary to prevent "free riding." By this, they appear to mean that they feel they need more exclusivity than patent law gave them, and so they signed agreements to create their own exclusivity by agreeing not to compete.

The weakness of these justifications highlights the anticompetitive nature of Defendants' conduct. But at this stage of the proceedings it is also irrelevant. Weak as they are, every one of those purported justifications is a factual claim about the world that contradicts the detailed allegations of the Complaint. That's not how a motion to dismiss works. Even if this Court thought that Defendants' arguments, if true, could justify the scheme to monopolize the market, it should still deny their motions. The factual allegations of the Complaint, not factual allegations in a motion to dismiss, must be taken as true. And when they are, there can be no question that they make out a violation of the antitrust laws.

II. BACKGROUND

The Complaint alleges that Gilead, through an array of anticompetitive practices—including horizontal agreements constituting *per se* violations of the antitrust laws—has acquired and maintained a monopoly in the market for drugs that comprise the modern HIV treatment regimen known as "combination antiretroviral therapy" ("cART"). It has used those agreements to extend its control over the market even after its core patents expire.

Modern cART regimens use a combination or "cocktail" of drugs, most often consisting of two nucleotide/nucleoside analogue reverse transcriptase inhibitors ("NRTIs") taken with at least one antiretroviral drug of another class, such as an integrase inhibitor, commonly referred to as "third agents." ECF No. 118, Corrected Consolidated Class Action Complaint ("Compl.") ¶ 2. Gilead was the exclusive maker (and is still the dominant maker) of one of the principal NRTIs used in cART regimens: Tenofovir. *Id.* Through the anticompetitive scheme alleged in the Complaint, Gilead used its control over Tenofovir to monopolize the market for cART and to extend that control even after the expiration of its central patents. *Id.*

Gilead expected generic competition to Tenofovir and its other NRTI product, emtricitabine ("FTC"), as early as 2009 and 2011, respectively. *Id.* ¶ 96. That competition would immediately end Gilead's market dominance, so Gilead designed an anticompetitive scheme to thwart it and extend control of the market. *Id.* ¶ 3. In exchange for a share of the monopoly profits that Gilead's scheme generated, each of Gilead's coconspirators—Bristol-Myers Squibb ("BMS"), Janssen, and Japan Tobacco—agreed to help Gilead to maintain and expand its monopoly. *Id.* ¶ 99.

Generic Tenofovir (specifically, tenofovir disoproxil, "TDF") became available in December 2017. *Id.* ¶ 62. Generic lamivudine ("3TC")—a close substitute for Gilead's FTC—had become available in 2012. *Id.* ¶¶ 61–62. Access to two generic NRTIs needed for the cART backbone should have spelled the end of Gilead's cART monopoly and the advent of robust and innovative competition. Instead, Gilead and its coconspirators used the anticompetitive restraints described below to lock out competition on more than 75% of all sales of NRTIs, 50% of third agents, and 75% of "booster" drugs in the cART market. *Id.* ¶ 6. Despite the availability of two generic NRTIs, the restraints and other elements of Gilead's anticompetitive scheme have allowed it to maintain a share in the cART market of

70–93%, keeping prices outrageously high and deadening innovation. *Id.* ¶¶ 177–241, 387.

A. The Anticompetitive Scheme

Gilead's scheme has four principal components.

1. First Round of No-Generics Restraints

Gilead coformulated the original version of Tenofovir—TDF—with the coconspirators' third agents into single pills known as fixed-dose-combination drugs ("FDCs"). *Id.* ¶ 4. Each of the collaboration agreements included a "No-Generics Restraint." That restraint prevented the coconspirator from marketing a competing version of the FDC made with a generic version of TDF and/or FTC *even after Gilead's patents on them expired.* *Id.* ¶ 3. This allowed Gilead to shield TDF and FTC from generic competition by moving sales of the standalone versions of those products to the FDCs, which were protected from generic competition by the coconspirators' longer and/or stronger patents on their third agents. *Id.* ¶¶ 109, 128, 151, 180, 281. And the No-Generics Restraints prohibit the coconspirators from marketing a cheaper version of the FDC comprising the coconspirator's still-on-patent third agent and a generic version of Gilead's TDF and/or FTC—even after Gilead's patents expired.

The No-Generics Restraints thus impair generic competition to Gilead's TDF and FTC in both of the forms the competition could take. The restraints prohibit the coconspirator from using a generic version of Gilead's components in the FDC. And with the FDCs providing a competition-free receptacle for those components, Gilead moved sales from the standalone versions of those components—which were threatened with competition from generic-drug manufacturers—to the FDCs. *Id.* Under state drug-substitution laws, pharmacists receiving a prescription for the FDC cannot dispense generic versions of the standalone components. *Id.* ¶ 183. Thus, the coconspirators cut off all avenues of generic competition to Gilead's components: Gilead switched sales of the vulnerable-to-generic-competition standalone components to the FDCs, rendering generic standalone components non-substitutable at the pharmacy counter, and the No-Generics Restraints prohibited the coconspirators from making the FDCs with generic versions of the components even after their patents expired. *Id.* ¶¶ 183–84.

Each of the agreements with Gilead provides several means for the coconspirator to share in the supracompetitive profits that the No-Generics Restraints generated. The restraints increased Gilead's incentive to move sales from TDF and/or FTC to the TDF-based FDCs, resulting in the coconspirator

selling more of its third agents. *Id.* ¶ 178. The restraints also dampened competition in the cART market, generating higher market-wide prices. *Id.* And Gilead directly paid the coconspirator through the royalty and other provisions of the agreements. *Id.* Gilead then returned the favor by shielding BMS and Janssen's HIV drugs from imminent generic competition, allowing them to coformulate FDCs that combined their vulnerable products with a Gilead booster drug, Cobicistat ("COBI"), which enjoyed much longer patent protection. *Id.* ¶ 5.

The No-Generics Restraints took a variety of forms. One type is an express agreement by one or both of the conspirators not to market an AB-rated version of the FDC (i.e., a generic version that is substitutable at the pharmacy counter) even after the other coconspirator's component is available as a generic. In many instances, the restraint is even broader, prohibiting the marketing of not just an AB-rated version of the FDC, but also a "comparable" version—one made with, for example, 3TC instead of Gilead's FTC.

Defendants used this form of No-Generics Restraint in the agreement between Gilead and Janssen covering Complera (the FDC comprising Gilead's Truvada (TDF/FTC) and Janssen's rilpivirine ("RPV")) and Odefsey (Gilead's Descovy (TAF/FTC) and Janssen's RPV). *Id.* ¶¶ 145, 153; ECF No. 143, Declaration of Heather M. Burke in Support of Gilead's Motion to Dismiss ("Burke Decl."), Ex. E ("Complera Agreement") & Ex. G ("Complera/Odefsey Agreement"). The agreements prevent Janssen from marketing an FDC with the same or comparable ingredients (those made with 3TC instead of Gilead's FTC) as Complera or Odefsey, even after Gilead's patents expire. Compl. ¶¶ 145, 153; Complera Agreement § 17.2; Complera/Odefsey Agreement § 17.2.1. The agreements provide that the selling price of these products—even after Gilead's patents expire—will be the combined prices of the *brand components* when sold separately, thus forbidding any generic price reductions. Compl. ¶¶ 147, 154. The conspirators share revenues based on the ratio of the net selling prices of the conspirator's component(s). And Janssen benefits even more handsomely because Gilead buys the Janssen components at the market rate less 30%. *Id.*

Defendants also used this form of No-Generics Restraint in their mutual non-competition agreements involving Janssen's darunavir ("DRV"). Burke Decl., Ex. F ("Prezcobix Agreement") & Ex. H ("Symtuza Agreement"). The agreements regarding Prezcobix (Gilead's COBI and Janssen's DRV)

and Symtuza (Gilead's COBI, TAF, and FTC, with Janssen's DRV) prohibit Gilead from making FDCs with the same ingredients as Prezcobix or the same or comparable ingredients as Symtuza even after Janssen's DRV patents expire. Compl. ¶ 168; Prezcobix Agreement § 14.2(a); Symtuza Agreement § 14.3.2. The agreements also prevent Janssen from making FDCs with the same or comparable ingredients to Gilead's components, such as 3TC and generic ritonavir ("RTV")—a substitute for COBI—even after Gilead's patents expire. Compl. ¶ 168; Prezcobix Agreement § 14.3(b); Symtuza Agreement § 14.2.1. The agreements provide that the selling price of these FDCs will be the combined prices of the brand components when sold separately. Compl. ¶ 168. The conspirators share revenues based on the ratio of the net selling prices of their components. *Id.* ¶ 170. Gilead and Janssen's agreements regarding Odefsey, Prezcobix, and Symtuza were all part of the same conspiracy, each agreement being expressly contingent on the others and signed on the same day. *Id.* ¶ 169.

Gilead and BMS also used this form of No-Generics Restraint in their mutual non-competition agreement regarding Evotaz, the FDC comprising Gilead's COBI and BMS's atazanavir ("ATV"). Burke Decl., Ex. C ("Evotaz Agreement"). The agreement prohibits Gilead from making an FDC with the same ingredients as Evotaz even after BMS's ATV patents expire and prevents BMS from making an FDC with the same or comparable ingredients (made with generic RTV rather than Gilead's COBI) of the product even after the COBI patents expire. Compl. ¶ 134.[1] Moreover, the restraint applies not only to the specific form and dosage strength of Evotaz, but any FDC whose active pharmaceutical ingredients are ATV and COBI. Evotaz Agreement § 1.135. BMS sets the selling price of Evotaz and pays a portion of the proceeds to Gilead. Compl. ¶ 134.

A twist on the same form of No-Generics Restraint governed the conspiracy between Gilead and BMS regarding Atripla, the FDC comprising Gilead's TDF and FTC with BMS's efavirenz ("EFV"). Burke Decl., Ex. A ("Atripla Agreement"). The conspirators purportedly created a formal "joint venture" entity. A joint committee sets the selling price of the FDC, which they set at the combined price of the brand components when sold separately, and the conspirators shared revenues based on the ratio of

[1] Sections 14.2 and 14.3 of the Evotaz Agreement expressly provide that each competitor will not make a version of the drug made with its component and a generic version of the competitor's component (*see* 1.90, defining a "generic"). The term of the agreement extends to the later of (1) 10 years after the first commercial marketing of the FDC, and (2) the expiration or invalidation of the last of the COBI patents. Evotaz Agreement §§ 16.1, 1.169, 9.3.

the net selling prices of the conspirator's components. *Id.* ¶ 121. The conspirators effected the No-Generics Restraint through an express restraint, license restrictions, and a termination provision. Gilead and BMS granted licenses to the joint venture to use their respective components, but with an express restriction that prevented either party from making a version of Atripla with the same components while the venture existed. *Id.* ¶¶ 123–25; Atripla Agreement §§ 2.9(a), 1.94, 1.202, & Recitals. Either party could terminate the venture if a generic version of the other party's components became available. Compl. ¶ 124. But that termination right was subject to two conditions: (1) the terminating party would have to pay a substantial penalty, in the form of royalties that extended beyond the patent's term; and (2) the termination would end the non-terminating party's access to the terminator's components. *Id.* ¶¶ 124, 126. If BMS terminated, Gilead could not make an AB-rated version of Atripla because it would no longer have access to BMS's EFV; if Gilead terminated, BMS could not make an AB-rated version because it would no longer have access to Gilead's TDF or FTC. Thus, the agreement imposed a penalty on terminating due to the availability of generics, and, while not prohibiting the terminating party from using a generic component in the FDC, prohibited the non-terminating party from making an AB-rated version of Atripla. *Id.*

The third form of No-Generics Restraint governed Gilead and Japan Tobacco's Stribild, an FDC comprising Japan Tobacco's elvitegravir ("EVG") and Gilead's TDF, FTC, and COBI, and the FDC Genvoya, comprising EVG, TAF, FTC, and COBI. Burke Decl., Ex D. ("EVG Agreement"). Japan Tobacco granted to Gilead the exclusive right—exclusive even as to Japan Tobacco—to sell EVG in the United States, but not in Japan (where Japan Tobacco retained such rights). Compl. ¶ 103; EVG Agreement § 6.1. This precludes Japan Tobacco or its licensees from making and selling an EVG-containing FDC with generic TDF, generic FTC, and generic COBI, or comparable versions comprising, for example, EVG and generic TDF, generic 3TC, and generic RTV. Compl. ¶¶ 112–13. Absent the No-Generics Restraint, Japan Tobacco would have collaborated with generic manufacturers in the United States to produce and sell these competing versions. *Id.* Under the agreement, Gilead sets the prices for Stribild and Genvoya and pays royalties to Japan Tobacco. *Id.* ¶¶ 105–06.

Gilead and the coconspirators entered into the first round of No-Generics Restraints beginning in the Fall 2004 and continuing through 2009. *Id.* ¶¶ 103, 118, 142. Those first-round restraints cover the

Gilead–Janssen FDC Complera (precluding FDCs with the same or comparable ingredients), the Gilead–Japan Tobacco FDC Stribild (precluding FDCs with the same or comparable ingredients), and the Gilead–BMS FDC Atripla (precluding FDCs with the same ingredients).

2. Anticompetitive Agreements with Teva

Despite facing challenges to its core patents, Gilead was able to stave off generic competition until December 2017 for TDF and September 2020 for FTC. It did so by inducing its principal generic competitor, Teva Pharmaceuticals, to withdraw its challenges to Gilead's patents and delay entry into the market.

Beginning in September 2008, Teva became the "first filer"—the first generic-drug manufacturer to file an Abbreviated New Drug Application ("ANDA") with a Paragraph IV certification—with respect to Viread (standalone TDF), Truvada (TDF/FTC), and Atripla (TDF/FTC, and BMS' EFV). *Id.* ¶¶ 327–32; *see also* ¶¶ 71–89 (background on Hatch Waxman Act). Teva's Paragraph IV certification declared that Gilead and BMS's relevant patents were invalid or would not be infringed by Teva's generic versions of those products, and that Teva sought FDA approval to enter the market before those patents expired. *Id.* ¶¶ 75–76. At least six other generic manufacturers—"second filers"—lined up behind Teva, also challenging the patents on some or all of those drugs. *Id.* ¶¶ 335, 355.

Teva and the second filers posed a serious threat to Gilead (and BMS). And the second filers posed a serious threat to Teva. As the first filer, Teva was eligible to get the coveted 180-day ANDA Exclusivity, which would prevent any second filer from entering the market until 180 days after Teva entered. *Id.* ¶ 77. Marketing the only ANDA generic is enormously valuable to the manufacturer, potentially generating hundreds of millions of dollars. *Id.* ¶¶ 351, 360.

But any 180-day ANDA Exclusivity that Teva might get was defeasible. First, a second filer could get a final court decision that the brand manufacturer's patents are invalid or not infringed. The first filer would then forfeit its ANDA Exclusivity if it did not enter the market within 75 days of the court decision. *Id.* ¶ 318. And the first filer *would* fail to enter the market within 75 days if it settled its patent litigation with the brand manufacturer by agreeing to a long delay in entering the market (as Teva in fact did here). *Id.* ¶¶ 318–19. Second, the ANDA Exclusivity does not prevent the brand manufacturer from giving a second filer a license to enter the market, including a license to enter before

the first filer. *Id.* ¶ 321. A second filer could use the leverage of its patent challenge to wrangle such a license from the brand manufacturer. *Id.*

The second filers competitively threatened both Gilead and Teva, so they worked together to defeat that threat. They settled their patent litigation over TDF (Viread), with Gilead granting a Most-Favored Entry ("MFE") provision to Teva. 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. *Id.* ¶ 343. The agreement also included a Most-Favored-Entry-*Plus* clause ("MFEP"). The MFEP provided that Gilead would not grant a license for a second filer to enter the market any earlier than six weeks after Teva entered. *Id.* Together, the MFE and MFEP closed both of the avenues that Congress had left open for second filers to enter the market before the first filer. This eliminated second filers' incentive to continue spending money on patent litigation in an attempt to get a period of de facto exclusivity in the generic sector of the market. *Id.* ¶¶ 332, 336.[2]

This protection from second filers' competition on generic Viread was worth more than $106 million to Teva. *Id.* ¶ 351. In exchange for that protection and the profits it generated, Teva agreed to delay entering the market for more than four and a half years, until December 2017, just six weeks before the TDF patents expired. *Id.* ¶¶ 343–44. Teva's agreed delay in entering the market protected more than $2 billion in profits for Gilead. *Id.* ¶ 351.

The MFE and MFEP worked just as Gilead and Teva intended. After learning of those clauses, six second filers agreed to not pursue Paragraph IV challenges to Gilead's TDF patents and to stay out of the Viread market until exactly six weeks after Teva entered. *Id.* ¶ 349.

Gilead and Teva then repeated the same scheme—only worse—in settling their patent litigation over FTC, affecting both Truvada (TDF/FTC) and Atripla (TDF/FTC/ATV). Gilead and Teva had litigated all the way through trial and were awaiting a decision from the court. Then Gilead agreed to give Teva an MFE and an MFEP, with the MFEP guaranteeing Teva that Gilead would not grant a license to any second filers to enter the market sooner than 180 days after Teva entered. *Id.* ¶ 357. At

[2] Gilead compounded the anticompetitive effects of the MFE and MFEP by also including those clauses in agreements with the second filers. When the later filers were deciding whether to accept the very late entry date, they knew that any litigation victory they might achieve would trigger the simultaneous entry of not only Teva, but also numerous other generic manufacturers. Compl. ¶¶ 323, 346.

least five second filers had lined up to challenge the patents on Truvada and/or Atripla. *Id.* ¶ 355.

Protection from second filers' competition on generic Truvada and Atripla was worth more than $1.5 billion to Teva. *Id.* ¶ 360. This protection was especially valuable to Teva because it had failed to get tentative approval of its ANDA within 30 months of its application, thereby forfeiting the statutory 180-day ANDA Exclusivity. *Id.* ¶ 356. The agreement re-created for Teva the exclusivity that the statute had specifically denied to it. *Id.* ¶¶ 318, 322.

In exchange, Teva agreed to delay entering the market for more than six and a half years, until September 2020, just one year before the FTC patents expired. *Id.* ¶ 357. And again the scheme worked, with the other five generic manufacturers abandoning their Paragraph IV challenges to the patents, thus preserving more than $25 billion in profits for Gilead and BMS. *Id.* ¶¶ 355, 359, 360.

3. Second Round of No-Generics Restraints

The delay that it bought from Teva gave Gilead the time it needed to ensure that, when Teva's generics finally did enter the market, they could not put even a dent in Gilead's cART monopoly. With Teva (and all other generics) sidelined until 2017 for TDF and 2020 for TDF/FTC, Gilead used the time to move the sales of T**D**F-based products to T**A**F-based products. TAF (tenofovir alafenamide) has a better side-effects profile than TDF. *Id.* ¶ 9. But Gilead had stopped developing TAF in 2004 after reaching the No-Generics Restraint deal with BMS for Atripla and negotiating one with Japan Tobacco for Stribild. *Id.* ¶¶ 202–29. With the No-Generics Restraint strategy in place, Gilead shelved its superior Tenofovir product, TAF, to roll out much later, in the market-switch part of the scheme. *Id.* ¶ 203.

TDF and TAF are both forms of Tenofovir, but generic TDF is not automatically substitutable for TAF at the pharmacy counter. So Gilead's moving TDF-based products (standalone TDF and TDF-based FDCs) to TAF-based products protected Gilead's Tenofovir-based franchise from generic competition. *Id.* ¶ 7.

The first step in this part of Gilead's scheme was to cloak the TAF-based products in No-Generics Restraints. Having signed the second of the generic-delay deals with Teva in February 2014, Gilead filed an application with the FDA to market Genvoya—a TAF-based version of Stribild—in November 2014. *Id.* ¶ 254. Genvoya was protected by the No-Generics-Restraint agreement with Japan Tobacco until 2030. *Id.* ¶ 111. Then in December 2014, Gilead reached new No-Generics-Restraint

deals with Janssen for Odefsey—a TAF-based version of Complera—and for the new TAF-based FDC Symtuza. Both of those restraints extend to 2026. *Id.* ¶¶ 430–31.

4. Anticompetitive Tactics to Switch Sales to TAF-based FDCs

With the new round of No-Generics Restraints in place, Gilead implemented the next step in this part of its scheme—moving the sales from TDF-based to TAF-based versions of the drugs. In order to get doctors and patients to switch to the TAF-based FDCs, Gilead intentionally degraded some of its products and used other anticompetitive tactics that made economic sense for Gilead *solely* because they had the effect of impairing competition. *Id.* ¶¶ 276–77. These anticompetitive tactics included:

Intentionally making TDF-based Stribild less safe: Gilead knew that the dosage of TDF in Stribild was much higher than needed and would subject patients to increased risk of significant adverse side effects. But Gilead left the dosage dangerously high in order to artificially magnify the safety differences between Stribild and the TAF-based version, Genvoya, thus easing the switch of prescriptions from TDF-based Stribild to TAF-Genvoya. *Id.* ¶¶ 242–47.

Creating an artificial price difference between Stribild and Genvoya: Gilead raised the price of Stribild substantially above the price of new-and-improved Genvoya. Gilead created that artificial price difference by raising the price of Stribild above its profit-maximizing level—a level revealed by the product's historical pricing pattern. *Id.* ¶ 248.

Intentionally delaying standalone TAF: Gilead intentionally delayed, for one year, applying for FDA approval for a standalone version of TAF. This ensured that, during a key sales-switching period of 2015–16, the safer TAF was available *only* through purchase of a Gilead TAF-based FDC. *Id.* ¶¶ 253–61. Patients who wanted to switch to safer TAF had to buy a Gilead TAF-based FDC. By the time standalone TAF entered the market in November 2016, Gilead had succeeded in converting more than half of all Stribild prescriptions to Genvoya and of Complera prescriptions to Odefsey. *Id.* ¶ 265. That pattern of rapid cannibalization continued through 2018. *Id.* ¶ 268.

Intentionally degrading standalone TAF's safety: When finally making TAF available as a standalone product, Gilead intentionally degraded its safety. Gilead made standalone TAF available only in a much greater dose—with consequent greater risk of side effects—than the dose that Gilead used in its FDCs. Gilead sold standalone TAF only in 25mg strength while making it available in 10mg strength

when purchased as part of a Gilead FDC. *Id.* ¶¶ 262–69. This is especially problematic for patients who also need a "booster" drug (such as COBI or RTV), which has the effect of enhancing TAF's dangerous side effects. *Id.* ¶ 265. For exactly that reason, Gilead makes Descovy (TAF/FTC) available *only outside the United States* in reduced 10mg strength as well as the 25mg strength available here. *Id.* ¶ 268.

Intentionally restricting TAF's indications: Gilead also degraded standalone TAF by severely limiting the FDA-approved indications for its use. Gilead did not seek FDA approval for using standalone TAF to treat HIV, getting it approved instead only for treatment of Hepatitis B. *Id.* ¶¶ 270–75. TAF obviously is effective in treating HIV, as demonstrated by the clinical trials that Gilead submitted to the FDA. *Id.* ¶ 271. And Gilead sought and received FDA approval with an anti-HIV indication for the TAF-based FDCs. But Gilead intentionally withheld an HIV indication from standalone TAF so that, again, if patients wanted to use TAF in an FDA-approved regimen, they had to buy a Gilead TAF-based FDC. *Id.* ¶ 272.[3]

Degrading these products and engaging in these other anticompetitive tactics cost Gilead hundreds of millions of dollars in sales of standalone TAF every year. But impairing competition was even more valuable. *Id.* ¶ 277. Gilead's billion-dollar investment in impairing competition to the TAF-based FDCs has paid off: by 2017, when TDF finally faced generic competition, Gilead had switched more than 60% of its HIV product sales to the reformulated, TAF-based FDCs. *Id.* ¶ 12.

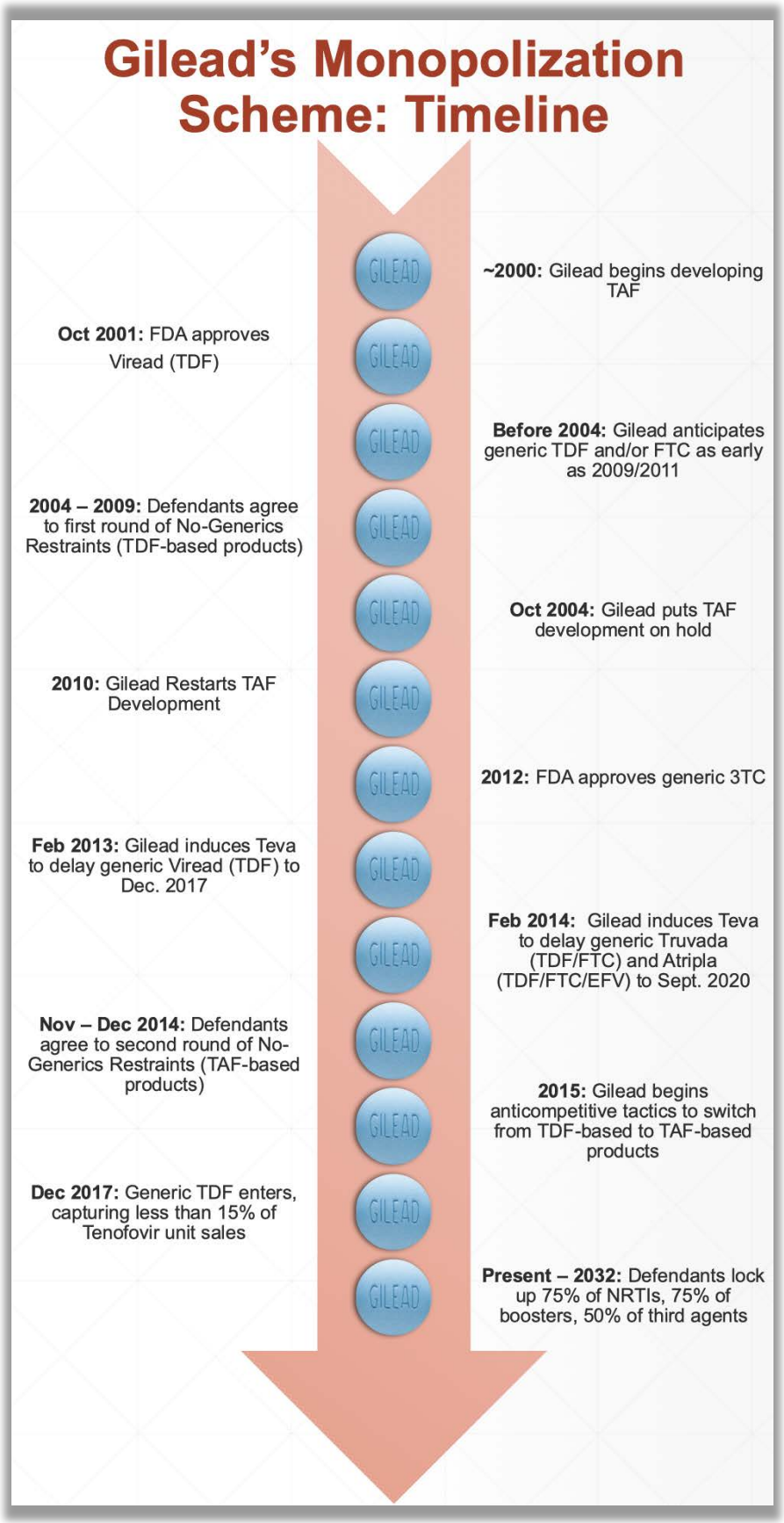
Degrading TAF was a significant departure from Gilead's longstanding practice. Immediately upon marketing TDF in 2001, Gilead made it available as a standalone product and obtained FDA approval for its use in treatment of HIV. *Id.* ¶¶ 279–84. Gilead continued this pattern when it began marketing Tenofovir-based FDCs, *always* from 2004 through 2014 making standalone Tenofovir (TDF) in the same strength and with the same indications as Gilead's Tenofovir-based FDCs. *Id.* ¶ 280. Consequently, (1) doctors co-prescribed and co-administered standalone Tenofovir as a "backbone" drug for use with third agents, and (2) when developing and designing their third agents, Gilead's competitors relied on reasonable access to the best available form of Tenofovir as a backbone drug. *Id.* ¶¶ 281, 283–

[3] Gilead's decision to forgo the HIV indication for standalone TAF also forced would-be competitors to re-perform time-consuming and expensive clinical trials that Gilead had already performed. Compl. ¶¶ 288–312.

84. Gilead thus profited from Tenofovir's use both by selling it as an ingredient in its FDCs and permitting competitors to market their third agents to be co-administered with the same form, strength, and indications of Tenofovir that Gilead used in its FDCs. Competitors had sunk substantial resources into promoting their third agents to be co-administered with Tenofovir, and, given the high barriers to entry, they could not feasibly start over from scratch and develop their own substitutes for Tenofovir in time to blunt the anticompetitive effects of Gilead's conduct. *Id.* ¶ 283. Gilead thus impaired competition from equally efficient rivals who make only some of the components in Gilead's TAF-based FDCs. *Id.* ¶ 286. Gilead has never offered a public justification for its conduct in degrading standalone TAF, and it has no legitimate justification. *Id.* ¶ 282.

Despite the availability of generic TDF, generic 3TC, and generic RTV, Gilead has maintained its monopoly in the cART market. Gilead inked deals with Janssen, BMS, and Japan Tobacco that provided vehicles for Gilead to shield its Tenofovir and FTC from generic competition. The first round of No-Generics Restraints provided the original competition-free instruments. Then Gilead reformulated Tenofovir into TAF and bought from Teva the delay that it needed to switch sales from TDF-based to TAF-based products. Then, after securing a second round of No-Generics Restraints with broader scope and longer terms, Gilead used anticompetitive tactics to make the switch to TAF-based products. With open competition, generic TDF would have taken 80% of unit sales of Tenofovir, and competitors would have formulated a plethora of FDCs using generic TDF and generic 3TC as the backbone drugs, swiftly ending Gilead's cART monopoly. *Id.* ¶¶ 196–98. But Gilead's anticompetitive scheme resulted in generic TDF getting only 15% of Tenofovir unit sales and Gilead's cART market share remaining above 80%. *Id.* ¶¶ 391–93.

A timeline of Gilead's anticompetitive scheme follows on the next page:


Gilead's Monopolization Scheme: Timeline
~2000: Gilead begins developing TAF
Oct 2001: FDA approves Viread (TDF)
Before 2004: Gilead anticipates generic TDF and/or FTC as early as 2009/2011
2004 – 2009: Defendants agree to first round of No-Generics Restraints (TDF-based products)
Oct 2004: Gilead puts TAF development on hold
2010: Gilead Restarts TAF Development
2012: FDA approves generic 3TC
Feb 2013: Gilead induces Teva to delay generic Viread (TDF) to Dec. 2017
Feb 2014: Gilead induces Teva to delay generic Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV) to Sept. 2020
Nov – Dec 2014: Defendants agree to second round of No-Generics Restraints (TAF-based products)
2015: Gilead begins anticompetitive tactics to switch from TDF-based to TAF-based products
Dec 2017: Generic TDF enters, capturing less than 15% of Tenofovir unit sales
Present – 2032: Defendants lock up 75% of NRTIs, 75% of boosters, 50% of third agents

B. Anticompetitive Effects

The Complaint alleges in detail the scheme's substantial anticompetitive effects.

First, several components of the relevant FDCs, or substitutes for those components, have already *in fact* become available as generics: generic TDF in December 2017; generic 3TC, a substitute for Gilead's FTC, in 2012; generic RTV, a substitute for Gilead's COBI, in March 2018; and a generic version of BMS's ATV in December 2017. *Id.* ¶¶ 61–62, 137. Absent the No-Generics Restraints:

- Japan Tobacco or its licensee would be selling a comparable version of Stribild (TDF/FTC/COBI/EVG) comprising its EVG together with genericTDF/generic3TC/genericRTV, and a comparable version of the EVG/COBI components of both Stribild and Genvoya, comprising EVG/genericRTV. *Id.* ¶¶ 112–13.
- Janssen or its licensee would be selling a comparable version of Complera (TDF/FTC/RPV), comprising Janssen's RPV together with genericTDF/genericRTV, and a comparable version of components of Symtuza (the DRV/COBI components), comprising Janssen's DRV and genericRTV. *Id.* ¶¶ 157, 172.
- Gilead or its licensee would be selling an AB-rated version of Evotaz, comprising Gilead's COBI and a generic version of BMS's ATV. *Id.* ¶¶ 137–38.

Untainted competitors in the conspirators' position—either themselves or in collaboration with generic-drug manufacturers—would have developed and marketed these competing products because it would have been in their economic interest to do so. Producing these competing FDCs would have dramatically lowered the conspirators' costs and thereby allowed them to sell more of the FDCs at an equal or higher profit margin. *Id.* ¶ 186. For example, Gilead–Janssen's Complera (TDF/FTC/RPV) sells for $35,000 for a yearly course of treatment; a comparable version made with generic TDF and generic 3TC would sell for half that amount. *Id.* ¶ 188. FDCs originally created with one or more generic components are sold at about a 50% discount to those containing only on-patent components. *Id.* ¶ 187. And immediately upon the availability of generic TDF, BMS (whose No-Generic Restraint applied only to the same components, not comparable components) partnered with generic manufacturer Mylan to market a comparable version of Atripla, comprising BMS's ATV together with generic TDF and generic 3TC. That FDC sells at a 40% discount to Gilead's Atripla. *Id.* ¶ 140.

Moreover, by prohibiting the coconspirator from making a competing version of the FDC, the No-Generics Restraints incentivized the collaborator to move the sales of its standalone component into the FDC, thus shielding it from competition from generic versions of the standalone product. Having such a generic-free haven for their components, Gilead cannibalized its sales of TDF/FTC into the restraints-protected FDCs, and BMS did likewise with respect to its standalone product Reyataz (ATV). *Id.* ¶¶ 109, 128, 136, 151, 180, 281. That conduct robbed consumers of the 80% price discounts—driven by automatic generic substitution at the pharmacy counter—that they would have received on a much larger base of prescriptions for those standalone products. *Id.* ¶ 189. And the No-Generics Restraints ensured that purchasers would not get those price discounts indirectly through lower pricing of generic-drug-based versions of the FDCs. *Id.*

Second, this competition—and more—should not only have occurred, it should have occurred much sooner than December 2017. Generic TDF would have been available much earlier than December 2017, and generic FTC would already be available, absent Gilead's anticompetitive agreements with Teva. *Id.* ¶¶ 351, 360. Likewise, those generics would have been available long before December 2017 absent the No-Generics Restraints. Gilead's coconspirators, either directly themselves or in partnership with generic manufacturers, would have had competitive incentives to challenge Gilead's patents. *Id.* ¶¶ 114–15, 130, 158–59. Unlike generic manufacturers, those coconspirators had royalty-free access to the third agents, were not subject to New Chemical Entity exclusivities, and/or owned the patents on the FDCs. *Id.* The No-Generics Restraints thus sidelined the competitors best positioned to challenge the patents and prompt the earlier entry of generic TDF, FTC, and ATV. Absent Gilead's anticompetitive agreements with Teva, or its No-Generics Restraints with Janssen, BMS, and Japan Tobacco, competing versions (AB-rated or comparable) of Atripla would have been available as early as 2011, Complera as early as February 2014, and Stribild as early as February 2015. *Id.*

Third, Defendants' conduct has thwarted innovation in this vitally important drug class. With the anticompetitive scheme having relieved the competitive pressure on Gilead, it shelved its development of lower-side-effects TAF in 2004, directly linking its decision to the No-Generics Restraints. *Id.* ¶¶ 202–29. This allowed Gilead to hold TAF in reserve to use later, once generic TDF became imminent. *Id.* ¶ 203. The hiatus from competition also enabled Gilead to forgo making its FDCs with other, superior

third agents. *Id.* ¶¶ 230–37. From 2004 through 2017 Gilead generated more than $59 billion in revenue from its HIV franchise in the United States, despite having developed only one new pharmaceutical compound—COBI. *Id.* ¶ 200. And Defendants' monopolizing the cART market has prevented other manufacturers from developing at least 28 potential FDCs, halving the number available to HIV patients. *Id.* ¶¶ 196–97.

C. Market Power

Gilead had the market power to deprive consumers of competitive prices and innovation. Most directly, the Complaint alleges that Gilead has *in fact* deprived consumers of these benefits. Other direct indicia of market power include Gilead's gross profit margin on its cART drugs, which has always exceeded 75% and reached as high as 91%. *Id.* ¶ 374. These margins are 15 times those that indicate substantial market power. *Id.* The gross margin on each of the Defendants' relevant drugs was at all times at least 70%. *Id.* ¶ 373. Nor did Defendants ever reduce the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs. *Id.*

If Plaintiffs were required to show market power through circumstantial rather than direct evidence, the Complaint easily does so. The definition of the relevant product market depends on the exclusionary conduct that the court is examining. *Id.* ¶ 375. Much of Defendants' anticompetitive conduct delayed and impaired competition to individual drugs (i.e., Defendants' standalone drugs and the FDCs) from AB-rated or comparable versions of them. Therefore, one set of relevant product markets is the market for each of those drugs and generic or comparable versions of it. At all relevant times, the manufacturer had greater than an 85% share of the relevant market for each of its drugs. *Id.* ¶ 378.

Another purpose of Defendants' exclusionary conduct was to ensure that Gilead maintained and extended its monopoly in the cART market. Scientists, doctors, and governmental agencies recognize the existence of a cART market, a set of HIV medicines generally comprising two NRTIs as a "backbone," plus a third agent and, where necessary, a booster. *Id.* ¶¶ 56, 64, 381–82. At all relevant times, Gilead's unit share of the cART market has ranged from not less than 70% to as much as 93%. *Id.* ¶ 392.

D. Ongoing and Future Harm

Unless enjoined by this Court, Defendants' unlawful conduct will have additional and intensified

anticompetitive effects once generic versions of any of FTC, TAF, COBI, or DRV become available. Absent the No-Generics Restraints, Gilead's coconspirators would accelerate the future marketing of AB-rated or comparable versions of Stribild, Complera, Genvoya, Odefsey, and Symtuza. *Id.* ¶¶ 429–32. The Court's intervention is also needed to ameliorate the anticompetitive effects of Gilead's unlawful degrading of Stribild and its degrading of and regulatory gaming with respect to TAF. *Id.* ¶ 433. For example, unless enjoined by this Court, Gilead's regulatory gaming will significantly delay and impair the competition from generic standalone TAF and generic-TAF-based FDCs that should flourish in or about May 2023. *Id.*

Other future harms include the delayed entry of generic Atripla and generic Truvada, each of which will cost consumers more than an *additional* $1 billion, and the latter of which will prevent tens of thousands of patients from gaining access to an affordable drug indicated for pre-exposure prophylaxis ("PrEP"), i.e., for *preventing* HIV infection. *Id.* ¶¶ 434–35. Finally, Plaintiffs seek equitable relief to cure Gilead's delay in developing TAF, including an order enjoining Gilead from enforcing any of its TAF-related NCE exclusivities and 30-month stays. *Id.* ¶¶ 437–38.

III. LEGAL STANDARD

To withstand a Rule 12(b)(6) motion to dismiss, a plaintiff "need only allege 'enough facts to state a claim to relief that is plausible on its face."' *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 n.12 (2011) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In making this determination, the Court must "take all allegations of material fact as true and construe them in the light most favorable to the nonmoving party." *In re NFL's Sunday Ticket Antitrust Litig.*, 933 F.3d 1136, 1149 (9th Cir. 2019). A claim is sufficiently pleaded when the facts alleged allow the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the factual allegations "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), "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (citations omitted).

IV. ARGUMENT

A. The Complaint Sufficiently Alleges that the No-Generics Restraints Are *Per Se* Illegal or, at a Minimum, Unreasonable Restraints of Trade Under the Rule of Reason

Gilead and Janssen ask the Court to engage in extensive fact finding outside the record and conclude—as a matter of law—that the No-Generics Restraints are lawful "ancillary restraints" to legitimate joint ventures. Gilead Mem. at 18–22; Janssen Mem. at 9–10. This turns both the *Twombly*/*Iqbal* pleading standard and foundational antitrust jurisprudence on its head. Defendants are horizontal competitors who expressly agreed not to compete with each other. That is illegal *per se*. The existence of patents cannot justify those agreements, because the agreements extend for years after those patents expire. And calling the No-Generics Restraints a "joint venture" can't help Defendants either, for multiple reasons. On this record there is no bona fide joint venture. Even if there were, it would not require or justify agreements like those at issue here. And even if those agreements were properly ancillary to a legitimate joint venture, that would at most justify applying the rule of reason rather than *per se* illegality. That would not warrant dismissal.

1. The No-Generics Restraints Are *Per Se* Unlawful Patent-Extension Agreements.

The No-Generics Restraints serve "no purpose except stifling of competition." *White Motor Co. v. United States*, 372 U.S. 253, 263 (1963). The Complaint alleges, in exhaustive detail, how Gilead forged these express non-competition pacts with each of Janssen, BMS, and Japan Tobacco in order to insulate its drugs from generic competition *even after its patents have expired.* Compl. ¶¶ 94–175. Gilead notes that the offending provisions are not labelled "No-Generics Restraints" and suggests they "simply restrict" each partner "from competing against the ventures' FDCs with substantially similar FDCs, without regard to the existence or non-existence of patent protection or regulatory exclusivity." Gilead Mem. at 3. But that is precisely the point. Gilead does not, and cannot, deny that these provisions restrain the parties from competing with the same or similar versions of the FDCs using generic components even *after* loss of patent exclusivity. Nor does Gilead even disclaim that the purpose of the restraints is to inhibit generic competition post-patent expiration. The restraints are agreements among horizontal competitors not to compete. Agreements among horizontal competitors not to compete with

each other are by their nature anticompetitive. They are illegal *per se* because they have a "pernicious effect on competition and lack of any redeeming virtue." *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 406–07 (1945); *Northrop Corp. v. McDonnell Douglas Corp.*, 705 F.2d 1030, 1050 (9th Cir. 1983).

The No-Generics Restraints violate a foundational rule, recently reaffirmed by the Supreme Court, that agreements effectively extending a patent's term are *per se* illegal. *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964) (ruling that "a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*"); *Kimble v. Marvel Entm't, LLC*, 576 U.S. ___, 135 S. Ct. 2401, 2405 (2015) (reaffirming *Brulotte*). In *Kimble*, the Court refused to abandon *Brulotte*'s *per se* rule in favor of a case-by-case analysis under the rule of reason, reaffirming the "sharp line cutting off patent rights after a set number of years." *Id.* at 2411. The Court emphasized that a patent's term is "an all-encompassing bright-line rule," which does not call "for practice-specific analysis." *Id.* at 2413. Rather, there is a longstanding "categorical principle that all patents, and all benefits from them, must end when their terms expire." *Id*. Notably, in *Brulotte* and *Kimble*, the Court condemned patent term extensions as *per se* illegal even in the context of *vertical* agreements, which are given much more lenient antitrust treatment. Defendants' *horizontal* patent-term extension agreements warrant even stricter scrutiny and should be condemned as a *per se* unlawful extension of their patent monopolies.[4] *See Scott Paper Co. v. Marcaulus Mfg. Co.*, 326 U.S. 249, 256 (1945) ("[A]ny attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, *whatever the legal device employed*, runs counter to the policy and purpose of the patent laws.") (emphasis added).

Courts have also condemned as illegal *per se* efforts by pharmaceutical companies to restrain

[4] *Brulotte* and *Kimble* involved claims of patent misuse, a doctrine that "is closely intertwined with antitrust law." *Linzer Prod. Corp. v. Sekar*, 499 F. Supp. 2d 540, 552 (S.D.N.Y. 2007) (citing 1 H. Hovenkamp, M. Janis, M. Lemley, & C. Leslie, IP and Antitrust, § 3.01, p. 3-3 (3d ed., Supp. 2018)). Patent misuse prohibits undermining competition by "impermissibly broad[ing] the physical or temporal scope of the patent grant with anticompetitive effect." *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997) (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986)). Judge Posner has recognized "there is increasing convergence of patent-misuse analysis with standard antitrust analysis." *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 511 (7th Cir. 1982). Thus, patent misuse "is largely coextensive with antitrust doctrine," 1 IP and Antitrust § 3.02[D], p. 3-13, and should at the very least inform the Court's determination of which mode of analysis under the Sherman Act applies to the restraints at issue here. But even if patent misuse and antitrust were unrelated doctrines, *Brulotte* and *Kimble* at a minimum make clear that patent law cannot justify or excuse the No-Generics Restraints, which are otherwise facially anticompetitive.

generic competition outside the patent scope in the context of patent litigation settlements. For example, in *In re Cardizem*, the settlement included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market "other bioequivalent or generic versions of [the drug] that were not at issue in the pending litigation." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 909 n.13 (6th Cir. 2003). This restraint extended beyond the legitimate scope of the patent by reaching non-infringing products and was therefore a *per se* illegal effort to preclude the generic competitor from entering the market with a product that does not infringe any patent owned by drug maker. *See In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 397 (2d Cir. 2005) (recognizing that a settlement agreement "extend[ing] the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products" is *per se* unlawful), *opinion amended and superseded*, 466 F.3d 187 (2d Cir. 2006); *see also Andrx Pharms v. Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005) (agreement "to refrain from ever marketing a generic [version of the drug]" is outside "the scope of the exclusionary potential of the patent"); *see also* Mark D. Janis, Herbert J. Hovenkamp & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1765 (2003) (a restraint that "require[s] one firm to obtain a competitor's permission to enter when no patent was at issue [is] a *per se* unlawful market division").[5] The No-Generics Restraints at issue here extend beyond the temporal scope of the patent. Because these restraints have a clearly "pernicious effect on competition and lack of any redeeming virtue," they are illegal *per se*. *N. Pac. Ry.*, 356 U.S. at 5.

2. Defendants Cannot Justify Their Naked Agreements Not to Compete by Calling Them Joint Ventures.

In an attempt to evade scrutiny of these plainly anticompetitive restraints, Gilead and Janssen claim that each of their agreements "constitutes a joint venture for antitrust purposes." Janssen Mem. at 8; Gilead Mem. at 19–21. That argument is based on a fundamental misunderstanding of the law, the facts alleged, and the procedural posture of the case.

a. Defendants Misstate the Legal Standard Governing Joint Ventures.

[5] The Supreme Court subsequently applied the rule of reason to a reverse-payment settlement *within the scope of the patent* in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), but that decision does not necessarily mandate rule-of-reason treatment in all cases that involve a reverse payment. Where, as in *In re Cardizem* and here, the reverse payment is accompanied by a restraint on the generic manufacturer's ability to compete *outside* the scope of the patent, this type of naked market division remains *per se* illegal.

Relying on *Texaco Inc. v. Dagher*, 547 U.S. 1 (2006), Gilead glibly asserts the "law is settled" that the No-Generics Restraints "are analyzed under the rule of reason and that, if reasonably ancillary to the procompetitive purposes of the venture, are 'valid' as a matter of law." Gilead Mem. at 3. This is a misstatement of the law.

"Section 1 of the Sherman Act proscribes contracts, combinations or conspiracies that unreasonably restrain trade." *Gorlick Distrib. Ctr., LLC v. Car Sound Exhaust Sys., Inc.*, 723 F.3d 1019, 1024 (9th Cir. 2013). Plaintiffs may prosecute § 1 claims under two theories of liability. First, plaintiffs can allege that a restraint is illegal *per se* because it is "so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality." *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 692 (1978). If the *per se* rule does not apply, a restraint is analyzed under the rule of reason. Under that standard, the factfinder conducts "a fact-specific assessment of market power and market structure to assess the restraint's actual effect on competition." *Ohio v. Am. Express Co.*, __ U.S. ___, 138 S. Ct. 2274, 2284 (2018) (cleaned up) (summarizing three-step burden-shifting framework). No bright line separates restraints that are subject to *per se* condemnation versus rule-of-reason analysis. *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla.* ("*NCAA*"), 468 U.S. 85, 104 n.26 (1984). Even if the *per se* rule does not clearly apply, courts need not default to the full rule of reason. An "abbreviated or 'quick-look' analysis" is appropriate when an "observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets" despite claims of efficiency. *Cal. Dental Ass'n v. Fed. Trade Comm'n*, 526 U.S. 756, 770 (1999).

Whether a restraint is subject to *per se* condemnation or analyzed under the rule of reason is a function of two other relevant categorizations. First, antitrust draws a fundamental distinction between horizontal and vertical agreements. Horizontal agreements, such as those at issue here, are contracts or conspiracies between actual or potential competitors at the same level in the distribution chain. Vertical restraints, on the other hand, are "those imposed by agreement between firms at different levels of distribution." *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 730 (1988). Horizontal agreements "are antitrust's most 'suspect' classification" and "as a class deserve stricter scrutiny than" vertical agreements because "they pose the most significant dangers of competitive harm." 11 Phillip E. Areeda

& Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 1902a, at 190–91 (4th ed., 2018 Cum. Supp. 2010–2017).

Second, courts distinguish between "naked" and "ancillary" restraints. "Naked" restraints have "no purpose except stifling of competition" and are thus *per se* illegal. *White Motor*, 372 U.S. at 263. Under the ancillary restraint doctrine, "some agreements [that] restrain competition may be valid" under the rule of reason "if they are 'subordinate and collateral to another legitimate transaction and necessary to make that transaction effective.'" *Los Angeles Mem'l Coliseum Comm'n v. Nat'l Football League*, 726 F.2d 1381, 1395 (9th Cir. 1984) (quoting Robert H. Bork, *The Rule of Reason and the Per Se Concept: Price Fixing And Market Division*, 74 Yale L.J. 775, 797–98 (1965)); *see also Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 339 (2d Cir. 2008) (Sotomayor, J., concurring) (explaining that a restraint is ancillary when it has "a reasonable procompetitive justification, related to the efficiency enhancing purposes of the joint venture" and is "reasonably necessary to achieve a joint venture's efficiency-enhancing purposes"); Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for Collaborations Among Competitors* § 3.2 at 4 (April 2000) ("*Collaboration Guidelines*") (a restraint is ancillary when it is "reasonably related to, and reasonably necessary to achieve procompetitive benefits from, an efficiency-enhancing integration of economic activity").

In *Dagher*, the Supreme Court held that it was not *per se* illegal for "a lawful, economically integrated joint venture to set the prices at which the joint venture sells its products." 547 U.S. at 3. Following *Dagher*, antitrust analysis of joint venture involves a multi-step inquiry. A threshold question is whether the joint venture is in fact a legitimate, fully integrated enterprise "regarded as a single firm competing with other sellers in the market." *Id* at 6. If not—if the collaboration is not a legitimate joint venture that is integrating economic activity in ways that could not otherwise be achieved without a single entity—the horizontal agreement cannot obtain protection as a joint venture. Even assuming there is a bona fide joint venture effectively acting as a single firm, antitrust law constrains the decisions a joint venture can make. The Court in *Dagher* distinguished between three types of restraints: (1) restraints that relate to the joint venture's core activities, (2) restraints that are ancillary to the joint venture's efficiency enhancing purpose, and (3) naked restraints on competition. "Accordingly, under *Dagher*, a joint venture's core activities are subject to a rule of reason analysis. Non-core activities that are naked

restraints on trade are *per se* unreasonable. However, if the challenged restraint is 'ancillary to the legitimate and competitive purposes of the joint venture,' it may be deemed valid by the factfinder under the rule of reason." *Med. Ctr. at Elizabeth Place, LLC v. Premier Health Partners*, No. 3:12-CV-26, 2017 WL 3433131, at *4 (S.D. Ohio Aug. 9, 2017).

b. Gilead Mischaracterizes *Dagher* and the Function of the Ancillary Restraints Doctrine.

Gilead misconstrues *Dagher* for the proposition that ancillary restraints are "valid" as a matter of law. Gilead Mem. at 19. This reading is inconsistent with black letter law. "To say that a restraint is ancillary is not to say that it is legal." 2 IP and Antitrust § 30.03[B], p. 30-11. Rather, as the Supreme Court and the Ninth Circuit have long recognized, "[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.'" *Aydin Corp. v. Loral Corp.*, 718 F.2d 897, 901 (9th Cir. 1983) (quoting Robert H. Bork, *Ancillary Restraints and the Sherman Act*, 15 A.B.A. Antitrust Sec. Proc. 211 (1959)). "The ancillary restraint must then be tested under the rule of reason." *Los Angeles Mem'l Coliseum Comm'n*, 726 F.2d at 1395; *see also Prof'l Eng'rs*, 435 U.S. at 689 (the rule of reason is the "standard for testing" the legality of restrains that are "ancillary to a legitimate transaction.").[6] The Department of Justice and the FTC have incorporated this well-established rule into the Competitor Collaboration Guidelines, which provide that ancillary restraints, i.e., agreements that "otherwise might be considered per se illegal" are "analyzed under the rule of reason to determine their overall competitive effect." *See Collaboration Guidelines* § 1.2 at 4.

Gilead relies on dicta in *Dagher* stating that, under the doctrine of ancillary restraints, courts must

[6] Other federal courts of appeal have uniformly employed the ancillary restraints doctrine to distinguish between restraints subject to *per se* condemnation and those that must be evaluated under the rule of reason. *See, e.g.*, *Addamax Corp. v. Open Software Found., Inc.*, 152 F.3d 48, 51–52 (1st Cir. 1998) (applying the rule of reason to a restraint found to be ancillary); *SCFC ILC, Inc. v. VISA USA, Inc.*, 36 F.3d 958, 964 (10th Cir. 1994) (same); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.* 792 F.2d 210, 214 (D.C. Cir. 1986) (same); *Nat'l Bancard Corp. v. VISA USA, Inc.*, 779 F.2d 592, 603 (11th Cir. 1986) (same); *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189–92 (7th Cir. 1985) (same). As the leading antitrust treatise explains, "[d]etermining whether a restraint is ancillary is simply a way of deciding whether it can be condemned as illegal 'per se,' or upon a relatively quick look; or whether a more complete analysis of the market and likely competitive effects is essential." 11 Areeda & Hovenkamp ¶ 1908a, at 299. It is therefore well settled that if the court determines "the provision is ancillary, then the rule of reason applies." *Gerlinger v. Amazon.Com, Inc.*, 311 F. Supp. 2d 838, 849 (N.D. Cal. 2004). None have held, as Defendants claim here, that ancillary restraints are legal *per se*.

determine whether the "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 8. This statement should not be construed as overturning decades of antitrust law *sub silentio* and establishing a new rule of *per se* legality. Rather, the statement should be viewed in context. *See* 11 Areeda & Hovenkamp ¶ 1906, at 281 ("*Dagher* must be read against its facts."). Plaintiffs in *Dagher* had abandoned any claim under the rule of reason; their *per se* price fixing claim was the only claim left in the case. The Supreme Court found no *per se* violation for case-specific reasons: plaintiffs had challenged a core activity of a legitimate joint venture. Because plaintiffs did not bring a rule of reason claim *in that particular case*, finding that the restraint is ancillary would end the inquiry. Accordingly, the only interpretation of *Dagher* consistent with well-established antitrust principles and controlling precedent is that naked restraints are *per se* unlawful, whereas an ancillary restraint *may* be "valid" under the rule of reason.

Gilead has not cited any case to support its radical reinterpretation of the ancillary restraints doctrine. Indeed, the foundational cases that Gilead relies upon support Plaintiffs' reading. *See Broadcast Music, Inc. v. Columbia Broad. Sys., Inc.* ("*BMI*"), 441 U.S. 1 (1979) (rejecting *per se* condemnation on the specific facts before it but remanding for application of the rule of reason); *Rothery Storage*, 792 F.2d at 224 ("To be ancillary, and hence exempt from the per se rule, an agreement must be subordinate and collateral to a separate, legitimate transaction."); *Polk Bros.*, 776 F.2d at 189–90 ("The reason for distinguishing between 'ancillary' and 'naked' restraints is to determine whether the agreement is part of a cooperative venture with prospects for increasing output. If it is, it should not be condemned *per se*."). As then-Judge Sotomayor clarified in a post-*Dagher* opinion, the ancillary restraints doctrine "effectively isolates" the circumstances when exclusionary conduct "should be reviewed under the rule of reason, as a reasonably necessary part of a joint venture, and when it should be reviewed as a naked restraint." *See Salvino*, 542 F.3d at 341.[7]

c. The Complaint Does Not Support the Conclusion that the No-Generics

[7]Gilead's reliance on an outlier law review article is unpersuasive. The article recognizes that federal courts use the "ancillary restraints doctrine merely to distinguish between per se and rule-of-reason conduct" whereas the author proposes to "go beyond" that approach and make ancillarity "completely determinative of . . . legality." Thomas A. Piraino Jr., *The Antitrust Analysis of Joint Ventures after the Supreme Court's* Dagher *Decision*, 57 Emory L.J. 735, 794 (2007-2008). That is not the law.

Restraints Are Merely Ancillary to a Bona Fide Joint Venture.

Just calling something a joint venture does not make it one. The Supreme Court looks beyond labels to recognize underlying collusion among competitors. *See Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 197 (2010) (defendants cannot "evade § 1 scrutiny simply by giving the ongoing violation a name and a label") (citing *Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 598 (1951) (otherwise "every agreement and combination to restrain trade could be so labeled")). Although Plaintiffs do not contend that creating or marketing FDCs is itself anticompetitive, Compl. ¶ 93, this allegation is *not* an admission or concession that Gilead's collaborations were, in fact, legitimate joint ventures. On this record, there is no evidence to suggest that the agreements to extend Gilead's patent terms are in fact legitimate, fully integrated enterprises "regarded as a single firm competing with other sellers in the market." *Dagher*, 547 U.S. at 6. Indeed, there is no evidence that any agreements other than Gilead's deal with BMS regarding Atripla had any of the classic indicia of a joint venture, such as separate corporate status, a separate office, technical collaboration, or separate employees. Rather, what Gilead calls "joint ventures" are little more than agreements not to use generics and to share profits.

Even if the Defendants had all created legitimate joint ventures—a characterization issue the Court cannot resolve on a motion to dismiss—that would not give Defendants blanket immunity. "Obviously, the most significant competitive threats arise when joint venture participants are actual or potential competitors." *Am. Needle*, 560 U.S. at 197 (quoting Areeda & Hovenkamp, ¶ 1478a, at 318). Unlike *Dagher*, here the Plaintiffs' § 1 claims are not directed to a "core activity" of any joint venture. Rather, Plaintiffs challenge specific horizontal restraints contained within the agreements that extend Gilead's patents beyond their expiration. Janssen's own authority recognizes that "[w]hen a plaintiff challenges a provision or practice of the venture as anticompetitive, then *per se* review may be appropriate depending on the circumstances." *In re ATM Fee Antitrust Litig.*, 554 F. Supp. 2d 1003, 1012 (N.D. Cal. 2008) (citing *NCAA*, 468 U.S. at 113–115, as recognizing that a restraint may be "naked" even though it is contained in a joint venture agreement that is, overall, quite competitive). It is appropriate to "disaggregate particular conduct from the venture as a whole, and submit that conduct to individual scrutiny." *Id.* Here, even if there were a legitimate joint venture, agreeing to ban generics even after a patent expires should not be viewed as legitimate and necessary to furthering the purpose of any valid

joint venture.

Defendants also cannot prevail by invoking the ancillary restraints doctrine on a motion to dismiss. At this early stage of the proceedings, "the court cannot hold that the agreement is ancillary simply because [defendant] posits that it is. The court must instead make that determination based on factual evidence relating to the agreement's formation and character." *United States v. eBay, Inc.*, 968 F. Supp. 2d 1030, 1039 (N.D. Cal. 2013). Although whether to apply a *per se*, quick look, or rule-of-reason analysis is a question of law, "underpinning that purely legal decision are numerous factual questions." *In re Wholesale Grocery Prod. Antitrust Litig.*, 752 F.3d 728, 733–34 (8th Cir. 2014). And whether a restraint is "naked" or "ancillary" is "quintessentially one of fact." *Brennan v. Concord EFS, Inc.*, 369 F. Supp. 2d 1127, 1133 (N.D. Cal. 2005). "[T]he court simply cannot determine with certainty the nature of the restraint, and by extension, the level of analysis to apply" in ruling on a motion to dismiss. *eBay*, 968 F. Supp. 2d at 1040.[8]

In any event, Defendants cannot offer any plausible reason to think the No-Generics Restraints are reasonable and necessary to a legitimate business purpose, much less that they must be so as a matter of law. Gilead and Janssen's sole "procompetitive" justification is that the restraints are necessary to prevent "free riding." Gilead Mem. at 21; Janssen Mem. at 9. Noting the high cost of submitting an New Drug Application, Gilead suggests that prohibiting the use of generic drug components to make competing FDCs prevents the parties from "cynically 'free riding' on the venture's regulatory and promotional activity." Gilead Mem. at 21. However, generic competition following the expiration of a

[8] Courts routinely hold that choosing the mode of analysis requires fact discovery and is not properly decided on a motion to dismiss. *See, e.g.*, *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 754 (N.D. Ill. 2019) (declining to determine whether *per se* or rule of reason applied at the motion to dismiss stage, finding it "sufficient for plaintiffs to plausibly allege that defendants engaged in conduct that resulted in an unreasonable restraint of trade."); *In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1297 n.8 (D. Kan. 2018) (on a motion to dismiss, "the court need not decide what rule to apply to analyze the reasonableness of the alleged restraints of trade supporting the class plaintiffs' conspiracy claims . . . the court just needs to determine whether the class plaintiffs have alleged a plausible conspiracy under the antitrust laws."); *In re Blue Cross Blue Shield Antitrust Litig.*, 26 F. Supp. 3d 1172, 1186 (N.D. Ala. 2014) ("[W]hether a per se, quick look, or rule of reason analysis applies is a question of law; however, that question is predicated on a factual inquiry into the restraint's competitive effect" and "neither the parties nor the court has had the opportunity to develop the factual record necessary to make that determination."); *In re High-Tech Employee Antitrust Litig.*, 856 F. Supp. 2d 1103, 1122 (N.D. Cal. 2012) ("[T]he Court need not decide now whether per se or rule of reason analysis applies. Indeed, that decision is more appropriate on a motion for summary judgment.").

patent is not actually "free riding." It is competition, and it is expressly permitted—indeed, encouraged—under the legal regime pursuant to which patent holders are granted monopolies only for a limited time. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) ("An exclusive enjoyment is guaranteed him for seventeen years, but, upon expiration of that period, the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and profit by its use.") (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186–87 (1933)).

As the Second Circuit has explained, "what Defendants call 'free riding'—generic substitution by pharmacists following the end of [a drug]'s exclusivity period—is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch–Waxman Act by promoting drug competition . . . and by preventing the practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 657–58 (2d Cir. 2015) (internal quotation marks and citations omitted); *see also FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (recognizing that the Hatch Waxman Act encourages generic manufacturers to "piggy-back" on brand's approval efforts, thus speeding "'the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition"). Defendants' purported justification is thus "premised on the notion that competition itself is unreasonable," which the Supreme Court has repeatedly found "insufficient as a matter of law." *Collaboration Guidelines* § 3.2 at 9 (citing *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 463–64 (1986); *NCAA*, 468 U.S. at 116–17; *Prof'l Eng'rs*, 435 U.S. at 693–96).

Gilead and Janssen's reliance on *Broadcast Music* and *NCAA* is similarly misplaced. The Supreme Court has characterized those decisions as limited to situations where the "restraints on competition are essential if the product is to be available at all." *Am. Needle*, 560 U.S. at 203 (quoting *NCAA*, 468 U.S. at 101, 104 and *BMI*, 441 U.S. at 23). Defendants have not demonstrated (nor could they demonstrate on a motion to dismiss) that the No-Generics Restraints or any other restraint on competition is essential to formulating and marketing a fixed-dose combination drug. And even if Defendants could conceivably make this showing at some later juncture, the Ninth Circuit has held that the restraint "must still be reasonably ancillary to the legitimate cooperative aspects of the venture."

Freeman v. San Diego Ass'n of Realtors, 322 F.3d 1133, 1151 (9th Cir. 2003). Defendants cannot demonstrate that the No-Generics Restraints are ancillary on a motion to dismiss, and their "free riding" argument confirms rather than refutes the restraints' anticompetitive purpose and effect.

Japan Tobacco similarly waves at, but fails to identify, any procompetitive benefits to the No-Generics Restraint that would justify a rule-of-reason analysis, instead making vague references to the "new and improved" HIV treatments Gilead brought to market. JT Mem. at 6–7. That does not suffice, particularly on a motion to dismiss. *See Northrop*, 705 F.2d at 1050–54; Compl. ¶¶ 444, 453 (alleging there is and was no cognizable, non-pretextual procompetitive justification that outweighs the agreement's harmful effects). Japan Tobacco needs to justify the restraint, not the license; and Japan Tobacco's argument contradicts Plaintiffs' detailed factual allegations about how the No-Generics Restraint suppressed the introduction of new, safer, and cheaper antiretroviral treatments and how any new products were more expensive and delayed in their release, allegations which must be taken as true for purposes of this motion. *See, e.g.*, *In re Suboxone* (*Buprenorphine Hydrochloride & Naloxone*) *Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, at *10 (E.D. Pa. Oct. 30, 2017) (dismissing defendants' argument that "the true purpose of the joint venture was pro-competitive innovation" and reiterating that at the pleading stage, plaintiffs need only "allege the anticompetitive nature of a defendant's conduct"). This record provides no basis for Japan Tobacco's assertion that the existence of those new and improved treatments requires the anticompetitive agreement to extend the life of Gilead's patents.

Finally, even if Defendants could ultimately prove that the restraints are ancillary at a future stage in the litigation based on *evidence* not argument, that would only relieve them of *per se* liability. Plaintiffs may proceed even against legitimately ancillary restraints under the rule of reason. So, even if Defendants were correct about every point they make, their ancillary restraints argument provides no justification for dismissing the complaint.

3. BMS Mischaracterizes Its Agreements with Gilead, Which Are Just as Anticompetitive as the Others.

BMS argues that the Complaint fails to state a claim for relief because the Atripla Agreement does not include a No-Generics Restraint and the Evotaz Agreement is just a "lawful" exclusive license

authorized by the Patent Act. BMS Mem. at 5–9. But BMS mischaracterizes the very agreements for which it asks the Court to take judicial notice. Plaintiffs sufficiently allege, and the text of the agreements confirm, that both agreements include de facto or express No-Generics Restraints and are thus *per se* illegal or, at a minimum, unlawful under the rule of reason. BMS also cannot evade antitrust scrutiny merely because the Evotaz Agreement includes an exclusive patent license.

a. The Complaint Accurately Alleges That the Atripla Agreement Has No-Generics Restraints.

Gilead and BMS styled their collaboration as a joint venture. Each party granted royalty-free sublicenses to the "joint venture" entity for the use of the companies' respective drug components. Compl. ¶ 120. BMS argues that §§ 6.1 and 6.2 of the Atripla Agreement reserved the conspirators' rights to make competing, generic-component-based versions of Atripla. BMS Mem. at 6. Plaintiffs' Complaint alleges otherwise. Compl. ¶¶ 123–25. The Agreement confirms the allegation's accuracy and entirely disposes of BMS's argument.

The restriction on the conspirators' right to make competing versions of Atripla is not in §§ 6.1 and 6.2, but in § 2.9(a) (among other provisions).[9] The conspirators "agree to abide by the . . . principle[]" (§ 2.9), that "the purposes of the JV are . . . to optimize the commercial potential of the Combination Product," and:

> For the avoidance of doubt, nothing in this Agreement or in the Operating Agreement shall be deemed to restrict or prohibit either Member Party or any of its Affiliates from (x) commercializing its Single Agent Product(s) and/or Double Agent Product as applicable, (y) . . . 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.

Atripla Agreement § 2.9(a) (emphasis added). The "Combination Product" that the conspirators are prohibited from making outside their collaboration is a product comprising the pharmaceutical

[9] The restriction is reflected throughout the Agreement. *See, e.g.*, Atripla Agreement §§ 6.3(a), 6.4(b), 6.4(c), 6.6(a), 6.6(b), 6.7(a).

ingredients (brand *or generic*) TDF/FTC/ATV. *Id*. §§ 1.94, 1.202, and first Recital on p. 1.[10] And rather than allowing each conspirator to compete with a generic-component-based version of Atripla, the Agreement requires each of them to help the other defend against a challenge to its patents. *Id*. § 11.3(a)–(b).

The Complaint accurately alleges that the only way for one of the conspirators to make a competing version of Atripla was to terminate the other's participation in the collaboration. Compl. ¶ 123. One conspirator could terminate the other's participation if generic versions of the other's components became available. Compl. ¶ 124; Atripla Agreement § 14.5. The Agreement further provided, however, that if one party elected to terminate the other's interest on that ground, the terminator would be required to pay a substantial penalty, comprising three years of additional royalty payments. Compl. ¶ 124; Atripla Agreement § 14.6(b). Moreover, the terminated party would no longer have access to the other's drug component. Compl. ¶ 126; Atripla Agreement §14.6(b)(i). The Agreement thus ensured that, until all relevant patents of *both* of the conspirators expired, consumers could never get a competing, AB-rated version of Atripla—despite the expiration of one of the conspirator's patents. Compl. ¶ 126.

In short, the Atripla Agreement had an express No-Generics Restraint during the life of the collaboration and a de facto restraint even after its termination. And even then it would have to pay a penalty to terminate the agreement. If the parties had, in fact, entered into an agreement that allowed BMS to create a competing version of Atripla with generic TDF and FTC, as BMS claims, there would be no reason to include those penalty provisions, which demonstrate that the Atripla Agreement was a de facto exclusive deal. The arrangement had the same pernicious effects on competition as Gilead's other horizontal agreements. *Cf. ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 282 (3d Cir. 2012) ("[T]he

[10] This is an antitrust case, not a contract dispute. The Complaint's allegations regarding the Agreement's restraints are compelled by its plain language, but the allegations would prevail even if the Agreement were ambiguous. *See, e.g.*, *Picone v. Shire PLC*, No. 16-cv-12396-ADB, 2017 WL 4873506, at *10–11 (D. Mass. Oct. 20, 2017) (denying motion to dismiss and rejecting defendants' argument that written contract "unambiguously contradict[ed]" restraint as alleged in complaint; written contract did not "on its own preclude the existence of" restraint as alleged); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 244 (D. Conn. 2015) (denying motion to dismiss and rejecting defendants' contention that "the challenged settlement agreement actually does [not] prevent Boehringer from introducing an authorized generic," observing that the court "need not determine now who is correct by ruling on the construction of the agreement.").

law is clear that an express exclusivity requirement is not necessary because de facto exclusive dealing may be unlawful."); *McWane, Inc. v. FTC*, 783 F.3d 814, 833–35 (11th Cir. 2015) (rejecting "formalistic distinctions" between express and de facto exclusive dealing arrangements).[11]

Plaintiffs thus sufficiently allege that the Atripla Agreement included a No-Generics Restraint that is *per se* illegal or alternatively an unreasonable restraint of trade under the rule of reason.

b. The Evotaz Agreement Contains Express No-Generics Clauses and Is Not Immune from Scrutiny Merely Because It Includes an Exclusive License.

BMS also cannot escape antitrust scrutiny by arguing that the Evotaz Agreement is merely a "lawful" exclusive license for COBI authorized by the Patent Act. *See* 35 U.S.C. § 261. As the leading antitrust treatise explains, "[a]ssuming the patent is valid, the Patent Act expressly permits exclusive licenses, but this fact alone does not render them immune from antitrust scrutiny." Areeda & Hovenkamp, ¶ 2046, at 330; *see also Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 47 (1990) (holding that an agreement not to compete based on an exclusive license was "unlawful on its face"); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015) ("[E]ven exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways.").[12] To the contrary, the Supreme Court has repeatedly "struck down overly restrictive patent licensing agreements" as violations of the antitrust laws. *Actavis*, 570 U.S. at 149; *see, e.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952) ("Patents give no protection from the prohibitions of the Sherman Act . . . when the licenses are used, as here, in the scheme to restrain."); *United States v. Line Material Co.*, 333 U.S. 287, 313–15 (1948) (condemning a patent licensing scheme as *per se* illegal notwithstanding the

[11] While the Ninth Circuit has not expressly adopted de facto exclusive dealing, *Aerotec Int'l, Inc. v. Honeywell Int'l, Inc.*, 836 F.3d 1171, 1182 (9th Cir. 2016), *Aerotec* cited these cases with approval and effectively recognized the doctrine. In any event, the legal wrong here is not traditional exclusive dealing, which is a one-way, vertical contract, but a much more pernicious bilateral agreement not to compete among horizontal competitors.

[12] The Justice Department and FTC's intellectual property licensing guidelines also confirm that exclusive patent licenses are not immune from antitrust scrutiny. *See* U.S. Dep't of Justice & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 4.1.2 at 20 (Jan. 12, 2017) ("*IP Guidelines*").

dissent's reliance on § 261 (then codified as § 47), 333 U.S. at 333–34 (Burton, J., dissenting).[13]

In any event, BMS mischaracterizes the agreement: It contains *express*, reciprocal no-generics clauses. Sections 14.2 and 14.3 provide that Gilead and BMS "shall not," without the express written consent of the other party, "make, use, sell, have sold, offer for sale, or import" a generic version of Evotaz—with a limited exception for licensing generic Evotaz in certain developing countries. Evotaz Agreement §§ 14.2, 14.3; *see also* definitions at §§ 1.1, 1.135, 1.2, 1.48, 1.84, 1.90, 6.6, and Ex. D (listing "Access Countries")). Accordingly, BMS's claim that the Evotaz Agreement is merely a one-way exclusive patent license is belied the text of the agreement itself.

Through the Evotaz Agreement, Gilead promised not to make a competing generic version of the FDC even after BMS's patents on ATV expired—a deal that was designed "to protect BMS's product, not Gilead's, from generic competition." Compl. ¶¶ 132–34; Evotaz Agreement §§ 9.3, 14.2, 16.1. Neither Section 261 nor any other provision of the Patent Act authorizes agreements extending beyond a patent's expiration. As previously explained, such agreements are *per se* unlawful because of the "categorical principle that all patents, and all benefits from them, must end when their terms expire." *Kimble*, 135 S. Ct. at 2413. Plaintiffs therefore sufficiently allege that the No-Generic Restraint in the Evotaz Agreement is *per se* illegal or, at a minimum, an unreasonable restraint of trade in violation of Sherman Act § 1.

4. The Complaint's Allegations of a Conspiracy Between Gilead and Japan Tobacco are Legally and Factually Sound.

Japan Tobacco goes even further than BMS—arguing that "by virtue" of its exclusive license with Gilead, the firms lacked conspiratorial capacity as a matter of law under *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984). JT Mem. at 9–11. This argument is baseless. *Copperweld* reflects the logical principle that a party cannot conspire with itself, and that "itself" includes agreements with its wholly-owned subsidiaries. But Gilead and Japan Tobacco are not the same

[13] The Supreme Court has evaluated numerous intellectual property licenses at a minimum under the rule of reason or higher levels of antitrust scrutiny. *See, e.g.*, *Am. Needle*, 560 U.S. 183 (evaluating exclusive trademark license under the rule of reason); *Palmer*, 498 U.S. at 47, 50 (condemning as *per se* illegal an exclusive license to copyrighted materials and trademarks); *BMI*, 441 U.S. at 7–19 (evaluating blanket copyright licenses under the rule of reason even though they are expressly authorized by the Copyright Act).

entity. Not even close. They are free-standing, separately owned companies that have no relationship to each other except for the conspiracy they entered into. The exclusive license between them is unlawful precisely insofar as it prevents Japan Tobacco from competing with Gilead to market FDCs using EVG and generic TDF or FTC once Gilead's patents on TDF or FTC expire.[14] Gilead and Japan Tobacco's decision to structure their license in this fashion is obviously not one of a "single entity." *See Am. Needle*, 560 U.S. at 200 (agreement of teams to cooperate in exploiting their intellectual property cannot be the basis for a single-entity defense; "[a]part from their agreement . . . there would be nothing to prevent each of the teams from making its own market decisions relating to . . . the granting of licenses to use its trademarks"); *id.* at 198, 200 ("'Absence of actual competition may simply be a manifestation of the anticompetitive agreement itself.'") (quoting *Freeman*, 322 F.3d at 1149); *King Drug*, 791 F.3d at 407.

Levi Case Co., Inc. v. ATS Products, Inc., 788 F. Supp. 428 (N.D. Cal. 1992), is not to the contrary. There, the court concluded that a patentee/inventor and its principal sublicensee could not compete (and therefore could not conspire) because the patentee had granted an exclusive license.[15] But unlike here, the plaintiff in that case (a competing sublicensee of the principal sublicensee) did not allege any anticompetitive conduct in connection with the exclusive license itself or any harm arising from the failure of the alleged conspirators to compete. Rather, the court assumed the validity of the exclusive license and characterized the dispute as involving subsequent "contract troubles" between the two

[14] Japan Tobacco does not dispute that its license with Gilead prevents it from competing in this fashion; the Complaint accurately refers to this prohibition as a No-Generics Restraint.

[15] It is questionable whether *Levi Case*'s reasoning survives *American Needle*, which focuses the *Copperweld* inquiry on whether alleged conspirators have *any* independent economic interests with respect to the conduct at issue. *See Am. Needle*, 580 U.S. at 198 ("*partially* unite[d]" economic interests are insufficient for single-entity treatment) (emphasis in original); *see also In re EpiPen*, 336 F. Supp. 3d at 1301-02 (*Copperweld* inapplicable to alleged conspiracy between manufacturing patentee and its exclusive distributor because while they "shared a 'unified interest' in protecting the EpiPen monopoly," they also "had separate interests"); *Townshend v. Rockwell Int'l Corp.*, No. C99-0400SBA, 2000 WL 433505, at *6 n.2 (N.D. Cal. Mar. 28, 2000) (patentee and manufacturing licensee can conspire because they had different interests and motivations with respect to patented technology).

sublicensees. *Id.* at 430.[16]

Furthermore, *Levi Case* did not hold that *Copperweld* created a broad grant of immunity for any activity arising out of the licensee–licensor relationship, as Japan Tobacco concedes. JT Mem. at 10. Other courts, distinguishing *Levi Case*, have consistently held that *Copperweld* does not apply to claims where, as here, plaintiffs allege that the grant of a license is part of a larger anticompetitive scheme. *See, e.g.*, *In re Suboxone*, 2017 WL 4910673, at *9 (scheme to extend exclusivity on patented drug); *Townshend*, 2000 WL 433505, at *6 (scheme "to unlawfully expand the market power conferred by [the] patents"); *In re EpiPen*, 336 F. Supp. 3d at 1302 ("concerted effort to . . . prevent EpiPen competitors from entering the . . . market"); *Pecover v. Elecs. Arts Inc.*, 633 F. Supp. 2d 976, 984 (N.D. Cal. 2009) ("aggregation of multiple exclusive agreements to choke off competition in a way that is not legally sanctioned").

Japan Tobacco also argues that it is not an actual or potential competitor of Gilead's because the complaint fails to allege that it ever had any drug marketing presence in the United States. JT Mem. at 11 n.8. Of course, even parties that are not actual or potential competitors can have conspiratorial capacity under § 1, as Japan Tobacco itself recognizes. *Id.* at 6 n.4 (citing the *IP Guidelines* for proposition that "vertical exclusive licensing arrangements are evaluated under the Rule of Reason");[17] *see also Am. Needle*, 560 U.S. at 199 ("a nut and a bolt can only operate together, but an agreement between nut and bolt manufacturers is still subject to § 1 analysis").

In any event, Japan Tobacco's argument ignores the allegations that absent the No-Generics Restraints it would have marketed an AB-rated version of the FDCs "either directly [itself] or through a

[16] The other cases cited by Japan Tobacco are similarly inapposite and barely implicate *Copperweld*. *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. CIV.A. 10-1077, 2011 WL 2550835 (D. Del. June 10, 2011), involved a claim that a patent infringement suit brought by an exclusive licensee and the patent holder was an unlawful restraint of trade. The court dismissed the claim primarily because the plaintiff had not alleged a plausible conspiracy. *Id.* at *5. The exclusive license itself (and *Copperweld*) supported the court's conclusion because the patent holder was a necessary party to the infringement suit. *Id.* In *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. CIV. A. 99-6299, 2000 WL 987865 (E.D. Pa. July 18, 2000), the court held that an agreement by a patent holder to distribute its patented products exclusively through a distributor rather than sell directly to the plaintiff could not be the basis for a § 1 claim, regardless of *Copperweld*.

[17] Even a finding that the No-Generics Restraint constitutes a vertical agreement would not spare Japan Tobacco. The Supreme Court has held that agreements to effectively extend a patent are *per se* illegal even in the context of vertical agreements. *See Kimble*, 135 S. Ct. at 2413. Moreover, the absence of horizontal competition would not foreclose liability for conspiracy to monopolize as an aider and abettor.

collaboration with a generic manufacturer." Compl. ¶ 191. In *In re Suboxone*, the court held that the complaint stated a viable conspiracy claim against a supplier who gave an exclusive license for follow-on technology to an incumbent monopolist who used the technology to maintain and extend its monopoly. The court concluded that, although the supplier was not itself a drug manufacturer, its technology was compatible with that of other manufacturers who were direct competitors of the licensee, and therefore the complaint allowed "the reasonable inference that [the licensor] could have competed in the relevant market outside of its agreement with [the licensee]." 2017 WL 4910673, at *9. Plaintiffs' Complaint similarly alleges that Japan Tobacco's EVG is chemically and practically compatible with generic TDF, generic FTC, and generic RTV. Compl. ¶¶ 113, 197. And absent the No-Generics Restraint Japan Tobacco would have been motivated to compete, and would in fact have competed, against Gilead, either directly or via a collaboration with a generic-drug manufacturer. *Id.* ¶¶ 4, 112–14, 191.

5. Janssen and Its Parent Company, Johnson & Johnson, Are Both Liable As Direct Participants in the Conspiracy.

Johnson & Johnson asserts that it should be dismissed from this case because Plaintiffs are "presumably" relying on its status as the corporate parent of Janssen R&D Ireland as the sole basis for liability. *See* Janssen Mem. at 12–13. But Rule 12(b)(6) does not allow for presumptions in favor of the moving party. Quite the opposite: the factual allegations in the Complaint must be presumed true and should be liberally construed in Plaintiffs' favor. *See In re NFL's Sunday Ticket*, 933 F.3d at 1149. Here, the Complaint uses the term "Janssen" to refer to both Janssen R&D Ireland (a Johnson & Johnson subsidiary that is the signatory to the agreements with Gilead) and Johnson & Johnson (the parent company that runs a multinational pharmaceutical business). *See* Compl. ¶ 48. The Complaint alleges that *both* Janssen *and* Johnson & Johnson were direct participants in the conspiracy with Gilead: both defendants negotiated and abided by the No-Generics Restraints; both defendants encouraged doctors to switch prescriptions to the FDCs insulated from generic competition; and both defendants shared in the monopoly profits that the unlawful agreements generated. *See id.* ¶¶ 145–75; *see In re Cathode Ray Tube* (*CRT*) *Antitrust Litig.*, 738 F.Supp.2d 1011, 1019 (N.D. Cal. 2010) ("In complex, multinational, conspiracy cases, courts in this district review specific allegations in the context of the complaint taken as a whole.").

Although a number of corporate entities within the Janssen Pharmaceutical Companies of Johnson & Johnson may be involved in various aspects of the Gilead–Janssen collaboration, neither the Plaintiffs nor the Court can determine with certainty at this stage of the proceedings which entities and officers took what specific actions to further the conspiracy—that is what discovery is for. But it is clear that, at a minimum, Janssen R&D Ireland and Johnson & Johnson were participants. In fact, the very documents for which Defendants seek judicial notice demonstrate Johnson & Johnson's direct involvement. For example, 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. *See, e.g.*, Burke Decl., Ex. G §§ 1.103, 1.199, 1.275, 6.7.1.2. The agreement also requires the parties to send copies of all collaboration-related reports and communications to Johnson & Johnson's General Counsel. *Id.* § 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. *Id.* Annex S-2 at GIL_000001046.

There should be no dispute that Plaintiffs plausibly allege that both Janssen and Johnson & Johnson are participants in the alleged conspiracy.

6. The Complaint Sufficiently Alleges Antitrust Injury.

The Complaint extensively describes the No-Generics Restraints' anticompetitive effects, including how they increased prices and reduced innovation. Compl. ¶¶ 176–241. Defendants do not challenge the Complaint's core allegation of antitrust injury—that the presence of a competitor otherwise precluded by the No-Generics Restraints would have had drastic price-lowering effects in the market. *See id.* ¶¶ 180, 184, 186-88, 502, 517, 532. Instead, Defendants offer a series of arguments disputing the truth of Plaintiffs' allegations that untainted competitors in Defendants' position would have marketed competing products. JT Mem. at 6–8; Janssen Mem. at 11–12; BMS Mem. at 10–12. These arguments fail as both a legal and factual matter.

Legally, Defendants' arguments fail because they deny the obvious: 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 Restraints. In the analogous context of pharmaceutical settlement "reverse payments," courts conclude that the existence of the restraint is evidence that, in its absence, generic

entry would in fact have occurred. *See, e.g.*, *In re Cardizem*, 332 F.3d at 911 (a reverse payment is "presumed to have the effect of reducing competition in the market for [the brand-name drug] and its generic equivalents to the detriment of consumers," and "a trier of fact may well find that the $89 million payment renders incredible the defendants' claim that [the generic] would have refrained from marketing"); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 811 (D.C. Cir. 2001) ("[The generic's] argument that any rational actor would wait for resolution of the patent infringement suit [before entering the market] is belied by the quid of [the brand manufacturer's] quo.").

Causation here is confirmed by the tight link between the No-Generics Restraints and the injury alleged. The Complaint alleges in detail that generic drugs, when unimpaired by anticompetitive conduct, rapidly take 80% or more of the sales from the brand product, delivering substantial price discounts to consumers. Compl. ¶ 189. The No-Generics Restraints impaired generic competition in both of the forms it might have taken: they (1) prevented the conspirators from making generic-drug-based versions of the FDCs, (2) and thereby created a competition-free haven that incentivized Gilead to shift sales from its vulnerable-to-generics standalone products into the restraint-protected FDCs. And the Complaint alleges that in fact Plaintiffs have suffered *the precise competitive injury that the No-Generics Restraints were likely to cause*. Gilead in fact cannibalized the sales of TDF and/or FTC into the restraint-protected FDCs. *Id*. ¶¶ 109, 128, 151, 180, 281. Instead of garnering 80% of Tenofovir sales, generic TDF got less than 15%. *Id*. ¶ 391. No conspirator whose restraint prohibits it[18] has made an AB-rated or comparable version of any of the FDCs. Consequently, the prices of those FDCs remain the same—the combined price of the components when sold as standalone *brand* products—despite the availability of generic TDF, generic 3TC, and generic RTV. *Id*. ¶¶ 180, 187. In short, the Complaint alleges that Plaintiffs have suffered the type of injury whose likelihood of occurring renders the No-Generics Restraints unlawful—delayed generic drugs and higher prices resulting from a conspiracy to keep generic drugs off the market.

These circumstances elicit a legal presumption that the restraints caused the injury. *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 101 (2d Cir. 2017) (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d

[18] See below regarding the special significance of BMS's marketing of a comparable version of Atripla.

677, 695 (2d Cir. 2009)). In antitrust cases, injury is *presumed* "where the anticompetitive conduct 'is deemed wrongful because it is believed significantly to increase the risk of a particular injury' and that injury occurred." *Id.* (quoting *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012)); *see also Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264 (1946) (adopting for antitrust law the "well-settled principle" of torts that "the jury [may] conclude as a matter of just and reasonable inference from the proof of defendants' wrongful acts and their tendency to injure plaintiffs' business . . . that defendants' wrongful acts had caused damage to the plaintiffs"); *In re Neurontin Mktg. & Sales Practices Litig*, 712 F.3d 21, 45 (1st Cir. 2013) (borrowing this principle from antitrust law and applying it in pharmaceutical RICO case).[19]

That legal presumption is easily sufficient to defeat these motions to dismiss. Indeed, even *at summary judgment* "it would be [*Defendants*'] burden to show that some other factors . . . are the 'true' cause of the delay [or exclusion], and therefore the 'true' cause of the artificially high drug prices plaintiffs paid." *In re Actos*, 848 F.3d at 101. Defendants cannot prevail on a motion to dismiss with arguments that amount to an affirmative defense. *See United States v. McGee*, 993 F.2d 184, 187 (9th Cir. 1993) (plaintiffs are "not required to plead on the subject of an anticipated affirmative defense.").

Regardless of the dispositive legal presumption, Defendants cannot prevail by ignoring or contradicting the Complaint's detailed factual allegations of causation. Their arguments depend on purported facts that are outside the Complaint and are themselves implausible. *UFCW Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1067–69 (N.D. Cal. 2014); *Tucker v. Apple Computer, Inc.*, 493 F. Supp. 2d 1090, 1101 (N.D. Cal. 2006). Defendants cannot overcome on this motion the fundamental proposition that causation is a fact-intensive and context-dependent issue usually best left "for the jury to be determined as a fact." *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 566 (1931)*; see also Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 840-41 (1996); *Zenith*

[19] In the tort context, as in antitrust, "once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation." *BCS Servs., Inc. v. Heartwood LLC*, 637 F.3d 750, 758 (7th Cir. 2011); *see also Liriano v. Hobart Corp.*, 170 F.3d 264, 271 (2d Cir. 1999) ("When a defendant's negligent act is deemed wrongful precisely because it has a strong propensity to cause the type of injury that ensued, that very causal tendency is evidence enough to establish a *prima facie* case of cause-in-fact."); *see generally Associated Gen. Contractors of Cal., Inc. v. Cal. St. Council of Carpenters*, 459 U.S. 519, 103 (1983) (tort and contract common law principles of causation can apply to antitrust injury).

Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 123–24 (1969).

Japan Tobacco asserts that it would not have offered a competing product containing EVG and generic versions of TDF, 3TC (or FTC) and RTV (or COBI) because TDF was inferior to TAF. JT Mem. at 7. But the Complaint alleges that, but-for the No-Generics Restraints, Japan Tobacco would have made generic-TDF-based FDCs nearly a year before TAF was introduced in November 2015. Compl. ¶¶ 110, 114–15. Moreover, Japan Tobacco's unspoken factual premise—that the now-remaining sales of Stribild are insufficient to economically justify marketing a competing version—is wholly outside the Complaint. Regardless, the restraint prevented Japan Tobacco from introducing TAF-based as well as TDF-based products. *Id.* ¶¶ 117, 192. Thus, consumers of both Stribild and Genvoya were, or will be, overcharged because Japan Tobacco (or its licensee) would have marketed competing TDF and TAF-based products but for the agreement. *Id.* ¶ 117.

Japan Tobacco also argues that it would have no incentive to market an EVG product in competition with Gilead because the Complaint alleges that Dolutegravir is superior to EVG. JT Mem. at 7. This ignores Plaintiffs' allegations. Plaintiffs allege that by eliminating Japan Tobacco as a competitor, the No-Generics Restraint caused Gilead to forgo introducing an FDC containing Dolutegravir instead of EVG. Compl. ¶¶ 230–37. That does not render Plaintiffs' injury implausible. It instead supports a finding that Japan Tobacco's conduct injured Plaintiffs *twice over*: by the price overcharge caused by the absence of a competitor and by the poor quality of the product on which they paid the overcharge.

Japan Tobacco also argues that it is implausible to suggest that it would have competed with a generic-TDF-based product any earlier than December 2017, when generic TDF actually became available. JT Mem. at 8. This directly contradicts the Complaint's detailed allegations that, unlike generic manufacturers, Japan Tobacco and Gilead's other coconspirators had royalty-free access to the third agents, were not subject to New Chemical Entity exclusivities, and/or owned the patents on the FDCs. *Id.* ¶¶ 114–15. They were thus best positioned and motivated to challenge Gilead's patents, either themselves or in collaboration with a generic-drug manufacturer. Compl. ¶¶ 114-15, 130, 158-59,

191.[20]

Janssen argues that the products "are lawfully protected from generic competition by patents or regulatory exclusivity" and thus harm from the agreements is speculative "until the Gilead and Janssen intellectual property protections expire." Janssen Mem. at 12. But this misrepresents the theory of the case in two ways. First, as to Complera and Odefsey, the agreements prevented Janssen itself (or its licensee) from competing by using generic components even after Gilead's TDF patents expired—when only Janssen's intellectual property and regulatory exclusivities remained. Compl. ¶¶ 148, 158–61. Second, absent the restraint, Janssen could have challenged Gilead's patents before they expired by filing an NDA or ANDA. *Id.* ¶¶ 158-61, 185, 191. The agreement eliminated the risk of that competition. *Id.* ¶¶ 191, 427.

Janssen also argues that nothing prevents third parties from introducing their own competing products. Janssen Mem. at 12. But, again, Janssen owned the intellectual property and exclusivities that remained after Gilead's patent expirations. Janssen's argument ignores Plaintiffs' allegations that the agreement is unlawful because it removed the risk of competition *from Janssen*. Until its own patents expire, only Janssen can market AB-rated or comparable versions of the FDCs containing the Janssen components, and the Complaint alleges that AB-rated and comparable versions of the FDCs are the most competitively significant. *Id*. ¶¶ 183, 187–89, 370, 378–79.

BMS argues that it is speculative whether it would have marketed a competing product because it does not have a generics division, would have needed FDA approval, and might have lost patent litigation against Gilead. BMS Mem. at 11. BMS's factual arguments have no place in a motion to dismiss. As numerous courts in generic-drug-suppression cases have held, a plaintiff's complaint need not "rule out a litany of alternative possible causes of [the generic's] delayed market entry." *In re Actos*, 848 F.3d at 100–01 (reversing dismissal on causation and rejecting defendant's argument that the generic

[20] Japan Tobacco argues that it had "no duty" to develop an HIV drug with EVG, JT Mem. at 8, but Plaintiffs do not allege that it did. Plaintiffs allege that Japan Tobacco entered into an unlawful agreement not to develop competing FDCs with EVG, and that it otherwise would in fact have done so. Japan Tobacco did not need a "crystal ball" to foresee that Gilead's patents on FTC and TDF would expire during the term of their collaboration agreement—their stated terms expired before those claiming EVG. Compl. ¶¶ 108, 347, 355.

might have lost patent litigation or failed to get FDA approval).[21] And BMS's argument about the absence of a generics division is irrelevant: BMS in fact partnered with generic-drug manufacturer Mylan to make a comparable version of Atripla (made with genericTDF/generic3TC/EFV) as soon as generic TDF became available—and sold that competing version at a 40% discount to Gilead's Atripla. Compl. ¶¶ 140, 191. The No-Generics Restraint prohibited BMS from making only an AB-rated version, not a comparable version. Neither BMS nor any other Defendant can plausibly deny—certainly on this motion to dismiss—that they would have made competing FDCs absent the restraints.

Regarding Evotaz, BMS asserts that Gilead's choice was between licensing COBI to BMS *with the No-Generics Restraint* to make Evotaz in 2011, or waiting until BMS's ATV patents expired in 2017 and making a COBI/genericATV FDC itself (or with a generic-manufacturer partner). BMS Mem. at 11. BMS's unspoken factual premise is that it would not have done the deal if Gilead refused a No-Generics Restraint. That is a flat-out admission of anticompetitive intent and effect. A deal that's not worth doing without a naked horizontal restraint is a deal whose only purpose is to generate supracompetitive profits that competition would not yield. And even if BMS's factual premise were a justification rather than a confession, it would have no legitimate place in a motion to dismiss.

Lastly, BMS argues that individual components of the FDCs were available and patients could have taken them as separate pills when a generic version of one pill became available. BMS Mem. at 11–12. This ignores at least three of the Complaint's central allegations: (1) the No-Generics Restraints delayed the entry of generic versions of the standalone products (Compl. ¶ 190); (2) the No-Generics Restraints substantially reduced the prescription base for the standalone products (*id.* ¶¶ 128, 136); and (3) AB-rated or comparable versions of the FDCs, not assemblages of individual pills, are the most competitively significant products (*id.* ¶¶ 183, 187–89, 370, 378–79).

B. The Complaint Sufficiently Alleges a Conspiracy to Monopolize

The Court should deny Defendants' motion to dismiss Plaintiffs' conspiracy-to-monopolize claims. *See* BMS Mem. at 12–13; Janssen Mem. at 5–7; JT Mem. at 3–5. The Complaint alleges that

[21] *See, e.g., In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 12-MD- 2343, 2013 WL 2181185, at *16 (E.D. Tenn. May 20, 2013)*; In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *12 (D.N.J. Aug. 28, 2009); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003).

Gilead's monopoly in the cART market was under threat as its core patents neared the end of their lives. Each of the coconspirators helped Gilead maintain that monopoly by using the No-Generics Restraints to shield Gilead's products from generic competition even after its patents expired. Each of the coconspirators did so because the collaboration allowed them to reap the continued monopoly profits that the unlawful agreements generated. These allegations easily state a claim of conspiracy to monopolize.

1. The Complaint Sufficiently Alleges that Each Defendant Conspired with Gilead to Maintain Its cART Monopoly.

The elements of a conspiracy to monopolize are: "(i) the existence of a combination or conspiracy to monopolize; (ii) an overt act in furtherance of the conspiracy; (iii) the specific intent to monopolize; and (iv) causal antitrust injury." *Paladin Assocs., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1158 (9th Cir. 2003).

Regarding the existence of a conspiracy, each of the coconspirators here is a highly sophisticated participant in the cART market. During all relevant times, they knew that Gilead dominated the cART market, with market shares ranging from 70–93%, a fact that Gilead repeatedly touted. Compl. ¶ 392. But as early as 2009 Gilead's flagship Tenofovir product was vulnerable to generic competition that could have ended Gilead's dominance. In order to head off that threat, Gilead and each coconspirator entered into the No-Generics Restraints. *Id.* ¶ 2. The coconspirators were the competitors best positioned to challenge Gilead's patents and to begin marketing competing versions of the FDCs as soon as Gilead's components were available as generics. *Id.* ¶¶ 97, 191. But "[i]nstead of competing, each of BMS, Japan Tobacco, and Janssen helped Gilead protect its drugs from generic competition." *Id.* ¶ 99.[22]

Why did each of BMS, Janssen, and Japan Tobacco help Gilead maintain its cART monopoly? Because "[i]n exchange, they each shared in the supracompetitive profits that the impairment of competition made possible." *Id.* ¶ 99. Specifically, each coconspirator benefitted because (1) Gilead switched its standalone products to the FDCs, thereby increasing the sales of the coconspirator's components; (2) Gilead's continued monopoly increased prices for all drugs in the cART market in

[22] The Complaint alleges in detail that the purpose and effect of the No-Generics Restraints was to protect Gilead's Tenofovir products from generic competition, allowing Gilead to maintain and extend its monopoly in the cART market. *See, e.g.*, Compl. ¶¶ 103, 112–17, 123, 129-130, 145, 152–53, 157-161, 162, 169, 378, 380. 401.

which the coconspirators participated; and (3) Gilead paid the coconspirators through the royalty provisions of the collaboration agreements. *Id.* ¶¶ 4, 178, 405. And for two of the coconspirators—BMS and Janssen—Gilead returned the favor by helping them protect their vulnerable products from generic competition. *Id.* ¶¶ 131–34, 162–164.

In sum, "Gilead's conscious objective was to further its dominance in the cART Market by and through the overarching anticompetitive scheme," and "[e]ach of Janssen, Japan Tobacco, and BMS consciously committed to" that scheme. *Id.* ¶¶ 443, 444. Each of the coconspirators "knowingly, willfully, and wrongfully maintained Gilead's monopoly power and harmed competition by . . . [e]ntering into and abiding by the illegal No-Generics Restraints." *Id.* ¶ 445.

The standards in this Circuit for pleading the first element of a conspiracy-to-monopolize claim are straightforward: A defendant is liable for conspiracy to monopolize where it "knew or . . . should have known that [the monopolist] would use the [agreement with the conspirator] for monopolistic purposes." *Syufy Enterprises v. Am. Multicinema, Inc.*, 793 F.2d 990, 1000 (9th Cir. 1986). In addition, the conspirator must "share[] with [the monopolist] a common purpose in monopolizing the . . . market." *Id.* at 1001. The Complaint readily meets these standards. Gilead had a monopoly; it was under threat. Each coconspirator purposefully helped Gilead head off that threat by shielding its vulnerable products via the No-Generics Restraints; and each coconspirator consciously helped Gilead maintain the monopoly so that it could participate in the supracompetitive profits that its participation made possible.

Defendants try to defeat this claim by mischaracterizing it. They assert that Plaintiffs have tried to allege "a hub-and-spoke type" conspiracy and have failed to allege the agreement among the "spokes"—among BMS, Janssen, and Japan Tobacco—that are necessary for such a claim. Janssen Mem. at 6. But Plaintiffs do not allege a hub-and-spoke conspiracy; Plaintiffs allege that each of BMS, Janssen, and Japan Tobacco conspired with Gilead to maintain and extend its monopoly.

A hub-and-spoke conspiracy arises when an entity in a vertical relationship with each of the spokes organizes an anticompetitive horizontal agreement among them. The horizontal agreement among the spokes causes the anticompetitive effects. *See In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d 1186, 1192–93 (9th Cir. 2015) ("A traditional hub-and-spoke conspiracy has three elements: (1) a hub, such as a dominant purchaser; (2) spokes, such as competing manufacturers or

distributors that enter into vertical agreements with the hub; and (3) the rim of the wheel, which consists of horizontal agreements among the spokes."). In such a case, a plaintiff who alleges a hub-and-spoke conspiracy must allege the "rim"—a horizontal agreement among the spokes—if they want to prove a horizontal rather than a vertical agreement.

Plaintiffs here need not allege a separate horizontal agreement among BMS, Janssen, and Japan Tobacco because Plaintiffs do not allege a hub-and-spoke conspiracy. *See, e.g., Church & Dwight Co., Inc. v. Mayer Labs., Inc.*, No. C-10-4429 EMC, 2011 WL 1225912, at *7, 14 (N.D. Cal. Apr. 1, 2011) (Chen, J.) (denying motion to dismiss conspiracy-to-monopolize claim where the exclusionary conduct was a series of agreements between the monopolist supplier and multiple retailers, none of which retailers conspired among themselves). Gilead is a horizontal competitor of each of the coconspirators, not a ringmaster in a vertical relationship with each of them. Gilead had a vulnerable monopoly, and that monopoly, not any agreement among BMS, Janssen, and Japan Tobacco, causes the anticompetitive effects. Each of BMS, Janssen, and Japan Tobacco separately, not acting collectively, conspired with Gilead to maintain that monopoly. Each of them separately is liable for conspiring with Gilead to maintain the monopoly; indeed, each of them would have been liable as a facilitator of Gilead's monopolistic conduct if it had been the *only* coconspirator that entered into No-Generics Restraints with Gilead. *See, e.g., Int'l Travel Arrangers, Inc. v. W. Airlines, Inc.*, 623 F.2d 1255 (8th Cir. 1980) (monopolist airline and its advertising agency held liable for conspiracy under Sherman Act to wage false and deceptive advertising campaign to eliminate competitive threat of travel group charters); *Spectators' Commc'n Network Inc. v. Colonial Country Club*, 253 F.3d 215, 222 (5th Cir.2001) (conspiracy may be found even "when one conspirator lacks a direct interest in precluding competition, but is enticed or coerced into knowingly curtailing competition by another conspirator who has an anticompetitive motive"); *accord Ward v. Apple Inc.*, 791 F.3d 1041, 1044 (9th Cir. 2015) (assuming viability of claim that Apple conspired with ATTM, through exclusivity agreement, to help ATTM maintain a monopoly in iPhone voice and data services market).

Neither *Syufy* nor any other authority requires that a conspiracy-to-monopolize claim comprise three or more conspirators rather than just two (Gilead and, separately, each of BMS, Janssen, and Japan Tobacco). Instead, each conspirator is separately liable for conspiring with the monopolist, regardless of

any agreement among themselves. *Church & Dwight*, 2011 WL 1225912, at *7 & *14; *see also In re Suboxone*, 2017 WL 4910673, at *8–9 (denying motion to dismiss claim that a single coconspirator gave exclusive patent license to monopolist who used the technology to maintain its monopoly).

The distinction between Defendants' hypothesized hub-and-spoke conspiracy and Plaintiffs' actually alleged conspiracies undermines all of Defendants' arguments. Plaintiffs need not allege a horizontal agreement among the purported spokes (Janssen Mem. at 7); need not allege "interdependence" among them that can sometimes substitute for an express agreement (*id*.); need not allege any communications among them (BMS Mem. at 12); and need not allege that they were aware of each other's activities (Janssen Mem. at 5). Each of BMS, Janssen, and Japan Tobacco is liable not because they conspired with each other, but because each of them separately conspired with Gilead to join its scheme to maintain and extend its monopoly and to share in the profits from that monopoly.[23]

Defendants' other arguments are equally baseless. It is clearly plausible that each of the coconspirators would have conspired with Gilead to maintain its monopoly. *Contra* BMS Mem. at 13; Janssen Mem. at 8. Doing so increased the sales of their third agents, raised prices in the cART market in which they sold, and allowed them to directly share in the supracompetitive prices on their and Gilead's FDCs, and Gilead returned the favor by helping them protect their vulnerable products from generic competition. Compl. ¶¶ 4, 99, 131–34, 162–64, 178, 405. And Plaintiffs plainly allege harm in the cART market, not only in separate markets for each of the FDCs. *Contra* JT Mem. at 4; *see* Compl. ¶ ¶ 180, 187, 196, 269, 399.

2. The Complaint Sufficiently Alleges Specific Intent to Monopolize.

Defendants assert that the Complaint fails to allege that they had the "specific intent" to monopolize. Janssen Mem. at 8; JT Mem. at 1. Not so. Again, the Complaint alleges in detail that Gilead dominated the cART market (Compl. ¶ 392); generic competition would have ended that dominance (*id*. at ¶ 2); each of the coconspirators entered into the No-Generics Restraints order to "head

[23] Defendants misread the Complaint to allege "an overarching conspiracy" in which all of the coconspirators agreed with each other. Janssen Mem. at 7. That's not what the Complaint says. It alleges that Gilead monopolized the cART market through "an overarching anticompetitive scheme" that included Gilead's degrading Stribild and artificially raising its price, degrading standalone TAF, abusing the regulatory process, and causing delayed entry of generic versions of Viread, Truvada, and Atripla. And each of BMS, Janssen, and Japan Tobacco conspired with Gilead to maintain and extend its monopoly by "[e]ntering into and abiding by the No-Generics Restraints." Compl. ¶ 454.

off th[at] threat of generic competition" (*id.*); but "[i]nstead of competing, each of BMS, Japan Tobacco, and Janssen helped Gilead protect its drugs from generic competition" (*id.* at ¶ 99); and each of them did so in order to "share[] in the supracompetitive profits that the impairment of competition made possible" (*id.*). The Complaint further alleges that each of the coconspirators "consciously committed to the overarching anticompetitive scheme" and "knowingly, willfully, and wrongfully maintained Gilead's monopoly power and harmed competition by . . . [e]ntering into and abiding by the illegal No-Generics Restraints." *Id.* ¶¶ 444, 445.

These allegations easily plead specific intent to monopolize. In the Ninth Circuit, proof of such intent, which is usually litigated in the context of an attempt-to-monopolize claim, can be inferred from the fact that the conspirator engaged in conduct likely to create or maintain the monopoly.[24] *See, e.g.*, *Talking Yellow Pages, Inc. v. Pac. Telesis Grp.*, 972 F.2d 1343 (9th Cir. 1992); *Thurman Indus., Inc. v. Pay'n Pak Stores, Inc*., 875 F.2d 1369, 1378 (9th Cir. 1989); *Gough v. Rossmoor Corp*., 585 F.2d 381, 390 (9th Cir. 1978); *see also Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946) ("Where the conspiracy is proved, as here, from the evidence of the action taken in concert by the parties to it, it is all the more convincing proof of an intent to exercise the power of exclusion acquired through that conspiracy."). Indeed, "[s]pecific intent to monopolize will normally be proved by inference from conduct." *Hunt-Wesson Foods, Inc. v. Ragu Foods, Inc.*, 627 F.2d 919, 926 (9th Cir. 1980) (citing *California Comput. Prods., Inc. v. IBM Corp.*, 613 F.2d 727, 736-37 (9th Cir. 1979)). And the existence of market power fortifies the inference of specific intent from the anticompetitive conduct. *Id.* at 927 (reversing dismissal of conspiracy-to-monopolize claim where plaintiff alleged substantial market power and exclusionary conduct likely to maintain that power); *see also Fleer Corp. v. Topps Chewing Gum, Inc.*, 658 F.2d 139, 154 (3d Cir. 1981).

In *In re NFL's Sunday Ticket*, the Ninth Circuit recently and emphatically reversed the dismissal of a conspiracy-to-monopolize claim on a motion dismiss, concluding that "the complaint adequately alleges that the interlocking NFL-Team and NFLDirecTV agreements were designed to maintain market

[24] It is not clear in the Ninth Circuit that specific intent is necessary in a conspiracy-to-monopolize claim at all. *See Eichman*, 880 F.2d at 162 (9th Cir. 1989) ("It is unclear in this Circuit whether a showing of specific intent is necessary to establish a conspiracy to monopolize under Section 2."). If it is not required, Defendants' argument necessarily fails.

power, which is sufficient to allege defendants' specific intent." 933 F.3d at 1159. Similarly, the Complaint here alleges in detail that Gilead had a monopoly in the cART market and that the specific purpose and actual effect of the No-Generics Restraints was to impair generic competition and thereby help Gilead maintain and extend that monopoly. These allegations, which must be taken as true on a motion to dismiss, easily satisfy any specific-intent element of the claim.

C. The Complaint Sufficiently Alleges that Gilead's Product-Switching Tactics Were Anticompetitive

Plaintiffs allege that Gilead used a series of anticompetitive tactics in order to move the TDF-based products to the TAF-based FDCs that were protected by the new round of No-Generics Restraints with broader scope and longer terms. Compl. ¶¶ 8, 247, 261, 315. Specifically, Gilead (1) intentionally degraded TDF-based Stribild by using a TDF dose that it knew was dangerously high in order to create a better contrast between Stribild and its TAF-based analogue, Genvoya (Compl. ¶¶ 242–47); (2) raised the price of Stribild above the profit-maximizing level in order to create an artificial price advantage for Genvoya (*id.* ¶ 248); (3) delayed applying for FDA approval for standalone TAF (Vemlidy), so that patients could get new, safer TAF only through the TAF-based FDCs (*id*. ¶¶ 253–61); (4) made standalone TAF available only in 25 mg strength instead of the safer 10 mg strength that it used in TAF-based FDCs (*id*. ¶¶ 262–69); and (5) applied for FDA approval for standalone TAF only for Hepatitis B, not for HIV, while getting FDA approval for HIV indications for TAF-based FDCs (*id*. ¶¶ 270–75).

Gilead cites *AIDS Healthcare Found., Inc. v. Gilead Scis., Inc.* ("*AHF*"), No. 16-443, 2016 WL 3648623 (N.D. Cal. Jul. 6, 2016), *aff'd on other grounds*, 890 F.3d 986 (Fed. Cir. 2018), for the broad proposition that it can bring its products to market whenever and however it chooses, free from antitrust scrutiny. Gilead Mem. at 22. Neither *AHF* nor any other case supports such blanket immunity. Instead, the venerable principle is that a manufacturer may "freely to exercise his own independent discretion" on how to market its products, but *only* "[i]n the absence of any purpose to create or maintain a monopoly." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919); *see also Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 483 n.32 (1992) ("It is true that as a general matter" a monopolist can choose how to market its products, but that right "is not absolute; it exists only if there are legitimate competitive reasons for [the conduct]."). The Ninth Circuit has held, for example, that a monopolist may

improve its product, despite the effect on competitors, "unless the monopolist abuses or leverages its monopoly power in some other way when introducing the product." *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010); *see also Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983) ("*As a general rule*, any firm, even a monopolist . . . may bring its products to market whenever and however it chooses.") (emphasis added).

One test for identifying such "abuses" is whether the monopolist's conduct would make economic sense *for itself* if the conduct did not have the effect of impairing competition. Where conduct would be a money-loser for the monopolist if it did not impair competition, its sole purpose and likely effect must be anticompetitive. *See MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1132 (9th Cir. 2004) (conduct is unlawfully exclusionary when it "indicate[s] a willingness to sacrifice short-term benefits in order to obtain higher profits in the long run from the exclusion of competition"). This is not the only test for abusive, exclusionary conduct, but it is one endorsed and applied by numerous courts to many types of conduct. *See, e.g.*, *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610–11 (1985) (conduct was unlawfully exclusionary because defendant "was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival"); *Verizon Commc'ns Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S. 398, 408 (2004) (noting that conduct in *Aspen Skiing* reflected "a willingness to forsake short-term profits to achieve an anticompetitive end"); *Covad Commc'ns v. Bell Atlantic Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005) (a predatory practice is "one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor"); *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1075 (10th Cir. 2013) (monopolist's conduct is exclusionary when it is "irrational but for its anticompetitive effect"); *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 148 (4th Cir. 1990) (conduct exclusionary if monopolist made "a short term sacrifice in order to further its exclusive, anticompetitive objective").

The Complaint specifically alleges that Gilead's product-switching tactics would have made no economic sense for Gilead if they did not impair competition. Compl. ¶¶ 276–77. That conduct—degrading the safety of multiple products, raising price above the profit-maximizing level, intentionally delaying an improved product, and withholding an HIV indication from a product that is obviously

effective against HIV—self-evidently would be money-losing propositions if they did not have the ultimate purpose of impairing competition. The Complaint alleges that they *were* money-losers, costing Gilead hundreds of millions of dollars a year, but that they all helped move Gilead's franchise from the TDF-based products to the longer-restraint-protected TAF-based products, ultimately garnering it billions more. *Id.* ¶¶ 12, 277.[25]

The Complaint also alleges two other bases for finding this conduct exclusionary: (1) Gilead's making TAF unavailable (for one year) and available only without an HIV indication (continuing to today) impairs competition from equally efficient manufacturers of third agents who, unlike Gilead, did not have access to TAF and do not have access to it with an HIV indication (*id.* ¶ 286); and (2) Gilead's prior course of dealing led its competitors to rely on the availability of Tenofovir with the same form/dosage/indications and to forgo developing an alternative (*id.* ¶ 283).

In an analogous case, *Safeway Inc. v. Abbott Lab*, No. C 07-05470 CW, 2010 WL 147988 (N.D. Cal. Jan. 12, 2010), the court held that both types of allegations state a claim of exclusionary conduct under § 2. In *Safeway*, Abbott Labs made a "booster" drug, Norvir. In order to push prescriptions from standalone Norvir to an FDC comprising Norvir and another Abbott component, Abbott raised the price of standalone Norvir by 400%, making the price of the FDC barely above that of standalone Norvir. *Id.* at *1. The Court denied Abbott's motion to dismiss the complaint, holding that competitors who depended on using their third agents together with standalone Norvir could not profitably match the price of Abbott's FDC, even if they operated as efficiently as Abbott. *Id.* at *4. Abbott's pricing scheme "ha[d] the potential to exclude a hypothetical equally efficient producer of the competitive product." *Id.* (quoting *Cascade Health Sols. v. Peacehealth*, 515 F.3d 883, 906 (9th Cir. 2008)). Here, Gilead went far beyond indirectly making the product unavailable to competitors through high pricing; it denied them access to it altogether, then denied them access to it altogether with an HIV indication. No third-agent manufacturer, even if *more* efficient than Gilead, can compete on equal footing.

Safeway found that Abbott's conduct was also unlawfully exclusionary because its prior, moderate pricing of Norvir "induc[ed] its competitors to rely on the availability of Norvir on these terms

[25] The same no-economic-sense test also supports Plaintiffs' claim that Gilead engaged in unlawful regulatory gaming in not getting an HIV indication for standalone TAF. *See* Compl. ¶¶ 288–312. So do the other two bases discussed immediately below.

and to forgo development of their own . . . boosters." 2010 WL 147988, at *8; *see also id*. at *6 ("liability under Section 2 can arise when a defendant voluntarily alters a course of dealing and 'anticompetitive malice' motivates the defendant's conduct") (citing *MetroNet Svcs.*, 383 F.3d at 1131–32)). Plaintiffs here allege exactly such prior course of dealing, with the same reliance, and with the same anticompetitive purpose and result. Compl. ¶¶ 283–86.

Defendants' principal case, *AHF*, is irrelevant here. The plaintiffs' claim in *AHF* was that Gilead and each of Janssen and Japan Tobacco, in violation of § 1, unlawfully "tied" the sale of TAF to the third agents by creating the FDCs, i.e., that *making FDCs* is itself anticompetitive. That claim is fundamentally *the opposite* of what Plaintiffs allege here, that Defendants' conduct has impaired the innovation of more, better, and less expensive FDCs sooner. True, the *AHF* court stated that Gilead "had no duty to pursue FDA approval of the standalone version," 2016 WL 3648623, at *7, but that half sentence cannot withstand the authority and analysis above once it is clear that Gilead refused to seek such approval despite the sacrifice of profits it entailed only because it was an integral part of its anticompetitive scheme.

The *AHF* plaintiffs' monopolization claim failed because they did not define any relevant market, and their substantive theory that "tying" the components together would altogether insulate the TAF patents from challenge was untrue. *Id*. at *6–8. The court also rejected those plaintiffs' claim that Gilead's shelving of TAF development in 2004 was exclusionary conduct. *Id*. at *9. In stark contrast, Plaintiffs here have pointedly alleged direct evidence of market power and carefully identified the relevant markets. Plaintiffs do not allege that the TAF patents are beyond challenge, that FDCs themselves are illegal, or that Gilead's shelving of TAF development in 2004 was exclusionary conduct—it was instead an anticompetitive *effect* of the No-Generics Restraints. Compl. ¶ 202 (shelving of TAF development was "[o]ne of the most severe anticompetitive effects of the No-Generics Restraints").

Finally, Gilead's anticompetitive switching tactics did not exist in a vacuum in the marketplace and do not exist in one in this lawsuit. The five tactics were a part of Gilead's overall anticompetitive scheme, which included two sets of No-Generics Restraints among four competitors affecting 17 drugs, and two patent settlements that unlawfully induced a generic manufacturer to delay entry. *AHF* alleged

only one of the five tactics and did not allege any of the No-Generics Restraints or any of the anticompetitive patent agreements. This is a profoundly different lawsuit alleging the tactics in a fundamentally different competitive and legal context.

D. The Complaint Sufficiently Alleges that Gilead Used Most-Favored-Entry Provisions to Unlawfully Delay Entry of Generic Viread, Truvada, and Atripla

The Complaint alleges that Gilead's patents on Viread, Truvda, and Atripla were weak, Compl. ¶ 96, and Gilead knew that there was a substantial risk that it would lose the litigation with Teva challenging those patents. *Id.* ¶¶ 330, 332. Nevertheless, Gilead was able to obtain Teva's agreement to stay out of the market until nearly the date of patent expiration (six weeks before patent expiration in the case of Viread and one year in the case of Truvada and Atripla) in exchange for "most favored entry" (MFE) and "most favored entry plus" (MFEP) clauses. *Id.* ¶¶ 343, 357. Those clauses (sometimes known as "acceleration clauses") guaranteed that no other generic would enter before Teva, and essentially guaranteed that Teva would be the only generic on the market for a period of time (six weeks in the case of Viread and six months in the case of Truvada and Atripla). *Id.* ¶ 344.[26] That exclusivity was worth more than $100 million to Teva in the case of Viread and $1.5 billion in the case of Truvada and Atripla. *Id.* ¶¶ 339, 360.

The MFEs and MFEPs insulated Teva from the statutory 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. *Id.* ¶ 336. In fact, in the case of Truvada (and possibly Atripla as well), the MFEP clauses resurrected the 180-day exclusivity period that Teva had forfeited under the statute by failing to gain timely tentative approval from the FDA. *Id.* ¶ 356. With their statutory means of obtaining equal or earlier entry essentially foreclosed by the MFE and MFEP

[26] Teva agreed to drop its patent challenges and stay out of the market until December 15, 2017 in the case of generic Viread and until September 30, 2020 in the case of generic Truvada and Atripla. Compl. ¶¶ 342, 357. The MFEs provided that, if any second filer entered the market before the agreed-upon date, Teva's entry date would be moved up accordingly. *Id.* ¶¶ 343, 357. And the MFEPs provided that Gilead would not grant any other manufacturer a license to enter the market with generic Viread until at least six weeks after Teva's agreed entry date, *id.* ¶ 343, nor with generic Truvada or generic Atripla until at least *six months* after Teva's agreed entry date, *id.* ¶ 357 (emphasis in original). *See also* ECF No. 144 Declaration of Jeremy K. Ostrander, Ex. I, at 3; Ex. J, at 4.

clauses, subsequent filers, as intended, agreed to settlements with Gilead that delayed their entry until after the period of generic exclusivity provided by Gilead to Teva. *Id.* ¶¶ 348, 359.

Absent the MFE and MFEP clauses, Teva and/or the second filers would have entered the market with generic Viread much sooner than they did, and much sooner than they will with generic Truvada and Atripla. *Id.* ¶¶ 351, 360.[27] As a result of the delay, consumers have paid or ultimately will pay billions of dollars more than they should for these drugs, and many thousands of people will be unable to access PrEP and will needlessly become infected with HIV. *Id.* ¶¶ 434–36. The delay in the entry of generic Viread and Truvada further harmed competition because it gave Gilead additional time to switch its TDF-based franchise to a TAF-based franchise, with its longer and broader No-Generics Restraints. *Id.* ¶ 352.

Gilead's arguments that the "Complaint's factual allegations establish that the patent settlement agreements, including the challenged 'acceleration' provisions, were procompetitive and entirely lawful" under *Actavis* are wrong. Gilead Mem. at 4. Rather, the Complaint plausibly alleges that the MFEs and MFEPs were intended to and did deter earlier entry by subsequent filers. And by so doing, the clauses provided Gilead with the currency to pay Teva to delay its entry. Thus, the settlements are prima facie anticompetitive under the rule of reason, suspect reverse-payment settlements under *Actavis*, and unlawful components of Gilead's broader scheme to monopolize the cART market. *Cf. In re: Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3d Cir. 2017) (reverse payment settlement may be unlawful restraint of trade under § 1 of Sherman Act or monopolistic conduct under § 2).

1. MFEs and MFEPs Are Analogous to Anticompetitive MFNs.

Gilead argues that acceleration clauses are "indisputably procompetitive" because, if they are triggered, they lead to more generic entry than otherwise. Gilead Mem. at 27. In fact, however, although

[27] Gilead contends that the very late entry dates agreed to by Teva and later filing generics show that the patents were not weak. Gilead Mem. at 30–31. But that simply *assumes* that the value provided by the MFEs and MFEPs had no effect on the entry dates, which is precisely the opposite of what the Complaint alleges. Moreover, one can infer little about the strength of the patent from a "cheap" settlement motivated by a litigation blunder, as Gilead suggests occurred in the Viread case. *See id.* at 17. Gilead also erroneously contends that the only way Teva or another generic could have obtained an earlier entry date was by successfully challenging the patent. *See id.* at 30. But another route would have been to obtain an earlier agreed-upon date. In any event, these are factual questions not appropriate to resolve on a motion to dismiss.

the MFE and MFEP clauses nominally provided for Teva's entry to potentially be *accelerated*, the intended and actual effect of the MFEs and MFEPs was to *delay* the entry of both Teva and other generic manufacturers. The former Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—testified before Congress that MFEs, or what he referred to as "poison pill" provisions, 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." [28] Acceleration clauses may appear "[a]t first blush" to benefit consumers by potentially expediting entry by the settling generic, but this is a mirage:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. *Consumers are the biggest losers under this system.* If subsequent filers do not have the incentive to take on the cost of multimillion dollar patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[29]

An MFE clause works like a "most favored nation" (MFN) pricing clause between a supplier and customer. But instead of guaranteeing a best price, the MFE clause guarantees a best entry date. And an MFEP clause works like an "MFN plus" clause by which a supplier promises it will charge a higher price to other customers. But instead of a higher price, the MFEP clause guarantees that other generics will receive a later licensed entry date. MFNs may appear to benefit consumers by requiring lower prices but in fact can have the intended effect of raising prices and excluding competitors and thus may be unlawful under the rule of reason. *See, e.g., United States v. Delta Dental of R.I.*, 943 F. Supp. 172, 176 (D.R.I. 1996) (MFNs violate the rule of reason if they "produce substantial anticompetitive effects in particular circumstances"); *United States v. Apple Inc.*, 952 F. Supp. 2d 638, 694 (S.D.N.Y. 2013) (MFN "did not promote competition, but destroyed it"); *United States v. Blue Cross Blue Shield of Mich.*, 809 F. Supp.

[28] *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce*, H.R. 1706, 111th Cong., at 228 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), available at http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf.

[29] *Id.* at 218. A recent study confirms that acceleration clauses in patent settlements rarely accelerate entry. *See* Keith M. Drake & Thomas G. McGuire, Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements (July 8, 2019), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3416632.

2d 665, 671 (E.D. Mich. 2011) (MFN "violates the rule of reason if it may suppress or even destroy competition, rather than promote competition") (internal quotations omitted); Jonathan B. Baker & Judith A. Chevalier, *The Competitive Consequences of Most-Favored-Nation Provisions*, 27 Antitrust, No. 2, at 20, 24 (Spring 2013) ("MFNs may . . . harm competition by assisting an incumbent in foreclosing the entry or expansion of rivals" or "it may simply dampen competition among non-coordinating rivals").

MFN-plus clauses employed by dominant firms are particularly suspect. *See Blue Cross Blue Shield of Mich.*, 809 F. Supp. 2d at 669; Steven C. Salop & Fiona Scott Morton, *Developing an Administrable MFN Enforcement Policy*, 27 Antitrust No. 2, at 15, 18 (Spring 2013). Just as MFNs may deter or dampen the incentives of competitors of the MFN holder to strive for better prices, so too the MFEs and MFEPs here essentially eliminated other generics' incentives to strive for an entry date equivalent to or even better than the date Teva had negotiated.

Gilead does not challenge the MFN analogy, but rather contends that "MFN provisions in settlement agreements are common and widely accepted as lawful." Gilead Mem. at 27. However, most MFNs in settlements (including the ones in the cases cited by Gilead) do not concern the entry conditions of rivals; indeed, most have no conceivable anticompetitive consequences or even any commercial impact. And when they do raise competition problems, courts decline to enforce them. *See, e.g., In re Chicken Antitrust Litig.*, 560 F. Supp. 943, 948–49 (N.D. Ga. 1979) (refusing to enforce MFN in settlement that would enable economically stronger competitors to eliminate marginal producers from the marketplace); *cf. United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 668 (1965) (MFN in union labor agreement with large operators violates Sherman Act where purpose and effect is to inhibit competition from rival producers). There is no basis for immunizing MFNs in settlements from the Sherman Act, particularly when agreed to by horizontal competitors. *See Trinko*, 540 U.S. at 408 (collusion is "the supreme evil of antitrust").

2. MFEs and MFEPs Are Inconsistent with the Hatch-Waxman Forfeiture Provisions.

Gilead contends that it would be "economically irrational" for a first-filing generic "to settle for an entry date without including an acceleration clause" because subsequent filers would be able to "usurp the benefits" of the first filer's patent challenge. Gilead Mem. at 28–29. However, a first filer that negotiates a *favorable* entry date based on the strength of the patent has little to fear that second filers

will obtain a more favorable entry date. Accordingly, there is no reason to believe that settlements without MFE clauses are "irrational" or impossible. *See* Drake & McGuire, *supra*, at 3 (acceleration clauses in patent settlements ubiquitous but not universal); *see also* Apotex 2009 Statement, *supra*, at 226 (prohibiting MFEs "will shorten the period of delay first filers are willing to accept in settlements").

More to the point, the risk of being usurped by second filers is a risk that the Hatch Waxman Act expressly contemplates by providing that a first filer will forfeit its 180-day period of exclusivity under certain circumstances, including if it fails to come to market promptly after a court decision that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I); *see Ranbaxy Labs., Ltd. v. Burwell*, 82 F. Supp. 3d 159, 166 (D. D.C. 2015) (Congress sought to ensure that first filer exclusivity "'cannot be used as a bottleneck to prevent additional generic competition'" (quoting Senator Schumer, a primary sponsor of forfeiture amendments, 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003))); *see id.* at 196 (forfeiture provisions "designed to eliminate 'parking' exclusivity rights and to speed generic drug's progress to market"). Congress intended that the threat of entry by second filers would motivate first filers to enter sooner. MFEs take that incentive away.

Furthermore, the MFEP clauses are quite unlike typical MFNs in settlement agreements because they guarantee that subsequent settlers will receive *worse* terms than the first settler. Gilead says that it is not anticompetitive "for a first filer patent challenger to demand—and receive—in settlement a period of exclusivity like the one accorded under the Hatch Waxman Act." Gilead Mem. at 29. However, Teva had forfeited its exclusivity with respect to Truvada (and possibly Atripla) by failing to obtain timely tentative approval from the FDA. 21 U.S.C. § 355(j)(5)(D)(i)(IV). So Gilead was offered Teva a hiatus from competition—via a private agreement among horizontal competitors—that Congress had specifically withheld. And Gilead precluded other generics from achieving *de facto* exclusivity that would have motivated them to continue the patent fight. It did that in order to discourage challenges to its weak patents.

3. *Actavis* Supports the Plaintiffs' Claims.

Gilead contends that acceleration clauses are lawful under *Actavis*, which established that "reverse payment" settlements are suspect under the antitrust laws. According to Gilead, an acceleration clause is not a reverse payment because "it simply sets an entry date for the patent challenger, with the

possibility that the patent challenger might be permitted to enter even earlier under certain circumstances." Gilead Mem. at 30. Gilead is wrong for several reasons. As an initial matter, a patent settlement may be unlawful under the antitrust laws even in the absence of a reverse payment. *See Actavis*, 570 U.S. at 149–51 (explaining that the Court's precedents "make clear that patent-related settlements can sometimes violate the antitrust laws" and "find[] challenged [anticompetitive] terms and conditions unlawful unless patent law policy offsets antitrust law policy strongly favoring competition"). Moreover, a settlement agreement with an acceleration clause is unlike an early-entry settlement *alone*, which *Actavis* countenanced.[30] *See id.* at 158.

"Payments" under *Actavis* need not be payments of cash. They extend to anything of value the patentee gives to the generic in exchange for the generic delaying entry into the market. *See, e.g.*, *King Drug*, 791 F.3d at 403 (holding that *Actavis* is not limited to cash payments and can include other valuable benefits); *In re Loestrin 24 FE Antitrust Litig.*, 261 F. Supp. 3d 307 (1st Cir. 2016) (same). The MFEs and MFEPs satisfy *Actavis*'s criteria for a suspect payment. *See* Michael A. Carrier, *Payment After* Actavis, 100 Iowa L. Rev. 7, 37–41 (2014); California Assembly Bill No. 824, Business: Preserving Access to Affordable Drugs (2019-2020 Reg. Sess.), approved by Governor, Oct. 8 2019 (clarifying that presumptively anticompetitive payment under California law includes an acceleration clause, among other things). By preserving (or indeed creating) a period of generic exclusivity for Teva, the MFEs and MFEPs are similar to agreements not to launch an "authorized generic," which courts uniformly hold are reverse payments. *See King Drug*, 791 F.3d at 411.

[30] Gilead argues that the FTC does not treat acceleration clauses as reverse payments, but the FTC's position is not so clear. The FTC's citation to *Actos* in *In re Impax Labs., Inc*, No. 9373, 2019 WL 1552939, at *22 (F.T.C. March 28, 2019), can hardly be read to endorse the view that acceleration clauses are *per se* procompetitive, particularly given the limited nature of *Actos*'s holding. Elsewhere, the FTC has suggested otherwise. *See* First Amended Compl., *FTC v. Cephalon, Inc.*, No. 2:08-cv-02141, ECF No. 40 at ¶ 60 (E.D. Pa. Aug. 12, 2009) (alleging that brand firm "provided an additional incentive to . . . First Filers to settle by including a 'most favored nation' clause'" the effect of which "was to make it less attractive for each successive generic company to continue to litigate or enter at risk because that clause would automatically permit each generic company that had settled to compete without any risk with any non-settling generic company"). Moreover, there is no indication that the FTC treats *MFEP*s as permissible, particularly when the first filer has forfeited its statutory exclusivity. (The acceleration clause referenced by the FTC in its *Actavis* brief, *see* Gilead Mem. 30, did not involve such a clause.) In any event, the FTC's failure to object to settlements with acceleration clauses would not immunize them under the Sherman Act. *Cf. Lipitor*, 868 F.3d at 263 ("[I]t is erroneous to conclude that the FTC's inaction equates to a determination that the settlement agreement does not run afoul of the Sherman Act.").

First, the clauses were very valuable to Teva. *Cf. Actavis*, 570 U.S. at 144 (recognizing that 180-day period of exclusivity for first filer can be "worth several hundred million dollars" and constitute the "vast majority of potential profits for a generic drug manufacturer") (internal quotation marks omitted). Given the number of subsequent filers lined up after Teva, *see* Compl. ¶¶ 335, 355, and particularly in light of its forfeiture of statutory exclusivity with respect to Truvada (and possibly Atripla), Teva faced a significant risk that it would not enjoy any exclusivity absent the clauses.

Second, because the clauses were very valuable to Teva, they enticed it to agree to delay entry. *Id.* ¶¶ 344, 360. As with a payment in cash or a no-AG agreement, "if the brand uses [an MFE] to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospect of a more competitive market)." *King Drug*, 791 F. 3d at 405. "In addition, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted." *Id.*

Third, Teva could not have obtained the equivalent of the MFEs and MFEPs even if it had won the patent cases. *See* Carrier, *supra*, at 39–42. This is plainly true with respect to Truvada (and possibly Atripla) as to which Teva had forfeited its exclusivity. But under no circumstances would a patent-case victory have *guaranteed* that no other generic would enter the market before Teva. *See Burwell*, 82 F. Supp. 3d at 165 ("While the 180-day exclusivity period holds out the promise of substantial monetary compensation for first-to-file generic manufacturers, it is not guaranteed.").

In short, the complaint plausibly alleges that the MFEs and MFEPs were intended to, and did, allow Gilead to extend its monopoly on Viread, Truvad, and Atripla, and to successfully transition its TDF-based franchise to its TAF-based products and their longer and broader No-Generics Restraints. *See Actavis*, 570 U.S. at 158 ("If the basic reason [for a reverse payment in a settlement agreement] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.").

4. Case Law on Acceleration Clauses Supports the Plaintiffs' Claim.

Gilead is incorrect in contending that the "only court to squarely address" acceleration clauses held them to be *per se* lawful. Gilead Mem. at 26 (citing the unpublished decision *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244 (RA), 2015 WL 5610752 (S.D.N.Y. Sep. 22, 2015)). A more recent

district court decision, *In re Loestrin*, 261 F. Supp. 3d at 333–34, refused to dismiss a complaint alleging that an acceleration clause was an anticompetitive reverse payment and rejected the argument that such clauses are inherently procompetitive and not subject to antitrust scrutiny.[31]

In any event, *In re Actos* did not hold that acceleration clauses are *per se* lawful, and it is distinguishable on several grounds.[32] First, the court concluded that the complaint in that case did not plausibly allege a "deterrent effect" on subsequent generic filers, but "another case may present circumstances in which such a deterrent effect is plausible." *In re Actos*, 2015 WL 5610752, at *15. Second, *In re Actos* did not involve a settling generic that had forfeited its statutory 180-day exclusivity. *See id.* (noting that "under the statutory scheme, there is no plausible scenario in which another generic would have been entitled to earlier entry"). Third, *In re Actos* did not consider whether the addition of an MFEP clause would have altered its analysis. Fourth, *In re Actos* expressly declined to consider whether an acceleration clause may be unlawful under the rule of reason even if it cannot be characterized as a reverse payment. *Id.* at *16. [33]

After "factual and expert discovery," Gilead may seek to show "that there were no anticompetitive effects, or that, under the second prong of the rule of reason analysis, the 'challenged payment was justified by some procompetitive objective.'" *In re Loestrin*, 261 F. Supp. 3d at 334 (quoting *In re Nexium* (*Esomeprazol*) *Antitrust Litig.*, 42 F. Supp. 2d 231, 262-63 (D. Mass. 2014)). But Gilead's efforts to establish that acceleration clauses are always procompetitive as a matter of law should be rejected. *See UFCW Local 1776*, 74 F. Supp. 2d at 1067 & n.16 (procompetitive justifications "may

[31] To be sure, the acceleration clause in *In re Loestrin* was only one component of an alleged reverse payment, which also included a no-AG agreement and side deals, but that fact was not essential to the reasoning of the court. Rather, the court concluded that the plaintiffs, as here, "plausibly alleged that the acceleration clause had anticompetitive effects." *In re Loestrin*, 261 F. Supp. 3d at 334. Moreover, here the reverse payment settlement is only one component of a larger scheme to monopolize the cART market. *Cf. In re NFL's Sunday Ticket*, 933 F.3d at 1152 (courts must "take a holistic look at how the interlocking agreements actually impact competition.").

[32] Nor is *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) apt. It applied the scope-of-the patent test, which was overruled by *Actavis*. *See UFCW Local 1776*, 74 F. Supp. 3d at 1068.

[33] To the extent that the court in *Actos* opined that an acceleration clause can never be a reverse payment, it is wrong and inconsistent with *Loestrin*. The court misapprehended the issue under *Actavis*. It is not whether there would be "more diverse generic competition" in the absence of an acceleration clause, but whether initial entry by generics would have been sooner. *Actos*, 2015 WL 5610752, at *16. Moreover, the presence of a reverse payment does not make a settlement "unlawful," *id.*; it merely shifts the burden to the defendant to justify it. *Actavis*, 570 U.S. at 156.

not be raised in a motion to dismiss"). Finally, and independently, even if Gilead's conduct was not separately unlawful it may be part of a broader anticompetitive pattern and practice.

E. The Complaint Sufficiently Alleges an Overarching Anticompetitive Scheme

While Defendants seek to scrutinize the relevant acts in isolation, Plaintiffs allege they were part of an overall anticompetitive scheme. The allegations concerning Gilead's product-switching tactics and Gilead providing MFE and MFEPs to Teva, even if not independently unlawful, are part of an overall scheme to monopolize anchored by the No-Generics Restraints that *collectively* produced anticompetitive effects. Compl. ¶¶ 1, 445, 454, 463, 472, 480, 488. Thus, even if Defendants were correct that each individual act was innocuous, that still would not justify dismissal of Plaintiffs' case.

"[T]he law requires that the 'character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.'" *In re NFL's Sunday Ticket*, 933 F.3d at 1152 (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698-99 (1962)). "[W]e must give plaintiffs 'the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.'" *Id.* at 1152–53 (quoting *City of Long Beach v. Standard Oil Co. of California*, 872 F.2d 1401, 1404–05 (9th Cir. 1989), *opinion amended on denial of reh'g*, 886 F.2d 246 (9th Cir. 1989)). As such, even if every individual act in isolation produced no anticompetitive effect, they may still comprise an unlawful scheme where the acts collectively "work[] in tandem" to "restrain competition." *Id.* at 1153; *see, e.g.*, *Schneiderman*, 787 F.3d at 654–55 (combination of acts may be anticompetitive even though "neither [individual act] alone is anticompetitive"); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Plaintiffs are entitled to claim that . . . acts as a group have an anticompetitive effect even if the acts taken separately do not.").

Plaintiffs allege that the individual acts of the overarching scheme do "work in tandem" to "restrain competition." The No-Generics Restraints prevented the respective licensors from competing against Gilead with the same or comparable TDF-based FDCs, while the MFE and MFEPs delayed generic introduction of TDF, TDF/TFC, and TDF/FTC/EFV, the combined effect of which prolonged Gilead's monopoly on TDF-based products. Compl. ¶¶ 3-4, 11. Moreover, delaying TDF-based competition enabled Gilead to delay TAF's introduction, when further No-Generics Restraints, along

with Gilead's unilateral tactics manipulating the prescription base, continued to prevent competition in the marketplace. *Id.* at ¶¶ 7-10, 12. Plaintiffs do plausibly allege the individual acts and agreements produced anticompetitive effects and are unlawful. But even if that weren't true, Defendants' arguments attacking them in isolation cannot result in dismissal where, as here, their "overall combined effect" is alleged to have restrained competition and prolonged Gilead's monopoly in the cART market.[34] *Id.* at ¶¶ 1-2, 6, 13-14; *see City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements.").

F. The Complaint Sufficiently Alleges Market Power

Plaintiffs allege that Defendants' No-Generics Restraints are illegal *per se*. *See, e.g.*, Compl. ¶¶ 94, 498, 505, 513, 520, 528, 535. Conduct that is illegal *per se* does not require market definition and proof of market power. *See Big Bear Lodging Ass'n v. Snow Summit, Inc.*, 182 F.3d 1096, 1105 (9th Cir. 1999).

To the extent that certain other claims require an allegation of market power, the Complaint alleges direct evidence of such power, including that Defendants in fact caused anticompetitive effects, had astronomically high profit margins, and never reduced their prices to the competitive level in response to entry or pricing actions by other products in the therapeutic class. Compl. ¶¶ 373–74; *see, e.g., Indiana Fed'n of Dentists*, 476 U.S. at 60–61 ("Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects.") (internal citations and quotation marks omitted); *Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325, 1336 (7th Cir. 1986) ("Market share is just a way of estimating market power, which is the ultimate consideration. When there are better ways to estimate market power, the court should use

[34] While the No-Generics-Restraints with respect to Evotaz, Symtuza, and Prezcobix, prevented Gilead from offering a competing product against BMS and Janssen, Plaintiffs also allege those agreements had a synergistic effect with the other conduct and agreements to prolong Gilead's monopoly. Compl. ¶¶ 5. 131–38, 163–75 (alleging agreements were a quid pro quo for prolonging Gilead's monopoly and additionally anticompetitive).

them"); *Allen-Myland, Inc. v. Int'l Bus. Machines Corp.*, 33 F.3d 194, 209 (3d Cir. 1994) (same).

Plaintiffs also plead market power by alleging high market shares within relevant geographic and product markets. Compl. ¶¶ 375–76, 380, 397. When pleading market power indirectly by alleging high market shares, the plaintiff must allege both that a relevant market exists and that the defendant has power within that market. *Am. Ad Mgmt., Inc. v. GTE Corp.*, 92 F.3d 781, 790 (9th Cir. 1996). However, there is no requirement that the relevant market be pleaded with specificity and, as the validity of the relevant market is typically a factual element properly subjected to factual testing at summary judgment or trial, an antitrust complaint's relevant market definition is sufficient at the motion to dismiss phase unless "facially unsustainable." *Newcal Indus., Inc. v. Ikon Office Sol.*, 513 F.3d 1038, 1045 (9th Cir. 2008); *Oltz v. St. Peter's Cmty. Hosp.*, 861 F.2d 1440, 1446 (9th Cir. 1988) ("Defining the relevant market is a factual inquiry ordinarily reserved for the jury."); *see also High Tech. Careers v. San Jose Mercury News*, 996 F.2d 987, 990 (9th Cir. 1993) (relevant market definition depends on "a factual inquiry") (quotations omitted).[35]

Defendants' arguments concern only the relevant product markets (Gilead Mem. at 31–34; Janssen Mem. at 10–11; JT Mem. at 4),[36] and center on the faulty proposition that Plaintiffs may plead only *one* relevant product market. This is incorrect. In antitrust litigation, markets are defined around specific theories of anticompetitive harm. *See, e.g., U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) ("the nature of the claim can affect the proper market definition"); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 668 (2016) ("[i]t must be remembered that articulating a relevant market definition is not an end in itself, but is in the service of answering the question of market power"); Franklin Fisher, *Detecting Market Power*, in ABA Section of Antitrust Law, Issues in Competition Law And Policy 355 (2008) ("Absent knowing what the alleged act is, one typically does not know where to begin in analyzing the existence of market power that could enable the alleged act to reduce competition."); Ariel Katz, *Making Sense of Nonsense: Intellectual Property, Antitrust, and*

[35] Despite Gilead's assertion, *Siegler v. Sorrento Therapeautics, Inc.* does not hold otherwise. There, the plaintiff's complaint was dismissed for the lack of clarity regarding the relevant market, a "complete lack of any pleadings as to interchangeability to fungibility," and the non-existence of the asserted market. *Siegler v. Sorrento Therapeutics, Inc.*, No. 3:18-CV-01681-GPC-NLS, 2019 WL 3532294, at *15 (S.D. Cal. Aug. 2, 2019). None of that is true here.

[36] Defendants do not contest the geographic market, the entire United States. Compl. ¶ 397.

Market Power, 49 Ariz. L. Rev. 837, 880 (2007) ("Without a specific challenged conduct, a specific context, and an identified antitrust question that demands an answer, the market is an empty concept in antitrust analysis.").

Where there are multiple theories of harm, they might need to be analyzed in the context of multiple relevant markets. *See, e.g.*, *United States v. Philadelphia Nat. Bank*, 374 U.S. 321, 357 (1963) (explaining that the proper question to determine market is "where, within the area of competitive overlap, the effect of the merger on competition will be direct and immediate"); *Brown Shoe Co. v. United States*, 370 U.S. 294, 325–28, 336–39 (1962) (defining one relevant market for the vertical aspects of a merger and a different relevant market for the horizontal aspects of the merger); *U.S. Healthcare,*, 986 F.2d at 598 (confirming that "the nature of the claim can affect the proper market definition"); *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 40–48 (D.D.C. 2015) (finding multiple markets to be relevant); Herbert Hovenkamp, *Federal Antitrust Policy* § 3.2c, at 118 (5th ed. 2016) ("The existence of a relatively large relevant market does not preclude the existence of smaller relevant markets within it."). Because Plaintiffs allege that the purpose and effect of Defendants' conduct was to unlawfully impair competition in multiple ways, such harm is properly evaluated in distinct markets.

Rather than establish that either of Plaintiffs' two principal types of product market definitions is facially unsustainable, Defendants improperly pit the two market definitions against each other in a contrived effort to create inconsistency. Gilead Mem. at 32–33; Janssen Mem. at 11; JT Mem. at 4. A relevant product market properly consists of "commodities reasonably interchangeable by consumers for the same purposes." *In re Nexium* (*Esomeprazole*) *Antitrust Litig.*, 968 F. Supp. 2d 367, 395 (D. Mass. 2013) (quotation omitted); *see also Brown Shoe*, 370 U.S. at 325 ("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.") (emphasis added). Products are not reasonably interchangeable merely because they share similar forms or functions, but rather "[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes." *In re Nexium*, 968 F. Supp. 2d at 387–88 (quotation omitted). Plaintiffs have sufficiently pleaded two principal types of markets, each aligning with a theory of harm and encompassing the only relevant interchangeable

products.

In any event, Defendants' argument that Plaintiffs must pick a single market cannot help them, because their conduct is unlawful regardless of which market is analyzed.

1. Defendants' Anticompetitive Suppression of Generic Competition Is Properly Viewed Within the Market for Each Brand Name Product and Its Generic Equivalent.

Plaintiffs allege that one purpose and effect of Defendants' No-Generics Restraints and other unlawful conduct was to impair competition from generic versions of each of the brand name drugs at issue. Under the test of reasonable interchangeability, the relevant market for evaluating this conduct is the market for each of the brand name products and its AB-rated generic equivalent.[37] *Coalition for ICANN Transparency, Inc. v. VeriSign*, 611 F.3d 495, 507 (2010); Compl. ¶¶ 376–78. At competitive prices, none of the brand drugs exhibits significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of the brand drugs. *Id.* ¶ 362. Each of the brand name drugs is differentiated from all drug products other than AB-rated generic versions. They differ in their uses, suitability for the prescribed use, and side effect profiles. *Id* ¶ 363. Defendants' argument that there are other drugs to treat HIV infection is irrelevant; courts routinely recognize a relevant product market of one product, or one product and its AB-rated generic. *See, e.g.*, *Eastman Kodak*, 504 U.S. at 482 ("This Court's prior cases support the proposition that in some instances one brand of a product can constitute a separate market."); *In re Nexium*, 968 F. Supp. 2d at 388 (holding a single branded drug and its generic to be a plausible relevant market); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005) (same); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680–81 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003) (same).

Defendants' conduct caused supracompetitive pricing within this market. Typically, AB-rated generics are initially priced significantly below the corresponding branded drug. As a result, upon its entry, the generic rapidly takes sales away from the originator drug. As more AB-rated versions of the branded drug enter the market, prices predictably plunge even further. Compl. ¶ 401. Therefore, each Defendant needed to control only each of its brand drugs and its AB-rated generic equivalents, and no

[37] Defendants misstate Plaintiffs' theory, improperly conflating the substitutability of a brand name product versus its generic equivalent *within an FDC product* with the substitutability *between FDC products.* Gilead Mem. at 32–33; Janssen Mem. at 11.

other products, in order to maintain the price of the brand drug profitably at supracompetitive prices. *Id.* ¶ 371. That other drugs existed within the broader cART market does not insulate Defendants from the competitive harm caused within each brand/generic market. *See, e.g.*, *In re Aggrenox*, 199 F. Supp. 3d at 666 (finding that competition with "imperfectly interchangeable substitutes" does not prevent findings of market power and supracompetitive pricing).

Plaintiffs also detail conditions in the HIV therapeutic class that allow Defendants to profitably raise prices above the competitive level and reduces the price elasticity of demand. This marketplace is "stickier" than normal competitive marketplaces outside the pharmaceutical industry. Once a physician and patient find a brand name, or its AB-generic equivalent, that is well tolerated, the doctor and patient are very unlikely to switch to a different HIV drug based on variations of price of 10% or less, justifying treating them as separate markets. *See, e.g.*, *California v. Sutter Health Sys.*, 130 F. Supp. 2d 1109, 1128 (N.D. Cal. 2001); Compl. ¶¶ 181–82, 364. As Plaintiffs allege, the result of these pharmaceutical marketplace imperfections is that brand manufacturers gain and maintain market power with respect to many branded HIV prescription pharmaceuticals, including those at issue here. *See, e.g.*, *In re Loestrin*, 261 F. Supp. 3d at 328 (upholding market definition at motion to dismiss, despite existence of other similar birth control drugs, where plaintiffs pled characteristics of the pharmaceutical marketplace affecting the relationship between price and demand); Compl. ¶ 369.

Contrary to Defendants' assertions, Plaintiffs plainly allege that Defendants had market power over each of the relevant FDCs and each FDC's AB-rated generic equivalent.[38] Plaintiffs allege that the gross margin on each drug was at least *70%*. Compl. ¶ 373. Defendants' market power is further demonstrated by Defendants' power to maintain the price of those brand drugs at supracompetitive levels without losing sufficient sales to other products, except for AB-rated generic versions of those brand

[38] "Gilead had market power over each of Viread, Emtriva, Truvada, Vemlidy, Descovy, Tybost, and their generic equivalents; Gilead and BMS had market power over each of Atripla and Evotaz and their generic equivalents; Gilead and Japan Tobacco had market power over each of Stribild and Genvoya and their generic equivalents; Gilead and Janssen had market power over each of Complera, Odefsey, Prezcobix, and Symtuza and their generic equivalents; BMS had market power over Reyataz and its generic equivalents; and Janssen had market power over each of Edurant and Prezitsa and their generic equivalents." Compl. ¶ 361; *see also id.* ¶ 378 (detailing Defendants' market power as to each of these products).

drugs, to make the supracompetitive prices unprofitable.[39] *Id.* ¶ 369. Defendants sold these brand drugs at prices well in excess of marginal costs, substantially in excess of the competitive price, and enjoyed unusually high profit margins—evidence of their market power. *Id*. And Gilead agreed to share profits in exchange for No-Generics Restraints, which would make no economic sense unless it would profit from continuing its market power in each of those markets after its patents expired. But for Defendants' unlawful conduct, each of the relevant drugs would already be facing competition from AB-rated drugs and/or comparable FDCs, or would face such competition sooner than it will. *Id.* ¶ 399. Plaintiffs sufficiently allege that Defendants engaged in anticompetitive behavior within a relevant product market in which each exercised market power.

2. Defendants' Anticompetitive Suppression of Competition within the Broader Therapeutic Class Is Properly Viewed Within the cART Market.

Plaintiffs allege that an additional and/or alternative purpose and effect of Defendants' unlawful conduct was to impair competition among drugs used in the cART regimen. Specifically, Gilead used its monopoly in the cART Market—secured in part through its dominance of Tenofovir, a central TDF NRTI in the cART regimen—to unlawfully extend Defendants' patent protection for their drugs, impair entry by would-be generic or comparable competitors in the market, and charge supracompetitive prices for across the cART Market.[40] *See, e.g.*, Compl. ¶¶ 1, 176–241, 380. These allegations constitute a separate theory of harm, and thus impact a separate market. The relevant product market for these allegations is the larger cART Market, as this is the market in which Gilead's monopoly arose and in which Defendants' anticompetitive practices had the intended and predictable effect of causing market-wide antitrust injury in the form of supracompetitive pricing and diminished output.

There is nothing inconsistent in the idea of a broad market for multiple drugs coexisting with

[39] The existence of other branded HIV drugs has not constrained the price of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, or Symtuza to the competitive level. Compl. ¶ 370. Defendants' unsubstantiated claim of "robust interbrand competition among FDCs" is therefore without merit, and Plaintiffs' allegations as to interchangeability must be taken as true.

[40] The cART Market is defined as a set of modern antiretroviral drug regimens used to treat HIV that comprise a combination of drugs. Compl. ¶ 2. The cART regimen treatment is distinct from other drugs and regimens used to treat HIV. *Id.* ¶¶ 2, 381. Janssen's attempts to redefine the cART Market in order to exclude its own products is unsupported and unavailing. It is the Complaint, not Janssen's motion to dismiss, that defines the market for purposes of this motion.

narrower markets defined to analyze other conduct or harm. This is illustrated through a simple analogy: Two suppliers agree to fix prices on apples. One of those two suppliers is also a supplier of a wide variety of other types of fruit, and also agrees to fix prices with other suppliers on oranges, bananas, and pears, with the effect that prices on apples were higher than they would have been if the two suppliers had "only" fixed the prices of apples. Clearly multiple markets are relevant: markets for each of the specific types of price-fixed fruits, and the broader all-fruit market. *See* David Glasner and Sean P. Sullivan, *The Logic of Market Definition*, ANTITRUST L.J. (forthcoming 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3223025 (explaining that courts should consider different theories of harm by examining its effects through the lens of multiple markets). Plaintiffs' Complaint is replete with facts establishing the existence of, and harm in, the cART Market.

Gilead's attempt to compare Plaintiff's Complaint to the complaint at issue in *AHF* is unavailing. Gilead Mem. at 33–34. There, the court held that plaintiffs failed to allege facts supporting the proffered market definition. *AHF*, 2016 WL 3648623, at *7, 23. Here, Plaintiffs detail the market's contours (*see, e.g.*, Compl. ¶ 2), how Gilead used its patents and No-Generics Restraints to dominate that market (*see, e.g., id.* ¶¶ 2, 57, 389), how that anticompetitive conduct caused antitrust injury in the form of delayed entry of safer, better drugs and supracompetitive prices for Defendants' drugs (*see, e.g., id.* ¶¶ 196-198, 269-287, 395), and how the No-Generics Restraints provided several means for Gilead's coconspirators to share in the supracompetitive profits and benefit from the dampened competition within the cART market (*see, e.g., id.* ¶¶ 178, 180, 187, 400).

Plaintiffs sufficiently allege that Defendants exercised market power within the cART market. Specifically, Plaintiffs allege that more than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's cART products every day, securing Gilead a market share of between 70 and 93% of the cART. *Id.* ¶¶ 2, 389–91. This dominance had the predictable effect of causing market-wide price increases. *Id.* ¶ 403.

G. The Complaint Sufficiently Alleges State Law Claims

1. The Court Should Defer Consideration of Absent Class Members' Standing Under Sister State Laws for Class Certification.

Gilead argues that the named Plaintiffs lack Article III standing to pursue state law claims of

absent class members who purchased cART drugs in states other than those in which the named Plaintiffs purchased. Gilead's argument conflates questions of standing with questions of class certification.

Plaintiffs have unquestionably pleaded antitrust injury caused by Defendants' conduct and thus have standing. As a result of the unlawful conduct detailed in the Complaint, Plaintiffs and other class members were deprived of the opportunity to purchase lower-priced generic or comparable products instead of expensive brand products, forced to pay artificially inflated prices for the brand products and/or paid for products that were inferior to what they would have been absent Gilead and its co-conspirators' conduct. *See, e.g.*, Compl. ¶¶ 180, 404, 512–18, 522–26. That is true of all class members. That is classic antitrust injury.

The Ninth Circuit has held that dissimilarities between the claims of class representatives and those of absent class members "are relevant only to class certification, not to standing." *Melendres v. Arpaio*, 784 F.3d 1254, 1263 (9th Cir. 2015) (quoting 1 William B. Rubenstein, Newberg on Class Actions § 2:6 (5th ed. 2019)). This Court has applied *Melendres* to specifically hold that named plaintiffs need not be found to have "standing" to pursue the claims of absent class members whose claims arise under other state laws: "[O]nce the named plaintiffs demonstrate their individual standing to sue, as Plaintiffs have done here, . . . the standing inquiry may be concluded; the disjuncture may better be addressed in the context of class certification." *In re Chrysler-Dodge-Jeep Ecodiesel Mktg., Sales Practices, & Prod. Liab. Litig.*, 295 F. Supp. 3d 927, 955–56 (N.D. Cal. 2018) (Chen, J.). While *Melendres* did not directly confront the issue of sister-state claims, "this distinction appears immaterial." *Id.*; *see also Pecanha v. The Hain Celestial Grp., Inc.*, No. 17-CV-04517-EMC, 2018 WL 534299, at *9 (N.D. Cal. Jan. 24, 2018) (Chen, J.) ("[T]his case involves named plaintiffs who cannot bring legal claims pursuant to state laws for states where they do not reside. While this is a distinction between *Melendres* and the instant case, the distinction is not material for purposes of taking the class certification approach."); *Kutza v. Williams-Sonoma, Inc.*, No. 18-CV-03534-RS, 2018 WL 5886611, at *3 (N.D. Cal. Nov. 9, 2018) (declining to dismiss nationwide claims when named class members were exclusively from California).[41]

[41] A district court that went the other way on this issue expressly noted its disagreement with this Court. *See Jones v. Micron Tech. Inc.*, No. 18-CV-02518-JSW, 2019 WL 4232417, at *6 (N.D. Cal. Sept. 3, 2019) (White, J.) ("the Court respectfully disagrees with the reasoning in *Chrysler-Dodge-Jeep*").

Numerous courts have followed this approach. *See, e.g., In re Asacol Antitrust Litig.*, 907 F.3d 42, 49 (1st Cir. 2018) (varying state laws were "materially the same," and therefore any differences had "no relevant bearing on the personal stake of the named plaintiffs in litigating the case to secure such judgments"); *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 93 (2d Cir. 2018) ("[A]s long as the named plaintiffs have standing to sue the named defendants, any concern about whether it is proper for a class to include out-of-state, nonparty class members with claims subject to different state laws is a question of predominance under Rule 23(b)(3), not a question of 'adjudicatory competence' under Article III.") (internal citations omitted); *see also In re Zetia* (*Ezetimibe*) *Antitrust Litig.*, No. CV 2:18-MD-2836, 2019 WL 1397228, at *23 (E.D. Va. Feb. 6, 2019), *report and recommendation adopted as modified,* No. MDL 2:18MD2836, 2019 WL 3761680 (E.D. Va. Aug. 9, 2019) ("[W]hether named plaintiffs may properly represent absent class members is *exactly* the focus of the Rule 23 class certification analysis. The named class representatives are not themselves seeking recovery under the laws of foreign states.") (emphasis in original); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 831 (E.D. Pa. 2019) (allowing sister-state claims to survive motion to dismiss when state law claims "largely parallel those of the putative class members").

2. Plaintiffs May Apply California's Cartwright Act to a Nationwide Class.

California's Cartwright Act may be applied to a nationwide class where, as here, the other interested states do not have an interest in barring their own citizens from recovering damages. *In re Qualcomm*, 328 F.R.D. 280, 312 (N.D. Cal. 2018) (citing *In re Qualcomm*, 292 F. Supp. 2d 948, 977–81 (N.D. Cal. 2017)), *on appeal sub nom. Stromburg v. Qualcomm, Inc.*, No. 18-80135 (9th Cir. Oct. 11, 2018). Gilead devotes a single sentence to their contrary argument. This is insufficient.

In fact, a full choice-of-law analysis is not appropriate at this stage in the litigation. It is "better suited for the class certification stage" where, as here, "the record with respect to balancing the competing states' interests is not sufficiently developed." *Bias v. Wells Fargo & Co.*, 942 F. Supp. 2d 915, 928 (N.D. Cal. 2013).[42] This is particularly true "when dealing with a potential nationwide class

[42] *See, e.g., Forcellati v. Hyland's, Inc.*, 876 F Supp. 2d 1155, 1159 (C.D. Cal. 2012) (finding that choice-of-law analysis should happen at class certification because "[u]ntil the [p]arties have explored the facts in this case, it would be premature to speculate about whether differences in various states' consumer protections laws are material.")

action" where the analysis is "more difficult, and premature" at the motion to dismiss phase. *Id.* (citation omitted); *see also Ramirez v. Baxter Credit Union*, No. 16-CV-03765-SI, 2017 WL 1064991, at *7 (N.D. Cal. Mar. 21, 2017) (choice of law analysis in nationwide class action premature at motion to dismiss); *Nguyen v. Barnes & Noble Inc.*, No. SA CV 12-812-JLS(RNBx), 2015 WL 12766050, at *4 (C.D. Cal. Nov. 23, 2015) (deferring choice of law analysis until class certification and noting that "most courts in [the Ninth Circuit] hold that a claim should not be dismissed based on a conflict of law analysis at the pleading stage, especially "when dealing with a potential nationwide class action.") (citation omitted); *Andriesian v. Cosmetic Dermatology, Inc.*, No. 3:14-CV-01600-ST, 2015 WL 1638729, at *11 (D. Or. Mar. 3, 2015) (collecting cases), *report and recommendation adopted*, No. 3:14-CV-01600-ST, 2015 WL 1925944 (D. Or. Apr. 28, 2015).

To the extent the Court wishes to analyze the choice-of-law question at this stage, Plaintiffs have pleaded adequate facts to establish that the nationwide application of the Cartwright Act would not violate Gilead's due process rights. Gilead has failed to meet its burden to show otherwise.

a. Applying the Cartwright Act Comports with Due Process.

Gilead's claim that nationwide application of the Cartwright Act would violate due process is unsupported by the facts and incorrect as a matter of law. The "modest restrictions" of due process "on the application of foreign law" are satisfied when California has "a significant contact or significant aggregation of contacts, creating state interests, such that choice of law is neither arbitrary nor fundamentally unfair." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 818 (1985); *see also AT&T Mobility LLC v. AU Optronics Corp.*, 707 F.3d 1106, 1007 (9th Cir. 2013); *Qualcomm*, 328 F.R.D. at 312. Here, with California-based Gilead masterminding the scheme, such contacts are omnipresent. *See, e.g., AT&T Mobility*, 707 F.3d at 1113 ("[A]nticompetitive conduct by a defendant within a state . . . establishes a significant aggregation of contacts.") (citation and footnote omitted).

b. Gilead Has Not Even Attempted to Meet Its "Substantial Burden" to Overcome the Presumption that California Law Applies.

As the complaint alleges sufficient California contacts, "the Court presumes that such law applies to the claims of the nationwide class unless the defendants meet the 'substantial burden' of showing that foreign law, rather than California law, applies." *Keilholtz v. Lennox Health Prods. Inc.*, 268 F.R.D. 330, 340 (N.D. Cal. 2010) (applying California law to nationwide class where defendants' conduct emanated

from California). "The fact that two or more states are involved does not in itself indicate there is a conflict of laws problem." *Washington Mut. Bank, FA v. Superior Court*, 24 Cal.4th 906, 919–20 (2001). As the proponent of another forum's law, Gilead bears the burden of identifying the applicable law, establishing that the other forum's law differs materially from California's, and demonstrating how applying that law will further the interest of that jurisdiction. *Id.* Gilead has offered no evidence of the relevant law in *any* other jurisdiction, let alone articulated material differences or competing interests. The motion should be denied on this basis alone. *See Tasion Commc'ns, Inc. v. Ubiquiti Networks, Inc.*, No. C-13-1803 EMC, 2013 WL 4530470, at *11–12 (N.D. Cal. Aug. 26, 2013) (Chen, J.).

c. Gilead Fails to Demonstrate Any "True Conflict."

Because Gilead failed to meet its burden at the first steps in the choice-of-law analysis (the difference between California and any other law), let alone identify any conflict, "this Court does not reach the issue of which jurisdiction has the greatest interest in applying its law to Plaintiff's claims." *Id.* at *12. Nonetheless, California has a clear interest in furthering the primary goal of the Cartwright Act—eliminating restraints of trade and impairments to the free market—to punish and deter Gilead's unlawful and anticompetitive conduct that occurred within its borders. No foreign state has an interest in preventing its citizens from recovering for the harms caused by such conduct. *Qualcomm*, 328 F.R.D. at 313–14 (explaining that the interest of foreign non-repealer states is in protecting businesses domiciled in that state by limiting suits for damages to those brought by direct purchasers, *not* in denying recovery to citizens of its state). As for the non-U.S. based defendants, none have any expectation in the application of one state's laws over another or that the application of California law offends due process. *See, e.g.*, *In re Lithium Ion Batteries Antitrust Litig.*, No. 13-MD-2420 YGR, 2017 WL 1391491, at *13 (N.D. Cal. Apr. 12, 2017); *In re Optical Disk Drive Antitrust Litig.*, No. 3:10-MD-2143 RS, 2016 WL 467444, at *12 (N.D. Cal. Feb. 8, 2016).

To the extent that there may be other states' interests in play (and whether this will be the case cannot be determined until after the motions to dismiss are ruled upon, further counseling in favor of deciding this issue at the class certification stage), they do not necessarily support Gilead's positions. For example, New York, where the BMS entities are located, has enacted the Donnelly Act which, like the Cartwright Act, aims to prohibit contracts and agreements that restrain competition. *See* N.Y. Gen.

Bus. Law § 340(1); *see also In re Aluminum Warehousing Antitrust Litig.*, 95 F. Supp .3d 419, 456 (S.D.N.Y. 2015) ("[T]he Donnelly Act and the Cartwright Act are modeled on §1 of the Sherman Act [and the] requirements for establishing claims under these statutes are essentially the same as those for doing so under the Sherman Act."); *Universal Grading Serv. v. eBay, Inc.*, No. C-09-2755 RMW, 2012 WL 70644, at *10 (N.D. Cal. Jan. 9, 2012), *aff'd sub nom. Universal Grading Serv., LLC v. eBay, Inc.*, 563 F. App'x 571 (9th Cir. 2014) ("As with the Donnelly Act, it is well established that interpretation of federal antitrust law is . . . applicable to the Cartwright Act."). Gilead's choice of law argument fails.[43]

3. Plaintiffs Have Standing Under the Laws of Illinois, Puerto Rico, Rhode Island, Utah, Maryland, and Massachusetts.

Gilead contends the laws of six jurisdictions "bar" Plaintiffs from pursing their state law antitrust claims as indirect purchasers. Gilead Mem. at 35–36. Gilead is wrong as to each.

Gilead first contends that, despite the Illinois Antitrust Act ("IAA") authorizing indirect purchasers to pursue antitrust claims, Illinois actually prohibits Plaintiffs from pursuing an indirect purchaser claim in this Court as a class action. But the statutory language Gilead relies upon only prohibits class actions *in Illinois state court*; it provides that "no person other than the Attorney General of this State shall be authorized to maintain a class action *in any court of this State* for indirect purchasers asserting claims under this Act." 740 Ill. Comp. Stat. § 10/7(2) (emphasis added). Pursuant to this express statutory language, and applying the Supreme Court's decision in *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393 (2010), the procedural limitations applicable in state court do not trump Rule 23, which governs and authorizes class claims to proceed in *federal* court. *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 817–18 (N.D. Ill. 2017) (applying Illinois state law and holding IAA restriction on indirect purchaser class cases does not apply to cases brought in federal court); *Rockford*, 360 F. Supp. 3d at 763–65 (same); *In re Lithium Ion Batteries*, 2014 WL 4955377, at *20–21 (same); *In re EpiPen*, 336 F. Supp. 3d at 1311–12 (same); *In re Zetia*, 2019 WL 1397228, at

[43] Even if Gilead had met its burden on the choice-of-laws issue, dismissal is nonetheless improper because it "offers no explanation for why the fact that California law did not apply would necessarily require dismissal of Plaintiff's claims in this forum. Defendant offers no argument that venue is improper in this District, and this Court routinely applies the law of other jurisdictions in cases pending before it." *Tasion Commc'ns*, 2013 WL 4530470, at *12.

*25–26 (same); *In re Solodyn* (*Minocycline Hydrochloride*) *Antitrust Litig.*, No. 14-MD-02503-DJC, 2015 WL 5458570, at *16–17 (D. Mass. Sept. 16, 2015) (same); *In re Aggrenox Antitrust Litig.*, No. 3:14-MD-2516, 2016 WL 4204478, at *5–6 (D. Conn. Aug. 9, 2016) (same).[44]

Gilead's assertion that the remaining five states' laws bar claims by indirect purchasers similarly fails. First, Plaintiffs may bring claims under the Puerto Rico Anti-Monopoly Act. The express language of the statute broadly permits "[a]ny person" subject to antitrust injury to bring suit. 10 L.P.R.A. § 268. Courts have thus interpreted the statute to permit indirect purchasers to bring antitrust claims for damages. *See Rivera-Muniz v. Horizon Lines Inc.*, 737 F. Supp. 2d 57, 61 (D.P.R. 2010). As the *Rivera-Muniz* court explained, the Puerto Rico Supreme Court has "unequivocally rejected limitations to private antitrust standing," including the federal limitation announced in *Illinois Brick*. *Rivera-Muniz v. Horizon Lines Inc.*, No. 09–2081 (GAG), 2010 WL 3703737, at *1 (D.P.R. Sept. 13, 2010). Despite the absence of an *Illinois Brick* repealer statute, these interpretations of Puerto Rico law counsel against dismissal. *See Actavis*, 2018 WL 7197233, at *23 (adopting the reasoning of *Rivera-Muniz* and the Puerto Rican Supreme Court and finding indirect purchasers have standing in pharmaceutical antitrust case).

Likewise, the Rhode Island Antitrust Act was amended to enact an *Illinois Brick* repealer provision effective July 15, 2013. *See* R.I. Gen. Laws § 6-36-7(d). Gilead contends that damages are available only for conduct which occurred after that date. This is incorrect. The repealer provision should be applied retroactively. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 273 (1994); see *also Pion v. Bess Eaton Donuts Flour Co.*, 637 A.2d 367, 371 (R.I. 1994) ("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."). Even prior to the 2013 amendment, Rhode Island allowed "[a]ny person or public body" to bring suit under the RIAA. As a result, the 2013 amendment was a non-

[44] Because Plaintiffs' IAA claim may proceed, so may their claims under the Illinois Consumer Fraud and Deceptive Business Practices Act ("ILCFA"). *See Siegel v. Shell Oil Co.*, 480 F. Supp. 2d 1034, 1046–48 (N.D. Ill. 2007) (consumers can bring an ILCFA when conduct is also actionable under the IAA); *Batson v. Live Nation Entm't, Inc.*, 746 F.3d 827, 831 (7th Cir. 2014) ("an unfair practice might be covered by both the antitrust law and the [Illinois] Consumer Fraud Act"); *Sergeants Benevolent Assoc. Health & Welfare Fund v. Actavis, PLC*, No. 15 CIV 6549 (CM), 2018 WL 7197233, at *41–43 (S.D.N.Y. Dec. 26, 2018) (allowing ILCFA claim premised on antitrust conduct to proceed).

substantive confirmation that Rhode Island does not follow *Illinois Brick*.[45]

The Maryland Antitrust Act was similarly amended in 2017 to add an *Illinois Brick* repealer provision establishing that "a person whose business or property has been injured . . . may maintain an action for damages . . . 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 Com. Law § 11-209(b)(2) (emphasis added). Furthermore, "person" is defined broadly to include individuals and entities. Md. Code, Com. Law § 11-201. Given this statutory language, Plaintiffs are not barred from seeking damages for Gilead's violations of the MAA. Gilead cites to a 2002 Maryland Appellate court case, *Davidson v. Microsoft Corp.*, 792 A.2d 336, 340–41 (Md. App. 2002), to support its argument, but this case is obviously inapplicable given the 2017 amendment to the MAA.

Gilead next contends that Plaintiffs lack standing to pursue claims under the Utah Antitrust Act because none of the plaintiffs reside in Utah. But the Utah Antitrust Act does not require that named plaintiffs in class actions be citizens or residents of the state to maintain an action. "Allegations [such as those made in the Complaint] that members of the putative class presumably include Utah . . . citizens are residents are sufficient to overcome a motion to dismiss." *In re Generic Pharms. Pricing*, 368 F. Supp. 3d 838–39 (citing *Hosp. Auth. of Metro. Gov't of Nashville v. Momenta Pharm., Inc.*, 353 F. Supp. 3d 678, 695–96 (M.D. Tenn. 2018)); *see also In re Liquid Aluminum Sulfate Antitrust Litig.*, No. 16-MD-2687 (JLL), 2017 WL 3131977, at *28 (D.N.J. July 20, 2017) (declining to dismiss the plaintiffs' Utah antitrust claim where they alleged that "members of the putative classes made purchases in Utah"); *In re Asacol Antitrust Litig.*, No. 15-CV-12730-DJC, 2016 WL 4083333 at *13 (D. Mass. July 20, 2016) (same).

Finally, Gilead argues that union welfare-plan Plaintiffs lack standing to bring claims under the Massachusetts Consumer Protection Act. However, union welfare-plan Plaintiffs can maintain an action under one of either § 9 or § 11 of Mass G.L. c. 93A. Some courts have held that third-party payors may state a claim under § 11, which "grants a cause of action to [a]ny person engaged in the conduct of any

[45] In any event, if the amendment did not apply retroactively, the provision would only preclude potential damages before July 15, 2013, regardless of when the actionable conduct occurred. *In re Packaged Seafood Prods. Litig.*, No. 15-MD-2670 JSL (MDD), 2019 WL 3429174, at *24 (S.D. Cal. July 30, 2019).

trade or commerce, which . . . has [been] interpreted to mean persons acting in a business context." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 191 (1st Cir. 2009) (internal quotation marks and citations omitted) (allowing third-party payors to recover under § 11); see also *Actavis*, 2018 WL 7197233, at *44 (holding that "indirect purchaser actions are permitted under Massachusetts' consumer protection law"). Alternatively, union welfare-plan Plaintiffs have standing under § 9 because they are non-profit entities that are "not motivated by the desire to make money." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 81–82 (D. Mass. 2007); *see also In re Lorazepam & Clorazepate Antitrust Litig.*, 295 F. Supp. 2d 30, 45–46 (D.D.C. 2003) (finding that third-party payor could maintain action under § 9, in part, because entity did not engage in "trade or commerce" for purposes of the statute when it did "not profit under the specific transactions at issue (i.e., payment for its members' prescription drug claims)"). Gilead's arguments are misguided.

4. Plaintiffs Sufficiently Allege Concerted Action Where Necessary.

Contrary to Gilead's argument, Gilead Mem. at 36–37, Plaintiffs sufficiently plead the concerted action required for its monopolization claims against Gilead under Kansas, New York and Tennessee law. To state a claim for monopolization or attempted monopolization under the antitrust statutes of Kansas, New York and Tennessee, a complaint need only allege that defendant engaged in more than unilateral acts restraining competition; the requisite concerted action is present where defendant was part of an "arrangement"—which need not rise to the level of an "agreement" or "conspiracy." *See* N.Y. Gen. Bus. Law § 340(1) (extending antitrust liability to "arrangements" restraining competition); Tenn. Code Ann. § 47-25-101 (same); Kan. Stat. Ann. § 50-112 (same); *Actavis*, 2018 WL 7197233, at *27–29 (denying motion to dismiss monopolization claims under New York and Tennessee law where complaint alleged concerted action); *O'Brien v. Leegin Creative Leather Prods., Inc.*, 277 P.3d 1062, 1087–88 (Kan. 2012) (reversing summary judgment on Kansas antitrust claim where evidence "at least circumstantially support[ed] a reasonable inference of more than a unilateral policy or action").

This requirement is more than satisfied here. As Gilead acknowledges, "[t]he centerpiece of the Complaint is its attack on *joint ventures and other collaborations Gilead formed with other pharmaceutical companies*." Gilead Mem. at 1(emphasis added). Those arrangements constitute concerted action. They include the No-Generic Restraints discussed at length in the Complaint and

specifically incorporated into the monopolization counts. Compl. ¶¶ 4, 93–237, 472, 488. Moreover, the Complaint alleges Gilead engaged in other concerted action in restraint of competition—the unlawful agreements with Teva securing its delayed entry into the market. Compl. ¶¶ 313–60. In short, concerted action is alleged, and the monopolization claims against Gilead under Kansas, New York, and Tennessee law should accordingly proceed.

5. Plaintiffs' Allegations Are Sufficient to State Claims for Relief Under State Consumer Protection Statutes.

Gilead improperly invites the Court to read the Complaint in a completely fragmented manner and dismiss all state consumer protection claims. Gilead Mem. at 37–38. The Complaint provides extensive factual allegations demonstrating that Defendants, including Gilead, engaged in an unfair, deceptive, and unconscionable scheme to restrain competition and maintain high prices for various drugs used to treat HIV infection. Moreover, all of the Complaint's detailed factual allegations are incorporated into the state consumer protection claims. Compl. ¶ 493; *see In re Solodyn*, 2015 WL 5458570, at *15 (finding end-payors sufficiently stated claims under state statutes where claims "incorporate by reference the entire complaint, which contains many allegations of unfair competition and anticompetitive injury"); *see also In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 378–79 (E.D.N.Y. 2010) (finding that at the pleading stage, it is sufficient to "outline[] only the broad contours of the state law causes of action" and "draw[] the connection between the statutes and the defendant's offending conduct").

a. Plaintiffs May Assert Antitrust Claims Under Consumer Protection Theories.

Despite Gilead's unwarranted assertions to the contrary, Gilead Mem. at 37, Plaintiffs properly allege claims under state consumer protection acts that grant broad remedies based upon various types of unlawful conduct including unfair, unconscionable, *or* deceptive conduct, in the disjunctive. Many of these statutes also contain "harmonization" provisions providing a legislative mandate that the statutes be interpreted in accordance with the Federal Trade Commission ("FTC") Act, which prohibits

anticompetitive conduct.[46] Furthermore, Courts frequently refuse to dismiss consumer protection claims premised on antitrust injuries.[47]

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[46] *See FTC v. Cement Inst.*, 333 U.S. 683, 694 (1948) ("[A]ll conduct violative of the Sherman Act may likewise come within the unfair trade practice prohibitions of the Trade Commission Act."); *Indiana Fed'n of Dentists*, 476 U.S. at 454 ("unfairness" in the FTC Act encompasses "practices that violate the Sherman Act and the other antitrust laws").

[47] **Arizona**: The Arizona statute was amended in 2013 to add language prohibiting "unfair" acts or practices, Ariz. Rev. Stat. Ann. § 44-1522(A); 2013 Ariz. Legis. Serv. Ch. 143 (H.B. 2396), and it also includes an FTC Act harmonization provision. Ariz. Rev. Stat. Ann. § 44-1522(C); **California**: California's Unfair Competition Law is written broadly to prohibit any unlawful, unfair, *or* fraudulent business practice. *See Friedman v. AARP, Inc.*, 855 F.3d 1047, 1051–52 (9th Cir. 2017); *see also In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 421 (D.N.J. 2018) (sustaining UCL claim for antitrust injuries); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 160 (E.D. Pa. 2009) (same); **D.C.**: D.C.'s statute does not require allegations of fraud or deception and encompasses claims based on anticompetitive conduct that harmed purchasers. *See In re TFT-LCD* (*Flat Panel*) *Antitrust Litig.*, 586 F. Supp. 2d 1109, 1125–26 (N.D. Cal. 2008); *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 350 F. Supp. 2d 160, 196 (D. Me. 2004); *In re Packaged Seafood Prods. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1073 (S.D. Cal. 2017); *In re Chocolate Confectionary Antitrust Litig.*, 602 F. Supp. 2d 538, 583 (M.D. Pa. 2009); **Idaho**: Plaintiffs may state a claim for anticompetitive conduct under the Idaho Consumer Protection Act even if that conduct is not deceptive. *In re New Motor Vehicles*, 350 F. Supp. 2d at 184; *see also* Idaho Code § 48-604(1) (FTC Act harmonization provision); *see also In re Intel Corp. Microprocessor Antitrust Litig.*, 496 F. Supp. 2d 404, 418 (D. Del. 2007) (plaintiffs sufficiently alleged deceptive or unconscionable trade practices under ICPA in alleging antitrust injuries); **Illinois**: The Illinois statute includes an FTC Act harmonization provision. 815 Ill. Comp. Stat. § 505/2; *see also Siegel*, 480 F. Supp. 2d at 1044 (price-fixing allegations actionable under Illinois consumer protection act); **Kansas**: Claims premised on anticompetitive conduct can be brought under Kansas's consumer protection statute. *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 278 (D. Mass. 2004); *In re Microprocessors*, 496 F. Supp. 2d at 418; *In re Universal Serv. Fund Tel. Billing Practices Litig.*, 300 F. Supp. 2d 1107, 1114 (D. Kan. 2003). Moreover, the Kansas statute expressly provides that it should be "liberally construed" to protect consumers. Kan. Stat. Ann. § 50-623; **Maine**: Maine's statute does not require allegations of deception and encompasses claims based on anticompetitive conduct. *In re New Motor Vehicles*, 350 F. Supp. 2d at 187 n.40; *In re Microprocessors*, 496 F. Supp. 2d at 418. The statute contains an FTC Act harmonization provision. *See* Me. Rev. Stat. tit. 5 § 207(1); **Michigan**: The Michigan Consumer Protection Act prohibits "unfair, unconscionable, *or* deceptive methods, acts, or practices, and contains an FTC harmonization provision. Mich. Comp. Laws § 445.903, 911. *See In re Packaged Seafood*, 242 F. Supp. 3d at 1076 (price-fixing conspiracy sufficient to allege a fraud-based claim under the MCPA); *In re Solodyn*, 2015 WL 5458570, at *17 (same); **Nevada**: The Nevada Deceptive Trade Practices Act provides that "deceptive trade practices" include making "false or misleading statements of fact concerning the price of goods or services for sale," § 598.0915.13, failing "to disclose a material fact in connection with the sale . . . of goods or services," § 598.0923(2), or violating "a state or federal statute or regulation relating to the sale . . . of goods or services"; *see also In re Packaged Seafood*, 242 F. Supp. 3d at 1080–81 (allowing NDTPA claim premised on antitrust violations); *see also DDAVP*, 903 F.Supp.2d at 227 (permitting indirect purchaser claims under the NDTPA); **New Mexico**: Courts have allowed price manipulation claims brought pursuant to the New Mexico Unfair Trade Practices Act. *See In re Packaged Seafood*, 242 F. Supp. 3d at 1082; *In re Chocolate Confectionary*, 602 F. Supp. 2d at 585–86; **New York**: Section 349 of the New York General Business Law extends "far beyond the reach of common law fraud," and allegations of anticompetitive conduct are sufficient to state a claim where, as here, consumers ultimately paid higher prices as a result of the misconduct. *See New York v. Feldman*, 210 F. Supp. 2d 294, 301 (S.D.N.Y. 2002); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 228 (S.D.N.Y. 2012) (anticompetitive conduct "imbued with a degree of subterfuge" is actionable); *Macquarie Grp. Ltd. v. Pac. Corp. Grp., LLC*, No. 08 CV 2113-IEG-WMC, 2009 WL 539928, at *9 (S.D. Cal. Mar. 2, 2009) (conspiracy to prevent market

To the extent that any state consumer statutes require Plaintiffs to plead deceptive conduct, Plaintiffs have done so by alleging a conspiracy between Gilead and its coconspirators to monopolize the cART market and maintain artificially high prices, a fact that Defendants concealed from Plaintiffs. *See In re Generic Pharms. Pricing*, 368 F. Supp. 3d at 846 (finding end-payor plaintiffs in price-fixing case sufficiently alleged "deceptive and/or unconscionable conduct" at pleading stage).

b. Plaintiffs Have Stated Claims Under All State Consumer Statutes.

Gilead argues that nine state consumer protection statutes listed in the Complaint permit only "consumers" to sue for statutory violations, and as such, the claims of the five union welfare plans should be dismissed for these states. Gilead Mem. at 38–39.[48] However, 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. *See, e.g.*, D.C. Code § 28-3901 (defining consumer as a person or entity who purchases for purposes other than resale); Me. Rev. Stat. tit. 5 § 213(1) (allowing any "person," which statutorily includes entities, to bring a claim based on purchases for "personal, family, or household purposes"); Mo.

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entry thereby allowing defendant to charge artificially high prices stated Section 349 claim); **Rhode Island**: Rhode Island's consumer protection statute contains an FTC Act harmonization provision. *See* 6 R.I. Gen. Laws § 6-13.1-3. The Rhode Island Supreme Court has expressly held that practices which violate other statues and the common law are actionable as "unfair" practices under the statute. *Ames v. Oceanside Welding & Towing Inc.*, 767 A.2d 677, 681 (R.I. 2001). Thus, a plaintiff can state a claim under Rhode Island's consumer protection statute by alleging an anticompetitive conspiracy that harmed purchasers. *See In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 536 F. Supp. 2d 1129, 1145 (N.D. Cal. 2008); *In re Liquid Aluminum Sulfate*, 2017 WL 3131977, at *28; *In re Packaged Seafood*, 242 F. Supp. 3d at 1084; *In re Auto. Parts Antitrust Litig.*, No. 12-MD-02311, 2014 WL 2993742, at *26 (E.D. Mich. July 3, 2014); **Tennessee**: The Tennessee statute includes an FTC Act harmonization provision. *See* Tenn. Code Ann. § 47-18-115. Furthermore, Tennessee's antitrust and consumer protection statutes are not exclusive, but instead are "cumulative remedies." *Blake v. Abbott Labs., Inc*., No. 03A01-9509-CV-00307, 1996 WL 134947, at *5–7 (Tenn. Ct. App. Mar. 27, 1996); **Utah**: Utah's Consumer Sales Practices Act must be "liberally construed to protect consumers," and a plaintiff must be permitted to present evidence "if it appears an act even may be unconscionable." *In re Packaged Seafood*, 242 F. Supp. 3d at 1087 (denying motion to dismiss price fixing claims under Utah act); Utah Code Ann. § 13-11-5; *In re Microprocessors*, 496 F. Supp. 2d at 418. The statute also contains an FTC Act harmonization provision. Utah Code Ann. § 13-11-2(4). Defendants' cited case, *DRAM*, 516 F. Supp. 2d at 1117, failed to recognize the breadth of the statute's prohibition of "unconscionable" conduct; **West Virginia**: West Virginia's statute prohibits "[u]nfair methods of competition" and contains a FTC Act harmonization provision. W. Va. Code §§ 46A-6-104, 46A-6-101(1). Claims premised on anticompetitive conduct can be brought under the statute. *See In re Packaged Seafood*, 242 F. Supp. 3d at 1087–88; *FTC v. Mylan Labs. Inc.*, 99 F. Supp. 2d 1, 10 (D.D.C. 1999); *In re Pharm. Indus. Average Wholesale Price Litig.*, 233 F.R.D. 229, 237 (D. Mass. 2006).

[48] Gilead specifically moves to dismiss claims brought pursuant to the consumer protection statutes of D.C., Hawaii, Kansas, Maine, Missouri, Montana, North Carolina, Rhode Island, and Vermont.

Rev. Stat. §§ 407.010, 407.025 (any person or entity can bring claim based on purchases for "personal, family, or household purposes"); R.I. Gen. Laws §§ 6-13.1-1, 1-5.2(a) (any person or entity may bring a claim based on purchases of goods primarily for "personal, family, or household purposes"); Utah Code §§ 13-11-3(2)(a) (defining "consumer transaction" as one "primarily for personal, family, or household purposes"). Third-party payors do not purchase drugs for resale, distribute products, or act as intermediaries in the distribution chain. While they do not personally use the products, they nonetheless purchase them for others' personal use. The transactions affected by Defendants' anticompetitive conduct are consumer transactions.

Furthermore, as many courts have held, "[w]hether [end payors] will ultimately be able to show that they are 'consumers' who made purchases that entitle them to recovery under the relevant state laws is a question for resolution later in this litigation." *In re Generic Pharms.* 368 F. Supp. 3d at 847–48 (finding that plaintiffs sufficiently alleged violations of numerous state consumer protection statutes when they alleged "they are entitled to recover for state consumer protection violations on behalf of at least some of the named plaintiffs and members of the putative class"); *see also Geico v. Indem. Ins. Co. v. Kannaday*, No. 06-1067-JTM, 2007 WL 2990552, at *3 (D. Kan. Oct. 11, 2007) (referring to third-party payors as consumers under Kansas Unfair Trade and Consumer Protection Act); Me. Stat. tit. 5, §§ 206(2), 213(1) (allowing "[a]ny person who purchases . . . goods, services or property . . . primarily for personal, family or household purposes" to sue and "person" is defined to include entities.); *Sanford v. Nat'l Ass'n for the Self-Employed, Inc.*, 640 F. Supp. 2d 82, 90 (D. Me. 2009) (holding the personal, family or household modifiers apply to the purpose of the purchase, not the identity of the person making it); *Hyde v. Abbot Labs., Inc.*, 473 S.E. 2d 680, 688 (N.C. Ct. App. 1996) (finding that indirect purchasers may bring suit under the North Carolina Consumer Protection Statute).

c. Class Actions Are Not Barred Under the Consumer Protection Statutes of Montana, Utah, Kansas, Tennessee, and Illinois.

Gilead mistakenly argues that various states' consumer protection statutes bar class action suits. Gilead Mem. at 39–40.

The Montana Consumer Protection Act "does not prevent individuals who would otherwise be members of the class from bringing their own separate suits or joining in a preexisting lawsuit." *In re*

Hydroxycut Mktg. and Sales Practices Litig., 299 F.R.D. 648, 654 (S.D. Cal. 2014). Thus, "[t]he substantive rights of these individuals are not affected" by whether the case proceeds as a class action. *Id.* at 654*; see also In re Automotive Parts Antitrust Litig.*, 50 F. Supp. 3d 836, 861 (E.D. Mich. 2014) ("[T]he Montana statute addresses class actions only in the context of the procedures available to enforce the right in state court" and "does not alter the substantive scope of the right to relief."); *Wittman v. CBI*, No. 15-105-BLG-BMM, 2016 WL 3093427, at *6 (D. Mont. June 1, 2016) (same).

The Utah Consumer Sales Practices Act does not ban class actions. Rather, the statute provides that class members may only seek actual, not statutory, damages. *See* Utah Code § 13-11-19(4)(a) (permitting class actions for "actual damages" caused by certain statutory violations); *In re Solodyn Litig.*, 2017 WL 4621777, at *20 (allowing Utah class claims for antitrust injuries to proceed and finding "Utah consumer protection law provides that class members waive statutory damages; it does not bar class actions"). Like Utah's law, the Kansas Consumer Protection Act does not completely ban class actions. *See* Kan. Stat. § 50-634(d) (permitting class actions for damages caused by certain statutory violations).

The Tennessee Consumer Protection Act ("TCPA") grants individuals the right to recover damages. Allowing such recovery via a class action will not affect the substantive right to relief for plaintiffs. Courts have found that Rule 23 supersedes the TCPA's class action bar. *See In re FedEx Ground Package Sys., Inc. Emp't Practices Litig.*, No. 3:05-MD-527 RM, 2010 WL 597997, at *2–3 (N.D. Ind. Feb. 17, 2010) (granting class certification of claim brought under TCPA); *Thorogood v. Sears Roebuck & Co.*, 547 F. 3d 742, 746 (7th Cir. 2008) ("[Defendant] argues that the Tennessee rule precludes the maintenance of the present case as a class action. That is wrong.").

Finally, Plaintiffs have independently stated a claim pursuant to the Illinois ILCFA regardless of the viability of Plaintiffs' IAA claim. *See Siegel*, 480 F. Supp. 2d at 1048–49 (plaintiffs may elect to pursue remedies under the ILCFA where the IAA may also provide relief). The same conduct may serve as the predicate for claims under the IAA and ILCFA. *See Batson*, 746 F.3d at 831 ("an unfair practice might be covered by both the antitrust law and the Consumer Fraud Act").

6. Plaintiffs Complied With Pre-Suit Notice Requirements.

Gilead argues that Plaintiffs' claims under the antitrust laws of Arizona, Hawaii, Nevada, and

Utah and consumer-protection laws of Alabama, Massachusetts, and West Virginia must be dismissed for failure to plead compliance with the applicable notice and demand provisions. Gilead Mem. at 40. Plaintiffs are not required to plead compliance with these requirements to state a claim under the relevant statutes. *See In re Generic Pharms. Pricing*, 368 F. Supp. 3d. at 834–35 (holding that notice and demand requirements "are not a pleading requirement."). Regardless, 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. Declaration of Jayne A. Goldstein in Support of Plaintiffs' Opposition, Exs. P, Q, U, W. On the same day, 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. *Id.*, Exs. A–O. Plaintiffs did not serve demand letters pursuant to the Alabama Deceptive Trade Practices Act 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." Ala. Code § 8-19-10(e). Because none of the Defendants maintain a place of business or keep assets within the state of Alabama, *see* Compl. ¶¶ 29–42, there is no basis to dismiss Plaintiffs' claim under the Alabama Deceptive Trade Practices Act.

V. CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss should be denied in their entirety. If the Court finds any of the claims in the Complaint defective, Plaintiffs respectfully request leave to amend.

Dated: October 18, 2019

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FILER'S ATTESTATION

Pursuant to Local Rule 5-1(i)(3) of the Northern District of California, regarding signatures, I, Mark A. Lemley, attest that concurrence in the filing of this document has been obtained.

Dated: October 18, 2019

/s/ Mark A. Lemley
MARK A. LEMLEY

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2019 the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the attorneys of record in this case.

Dated: October 18, 2019

/s/ Mark A. Lemley
MARK A. LEMLEY