

United States District Court  
Northern District of California

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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

IN RE HIV ANTITRUST LITIGATION

Case No. [19-cv-02573-EMC](#)

**ORDER GRANTING IN PART AND  
DENYING IN PART DEFENDANTS’  
MOTIONS FOR SUMMARY  
JUDGMENT**

Docket Nos. 1491-1494, 1501

In this antitrust action, Plaintiffs have sued pharmaceutical companies that manufacture and sell drugs used to treat HIV. Defendants are brand manufacturers Gilead and Janssen as well as generic manufacturer Teva. Plaintiffs allege that the brand companies engaged in anticompetitive conduct designed to stave off generic competition and/or that Teva conspired in that endeavor to its benefit.<sup>1</sup>

Currently pending before the Court are multiple summary judgment motions. Having considered the parties’ briefs and accompanying submissions, as well as the oral argument of counsel, the Court hereby **GRANTS** Defendants’ motion on the TAF claims, **DENIES** Plaintiffs’ motion on market power, **DENIES** Plaintiffs’ motion on the NGR claims, **GRANTS** in part and

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<sup>1</sup> Some Plaintiffs have filed class actions; others have filed individual actions. The class actions are brought by the End-Purchaser Plaintiffs (“EPPs”) and the Direct-Purchaser Plaintiffs (“DPPs”). Individual actions have been brought by the Retailer Plaintiffs, United HealthCare, and the Individual Health Plan Plaintiffs.

As for Defendants, several Gilead entities and several Janssen entities have technically been sued (as well as Teva). For convenience, the Court refers to the Gilead entities collectively as “Gilead” and the Janssen entities collectively as “Janssen.” Although Gilead, Janssen, and Teva are all Defendants in this action, not all Plaintiffs have sued all Defendants. BMS was previously a defendant in the suit but all claims against it appear to have been settled.

1 **DENIES** in part Defendants’ motion on the NGR claims, and **DENIES** Defendants’ motion on the  
2 MFE/MFEP claims.

3 Also pending before the Court are *Daubert* motions that were filed in conjunction with the  
4 summary judgment motions. After briefing on the motions was completed, the parties agreed that  
5 most, if not all, did not need to be decided in order for the Court to adjudicate the summary  
6 judgment motions. The Court agrees and therefore defers ruling on the bulk of the motions. The  
7 Court addresses only a subset of Defendants’ *Daubert* motions. That specific portion of  
8 Defendants’ *Daubert* motions is **DENIED**.

### 9 I. GENERAL BACKGROUND

10 The Court’s prior orders have outlined the antitrust claims brought by Plaintiffs. *See, e.g.,*  
11 *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 573 (N.D. Cal. 2020) (order on motion to dismiss);  
12 Docket No. 1388 (class certification order). The Court assumes familiarity with those orders. For  
13 purposes of this order, the Court provides a brief overview only.

14 Plaintiffs’ antitrust claims, in essence, are predicated on three categories of alleged  
15 anticompetitive conduct.

- 16 • **TAF claims.** One of the primary drugs used to treat HIV is tenofovir, which is  
17 manufactured by Gilead. TDF was the first tenofovir drug made by Gilead; TAF  
18 was its successor. According to Plaintiffs, in order to extend the life of its tenofovir  
19 franchise, Gilead delayed development of TAF until a generic version of TDF was  
20 imminent and then used anticompetitive techniques to switch HIV patients over  
21 from TDF-based drugs to TAF-based drugs.
- 22 • **NGR claims.** HIV is currently treated through a “cocktail” (*i.e.*, combination) of  
23 drugs. Gilead and Janssen, as well as Gilead and BMS, entered into collaboration  
24 agreements so that they could combine certain of their drugs together (sometimes  
25 making a complete HIV treatment regimen). The combination drugs are known as  
26 fixed-dose combination drugs (“FDCs”).<sup>2</sup> The brand manufacturers’ collaboration

27  
28 <sup>2</sup> When an FDC is a complete HIV treatment regimen, it is known as a single-tablet regimen (“STR”).

1 agreements contain what Plaintiffs have called No-Generic Restraints (“NGRs”).<sup>3</sup>  
 2 The NGRs are noncompete provisions – *i.e.*, provisions that prevent a collaborator  
 3 from offering an identical or near identical FDC that competes with the joint  
 4 venture’s FDC. Essentially, they provide that, even if one collaborator’s  
 5 component drug loses its patent protection (*i.e.*, a generic version now becomes  
 6 available), the other collaborator is barred from making a FDC comprised of its  
 7 own component drug and a generic version of the first collaborator’s component  
 8 drug.

- 9 • **MFE/MFEP claims.** Teva filed what is known as abbreviated new drug  
 10 applications (“ANDAs”) so that it could manufacture generic versions of certain  
 11 FDCs affiliated with Gilead – namely, Truvada and Complera. Both drugs have  
 12 FTC (a Gilead drug) as a component. Gilead sued Teva for infringement of its  
 13 FTC patents. After a bench trial, but before closing argument and a final decision,  
 14 Gilead and Teva settled their dispute. Under the settlement agreement, Teva agreed  
 15 to delay its entry into the market (which was a benefit to Gilead). In exchange,  
 16 Gilead agreed to a provision that gave Teva “most favored entry” and/or “most  
 17 favored entry plus” (“MFE” and/or “MFEP”).<sup>4</sup> The MFE/MFEP provision is  
 18 essentially an acceleration provision. Most notably, it provided that, if Gilead were  
 19 to give another manufacturer a license to enter the market and that manufacturer’s  
 20 entry date was earlier than the one that had been given to Teva, then Teva’s entry  
 21 date would be accelerated so that it would be 180 days earlier than the one given to  
 22 the manufacturer.

23 As indicated above, Gilead is implicated in all three of Plaintiffs’ claims, Janssen is  
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25 <sup>3</sup> Because the Court has used the term “NGR” in its prior orders, it continues to do so here. The  
 26 Court recognizes, however, that Defendants disagree with the use of that term, and it makes no  
 27 ruling here as to what term should be used before the jury at trial.

28 <sup>4</sup> Similar to above, the Court continues to use the terms “MFE” and “MFEP” even though  
 Defendants disagree with the use of those terms. The Court makes no ruling as to what terms  
 should be used before the jury at trial.

1 implicated in the NGR claims only, and Teva is implicated in the MFE/MFEP claims only.  
2 Although the claims are discrete, Plaintiffs maintain that they should be considered collectively as  
3 to Gilead. Plaintiffs take the position that Gilead had a scheme to dominate the market in  
4 “foundational” HIV drugs, and its conduct in all three categories above was a part of that scheme.  
5 *See Opp’n* at 48. Plaintiffs also assert that there is a narrative tie between some of the claims –  
6 *e.g.*, Gilead’s collaboration agreements with Janssen and BMS, which contain NGRs, gave  
7 extended protection to TDF and thereby gave Gilead more time to move over HIV patients from  
8 TDF-based drugs to TAF-based drugs.

## 9 **II. LEGAL STANDARD**

10 In their pending motions for summary judgment, Defendants have moved for relief on all  
11 three claims. If Defendants’ motions are granted, the case would be disposed of in its entirety.  
12 Plaintiffs have moved for partial summary judgment only. Specifically, Plaintiffs argue that  
13 Defendants undisputedly have market power for certain drugs (implicated in the NGR and  
14 MFE/MFEP claims). Plaintiffs also argue that they are entitled to summary judgment on the NGR  
15 claims.

16 Federal Rule of Civil Procedure 56 provides that a “court shall grant summary judgment  
17 [to a moving party] if the movant shows that there is no genuine dispute as to any material fact and  
18 the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). An issue of fact is  
19 genuine only if there is sufficient evidence for a reasonable jury to find for the nonmoving party.  
20 *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). “The mere existence of a  
21 scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could  
22 reasonably find for the [nonmoving party].” *Id.* at 252. At the summary judgment stage, evidence  
23 must be viewed in the light most favorable to the nonmoving party and all justifiable inferences  
24 are to be drawn in the nonmovant’s favor. *See id.* at 255.

25 Where a defendant moves for summary judgment based on a claim for which the plaintiff  
26 bears the burden of proof, the defendant need only point to the plaintiff’s failure “to make a  
27 showing sufficient to establish the existence of an element essential to [the plaintiff’s] case.”  
28 *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

1 Where a plaintiff moves for summary judgment on claims that it has brought (*i.e.*, for  
2 which it has the burden of proof), it “must prove each element essential of the claims . . . by  
3 undisputed facts.” *Cabo Distrib. Co. v. Brady*, 821 F. Supp. 601, 607 (N.D. Cal. 1992); *see also*  
4 *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986) (stating that, “if the movant bears  
5 the burden of proof on an issue, either because he is the plaintiff or as a defendant he is asserting  
6 an affirmative defense, he must establish beyond peradventure all of the essential elements of the  
7 claim or defense to warrant judgment in his favor”) (emphasis omitted).

8 Below the Court addresses Defendants’ motion on the TAF claims first. Next, it considers  
9 Plaintiffs’ motion on market power (since it has bearing on both the NGR claims and the  
10 MFE/MFEP claims). A discussion of the cross-motions on the NGR claims follows, and then a  
11 discussion of the MFE/MFEP claims.

### 12 III. TAF CLAIMS

13 Plaintiffs assert the TAF claims against Gilead only. Gilead has moved for summary  
14 judgment on the TAF claims in their entirety.

#### 15 A. Relevant Background

16 Tenofovir is a drug used to treat HIV. It cannot be administered orally by itself. However,  
17 Gilead has developed two “prodrugs” of tenofovir that allow it to be swallowed: TDF and TAF.  
18 TAF is essentially the successor drug to TDF.

19 In 2001, Viread (TDF) was approved by the FDA. *See Hardy Rpt.* ¶ 85. Shortly after  
20 Viread’s approval, Gilead began developing TAF. *See Hardy Rpt.* ¶ 95.

21 In 2003, Gilead completed a phase 1b clinical trial for TAF. *See Hardy Rpt.* ¶ 96.  
22 Although the results for TAF looked promising, *see Hardy Rpt.* ¶ 97 (indicating that, based on the  
23 results, TAF “could prove to be a safer form of TDF for patients with kidney and bone disease”),  
24 Gilead decided not to move forward with phase 2 and 3 studies for TAF. Rather, in October 2004,  
25 Gilead announced it was discontinuing TAF’s development. *See Hardy Rpt.* ¶ 100. According to  
26 Plaintiffs, although Gilead publicly claimed that TAF was not sufficiently differentiated from TDF  
27 to warrant continued development, *see Hardy Rpt.* ¶ 100; *Follansbee Rpt.* ¶ 179, Gilead had other  
28 reasons for discontinuing development. Specifically, Gilead wanted to delay introducing TAF

1 until 2015, which was a few years before the TDF patents would expire in 2017, so that Gilead  
2 could use TAF as a means of extending the life of its tenofovir franchise. *See, e.g.*, Huttinger  
3 Decl., Ex. 119 (internal Gilead memo, dated 9/18/2003) (doing a financial analysis that “assumes  
4 . . . Gilead will develop [TAF] to replace both [TDF] and the TDF/FTC combination product in  
5 order to extend the exclusivity of the tenofovir franchise by four years”).

6 Several years later, in or about 2010, Gilead reopened development of TAF. Plaintiffs  
7 maintain that Gilead followed the playbook it had set out earlier: Gilead would introduce TAF and  
8 move HIV patients over from TDF-based drugs to TAF-based drugs before the TDF patents could  
9 expire in 2017 or 2018. *See, e.g.*, Huttinger Decl., Ex. 131 (internal Gilead memo, dated  
10 5/12/2010) (stating that TAF “should be considered for development as a stand alone agent and in  
11 fixed dose combination with FTC as a replacement for [TDF] based on the following: [*inter alia*]  
12 Additional patent life beyond [TDF]”); Huttinger Decl., Ex. 132 (internal Gilead email, dated  
13 5/5/2010) (commenting that Gilead should “try to initiate new patients on [TAF] and switch as  
14 many TDF patients as possible to [TAF] within the window of launch (2015) and TDF patent  
15 expiration (2017/2018)”); Huttinger Decl., Ex. 133 (internal Gilead memo, dated 6/2010) (stating  
16 that “[t]he success of [TAF] would stem from convincing HIV prescribers to switch as many  
17 patients as possible from a TDF-containing regimen to a [TAF]-containing regimen between 2015  
18 and 2018”).

19 Plaintiffs assert that, to channel HIV patients from TDF-based drugs to TAF-based drugs,  
20 Gilead engaged in the following conduct:

21 **1. Safety.** Gilead promoted its TAF-based drugs as safer compared to its TDF-based  
22 drugs. Gilead promoted the safety of TAF-based drugs in three primary ways.

23 First, Gilead intentionally degraded the safety of Stribild, a TDF-based drug. Stribild is a  
24 FDC (comprised of TDF/FTC/EVG/COBI) that includes a booster (COBI). The booster is used so  
25 that another component in Stribild (EVG) can be taken once daily instead of twice a day. *See*  
26 Gant Decl., Ex. 20 (Bischofberger Depo. at 214). However, coadministration of tenofovir with a  
27 booster increases tenofovir exposure and therefore kidney toxicity. *See* Hardy Rpt. ¶ 118. In spite  
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1 of this, Gilead kept the dose of TDF in Stribild at a full 300 mg.<sup>5</sup> See Hardy Rpt. ¶ 121 (stating  
2 that 300 mg was a “dosage only demonstrated to be appropriate for achieving efficacy *without* a  
3 booster”) (emphasis in original).

4 In contrast, Gilead took a different approach with Genvoya, the TAF-based drug that was  
5 the successor to Stribild. Genvoya (comprised TAF/FTC/EVG/COBI) has the same components  
6 as Stribild except that it contains TAF instead of TDF. For Genvoya, Gilead did adjust the dosage  
7 of TAF down (from 25 mg to 10 mg) because the booster (COBI) increases tenofovir exposure.  
8 See Hardy Rpt. ¶ 119.

9 Second, Gilead designed clinical studies for its TAF-based drugs to make them look  
10 superior to TDF-based drugs. Specifically, Gilead chose to compare Genvoya with Stribild, even  
11 though Stribild had a standard dose of boosted TDF while Genvoya had a reduced dose of boosted  
12 TAF. See Hardy Rpt. ¶ 131. Plaintiffs emphasize that Gilead never compared unboosted TAF  
13 regimens and unboosted TDF regimens. See Opp’n at 43.

14 Third, Gilead deceptively marketed TAF’s safety to physicians, HIV patients, and payors –  
15 e.g., relying on the flawed Genvoya-Stribild comparison and concealing that TAF was safer for  
16 only a “modest subset of TDF patients – those with acute renal/bone conditions (~17%).” Opp’n  
17 at 44-45.

18 **2. Pricing.** Gilead manipulated the price of TDF-based Stribild. To make TAF-based  
19 Genvoya more attractive over Stribild, Gilead increased the price of Stribild two times in 2016 –  
20 by 4.9% in January 2016 and then by 6.9% in July 2016. See Mot. at 10. This put Stribild at a  
21 12% premium over Genvoya, even though Genvoya was the newer drug. And this translated to a  
22 difference of about \$4,000 per year in terms of wholesale acquisition cost. See Rubinfeld Reb.  
23 Rpt. ¶ 142 (“[G]iven the annual WAC cost of Stribild and Genvoya was \$37,595 and \$33,525 by  
24 the end of 2017 respectively, Gilead had created a substantial premium of more than \$4,000 per  
25 patient per year.”). The pricing difference affected payors’ formulary coverage decisions.<sup>6</sup> See,

26 \_\_\_\_\_  
27 <sup>5</sup> When Viread (TDF) was approved in 2001, it was at a dosage of 300 mg. See Follansee Rpt. ¶  
28 87. In other words, 300 mg is the approved dosage of TDF.

<sup>6</sup> As explained by Plaintiffs’ expert, Dr. Rubinfeld, health plans have “mechanisms to encourage



1 e.g., Huttinger Decl. Ex. 196 ( [REDACTED] (noting that “[a] therapeutic substitution from  
2 Stribild to Genvoya and from Complera to Odefsey has been approved . . . [;] [n]ew contracting  
3 has made Genvoya and Odefsey preferred over Stribild and Complera because they are lower in  
4 cost”).

5 Thus, according to Plaintiffs, through safety manipulation and differential pricing, Gilead  
6 put pressure on doctors, HIV patients, and payors to transition from TDF-based drugs to TAF-  
7 based drugs.

8 Finally, Plaintiffs point out that, when Gilead did make its TAF-based drugs available, it  
9 chose to withhold release of TAF as a standalone drug for HIV treatment. While Gilead did  
10 launch a standalone version of TAF, it did so only for an indication of hepatitis, and not for an  
11 indication of HIV. Gilead did this even though there was demand for standalone TAF for HIV  
12 purposes, *see* Huttinger Decl., Ex. 200 (internal Gilead email, dated 3/1/2016) (noting that  
13 “[d]emand for standalone TAF for HIV remains and community is going to continue to advocate  
14 for it”), and even though Gilead stood to profit from a release of standalone TAF for HIV  
15 purposes. *See, e.g.,* Huttinger Decl., Ex. 199 (internal Gilead document, dated 10/22/2012) (at  
16 Figure 10, forecasting profits for “TAF Single Agent” in the United States – as high as \$62 million  
17 for the year 2018). Gilead’s internal documents reflected that it believed there was “[s]ome  
18 commercial risk . . . associated with having TAF SA [standalone] for HIV available in the US,”  
19 with the “primary risk” being that “it may facilitate the break-up of STRs, an approach that is  
20 inconsistent with the ongoing Gilead STR platform,” and another risk being “the availability of  
21 TAF SA may encourage its use with generics.” Huttinger Decl., Ex. 202 (internal Gilead  
22 document, dated 12/6/2013).

23 **B. Scope of TAF Claims**

24 As an initial matter, the Court takes note that, at the hearing, Plaintiffs clarified the scope  
25 of their TAF claims. As indicated above, the TAF claims appeared to be based on three different  
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27 \_\_\_\_\_  
28 their members to use generic drugs,” including by putting generic drugs into “a preferred tier in  
[the] health plans’ formularies.” Rubinfeld Rpt. ¶ 100. “Consumers generally pay lower co-  
payments for drugs that are on the preferred tier . . . .” Rubinfeld Rpt. ¶ 101.



1 acts by Gilead: (1) Gilead’s decision to delay development and introduction of TAF into the  
 2 market; (2) Gilead’s pressure on HIV patients to move from TDF-based drugs to TAF-based  
 3 drugs; and (3) Gilead’s decision to release standalone TAF without an indication for HIV. At the  
 4 hearing, Plaintiffs conceded that they are *not* asserting that Gilead engaged in anticompetitive  
 5 conduct by (1) deciding to delay development and introduction of TAF into the market and (3)  
 6 deciding to release standalone TAF without an HIV indication. Implicitly, Plaintiffs’ concession  
 7 was based on authority holding that, “as a general rule, ‘any firm, even a monopolist, may . . .  
 8 bring its products to market whenever and however it chooses.’”<sup>7</sup> *Foremost Pro Color, Inc. v.*  
 9 *Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983).

10 Plaintiffs, however, maintain that Gilead’s conduct in (1) and (3) could still be relevant  
 11 *evidence* in their case, including with respect to Gilead’s anticompetitive conduct based on (2).  
 12 Plaintiffs also assert that they *do* have a claim for an antitrust violation based on (2) – *i.e.*, Gilead’s  
 13 forced “switching” of HIV patients from TDF-based to TAF-based drugs. According to Plaintiffs,  
 14 Gilead was motivated to delay on TAF (*i.e.*, (1)) so that it could maximize profits from TDF  
 15 without worrying about TAF cannibalizing TDF sales; when Gilead did reopen development of  
 16 TAF, it did so in order to transition HIV patients to TAF-based drugs when the TDF patents were  
 17 due to expire, and, in the meantime, the NGRs would give additional protection to TDF so that  
 18 Gilead had time to move patients over.

19 For purposes of summary judgment, the Court need only address the switching (or  
 20 “product hopping”) claim (*i.e.*, (2)). Both parties agreed that the issue of whether (1) and (3)  
 21 should be admitted as evidence is one that can be dealt with at a time closer to trial. The Court  
 22 notes, however, that Plaintiffs’ evidentiary arguments are not entirely without force, at least with  
 23 respect to (1). The Court now turns to the switching/product hopping claim.

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 25 <sup>7</sup> At the hearing, Plaintiffs were not able to articulate how either of the decisions above could  
 26 have, *e.g.*, facilitated the anticompetitive conduct that Plaintiffs are challenging (such as the forced  
 27 transition of HIV patients from TDF-based to TAF-based drugs). *See Staley v. Gilead Scis., Inc.*,  
 28 446 F. Supp. 3d 578, 614 (N.D. Cal. 2020) (taking note of a Second Circuit case holding that new  
 product introductions are not automatically immune from antitrust scrutiny but that “‘it is not the  
 product introduction itself, but some associated conduct, that supplies the [antitrust] violation’”)  
 (emphasis omitted).

1 C. Switching/Product Hopping Claim

2 With respect to the switching/product hopping claim, the Court begins with the legal  
3 parameters of the claim. Particularly instructive is the Second Circuit’s decision in *New York v.*  
4 *Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (hereinafter “*Namenda*”).<sup>8</sup> There, the state of New  
5 York filed an antitrust suit against affiliated pharmaceutical companies based on their conduct  
6 related to Alzheimer’s drugs. The companies had an Alzheimer’s drug known as Namenda IR,  
7 which was nearing the end of its patent exclusivity in 2015. The companies then introduced a new  
8 drug known as Namenda XR which would have patent exclusivity until 2029. *See id.* at 642.  
9 Both Namenda IR and Namenda XR had the same active ingredient and the same therapeutic  
10 effect. The only real medical difference was that Namenda IR had to be taken twice a day, and  
11 Namenda XR only once a day. *See id.* at 647. However, once a generic version of Namenda IR  
12 became available, state drug substitution laws would not allow a pharmacist to dispense generic  
13 Namenda IR if a patient were prescribed Namenda XR because generic Namenda IR was only  
14 AB-rated for Namenda IR, and not Namenda XR. *See id.* at 645 (“To receive an AB-rating, a  
15 generic must not only be bioequivalent but pharmaceutically equivalent to the brand drug,  
16 meaning it has the same active ingredient, dosage form, strength, and route of administration as  
17 the brand drug.”).

18 When the companies introduced Namenda XR to the market, they made an active effort to  
19 convert patients from Namenda IR to Namenda XR, precisely because of the “patent cliff” that IR  
20 was facing. Initially, the companies sold both IR and XR “but stopped actively marketing IR.  
21 During that time, they [also] spent substantial sums of money promoting XR to doctors,  
22 caregivers, patients, and pharmacists”; “sold XR at a discounted rate, making it considerably less  
23 expensive”; and “issued rebates to health plans to ensure that patients did not have to pay higher  
24 co-payments for XR.” *Id.* at 648. The Second Circuit called this effort to convert patients to XR a  
25 “soft switch.”

26 About half a year later, the companies changed tactics and adopted a “more direct  
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28 <sup>8</sup> Because there is a Supreme Court case also commonly referred to as *Actavis*, the Court shall refer to this Second Circuit decision as *Namenda*.

1 approach” because their “internal projections estimated that only 30% of Namenda IR users would  
 2 voluntarily switch” to XR before the entry of generic IR. *Id.* The companies publicly announced  
 3 that they would be discontinuing IR – *i.e.*, withdrawing it from the market. The court called this  
 4 effort a “hard switch” or “forced switch.” *See id.*

5 The state of New York filed suit and sought a preliminary injunction to stop the companies  
 6 from restricting access to Namenda IR during the course of the litigation. The district court  
 7 granted the preliminary injunction, and, on appeal, the Second Circuit affirmed.

8 In so ruling, the Second Circuit first took note of “[w]ell-established case law mak[ing]  
 9 clear that product redesign is anticompetitive when it coerces consumers and impedes  
 10 competition.” *Id.* at 652. Although “neither product withdrawal nor product improvement alone  
 11 is anticompetitive[,] . . . when a monopolist *combines* product withdrawal with some other  
 12 conduct, the overall effect of which is [1] to coerce consumers rather than persuade them on the  
 13 merits and [2] to impede competition, its actions are anticompetitive under the Sherman Act.” *Id.*  
 14 at 653-54; *see also Allied Ortho. Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 994,  
 15 1002 (9th Cir. 2010) (finding no antitrust violation because the undisputed evidence showed that  
 16 the new design was “an improvement over the previous design” and there was “no evidence that  
 17 Tyco used its monopoly power to force customers to adopt its new product”; acknowledging that  
 18 “[a] monopolist’s discontinuation of its old technology may violate Section 2 if it effectively  
 19 forces consumers to adopt its new technology”).

20 Regarding the element of consumer coercion, the Second Circuit concluded that the  
 21 companies’ “hard switch crosses the line from persuasion to coercion.” *Namenda*, 787 F.3d at  
 22 654.

23 By effectively withdrawing Namenda IR prior to generic entry,  
 24 Defendants forced patients to switch from Namenda IR to XR – the  
 25 only other memantine drug on the market. In fact, the district court  
 26 found that Defendants devised the hard switch because they  
 27 projected that only 30% of . . . patients would voluntarily switch to  
 28 Namenda XR prior to generic entry. Defendants’ hard switch was  
 expected to transition 80 to 100% of Namenda IR patients to XR  
 prior to generic entry, and thereby impede generic competition.

*Id.*

1           Although the companies argued that no distinction should be made between the soft and  
2 hard switches, the Second Circuit was not persuaded because

3                           this argument ignores [a] basic tenet[]: the market can determine  
4 whether one product is superior to another only “so long as the free  
5 choice of consumers is preserved.” Had Defendants allowed  
6 Namenda IR to remain available until generic entry, doctors and  
7 Alzheimer's patients could have decided whether the benefits of  
8 switching to once-daily Namenda XR would outweigh the benefits  
9 of adhering to twice-daily therapy using less-expensive generic IR  
10 (or perhaps lower-priced Namenda IR). By removing Namenda IR  
11 from the market prior to generic IR entry, Defendants sought to  
12 deprive consumers of that choice. In this way, Defendants could  
13 avoid competing against lower-cost generics based on the merits of  
14 their redesigned drug by forcing Alzheimer’s patients to take XR,  
15 with the knowledge that transaction costs would make the reverse  
16 commute by patients from XR to generic IR highly unlikely.

17 *Id.* at 654-55.

18           The Second Circuit then held that the hard switch would likely have anticompetitive and  
19 exclusionary effects.

20                           Forcing patients to switch to XR would prevent generic substitution  
21 because generic versions of IR are not AB-rated to Namenda XR.  
22 And if, as Defendants' own internal predictions estimate, the hard  
23 switch successfully converted 80 to 100% of IR patients to XR prior  
24 to generic entry, there would be “few to no prescriptions” left for  
25 which generics would be eligible to compete. Because Defendants'  
26 forced switch “through something other than competition on the  
27 merits[] has the effect of significantly reducing usage of rivals'  
28 products and hence protecting its own . . . monopoly, it is  
anticompetitive.”

29 *Id.* at 655. The court acknowledged that, theoretically, Alzheimer’s patients were free to switch  
30 back to IR – specifically, take a generic version once it was available. However, in practice,  
31 switching back was “highly unlikely” because it would involve high transaction costs – *e.g.*, a  
32 patient would have to obtain a new prescription from a doctor, but doctors and caregivers are  
33 reluctant to make changes to medication if the current treatment is working. *Id.* at 656.

34           Based on *Namenda*, Gilead argues that a critical element in a switching/product hopping  
35 claim is coercion. Plaintiffs disagree. They contend that this Court rejected that requirement in  
36 one of its prior orders addressing a 12(b)(6) motion to dismiss. *See* Opp’n at 49 (citing *Staley*, 446  
37 F. Supp. 3d at 615. Plaintiffs are incorrect. In its prior decision, the Court was never squarely  
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1 presented with switching/product hopping authority and the issue of coercion. Thus, the Court  
2 necessarily did not express an opinion on whether coercion is required in a switching/product  
3 hopping situation. Moreover, implicit in the Court’s prior order was an endorsement of the  
4 coercion element – *i.e.*, Plaintiffs’ theory was that product superiority was not driving the  
5 transition from TDF to TAF but rather something else. Furthermore, a coercion element is  
6 necessarily a part of Plaintiffs’ claim here because how else could there be anticompetitive  
7 conduct unless HIV patients’, doctors’, and/or payors’ choices regarding products were  
8 constrained? *See id.* at 654-55 (noting as a basic tenet that “the market can determine whether one  
9 product is superior to another only ‘so long as the free choice of consumers is preserved’”).  
10 Finally, this case is similar to *Namenda*. As in *Namenda*, the switch to the new product impaired  
11 competition from generic manufacturers; Gilead forced patients to switch over from TDF to TAF,  
12 knowing that generics for TDF would not be AB-rated for TAF.

13 Plaintiffs suggest that coercion is not necessary where there is deceptive marketing. *See In*  
14 *re Suboxone Antitrust Litig.*, No. 2445, 2022 U.S. Dist. LEXIS 150424, at \*109-10 (E.D. Pa. Aug.  
15 22, 2022) (where defendant claimed that it was safer to administer a drug in “film” form rather  
16 than tablet form, noting that “Plaintiffs have produced evidence that [defendant] actively sought to  
17 deprive consumers of the ability to actively evaluate safety claims and make the choice between  
18 film and tablets”). But here (as in *Suboxone*), the crux of the deceptive marketing relates to safety.  
19 Thus, the asserted anticompetitive element of deception in this case essentially bleeds into the  
20 larger issue of whether there was “coercion” because of safety concerns.

21 That being said, the Court does not accept all of Gilead’s characterizations as to what  
22 constitutes a viable switching/product hopping claim. Most notably, Gilead suggests that there is  
23 a viable claim only where the antitrust defendant *withdraws* the old product from the market, thus  
24 forcing consumers over to the new product. Although *Namenda* did involve withdrawal of  
25 Namenda IR in order to drive consumers over to Namenda XR, that does not mean the free choice  
26 of consumers can be constrained only where the old product is withdrawn from the market.  
27 Indeed, at the hearing, Gilead acknowledged that, if a pharmaceutical company were to leave its  
28 old drug on the market but to charge an exorbitant price for it, while pricing the new drug

1 considerably less, that would effectively leave consumers or payors with little choice but to move  
 2 over to the new drug. *See also In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 307, 329-30  
 3 (D.R.I. 2019) (noting that “[a] hard switch may occur ‘in effect’ where the branded product  
 4 remains on the market in some limited fashion”). This is not to say that withdrawal of an old  
 5 product, or the continued availability of such, is of no relevance in a switching/product hopping  
 6 case. The Court is simply noting here that withdrawal of an old product is not the only means of  
 7 coercion. *Cf. Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Ltd. Co.*, 838 F.3d 421,  
 8 4401-41 (3d Cir. 2016) (although concluding that the switching/product hopping claim asserted  
 9 was not viable, indicating that “the disposition of [a] claim will necessarily turn on the facts and  
 10 circumstances surrounding a company’s alleged anticompetitive conduct”).

11 Having addressed the legal framework (*i.e.*, what constitutes a plausible claim of  
 12 anticompetitive switching/product hopping), the Court now turns to the facts of the instant case.  
 13 Defendants contend that no reasonable jury could find a coercion element based on the undisputed  
 14 facts. The Court agrees.

15 To the extent Plaintiffs assert coercion based on the pricing of Stribild, no reasonable jury  
 16 could find coercion based on that evidence by itself. Plaintiffs have essentially admitted that  
 17 doctors do not prescribe HIV drugs based on their price; similarly, for the most part, HIV patients  
 18 do not choose their drugs based on price (largely because it is the payors, and not the consumers,  
 19 who pay for the bulk of the cost). *See, e.g.*, Opp’n at 60 (stating that “[p]rice competition among  
 20 branded HIV treatments is muted[;] [o]nce HIV patients are stabilized on a treatment that is  
 21 working, they are likely to stay on that treatment, despite its price and changes in price”).  
 22 Plaintiffs do contend that the pricing of Stribild impacted payors – *i.e.*, their formulary coverage  
 23 decisions. But the question here is not whether the pricing differential *affected* formulary  
 24 coverage decisions; the question is whether the pricing differential was coercive (which makes  
 25 sense otherwise any rebate or discount might be deemed an antitrust violation). Even if a payor  
 26 had to pay \$4,000 more per patient for Stribild over Genvoya,<sup>9</sup> Plaintiffs have not explained how

27

28 <sup>9</sup> The Court acknowledges that payors may not have paid wholesale prices but presumably  
 wholesale prices give some indication of what retail prices would be.



1 that would be coercive to a payor, particularly when (1) a payor is not an individual consumer but  
2 rather a business entity, and (2) it is not clear how many HIV patients are typically covered by an  
3 average payor. Furthermore, Plaintiffs have not explained how, in the absence of coercion of  
4 payors, there is coercion relative to HIV patients even if they are affected by payors' formulary  
5 coverage decisions.

6 The critical question, therefore, is whether a reasonable jury could find coercion because  
7 Gilead promoted its TAF-based drugs (*e.g.*, Genvoya) as safer compared to its TDF-based drugs  
8 (*e.g.*, Stribild). The Court concludes that a reasonable jury could not so find.

9 According to Plaintiffs, Gilead was able to promote Genvoya as safer than Stribild by  
10 "degrading" the safety of the latter. However, the undisputed evidence does not support the claim  
11 that Stribild was degraded, let alone for anticompetitive reasons. Although Plaintiffs emphasize  
12 that Gilead did not reduce the dosage of TDF in Stribild (even though a booster was included as a  
13 component in the drug) and did reduce the dosage of TAF in Genvoya (which also included a  
14 booster), there was a science-based reason for that difference in conduct: specifically, the  
15 undisputed evidence is that TAF's response to a booster is much stronger compared to TDF's. *See*  
16 *Gant Decl.*, Ex. 26 (Kearney Depo. at 221, 226) (indicating that TDF is boosted by only 18%  
17 while TAF is boosted by 307%). Plaintiffs argue that "even the standard *unboosted* dosage of  
18 TDF was too high of an exposure for certain patients to tolerate," Opp'n at 55 (emphasis in  
19 original), but this ignores the fact that TDF was commonly used with boosters, as even Plaintiffs'  
20 expert Dr. Hardy conceded. *See Adam Reply Decl.*, Ex. 50 (Hardy Depo. at 217-18) (stating that  
21 the package insert for Viread (TDF) cautioned that there would be increased levels of tenofovir if  
22 used with a booster, but admitting that doctors commonly used TDF with a booster as part of a full  
23 regimen). Moreover, the FDA has never deemed Stribild unsafe. In fact, Stribild is still listed as a  
24 treatment option on the DHHS Guidelines related to HIV. *See Adam Reply Decl.*, Ex. 51  
25 (Follansbee Depo. at 178-80); *see also Hardy Rpt.* ¶¶ 43-44 (stating that "DHHS regularly issues a  
26 set of guidelines specifically aimed at providing HIV-treatment recommendations to healthcare  
27 professionals, based on the latest clinical evidence and expert opinions"; "[p]hysicians treating  
28 patients with HIV rely heavily on the DHHS Guidelines because they are the best source of



1 updated, organized, curated, and reliable information”).

2 Because Stribild was not degraded (*i.e.*, as a scientific matter), it was not improper for  
3 Gilead to design clinical trials comparing Stribild to Genvoya. That Gilead could have compared  
4 unboosted TDF to unboosted TAF does not mean that the comparison of Stribild to Genvoya (both  
5 boosted drugs) was inappropriate.

6 Moreover, it was not deceptive<sup>10</sup> or otherwise improper for Gilead to market Genvoya as  
7 being safer than Stribild, particularly given that the DHHS Guidelines indicate the same. The  
8 DHHS Guidelines expressly stated that TAF-based drugs have safety benefits compared to TDF-  
9 based drugs:

10 TAF/FTC was added as a 2-NRTI option in several Recommended  
11 and Alternative regimens . . . . The addition of TAF/FTC to these  
12 recommendations is based on data from comparative trials  
13 demonstrating that TAF-containing regimens are as effective in  
achieving or maintaining virologic suppression as tenofovir  
disoproxil Fumarate (TDF)-containing regimens and with more  
favorable effects on markers of bone and renal health.

14 Gant Decl., Ex. 47 (DHHS Guidelines at i). As noted above, DHHS issues guidelines on HIV  
15 treatments, and doctors rely on those guidelines because, *inter alia*, they are reliable. According  
16 to Plaintiffs’ medical expert, Dr. Hardy, the guidelines “are created by a panel of approximately 55  
17 individuals, who have unique experiences and expertise derived from several different areas of  
18 HIV treatment,” and the individuals “go through a rigorous confirmation process to demonstrate  
19 that they have no significant conflicts of interest with pharmaceutical companies or other potential  
20 influencers of this area of scientific expertise.” Hardy Rpt. ¶ 44. Before making its  
21 recommendations, the panel “carefully reviews all published, peer-reviewed scientific and medical  
22 information regarding antiretroviral therapy and follows a rigorous and structured grading  
23

24 \_\_\_\_\_  
25 <sup>10</sup> In their papers, the parties have a dispute over whether deceive marketing is actionable for  
26 antitrust purposes only when the marketing is clearly false. Plaintiffs contend that the “clearly  
27 false” standard applies only where false claims are made about a *competitor’s* product. *See Am.*  
28 *Prof’l Testing Serv. v. Harcrount Brace Jovanovich Legal & Prof’l Publ’ns.*, 108 F.3d 1147, 1152  
(9th Cir. 1997) (indicating that, “[a]lthough hardly a justification for falsehood, *buyer distrust of a*  
*seller’s disparaging comments about a rival seller* should caution us against attaching much  
weight to isolated examples of disparagement[;] [e]ssential, therefore, is a serious de minimis  
test”) (emphasis added). For purposes of this opinion, the Court assumes that Plaintiffs are  
correct.

1 system.” Hardy Rpt. ¶ 45; *see also* Pitrak Reb. Rpt. ¶ 53 (noting that Plaintiffs’ medical experts,  
 2 Dr. Hardy and Dr. Follansbee, do not “claim that the DHHS panel was misled by any Gilead  
 3 marketing or alleged misrepresentation of clinical data”). There is no indication that the DHHS  
 4 was misled in any way – *e.g.*, as to the components of Stribild and Genvoya and the differences  
 5 between the drugs. In fact, the components of the drugs appear to have been on the drug labels  
 6 and/or in the package inserts, thus making any claim of actual falsity untenable. *See, e.g.*, Pitrak  
 7 Rpt. ¶ 140 & n.84 (label for Stribild); Follansbee Rpt. ¶ 169 & n.198 (package insert for Stribild).

8 Plaintiffs protest that the benefits of TAF were limited to a small percentage of the HIV  
 9 patient population (about 17%) – *i.e.*, those with acute bone or renal conditions. But Plaintiffs fail  
 10 to address that HIV drugs are used for a patient’s lifetime; thus, even for a patient without an acute  
 11 bone or renal condition, there are implicitly some benefits to TAF over TDF.

12 Plaintiffs also contend that the Court should not parse out the individual acts taken by  
 13 Gilead – related to pricing and safety – but rather should evaluate their overall combined effect  
 14 given the broad antitrust scheme pled by Plaintiffs. *See City of Anaheim v. S. Cal. Edison Co.*,  
 15 955 F.2d 1373, 1376 (9th Cir. 1992) (stating that “it would not be proper to focus on specific  
 16 individual acts of an accused monopolist while refusing to consider their overall combined effect”  
 17 – although acknowledging that, “if all we are shown is a number of perfectly legal acts, it becomes  
 18 much more difficult to find overall wrongdoing”); *cf. Suboxone*, 2022 U.S. Dist. LEXIS 150424,  
 19 at \*92 (stating that, “when faced with allegations of a broad antitrust scheme, it is still appropriate  
 20 to consider the individual components of the scheme and whether those components could  
 21 constitute anticompetitive conduct, so long as [a] court keep[s] ‘the larger scope of the scheme in  
 22 context’”). While Plaintiffs make a fair point, here, the Court has considered not only the  
 23 individual acts but also the acts taken collectively and still concludes that no reasonable jury could  
 24 find a coercion element based on the undisputed facts.<sup>11</sup> Plaintiffs’ reliance on *Suboxone* is

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 26  
 27 <sup>11</sup> And even if there were a genuine dispute of fact related to coercion, Plaintiffs would likely run  
 28 into at least one additional obstacle. As Gilead argues, to the extent Plaintiffs seeks injunctive  
 relief, there seems to be a redressability problem – *i.e.*, Plaintiffs have not shown that injunctive  
 relief would address “any alleged ongoing harm” because, *e.g.*, “the pricing differential between  
 TDF- and TAF-based products in 2016-17 [has] long since passed.” Mot. at 21.

1 unavailing particularly as, in that case, there was no comparable source such as the DHHS  
2 Guidelines here on which doctors could rely.

3 For the foregoing reasons, the Court grants Gilead’s motion for summary judgment on the  
4 TAF claims – specifically, the switching/product hopping claims. As stated above, the Court’s  
5 ruling here does not adjudicate the issue of whether Gilead’s TAF-related conduct (such as its  
6 decision to delay development of the drug) will be admissible as evidence to support Plaintiffs’  
7 NGR or MFE/MFEP claims.

#### 8 **IV. MARKET POWER**

9 The Court turns next to Plaintiffs’ motion for summary judgment on market power.  
10 Previously, the Court certified classes with respect to following drugs: Truvada, Atripla,  
11 Complera, Prezcobix, and Evotaz.<sup>12</sup> The Truvada and Atripla Classes (both damages classes)  
12 relate to Plaintiffs’ MFE/MFEP claims. The Complera Class (a damages class) and the Prezcobix  
13 and Evotaz Classes (both injunctive relief classes) relate to Plaintiffs’ NGR claims. Plaintiffs  
14 move for summary judgment on the issue of market power for each of the five drugs.<sup>13</sup>

15 “Market power is the power ‘to force a purchaser to do something that he would not do in  
16 a competitive market.’ It has been defined as ‘the ability of a single seller to raise price and  
17 restrict output.’” *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 464 (1992); *see also*  
18 *Aya Healthcare Servs. v. AMN Healthcare, Inc.*, 9 F.4th 1102, 1112 (9th Cir. 2021) (stating that  
19 “[m]arket power is the ability to raise prices above those that would be charged in a competitive  
20 market”); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1111 (N.D. Cal. 2004) (noting  
21 that the Federal Trade Commission Horizontal Merger Guidelines “define market power as ‘the  
22 ability profitably to maintain prices above competitive levels for a significant period of time’”).  
23

24 \_\_\_\_\_  
25 <sup>12</sup> The Court also certified a cART Foundation Drug Class. However, that class is not at issue  
26 here. Furthermore, given the Court’s ruling above on the TAF claims, it is not clear that the cART  
27 Foundation Drug Class has any claim remaining to pursue.

28 <sup>13</sup> In their papers, Defendants criticized Plaintiffs for (1) not identifying which specific defendant  
had market power for a given drug and (2) not specifying the period for which the defendant had  
market power. Plaintiffs, however, clarified in reply that it is the seller of a brand drug that  
has/had market power before generic entry, and other companies are implicated because of the  
allegation that there was a conspiracy to delay generic competition.

1 Market power may be demonstrated through either of two types of  
 2 proof. One type of proof is direct evidence of the injurious exercise  
 3 of market power. If the plaintiff puts forth evidence of restricted  
 4 output and supracompetitive prices, that is direct proof of the injury  
 5 to competition which a competitor with market power may inflict,  
 6 and thus, of the actual exercise of market power. The more common  
 7 type of proof is circumstantial evidence pertaining to the structure of  
 8 the market. To demonstrate market power circumstantially, a  
 9 plaintiff must: (1) define the relevant market, (2) show that the  
 10 defendant owns a dominant share of that market, and (3) show that  
 11 there are significant barriers to entry and show that existing  
 12 competitors lack the capacity to increase their output in the short  
 13 run.

14 *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (emphasis added).

15 A. Direct Evidence

16 According to Plaintiffs, there is no genuine dispute of fact that Defendants have/had  
 17 market power for the five drugs at issue based on direct evidence. As an initial matter, the Court  
 18 notes that the parties have a dispute as to what constitutes direct evidence of market power.  
 19 Plaintiffs assert that they need only show supracompetitive prices. Defendants argue that  
 20 Plaintiffs must show both supracompetitive prices and restricted output.

21 The Court previously considered this issue in *Intel Corp. v. Fortress Investment Group*  
 22 *LLC*, 511 F. Supp. 3d 1006 (N.D. Cal. 2021), noting as follows:

23 The Supreme Court has not clearly addressed this issue. In [*Ohio v.*  
 24 *American Express Co.*, 138 S. Ct. 2274 (2018)], the Court noted  
 25 that, if ““output is expanding at the same time prices are increasing,  
 26 rising prices are equally consistent with growing product demand,””  
 27 but, at another point, the Court used the disjunctive, stating “[t]his  
 28 Court will ‘not infer competitive injury from price and output data  
 absent some evidence that tends to prove that output was restricted  
 or prices were above a competitive level.’” *Id.* at 2284, 2288  
 (emphasis added). And although the Ninth Circuit has stated that  
 “[e]vidence of restricted output and supracompetitive prices is direct  
 evidence of market power,” *Theme Promotions, Inc. v. News*  
*America Marketing FSI*, 546 F.3d 991, 1001 (9th Cir. 2008)  
 (added); see also *Rebel Oil v. Atl. Richfield Co.*, 51 F.3d 1421, 1434  
 (9th Cir. 1995) (stating that, “[i]f the plaintiff puts forth evidence of  
 restricted output and supracompetitive prices, that is direct proof of  
 the injury to competition which a competitor with market power  
 may inflict, and thus, of the actual exercise of market power”),<sup>14</sup>

<sup>14</sup> *Accord Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1476 (9th Cir. 1997) (“The plaintiffs submitted evidence that Sunrise Hospital routinely charged higher prices than other hospitals while reaping high profits. With no accompanying showing of restricted output, however, the plaintiffs have failed to present direct evidence of market power.”), *overruled in part on other grounds by Lacey*

1 the Ninth Circuit has not provided its take on the statements above  
 2 in *American Express*; nor has it expressly addressed the question  
 whether supracompetitive pricing alone can establish market power.

3 *Id.* at 1026 (emphasis in original).

4 Both parties, however, point out that, post-*American Express*, the Ninth Circuit did  
 5 comment on direct evidence in *FTC v. Qualcomm Inc.*, 969 F.3d 974 (9th Cir. 2020). In  
 6 *Qualcomm*, the Ninth Circuit quoted *American Express* in stating that “[d]irect evidence includes  
 7 “‘proof of actual detrimental effects [on competition],’” ‘such as reduced output, increased prices,  
 8 or decreased quality in the relevant market.’” *Id.* at 989 (emphasis added). However, the Ninth  
 9 Circuit then went on to state the following:

10 Allegations that conduct “has the effect of reducing consumers’  
 11 choices or increasing prices to consumers do[] not sufficiently allege  
 an injury to competition . . . [because] [b]oth effects are fully  
 12 consistent with a free, competitive market.” *Brantley v. NBC*  
*Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012) (citations  
 13 omitted); *see also Brooke Grp. Ltd. v. Brown & Williamson Tobacco*  
*Corp.*, 509 U.S. 209, 237 (1993) (“Where . . . output is expanding at  
 14 the same time prices are increasing, rising prices are equally  
 consistent with growing product demand.”). Instead, in order to  
 15 prove a violation of the Sherman Act, the plaintiff must show that  
 diminished consumer choices and increased prices are the result of a  
 16 less competitive market due to either artificial restraints or predatory  
 and exclusionary conduct. *See Am. Express*, 138 S. Ct. at 2288  
 (“This Court will ‘not infer competitive injury from price and output  
 17 data absent some evidence that tends to prove that output was  
 restricted or prices were above a competitive level.’” (quoting  
 18 *Brooke Grp. Ltd.*, 509 U.S. at 237)).

19 *Id.* at 990.

20 Arguably, *Qualcomm* still leaves some ambiguity as to what the Ninth Circuit requires for  
 21 direct evidence. But there is a convincing argument that both supracompetitive prices and  
 22 restricted output are necessary. As the Third Circuit has explained, it is only “[i]f a firm can  
 23 profitably raise prices *without causing competing firms to expand output and drive down prices*,  
 24 that firm has monopoly power,’ and therefore ‘[t]he existence of monopoly power may be proven  
 25 through direct evidence of supracompetitive prices and restricted output.’” *Mylan*, 838 F.3d at  
 26 434 (emphasis added). The Court also notes that, in the pharmaceutical context, there may be

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 v. *Maricopa Cty.*, 693 F.3d 896 (9th Cir. 2012).

1 reasons to be cautious about finding market power based on supracompetitive pricing alone – *i.e.*,  
2 because, presumably, a brand drug will always be more expensive than a generic one, often for  
3 reasons which are not anticompetitive. *See Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38,  
4 55 (D.D.C. 2008) (noting that “[g]eneric drugs normally enter the market at a price lower than  
5 their branded equivalents” and that “[m]anufacturers of generic drugs also do not engage in the  
6 substantial marketing and promotional activities undertaken by manufacturers of branded drugs,  
7 resulting in lower costs associated with their products”; “[w]ithout a showing that Warner  
8 Chilcott’s higher prices were the result of restricted output – an inquiry that requires a showing as  
9 to the scope of the relevant market – Plaintiffs’ sources of evidence cannot unambiguously  
10 establish Warner Chilcott’s market power”). At the same time, it could be argued that, under  
11 traditional microeconomic principles, raising prices (whether by a monopolist or other competitor)  
12 would naturally tend to diminish demand (and hence output) relative to that market participant,  
13 and thus absolute categorical approach may not be appropriate. The Court need not resolve the  
14 “and/or” dichotomy at this juncture because, for the reasons discussed below, there are factual  
15 questions as to each element which preclude summary judgment.

16 1. Restricted Output

17 Defendants argue there is a genuine dispute of fact on market power because, to the extent  
18 Plaintiffs assert there is direct evidence of market power, they have failed to show that Defendants  
19 restricted output: “The reason for this is that output is increasing. For example, more than 35 new  
20 HIV products have been introduced in the market since Truvada was introduced.” Opp’n at 10.

21 In response, Plaintiffs argue that, even if they have to show restricted output, they have  
22 done so here – *i.e.*, Gilead conspired with Teva, Janssen, and/or BMS to delay generic competition  
23 and, therefore, output was restricted. *See Reply* at 28 (“[B]oth the reverse payments to Teva and  
24 the NGRs reduced output by eliminating generic manufacturers as a source of the relevant  
25 products for a period of time, thereby limiting available supply to that manufactured by the  
26 brand.”).

27 Although Plaintiffs’ theory of restricted output seems viable, the question at summary  
28 judgment is whether there is a question of fact as to restricted output. Here, there are (as discussed



1 below) disputed facts as to whether, *e.g.*, Teva or other generic manufacturers did in fact delay  
2 entry into the market as a result of the patent settlement agreement between Gilead and Teva.  
3 There are also disputed facts as to whether, even in the absence of the NGRs, Gilead, Janssen,  
4 and/or BMS would have made a “generic” version of the relevant FDC. Finally, it is debatable  
5 whether a fair assessment of output can be made in the instant case without knowing what the  
6 relevant product market is in the first place – an issue that informs the question of whether there is  
7 *indirect* evidence of market power.

8 2. Supracompetitive Pricing

9 Defendants also argue that, with respect to direct evidence of market power, there is a  
10 genuine dispute of fact on supracompetitive pricing. For the reasons discussed below, the Court  
11 agrees.

12 Plaintiffs take the position that, once a generic version of a brand drug is available, then the  
13 competitive price for the brand drug is the price of the generic; thus, the brand drug price which  
14 exceeds the generic drug price is necessarily supracompetitive. Plaintiffs’ explanation as to why  
15 the price of a generic drug is the competitive price seems to be as follows: because Defendants  
16 were (as alleged) trying to delay generic competition, “the competitive price must be the price that  
17 purchasers would have enjoyed had Defendants not taken action to prevent the entry of AB-rated  
18 generics, *i.e.*, the price of AB-rated generics.” Mot. at 62.

19 Plaintiffs’ position is problematic for several reasons. First, the authority on which  
20 Plaintiffs rely addresses a product market (not a competitive price) being defined based on the  
21 anticompetitive harm being claimed. *See Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 616  
22 (N.D. Cal. 2020) (stating that “what the appropriate product market is depends on what  
23 anticompetitive harm is being claimed”); *accord U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986  
24 F.2d 589, 598 (1st Cir. 1993) (indicating that one must “remember[] to ask, in defining the market,  
25 why we are doing so: that is, what is the antitrust question in this case that market definition aims  
26 to answer?”; adding that “the nature of the claim can affect the proper market definition”). But  
27 product market definition matters where *indirect* evidence of market power is being considered; at  
28 this juncture the focus is on *direct* evidence. Second, even if product market definition should be



1 considered for purposes of direct evidence, product market definition is only *informed* by what the  
 2 alleged anticompetitive conduct is; such conduct is not automatically dispositive of the matter.<sup>15</sup>  
 3 Indeed, as discussed below, product market definition typically turns on what products are  
 4 economic substitutes, and there are factual questions concerning the identification of such  
 5 substitutes. Finally, under Plaintiffs’ position, in any generic competition case, the competitive  
 6 price will be the generic price which, in turn, would seem to “render most brand name  
 7 pharmaceutical companies . . . *per se* monopolists prior to generic entry,” *Kaiser Found. v. Abbott*  
 8 *Labs.*, No. CV 02-2443-JFW (FMOx), 2009 U.S. Dist. LEXIS 107512, at \*29 (C.D. Cal. Oct. 8,  
 9 2009); this is a difficult proposition to embrace.

10 Plaintiffs also indicate there is direct evidence of market power based on Defendants’ gross  
 11 margins on their drugs – over █████ “which is almost at the top of the Lerner Index range and far  
 12 above the pharmaceutical industry average. The Lerner Index is the ratio of (a) the product’s price  
 13 minus marginal cost (or gross margin) to (b) its price, and is a common measure of market  
 14 power.” Opp’n at 61; *see also In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn.  
 15 2016) (stating that “[t]here are generally accepted economic means of analyzing the probability  
 16 that given prices are supracompetitive using price and marginal cost” and indicating the Lerner  
 17 Index is one such means). But as other courts have recognized, gross margins are not dispositive  
 18 on the issue of market power. *See In re Opana ER Antitrust Litig.*, No. MDL No. 2580, 2021 U.S.  
 19 Dist. LEXIS 105342, at \*32 (N.D. Ill. June 4, 2021) (stating that “the Lerner index is a well-  
 20 established method implemented in the field of economics to find evidence of market power,  
 21 although not conclusive in and of itself”).

22 Furthermore, here, there are concrete reasons why the gross margins on the drugs at issue  
 23 should not be dispositive, particularly for summary judgment purposes. First, there is evidence  
 24 that Defendants’ gross margins are in line with those of other pharmaceutical companies. *See Wu*  
 25 *Rpt.* ¶ 292 (asserting that “Gilead’s gross margins are not out of line with the pharmaceutical  
 26 \_\_\_\_\_

27 <sup>15</sup> Otherwise, an antitrust plaintiff might well have an incentive to manipulate what the relevant  
 28 market is by narrowly defining what the anticompetitive conduct is. *Cf. Staley*, 446 F. Supp. 3d at  
 616. (stating that “[d]efining a product market is simply a way to determine whether a defendant  
 has market power”).

1 industry”). Second, there is evidence that “[m]arginal cost pricing . . . is not the applicable  
2 competitive benchmark in the pharmaceutical industry [because of] the high levels of R&D and  
3 other fixed and quasi-fixed costs.” Wu Rpt. ¶ 285; *see also United States v. Eastman Kodak Co.*,  
4 63 F.3d 95, 109 (2d Cir. 1995) (stating that “[c]ertain deviations between marginal cost and price,  
5 such as those resulting from high fixed costs, are not evidence of market power”; noting that  
6 “there was overwhelming evidence that Kodak’s film business is subject to enormous expenses  
7 that are not reflected in its short-run marginal costs” such as 8-9% of revenues being used for  
8 research and development and plants costing hundreds of millions of dollars); *In re Intuniv*  
9 *Antitrust Litig.*, 496 F. Supp. 3d 639, 659 (D. Mass. 2020) (stating that, “[i]n the market for a  
10 product with high fixed costs,’ such as a brand pharmaceutical product, ‘evidence that prices  
11 routinely exceed marginal costs may not necessarily be evidence that prices are supracompetitive,  
12 because even competitive prices may exceed marginal cost’[;] [a]s Judge Casper explained in  
13 *Solodyn*, treating such evidence as sufficient to establish market power would result in finding that  
14 all pharmaceutical companies exercised monopoly power”).

15       Regarding the latter, Plaintiffs contend that research and development costs are not fixed  
16 costs but rather sunk costs, and, because “[s]unk costs are one-time costs undertaken in the past  
17 and do not recur,” they “do not have to be covered by a firm’s price to support the firm’s  
18 continued participation in the market.” McGuire Market Power Reb. Rpt. ¶ 45 (emphasis in  
19 original); *see also Aggrenox*, 199 F. Supp. 3d at 667 (acknowledging *Kodak*’s statement that  
20 “fixed costs, rather than market power, can explain ‘certain deviations between marginal cost and  
21 price,’ but [stating] that will generally be true only if those are ongoing rather than historical fixed  
22 costs (the latter of which are sunk costs)”; “prices in a competitive market will tend . . . toward  
23 marginal cost, so prices substantially above that cost are supracompetitive by definition”); *cf. In re*  
24 *Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 302 n.4 (D.R.I. 2019) (stating that “[h]igh  
25 brand margins indeed may be necessary to recoup costs sunk into research and development, but  
26 the antitrust laws are not concerned with why brands need these margins, but instead how they got  
27 and, more to the point, maintained them”). While Plaintiffs’ expert, Dr. McGuire can advance this  
28 position, it is disputed by Defendants’ expert, Dr. Wu, and even some of the authority on which

1 Dr. McGuire relies seems to make statements favorable to Defendants. *See* Docket No. 1443-3  
2 (Opp'n at 48-49) (in opposition to motion to exclude Dr. Wu, pointing out that some of the  
3 academic literature cited by Dr. McGuire indicates that research and development costs do affect  
4 drug pricing). This battle of the experts cannot be resolved at summary judgment.

5 B. Indirect Evidence

6 Plaintiffs maintain that, even if there is a genuine dispute on market power based on direct  
7 evidence, there is no genuine dispute based on indirect evidence. As noted above, for indirect  
8 evidence of market power, "a plaintiff must: (1) define the relevant market, (2) show that the  
9 defendant owns a dominant share of that market, and (3) show that there are significant barriers to  
10 entry and show that existing competitors lack the capacity to increase their output in the short  
11 run." *Rebel Oil*, 51 F.3d at 1434. In the instant case, Plaintiffs contend that the product market is  
12 made up of only the brand drug and its AB-rated generic and, because Defendants had 100% of  
13 the market share for a given brand drug (until there was actual generic entry), that is quintessential  
14 market power. *See* Mot. at 63.

15 As indicated above, Plaintiffs' argument hinges on the issue of product market. A product  
16 market consists of the product at issue and all economic substitutes for that product. *See Hicks v.*  
17 *PGA Tour, Inc.*, 897 F.3d 1109, 1120 (9th Cir. 2018).

18 Economic substitutes have a "reasonable interchangeability of use"  
19 or sufficient "cross-elasticity of demand" with the relevant product.  
20 Including economic substitutes ensures that the relevant product  
21 market encompasses "the group or groups of sellers or producers  
who have actual or potential ability to deprive each other of  
significant levels of business."

22 *Id.*; *see also Truck-Rail Handling Inc. v. BNSF Ry. Co.*, No. C 02-02825 JSW, 2005 U.S. Dist.  
23 LEXIS 61300, at \*16 (N.D. Cal. Mar. 8, 2005) (stating that "products may be considered  
24 'reasonably interchangeable,' where there is cross-elasticity of demand, *i.e.* if customers would  
25 switch to alternatives in response to a price increase in the alleged monopolist's product"; in other  
26 words, a product market includes "'substitute products that constrain the monopolist's pricing").<sup>16</sup>

27 \_\_\_\_\_  
28 <sup>16</sup> The Ninth Circuit has also noted that a market's boundaries "may be determined by examining  
such practical indicia as industry or public recognition of the submarket as a separate economic

1           The Court is not persuaded that Plaintiffs are entitled to summary judgment on the issue of  
2 product market. As Defendants argue, there are questions of fact as to whether there are HIV  
3 drugs other than generics that could be economic substitutes for Defendants' brand drugs.  
4 Plaintiffs' medical experts admit that there are other drugs that can be used to treat HIV (including  
5 non-Gilead drugs), and there is evidence that some HIV patients did switch from one of  
6 Defendants' drugs to those other HIV drugs (including non-Gilead drugs), even before generic  
7 entry.<sup>17</sup> See, e.g., Toto Decl., Ex. 11 (at slide 13, noting that "[a] higher switch rate to Triumeq [a  
8 non-Gilead drug] is observed from Atripla"). There is also evidence that Gilead considered the  
9 prices of other HIV drugs in setting the pricing for its drugs. See, e.g., Toto Decl., Ex. 6 (Meyers  
10 Depo. at 23-24) (testifying that Gilead "anchored our pricing to existing price points" – e.g., "we  
11 anchored tenofovir to abacavir," "FTC to 3TC," and "elvitegravir to raltegravir"); Toto Decl., Exs.  
12 18-19 (showing similar prices for HIV regimens in 2011 and 2013). In addition, Gilead "adjusted  
13 its co-pay assistance offerings based on its competitors' offerings." Opp'n at 5; see also Toto  
14 Decl., Ex. 20 (at slide 1, assessing options for Gilead to take after competitor GSK expanded its  
15 co-pay program). In short, there is some evidence of cross-elasticity of demand. Accordingly, the  
16 Court cannot say that a reasonable jury could reach only the one conclusion favored by Plaintiffs –  
17 i.e., that the product market is made up of solely the brand drug and its generic Cf. *Mylan*, 838  
18 F.3d at 436 (rejecting plaintiff's argument that the relevant product market consisted of the brand  
19 drug and generic; agreeing "with the District Court's conclusion that the market was much broader  
20 and consisted of all oral tetracyclines prescribed to treat acne" because there was a consensus  
21 among dermatologists that all oral tetracyclines treat acne with similar effectiveness and "health

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22  
23 entity, the product's peculiar characteristics and uses, unique production facilities, distinct  
24 customers, distinct prices, sensitivity to price changes, and specialized vendors." *Image Tech.*  
25 *Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1204 (9th Cir. 1997) (quoting *Brown Shoe Co. v.*  
*United States*, 370 U.S. 294, 325 (1962)).

26 <sup>17</sup> Defendants suggest that switching was driven by HIV patients moving over from older drugs to  
27 newer/more innovative/better quality drugs. The Court acknowledges that some switching seems  
28 to have been made from one Gilead drug to another Gilead drug. The Court also acknowledges  
Plaintiffs' contention that Dr. Wu's switching analysis for Truvada specifically is flawed because  
he excluded sales of Truvada used for PrEP purposes. Plaintiffs are free to make these points to  
the jury but, for summary judgment purposes, they are not dispositive.

1 insurers and other managed care providers encouraged the widespread substitution of numerous  
2 other oral tetracyclines for Doryx”); *Intuniv*, 496 F. Supp. 3d at 663-64 (concluding that there was  
3 a question of fact as to whether product market was broader in scope than just the brand drug and  
4 generic; there was, *e.g.*, evidence that defendant used rebates and coupons to make the price of the  
5 brand drug cheaper, which indicated that the defendant was “competing with other non-stimulant  
6 ADHD treatments”).

7 In response, Plaintiffs argue that, while a non-Gilead therapeutic equivalent may have  
8 provided *some* restraint on the price of a given brand drug, that restraint was limited in nature, and  
9 only the generic was able to constrain prices to the competitive level (*i.e.*, the generic price). *See*  
10 *Mot.* at 65; *see also* Reply at 19 (asking “whether any price competition that Defendants faced  
11 from therapeutic alternatives drove prices *to the level that generic versions of the drugs would*  
12 *have delivered*”). The problem with Plaintiffs’ argument is that there are disputed questions of  
13 fact as to what was/is the competitive price with respect to a given brand drug. Plaintiffs’  
14 assertion turns on questions of degree, not absolutes; this implies there are question of fact.  
15 Whether the generic price is *the* competitive price is hotly disputed.

16 Accordingly, the Court denies Plaintiffs’ motion for summary judgment on market power.  
17 Contrary to what Plaintiffs contend, there are genuine disputes of material fact on both direct  
18 evidence and indirect evidence.

## 19 V. NGR CLAIMS

20 Plaintiffs assert the NGR claims against Gilead and Janssen. Both parties have moved for  
21 summary judgment on the NGR claims.

### 22 A. Relevant Background

23 Gilead and Janssen, as well as Gilead and BMS, entered into collaboration agreements to  
24 make FDCs (fixed-dose combination drugs). A FDC is, as its name suggests, made up of more  
25 than one drug. For example, Truvada (a Gilead drug) is a FDC because it is made up of two  
26 components: TDF and FTC. If a FDC is a *complete* HIV regimen on its own, then it is a STR  
27 (single-tablet regimen). Truvada is not a STR because it is made up of two NRTIs only  
28 (TDF/FTC) and needs to be taken with a third agent in order for the HIV regimen to be complete.

1 Under the collaboration agreements, Gilead and the other pharmaceutical company would  
 2 each contribute one or more drugs to making a FDC.<sup>18</sup> Because Gilead’s main drugs were NRTIs  
 3 and Janssen and BMS’s main drugs were third agents, some of the collaboration agreements  
 4 enabled the companies to offer STRs (*i.e.*, complete HIV regimens). *See* Mot. at 7. Without a  
 5 collaboration agreement, a FDC would not have been possible by a *single* collaborator for several  
 6 years because each collaborator’s drug contribution was protected by a patent that blocked the  
 7 other collaborator from offering the FDC on its own. “For example, if [Janssen] had not  
 8 collaborated with Gilead on Complera [made up of Janssen’s RPV and Gilead’s TDF/FTC],  
 9 Janssen would have had to wait until 2018 for generic 3TC<sup>[19]</sup> and generic TDF to become  
 10 available, thus depriving patients of an FDC utilizing the innovative RPV component for at least  
 11 seven years.” Mot. at 7-8; *see also* Reply at 3.

12 Each collaboration agreement entered into by Gilead and either Janssen or BMS contains  
 13 what Plaintiffs have called a NGR – *i.e.*, a noncompete provision related to generics. There are a  
 14 total of five collaboration agreements at issue.<sup>20</sup>

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22  
 23 <sup>18</sup> For some of the collaboration agreements, Gilead made financial contributions to the  
 24 development of the FDC. For instance, Gilead contributed money toward the development of  
 25 Symtuza. *See* Saint-Antoine Decl., Ex. 32 (Symtuza Agmt. § 9.1.2). Gilead also contributed  
 26 financially to Janssen’s development of RPV which was used to make Complera. *See* Mot. at 2  
 27 (noting that “Gilead agreed to reimburse Janssen up to \$100 million for costs associated with  
 28 developing RPV, which was in clinical trials and was two years away from FDA-approval when  
 the Complera Agreement was executed”); *see also* Saint-Antoine Decl., Ex. 29 (Complera Agmt.  
 § 10.1).

<sup>19</sup> 3TC is a drug that, in essence, can be used in lieu of FTC (or generic FTC).

<sup>20</sup> Plaintiffs are no longer asserting a NGR claim based on the Atripla Agreement.



Agreement	Date	Components
Complera Agreement (Gilead/Janssen)	July 2009	RPV TDF FTC
Odefsey Agreement (Gilead/Janssen)	December 2014	RPV TAF FTC
Prezcobix Agreement (Gilead/Janssen)	June 2011	DRV COBI
Symtuza Agreement (Gilead/Janssen)	December 2014	DRV TAF FTC COBI
Evotaz Agreement (Gilead/BMS)	October 2011	ATV COBI

Essentially, each NGR provided that a collaborator could not enter into competition with the collaboration drug (the FDC) by making an identical drug *or a near-identical one*. In other words, even if the first collaborator’s drug used in the FDC lost its patent protection, the second collaborator could not then make a FDC consisting of its own patent-protected drug and a generic version of the first collaborator’s drug. *See, e.g.,* Huttinger Decl., Ex. 85 (Summary of License and Collaboration Agreement, effective date 7/16/2009) (regarding Complera, stating that Janssen “cannot make a combination of [RPV] plus a generic version of Truvada after the patents on Truvada expire until the Agreement terminates, unless [Janssen] uses dosages therapeutically different from those in the [combination product]”).

According to Plaintiffs, an NGR provided a way for the first collaborator to effectively get extended protection for its drug even after the patents that had protected the drug expired.

Defendants, in turn, argue that the NGRs were reasonably necessary in order for the collaborations to take place in the first instance and that the NGRs do not restrain any more than does an exclusive license: “For example, in terms of substantive licensing rights, . . . Janssen [could not] introduce a generic version of Complera (TDF/FTC/RPV) without practicing the RPV patents it exclusively licensed to Gilead in the field of use for Complera.” Mot. at 12. Defendants also assert that the NGRs are narrow noncompetes because (1) the NGRs did not prevent a



1 collaborator from developing *different* cART drugs (including ones that would compete with the  
2 collaboration FDC), *see* Mot. at 10, and (2) the NGRs affected only the parties to the collaboration  
3 and “have no effect on third-party generic manufacturers.” Mot. at 9; *see also* Reply at 4 (arguing  
4 that the NGRs did not “impede *any* entry by generic manufacturers”; Plaintiffs’ theory “has  
5 nothing to do with the generic industry [and] is premised entirely on the wholly unsubstantiated  
6 allegation that *one of the brand collaborators* would have entered with a generic version of its  
7 own joint venture product”) (emphasis in original). With respect to (1), Janssen did in fact  
8 collaborate with other pharmaceutical companies to create FDCs to treat HIV. For example,  
9 Janssen contributed its drug RPV to make FDCs with another company known as ViiV – *e.g.*,  
10 Juluca and Cabenuva.

11 B. Ancillary Restraint

12 As the Court noted in a prior order, “agreements between competitors – what are known as  
13 ‘horizontal agreements’ – are suspect from an antitrust perspective.” *Staley v. Gilead Scis., Inc.*,  
14 446 F. Supp. 3d 578, 594 (N.D. Cal. 2020). But a horizontal agreement is not automatically  
15 deemed per se unlawful. *Cf. O’Bannon v. NCAA*, 802 F.3d 1049, 1070 (9th Cir. 2015) (stating  
16 that “[s]ome types of restraints . . . have such predictable and pernicious anticompetitive effect,  
17 and such limited potential for procompetitive benefit that they are deemed unlawful per se”; but  
18 “[p]er se treatment is proper only ‘[o]nce experience with a particular kind of restraint enables the  
19 [c]ourt to predict with confidence that the rule of reason will condemn it’”). Indeed, a per se rule  
20 does not make sense “where fusions or integrations of economic activity [between competitors]  
21 occur[.]” and the competitors agree to a restraint simply to “eliminate[.] rivalry within [their]  
22 enterprise [as a] means of enhancing the [enterprise’s] efficiency.” *Rothery Storage & Van Co. v.*  
23 *Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986); *see also* Areeda & Hovenkamp,  
24 Antitrust Law ¶ 2134 (noting that, “[w]hen the noncompetition agreement is . . . an agreement  
25 creating a new business, the offsetting benefits can be significant”). The ancillary restraints  
26 doctrine recognizes this principle.

27 Under the "ancillary restraints" doctrine, a horizontal agreement is  
28 "exempt from the per se rule," and analyzed under the rule-of-reason  
[instead], if it meets two requirements. These requirements are that

1 the restraint must be (1) "subordinate and collateral to a separate,  
2 legitimate transaction," and (2) "reasonably necessary" to achieving  
3 that transaction's pro-competitive purpose.

4 *Aya Healthcare Servs. v. AMN Healthcare, Inc.*, 9 F.4th 1102, 1109 (9th Cir. 2022); *see also*  
5 *Areeda & Hovenkamp*, Antitrust Law ¶ 1905 (stating that "[a] restraint is ancillary if it somehow  
6 makes the market more competitive by facilitating the creation of a new product or process,  
7 enabling new entry, or expanding output").

8 According to Gilead/Janssen, the NGRs are ancillary restraints and therefore subject to the  
9 rule of reason. Gilead/Janssen also argue that, under a rule-of-reason analysis, they are entitled to  
10 summary judgment. Plaintiffs have not moved on summary judgment based on the rule of reason.  
11 Rather, Plaintiffs contend that quick look review, instead of the rule of reason, should apply. *See*  
12 *Cal. ex rel. Harris*, 651 F.3d 1118, 1134 (9th Cir. 2011) (noting that "the rule of reason analysis  
13 can sometimes be applied 'in the twinkling of an eye'"; "this truncated rule of reason or 'quick  
14 look' antitrust analysis may be appropriately used where 'an observer with even a rudimentary  
15 understanding of economics could conclude that the arrangements in question would have an  
16 anticompetitive effect on customers and markets'"). Plaintiffs assert that, under the quick look  
17 standard, they are entitled to summary judgment.

18 As an initial matter, the Court notes that the Ninth Circuit has not clearly articulated how  
19 quick look review applies when analyzing ancillary restraints. As noted above, in *Aya* (and in  
20 other cases), the Ninth Circuit has discussed the ancillary restraints doctrine in terms of the per se  
21 rule and rule-of-reason standard only. *See, e.g., Aydin Corp. v. Loral Corp.*, 718 F.2d 897, 901  
22 (9th Cir. 1983) (stating that "[t]he proper function of ancillarity in the antitrust analysis 'is to  
23 remove [in some instances] the per se label from restraints otherwise falling within the category'[:]  
24 [w]hether a restraint that does not fall within a per se category is ancillary to a valid agreement is  
25 relevant only in the sense that ancillarity increases the probability that the restraint will be found  
26 reasonable"). The Seventh Circuit, however, has indicated that an ancillary restraints analysis is,  
27 in some respects, a quick look review in and of itself, *i.e.*, to determine whether a full-blown rule-  
28 of-reason analysis is warranted:

A court must distinguish between "naked" restraints, those in which

1 the restriction on competition is unaccompanied by new production  
 2 or products, and “ancillary” restraints, those that are part of a larger  
 endeavor whose success they promote. . . .

3 . . . .

4 A court must ask whether an agreement [not to compete] promoted  
 enterprise and productivity at the time it was adopted. If it *arguably*  
 5 did, then the court must apply the Rule of Reason to make a more  
 discriminating assessment. . . .

6 A restraint is ancillary when it *may* contribute to the success of a  
 cooperative venture that promises greater productivity and output.  
 7 If the restraint, viewed at the time it was adopted, *may* promote the  
 success of this more extensive cooperation, then the court must  
 8 scrutinize things carefully under the Rule of Reason. Only when a  
 quick look reveals that “the practice facially appears to be one that  
 9 would always or almost always tend to restrict competition and  
 decrease output” should a court cut off further inquiry.

10  
 11 *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 188-89 (7th Cir. 1985) (emphasis  
 12 added); *see also* Areeda & Hovenkamp, Antitrust Law ¶ 1908 (stating that “[d]etermining whether  
 13 a restraint it ancillary is simply a way of deciding whether it can be condemned as illegal ‘per se,’  
 14 or upon a relatively quick look; or whether a more complete analysis of the market and likely  
 15 competitive effects is essential”); *cf. MLB Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 338 (2d Cir.  
 16 2008) (Sotomayor, J., concurring) (stating that “a *per se* or quick-look approach may apply to [a]  
 17 joint venture[] . . . where a particular challenged restraint is not reasonably necessary to achieve  
 18 any of the efficiency-enhancing benefits of a joint venture and serves only as [a] naked restraint  
 19 against competition”).

20 Notably, in its most recent case on the ancillary restraints doctrine, the Ninth Circuit quoted  
 21 *Polk* with approval: “‘A restraint is ancillary when it *may* contribute to the success of a  
 22 cooperative venture that promises greater productivity and output.’” *Aya*, 9 F.4th at 1110  
 23 (emphasis added). Accordingly, even though the Ninth Circuit has stated that a restraint is  
 24 ancillary only if, *inter alia*, it is “‘reasonably necessary’ to achieving [the] transaction’s pro-  
 25 competitive purpose,” *id.* at 1109, the “reasonably necessary” requirement does not demand as  
 26 much rigor as the language might suggest. *See also Med. Ctr. at Elizabeth Place, LLC v. Atrium*  
 27 *Health Sys.*, 922 F.3d 713, 726 (6th Cir. 2019) (rejecting the contention that “an ancillary restraint  
 28 must be *necessary* to achieve the joint venture’s efficiency-enhancing purpose”; so long as a

1 restraint *arguably* or *plausibly* promotes enterprise and productivity, that is sufficient to warrant  
 2 application of the rule of reason) (emphasis in original); *cf. Aya*, 9 F.4th at 1111 (stating that a  
 3 defendant “need not satisfy a less-restrictive-means test to demonstrate that the [restraint] is an  
 4 ancillary [one]”; “the less restrictive alternative analysis falls within the rule-of-reason analysis,  
 5 not the ancillary restraint consideration.”). Indeed, in *Aya*, the Ninth Circuit concluded that a  
 6 restraint was reasonably necessary because, without it, the defendant ““would *likely* be less willing  
 7 or unwilling” to enter into the parties’ cooperative agreement.<sup>21</sup> *Aya*, 9 F.4th at 1109 (emphasis  
 8 added).

9 The Court thus follows the approach expressly taken by the Seventh Circuit – and  
 10 implicitly followed by the Ninth Circuit – in evaluating whether the NGRs are ancillary

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 12  
 13 <sup>21</sup> In *Aya*, the plaintiff and defendant were both healthcare staffing agencies that placed travel  
 14 nurses on temporary assignment. *See Aya*, 9 F.4th at 1106. Because the defendant was unable to  
 15 fill the demand of its hospital customers for travel nurse assignments, it began to refer “spillover  
 16 assignments” to its network of subcontractors (other healthcare staffing agencies). The plaintiff  
 17 and defendant entered into a subcontracting agreement, and that agreement contained a provision  
 18 that prohibited the plaintiff from soliciting the defendant’s employees. The defendant terminated  
 19 its relationship with the plaintiff after the plaintiff began to actively solicit the defendant’s travel  
 20 nurse recruiters. *See id.* at 1106-07. The plaintiff then sued the defendant, arguing that the  
 21 nonsolicitation agreement was an antitrust violation. The Ninth Circuit recognized that the  
 22 parties’ nonsolicitation agreement was a horizontal restraint because, even though “the parties  
 23 were ‘in a subcontractor-subcontractee relationship,’ the agreement ‘restricts [the defendant’s]  
 24 actual or potential employer-rival . . . from competing with [the defendant] for its employees by  
 25 soliciting them to work for [the plaintiff].’” *Id.* at 1109. But the Ninth Circuit held that the  
 26 nonsolicitation agreement was

27 reasonably necessary to the parties’ pro-competitive collaboration.  
 28 The purpose of the parties’ contract was to supply hospitals with  
 traveling nurses. The non-solicitation agreement is necessary to  
 achieving that end because it ensures that [the defendant] will not  
 lose its personnel during the collaboration. As the district court  
 noted, [the defendant] may want to “guard[] its investments and  
 establish[] . . . relationships with only those agencies that agree,  
*inter alia*, not to abuse the relationship by proactively raiding [the  
 defendant’s] employees, [associate vendors], and customers.”  
 Without the restraint, [the defendant] “would likely be less willing  
 or unwilling to deal with other agencies to supply travel nurses to  
 hospitals which, as [the plaintiff] also recognize[d], already  
 experience a ‘chronic shortage of nurses.’” And with the restraint,  
 [the defendant] may collaborate with its competitor for the benefit of  
 its client without “cutting [its] own throat.”

*Id.* at 1110.

1 restraints.<sup>22</sup> Notably, the ancillary restraints issue appears to be one for the Court, and not a jury,  
 2 to decide. *See Staley*, 446 F. Supp. 3d at 596 (noting that “‘the decision of what mode of analysis  
 3 to apply . . . is entirely a question of law for the Court,’ although that legal question ‘might involve  
 4 factual disputes’”); *cf. Med. Ctr. at Elizabeth Place, LLC v. Atrium Health Sys.*, 922 F.3d 713, 727  
 5 (6th Cir. 2019) (stating that “whether a given restraint falls within the per se category is a question  
 6 of law”). The Court analyzes the issue here using this framework.

7 In the instant case, there is no real dispute that the NGRs are “‘subordinate and collateral to  
 8 a separate, legitimate transaction’” (*i.e.*, the collaboration agreements). *Id.* at 1109; *see also*  
 9 Opp’n at 31 (acknowledging that “‘introducing new FDCs increases consumer choice and  
 10 combining HIV drugs reduces pill burden and may increase adherence and improve treatment  
 11 outcomes’”). Plaintiffs’ main contention is that the NGRs were not reasonably necessary in order  
 12 for the collaborations to have taken place in the first instance. According to Plaintiffs, the NGRs  
 13 are inherently suspect because they effectively give protection to a collaborator’s drug even after  
 14 the patent protecting the drug has expired. Plaintiffs also argue that the NGRs were not  
 15 reasonably necessary for the collaborations because the collaboration agreements would have been  
 16 profitable for Gilead and Janssen, or Gilead and BMS, even if no NGRs were included. In other  
 17 words, because significant profits could still be made, Plaintiffs assert that the companies would  
 18 have entered into the collaborations even without any NGRs. Finally, Plaintiffs contend that  
 19 Gilead/Janssen’s justifications for the NGRs – preventing a collaborator from free riding on the  
 20 efforts of the joint venture and protecting each collaborator’s know-how – are not cognizable  
 21 and/or not plausible.

22 Although Plaintiffs’ arguments above are not without any merit, they cannot prevail as a  
 23

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24 <sup>22</sup> In their papers, Plaintiffs have cited the Seventh Circuit’s decision in *Polk* approvingly.  
 25 Although Plaintiffs’ initial interpretation of *Polk* was not entirely consistent with the Court’s  
 26 interpretation above, *see* Opp’n at 30 (arguing that, under *Polk*, “even if the Court finds the NGRs  
 27 to be ancillary restraints, they still must be scrutinized using the quick look approach or evaluated,  
 28 at a minimum, under a full-blown rule of reason analysis”), their subsequent interpretation, as  
 articulated in their sur-reply, is. *See* Sur-Reply at 10 (stating that both the quick look doctrine and  
 the ancillary restraints “serve as screening tools that allow the Court to determine the appropriate  
 mode of analysis without a full-blown economic assessment of market power and effects”); *cf.*  
 Sur-Reply at 18 (conceding that the Ninth Circuit’s decision in “*Aya* can be interpreted to adopt a  
 plausibility standard with respect to the ancillary restraints doctrine”).

1 matter of law. First, while Plaintiffs correctly note that “all patents, and all benefits from them,  
2 must end when their terms expire,” *Kimble v. Marvel Entm't, LLC*, 576 U.S. 446, 463 (2015), that  
3 is simply a reflection of patent law. What transgresses patent law is not necessarily equivalent to  
4 what transgresses antitrust law. In *Kimble*, the Supreme Court held that the payment of royalties  
5 after patent expiration was unlawful as a matter of patent law only, not antitrust law. *See id.* at  
6 462-63 (noting that precedent “did not rely on the notion that post-patent royalties harm  
7 competition”; “in deciding whether post-expiration royalties comport with patent law, *Brulotte* did  
8 not undertake to assess that practice’s likely competitive effects” but rather “applied a categorical  
9 principle that all patents, and all benefits from them, must end when their terms expire.”).  
10 Therefore, conduct that protects a product after patent expiration is not automatically an antitrust  
11 violation, nor is it inherently suspect (though it may be taken into account as part of the antitrust  
12 calculus).

13         Second, there is no dispute that the collaborations in and of themselves are procompetitive,  
14 making new products available and earlier in time (*i.e.*, compared to when products using generic  
15 components would be available). And as Defendants argue, the NGRs plausibly facilitated those  
16 collaborations, and made it more likely that Gilead and Janssen, or Gilead and BMS, would enter  
17 into the collaborations in the first place. The brand manufacturers were more likely to enter into  
18 collaborations with the NGRs because the NGRs prevented a collaborator from competing with  
19 the collaboration by selling, an identical or near identical drug. *See Princo Corp. v. ITC*, 616 F.3d  
20 1318, 1336 (Fed. Cir. 2010) (stating that “‘ancillary restraints’ that are often important to  
21 collaborative ventures [include] agreements between the collaborators not to compete against their  
22 joint venture”); *Engine Specialties, Inc. v. Bombardier, Ltd.*, 605 F.2d 1, 11 (1st Cir. 1979)  
23 (stating that a certain provision was “not offensive in and of itself” because it simply stated that  
24 “neither of the parties to the joint venture will compete with it by acting as agents for other  
25 parties”); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 280 (6th Cir. 1898) (Taft, J.)  
26 (noting that, “when two men became partners in a business, although their union might reduce  
27 competition, this effect was only an incident to the main purpose of a union of their capital,  
28 enterprise, and energy to carry on a successful business, and one useful to the community[;]



1 [r]estrictions in the articles of partnership upon the business activity of the members, with a view  
2 of securing their entire effort in the common enterprise, were, of course, only ancillary to the main  
3 end of the union, and were to be encouraged”). Even if, as Plaintiffs contend, significant profits  
4 could have been made from collaborations without any NGRs, it is plausible that the brand  
5 manufacturers were less willing to collaborate without them.

6 Furthermore, the NGRs may have facilitated the collaborations in other ways – because, as  
7 Defendants contend, they arguably prevented a collaborator from free riding on the efforts of the  
8 joint venture and/or protected each collaborator’s know-how. Courts and other authorities have  
9 recognized that free riding is a legitimate concern when people or entities embark on a joint  
10 venture. *See, e.g., Rothery*, 792 F.2d at 217, 221 (national moving company, Atlas, required that  
11 any independent moving company doing business as its agent either (1) “abandon its independent  
12 interstate authority and operate only under Atlas’ authority” or (2) “create a new corporation . . . to  
13 conduct interstate carriage separate from its operation as an Atlas agent”; concluding that “the  
14 challenged agreement enhances the efficiency of the van line” by eliminating “the problem of the  
15 free ride”: “[t]o the degree that a carrier agent uses Atlas’ reputation, equipment, facilities, and  
16 services in conducting business for its own profit, the agent enjoys a free ride at Atlas’ expense”);  
17 *Med. Ctr. at Elizabeth Place*, 922 F.3d at 730 (defendant-hospitals contracted with physicians and  
18 payers on the condition that they not do business with plaintiff-hospital; stating that “Hospital  
19 Defendants had a plausible concern that, without these contracts, physicians who invested in  
20 [plaintiff] could rent office space at a [defendant]-associated hospital, free ride on the reputation  
21 and facilities of that hospital, and then refer patients out to [plaintiff]”); *Aya*, 9 F.4th at 1110  
22 (defendant-health care staffing agency hired plaintiff-health care staffing agency as a  
23 subcontractor and included a nonsolicitation provision in their contract; finding that restraint  
24 reasonably necessary because “it ensures that [defendant] will not lose its personnel during the  
25 collaboration”: defendant “may want to ‘guard[] its investments and establish[] [subcontracting]  
26 relationships with only those agencies that agree, *inter alia*, not to abuse the relationship by  
27 proactively raiding [defendant’s] employees, [associate vendors], and customers”); *see also*  
28 *Areeda & Hovenkamp*, Antitrust Law ¶ 2213c (stating that “joint venturers may have quite

1 legitimate reasons for restraining members’ competitive business outside the venture,” with  
2 “[m]ost such concerns apply[ing] to some variation of the free rider problem[;] [b]asically, the  
3 venture must have some way of protecting the intellectual property, trade secrets and other  
4 learning of the venture from being used in competition with the venture itself,” and, “[i]f such  
5 protection is insufficient the venture will be deterred from forming in the first place”).

6 In the case at bar, the brand manufacturers had a plausible concern that there could be free  
7 riding on their joint ventures – *i.e.*, one collaborator could piggyback on the time, effort, and  
8 expense/investment put into the joint venture FDC and offer its own competing FDC once generic  
9 components were available (that it could combine with its own brand component). *See, e.g.*,  
10 Saint-Antoine Decl., Ex. 7 (Gilead/O’Connell Depo. at 305-06) (referring to “the investments  
11 Gilead would need to make financially and in resources and time in developing R/F/TAF being  
12 subverted by our partner on that drug developing a direct competitor containing those  
13 components”); Saint-Antoine Decl., Ex. 38 (Gilead/O’Connell email) (stating that “[t]he mutual  
14 non-compete remains an important issue to Gilead senior management” as “[i]t would be  
15 untenable for our partner to develop a DRV combo containing TDF while Gilead is investing in  
16 development of the STR”); Huttinger Decl., Ex. 101 (Gilead/O’Connell email) (stating that, “[i]n  
17 my view, this [NGR] would be a nice ‘get’ and is justified as a way to encourage the parties to  
18 commit exclusively to investing in this new improved product[;] [w]e clearly don’t want our  
19 investments in R/F/TAF to be wasted by one party developing a direct competitor”); Saint-  
20 Antoine Decl., Ex. 27 (Janssen/Stoffels email) (stating that “[w]e need to be sure, we have  
21 exclusivity to the DRV-COBI combo to avoid generic entrance including by [Gilead]  
22 themselves”).

23 Plaintiffs correctly note that generic piggybacking is authorized and/or encouraged by  
24 federal law: for example, the Hatch-Waxman Act expressly allows a generic manufacturer to file  
25 an abbreviated new drug application instead of a new drug application. *See FTC v. Actavis, Inc.*,  
26 570 U.S. 136, 142 (2013) (noting that “[t]he Hatch-Waxman Act permits a generic manufacturer  
27 to file an Abbreviated New Drug Application [instead of a New Drug Application] specifying that  
28 the generic has the ‘same active ingredients as,’ and is ‘biologically equivalent’ to, the already-

1 approved brand-name drug” – thus allowing a generic manufacturer “to piggyback on the [brand  
2 drug] pioneer’s approval efforts”). And clearly, generic piggybacking can happen without any  
3 collaboration. But contrary to what Plaintiffs suggest, this does not necessarily mean that joint  
4 venture efforts would not be of any value to a collaborator wanting to make a competing FDC  
5 with its own brand component plus generic components. Arguably, joint venture efforts in which,  
6 *e.g.*, technical information is shared and made available, would make it easier for the company to  
7 make its own competing FDC. And the enhanced risk of that piggybacking via the joint venture  
8 could likely make the other collaborator less willing to enter into the collaboration.

9 The NGRs also made Gilead, Janssen, and/or BMS more likely to collaborate because they  
10 plausibly provided protection for the companies’ know-how – including that related to “clinical  
11 development, regulatory approval, and manufacturing of each FDC.”<sup>23</sup> Mot. at 21. *See, e.g.*,  
12 Saint-Antoine Decl., Ex. 6 (Gilead/Meyer Depo. at 73-74) (testifying that, “[b]y 2014 we had  
13 essentially handed over the keys to the shop, if you will, to Janssen,” including proprietary  
14 “[i]nformation around how we scaled up manufacturing, our regulatory filing processes, our co-  
15 formulation capabilities and techniques”); Saint-Antoine Decl., Ex. 2 (Janssen/Watson Depo. at  
16 104-05) (testifying that Gilead was getting “unique insight . . . into the way that we would develop  
17 [the drug] and how we would manufacture it”; “we were also investing heavily in the development  
18 program and working together, by the way, on that development program, which is every different  
19 from taking an exclusive license, paying an upfront in milestones and the partners never doing  
20 anything together”); Saint-Antoine Decl., Ex. 2 (Janssen/Watson Depo. at 95-96) (stating that “we  
21 were sharing our development strategy and plans[;] [s]o the fact that they can comment on our  
22 protocols, they were seeing, way ahead of the rest of the market, what we planned to do in terms  
23 of studying this asset and putting, you know, the plans together to develop the fixed-dose  
24 combination” – “[s]o now they have a distinct advantage by seeing our clinical strategy and our  
25

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26 <sup>23</sup> To the extent Plaintiffs point out that the collaboration agreements already included  
27 confidentiality provisions that protected know-how, that is an argument that there was a less  
28 restrictive alternative available – which is part of a rule-of-reason analysis. Moreover, Defendants  
have raised plausible arguments that confidentiality provisions have limitations (*e.g.*, it is likely  
easier to prove a violation of a noncompete clause as opposed to a confidentiality clause) and that  
noncompete provisions thereby give added assurances to collaborators.

1 clinical expertise that went into that plan” and “there would have to be certain manufacturing  
 2 information shared between the parties [too]”); Saint-Antoine Reply Decl., Ex. 73  
 3 (Gilead/O’Connell Depo. at 107-08) (testifying that Janssen would give Gilead, *e.g.*, “safety  
 4 reports on darunavir [component used in Prezcoibix and Symtuza],” “regulatory filings,”  
 5 “proprietary data that goes into those regulatory filings,” “technique, manufacturing secrets,” and  
 6 “process development secrets”); Saint-Antoine Reply Decl., Ex. 75 (Janssen and Gilead  
 7 exchanging draft summaries of “Biopharmaceutical Studies and Associated Analytical Methods”  
 8 regarding Complera); Saint-Antoine Reply Decl., Ex. 76 (in slides related to Symtuza meeting,  
 9 indicating that Gilead/Janssen discussed Janssen’s proposed “Development Plan” and “Clinical  
 10 Studies” and that Gilead provided “Clinical Trial Materials” Gilead to provide “Clinical Trial  
 11 Materials” on COBI, FTC, and TAF); Saint-Antoine Reply Decl., Ex. 77 (in minutes related to  
 12 Prezcoibix, indicating that Gilead would conduct clinical studies evaluating whether COBI  
 13 “adequately boosts . . . DRV”).

14 To be clear, this is not to say that the NGRs thereby withstand antitrust scrutiny. The  
 15 Court’s only conclusion here is that, because the NGRs *may* have facilitated the collaborations,  
 16 they fall within the ancillary restraint rubric and therefore a more searching analysis under the rule  
 17 of reason must be done.

18 Accordingly, the Court holds that there is a sufficient showing that the NGRs are ancillary  
 19 restraints. The NGRs arguably facilitate the procompetitive collaborations in several ways:  
 20 because they plausibly prevent a collaborator from competing with the collaboration with an  
 21 identical or near identical drug; prevent a collaborator from free riding on the joint venture efforts;  
 22 and protect a collaborator’s know-how. The rule of reason therefore applies.<sup>24</sup>

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23  
 24 <sup>24</sup> Even if Plaintiffs are correct that the Court should do a quick-look review *after* finding the  
 25 NGRs to be ancillary restraints, they would fare no better. “[Q]uick-look analysis carries the day  
 26 when the great likelihood of anticompetitive effects can easily be ascertained,” *i.e.*, “where a  
 27 practice has obvious anticompetitive effects” or where there are not even any “plausibl[e]”  
 28 procompetitive effects. *Cal. Dental Ass’n v. F.T.C.*, 526 U.S. 756, 770 (1999). Here, it is hard to  
 say that anticompetitive effects are obvious if only because whether there are anticompetitive  
 effects will turn in part on what the product market is. *See Worldwide Basketball & Sport Tours,  
 Inc. v. NCAA*, 388 F.3d 955, 961 (6th Cir. 2004) (“Under the ‘quick-look’ approach, extensive  
 market and cross-elasticity analysis is not necessarily required, but where, as here, the precise  
 product market is neither obvious nor undisputed, the failure to account for market alternatives

1 At the hearing, Plaintiffs argued that, at the very least, the expanded NGR for Complera  
2 should not be considered an ancillary restraint and should instead be subject to quick look review.  
3 The NGR in the original Complera Agreement from 2009 precluded a collaborator from  
4 competing with generic versions of the component drugs only (RPV/TDF/FTC). In 2014, when  
5 the parties entered into the Odefsey Agreement (Odefsey being the “successor” drug to Complera  
6 but using TAF instead of TDF), the parties also agreed to broaden the NGR for Complera – *i.e.*, so  
7 that a collaborator was precluded from using not only generic FTC but also 3TC (a substitute drug  
8 for FTC). Plaintiffs contend that Janssen agreed to the broadening of the Complera NGR only  
9 when Gilead agreed to provide a reciprocal benefit to Janssen, *i.e.*, including a NGR in the  
10 Symtuza Agreement that would run to the benefit of Janssen. *See* Opp’n at 29. In short, the  
11 companies exchanged non-compete provisions (a broadened one for Gilead).

12 Although Plaintiffs may have a better argument here, the Court is not persuaded that the  
13 rule of reason should therefore be bypassed. As noted in one learned antitrust treatise:

14 An agreement between two established stores in a shopping center  
15 that divides the products they will sell and unaccompanied by any  
16 new integration or enterprise[] is . . . viewed with great suspicion.  
17 However, they may be justified nonetheless if they accompany  
18 secondary transactions that continue or expend the previously  
19 existing joint venture or business relationship[;] [f]or example, firms  
20 may already have developed a venture to engage in research and  
development of a product but negotiate a noncompetition agreement  
later, when they have succeeded and marketing is contemplated. *Or*  
*[firms] may have an established venture covering the development*  
*of a product but contemplate expansion of sales or development of a*  
*second product.*

21 Areeda & Hovenkamp, Antitrust Law ¶ 2134d2 (emphasis omitted and added). Here, there was  
22 such an established venture and Plaintiffs have not demonstrated there was no business  
23 justification (such as contemplated expansion of sales or development of a second product) for the  
24 expansion of the NGR. *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005), the main

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26 \_\_\_\_\_  
27 and to analyze the dynamics of consumer choice simply will not suffice.”); *Deutscher Tennis*  
28 *Bund v. ATP Tour, Inc.*, 610 F.3d 820, 832 (3d Cir. 2010) (“Because ‘the contours of the market’  
here are not ‘sufficiently well known or defined to permit the court to ascertain without the aid of  
extensive market analysis whether the challenged practice impairs competition,’ ‘quick look’ is  
not appropriate and proof of relevant market is required under full-scale rule of reason.”).

1 authority cited by Plaintiffs at the hearing, is not to the contrary. In *Polygram*, two companies  
 2 agreed to distribute together a recording of a concert given by the Three Tenors in 1998. They  
 3 then agreed to suspend, for a period of time, advertising and discounting of two different concert  
 4 albums by the Three Tenors, one distributed by one company in 1990 and the other distributed by  
 5 the other company in 1994. The D.C. Circuit noted that “[a]n agreement between joint venturers  
 6 to restrain price cutting and advertising with respect to products *not* part of the joint venture looks  
 7 suspiciously like a naked price fixing agreement between competitors.” *Id.* at 37 (emphasis  
 8 added). But *Polygram* differs from the instant case because, there, the earlier products were not  
 9 part of any joint venture between the companies. Here, the opposite is true.

10 Because the Court concludes that the NGRs are ancillary restraints, the rule of reason  
 11 applies, and Plaintiffs’ motion for summary judgment (which is dependent on a quick look review)  
 12 is denied.

13 C. Rule of Reason

14 Under the rule of reason,

15 the plaintiff has the initial burden to prove that the challenged  
 16 restraint has a substantial anticompetitive effect that harms  
 17 consumers in the relevant market. If the plaintiff carries its burden,  
 18 then the burden shifts to the defendant to show a procompetitive  
 19 rationale for the restraint. If the defendant makes this showing, then  
 the burden shifts back to the plaintiff to demonstrate that the  
 procompetitive efficiencies could be reasonably achieved through  
 less anticompetitive means.

20 *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018).

21 As noted above, Defendants contend that, under the rule of reason, they are entitled to  
 22 summary judgment on Plaintiffs’ NGR claims. The Court rejects the bulk of Defendants’ motion.  
 23 There are multiple disputes of fact that cannot be resolved at this juncture of the proceedings: for  
 24 example: what is the proper product market (discussed in Part IV, *supra*); whether a collaborator  
 25 would in the but-for world (*i.e.*, a world with no NGR), sell a competing FDC once a generic  
 26 component(s) became available; whether the NGRs prevent free riding or protect know-how; and  
 27 whether there are alternatives less restrictive than the NGRs (*e.g.*, a confidentiality provision).

28 The only issue that gives the Court pause is Defendants’ contention that Plaintiffs have



1 failed to show substantial anticompetitive effects with respect to the Prezcobix, Odefsey, and  
2 Symtuza Agreements. The following is undisputed with respect to these drugs.

- 3 • Prezcobix = DRV/COBI. DRV currently has patents and regulatory exclusivity  
4 that would block Gilead from entering with a “generic” version of Prezcobix until  
5 2026. COBI has patents that would block Janssen from entering with a “generic”  
6 version of Prezcobix until 2032.
- 7 • Odefsey = RPV/TAF/FTC. Although a generic version of FTC is now available,  
8 TAF has patents and regulatory exclusivity that would block Janssen from entering  
9 with a “generic” version of Odefsey until 2033. RPV has patents that would block  
10 Gilead from entering with the “generic” version of Odefsey until 2025.
- 11 • Symtuza = DRV/TAF/FTC/COBI. As noted above, although a generic version of  
12 FTC is now available, TAF has patents and regulatory exclusivity that would block  
13 Janssen from entering with a “generic” version of Symtuza until 2033 (and COBI  
14 patents would also be a block until 2032). DRV currently has patents and  
15 regulatory exclusivity that would block Gilead from entering with a “generic”  
16 version of Symtuza until 2026.

17 Because of the patents and regulatory exclusivities, Defendants argue that Plaintiffs cannot  
18 show anticompetitive effects as a result of the NGRs; in other words, it is (at least currently) the  
19 patents and regulatory exclusivities that bar competition, not the NGRs. *See also* Mot. at 15  
20 (asserting that, even if there were no NGRs, “neither of the collaborators can enter with generic  
21 versions of these three FDCs for the simple reason that their respective components are . . .  
22 protected, and they will be for years”). Defendants add that “any contention by Plaintiffs that they  
23 might suffer harm after these blocking patents begin to expire at the earliest in 2025 is pure  
24 speculation and insufficient to confer antitrust standing. The intense pace of innovation in HIV  
25 treatment makes any claim of future harm even more implausible.” Mot. at 15.

26 As indicated by the above, Defendants’ position is effectively a challenge to Plaintiffs’  
27 standing. In response, Plaintiffs argue that the Court already rejected Defendants’ standing  
28 argument in its class certification order. While Plaintiffs’ position is not without any basis, the

1 relevant part of the class certification order reflects that the Court’s focus at that time was  
 2 redressability. Here, Defendants are focusing on whether there is a sufficient threat of injury in  
 3 fact for purposes of standing. *See* Docket No. 56 (Order at 56) (“Defendants contend that the  
 4 EPPs lack standing to seek this injunctive relief [barring enforcement of the NGRs in the Evotaz  
 5 and Prezcobix Agreements] because of a redressability problem – *i.e.*, a decision favorable to the  
 6 EPPs would not likely redress the injury asserted. According to Defendants, this is because there  
 7 is no indication that ‘an injunction would result in Gilead selling generic-based versions of [the  
 8 drugs’ . . . .”).

9 Although the collaboration agreements at issue presently contain allegedly illegal  
 10 provisions (the NGRs), Plaintiffs have not demonstrated that they are suffering any injury *now* and  
 11 therefore Plaintiffs’ standing is predicated on a future injury. “A plaintiff threatened with future  
 12 injury has standing to sue if the threatened injury is *certainly impending*, or there is a *substantial*  
 13 *risk that the harm will occur.*”<sup>25</sup> *McGee v. S-L Snacks Nat’l*, 982 F.3d 700, 709 (9th Cir. 2020)  
 14 (emphasis added). Here, the Court cannot say that the threatened injury from the NGRs is  
 15 certainly impending because patents and regulatory exclusivities block generic versions of the  
 16 drugs at issue for several, if not many, years. It is not clear that there is a substantial risk of future  
 17 harm because generics for the drugs will not be available for years and – as Defendants point out –  
 18 potentially, the drugs at issue will effectively be obsolete when generics can be made given the  
 19 pace of innovation in the HIV drug arena. *See* Jena Rpt., Ex. 1 (listing FDA-approved drugs for  
 20 the treatment of HIV over the years, from 1987 to 2022).

21 Accordingly, the Court largely denies Defendants’ motion for summary judgment on the  
 22 NGR claims, but grants it as to Prezcobix, Odefsey, and Symtuza based on lack of standing for  
 23 injunctive and declaratory relief. This means that Plaintiffs’ NGR claims are limited to Complera  
 24 and Evotaz.

25  
 26  
 27 <sup>25</sup> A likelihood of future injury is required whether the relief sought is injunctive relief or  
 28 declaratory relief. *See Hodgers-Durgin v. De La Vina*, 199 F.3d 1037, 1044 (9th Cir. 1999) (“The  
 named plaintiffs’ failure to establish a likelihood of future injury similarly renders their claim for  
 declaratory relief unripe.”).

1 **VI. MFE/MFEP CLAIMS**

2 Finally, Plaintiffs assert the MFE/MFEP claims against Gilead and/or Teva. Gilead and  
3 Teva have moved for summary judgment on the MFE/MFEP claims.

4 Originally, Plaintiffs had claims based on two different settlement agreements entered into  
5 by Gilead/Teva: a 2013 agreement related to TDF (the “TDF Patent Settlement Agreement”) and a  
6 2014 agreement related to FTC (the “FTC Patent Settlement Agreement”). Plaintiffs are no longer  
7 moving forward with any claim based on the TDF Patent Settlement Agreement and instead are  
8 asserting claims based on the FTC Patent Settlement Agreement only.<sup>26</sup>

9 A. Relevant Background

10 Gilead launched Viread (TDF) in 2001; Truvada (FTC/TDF) in 2004; and Atripla  
11 (TDF/FTC/EFV) in 2006. *See* Defs.’ Appx. at 1; McGuire Rpt. ¶¶ 16, 19, 23. TDF and TDF/FTC  
12 are Gilead drugs; EFV is a BMS drug.

13 Viread, Truvada, and Atripla were all protected by patents. For example, Truvada was  
14 protected by TDF patents that would expire in 2018 and FTC patents that would expire as late as  
15 2021. Atripla was protected by TDF patents that would expire in 2017, FTC patents that would  
16 expire as late as 2021, and EFV patents that would expire in 2018. *See* Defs.’ Appx. at 4.

17 In 2008, Teva was the first drug manufacturer to file an ANDA for generic Truvada, as  
18 well as the first drug manufacturer to file an ANDA for generic Atripla.<sup>27</sup> In 2009, Teva was the  
19 first drug manufacturer to file an ANDA for generic Viread. In each ANDA (either as originally  
20 filed and/or as amended), Teva included a Paragraph IV certification – *i.e.*, stating that certain  
21 patents protecting the brand drugs were either invalid or not infringed. Gilead responded by filing  
22 patent infringement lawsuits so as to protect its TDF patents and FTC patents. *See* McGuire Rpt.

23 \_\_\_\_\_  
24 <sup>26</sup> *See* McGuire Rpt. at 26 n.113 (“Teva retained its statutory 180-day exclusivity with respect to  
25 Viread [TDF], and I have not been asked [by Plaintiffs] to render an opinion as to whether the  
acceleration clauses in the Viread [TDF] agreement are anticompetitive in that context.”).

26 <sup>27</sup> “The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug  
27 Application [instead of a New Drug Application] specifying that the generic has the ‘same active  
28 ingredients as,’ and is ‘biologically equivalent’ to, the already-approved brand-name drug.” *FTC*  
*v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). Essentially, a generic manufacturer is allowed “to  
piggyback on the [brand drug] pioneer’s approval efforts, [thus] ‘speed[ing] the introduction of  
low-cost generic drugs to market’ [and] furthering drug competition.” *Id.*

¶¶ 27-34. For ease of reference, the lawsuits are referred to as the TDF patent infringement suit and the FTC patent infringement suit.

Because Teva was the first ANDA filer with respect to the brand drugs above and had included Paragraph IV certifications in its ANDAs, Teva had the possibility of getting what is known as statutory exclusivity pursuant to the Hatch-Waxman Act.

Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route [in which the generic manufacturer certifies that the relevant patent for the brand drug is invalid or not infringed]. *That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug). During that period of exclusivity no other generic can compete with the brand-name drug. If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly “worth several hundred million dollars.”*<sup>[28]</sup> Indeed, the Generic Pharmaceutical Association said in 2006 that the “vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.”<sup>[29]</sup> The 180-day exclusivity period, however, can belong only to the first generic to file. Should that first-to-file generic forfeit the exclusivity right in one of the ways specified by statute, no other generic can obtain it.<sup>[29]</sup>

*Actavis*, 570 U.S. at 143-44 (emphasis added).

In April 2013, Gilead and Teva settled the TDF patent infringement suit. *See* Bock Decl., Ex. 16 (TDF Patent Settlement Agreement). The TDF Patent Settlement Agreement included what Plaintiffs call a MFE/MFEP clause and what Defendants call an acceleration clause. In essence, the settlement agreement provided that the default date for Teva’s entry into the market (for generic TDF) would be December 15, 2017; however, if Gilead were to license another company to sell generic TDF, then Teva’s date of entry would be advanced to six weeks earlier than the other company’s entry date. *See* Huttinger Decl., Ex. 16 (TDF Sett. Agmt. § 1.1)

<sup>28</sup> That being said, “[t]he [180-day exclusivity] period does not . . . prevent the brand-patentee from marketing its own ‘authorized generic.’” *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 396 (3d Cir. 2015).

<sup>29</sup> One example of forfeiture is if a first filer “‘fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.’” *Mylan Labs., Ltd. v. United States FDA*, 910 F. Supp. 2d 299, 302 (D.D.C. 2012).

1 (defining “License Effective Date”). In other words, Teva would be granted a period of  
2 exclusivity during which it would not have to compete with another generic manufacturer. The  
3 MFE/MFEP clause was an important part of the consideration for Teva when it agreed to settle the  
4 TDF patent infringement suit. *See* Huttinger Decl., Ex. 52 (emails, dated 2/17/2013, from  
5 Hashmall to Egosi) (“[Gilead’s negotiator] keeps saying that he wants to reach agreement on time  
6 first, but assumes will work out the other issues. Think I need to make clear that our proposal  
7 necessarily requires exclusivity.”; “The good news is that he more or less confirmed that Gilead is  
8 agreeable to exclusivity.”).

9 Several months after the TDF Patent Settlement Agreement, a bench trial was held in the  
10 FTC patent infringement suit. Evidence was presented from October 8 to 13, 2013. *See* McGuire  
11 Rpt. ¶ 40. Closing arguments were set for mid-February 2014. *See* Huttinger Decl., Ex. 59  
12 (email, dated 1/15/2014, from Rabinovic to Hashmall) (noting that “[w]e have closing on Feb  
13 14”). What took place during the period of October 2013 to February 2014 is critical to the  
14 pending motion.

15 In November 2013, shortly after the bench trial but before closing arguments, Gilead  
16 obtained additional patent protection for Truvada and Atripla – specifically, the first of several  
17 formulation patents that would not expire until (at the earliest) 2024.<sup>30</sup> *See* Mot. at 3; Defs.’ Appx.  
18 at 4 & n.4 (indicating that the first formulation patent was obtained in November 2013). (The  
19 formulation patents are also called combination patents.)

20 In mid-January 2014, before closing arguments in the FTC patent infringement suit were  
21 scheduled to begin, Gilead reached out to Teva with a settlement proposal: the settlement would  
22 provide Teva for an entry date of March 2021 (though this was negotiable) and that would likely  
23 cover the new formulation patents (even though they were not part of the litigation). *See*  
24 Huttinger Decl., Ex. 59 (email, dated 1/15/2014, from Hashmall) (stating that Gilead counsel had  
25 offered a settlement proposal). Internally, Teva expressed an interest in the proposal but noted,

26 \_\_\_\_\_  
27 <sup>30</sup> “[A] formulation patent is a patent that “seeks to cover the pharmaceutical formulation of an  
28 active pharmaceutical ingredient, i.e., the unique combination of the active pharmaceutical  
ingredient with excipients that make up the dosage form that is administered to the patient.”  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3857063/> (last visited 1/4/2023).

1 *inter alia*, that it would “like to test the entry date to see if we can get it to late 2019” and that it  
 2 would “*need all the usual triggers.*” Huttinger Decl., Ex. 59 (email, dated 1/24/2014, from  
 3 Rabinovic to Hashmall) (emphasis added). This was communicated to Gilead. On February 6,  
 4 2014, Gilead responded that it was willing to agree to an entry date of January 2021 and that it  
 5 would “discuss specifics of usual triggers once we have agreement on [the] above but *assumes*  
 6 *same or similar to tenofovir [TDF] deal.*” Huttinger Decl., Ex. 59 (email, dated 2/6/2014, from  
 7 Hashmall to Rabinovic) (emphasis added). As noted above, one of the important parts of the TDF  
 8 Patent Settlement Agreement was the MFE/MFEP.

9 Less than a week later, Gilead and Teva appeared to be close to reaching a resolution. *See*  
 10 Huttinger Decl., Ex. 60 (email, dated 2/12/2014, from Cannella) (“I received a voicemail message  
 11 from Hashmall [Teva attorney] last night. He said the reason for the ‘slight delay’ in getting back  
 12 to me was because they were ‘moving up the chain of command to get final authority’ on  
 13 something ‘I am pretty sure will be a basis to resolve this.’”). On February 13, 2014, Gilead  
 14 indicated as follows in a communication with Teva:

- 15 6. We’ll use the ramp-up, acceleration, and other ancillary  
 16 provisions of the TDF agreement as the template for drafting  
 this agreement with the following caveat.
- 17 7. Teva’s entry date for Truvada and Atripla will always be the  
 18 earlier of  
 a. 9/30/20 or  
 19 b. *a date that is 180 days earlier than the date Gilead  
 allows another generic or AG to come on the market.*

20 Huttinger Decl., Ex. 50 (email, dated 2/13/2014, from Cannella to Hashmall) (emphasis added). A  
 21 MFE/MFEP clause along those lines was subsequently included in the draft settlement agreement.

22 The FTC Patent Settlement Agreement was formally entered into in April 2014. *See Bock*  
 23 *Decl.*, Ex. 17 (FTC Patent Settlement Agreement). Under the settlement agreement, the parties  
 24 agreed that Teva could enter the market with generic Truvada and generic Atripla in September  
 25 2020 – *i.e.*, about a year before the FTC patents would expire in 2021. However, the settlement  
 26 agreement provided that, in certain circumstances, that entry date would be accelerated. Below is  
 27 the relevant provision from the FTC Patent Settlement Agreement:

28 “License Effective Date” means, with respect to a particular Teva



United States District Court  
Northern District of California

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ANDA Product or a particular FTC Generic Equivalent, on an FTC Combination Product-by-FTC Combination Product basis, the earliest to occur of the following dates:

- (i) September 30, 2020;
- (ii) the date on which a Final Court decision is entered holding that each of the ten-asserted unexpired patent claims included in the Licensed FTC Patents that were asserted against Teva in the Litigation is invalid or unenforceable;
- (iii) the date on which all of the Licensed FTC Patents listed in the Orange Book, with respect to the applicable Gilead Product or FTC Product, has been permanently abandoned or delisted from the Orange Book (excluding any such Licensed FTC Patents as have, as of such date, been held to be invalid or unenforceable);
- (iv) with respect to Teva ANDA Product only, and except with respect to any Access Use, to the extent that Gilead, any of its Affiliates, or a Third Party (under authorization from Gilead or its Affiliates, by license, sublicense, waiver, covenant not to sue or otherwise) plans or is authorized to sell the relevant FTC Generic Equivalent in the Territory on a date that falls any time before September 10, 2021, the date that is six (6) months prior to (1) the sale thereof by Gilead or its Affiliate or (2) the earliest permitted sale thereof by such Third Party, in the Territory; and
- (v) With respect to Teva ANDA Product only, and except with respect to any Access Use, to the extent that Gilead, any of its Affiliates, or a Third Party (under authorization from Gilead or its Affiliates, by license, sublicense, waiver, covenant not to sue or otherwise) plans or is authorized to sell the relevant FTC Authorized Generic in the Territory on a date that falls at any time before September 10, 2021, the date such FTC Authorized Generic is first sold in the Territory.

Bock Decl., Ex. 17 (FTC Sett. Agmt. § 1.1).

Item (i) above is the default date for Teva’s entry into the market: September 2020. Items (ii) and (v) above are what Plaintiffs have called MFE (“most favored entry”) clauses: Teva’s entry date is accelerated so that it is the *same* as the entry date for another generic manufacturer. For instance, under (ii), if another generic manufacturer proves Gilead’s patents invalid or unenforceable in litigation, then Teva can enter the market on the day of the final court decision finding the patents invalid or unenforceable. Under (v), if Gilead authorizes the sale of a generic drug pursuant to its NDA, then Teva can enter the market on the day of the first sale of the authorized generic.

1 Finally, item (iv) above is what Plaintiffs have called a MFEP (“most favored entry plus”) clause: Teva’s entry date is accelerated so that it is six months (180 days) *ahead* of the entry date  
2 for another generic manufacturer. In other words, if Gilead were to give a license to another  
3 generic manufacturer to make generic Truvada or Atripla, then Teva’s date of entry would be six  
4 months (180 days) ahead of any sale by the other generic manufacturer.  
5

6 Plaintiffs argue that, but for the MFE/MFEP clauses in the FTC Patent Settlement Agreement, the parties would have negotiated an earlier entry date for Teva purposes of settlement  
7 (*i.e.*, before September 2020), *or* Teva would have waited to get a decision in the patent  
8 infringement litigation – both situations being informed by the fact that “Teva was very likely to  
9 get a finding that the patents were invalid.” Opp’n at 2; *see also* Opp’n at 5 (arguing that, if  
10 Gilead and Teva had settled without a MFE/MFEP, then “rational manufacturers would have  
11 agreed on an entry date of May 2019”; if Teva had won the lawsuit, then generic entry for Truvada  
12 and Atripla would have taken place in February 2018 (once the *TDF* patents had expired)<sup>31</sup>). But,  
13 Plaintiffs contend, the MFE/MFEP clauses gave Teva more benefits, particularly compared to the  
14 litigation route. Although Teva was likely to prevail in the patent infringement suit, Teva had  
15 *forfeited* the 180 days of statutory exclusivity to which it was entitled as the first ANDA filer for  
16 Truvada and Atripla; therefore, a “victory on invalidity would also allow other generic[]  
17 [manufacturers] to enter the market when [Teva] did. Teva would make orders of magnitude more  
18 money if other generic[] [manufacturers] were not there to compete.” Opp’n at 2. According to  
19 Plaintiffs, the MFE/MFEP clauses gave *contractual* exclusivity to Teva for 180 days (effectively  
20 restoring at least in part the forfeited 180-day *statutory* exclusivity<sup>32</sup>); Teva explicitly  
21 acknowledged that it was getting the benefit of contractual exclusivity with the settlement. *See*  
22  
23

24  
25 <sup>31</sup> Both Truvada and Atripla have TDF as a component (in addition to FTC).

26 <sup>32</sup> Defendants’ expert Mr. Hoxie explains why it would not be possible for parties to *restore*  
27 statutory exclusivity as a contractual matter. *See* Bock Decl., Ex. 7 (Hoxie Rpt. ¶ 86) (“Once Teva  
28 forfeited its 180-day Hatch-Waxman exclusivity, there was no way to ‘restore’ that advantage;  
there was no way to prevent other ANDA filers from obtaining FDA final approval and launching  
their products, assuming these ANDA filers had confidence they would ultimately prevail in the  
patent litigation.”).

1 Huttinger Decl., Ex. 25 (Hashmall Depo. at 30-31, 69-70, 85, 91).<sup>33</sup> Teva never paid Gilead a  
 2 royalty for this contractual exclusivity even though Gilead presumably would have charged for  
 3 this benefit as part of an arms-length transaction unrelated to a settlement agreement. Thus,  
 4 Plaintiffs contend that the settlement with the MFE/MFEP provisions was one of “pay for delay”  
 5 (*i.e.*, a reverse payment settlement agreement as described by the Supreme Court in *Actavis*). *See*  
 6 Opp’n at 3. In short, Gilead effectively paid Teva to delay its entry. *See* McGuire Rpt. ¶ 117  
 7 (“An acceleration clause costs the brand . . . . [A] brand may not fully collect the royalties or other  
 8 payments it would otherwise collect if the conditional license represented by an acceleration  
 9 clause were part of an arms-length transaction unrelated to a patent settlement. Forgoing royalties  
 10 on a licensing deal constitutes a profit sacrifice . . . .”).

11 Defendants disagree that there was any exclusivity under the settlement agreement,  
 12 pointing out, *e.g.*, that, with the MFEP clause, Teva’s entry date is accelerated only where another  
 13 generic manufacturer is *licensed* to make a generic version of the brand drug; there is no  
 14 acceleration where a generic manufacturer launches its generic drug “*at risk*” (*i.e.*, without a  
 15 license from Gilead).

16 Plaintiffs counter that at-risk launch was never a serious concern, as demonstrated by the  
 17 fact that “every other generic [manufacturer] delayed its entry until exactly Day 181 after Teva’s  
 18 entry.”<sup>34</sup> Opp’n at 3; *see also* Opp’n at 11 (citing to Dr. McGuire’s report in support of the  
 19 position that an at-risk launch was very unlikely). Plaintiffs also assert that the MFE/MFEP  
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21 <sup>33</sup> Mr. Hashmall was Teva’s outside counsel and negotiator. In his deposition, he testified, *inter*  
 22 *alia*, that:

- 23 • The provision where Teva would get 180 days earlier than the date Gilead would  
 24 allow any other generic manufacturer was a form of contractual exclusivity. *See*  
 25 Huttinger Decl., Ex. 25 (Hashmall Depo. at 69-70, 85, 91).
- “[E]xclusivity would provide value to the client” because, “if Teva were the only  
 26 generic [manufacturer] on the market for a period of time, that would provide  
 27 monetary value to Teva.” Huttinger Decl., Ex. 25 (Hashmall Depo. at 30-31).

28 <sup>34</sup> As noted in Defendants’ opening brief, at the time that Gilead and Teva entered into the FTC  
 Settlement Agreement in April 2014, “three other generic manufacturers – Cipla, Lupin, and  
 Mylan – had filed Paragraph IV ANDAs for Truvada, Atripla, or both. After the Teva FTC  
 Settlement, Gilead settled with a total of ten other generic manufacturers as to Truvada and  
 Atripla.” Mot. at 7.

1 clauses served to delay the entry of other generic manufacturers until Day 181 because the clauses

2 substantially degrad[ed] both avenues for them to try to enter  
 3 sooner: litigation and settlement. First, “the MFE degrades the  
 4 subsequent generic[] [manufacturer’s] expected value of profits *from*  
 5 [*litigating*].” Ex. 3, McGuire MFE/P Rpt. ¶ 128. Second, the  
 6 MFE/P severely degrades their likelihood of getting an earlier entry  
 7 date than Teva *through settlement*: those “earlier entry dates . . . are  
 8 no longer profitable to Gilead because of the severe profit loss from  
 9 accelerating Teva’s entry date.” *Id.* “The net effect of the MFE and  
 10 MFE+ clauses is to push the bargaining range later in time, moving  
 11 the likely settlement date between Gilead and the subsequent  
 12 generic[] [manufacturers] from the Teva date . . . to six months  
 13 later.” *Id.*

14 Opp’n at 4 (emphasis in original). Thus, there is a plausible claim that, by virtue of the  
 15 MFE/MFEP, Teva was afforded, in practical effect, exclusivity which impacted competition. The  
 16 question is whether Plaintiffs have created a genuine dispute of fact with respect to their  
 17 MFE/MFEP claims.

18 B. Antitrust Injury

19 Antitrust claims generally require a plaintiff to prove (1) anticompetitive conduct and (2)  
 20 antitrust injury. *See, e.g., ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012)  
 21 (noting that “[s]ections 1 and 2 of the Sherman Act . . . each include an anticompetitive conduct  
 22 element, although each statute articulates that element in a slightly different way”; furthermore,  
 23 “to establish an actionable antitrust violation,” a plaintiff must prove not only that the defendant  
 24 engaged in anticompetitive conduct, but also that the plaintiff suffered antitrust injury). According  
 25 to Defendants, there is no genuine dispute that, with respect to the FTC Patent Settlement  
 26 Agreement, Plaintiffs cannot prove either element. Because Defendants address antitrust injury  
 27 before anticompetitive conduct, the Court does the same.

28 The antitrust injury claimed by Plaintiffs is delayed entry into the market by a generic  
 manufacturer – either Teva or another generic manufacturer. Defendants argue that there is a  
 causation problem, specifically, that there is no evidence that (1) Teva agreed to a delayed entry as  
 a result of the MFE/MFEP clause settlement agreement or that (2) another generic manufacturer(s)  
 delayed entry into the market as a result of the clause.

1           1.       Delay by Teva

2           Under the FTC Patent Settlement Agreement, the default entry date for Teva to sell generic  
3 Truvada and Atripla was September 2020.<sup>35</sup> Plaintiffs' theory is that, but for the MFE/MFEP  
4 clause in the settlement agreement, Teva would have secured an entry date *earlier* than September  
5 2020 because it was likely to prevail in the FTC patent infringement suit. According to Plaintiffs,  
6 if Teva and Gilead had settled the litigation without any MFE/MFEP, then they would have  
7 negotiated an agreement that would have allowed Teva to enter the market in May 2019;  
8 alternatively, if Teva had continued to litigate, then, upon prevailing in the lawsuit, it would have  
9 been able to enter the market in February 2018 (once the TDF patents expired).

10           a.       Teva's Subjective Assessment

11           According to Defendants, Plaintiffs' theory is flawed because Teva did not think that it  
12 was likely to prevail in the FTC patent infringement litigation – or with a challenge to Gilead's  
13 new formulation patents which were not a part of the litigation and would not expire until (at the  
14 earliest) 2024. Defendants maintain that, before any MFE/MFEP clause was expressly  
15 contemplated, Teva thought the best it could do (*i.e.*, based on the merits of the patents alone) was  
16 to get an entry date of November 2020. This date was *worse* than the September 2020 default  
17 entry date that Teva ended up getting under the FTC Patent Settlement Agreement. Thus,  
18 Defendants assert that Teva could not have delayed entry into the market as a result of the  
19 MFE/MFEP. *See* Mot. at 11 (arguing that “Teva was willing to accept” the entry date of  
20 September 2020 because “it saw only a 17.5% chance of doing better than November 2020 if it  
21 continued to litigate, and an 82.5% chance of doing worse”).

22           As an initial matter, Plaintiffs criticize Defendants' argument because it focuses solely on  
23 Teva. In other words, Plaintiffs argue that Defendants are incorrect in asserting that the question  
24 is what Teva would have done in the but-for world (*i.e.*, without the MFE/MFEP); rather, the  
25 question is what Teva *and Gilead* would have done (*i.e.*, what would their negotiation have been  
26

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27 <sup>35</sup> This date of entry was before the relevant patents protecting Truvada and Atripla would expire  
28 on their face. The FTC patents would expire at the latest in September 2021, and the formulation  
patents that Gilead acquired after initiating the patent infringement suits were not due to expire  
until 2024.

1 without the MFE/MFEP); Defendants have considered only half of the equation. *See* Opp’n at 12.  
 2 Plaintiffs add that, because only Teva has waived attorney-client privilege, Defendants have not  
 3 provided any information about Gilead’s contemporaneous, subjective assessment of the patent  
 4 infringement litigation or the strength of the formulation patents. *See* Opp’n at 20. Plaintiffs  
 5 make a fair legal point – *i.e.*, both Teva and Gilead’s beliefs matter in assessing what a  
 6 hypothetical negotiation would have yielded. *Cf. Asetek Danmark A/S v. CMI USA Inc.*, 852 F.3d  
 7 1352, 1362 (Fed. Cir. 2017) (noting that, in a patent infringement case, a prevailing patent owner  
 8 “may receive a reasonable royalty” and a reasonable royalty is calculated “using the common  
 9 hypothetical negotiation approach . . . under which the finder of fact ‘attempts to ascertain the  
 10 royalty upon which the parties would have agreed had they successfully negotiated an agreement  
 11 just before infringement began’”).

12 Moreover, even if the Court were to focus on Teva’s side of the negotiation equation,  
 13 Defendants’ position that “Teva’s contemporaneous subjective views” regarding its likelihood of  
 14 success are “dispositive” lacks merit.<sup>36</sup> Mot. at 11-12. Relying exclusively on Teva’s records of  
 15 its subjective views without any critical inquiry would be improper. This would bar the trier of  
 16 fact from assessing Teva’s credibility. And as Plaintiffs point out, there is an inherent danger in  
 17 automatically crediting Teva’s views: an “antitrust violation taints [a defendant’s] ‘real world’  
 18 conduct. In addition to eliminating the generic [manufacturer’s] incentive to negotiate for the  
 19 earliest possible entry date, the violation also incentivizes the generic [manufacturer] to ‘change  
 20 sides’ . . . and assert that the patents were strong rather than weak.” Opp’n at 13. There is a risk

21 \_\_\_\_\_  
 22 <sup>36</sup> Contrary to what Defendants suggest, the Supreme Court did not hold in *Actavis* that subjective  
 23 beliefs are dispositive. Admittedly, the Supreme Court did state as follows:

24 Although the parties may have reasons to prefer settlements that  
 25 include reverse payments, the relevant antitrust question is: What  
 26 are those reasons? If the basic reason is a desire to maintain and to  
 27 share patent-generated monopoly profits, then, in the absence of  
 28 some other justification, the antitrust laws are likely to forbid the  
 arrangement.

27 *Actavis*, 570 U.S. at 158. But as Plaintiffs point out, the Supreme Court was only considering the  
 28 issue of whether there was anticompetitive conduct, and not, as in the case at bar, the issue of  
 whether there was antitrust injury. Defendants have not demonstrated why the two contexts  
 should be equated.



1 of unilateral manipulation of the official record of the participants' intent in a way that would  
2 validate their conduct.

3 More fundamentally, the inquiry should focus on what a rational generic manufacturer  
4 would have done if it were in Teva's position. *See* Opp'n at 12. This was essentially the approach  
5 of the district court *In re Zetia (Ezetimibe) Antitrust Litigation*, No. MDL No. 2:18-md-2836, 2022  
6 U.S. Dist. LEXIS 172065 (E.D. Va. Aug. 15, 2022):

7 Without the alleged anti-competitive conduct, a jury may conclude  
8 that Glenmark's actions would be those of a Reasonable Firm, and  
9 Jon Clark's opinion is helpful to the trier of fact in evaluating  
causation.

10 The relevant question is how a reasonable profit-maximizing  
11 company would behave without the alleged anti-competitive  
12 conduct. *See* Pls.' Opp'n (ECF No. 1142, at 22 & n.88) (citing  
13 cases). Antitrust cases "presume the existence of rational economic  
14 behavior in the hypothetical free market." *Dolphin Tours, Inc. v.*  
15 *Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985)  
(citing *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th  
16 Cir. 1981)); *see also Lidoderm*, 296 F. Supp. 3d at 1162 (describing  
17 "the antitrust context, where but-for worlds are considered and  
18 profit-maximizing goals assumed"); *id.* at 1179 n.42 (reciting "a  
19 presumption of economical rationality").

20 *Id.* at \*56-57. The *Zetia* court relied on the Ninth Circuit's decision in *Dolphin Tours, Inc. v.*  
21 *Pacifico Creative Service, Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985). There, the appellate court  
22 noted that the antitrust plaintiff had

23 attempted to establish its lost profits by projecting the market share  
24 that it would have attained absent the anticompetitive activity. In  
25 using this approach, [the plaintiff] must presume the existence of  
26 rational economic behavior in the hypothetical free market. This  
27 includes a rational price differential between [the plaintiff's] prices  
28 and defendants' prices based on all competitors attempts to  
maximize their own profits, and the potential entry of other  
competitors into the market.

29 *Id.* at 1511. Other cases are in accord. *See In re Solodyn (Minocycline Hydrochloride) Antitrust*  
30 *Litig.*, No. CV 14-MD-02503, 2018 WL 734655, at \*2 (D. Mass. Feb. 6, 2018) (stating that the  
31 expert "Tupman cannot opine about what [the generic manufacturer] Impax thought, [but]  
32 Tupman may still opine about how a reasonable company sitting in Medicis' shoes may analyze  
33 the business context"); *King Drug Co. of Florence v. Cephalon, Inc.*, No. 2:06-cv-1797, 2015 U.S.

1 Dist. LEXIS 135264, at \*39 (E.D. Pa. Oct. 5, 2015) (stating that “[t]he challenged experts’  
 2 analyses are largely derived from the economic information available to Defendants at the time of  
 3 the settlement agreements, and these experts opine on what a rational, objective actor would have  
 4 considered in light of that information[;] [w]hile Plaintiffs assert that this type of objective  
 5 analysis is not relevant to the issues a jury would need to consider in conducting an *Actavis*  
 6 inquiry, they provide no support for this assertion,” and “[o]ther courts have permitted this type of  
 7 objective economic analysis in reverse-payment settlement cases”).

8 Furthermore, even on Defendants’ terms, Teva’s contemporaneous subjective views were  
 9 not as clear cut as Defendants have suggested. Below is a brief timeline of what Teva’s beliefs  
 10 were during the critical period of October 2013 to November 2014.

- 11 • **Pre-October 2013.** In the months before the FTC patent infringement trial, Teva’s  
 12 outlook on the case was not positive. For example, in a January 2013 email, Teva’s  
 13 Chief IP Counsel, Ms. Julie, noted that Teva had a “reasonable shot of success” in  
 14 the *TDF* patent infringement suit but indicated that that was not the case for the  
 15 *FTC* patent infringement suit. Bock Decl., Ex. 57 (email). In a July 2013 email,  
 16 Ms. Julie stated that the *FTC* patents were “troubling” and “our chances . . . are  
 17 low.” Bock Decl., Ex. 46 (email). And in another email from July 2013, Ms.  
 18 Rabinovic, Teva’s in-house IP counsel supervising the case, stated that “I am tired  
 19 of looking through my email to figure out how many times I told them the [FTC]  
 20 patents were difficult to overcome.” Bock Decl., Ex. 47 (email).
- 21 • **October 3, 2013.** However, shortly before the bench trial began in the *FTC* patent  
 22 infringement case, Teva seemed to have a more positive outlook on its chances in  
 23 the trial. Ms. Rabinovic noted in an email that Gilead had made a settlement  
 24 proposal and stated that “[w]e are feeling somewhat more positive about our  
 25 defenses”; “[w]e think we should make an aggressive offer for an entry date  
 26 between the 2016 and 2021 dates, around the December 2017 date we already  
 27 agreed on for a Viread launch” because “the case isn’t so bad now that the case is  
 28 narrow.” Huttlinger Decl., Ex. 66 (email).

- 1           • **October 8-13, 2013.** Evidence was presented in the FTC patent infringement  
2 bench trial. Closing arguments were set for February 2014.
- 3           • **November 2013.** Following the presentation of evidence at the bench trial, Ms.  
4 Julie asked her team to prepare assessments for the patents involved in the FTC  
5 patent infringement suit, as well as the new formulation patents. (According to Ms.  
6 Julie, the assessment was not for purposes of the infringement suit; rather, it was  
7 “in connection with Teva’s project to develop certain HIV products[,] internally  
8 designated new therapeutic entities (NTEs).” Bock Decl., Ex. 65 (Julie Decl. ¶ 8).)  
9 The team (consisting of a patent attorney and a patent agent) concluded that, based  
10 on the FTC patents and the new formulation patents, “the odds that Teva would be  
11 able to start selling in the United States before 2021 were 30%.” Bock Decl., Ex.  
12 65 (Julie Decl. ¶ 8). Although these were low odds, the team also concluded that,  
13 once the FTC patents expired in 2021, “the odds that Teva could start selling [were]  
14 75%” – *i.e.*, in spite of the new formulation patents. Bock Decl., Ex. 65 (Julie  
15 Decl. ¶ 9). The team “set the odds of overcoming the [formulation] patents at 75%  
16 in light of the fact that comparable European patents owned by Gilead had been  
17 revoked in the first instance in opposition proceedings before the European Patent  
18 Office (EPO) in 2011, and we hoped that similar arguments might succeed in  
19 District Court litigation in the United States.” Bock Decl., Ex. 65 (Julie Decl. ¶ 9);  
20 *see also* Huttinger Decl., Ex. 67 (ECF Page 746) (email, dated 11/13/2013) (in a  
21 legal slide, indicating that a certain product containing TDF/FTC had a 75%  
22 probability of launching in the United States in 2021). In mid-November 2013, one  
23 document reflected an even higher probability of launching in 2021 – 85%. *See*  
24 Huttinger Decl., Ex. 72 (ECF Page 797) (email, dated 2/10/2014, from Rabinovic  
25 to Julie) (attaching document dated 11/11/2013).
- 26           • **January 2014.** A slide presentation continued to refer to a 75% probability of  
27 launching in the United States in 2021 – *i.e.*, in spite of the new formulation patents  
28 which would not expire until 2024. *See* Huttinger Decl., Ex. 69 (slide).

- 1           • **Early to mid-January 2014.** An invalidity opinion on one of the new formulation  
2 patents (the ‘397), which had been prepared by Teva’s outside counsel, was  
3 circulated. *See* Huttinger Decl., Ex. 71 (email circulating opinion letter, dated  
4 11/27/2013). In the opinion letter, counsel stated its belief that certain claims of the  
5 ‘397 patent were invalid and that Teva would not infringe with respect to the valid  
6 claims. *See* Huttinger Decl., Ex. 71 (letter). Somewhat confusingly, Ms. Julie  
7 testifies in a declaration that, after getting the opinion letter and discussing the  
8 matter with her colleagues, she “concluded that Teva’s potential invalidity defense  
9 with respect to the [new formulation] patents had a substantially lower probability  
10 of success in U.S. District Court under U.S. patent law than the probability of  
11 ultimate success on the European patents at the EPO under European patent law,”  
12 and so she “revise[d] the odds of success for the [formulation] patents down to 30-  
13 40%.” Bock Decl., Ex. 65 (Julie Decl. ¶ 10); *see also* Huttinger Decl., Ex. 68  
14 (email, dated 1/14/2014, from Rabinovic to Julie) (suggesting revision down to  
15 30% probability of launching in the United States in 2021, *i.e.*, rather than 75%).
- 16           • **Mid-January 2014.** At about this same period, Gilead contacted Teva and offered  
17 a settlement proposal for the FTC patent infringement suit. Under the proposal,  
18 Teva would get an entry date of March 2021 (though this appeared negotiable) and  
19 Gilead would likely agree that the settlement would cover not just the FTC patents  
20 but also the new formulation patents. *See* Huttinger Decl., Ex. 43 (email, dated  
21 1/15/2014, from Hashmall).
- 22           • **February 10, 2014.** Ms. Julie commented in an email to her supervisor, Richard  
23 Egosi (Teva’s Chief Legal Officer), that Teva and Gilead “have had a bunch of  
24 back and forth” and, “[a]fter much negotiation, we just received an offer from them  
25 . . . which would put our entry date in November 2020. Gilead is willing to give us  
26 a license to the 2024 [formulation] patents as of the entry date as part of the  
27 settlement.” Huttinger Decl., Ex. 74 (email, dated 2/10/2014, from Julie to Egosi).  
28 Ms. Julie stated that “it makes sense to try to get the best settlement we can now,”

1 particularly because, “[i]f Gilead were to enforce [the formulation] patents (which  
2 they have indicated they will if we don’t settle), we believe our odds on prevailing  
3 are 30-40%.” Huttinger Decl., Ex. 74. Ms. Julie added that, with respect to the  
4 FTC patents (which were due to expire in 2021), “[w]e felt like trial went well for  
5 us, but it is difficult to give odds of greater than 50% (certainly before closing  
6 arguments).” Huttinger Decl., Ex. 74; *see also* Bock Decl., Ex. 65 (Julie Decl. ¶¶  
7 3-4, 7) (discussing this email). Mr. Egosi approved moving forward. *See* Bock  
8 Decl., Ex. 42 (email, dated 2/11/2014).

- 9 • **February 12, 2014.** Ildiko Mehes, Teva’s Vice President and General Counsel for  
10 North America, subsequently passed on Ms. Julie’s assessment to Allan Oberman,  
11 Teva Americas President and CEO. *See* Bock Decl., Ex. 49 (email, dated 2/12/2014,  
12 from Mehes to Oberman). Fred Killion, Teva’s Deputy Chief Legal Officer, then  
13 sent an email to Ms. Mehes and Mr. Oberman providing odds on what would  
14 happen if Teva did not settle: “If we DON’T SETTLE,” there was (1) “[a] 17.5  
15 percent chance of being able to enter 2+ years EARLIER than the settlement date . .  
16 . . (50% chance of winning this case x 35% chance of successfully challenging the 2  
17 new [formulation] patents that expire in 2024),” and (2) “[a]n 82.5 percent change  
18 of being unable to enter until LATER than the settlement date.” Bock Decl., Ex.  
19 49.

20 It appears Teva’s views on its likelihood of success varied over time – for both the FTC  
21 patents that were the subject of the patent infringement trial and the new formulation patents. By  
22 February 2014, when Gilead and Teva had basically reached a settlement, Teva seemed to believe  
23 it had a decent shot of success with respect to the FTC patents (50%). This seemed a more  
24 positive outlook compared to the pre-October 2013 period. While, in February 2014, Teva did  
25 claim a low chance of success on the formulation patents (30-40%), a few months earlier it had  
26 viewed its probability of success much more favorably (75% or more), and it is not entirely clear  
27 from the record *why* Teva’s views on the likelihood of had changed. As indicated above, the  
28 opinion letter on one of the new formulation patents actually seemed positive with respect to

1 Teva’s prospects, and Ms. Julie does not explain in her declaration submitted as part of the  
 2 summary judgment briefing why there was a lower probability of succeeding in the United States  
 3 compared to Europe.

4 In their papers, Plaintiffs argue that, in the absence of a real explanation, one could infer  
 5 that Teva’s change in views was related to its settlement discussions going on with Gilead:

6 [A] jury may reasonably conclude that Ms. Julie’s revised February  
 7 10 purported reassessment was prompted by *Gilead’s February 6*  
 8 *confirmation that it would agree to an MFE/P the “same or similar*  
 9 *to tenofovir [TDF] deal.”*<sup>37</sup> She knew that a six-week MFE/P (a la  
 10 TDF) would generate more than \$350 million profits for Truvada  
 11 and Atripla. Within hours of learning that a deal would include an  
 12 MFE/P, she for the first time solicited [Teva’s] NTE [new  
 13 therapeutic entity] team’s views on a potential settlement. She  
 14 learned that they would support settlement only if the odds on the  
 15 [formulation] patents were low.<sup>38</sup> The jury may conclude that she  
 16 simply gave the NTE team the low odds they required, securing  
 17 their support for the MFE/P-laden settlement.

18 Opp’n at 20 (emphasis in original and added).<sup>39</sup>

19 Defendants criticize Plaintiffs for not deposing Ms. Julie or other Teva executives to drill  
 20 down why Teva’s views changed. *See Reply* at 8. Although it does seem odd that Ms. Julie or  
 21 other Teva executives were not deposed, an inference can still be made in Plaintiffs’ favor (as  
 22 should be done at summary judgment) because Ms. Julie did not sufficiently explain her change in  
 23 views, not even in the declaration she submitted as part of the summary judgment briefing.

24 In their reply brief, Defendants protest that

25 it does not matter whether Ms. Julie personally believed the

26 \_\_\_\_\_  
 27 <sup>37</sup> *See* Huttinger Decl., Ex. 60 (email, dated 2/6/2014, from Hashmall to Rabinovic) (addressing  
 28 settlement discussions; taking note of Gilead’s comment that “[w]ill discuss specifics of usual  
 triggers once we have agreement on above but assumes same or similar to tenofovir [TDF] deal”).  
 For the TDF Settlement Agreement, there was an acceleration clause with a six-week exclusivity  
 period.

<sup>38</sup> *See* Huttinger Decl., Ex. 76 (email exchange, dated 2/6/2014, between Julie and Kogan) (Ms.  
 Julie asking, “Are you ok with [the settlement]?” and Ms. Kogan responding that “the decision  
 depends on the [formulation] patent strength[;] [i]f we can easily invalidate them, I wouldn’t settle  
 (from a pure NTE point of view) [but] [i]f the [formulation] patents are a barrier, then I would  
 settle”).

<sup>39</sup> This underscores the point discussed *supra*: there is a risk of manipulation of the record by  
 participants to justify or validate their conduct.



1 assessment of patent strength she expressed to senior management,  
 2 or whether, as Plaintiffs baselessly suggest, she instead had some  
 3 secret motive to express pessimism. It is undisputed that Teva's  
 4 relevant decision makers – the CLO [Chief Legal Officer] and the  
 5 President/CEO – approved the FTC Settlement based on the final  
 6 analysis from counsel that Teva had only a combined 17.5% chance  
 7 to prevail on the patents<sup>40</sup>. . . .

8 . . . .

9 Moreover, Plaintiffs' argument is truly bizarre: that a senior attorney  
 10 in Teva's general counsel's office deceived senior management to  
 11 gin up support for a settlement. This theory has no factual support  
 12 and borders on frivolous. It is certainly insufficient to defeat  
 13 summary judgment: "A party cannot create a dispute of fact by  
 14 simply questioning the credibility of a witness."

15 Reply at 10. Although Defendants' argument is not entirely lacking in merit, the issue here is  
 16 whether there are genuine disputes of fact that would preclude summary judgment. Here Plaintiffs  
 17 have articulated a basis for questioning Ms. Julie's change in views about Teva's likelihood of  
 18 success.<sup>41</sup>

19 b. Entry Date Negotiated Before MFE/MFEP

20 Defendants argue that, even if the Court does not rule in its favor on the above argument,  
 21 Plaintiffs' theory must still be rejected because the evidence shows that Gilead and Teva never  
 22 negotiated a MFE/MFEP until *after* they had already reached agreement on the default entry date  
 23 of September 2020, and thus this was no quid pro quo therefor. *See, e.g.*, Bock Decl., Ex. 65  
 24 (Julie Decl. ¶¶ 7, 12) (testifying that, in her email of 2/10/2014 (in which she recommended  
 25 settlement with Gilead for an entry date some time in the fourth quarter of 2020), she did not  
 26 mention a provision that would give Teva some kind of exclusivity because, "to the best of my  
 27 recollection, at that time no such exclusivity provision had been discussed between the parties");  
 28 Bock Decl., Ex. 12 (Pletcher Depo. at 70, 81) (General Counsel for Gilead at the time of the FTC  
 Settlement agreement testifying that, "in this negotiation with Teva, there were two parts[:] The  
 first part was what's the date going to be, and after that, you negotiate terms of an agreement";

<sup>40</sup> 17.5% = 50% chance of winning the FTC patent infringement trial x 35% chance of  
 successfully challenging the formulation patents that would expire in 2024.

<sup>41</sup> There may also be an argument that a "cat's paw" theory should apply – *i.e.*, that so long as the  
 company decisionmakers were influenced by Ms. Julie, that is a sufficient basis to hold the  
 company liable.

1 also testifying that, until the draft FTC settlement agreement “went out, the only terms that we had  
2 discussed were the date” – *i.e.*, not the 180-day contractual exclusivity provision). Defendants  
3 thus contend there is no evidence that Teva agreed to a delayed entry date *in exchange* for getting  
4 a MFE/MFEP. Defendants admit that “there was likely an assumption that the final settlement  
5 would include *some* form of acceleration provision [because] the vast majority of Hatch-Waxman  
6 Act settlements include such provisions.” Mot. at 15 (emphasis in original). But, because Gilead  
7 and Teva did not “negotiate the *specific terms* of the acceleration provision until after they agreed  
8 to the September 2020 entry date,” Mot. at 15 (emphasis added), no reasonable jury could say the  
9 entry date was impacted by the acceleration clause.

10 The problem with Gilead’s argument is that there is a disputed question of fact – *i.e.*,  
11 whether there was an implicit agreement on an acceleration clause with exclusivity at the time  
12 Gilead and Teva reached agreement on the default entry date of September 2020.

13 As noted above, the parties started settlement discussions in mid-January 2014, prior to  
14 closing arguments. Internally, Teva expressed an interest in Gilead’s settlement proposal but  
15 noted, *inter alia*, that it would “like to test the entry date to see if we can get it to late 2019” and  
16 that it would “*need all the usual triggers.*” Huttinger Decl., Ex. 59 (email, dated 1/24/2014, from  
17 Rabinovic to Hashmall) (emphasis added). On February 6, 2014, Gilead responded that it was  
18 willing to agree to an entry date in January 2021 and that it would “discuss specifics of usual  
19 triggers once we have agreement on [the] above but *assumes same or similar to tenofovir [TDF]*  
20 *deal.*” Huttinger Decl., Ex. 59 (email, dated 2/6/2014, from Hashmall to Rabinovic) (emphasis  
21 added). As noted above, one of the important parts of the TDF Settlement Agreement was the  
22 MFE/MFEP.

23 Furthermore, it is questionable whether Gilead and Teva would *conclusively* agree on an  
24 entry date without knowing what the other terms of the settlement would be. Certainly, a contrary  
25 inference can be drawn. Indeed, Plaintiffs make a fair argument that “[i]t defies reason that the  
26 parties had already ‘definitively’ agreed on an entry date and then Gilead just gave a \$600 million  
27 gift to Teva [*i.e.*, the royalties that Gilead could have charged Teva for giving Teva contractual  
28 exclusivity].” Opp’n at 15. “It also defies the testimony of Teva’s negotiator, Mr. Hashmall, that

1 getting the six month MFE/P was ‘key to [Teva’s] willingness to settle.’” Opp’n at 15. At the  
 2 very least, given that reasonable inferences are to be drawn in favor of the non-moving party for  
 3 summary judgment purposes, there is a disputed issue of fact here.

4 2. Other Generic Manufacturers

5 Given that Plaintiffs have evidence to support their position that Teva did agree to delay  
 6 entry because of the MFE/MFEP, that is enough for them to get by summary judgment. In other  
 7 words, the Court need not examine whether other generic manufacturers also delayed their entry  
 8 into the market as a result of the MFE/MFEP. However, out of an abundance of caution, the Court  
 9 considers this issue and concludes that it also warrants denial of summary judgment: there is a  
 10 genuine dispute as to whether the MFE/MFEP delayed the entry of other generic manufacturers.

11 Defendants argue that the MFE/MFEP could not have been a deterrence to other generic  
 12 manufacturers because it did *not* accelerate Teva’s entry date if a generic manufacturer decided to  
 13 launch its generic drug *at risk* (*i.e.*, without a license from Gilead). According to Defendants,  
 14 “because none of the settlements between Gilead and Teva contained an at-risk launch  
 15 acceleration clause, generics had increasing incentive to launch at risk as additional generics  
 16 settled. Any generic that settled would not be able to launch earlier than the LED [licensed entry  
 17 date] if a non-settling generic opted to launch at risk and take its chances in court.” Hoxie Rpt. ¶  
 18 85; *see also* Hoxie Rpt. ¶ 106 (“Once Teva had settled and agreed to defer its launch, other  
 19 generics would have a golden opportunity and strong incentive to launch – if they felt confident  
 20 that they would not ultimately lose the patent litigation. A strong competitor had left the field.  
 21 There was no 180-day exclusivity blocking FDA approval. The litigation was well advanced.  
 22 Teva’s launch would not be accelerated by an at-risk launch by another generic.”). And  
 23 “[c]onsistent with these incentives, . . . most of the later generic filers who filed Paragraph IV  
 24 challenges did so only *after* Teva entered into its settlement with Gilead.” Mot. at 16-17  
 25 (emphasis in original); *see also* Hoxie Rpt. ¶ 80) Defendants concede that none of the generic  
 26 manufacturers actually went on to launch at risk (either the ten who had filed ANDAs for Truvada  
 27 or the eight who had filed ANDAs for Atripla), *see* Hoxie Rpt. ¶ 80, but suggest that was only  
 28 because of the strength of the patents at issue. *See* Hoxie Rpt. ¶ 102 (“Nothing in the settlement

1 agreement prevented other generic companies from obtaining FDA approval and launching a  
 2 product. The obstacle to launch was not the settlement agreement. The obstacle was the Orange  
 3 Book-listed patents, which Teva and the other ANDA filers ultimately chose to respect rather than  
 4 challenge.”).

5 But there is a genuine dispute of fact here because the strength of the FTC patents – as well  
 6 as the formulation patents – is not clear and therefore the fact that no generic manufacturer  
 7 launched at risk and instead settled with Gilead for an entry date of “Day 181” (*i.e.*, 180 days after  
 8 Teva) gives rise to an inference that they agreed to delay entry because of the MFE/MFEP in the  
 9 FTC Patent Settlement Agreement between Gilead and Teva. *See also* Opp’n at 4 (asserting that a  
 10 “MFE/P severely degrades [a generic manufacturer’s] likelihood of getting an earlier entry date  
 11 than Teva through settlement: those “earlier entry dates . . . are no longer profitable to Gilead  
 12 because of the severe profit loss from accelerating Teva’s entry date”). Plaintiffs have also  
 13 submitted evidence suggesting that an at-risk launch (that would not trigger acceleration of Teva’s  
 14 entry date) was not likely even though that door was technically left open by the settlement  
 15 agreement. For example, Plaintiffs’ expert Mr. Clark explains that not many generic  
 16 manufacturers have the financial resources to launch at risk (*i.e.*, launching at risk exposes the  
 17 generic manufacturer to potential damages – which can be very high for blockbuster drugs). *See*  
 18 Huttinger Decl., Ex. 7 (Clark Rpt. ¶ 24). In addition, Plaintiffs’ expert Dr. McGuire notes as  
 19 follows:

20 186. . . . Although at-risk entry is not uncommon for first filers,  
 21 it is unusual a non-first filer to launch at risk after the first  
 filer has settled.

22 187. The circumstances here make at-risk entry even less likely.  
 23 The *TDF* patents did not expire for many years after Gilead  
 24 had initiated [*FTC*] litigation against the earliest ANDA  
 25 filers, giving the litigation ample time to reach a legal  
 26 conclusion with respect to the patents at issue in the Teva  
 27 litigation before entry by subsequent filers was possible.  
 28 Any potential at-risk entrant would have little to gain relative  
 to its potential damages. Lastly, I am unaware of evidence  
 that Gilead, Teva, or any of the other generics expected that  
 a generic would launch at risk after the Gilead-Teva  
 Agreement was signed (or any time time). In fact, no  
 generics launched at risk.

1 McGuire Rpt. ¶¶ 186-87 (emphasis added); *see also* McGuire Reb. Rpt. ¶¶ 85-87 (going into  
 2 further details as to why the generic manufacturers were not likely to launch at risk). Another  
 3 expert of Plaintiffs makes fair criticisms of Defendants’ analysis – noting, *e.g.*, that the defense  
 4 expert, Mr. Hoxie, did not take into account that an at-risk launch would still “require FDA  
 5 approval which, if the brand-drug company sues the Paragraph IV applicant within 45 days, could  
 6 not occur for at least 30 months.” Clark Reb. Rpt. ¶ 36.

7 3. Summary

8 For the foregoing reasons, the Court rejects Defendants’ argument that they are entitled to  
 9 summary judgment because there is no evidence that the MFE/MFEP delayed either Teva’s entry  
 10 date or the entry date of other manufacturers. There is a genuine dispute of fact on those matters.

11 C. Anticompetitive Conduct

12 Defendants argue that, even if there may be a genuine dispute of fact on antitrust injury,  
 13 there is no genuine dispute of fact on anticompetitive conduct. Defendants take the position that  
 14 Plaintiffs are asserting a reverse payment theory under the Supreme Court’s *Actavis* decision, *see*  
 15 *Actavis*, 570 U.S. at 148 (noting that, where a plaintiff sues a defendant for patent infringement,  
 16 and the defendant does not have any claim that the plaintiff is liable to it for damages, then it is an  
 17 “unusual” settlement for the plaintiff to pay the defendant money under the settlement agreement),  
 18 but no reverse payment (*i.e.*, profit sacrifice) was ever made by Gilead to Teva (*i.e.*, in exchange  
 19 for the delayed entry date of Teva).

20 1. Non-Actavis Theory

21 As an initial matter, the Court notes that Plaintiffs are not clearly limiting themselves to a  
 22 reverse payment theory under *Actavis*. If Gilead was able to give an incentive to Teva to delay  
 23 entry into the market, that would plausibly anticompetitive in and of itself; it is not clear why  
 24 Gilead would also have to make a profit sacrifice before its conduct could be deemed a violation  
 25 of antitrust law.

26 Defendants suggest that a profit sacrifice is required because only “a profit sacrifice will  
 27 provide the necessary basis to infer the potential for patent weakness.” Mot. at 9; *see also Actavis*,  
 28 570 U.S. at 158 (stating that “[a]n unexplained larger reverse payment . . . would normally suggest

1 that the patentee has serious doubts about the patent’s survival”; thus, “the size of the unexplained  
2 reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a  
3 court to conduct a detailed exploration of the validity of the patent itself”). But Defendants’  
4 position is problematic because, even though a profit sacrifice might be one way to infer patent  
5 weakness, it is not clear why there could not be other ways for an antitrust plaintiff to show patent  
6 weakness. More fundamentally, regardless of the strength or weakness of a patent, if a patentee  
7 could give a generic manufacturer an incentive to delay entry even by means other than a direct  
8 reverse payment, that could be a plausible basis for anticompetitive conduct.

9           2.       Profit Sacrifice

10           In any event, Plaintiffs do, in fact, assert a reverse payment theory, and thus the Court  
11 considers whether there is any evidence of a reverse payment from Gilead to Teva. In this regard,  
12 the Court bears in mind that a reverse payment (or profit sacrifice) can be more complicated than  
13 might appear at first blush.

14           A reverse payment *can* be, but is not *required* to be, an outright payment of cash to the  
15 generic manufacturer. *See King Drug*, 791 F.3d at 403 (“We do not believe *Actavis*’s holding can  
16 be limited to reverse payments of cash.”). As the Third Circuit has underscored, “economic  
17 realities rather than a formalistic approach must govern,” and thus *Actavis* should be read  
18 “practically . . . to apply to potentially anticompetitive reverse payments regardless of their form.”  
19 *FTC v. AbbVie, Inc.*, 976 F.3d 327, 356 (3d Cir. 2020). Accordingly, the Third Circuit (among  
20 other courts) has held that a patentee’s agreement not to sell an authorized generic can be a reverse  
21 payment. *See King Drug*, 791 F.3d at 405 (stating that “a brand’s commitment not to produce an  
22 authorized generic means that it must give up the valuable right to capture profits”).

23           The Third Circuit has even held that there can be a reverse payment even where it is the  
24 *generic manufacturer* who pays cash to the patentee, and not the other way around. For example,  
25 if a patentee would ordinarily require a generic manufacturer to pay millions of dollars to settle a  
26 patent infringement suit (even though the merits of the patents might be debatable), but, through  
27 settlement, the generic manufacturer pays the patentee only a paltry sum, then it could be inferred  
28 that, effectively, there was a reverse payment because the patentee undercharged the generic



1 manufacturer. *See Abbvie*, 976 F.3d at 355 (noting that, “[i]f parties could shield their settlements  
2 from antitrust review by simply including a token payment by the purportedly infringing generic  
3 manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to  
4 eliminate the risk of competition would escape review”); *see also id.* (noting that, “in the Effexor  
5 XR litigation, we reinstated a complaint alleging a generic applicant delayed entry into the Effexor  
6 market in exchange for the brand-name producer’s agreement not to market an authorized generic  
7 – *even though the generic agreed to pay some royalties to the brand*”) (emphasis added); *In re*  
8 *Lipitor Antitrust Litig.*, 868 F.3d 231, 255 (3d Cir. 2017) (noting that, in spite of the brand’s  
9 claimed losses of hundreds of millions of dollars and “some likelihood of success given the entry  
10 of [a preliminary] injunction [in favor of the brand], which was affirmed on appeal” (and for  
11 which the brand paid a \$200 million bond), the brand and generic entered a settlement in which  
12 *the generic the brand only \$1 million*; this adequately stated a reverse payment claim for relief).  
13 *But see Mayor of Baltimore v. AbbVie, Inc.*, 42 F.4th 709, 715 (7th Cir. 2022) (suggesting that,  
14 under *Actavis*, a patent holder’s settlement with an alleged infringer for less than its full demand –  
15 but the alleged infringer still pays something to the patent holder – cannot be an antitrust violation  
16 because that is a traditional kind of settlement).

17 Taking into account that a reverse payment can take various forms, Plaintiffs have argued  
18 that there is evidence of a reverse payment in the instant case for two reasons:

- 19 (1) “Gilead recreated Teva’s forfeited regulatory exclusivity through private contract. Had  
20 Gilead created such exclusivity *unconnected* to a negotiation over Teva’s entry date,  
21 the going royalty rate was 90%. The cost to Gilead of foregoing those royalties was  
22 \$264.9 million.” Opp’n at 7 (emphasis added).
- 23 (2) Gilead incurred a risk (even if not great) that the MFE/MFEP would be triggered. If  
24 Teva’s entry date were “accelerated by the MFE+ clause, the date of initial entry  
25 occurs earlier and the period of Gilead’s brand sales without generic competition is  
26 shortened.” McGuire Rpt. ¶ 171.

27 Both reasons are plausible, and Defendants’ arguments to the contrary are not persuasive.  
28 For example, for the theory in (1), Defendants argue that it improperly “treats the creation of more

1 competition as a reverse payment, and the only ‘sacrifice’ at issue is merely a noncognizable  
2 ‘opportunity cost.’” Mot. at 20. But Defendants’ suggestion that an opportunity cost is not  
3 cognizable is not well supported. Although one could characterize a patentee’s giving up the right  
4 to sell an authorized generic a mere opportunity cost, that has been recognized by courts as a  
5 reverse payment. *See, e.g., King Drug*, 791 F.3d at 405. That result is perfectly logical;  
6 opportunities can have value.

7 Defendants’ reliance on, *e.g., Rebel Oil Co. v. Atlantic Richfield Co.*, 146 F.3d 1088, 1095  
8 (9th Cir. 1998), is not persuasive. *Rebel Oil* was a predatory pricing case. In general, predatory  
9 pricing means pricing below cost – with the goal of eliminating competitors. *See, e.g., Cargill,*  
10 *Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 117 n.12 (1986) (noting that “[m]ost commentators  
11 reserve the term predatory pricing for pricing below some measure of cost, although they differ on  
12 the appropriate measure”); *Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209,  
13 222 (1993) (noting that, when “the claim alleges predatory pricing . . . , a plaintiff seeking to  
14 establish competitive injury resulting from a rival’s low prices must prove that the prices  
15 complained of are below an appropriate measure of its rival’s costs”); *see also Rebel Oil*, 146 F.3d  
16 at 1090 (taking note of plaintiff’s allegation that defendant “charged predatory prices in an attempt  
17 to take away market shares from its competitors” and that, after defendant acquired 54% of the  
18 market, it “then engaged in price gouging, charging [higher] prices . . . to recoup its losses  
19 resulting from the previous low predatory prices”). In *Rebel Oil*, the Ninth Circuit simply  
20 rejected the plaintiff’s argument that below-cost pricing could be shown through the use of  
21 opportunity costs. The court stated that “[o]pportunity costs are vastly different from . . . marginal  
22 or variable costs, and we agree that ‘the use of the concept of opportunity costs [*to show predatory*  
23 *pricing*] must be held improper as a matter of law.” *Id.* at 1095 (bracketed information in  
24 original; emphasis added). Even if opportunity costs cannot be used to show predatory pricing,  
25 the instant case is not a predatory pricing case. *See also* Opp’n at 9 (arguing that *Rebel Oil* simply  
26 holds that “‘opportunity cost’ is not the right metric for measuring below-cost pricing in a  
27 unilateral predatory-pricing case, an entirely unrelated legal and economic issue”). Furthermore,  
28 as Plaintiffs point out, their theory here is not that Gilead “pass[ed] up an existing opportunity;

1 [rather], it *created* the exclusivity and gave it to Teva for free” even though it had value. Opp’n at  
2 8 (emphasis in original).

3 Defendants further argue that the theory in (1) sets up “an unworkable standard that would  
4 require courts to determine the best *business* outcome a company could theoretically obtain, and  
5 impose antitrust liability if the company chose a different course” (which is “why courts refuse to  
6 treat opportunity cost as a profit sacrifice”). Mot. at 20 (emphasis in original). But the theory of  
7 Plaintiffs’ claim is not complicated and does not require extensive second guessing of normal  
8 business judgment. Plaintiffs’ point is that Gilead would have charged *some* kind of royalty for  
9 the contractual exclusivity but did not charge *anything*. Furthermore, Defendants’ argument that  
10 their decisions should somehow be immune from judicial scrutiny would in some ways be an  
11 indictment of the rule of reason itself. The Court rejects Defendants’ argument.

12 Finally, Defendants assert that Plaintiffs have created an “impossible Catch-22”:

13 Plaintiffs suggest that charging a first-filing generic manufacturer  
14 any royalty *lower* than 90% is a reverse payment. Yet in other  
15 cases, the same plaintiffs’ counsel, supported by Dr. McGuire, have  
16 asserted that a patent settlement requiring royalties of 25% or *higher*  
17 was a reverse payment; there, they reasoned that the 25% royalty  
18 rate was improperly “high” because it discouraged the patentee from  
19 launching an authorized generic. Had Gilead charged the 90%  
20 royalty Plaintiffs suggest it was required to charge, there can be no  
21 doubt Plaintiffs and Dr. McGuire would argue that *that* was a  
22 reverse payment.

23 Mot. at 21 (emphasis in original). But whether a royalty payment would be anticompetitive would  
24 depend on the totality of the facts; Plaintiffs’ point here is simply that in negotiations *unrelated to*  
25 *a patent settlement* Gilead would have charged a 90% royalty (or something at least) for  
26 contractual exclusivity, and that, by charging nothing, Gilead effectively compensated Teva for its  
27 delayed entry.

28 As for the theory in (2), Defendants make a similar argument – *i.e.*, contending that a  
MFE/MFEP that accelerates a generic entry date is pro-competitive and that the sacrifice of an  
opportunity cost is not the kind of profit sacrifice required by *Actavis*. But even if there may be a  
pro-competitive aspect where there is acceleration, that can arguably be counterbalanced by  
anticompetitive aspect: that is, even though acceleration means generic competition comes earlier,

1 it also means delayed competition from other generics (and typically, the more generics there are,  
2 the cheaper the generic drugs are). In any event, to the extent there are pro-competitive benefits  
3 from the agreement, that factors into the rule-of-reason calculus, one which should be left for the  
4 jury.

5 D. Defendants' *Daubert* Motions

6 Defendants have argued that, if the Court is to deny its motion for summary judgment on  
7 the MFE/MFEP claims, it must address their *Daubert* motions to exclude two of Plaintiffs'  
8 experts, Mr. Lentz and Dr. McGuire. It does not appear that the *entirety* of the motions related to  
9 Mr. Lentz and Dr. McGuire needs to be decided.

10 For Mr. Lentz, Defendants make two arguments: (1) Mr. Lentz is not qualified to opine  
11 that the new formulation patents would have been found invalid or not infringed, and (2) his  
12 conclusions about both the FTC patent litigation and the new formulation patents conflict with  
13 Teva's internal assessment that it was not likely to prevail on either. For purposes of summary  
14 judgment, the Court need only address the second argument. As discussed above, Teva's  
15 subjective views are not dispositive, and therefore the *Daubert* motion on (2) is denied. The Court  
16 need not address (1) because Plaintiffs need not rely on Mr. Lentz's views regarding the  
17 formulation patents. They can rely instead on evidence that Teva itself looked favorably on its  
18 ability to launch a product in spite of the formulation patents and only belatedly (in February  
19 2014) changed its tune, and without explanation.

20 For Dr. McGuire, Defendants contend that he (1) improperly provides legal opinions, (2)  
21 incorrectly interprets the Supreme Court's *Actavis* decision, (3) fails to consider Teva's actual  
22 views when modeling the parties' negotiations, (4) improperly challenges the credibility of Teva's  
23 witnesses, and (5) speculates what Teva and Gilead would have done in the but-for world. At  
24 most, the third and fifth arguments are relevant to the motion for summary judgment. Neither of  
25 the arguments is persuasive. As discussed above, Teva's subjective views on its likelihood of  
26 success are not dispositive. Also, it is not improper for Dr. McGuire to opine as to what a rational  
27 company in Teva or Gilead's position would have done.

28 Accordingly, for the limited issues relevant to the motions for summary judgment, the

1 Court denies the *Daubert* motions related to Mr. Lentz and Dr. McGuire.

2 **VII. CONCLUSION**

3 For the foregoing reasons, the Court rules as follows:

- 4 • Defendants’ motion for summary judgment on the TAF claims is granted. *See*  
5 1378, 1493.
- 6 • Plaintiffs’ motion for summary judgment on market power is denied. *See* Docket  
7 Nos. 1407, 1501.
- 8 • Plaintiffs’ motion for summary judgment on the NGR claims is denied. *See* Docket  
9 Nos. 1407, 1501.
- 10 • Defendants’ motion for summary judgment on the NGR claims is granted in part  
11 and denied in part. The motion is denied, except as to the Prezcofix, Odefsey, and  
12 Symtuza Agreements, thus leaving only the Complera and Evotaz Agreements at  
13 issue for the NGR claims. *See* Docket Nos. 1377, 1492.
- 14 • Defendants’ motion for summary judgment on the MFE/MFEP claims is denied.  
15 *See* Docket Nos. 1376, 1491.
- 16 • Defendants’ *Daubert* motions as to Mr. Lentz and Dr. McGuire are denied (but  
17 only with respect to the specific issues discussed above). *See* Docket Nos. 1406,

18 The Court instructs the Clerk of the Court to file this order under seal. The Court orders  
19 the parties to meet and confer to determine which portions of this order may be publicly filed. The  
20 parties shall jointly file their request to file under seal within a week of the date of this order.

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1           The status conference set for January 9, 2023, at 3:00 p.m. remains on calendar. The  
2 parties shall be prepared to address which of the previously-filed *Daubert* motions still need  
3 resolution in light of the Court’s summary judgment rulings, as well as next steps.

4           This order disposes of Docket Nos. 1491, 1492, 1493, and 1501, as well as portions of  
5 Docket No. 1494.

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7           **IT IS SO ORDERED.**

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9           Dated: January 5, 2023

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12           EDWARD M. CHEN  
13           United States District Judge

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United States District Court  
Northern District of California