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.[1]

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

[1] 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.

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

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

I. GENERAL BACKGROUND

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

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

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

[2] When an FDC is a complete HIV treatment regimen, it is known as a single-tablet regimen ("STR").

agreements contain what Plaintiffs have called No-Generic Restraints ("NGRs").[3] The NGRs are noncompete provisions – *i.e.*, provisions that prevent a collaborator from offering an identical or near identical FDC that competes with the joint venture's FDC. Essentially, they provide that, even if one collaborator's component drug loses its patent protection (*i.e.*, a generic version now becomes available), the other collaborator is barred from making a FDC comprised of its own component drug and a generic version of the first collaborator's component drug.

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

As indicated above, Gilead is implicated in all three of Plaintiffs' claims, Janssen is

[3] Because the Court has used the term "NGR" in its prior orders, it continues to do so here. The Court recognizes, however, that Defendants disagree with the use of that term, and it makes no ruling here as to what term should be used before the jury at trial.

[4] 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.

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

II. LEGAL STANDARD

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

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

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

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

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

III. TAF CLAIMS

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

A. Relevant Background

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

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

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

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

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

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

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

First, Gilead intentionally degraded the safety of Stribild, a TDF-based drug. Stribild is a FDC (comprised of TDF/FTC/EVG/COBI) that includes a booster (COBI). The booster is used so that another component in Stribild (EVG) can be taken once daily instead of twice a day. *See* Gant Decl., Ex. 20 (Bischofberger Depo. at 214). However, coadministration of tenofovir with a booster increases tenofovir exposure and therefore kidney toxicity. *See* Hardy Rpt. ¶ 118. In spite

of this, Gilead kept the dose of TDF in Stribild at a full 300 mg.[5] *See* Hardy Rpt. ¶ 121 (stating that 300 mg was a "dosage only demonstrated to be appropriate for achieving efficacy *without* a booster") (emphasis in original).

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

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

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

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

[5] When Viread (TDF) was approved in 2001, it was at a dosage of 300 mg. *See* Follansee Rpt. ¶ 87. In other words, 300 mg is the approved dosage of TDF.

[6] As explained by Plaintiffs' expert, Dr. Rubinfeld, health plans have "mechanisms to encourage

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

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

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

B. Scope of TAF Claims

As an initial matter, the Court takes note that, at the hearing, Plaintiffs clarified the scope of their TAF claims. As indicated above, the TAF claims appeared to be based on three different

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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.

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

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

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

[7] At the hearing, Plaintiffs were not able to articulate how either of the decisions above could have, *e.g.*, facilitated the anticompetitive conduct that Plaintiffs are challenging (such as the forced transition of HIV patients from TDF-based to TAF-based drugs). *See Staley v. Gilead Scis., Inc.*, 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).

C. Switching/Product Hopping Claim

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

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

About half a year later, the companies changed tactics and adopted a "more direct

[8] Because there is a Supreme Court case also commonly referred to as *Actavis*, the Court shall refer to this Second Circuit decision as *Namenda*.

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

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

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

Regarding the element of consumer coercion, the Second Circuit concluded that the companies' "hard switch crosses the line from persuasion to coercion." *Namenda*, 787 F.3d at 654.

> By effectively withdrawing Namenda IR prior to generic entry, Defendants forced patients to switch from Namenda IR to XR – the only other memantine drug on the market. In fact, the district court found that Defendants devised the hard switch because they projected that only 30% of . . . patients would voluntarily switch to 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.

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

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

Id. at 654-55.

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

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

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

Based on *Namenda*, Gilead argues that a critical element in a switching/product hopping claim is coercion. Plaintiffs disagree. They contend that this Court rejected that requirement in one of its prior orders addressing a 12(b)(6) motion to dismiss. *See* Opp'n at 49 (citing *Staley*, 446 F. Supp. 3d at 615. Plaintiffs are incorrect. In its prior decision, the Court was never squarely

presented with switching/product hopping authority and the issue of coercion. Thus, the Court necessarily did not express an opinion on whether coercion is required in a switching/product hopping situation. Moreover, implicit in the Court's prior order was an endorsement of the coercion element – *i.e.*, Plaintiffs' theory was that product superiority was not driving the transition from TDF to TAF but rather something else. Furthermore, a coercion element is necessarily a part of Plaintiffs' claim here because how else could there by anticompetitive conduct unless HIV patients', doctors', and/or payors' choices regarding products were constrained? *See id.* at 654-55 (noting as a basic tenet that "the market can determine whether one product is superior to another only 'so long as the free choice of consumers is preserved'"). Finally, this case is similar to *Namenda*. As in *Namenda*, the switch to the new product impaired competition from generic manufacturers; Gilead forced patients to switch over from TDF to TAF, knowing that generics for TDF would not be AB-rated for TAF.

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

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

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

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

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

[9] The Court acknowledges that payors may not have paid wholesale prices but presumably wholesale prices give some indication of what retail prices would be.

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

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

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

updated, organized, curated, and reliable information").

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

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

> TAF/FTC was added as a 2-NRTI option in several Recommended and Alternative regimens . . . . The addition of TAF/FTC to these recommendations is based on data from comparative trials 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.

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

[10] In their papers, the parties have a dispute over whether deceive marketing is actionable for antitrust purposes only when the marketing is clearly false. Plaintiffs contend that the "clearly false" standard applies only where false claims are made about a *competitor's* product. *See Am. Prof'l Testing Serv. v. Harcrout Brace Jovanovich Legal & Prof'l Publns.*, 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.

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

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

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

[11] And even if there were a genuine dispute of fact related to coercion, Plaintiffs would likely run 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.

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

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

IV. MARKET POWER

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

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

[12] The Court also certified a cART Foundation Drug Class. However, that class is not at issue here. Furthermore, given the Court's ruling above on the TAF claims, it is not clear that the cART Foundation Drug Class has any claim remaining to pursue.

[13] 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.

> Market power may be demonstrated through either of two types of proof. One type of proof is direct evidence of the injurious exercise of market power. If 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. The more common type of proof is circumstantial evidence pertaining to the structure of the market. To demonstrate market power circumstantially, a plaintiff must: (1) define the relevant market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry and show that existing competitors lack the capacity to increase their output in the short run.

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

A. Direct Evidence

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

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

> The Supreme Court has not clearly addressed this issue. In [*Ohio v. American Express Co.*, 138 S. Ct. 2274 (2018)], the Court noted that, if "'output is expanding at the same time prices are increasing, rising prices are equally consistent with growing product demand,'" but, at another point, the Court used the disjunctive, stating "[t]his 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"),[14]

[14] *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*

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

Id. at 1026 (emphasis in original).

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

> Allegations that conduct "has the effect of reducing consumers' choices or increasing prices to consumers do[] not sufficiently allege an injury to competition . . . [because] [b]oth effects are fully consistent with a free, competitive market." *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012) (citations omitted); *see also Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 237 (1993) ("Where . . . output is expanding at the same time prices are increasing, rising prices are equally consistent with growing product demand."). Instead, in order to prove a violation of the Sherman Act, the plaintiff must show that diminished consumer choices and increased prices are the result of a 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 data absent some evidence that tends to prove that output was restricted or prices were above a competitive level.'" (quoting *Brooke Grp. Ltd.*, 509 U.S. at 237)).

Id. at 990.

Arguably, *Qualcomm* still leaves some ambiguity as to what the Ninth Circuit requires for direct evidence. But there is a convincing argument that both supracompetitive prices and restricted output are necessary. As the Third Circuit has explained, it is only "'[i]f a firm can profitably raise prices *without causing competing firms to expand output and drive down prices*, that firm has monopoly power,' and therefore '[t]he existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output.'" *Mylan*, 838 F.3d at 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).

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

1. Restricted Output

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

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

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

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

2. Supracompetitive Pricing

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

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

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

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

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

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

[15] Otherwise, an antitrust plaintiff might well have an incentive to manipulate what the relevant 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").

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

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

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

B. Indirect Evidence

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

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

> Economic substitutes have a "reasonable interchangeability of use" or sufficient "cross-elasticity of demand" with the relevant product. Including economic substitutes ensures that the relevant product 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."

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

[16] 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

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

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entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.'" *Image Tech. 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)).

[17] Defendants suggest that switching was driven by HIV patients moving over from older drugs to newer/more innovative/better quality drugs. The Court acknowledges that some switching seems 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.

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

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

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

V. NGR CLAIMS

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

A. Relevant Background

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

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

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

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[18] For some of the collaboration agreements, Gilead made financial contributions to the development of the FDC. For instance, Gilead contributed money toward the development of Symtuza. *See* Saint-Antoine Decl., Ex. 32 (Symtuza Agmt. § 9.1.2). Gilead also contributed financially to Janssen's development of RPV which was used to make Complera. *See* Mot. at 2 (noting that "Gilead agreed to reimburse Janssen up to $100 million for costs associated with 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).

[19] 3TC is a drug that, in essence, can be used in lieu of FTC (or generic FTC).

[20] 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

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

B. Ancillary Restraint

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

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

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

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

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

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

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

> the restriction on competition is unaccompanied by new production or products, and "ancillary" restraints, those that are part of a larger endeavor whose success they promote. . . .
>
> . . . .
>
> A court must ask whether an agreement [not to compete] promoted enterprise and productivity at the time it was adopted. If it *arguably* did, then the court must apply the Rule of Reason to make a more discriminating assessment. . . .
>
> A restraint is ancillary when it *may* contribute to the success of a cooperative venture that promises greater productivity and output. If the restraint, viewed at the time it was adopted, *may* promote the success of this more extensive cooperation, then the court must scrutinize things carefully under the Rule of Reason. Only when a quick look reveals that "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output" should a court cut off further inquiry.

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

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

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

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

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

> reasonably necessary to the parties' pro-competitive collaboration. 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.

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

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

Although Plaintiffs' arguments above are not without any merit, they cannot prevail as a

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[22] In their papers, Plaintiffs have cited the Seventh Circuit's decision in *Polk* approvingly. Although Plaintiffs' initial interpretation of *Polk* was not entirely consistent with the Court's interpretation above, *see* Opp'n at 30 (arguing that, under *Polk*, "even if the Court finds the NGRs to be ancillary restraints, they still must be scrutinized using the quick look approach or evaluated, 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").

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

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

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

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

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

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

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

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

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

[23] To the extent Plaintiffs point out that the collaboration agreements already included confidentiality provisions that protected know-how, that is an argument that there was a less 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.

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

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

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

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[24] Even if Plaintiffs are correct that the Court should do a quick-look review *after* finding the NGRs to be ancillary restraints, they would fare no better. "[Q]uick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained," *i.e.*, "'where a practice has obvious anticompetitive effects'" or where there are not even any "plausibl[e]" 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

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

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

> An agreement between two established stores in a shopping center that divides the products they will sell and unaccompanied by any new integration or enterprise[] is . . . viewed with great suspicion. However, they may be justified nonetheless if they accompany secondary transactions that continue or expend the previously existing joint venture or business relationship[;] [f]or example, firms 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*.

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

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and to analyze the dynamics of consumer choice simply will not suffice."); *Deutscher Tennis 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.").

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

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

C. Rule of Reason

Under the rule of reason,

> the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive 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.

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

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

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

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

- Prezcobix = DRV/COBI. DRV currently has patents and regulatory exclusivity that would block Gilead from entering with a "generic" version of Prezcobix until 2026. COBI has patents that would block Janssen from entering with a "generic" version of Prezcobix until 2032.
- Odefsey = RPV/TAF/FTC. Although a generic version of FTC is now available, TAF has patents and regulatory exclusivity that would block Janssen from entering with a "generic" version of Odefsey until 2033. RPV has patents that would block Gilead from entering with the "generic" version of Odefsey until 2025.
- Symtuza = DRV/TAF/FTC/COBI. As noted above, although a generic version of FTC is now available, TAF has patents and regulatory exclusivity that would block Janssen from entering with a "generic" version of Symtuza until 2033 (and COBI patents would also be a block until 2032). DRV currently has patents and regulatory exclusivity that would block Gilead from entering with a "generic" version of Symtuza until 2026.

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

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

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

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

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

[25] A likelihood of future injury is required whether the relief sought is injunctive relief or 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.").

VI. MFE/MFEP CLAIMS

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

Originally, Plaintiffs had claims based on two different settlement agreements entered into by Gilead/Teva: a 2013 agreement related to TDF (the "TDF Patent Settlement Agreement") and a 2014 agreement related to FTC (the "FTC Patent Settlement Agreement"). Plaintiffs are no longer moving forward with any claim based on the TDF Patent Settlement Agreement and instead are asserting claims based on the FTC Patent Settlement Agreement only.[26]

A. Relevant Background

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

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

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

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[26] *See* McGuire Rpt. at 26 n.113 ("Teva retained its statutory 180-day exclusivity with respect to 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.").

[27] "The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application [instead of a New Drug Application] specifying that the generic has the 'same active 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."*[28] 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.'" 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.[29]

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)

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[28] 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).

[29] 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).

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

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

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

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

[30] "[A] formulation patent is a patent that seeks to cover the pharmaceutical formulation of an 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).

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

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

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

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

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

> "License Effective Date" means, with respect to a particular Teva

> 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.

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 for another generic manufacturer. In other words, if Gilead were to give a license to another generic manufacturer to make generic Truvada or Atripla, then Teva's date of entry would be six months (180 days) ahead of any sale by the other generic manufacturer.

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 (*i.e.*, before September 2020), *or* Teva would have waited to get a decision in the patent infringement litigation – both situations being informed by the fact that "Teva was very likely to get a finding that the patents were invalid." Opp'n at 2; *see also* Opp'n at 5 (arguing that, if Gilead and Teva had settled without a MFE/MFEP, then "rational manufacturers would have agreed on an entry date of May 2019"; if Teva had won the lawsuit, then generic entry for Truvada and Atripla would have taken place in February 2018 (once the *TDF* patents had expired)[31]). But, Plaintiffs contend, the MFE/MFEP clauses gave Teva more benefits, particularly compared to the litigation route. Although Teva was likely to prevail in the patent infringement suit, Teva had *forfeited* the 180 days of statutory exclusivity to which it was entitled as the first ANDA filer for Truvada and Atripla; therefore, a "victory on invalidity would also allow other generic[] [manufacturers] to enter the market when [Teva] did. Teva would make orders of magnitude more money if other generic[] [manufacturers] were not there to compete." Opp'n at 2. According to Plaintiffs, the MFE/MFEP clauses gave *contractual* exclusivity to Teva for 180 days (effectively restoring at least in part the forfeited 180-day *statutory* exclusivity[32]); Teva explicitly acknowledged that it was getting the benefit of contractual exclusivity with the settlement. *See*

[31] Both Truvada and Atripla have TDF as a component (in addition to FTC).

[32] Defendants' expert Mr. Hoxie explains why it would not be possible for parties to *restore* statutory exclusivity as a contractual matter. *See* Bock Decl., Ex. 7 (Hoxie Rpt. ¶ 86) ("Once Teva 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.").

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

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

Plaintiffs counter that at-risk launch was never a serious concern, as demonstrated by the fact that "every other generic [manufacturer] delayed its entry until exactly Day 181 after Teva's entry."[34] Opp'n at 3; *see also* Opp'n at 11 (citing to Dr. McGuire's report in support of the position that an at-risk launch was very unlikely). Plaintiffs also assert that the MFE/MFEP

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[33] Mr. Hashmall was Teva's outside counsel and negotiator. In his deposition, he testified, *inter alia*, that:

- The provision where Teva would get 180 days earlier than the date Gilead would allow any other generic manufacturer was a form of contractual exclusivity. *See* 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 generic [manufacturer] on the market for a period of time, that would provide monetary value to Teva." Huttinger Decl., Ex. 25 (Hashmall Depo. at 30-31).

[34] 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.

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

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

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

B. Antitrust Injury

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

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. Delay by Teva

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

a. Teva's Subjective Assessment

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

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

[35] This date of entry was before the relevant patents protecting Truvada and Atripla would expire 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.

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

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

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[36] Contrary to what Defendants suggest, the Supreme Court did not hold in *Actavis* that subjective beliefs are dispositive. Admittedly, the Supreme Court did state as follows:

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

Actavis, 570 U.S. at 158. But as Plaintiffs point out, the Supreme Court was only considering the 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.

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

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

> Without the alleged anti-competitive conduct, a jury may conclude that Glenmark's actions would be those of a Reasonable Firm, and Jon Clark's opinion is helpful to the trier of fact in evaluating causation.
>
> The relevant question is how a reasonable profit-maximizing company would behave without the alleged anti-competitive conduct. *See* Pls.' Opp'n (ECF No. 1142, at 22 & n.88) (citing cases). Antitrust cases "presume the existence of rational economic behavior in the hypothetical free market." *Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) (citing *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981)); *see also Lidoderm*, 296 F. Supp. 3d at 1162 (describing "the antitrust context, where but-for worlds are considered and profit-maximizing goals assumed"); *id.* at 1179 n.42 (reciting "a presumption of economical rationality").

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

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

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

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

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

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

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

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

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

- **February 12, 2014.** Ildiko Mehes, Teva's Vice President and General Counsel for North America, subsequently passed on Ms. Julie's assessment to Allan Oberman, Teva Americas President and CEO. *See* Bock Decl., Ex. 49 (email, dated 2/12/204, from Mehes to Oberman). Fred Killion, Teva's Deputy Chief Legal Officer, then sent an email to Ms. Mehes and Mr. Oberman providing odds on what would happen if Teva did not settle: "If we DON'T SETTLE," there was (1) "[a] 17.5 percent chance of being able to enter 2+ years EARLIER than the settlement date . . . (50% chance of winning this case x 35% chance of successfully challenging the 2 new [formulation] patents that expire in 2024)," and (2) "[a]n 82.5 percent change of being unable to enter until LATER than the settlement date." Bock Decl., Ex. 49.

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

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

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

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

Opp'n at 20 (emphasis in original and added).[39]

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

In their reply brief, Defendants protest that

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

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[37] *See* Huttinger Decl., Ex. 60 (email, dated 2/6/2014, from Hashmall to Rabinovic) (addressing 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.

[38] *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").

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

> assessment of patent strength she expressed to senior management, or whether, as Plaintiffs baselessly suggest, she instead had some secret motive to express pessimism. It is undisputed that Teva's relevant decision makers – the CLO [Chief Legal Officer] and the President/CEO – approved the FTC Settlement based on the final analysis from counsel that Teva had only a combined 17.5% chance to prevail on the patents[40]. . . .
>
> . . . .
>
> Moreover, Plaintiffs' argument is truly bizarre: that a senior attorney in Teva's general counsel's office deceived senior management to gin up support for a settlement. This theory has no factual support and borders on frivolous. It is certainly insufficient to defeat summary judgment: "A party cannot create a dispute of fact by simply questioning the credibility of a witness."

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

b. Entry Date Negotiated Before MFE/MFEP

Defendants argue that, even if the Court does not rule in its favor on the above argument, Plaintiffs' theory must still be rejected because the evidence shows that Gilead and Teva never negotiated a MFE/MFEP until *after* they had already reached agreement on the default entry date of September 2020, and thus this was no quid pro quo therefor. *See, e.g.*, Bock Decl., Ex. 65 (Julie Decl. ¶¶ 7, 12) (testifying that, in her email of 2/10/2014 (in which she recommended settlement with Gilead for an entry date some time in the fourth quarter of 2020), she did not mention a provision that would give Teva some kind of exclusivity because, "to the best of my recollection, at that time no such exclusivity provision had been discussed between the parties"); 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";

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[40] 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.

[41] 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.

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

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

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

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

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

2. Other Generic Manufacturers

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

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

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

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

> 186. . . . . Although at-risk entry is not uncommon for first filers, it is unusual a non-first filer to launch at risk after the first filer has settled.
>
> 187. The circumstances here make at-risk entry even less likely. The *TDF* patents did not expire for many years after Gilead had initiated [*FTC*] litigation against the earliest ANDA filers, giving the litigation ample time to reach a legal conclusion with respect to the patents at issue in the Teva litigation before entry by subsequent filers was possible. 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.

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

3. Summary

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

C. Anticompetitive Conduct

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

1. Non-*Actavis* Theory

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

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

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

2. Profit Sacrifice

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

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

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

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

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

(1) "Gilead recreated Teva's forfeited regulatory exclusivity through private contract. Had Gilead created such exclusivity *unconnected* to a negotiation over Teva's entry date, the going royalty rate was 90%. The cost to Gilead of foregoing those royalties was $264.9 million." Opp'n at 7 (emphasis added).

(2) Gilead incurred a risk (even if not great) that the MFE/MFEP would be triggered. If Teva's entry date were "accelerated by the MFE+ clause, the date of initial entry occurs earlier and the period of Gilead's brand sales without generic competition is shortened." McGuire Rpt. ¶ 171.

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

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

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

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

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

Finally, Defendants assert that Plaintiffs have created an "impossible Catch-22":

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

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

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,

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

D. Defendants' *Daubert* Motions

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

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

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

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

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

VII. CONCLUSION

For the foregoing reasons, the Court rules as follows:

- Defendants' motion for summary judgment on the TAF claims is granted. *See* 1378, 1493.
- Plaintiffs' motion for summary judgment on market power is denied. *See* Docket Nos. 1407, 1501.
- Plaintiffs' motion for summary judgment on the NGR claims is denied. *See* Docket Nos. 1407, 1501.
- Defendants' motion for summary judgment on the NGR claims is granted in part and denied in part. The motion is denied, except as to the Prezcobix, Odefsey, and Symtuza Agreements, thus leaving only the Complera and Evotaz Agreements at issue for the NGR claims. *See* Docket Nos. 1377, 1492.
- Defendants' motion for summary judgment on the MFE/MFEP claims is denied. *See* Docket Nos. 1376, 1491.
- Defendants' *Daubert* motions as to Mr. Lentz and Dr. McGuire are denied (but only with respect to the specific issues discussed above). *See* Docket Nos. 1406,

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

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

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

IT IS SO ORDERED.

Dated: January 5, 2023

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California