IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION, INC.,

Plaintiff,

v.

GILEAD SCIENCES, INC., JOHNSON & JOHNSON, INC., JANSSEN SCIENCES IRELAND UC, JAPAN TOBACCO, INC.,

Defendants.
_____/

No. C 16-00443 WHA

ORDER GRANTING MOTIONS TO DISMISS

INTRODUCTION

In this action claiming antitrust violations and patent invalidity involving pharmaceutical treatments for human immunodeficiency virus, defendants move to dismiss. For the reasons stated below, defendants' motions are **GRANTED**.

STATEMENT

This case concerns the compound tenofovir, which was discovered in 1984 and is useful in treating human immunodeficiency virus ("HIV"). Plaintiff AIDS Healthcare Foundation, Inc., is a non-profit purchaser of drugs that contain "prodrugs" of tenofovir, which are compounds that are converted into their active ingredient once metabolized in the human body. AIDS Healthcare contends that defendant Gilead Sciences, Inc., improperly used the complex regulatory regime of the Food and Drug Administration that governs pharmaceutical drugs to

protect its position in the market for prodrugs of tenofovir. This order first explains the applicable regulations.

1. FDA REGULATORY REGIME.

New pharmaceutical drugs, such as those containing tenofovir prodrugs, can only be sold or marketed upon approval by the FDA. A company seeking approval for a new drug must conduct extensive research and clinical testing to establish the safety and efficacy of the drug and submit the results of that research as part of a "new drug application" ("NDA") before winning approval. A manufacturer seeking approval for a drug via an NDA must identify all patents (regardless of the patent owner) that it believes cover the drug in question, which the FDA lists in a publication called the "Orange Book."

In 1984, the Hatch-Waxman Act introduced a new procedure intended to encourage the entry of safe, effective, and affordable generic versions of drugs. Pursuant to the Hatch-Waxman Act, a manufacturer that wishes to make an identical copy of a drug that has already been approved can avoid duplicating the expense of research and clinical testing required as part of an NDA by filing an "abbreviated new drug application" ("ANDA"), which can be approved based on the clinical data from the original NDA. The filer of an ANDA must assure the FDA that its generic drug will not infringe the patents listed in the Orange Book for that drug. It can do so by stating, for each listed patent, that it will not market the generic version until the patent expires (if it has not already expired) *or by stating that the patent is invalid or not infringed by the generic product*.

The latter certification (invalidity/non-infringement) is known as a Paragraph IV certification and constitutes an artificial act of patent infringement. If the patent owner initiates litigation against the ANDA filer within forty-five days, the FDA cannot approve that ANDA's drug for thirty months or until a court issues final judgment invalidating the patent or finding that the ANDA's product will not infringe, whichever is earlier.

The Hatch-Waxman Act provides incentives to the first generic manufacturer to file a Paragraph IV certification for a given drug. Specifically, it guarantees (subject to limited exceptions) that the first-filing manufacturer will receive 180 days of exclusivity during which

the FDA may not approve any other ANDAs covering that drug. In other words, it guarantees a period of duopoly between the brand-name manufacturer and the first generic manufacturer to file an ANDA with a Paragraph IV certification.

The first-filing generic manufacturer is guaranteed that exclusivity period even if it settles litigation with a patent owner without resolving the invalidity or non-infringement issues. No later-filing manufacturer can obtain that exclusivity right from the FDA. Thus, when a patent owner settles litigation with the first generic manufacturer to file an ANDA with a Paragraph IV certification, the incentive for a later-filing generic manufacturer to press a challenge to the validity or scope of the patents listed in the Orange Book is significantly diminished. This is because, unlike the first filer, later filers will need to wait until the first filer has exhausted its exclusivity period before any later filers' ANDAs can be approved. The later filers would face competition from any other later filers, driving the margins on the generic products toward zero.

Generic drug manufacturers may alternatively seek approval of a modified generic version of a drug if the original drug has already won FDA approval. (Brand-name manufacturers may also use this process for modifications to their own drugs.) A modification might involve a substitution of certain ingredients, a change in dosage, or approval for a new indication. Although the modifications on the approved drug preclude a generic manufacturer from winning approval with an ANDA, the generic manufacturer may use a special kind of NDA under Section 505(b)(2) of the Hatch-Waxman Act.

Unlike a regular NDA, a Section 505(b)(2) application does not require an applicant to develop and submit original safety and efficacy data covering the product as a whole. Instead, the Section 505(b)(2) applicant may refer to the safety and efficacy data submitted as part of an NDA for a previously-approved drug. The applicant may then provide additional data that demonstrates the safety and efficacy of the proposed modifications.

As with an ANDA, a Section 505(b)(2) application requires the applicant to assure the FDA that the proposed product will not infringe the relevant patents in the Orange Book. Upon approval, the applicant for a modified version of a previously-approved drug is entitled to three

years during which the FDA will not approve an ANDA that relies on the supplemental safety and efficacy data submitted with the Section 505(b)(2) application (although a manufacturer could win approval with its own NDA supported by new data).

To offset generic manufacturers' ability to free-ride on the safety and efficacy data developed by the brand-name manufacturers via the ANDA and Section 505(b)(2) procedures, the Hatch-Waxman Act provides an incentive to brand-name manufacturers to encourage them to develop new products that contain ingredients never before approved by the FDA. Specifically, it grants such applicants a five-year period of "new chemical entity" ("NCE") exclusivity, which operates independent of any patent protection. NCE exclusivity bars the FDA from approving any application for a drug containing the covered new chemical entity for five years following approval of the first NDA containing that ingredient. The FDA also cannot receive applications for drugs containing that ingredient until the fourth year following the approval of the first NDA.

This order now turns to the drugs in question in our case.

2. DEVELOPMENT OF TENOFOVIR THERAPIES.

In its initial formulation, tenofovir needed to be injected intravenously. In 1997, defendant Gilead Sciences, Inc., obtained a patent on a "prodrug" of tenofovir, which could be administered orally and converted into its active ingredient once metabolized in the human body. That prodrug was called tenofovir disoproxil fumarate ("TDF").

In 2001, Gilead received FDA approval to offer TDF as a standalone drug and as part of several fixed-dose combination pills that combined TDF with other active ingredients. Physicians used the fixed-dose combination pills as part of a multi-drug regimen called highly-active antiretroviral therapy. That regimen gave physicians flexibility to prescribe different drug combinations to optimize treatment for patients with various needs (such as differing symptoms).

TDF had side effects involving bone and kidney toxicity. In 2002, Gilead hired physicians to conduct safety and efficacy research into an alternative formulation of a tenofovir prodrug, called tenofovir alafenamide fumarate ("TAF"). Meanwhile, in 2004, Gilead publicly

announced that it had abandoned development of TAF, although it filed seven patent applications relating to the use of TAF between 2004 and 2005. Gilead then resumed its clinical trials in 2011. In 2014, it published a study concluding that TAF had a higher absorption rate than TDF, thereby reducing the bone and kidney toxicity side effects.

In 2015, two years before the expiration of the patents covering TDF, Gilead sought FDA approval of three new combination drugs, which were new versions of Gilead's marquee drugs that substituted TAF for TDF, while keeping the remaining active ingredients the same. It licensed TAF to defendants Japan Tobacco, Inc., and Janssen Sciences Ireland UC, for use in combination with other ingredients for the manufacture of three new fixed-dose combination drugs.[1]

Below is a chart of the ingredients in Gilead's new drugs:

DRUG	LICENSEE	INGREDIENTS
Genvoya	Japan Tobacco	elvitefragir, cobicistat, emtricitabine, and TAF
Descovy	Japan Tobacco	emtricitabine and TAF
Odefsey	Janssen	rilpivirine, emtricitabine, and TAF

The FDA approved the first drug listed, Genvoya, in November 2015. Because TAF was a new chemical entity, the FDA also granted Gilead a five-year NCE exclusivity period over any product containing TAF, which period began in November 2015. Accordingly, no generic drug containing TAF can be approved by the FDA until November 2020. (The FDA may not receive applications until November 2019.) Additionally, Gilead listed twelve patents in the Orange Book covering Genvoya with expiration dates ranging from 2015 to 2032. Gilead's NCE exclusivity bears no relationship to the exclusive rights conferred by its patents.

The FDA approved Descovy and Odefsey in 2016. Because those drugs also contained TAF, they also fell within the protection of Gilead's NCE exclusivity period. Thus, the FDA may not approve any generic version of them until November 2020.

[1] Johnson & Johnson, Inc., is a distinct corporate entity from Janssen Sciences Ireland UC (although they are related). AIDS Healthcare defines them collectively as "Janssen" in its complaint. Johnson & Johnson joins in Janssen's motion to dismiss.

In the first quarter of 2016, Gilead applied for FDA approval of a standalone version of TAF for use in treating hepatitis B virus. It expects the application to be approved in November.[2]

* * *

Plaintiff AIDS Healthcare Foundation, Inc., provided HIV medical care nationwide to hundreds of thousands of patients. It purchased millions of dollars worth of drugs from Gilead and began purchasing Genvoya, Odefsey, and Descovy for pharmacies located in California and Nevada soon after they became available. AIDS Healthcare solicited various pharmaceutical manufacturers to begin making either a standalone TAF product or generic versions of the fixed-dose combination drugs. None responded.

AIDS Healthcare asked Gilead for a covenant not to sue for infringement if it ultimately began to sell a generic product containing TAF. (The proposed covenant did *not* cover claims against any generic manufacturers that might choose to develop a product containing TAF.) Gilead refused. AIDS Healthcare recognized that Gilead's patents covering TAF and Japan Tobacco's patent covering a combination therapy that included TAF served as barriers to entry for any generic TAF patent. Accordingly, it curbed or forestalled investment in research, education, and preparation for the distribution of generic TAF products as well as its efforts to encourage generic manufacturers to provide generic substitutes.[3]

AIDS Healthcare commenced this action in January 2016. After several defendants moved to dismiss, AIDS Healthcare amended its complaint. Several defendants were dismissed without prejudice by stipulation. The complaint now asserts seven claims: (1) declaratory judgment of patent invalidity, (2) monopolization in violation of Section 2 of the Sherman Antitrust Act, (3) conspiracy in violation of Section 1 of the Sherman Antitrust Act, (4) tying in violation of Section 1 of the Sherman Antitrust Act, (5) foreclosure of competition in violation

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[2] The fact that Gilead began developing standalone TAF does not appear in the complaint, but AIDS Healthcare concedes that fact in its brief, citing Gilead's December 2014 Form 10-K filed with the SEC, of which judicial notice is taken (Dkt. No. 35-2).

[3] AIDS Healthcare states in its brief that Japan Tobacco also refused a covenant not to sue. That allegation does not appear in the complaint, and Japan Tobacco contends it is factually false.

of the Cartwright Act, (6) violations of the California Unfair Competition Law, and (7) violations of the Nevada Unfair Trade Practices Law. Gilead moves to dismiss on all claims. Janssen and Johnson & Johnson move to dismiss the only claims against them, which are the Section 1 claims and the state law antitrust claims. Finally, Japan Tobacco moves to dismiss the only claims against it, which are the declaratory judgment claim, the Section 1 claims, and the state law antitrust claims. This order follows full briefing and oral argument.

ANALYSIS

1. DECLARATORY JUDGMENT OF PATENT INVALIDITY.

AIDS Healthcare seeks declaratory judgment of invalidity of five patents that cover the various combination drugs containing TAF, identified below:

PATENT	PATENT OWNER
7,390,791 — "Prodrugs of phosphonate nucleotide analogues."	Gilead
7,800,788 — "Prodrugs of phosphonate nucleotide analogues."	Gilead
8,754,065 — "Tenofovir alafenamide hemifumarate."	Gilead
8,148,374 — "Modulators of pharmacokinetic properties of therapeutics."	Gilead
8,633,219 — "Combination Therapy."	Japan Tobacco

Gilead and Japan Tobacco contend that AIDS Healthcare's prayer for declaratory judgment does not present a justiciable case or controversy and thus must be dismissed.

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007), the Supreme Court abrogated the Federal Circuit's stricter "reasonable apprehension of suit" test for determining the scope of jurisdiction over claims for declaratory judgment in patent suits in favor of a traditional test. Under *MedImmune*, a party seeking to establish declaratory judgment jurisdiction for a claim of patent invalidity must demonstrate that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Ibid.* "Immediacy" is measured based on consideration of "how far in the future

potential infringement is, whether the passage of time might eliminate or change any dispute, and how much if any harm the potential infringer is experiencing a the time of suit that an adjudication might redress." *Sandoz, Inc. v. Amgen, Inc.*, 773 F.3d 1274, 1278 (Fed. Cir. 2014). "Reality" is measured by considering "any uncertainties about whether the plaintiff will take an action that will expose it to potential infringement liability and, if so, exactly what action." *Ibid.*

AIDS Healthcare contends that this dispute is sufficiently real and immediate because it sought to encourage generic manufacturers to develop products that contain TAF, but none has responded. AIDS Healthcare presumes that no manufacturers have taken up that effort because TAF is protected by the above-identified patents. This ignores the fact that TAF is also protected by Gilead's NCE exclusivity, which bars the FDA from receiving any application for a drug containing TAF until November 2019 and from approving that drug until November 2020.

In *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345 (Fed. Cir. 2007), a generic drug manufacturer filed counterclaims for declaratory judgment of invalidity and unenforceability of patents covering a biologic product. The patent owner had charged the generic manufacturer with patent infringement but later dismissed those claims because the alleged infringement had not yet begun, although the generic manufacturer was "developing and submitting information to the FDA related to" the patent technology. Applying *MedImmune* (following supplemental briefs on that decision, which had come down after oral argument in *Benitec*), the Federal Circuit held that "the fact that [the generic manufacturer] may file an NDA in a few years does not provide the immediacy and reality required for a declaratory judgment" and affirmed the district court's judgment that it lacked subject matter jurisdiction over the claims for declaratory judgment.

In *Sandoz*, 773 F.3d at 1279, the Federal Circuit noted that it had never found a justiciable case or controversy before a drug manufacturer had applied for FDA approval. Although that decision declined to "adopt a categorical rule," the decision held that a generic manufacturer's ongoing preparations for a clinical trial could not establish a case or controversy

because "[a]ny dispute about patent infringement is at present subject to significant uncertainties — concerning whether it will actually arise and if so what specific issues will require decision." *Id.* at 1280.

Here, generic manufacturers are still several steps behind even the manufacturers in *Benitec* or *Sandoz*, and there is significant uncertainty about the nature of any hypothetical product. The NCE exclusivity ensures that the first act of "artificial infringement" (the filing of an ANDA) will not occur until 2019, at the earliest, and any proposed generic product cannot be approved until 2020. AIDS Healthcare's efforts to get a product to market on the early range of that timeline do not eliminate the uncertainty that the Federal Circuit identified as fatal in *Benitec* and *Sandoz*.

If we were writing on a clean slate, this order would hold that AIDS Healthcare, at least as a *purchaser* seeking to encourage manufacturers to prepare to make TAF-containing products as soon as Gilead's NCE exclusivity expires, could pursue its invalidity theories in district court as the first step in solving a multi-layered problem. (This would contrast with the *competitors* that could not pursue declaratory judgment in the decisions addressed above.) If AIDS Healthcare were to succeed in clearing away the allegedly invalid patents, then generic manufacturers would be all the sooner poised to apply for FDA approval for TAF-containing products when the application period opens in three-plus years. This would reduce the barriers to speedily bringing low-cost effective drugs to victims of HIV and AIDS. But our Federal Circuit's holdings insist that generic manufacturers must *first* wait until they can seek FDA approval to sue to invalidate the relevant patents. This delay will be compounded by the likelihood that the first generic manufacturer to challenge the patents via a Paragraph IV certification can be expected to withdraw that challenge as part of a settlement with Gilead or Japan Tobacco, a story regularly told under the Hatch-Waxman regime. *See* Scott Hemphill,

Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006).[4]

But the slate isn't clean. The Federal Circuit's interpretation of Article III prevents challenges of patents in district court at least until a generic drug manufacturer has neared completion of a product (and perhaps until the manufacturer has "infringed" by seeking FDA approval). This effectively extends NCE exclusivity beyond its five-year period by tacking on the time it takes to successfully challenge bad patents covering the new chemical entity.

The closest decision on point is *Consumer Watchdog v. Wisconsin Alumni Research Foundation*, 753 F.3d 1258, 1261 (2014). There, a consumer advocacy group appealed a decision from the Patent Trial and Appeal Board affirming the validity of a patent. That decision largely focused on alleged injuries relating to the consumer group's procedural rights to seek an appeal before the PTAB. Before reaching that issue, however, the Federal Circuit swiftly and without much discussion determined that the advocacy group lacked standing because it had not "engaged in any activity involving [the patented technology] that could form the basis for an infringement claim" and it did not "intend to engage in such activity." Also insufficient was the alleged burden the patent placed on taxpayer-funded research relating to the patented technology. The Federal Circuit cited no authority for that proposition, but it indicated that the Federal Circuit would extend the rule set forth in *Benitec* to entities other than competitors. (*Consumer Watchdog* predated *Sandoz*.)

Here, although AIDS Healthcare has encouraged manufacturers to make infringing products, and it has made preparations to encourage the use of such products, the infringing nature of that activity remains dependent on the resolution of the uncertainty identified in

[4] Entering pay-for-delay agreements is just one of many methods drug manufacturers use to delay generic entry. *See* Robin Feldman, *Fixing the Generic Regulatory Process*, SAN FRANCISCO DAILY JOURNAL, June 30, 2016, at 7.

Sandoz and *Benitec*, since, as stated, no manufacturer can even apply for FDA approval of an infringing product until 2019. Under the Federal Circuit's rule, that is insufficient.[5]

Accordingly, AIDS Healthcare's claim for declaratory judgment of patent invalidity is **DISMISSED**. No leave to amend may be sought because AIDS Healthcare cannot plead facts to overcome the hypothetical nature of any proposed infringing product.

2. SHERMAN ACT CLAIMS.

A. Tying.

AIDS Healthcare alleges that Gilead entered into agreements with Janssen and Japan Tobacco to tie sales of TAF to sales of Janssen's and Japan Tobacco's respective drugs by combining them into fixed-dose combination drugs (Genvoya, Descovy, and Odefsey) in violation of Section 1 of the Sherman Antitrust Act. To plead a claim for tying, a plaintiff must allege "(1) that there exist two distinct products or services in different markets whose sales are tied together; (2) that the seller possesses appreciable economic power in the tying product market sufficient to coerce acceptance of the tied product; and (3) that the tying arrangement affects a not insubstantial volume of commerce in the tied product market." *Paladin Assocs., Inc. v. Mont. Power Co.*, 328 F.3d 1145, 1159 (9th Cir. 2003) (internal quotations omitted).

Defendants argue that AIDS Healthcare fails on the first element because, regardless of the alleged demand for a standalone-TAF product, TAF has not been approved by the FDA for sale as a distinct product. (Rather, Gilead has only won FDA approval for the very combinations of products challenged as an illegal tying arrangement.) AIDS Healthcare responds that this is a factual challenge to its market definition, which must be resolved on a full factual record and that the proper test for the existence of two distinct products "turns not on the functional relation between them, but rather on the character of demand for the two items." *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 19 (1984).

[5] AIDS Healthcare could have pursued its anticipation and obviousness theories (but not its subject matter theory) through the *inter partes* review procedure at the United States Patent and Trademark office where it would have enjoyed a more favorable claim construction standard, but it could not have asserted its theories that the patents covered unpatentable subject matter or failed to enable one to make or use the invention. *See Cuozzo Speed Techs., LLC v. Lee*, 15-446, 2016 WL 3369425 (U.S. June 20, 2016).

AIDS Healthcare contends that the unique safety profile of TAF (as compared to TDF) and Gilead's plan to release a standalone TAF product demonstrate that the consumer demand for TAF is separable from that of the alleged tied products. The extent of consumer demand for standalone TAF is irrelevant because TAF *cannot* be sold as a standalone product as a matter of law. That is, far from possessing appreciable economic power in the market for standalone TAF, Gilead lacks *any* power to sell standalone TAF until the FDA approves Gilead's NDA for that drug, which required Gilead to undertake additional clinical testing and research.

The only decision to evaluate a tying arrangement involving a product that could not be sold legally is in accord. In *General Cigar Holdings, Inc. v. Altadis, S.A.*, 205 F. Supp. 2d 1335, 1355–56 (S.D. Fla. 2002) (Judge Frederico A. Moreno), the plaintiff challenged the defendant's efforts to leverage the promise of future sales of Cuban cigars (contingent on their becoming legal for sale in the United States) to force consumers to purchase the defendant's non-Cuban cigars. Because the ability to actually *sell* the alleged tying product was conditioned on the speculative possibility that the United States would lift the embargo on Cuban cigars, plaintiff could not state a claim for tying. So too here.

Whether or not there existed demand for a standalone TAF, that demand could not be met until the FDA approved it for sale. True, Gilead elected not to seek approval of TAF until several months after it released the first combination drug containing TAF, but it had no duty to pursue FDA approval of the standalone version. To hold otherwise would require manufacturers to seek approval of each component of the drug before seeking approval of the combination drug. This could entirely undermine the FDA's policy of encouraging the development of combination drugs. *See* Food and Drug Administration, *New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products*, GUIDANCE FOR INDUSTRY (October 2014) (Dkt. No. 81-2 at 2).

At all relevant times, the FDA has prohibited the sale of TAF as a standalone product. As such, AIDS Healthcare has failed to plead the existence of a market for a tying product in AIDS Healthcare's tying claim and Gilead's market power therein. Thus AIDS Healthcare's fourth claim must be **DISMISSED**.

AIDS Healthcare may not seek leave to amend its tying claim, inasmuch as it cannot plead around the defect that no market for the tying product exists.

B. Monopolization.

AIDS Healthcare also claims that Gilead engaged in monopolization in violation of Section 2 of the Sherman Antitrust Act. "There are three essential elements to a successful claim of Section 2 monopolization: (a) the possession of monopoly power in the relevant market; (b) the willful acquisition or maintenance of that power; and (c) causal 'antitrust' injury." *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp., LP*, 592 F.3d 991, 998 (9th Cir. 2010).

In its amended complaint, AIDS Healthcare alleges that Gilead improperly bundled TAF with the other ingredients in Genvoya, Descovy, and Odefsey as a means of maintaining its dominance in the TAF market. Specifically, it alleges that by bundling TAF with the other ingredients, it insulated the allegedly weak patents covering TAF from challenges, because any generic manufacturer seeking to produce a TAF product would need to invalidate all the patents listed in the Orange Book for those drugs before it could win FDA approval, rather than just the TAF patents.

In opposing Gilead's motion to dismiss, AIDS Healthcare entirely abandons this theory under Section 2, asserting it instead as a claim under California's Unfair Competition Law. Nevertheless, this order addresses the defects in AIDS Healthcare's Section 2 claim as pled.

First, AIDS Healthcare's Section 2 claim relies on the premise that Gilead possesses monopoly power over TAF-containing drugs. Nowhere in the complaint does AIDS Healthcare allege facts supporting a market definition limited to TAF-containing drugs. This failure to plead a market definition is fatal.

Second, AIDS Healthcare fails to allege any anticompetitive conduct on the part of Gilead. Gilead elected to release TAF as part of a combination drug before seeking approval for TAF as a standalone. "As a general rule, any firm, even a monopolist . . . may bring its products to market whenever and however it chooses." *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983). There is no legal basis for concluding that

Gilead had a *duty* to release TAF as a standalone product. *See Allied Orthopedic*, 592 F.3d at 1002 ("[A] monopolist has no duty to help its competitors survive or expand when introducing an improved product design.").

Third, AIDS Healthcare acknowledged in its brief on this motion that Gilead has already sought FDA approval of standalone TAF, which is expected to be granted by November 2016. Thus, no anticompetitive effect can result because Gilead has already taken steps to expose the alleged vulnerabilities of the patents protecting TAF several years before its NCE exclusivity will expire and the first possible generic TAF products can enter the market.

Fourth, any competitor seeking to market TAF in a new product after expiration of the NCE exclusivity period could file a Section 505(b)(2) application for such a new product. The application would require the competitor to conduct its own clinical trials about the differences between its product and the already-approved combination drug, but a change in formulation could enable the competitor to isolate the TAF patents (by certifying that any other patents are not infringed because the ingredients simply aren't present), thus defeating AIDS Healthcare's "insulation" theory.

In its brief, AIDS Healthcare pivots to a new theory that Gilead used its monopoly in TAF to monopolize an "aftermarket" for drugs used in combination with TAF, although that theory is not pled as the basis for its Section 2 claim. As argued, this theory fails for the same reason AIDS Healthcare's tying claim fails. There is no "foremarket" for TAF — it is *only* sold as one of several ingredients in the combination drugs Genvoya, Odefsey, and Descovy, and it is not yet approved for sale on its own. Accordingly, AIDS Healthcare's Section 2 claim must be **DISMISSED**.

AIDS Healthcare may seek leave to amend its monopolization claim to more clearly state the theory it intends to pursue.

C. Conspiracy.

AIDS Healthcare also claims that defendants conspired to commit the alleged monopolization already discussed in violation of Section 1 of the Sherman Antitrust Act. AIDS Healthcare does not address its conspiracy claim in its opposition brief at all. In any case, the

conspiracy claim fails for the same reason the monopolization claim fails. AIDS Healthcare may seek leave to amend this claim.

3. CARTWRIGHT ACT AND NEVADA CLAIMS.

AIDS Healthcare's claims under California's Cartwright Act and Nevada's Unfair Trade Practices Act mirror its claims under the Sherman Act. *See Dimidowich v. Bell & Howell*, 803 F.2d 1473, 1477 (9th Cir. 1986) (California); *Boulware v. State of Nevada Dep't of Human Res.*, 960 F.2d 793, 800 (9th Cir. 1992) (Nevada). The primary difference is that neither state law statute limits claims by indirect buyers to the exceptions set forth in *Illinois Brick v. Illinois*, 431 U.S. 720 (1977), and its progeny. Just as AIDS Healthcare's Sherman Act claims fail, so too do its claims under the Cartwright Act and the Nevada Unfair Trade Practices Act.

4. UCL CLAIMS.

California's Unfair Competition Law prohibits "unlawful, unfair, or fraudulent business act[s] or practices." Cal. Bus. & Prof. Code § 17200. "When determining whether a practice is 'unlawful,' section 17200 'borrows' violations of other laws . . . ." *AICCO, Inc. v. Ins. Co. of N. Am.*, 90 Cal. App. 4th 579, 587 (2001). Here, AIDS Healthcare seeks to "borrow" the violations asserted in its antitrust claims addressed above. As stated, those claims fail. Thus, AIDS Healthcare cannot state a claim under the unlawful prong.

AIDS Healthcare also asserts two theories under the "unfair" prong of the UCL. It first contends that defendants conspired to game the FDA system to insulate TAF from patent challenges by combining it with additional patented ingredients. This theory has already been rejected as a basis for a Section 2 claim, in part because Gilead had no duty to release a standalone TAF product. In *Chavez v. Whirlpool Corp.*, 93 Cal. App. 4th 363, 375 (2001), the California Court of Appeal held that conduct that is "deemed reasonable and condoned under the antitrust laws" could not support a claim under the unfair prong of the UCL. "To permit a separate inquiry into essentially the same question under the unfair competition law would only invite conflict and uncertainty and could lead to the enjoining of procompetitive conduct." *Ibid.* Thus, AIDS Healthcare's insulation theory cannot support its UCL claim.

AIDS Healthcare's second theory (which appears only in its brief, not in its complaint) fares no better. AIDS Healthcare contends that Gilead knew of the efficacy and safety benefits of TAF in 2004 but shelved its clinical trials until 2011, leading to FDA approval (and a grant of NCE exclusivity) in 2015, just before the patents on TDF were set to expire.

This, AIDS Healthcare contends, delayed the expiration date of Gilead's NCE exclusivity and thus delayed the moment that competitors would seek to challenge Gilead's patents on TAF. Further, it left consumers to bear the higher bone and kidney toxicity of TDF longer than necessary.

AIDS Healthcare fails to explain how this "delay" constituted *unfair competition*. Gilead's patents gave it a monopoly over both TDF and TAF. It had no obligation to introduce the improved product at an earlier date. Any competitor could have beaten Gilead to market (and thus NCE exclusivity). "Without more, it is not unlawful [under antitrust law] for any competitor in any market to delay the introduction of a new product or an entire line of new products until, as [the plaintiff] alleged in this case, the competition forces such introduction." *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983). Under *Chavez*, AIDS Healthcare cannot recast its claim that Gilead unreasonably restrained competition by allegedly delaying the release of TAF as a claim under the unfair prong of the UCL.

Accordingly, AIDS Healthcare's UCL claim must be **DISMISSED**. AIDS Healthcare may seek leave to amend this claim.

CONCLUSION

For the reasons stated above, all three defendants' motions to dismiss are **GRANTED**.

AIDS Healthcare may seek leave to amend its monopolization, conspiracy, and state law claims within **FOURTEEN CALENDAR DAYS** of this order with a formal motion noticed on the standard 35-day calendar. The motion must affirmatively identify how the proposed amendments cure the defects identified above. AIDS Healthcare should plead its best case, and it should address all defects identified in defendants' motions, not just those addressed herein. It should also specifically plead the theories it raised for the first time in its opposition to the instant motion. Theories raised for the first time in a brief will not be considered.

Both sides requested judicial notice of various documents reflecting FDA policy, financial disclosures of the parties, publications discussing tenofovir, and the patents-in-suit. To the extent not referred to above, the cited documents were not necessary to this order. Accordingly, the parties' requests for judicial notice are **DENIED AS MOOT**.

IT IS SO ORDERED.

Dated: July 6, 2016.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE