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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION,  
INC.,

No. C 16-00443 WHA

Plaintiff,

v.

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

**ORDER GRANTING  
MOTIONS TO DISMISS**

Defendants.

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**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

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

3 **1. FDA REGULATORY REGIME.**

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

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

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

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

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

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

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

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

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

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

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

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

15 **2. DEVELOPMENT OF TENOFOVIR THERAPIES.**

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

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

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

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

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

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

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

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

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

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 28 <sup>1</sup> 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.

1 In the first quarter of 2016, Gilead applied for FDA approval of a standalone version of  
2 TAF for use in treating hepatitis B virus. It expects the application to be approved in  
3 November.<sup>2</sup>

4 \* \* \*

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

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

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

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26 <sup>2</sup> The fact that Gilead began developing standalone TAF does not appear in the complaint, but AIDS  
27 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).

28 <sup>3</sup> 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.

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

7 **ANALYSIS**

8 **1. DECLARATORY JUDGMENT OF PATENT INVALIDITY.**

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

<u>PATENT</u>	<u>PATENT OWNER</u>
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

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

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

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

7 AIDS Healthcare contends that this dispute is sufficiently real and immediate because it  
8 sought to encourage generic manufacturers to develop products that contain TAF, but none has  
9 responded. AIDS Healthcare presumes that no manufacturers have taken up that effort because  
10 TAF is protected by the above-identified patents. This ignores the fact that TAF is also  
11 protected by Gilead’s NCE exclusivity, which bars the FDA from receiving any application for  
12 a drug containing TAF until November 2019 and from approving that drug until November  
13 2020.

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

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

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

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

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

1 *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81  
2 N.Y.U. L. REV. 1553, 1579 (2006).<sup>4</sup>

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

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

20 Here, although AIDS Healthcare has encouraged manufacturers to make infringing  
21 products, and it has made preparations to encourage the use of such products, the infringing  
22 nature of that activity remains dependent on the resolution of the uncertainty identified in  
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28 <sup>4</sup> 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.

1 *Sandoz* and *Benitec*, since, as stated, no manufacturer can even apply for FDA approval of an  
2 infringing product until 2019. Under the Federal Circuit’s rule, that is insufficient.<sup>5</sup>

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

6 **2. SHERMAN ACT CLAIMS.**

7 **A. Tying.**

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

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

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27 <sup>5</sup> AIDS Healthcare could have pursued its anticipation and obviousness theories (but not its subject  
28 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).

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

8           The only decision to evaluate a tying arrangement involving a product that could not be  
9 sold legally is in accord. In *General Cigar Holdings, Inc. v. Altadis, S.A.*, 205 F. Supp. 2d  
10 1335, 1355–56 (S.D. Fla. 2002) (Judge Frederico A. Moreno), the plaintiff challenged the  
11 defendant’s efforts to leverage the promise of future sales of Cuban cigars (contingent on their  
12 becoming legal for sale in the United States) to force consumers to purchase the defendant’s  
13 non-Cuban cigars. Because the ability to actually *sell* the alleged tying product was conditioned  
14 on the speculative possibility that the United States would lift the embargo on Cuban cigars,  
15 plaintiff could not state a claim for tying. So too here.

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

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

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

3 **B. Monopolization.**

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

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

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

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

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

1 Gilead had a *duty* to release TAF as a standalone product. *See Allied Orthopedic*, 592 F.3d at  
2 1002 (“[A] monopolist has no duty to help its competitors survive or expand when introducing  
3 an improved product design.”).

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

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

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

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

### 25 **C. Conspiracy.**

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

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

3 **3. CARTWRIGHT ACT AND NEVADA CLAIMS.**

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

11 **4. UCL CLAIMS.**

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

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

28

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

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

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

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

## 21 CONCLUSION

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


23 AIDS Healthcare may seek leave to amend its monopolization, conspiracy, and state law  
24 claims within **FOURTEEN CALENDAR DAYS** of this order with a formal motion noticed on the  
25 standard 35-day calendar. The motion must affirmatively identify how the proposed  
26 amendments cure the defects identified above. AIDS Healthcare should plead its best case, and  
27 it should address all defects identified in defendants’ motions, not just those addressed herein.  
28 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.

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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.

  
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WILLIAM ALSUP  
UNITED STATES DISTRICT JUDGE