App. 1

United States Court of Appeals for the Federal Circuit

AIDS HEALTHCARE FOUNDATION, INC.,
Plaintiff-Appellant

v.

GILEAD SCIENCES, INC., JAPAN TOBACCO INC.,
Defendants-Appellees

JOHNSON & JOHNSON, JANSSEN – SCIENCES IRELAND UC,
Defendants

No. 2016-2475

Appeal from the United States District Court for the Northern District of California in No. 3:16-cv-00443-WHA, Judge William H. Alsup.

Decided: May 11, 2018.

DANIEL P. HIPSKIND, Berger & Hipskind LLP, Los Angeles, CA, argued for plaintiff-appellant. Also represented by DORIAN S. BERGER.

GARY N. FRISCHLING, Irell & Manella LLP, Los Angeles, CA, argued for defendants-appellees. Gilead Sciences, Inc. also represented by JOHN PRESTON LONG, YITE JOHN LU, KEITH A. ORSO, JASON SHEASBY.

JEROME WAYNE HOFFMAN, Holland & Knight, LLP, Jacksonville, FL, for defendant-appellee Japan Tobacco Inc. Also represented by NEAL N. BEATON, New York, NY; BRUCE C. HAAS, CHRISTOPHER EARL LOH, Fitzpatrick, Cella, Harper & Scinto, New York, NY.

Before NEWMAN, DYK, and STOLL, *Circuit Judges.*

NEWMAN, *Circuit Judge*.

This appeal is from the dismissal of a declaratory judgment action filed by AIDS Healthcare Foundation, Inc. ("Healthcare" or "AHF") against Gilead Sciences, Inc. *et al.* ("Defendants") in the United States District Court for the Northern District of California.[1] On appellate review, we conclude that this action does not meet the requirements of the Declaratory Judgment Act.

BACKGROUND

The Defendants produce or sell several drug products containing the antiviral agent tenofovir alafenamide fumarate ("TAF"), which is used in the treatment of AIDS. The first TAF-containing drug product, brand name Genvoya®, received FDA approval in November 2015 and is a combination drug product containing TAF and other specified antiviral agents. Dist. Ct. Op. at *3. In 2016, the FDA approved two

[1] *AIDS Healthcare Found. v. Gilead Scis., Inc.*, No. C 16-00443 WHA, 2016 WL 3648623 (N.D. Cal. July 6, 2016) ("Dist. Ct. Op.").

additional TAF-containing combination products—Descovy® and Odefesey®—each of which contains at least one other antiviral agent. *Id.* The Defendants have patents or are licensees of patents on TAF and its combination products.

Healthcare provides medical care to persons afflicted with AIDS, including providing antiviral drugs such as the TAF products that Healthcare buys from the Defendants. *Id.* Healthcare filed this suit requesting declarations of invalidity for five patents purportedly covering TAF and various combination products. Healthcare told the district court that it brought this declaratory action in order to "clear out the invalid patents" so that it "would have the ability then to partner with generic makers and purchase generic TAF as soon as it could become available" on expiration of the five-year New Chemical Entity exclusivity set forth in 21 U.S.C. § 355(j)(5)(F)(ii). Tr. of Hr'g at 17:10–13, June 23, 2016, ECF No. 102; Dist. Ct. Op. at *4–5.

Healthcare argued that in view of the lengthy time consumed by litigating patent validity, such litigation needed to start well in advance of expiration of the five-year exclusivity period. *See, e.g.*, AHF Br. 5; Dist. Ct. Op. at *4–5. Healthcare filed this declaratory action in January 2016, two months after the FDA approved Genvoya®—the first TAF-containing product to receive FDA approval. The other TAF products were still undergoing clinical trials and FDA approval procedures. It is undisputed that no unlicensed source was offering a TAF product or preparing to do so when this declaratory action was filed.

The district court asked Healthcare to clarify its role with respect to TAF products:

> Court: But the Healthcare, AIDS Healthcare is not going to be manufacturing anything? Or will you even be buying anything?
>
> Counsel: We would be purchasing it. . . .
>
> Court: So AIDS Healthcare Foundation is a consumer?
>
> Counsel: It is a consumer. . . .

Tr. of Hr'g at 16:13–24, June 23, 2016, ECF No. 102. Healthcare told the district court that it "had reached out to a number of generic makers" but that "none of the generic makers wanted to enter the market because there was the fear of liability because of these patents." *Id.* at 17:3–10.

The district court ruled that Healthcare's actions in encouraging others to produce generic TAF products in the future, and Healthcare's interest in purchasing such products, did not create a case of actual controversy in terms of the Declaratory Judgment Act. Dist. Ct. Op. at *5–6. Healthcare appeals, arguing that there are several grounds on which it meets the declaratory judgment criteria, and that the district court erred in dismissing this action.

DISCUSSION

Exercise of the Constitution's judicial power is limited to actual cases and immediate controversies. *Muskrat v. United States*, 219 U.S. 346, 356 (1911). When this constitutional requirement is not met, a court has no authority to decide the issues presented, whatever the "convenience and efficiency" of such judicial action. *Hollingsworth v. Perry*, 133 S. Ct. 2652, 2661 (2013) (quoting *Raines v. Byrd*, 521 U.S. 811, 820 (1997)); *see Muskrat*, 219 U.S. at 356 ("[U]nless [the exercise of the judicial power] is asserted in a case or controversy within the meaning of the Constitution, the power to exercise it is nowhere conferred."). The Declaratory Judgment Act conforms to these principles, providing:

> In a case of actual controversy within its jurisdiction, except . . . , any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201(a).

A plaintiff seeking a declaratory judgment bears the burden of demonstrating that a case of actual controversy existed at the time the declaratory action was filed. *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 (Fed. Cir. 2012). That requires a

showing of injury-in-fact, connection between the challenged conduct and the injury, and redressability by the requested remedy. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103–04 (1998).

The existence of a patent, without more, does not create a case of actual controversy. *See Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) ("[J]urisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007))).

Healthcare presents several additional arguments for declaratory jurisdiction, including that (1) Healthcare is an indirect infringer of the TAF patents based on its requests to potential producers to provide the patented products; (2) Gilead's non-response to Healthcare's request for a covenant not to sue created a present controversy; and (3) public policy favors invalidation of invalid patents and thus the testing of "weak" patents. The district court, receiving all of Healthcare's arguments, correctly held that the declaratory judgment criteria were not met.

A

The declaratory requirement of immediacy and reality is not met by litigation delay

The foundation of a declaratory action is 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." *MedImmune Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). "The immediacy requirement is concerned with whether there is an immediate impact on the plaintiff and whether the lapse of time creates uncertainty." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014).

Healthcare argues that it meets this requirement because of the lengthy time required for patent litigation, such that an immediate start is needed. However, the time consumed by litigation of a speculative future controversy does not provide the "immediacy and reality" required for declaratory judgment actions; nor is a declaratory tribunal precluded from providing expedited relief when such is warranted. In this case, where there is no present infringement, no threat of or possibility of infringement litigation, and no meaningful preparation to infringe, the "immediacy and reality" criteria are not met. *See, e.g.*, *Prasco*, 537 F.3d at 1338–39.

The *Sandoz* court summarized the application of the law: "We have assessed 'immediacy' by considering

how far in the future the 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, at the time of suit, that an adjudication might redress." 773 F.3d at 1278. In *Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008), the court elaborated that "the issue of whether there has been meaningful preparation to conduct potentially infringing activity remains an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate," citing *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007), for the principle that "*MedImmune* requires that a court look at 'all the circumstances' to determine whether a justiciable Article III controversy exists." For "[i]f a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither 'immediate' nor 'real' and the requirements for justiciability have not been met." *Cat Tech*, 528 F.3d at 880. Thus "meaningful preparation to conduct potentially infringing activity" is "an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate." *Prasco*, 537 F.3d at 1336 n.4 (quoting *Cat Tech*, 528 F.3d at 880). Here, however, there was no showing or representation of such "meaningful preparation."

The district court observed the absence of evidence of preparation to produce a product covered by any of the TAF patents, and found "significant uncertainty

about the nature of any hypothetical product." Dist. Ct. Op. at *5. The uncertainty of whether future infringement might occur at all weighs against the immediacy and reality requirement of declaratory action. *Matthews*, 695 F.3d at 1328–29. In addition, precedent illustrates that the mere possibility of future infringement does not meet the immediacy and reality criteria, for "[a] party may not obtain a declaratory judgment merely because it would like an advisory opinion," *id.* at 1329 (quoting *Cat Tech*, 528 F.3d at 881). For example, in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1349 (Fed. Cir. 2007), this court held that a representation that the declaratory plaintiff "expects to begin work shortly" on "potentially infringing" activities was of insufficient immediacy to support a declaratory action.

The district court concluded that Healthcare's role as an encourager of others to provide infringing product in the future, and its role as a future purchaser of such product, fell short of the declaratory judgment requirements of immediacy and reality. Dist. Ct. Op. at *6. We note that the Hatch-Waxman statute created an artificial act of infringement by the filing of a certain abbreviated new drug application ("ANDA"); this is an explicit statutory basis for litigation before actual infringement occurs. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760–62 (Fed. Cir. 2016). Here, it is undisputed that no potential generic producer had filed an ANDA for any TAF-containing products at the initiation of this action, for TAF's New Chemical Entity period of exclusivity forecloses such a

filing until November 2019; nor is there any other basis for declaratory judgment jurisdiction. The district court correctly concluded that Healthcare, "in its current posture, cannot invoke any statutory relaxation of otherwise-applicable immediacy and reality requirements," *Sandoz*, 773 F.3d at 1281, and Healthcare has not otherwise shown that there is a controversy of sufficient immediacy and reality to create declaratory judgment jurisdiction.

B

Liability for inducing infringement requires that there be direct infringement

Healthcare argues that it is incurring present liability for inducing infringement, 35 U.S.C. § 271(b), by its attempts to persuade possible manufacturers to provide generic TAF products after the five-year New Chemical Entity period of exclusivity. Healthcare refers to its "public statements soliciting unlicensed production of TAF," AHF Br. 5, and its "request[s] to place orders with pharmaceutical manufacturers" for the patented TAF products. AHF Br. 13.

Liability for induced infringement requires that some other entity is directly infringing the patent. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016). Jurisdiction for a declaratory action premised on an inducement theory does not arise in the absence of "concrete steps [that] have been taken with the intent to conduct activity which could constitute infringement." *Fina*

Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1485 (Fed. Cir. 1998).

The district court was told that Healthcare's requests for generic production of TAF-containing drug products elicited no response from the solicited pharmaceutical manufacturers. Dist. Ct. Op. at *3; *see* Tr. of Hr'g at 18:3–11, June 23, 2016, ECF No. 102 (stating that no manufacturer responded to Healthcare's requests). There was no evidence or allegation that Healthcare's requests had induced potentially infringing activity.

The district court also considered Healthcare's role as a purchaser of TAF drugs. Dist. Ct. Op. at *5. "Such an economic interest alone, however, cannot form the basis of an 'actual controversy' under the Declaratory Judgment Act." *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1316 (Fed. Cir. 2011) (quoting *Microchip Tech. Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006)). The district court reached the correct conclusion, for as discussed *post*, a potential customer's interest in buying infringing product does not create present liability for induced infringement. *See Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1374–75 (Fed. Cir. 2011) ("In the absence of a controversy as to a legal right, a mere adverse *economic* interest is insufficient to create declaratory judgment jurisdiction.").

Healthcare also argues that its present actions "create liability for indirect infringement the moment an ANDA is filed." AHF Reply Br. 6. This theory of

possible future liability does not achieve the immediacy and reality required by the Declaratory Judgment Act.

The district court correctly held that declaratory standing did not arise on the theory of induced or indirect infringement.

C

An interest in buying infringing product is not an adverse legal interest for declaratory jurisdiction

Healthcare argues that its legal interests are adverse to the Defendants, thereby creating a present controversy subject to declaratory action. However, a general interest in a patented product, without foundation in actual case-or-controversy, does not create declaratory standing. Litigation-supportive adverse legal interests exist where there is "a dispute as to a legal right, such as an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring, if not for the fact that the declaratory plaintiff had preempted it." *Creative Compounds*, 651 F.3d at 1316; *see also AbbVie Inc. v. MedImmune Ltd.*, 881 F.3d 1334, 1336 (Fed. Cir. 2018) ("As a general principle, federal courts, when determining declaratory judgment jurisdiction, often look to the character of the threatened action that the declaratory-judgment defendant might have brought. In other words, courts examine declaratory actions, at least in part, by looking to the mirror image suit the declaratory defendant

might bring if and when it seeks coercive relief." (internal quotation marks and citations omitted)).

An adverse economic interest alone is insufficient. *Arris Grp.*, 639 F.3d at 1374; *see Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1296–97 (Fed. Cir. 2008) (explaining why "the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents" afforded jurisdiction to a generic manufacturer having an adverse economic interest). In response to the district court's inquiry, *see ante*, Healthcare verified that its sole interest was in buying cheaper product than was available from the Defendants.

The district court recognized that an actionable legal interest is not here present, for neither Healthcare nor any producer of TAF products is infringing or preparing to infringe any TAF patent. Precedent clearly counsels that an adverse economic interest is not of itself an adverse legal interest.

Healthcare argues that its risk of liability need not be absolute in order to establish an adverse legal interest sufficient to support declaratory standing, citing *Fina Research*, 141 F.3d at 1480, and *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003). These cases do not support Healthcare's argument.

In *Fina Research*, the declaratory plaintiff was a foreign entity that was manufacturing and selling an ingredient of drilling mud abroad; the holder of United States patents on compositions containing the drilling

mud had sent letters to the foreign producer, stating that the patentee would sue for infringement if the ingredient were introduced in the United States. The court held that such a direct threat of suit against an existing product and its producer established declaratory jurisdiction. *Fina Research*, 141 F.3d at 1482–84; *see also SanDisk*, 480 F.3d at 1382 (describing how the presentation of "a thorough infringement analysis" and "element-by-element" product analyses created a case or controversy supporting declaratory judgment jurisdiction). In contrast, here the record does not refer to threats of litigation on importation of existing product, or even an identification of any product whose importation may violate Gilead's patent rights. No such TAF-containing products are reported to exist.

In *Allergan*, the court considered whether a Hatch-Waxman proceeding was available on the filing of an ANDA directed to an unpatented product and use; the court held that a Hatch-Waxman action can be for induced infringement, and considered whether possible inducement of an infringing use that has not received FDA approval provided Hatch-Waxman jurisdiction. 324 F.3d at 1331–32. The unique facts of *Allergan* do not support the declaratory jurisdiction here requested by Healthcare.

Precedent illustrates the variety of circumstances in which declaratory jurisdiction has been considered, but no precedent supports Healthcare's position. The district court correctly held that Healthcare did not meet the criteria of declaratory judgment standing.

D

The absence of a covenant not to sue does not create a declaratory controversy

Healthcare argues that the Defendants did not agree to grant a covenant not to sue, and that since Gilead is known to protect its patent rights, the withholding of a covenant not to sue supports declaratory jurisdiction.

However, the absence of a covenant not to sue infringers did not create a justiciable case or controversy. Under the circumstances here, there was no affirmative act by the patentee to assert patent rights against Healthcare for any present or planned activity. *See generally BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993) (confirming the relevance of "a patentee's refusal to give assurances that it will not enforce its patent"); *see also SanDisk*, 480 F.3d at 1380–81 ("[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, *without some affirmative act by the patentee.*" (emphasis added)). The Defendants also point out that the covenant not to sue was not requested by Healthcare until after this suit was filed, and thus this aspect was not among the circumstances at the time of filing. Tr. of Hr'g at 18:11–24, June 23, 2016, ECF No. 102.

The absence of a covenant not to sue did not create a case-or-controversy between the Defendants and

Healthcare. *See Prasco*, 537 F.3d at 1341 ("[T]hough a defendant's failure to sign a covenant not to sue is one circumstance to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy—some affirmative actions by the defendant will also generally be necessary.") The absence of a covenant not to sue, even had it been timely requested and denied, does not here shift the balance to create a controversy of the immediacy and reality needed to support declaratory jurisdiction.

E

Policy aspects involve considerations in addition to declaratory principles

Healthcare argues that public policy is served by invalidation of invalid patents, and thus supports immediate challenge to the "weak" TAF patents. Yet the Hatch-Waxman Act is already a balance of several policy interests, seeking to preserve the patent incentive to invent new drugs, while enabling validity challenge by ANDA filers before actual infringement occurs. *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

The present policy reflects a balance of several factors and public interests; any policy change would require re-exploration of all aspects. Healthcare's proposal of a change in policy to facilitate challenge to drug patents would warrant legislative consideration, not departure from precedent. *SAS Inst., Inc. v. Iancu*,

138 S. Ct. 1348, 1358 (2018) ("Policy arguments are properly addressed to Congress, not this Court.")

CONCLUSION

The district court correctly held that Healthcare had not established a case of actual controversy within the meaning of the Constitution and the Declaratory Judgment Act. The dismissal of Healthcare's declaratory action is affirmed.

AFFIRMED

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

(Filed Jul. 6, 2016)

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

[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.

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.

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

[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).

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 of the Cartwright Act, (6) violations of the

[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.

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 [sic] 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,

[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.

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 *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]

---

[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

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).

---

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).

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).

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 /s/ William Alsup
WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE