

**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

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 & Hipkind 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 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.

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.”).

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 Judg-

ment Act. The dismissal of Healthcare's declaratory action is affirmed.

AFFIRMED