No. _____

In The

Supreme Court of the United States

AIDS HEALTHCARE FOUNDATION, INC.,

Petitioner,

v.

GILEAD SCIENCES, INC. and JAPAN TOBACCO INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Many patients with HIV depend on lifesaving, low-cost drugs provided by Petitioner AIDS Healthcare Foundation, Inc. ("AHF"), a non-profit organization. Respondent Gilead Sciences, Inc. has patented HIV drugs including Tenofovir Alafenamide ("TAF"). In addition to its patents on TAF, Gilead also obtained five years of exclusivity for drugs containing TAF from the U.S. Food and Drug Administration ("FDA"). During this five-year exclusivity period, AHF and its generic drug suppliers are prevented from filing an application with the FDA for approval of generic TAF. AHF seeks to introduce generic TAF to its patients as soon as possible (once Gilead's exclusivity period runs out) but is prevented from doing so by Gilead's patents on TAF. AHF filed a declaratory judgment action alleging invalidity of the patents, but the lower courts found that AHF lacked jurisdiction. This case presents the following question:

In the context of patent cases involving pharmaceutical products, does the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a party seeking to introduce a generic drug product to file an application for FDA approval of that generic drug product before it can file suit for declaratory relief for patent invalidity?

PARTIES TO THE PROCEEDINGS

The petitioner is AIDS Healthcare Foundation, Inc. The respondents are Gilead Sciences, Inc. and Japan Tobacco, Inc.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner does not have any parent corporations, and no publicly held company owns 10 percent or more of the stock of petitioner.

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The opinion of the United States Court of Appeals for the Federal Circuit, App. at 1, is reported at 890 F.3d 986 (Fed. Cir. 2018). The District Court opinion granting defendant's/respondent's motion to dismiss, App. at 18, is reported at 2016 U.S. Dist. LEXIS 87578 (C.D. Cal. July 6, 2016).

JURISDICTIONAL STATEMENT

The Court of Appeals decision in this case was issued on May 11, 2018. This petition is thus timely. Jurisdiction is conferred by 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

Article III of the Constitution of the United States provides in relevant part:

> SECTION 2. The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States. . . .

28 U.S.C. § 1331 provides:

> The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

28 U.S.C. § 1338(a) provides:

> The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights. . . .

28 U.S.C. § 2201(a) provides:

> (a) In a case of actual controversy within its jurisdiction, . . . 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.

STATEMENT OF THE CASE

This case challenges the lower courts' treatment of this Court's decision in *MedImmune Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). In contrast to the flexible, case-by-case test established by this Court in *MedImmune*, the District Court found that Federal Circuit jurisprudence requires a would-be competitor in the pharmaceutical field to wait until it files an application with the FDA for approval of its competing drug

product before it can maintain a suit seeking a declaratory judgment of patent invalidity.

Petitioner AIDS Healthcare Foundation ("AHF") is the largest non-profit provider of HIV and AIDS medical care in the United States and one of the largest purchasers of drugs used to treat HIV and AIDS. AHF provides large-scale HIV counseling and testing services, early intervention services, HIV medical care, research on HIV care and treatment, medical case management, pharmacy services, referrals, and innovative client retention protocols. It operates 46 Healthcare Centers in the United States spread throughout 14 states and the District of Columbia. Worldwide, AHF has more than 938,000 patients and clients.

Respondents Gilead Sciences, Inc. and Japan Tobacco Inc. own patents related to a lifesaving HIV drug, Tenofovir Alafenamide ("TAF").[1] The first TAF-containing product, Genvoya, was released by Gilead in November 2015. App. at 24. TAF itself is not a new compound; it is a prodrug of the compound Tenofovir, which was synthesized over 30 years ago. C.A.A. at 856. TAF is also not the first prodrug of Tenofovir. Several years before Respondents patented TAF, Gilead patented a similar prodrug called Tenofovir Disoproxil Fumarate ("TDF"). App. at 23. Despite similarities between TAF and TDF, TAF is a superior prodrug

[1] The patents covering TAF are U.S. Patent Nos. 7,390,791 (owned by Gilead); 7,800,788 (owned by Gilead); 8,754,065 (owned by Gilead); 8,148,374 (owned by Gilead); and 8,633,219 (owned by Japan Tobacco). C.A.A. at 7.

formulation of Tenofovir because a smaller dose can be utilized for the same therapeutic effect, thus reducing bone and kidney toxicity. *Id.* Despite the clinical superiority of TAF, AHF maintains that each of the TAF patents are invalid in light of the minor and obvious change in the Tenofovir prodrug.

A. FACTUAL BACKGROUND.

Tenofovir was discovered in 1984 by scientists in Czechoslovakia. C.A.A. at 857. In its original formulation, Tenofovir had to be administered intravenously, dramatically limiting its sales potential. App. at 23. In 1997, Gilead bought rights to sell Tenofovir and modified the chemical composition so it could be taken orally. *Id.* That modified chemical composition is TDF, which the FDA approved in 2001 and is marketed under the brand name Viread. C.A.A. at 857. TDF became the backbone of many HIV treatment regimens. From the outset, studies showed that TDF could cause significant kidney damage and bone toxicity. App. at 23. The toxicity of TDF was alarming because HIV-infected patients would likely receive treatment for decades, meaning the toxicity would continue to increase over time. The FDA took notice of the toxicity of TDF and required Gilead to study whether TDF was harmful. C.A.A. 1454-55. The FDA repeatedly warned Gilead about its sales tactics regarding TDF. For example, in 2002, the FDA said that Gilead salespeople had falsely stated that TAF had "no toxicities," was "benign," and was "extremely safe." *Id.* at 1462. In 2003, the FDA required Gilead to retrain its sales

representatives about the side effects associated with TDF. *Id.* at 1470.

Around the time it was under assault for misrepresenting the toxicity of TDF, Gilead began researching a different chemical version of Tenofovir, TAF. Gilead began research studies on TAF in 2002, but it did not publish the results of those studies until 2011. App. at 23. Instead, Gilead publicly said it was discontinuing research on TAF compounds even as it filed seven patent applications in 2004 and 2005 related to using TAF to treat HIV. *Id.*

Gilead did not seek FDA approval for TAF until 2015, which was also the first time generic drug makers could legally introduce generic TDF. *Id.* at 24. Consequently, patients that might have been treated with TAF, which was known to be effective and less toxic as early as 2002, were forced to wait more than a decade so that Gilead could profit from its patent and regulatory monopoly first on TDF and then on TAF for as long as possible. Gilead waited until TDF was about to go off patent to seek FDA approval and New Chemical Entity exclusivity ("NCE exclusivity") for TAF. NCE exclusivity prevents anyone from filing for FDA approval of any TAF-containing product until late 2019. *Id.* at 25.

TDF became a key component in many HIV treatment regimens, where it was combined with other drugs. C.A.A. at 830-31. These combination drug treatments are known as Highly Active Antiretroviral Therapy ("HAART"). HAART is aimed at reducing a

patient's viral load to maintain a patient's immune system. HAART regimens generally consist of three drugs: two drugs from the class of drugs known as Nucleoside Reverse Transcriptase Inhibitors ("NRTIs") and one drug from classes of drugs known as Non-Nucleoside Reverse Transcriptase Inhibitors ("NNRTI"), Protease Inhibitors ("PI"), or Integrase Nuclear Strand Transfer Inhibitors ("INSTI"). Tenofovir is an NRTI. Physicians regularly substitute different drugs in these categories to tailor treatment to particular conditions and symptoms exhibited by patients.

Notably, even after Gilead made TAF available, it did not release it as a standalone product (unlike TDF, which Gilead released both as a standalone product and as part of various combination drugs). C.A.A. 858. Instead, Gilead entered into licensing agreements with Japan Tobacco and others to sell fixed-dose combination therapies that enjoy the patent protections of not only the weak TAF patents, but also patents that cover the other pharmaceutical compounds in these combination drugs. *Id.* AHF's inability to obtain TAF on its own prevented AHF physicians from tailoring specific HAART therapies with TAF to its patients.

AHF wants to introduce lower-cost, generic versions of TAF to its patients as soon as possible because the prodrug is less toxic to patients than TDF. Respondents' patents stand in the way. Consequently, AHF sought to challenge the validity of Respondents' TAF patents. However, the FDA granted TAF a five-year New Chemical Entity ("NCE") exclusivity, which means that AHF and generic drug makers are barred

by statute from submitting an Abbreviated New Drug Application ("ANDA") – traditionally the mechanism used to trigger a declaratory judgment action because it constitutes a statutorily created "artificial infringement" – until November 2019.

Because neither AHF nor its generic drug partners can file an ANDA, AHF undertook a number of steps to speed the introduction of generic TAF, culminating in its filing of a declaratory judgment action against Respondents. Those steps included: (1) requesting to place orders with pharmaceutical manufacturers to make a standalone TAF product (App. at 25); (2) requesting from Gilead a covenant not to sue AHF relating to its activities directed to bringing generic TAF to market (*Id.* at 26); (3) providing written notice to Teva North America, Autobindo Pharma USA, Lupin Pharmaceuticals, and Sandoz, that AHF is "ready and able to distribute a generic version of TAF as a standalone compound (that would be used in a combination HIV treatment regime) or a generic tablet containing TAF" (C.A.A. at 841); (4) conducting an ongoing study of TAF in treating patients conducted by Otto Yang (Scientific Director for AHF), Michael Wohlfeiler (Chief of Medicine for AHF), and Robert Heglar (Deputy Chief of Medicine for AHF) (*Id.* at 845); (5) preparing clinicians and patients for treatments that incorporate generic TAF (*Id.* at 842); (6) educating the public, government agencies, hospitals, and advocacy organizations about generic TAF (*Id.*); (7) preparing for the distribution of HAART therapies incorporating generic TAF (*Id.*); (8) notifying Gilead in

writing that AHF intends "to manufacture, purchase, import and/or sell [TAF], which Gilead has claimed is subject to patents assigned and/or licensed to Gilead;" (*Id.* at 841) and (9) conducting analysis of potential combination therapies for HIV that incorporate TAF and drugs that are not part of Gilead's fixed-dose combination tablets (*Id.* at 843).

B. THE PRESENT ACTION AND DISTRICT COURT'S DECISION.

After undertaking actions to promote, purchase, and distribute generic TAF, on April 11, 2016, AHF filed a declaratory judgment action in the Northern District of California, invoking the Declaratory Judgment Act, 28 U.S.C. § 2201, and seeking declarations that Respondents' patents were invalid.[2] App. at 26. The District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

Respondents moved to dismiss the action, arguing that there was no justiciable controversy between the parties under Article III and the Declaratory Judgment Act. The District Court's decision said that the TAF patents "served as barriers to entry for any generic" and "[a]ccordingly, [AHF] curbed or forestalled investment in research, education, and preparation for

[2] AHF's complaint also sought relief for other alleged violations, including of the Sherman Act, the California Cartwright Act, and California and Nevada unfair trade practices law. Those issues are not before this Court.

the distribution of generic TAF products." App. at 26. The District Court explained that:

> [T]he 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.

Id. at 31.

The District Court also recognized the important policy goals that would be furthered by AHF's declaratory judgment action:

> 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.

Id. at 30-31.

Nonetheless, the District Court found AHF lacked Article III standing. The District Court explained:

> 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. . . . 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.

Id. at 30.

The District Court dismissed the case.

C. THE FEDERAL CIRCUIT'S DECISION.

The Federal Circuit (Newman, J., joined by Dyk and Stoll, JJ.) affirmed the dismissal, holding that "this action does not meet the requirements of the Declaratory Judgment Act." App. at 2. The Court of Appeals rejected AHF's argument that under this Court's decision in *MedImmune*, AHF has shown that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having:" (1) "adverse legal interests" that (2) are "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127 (citation omitted). The Court of Appeals explained:

> 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. 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 [AHF], "in its current posture, cannot invoke any statutory relaxation of otherwise-applicable immediacy and reality requirements. . . ."

Id. at 9 (internal citations omitted).

REASONS FOR GRANTING THE WRIT

The Federal Circuit's decision in this case adopts a *de facto* rule that a declaratory judgment action seeking to invalidate patents covering a pharmaceutical product covered by NCE exclusivity cannot occur until an ANDA is filed. The Appellate Court's reasoning effectively eliminates declaratory actions by parties during the NCE exclusivity period, even though no statute or court ruling requires such a rigid test. In fact, this Court's decisions counsel the opposite – that "the standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen v. Wright*, 468 U.S. 737, 752 (1984). The Appellate Court's decision gave only token consideration to the balancing of factors

approach endorsed by this Court in *MedImmune*, as well as the "irreducible constitutional minimum of standing," *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998). Instead, the Federal Circuit has adopted an inflexible declaratory judgment requirement (*i.e.*, filing an application for FDA approval) contrary to precedent.

Indeed, the Federal Circuit has repeatedly applied a similarly unbending approach to declaratory judgment actions relating to pharmaceutical products when FDA approval has not yet been sought. In *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007), the Federal Circuit said that the declaratory judgment plaintiff's

> activities of developing and submitting information to the FDA related to human application of RNAi does not present a case or controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction over the enforceability of the '099 patent. The fact that Nucleonics may file an NDA in a few years does not provide the immediacy and reality required for a declaratory judgment.

495 F.3d at 1348.

In *Sandoz, Inc. v. Amgen, Inc.*, 773 F.3d 1274 (Fed. Cir. 2014), the Federal Circuit explained, "we have found no justiciability where a declaratory-judgment plaintiff had not filed an application for the FDA approval required to engage in the arguably infringing activity." 773 F.3d at 1281.

The Federal Circuit's approach to declaratory judgment claims in the pharmaceutical industry results in the broad prohibition of declaratory judgment actions until FDA approval is sought (such as filing an ANDA). This rigid rule is squarely at odds with this Court's declaratory judgment standing decisions, as well as the "patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" *FTC v. Actavis, Inc.*, 570 U.S. 136, 151 (2013) (citation omitted). Indeed, "the 'public' also has a 'paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.'" *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 203 (2014) (citation omitted). The Federal Circuit's holding in this case harkens back to its outmoded "reasonable apprehension" test that *MedImmune* rejected. 549 U.S. at 132 n.11.

The Federal Circuit's improper approach to declaratory judgment suits filed before a generic manufacturer submits an application with the FDA for approval to market a generic pharmaceutical product also affects millions of Americans who rely on the speedy introduction of more affordable generic drugs for lifesaving treatments. Here, in an effort to obtain two separate windows of monopoly profits from the Tenofovir compound, Gilead waited until the twilight of its monopoly over TDF before introducing TAF. Now, patients are faced with the often-difficult choice of continuing to use an inferior product (TDF) with heightened risks of bone and kidney toxicity or pay far more for the superior TAF formulation. The Federal Circuit's

approach toward standing in the context of pharmaceuticals rewards this exact type of manipulation of patent filings and NCE exclusivity periods by allowing drug companies, such as Gilead, to delay market entry of safer or more effective drugs in an effort to extend monopoly pricing on earlier, inferior drugs and reduce generic competition.

As a result of the Federal Circuit's rigid rule, parties that wish to enter the market with a generic drug as soon as the drug companies' NCE exclusivity period ends cannot. As is the case here, even if a party is engaged in behavior that would confer declaratory judgment jurisdiction, the Federal Circuit's rule requires that party to wait to file a declaratory judgment action to invalidate patents covering a pharmaceutical compound until it has filed an application for FDA approval of a competing drug product, a process which cannot even begin to play out until the expiration of the NCE exclusivity period.

A. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S DECISIONS.

1) The Federal Circuit's Decision Is Contrary to This Court's Holdings on Article III and the Declaratory Judgment Act, and a Return to a Test This Court Already Rejected.

MedImmune teaches that bright line rules and rigid requirements are inappropriate when analyzing standing in a declaratory judgment suit: "Basically, the question in each case is whether 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." 549 U.S. at 127 (citing *Maryland Casualty Co. v. Pacific Coal & Oil Co*., 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941)).

Before *MedImmune*, the Federal Circuit followed the now rejected two-part test where a party could only bring a declaratory judgment action when there was both "(1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004) (citation omitted) (overruled in part by *MedImmune*, 549 U.S. at 132 n.11).

In *MedImmune*, the declaratory judgment plaintiff had licensed the patent at issue and was paying royalties. 549 U.S. at 121. Later, another patent issued that the patentee asserted was covered under the license agreement. *Id.* at 122. The plaintiff continued to pay royalties even though it thought the new patent was invalid. *Id.* Because it continued to license the patents, no threat of infringement existed. Nonetheless, this Court held that "under all the circumstances," the declaratory judgment plaintiff did not have to breach its license agreement before commencing suit. *Id.* at 127, 137. Thus, even without an explicit threat of infringement, Article III standing existed.

The Federal Circuit has acknowledged that *MedImmune* creates a "more lenient" standard that "facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases." *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008). It has also said that the "inquiry, focused on the combination of immediacy and reality, involves no brightline test." *Sandoz*, 773 F.3d at 1277. In another Federal Circuit case, the court explained there is "no facile, all-purpose standard to police the line between declaratory judgment actions which satisfy the case or controversy requirement and those that do not." *Cat Tech LLC v. TubeMaster, Inc*., 528 F.3d 871, 879 (Fed. Cir. 2008).

These Federal Circuit decisions pay lip service to the teachings of *MedImmune*, but in the context of declaratory judgment actions filed by would-be competitors in the field of a pharmaceutical product (as is the case here), the Appellate Court continues to improperly apply a rigid rule similar to the disallowed, pre-*MedImmune* "reasonable apprehension" test. The Federal Circuit's opinions focus on whether the declaratory judgment plaintiff has filed for FDA approval of a drug, creating a *de facto* rule that unless an ANDA or other drug approval application has been filed, a court has no declaratory judgment jurisdiction. The Federal Circuit has stated:

> [W]e have found no justiciability where a declaratory-judgment plaintiff had not filed an application for the FDA approval required to engage in the arguably infringing activity. On the other hand, where we have found a

> case or controversy in the Hatch-Waxman setting, we have focused on the presence of an application for the required FDA approval.

Sandoz, 773 F.3d at 1281.

As the District Court succinctly explained, "the Federal Circuit . . . had never found a justiciable case or controversy before a drug manufacturer had applied for FDA approval." App. at 29-30.

The absolute requirement that an application for FDA approval like an ANDA must occur before Article III standing attaches departs from this Court's jurisprudence, which requires a nuanced, fact-intensive approach to the question of declaratory judgment jurisdiction. *See*, *e.g.*, *Maryland Casualty*, 312 U.S. at 273 ("The difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy."); *MedImmune*, 549 U.S. at 132 n.11 (rejecting the Federal Circuit's previous "apprehension of suit" test); *Allen*, 468 U.S. at 752 ("[T]he standing inquiry requires careful judicial examination of a complaint's allegations. . . .").

2) The Appellate Court's Application of Its Rigid Rule Meant It Did Not Evaluate "All the Circumstances" of AHF's Declaratory Judgment Action.

The Federal Circuit affirmed the dismissal of AHF's lawsuit based on the court's flawed belief that

declaratory judgment jurisdiction exists only when an application for FDA approval has been filed. The District Court explained that 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)."

Absent the Federal Circuit's rigid rule, the District Court would have reached a different conclusion and found standing.

> 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. . . . 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. . . .

App. at 30-31.

The Federal Circuit adopted the District Court's reasoning, holding that AHF "fell short of the declaratory judgment requirements of immediacy and reality" in part because "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." *Id.* at 9. The lower courts' analyses improperly required an ANDA filing as a prerequisite for declaratory judgment jurisdiction.

As a result, the Federal Circuit did not analyze "all the circumstances" that brought AHF to the point of suing for declaratory judgment. A suit has Article III standing when 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*, 549 U.S. at 127.

As to the "substantial controversy prong" of the standing test, the Federal Circuit did not undertake the intensive factual analysis required to determine if an actual controversy exists between AHF and Gilead. For example, Gilead has a history of lawsuits against generic drug makers regarding TDF, the predecessor to TAF. *See*, *e.g.*, *Gilead Sciences, Inc. v. Teva Pharms. USA, Inc., et al.*, Case No. 10-cv-01796, Dkt. No. 1 ¶ 29 (S.D.N.Y.) (infringement action against generic maker seeking to make tenofovir disoproxil fumarate (TDF)); *Gilead Sciences, Inc. v. Lupin Limited*, Case No. 12-cv-06294, Dkt. No. 1 ¶ 13 (S.D.N.Y.) (infringement action against generic maker seeking to make combination drug that incorporated TDF); *Gilead Sciences, Inc. v. CIPLA Ltd.*, Case No. 12-cv-06351, Dkt. No. 45 ¶¶ 19, 44 (S.D.N.Y.) (infringement action against generic maker seeking to make tablets containing TDF). The Federal Circuit did not mention these lawsuits even though a patentee's "willingness to protect [its]

technology" is relevant to the jurisdictional inquiry. *See Vanguard Research, Inc. v. PEAT*, *Inc*., 304 F.3d 1249, 1255 (Fed. Cir. 2002) (finding Article III controversy based, in part, on related trade secrets misappropriation suit); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987).

The Federal Circuit should have looked at Gilead's litigious history over TDF in combination with other factors such as Gilead's refusal to provide a covenant not to sue and public statements that Gilead would enforce its patent rights, as part of a holistic analysis of whether the parties had a "substantial controversy," consistent with *MedImmune*'s "all the circumstances" standard. It did not. In dealing with whether the parties had a substantial controversy, the Federal Circuit merely concluded that "an actionable legal interest is not here present, for neither [AHF] nor any producer of TAF products is infringing or preparing to infringe any TAF patent." App. at 13.

Similarly, the Federal Circuit failed to analyze "all the circumstances" regarding the immediacy of the conflict between AHF and Gilead. The Federal Circuit said that the District Court found "significant uncertainty about the nature of any hypothetical product." *Id.* at 8-9. But, because the District Court was constrained by the Federal Circuit's *de facto* requirement that an ANDA be filed for declaratory judgment jurisdiction to exist, it did not analyze the particular facts pleaded by AHF either. Instead, it explained:

> 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*.

Id. at 30.

The District Court based its conclusion not on the particular facts before it, but on what it saw as the Federal Circuit's rule that without an ANDA on file, AHF could not maintain declaratory judgment jurisdiction. The Federal Circuit agreed with that conclusion. *Id.* at 9. Such a circular, truncated analysis cannot be a substitute for engaging in the factual inquiry required by *MedImmune.*

Had the lower courts analyzed "all the circumstances" pleaded by AHF, they would have seen that there are significant factual differences between the present case and *Benitec* and *Sandoz* that make this case much more certain and immediate. In those cases, the declaratory judgment plaintiffs were engaged in clinical trials that may or may not succeed in front of the FDA. *Benitec* at 1346; *Sandoz* at 1279-80. By contrast, the products AHF seeks to obtain and distribute are generic versions of Respondent Gilead's TAF-containing products, meaning those products must be bioequivalents (defined in part as where "the rate and extent of absorption of the drug do not show a

significant difference from the rate and extent of absorption of the listed drug"). 21 U.S.C. § 355(j)(8)(B)(i)-(ii). Put simply, the products AHF seeks must be functionally equivalent to Gilead's products. Consequently, there is no uncertainty about whether the products would meet with FDA approval or be infringing.

Other factors also point to the certainty of AHF's lawsuit, but the Federal Circuit failed to analyze these issues as well. For example, AHF's preparations to introduce generic TAF include soliciting the manufacture and importation of generic TAF, conducting research relating to generic TAF, and investigating HAART regimens incorporating generic TAF. C.A.A. at 841-42. Every introduction of an HIV drug by Gilead has led to the submission of ANDA applications from generic drug manufacturers following the expiration of NCE exclusivity. *Id.* at 1550-51. Notably, TAF's predecessor, TDF, was subject to multiple ANDA filings. *Id.* at 844. This history shows that generic entry for TAF products is not just probable, it is certain.

Had the District Court or Federal Circuit analyzed these factors, rather than adhere to the Federal Circuit's flawed, rigid test, the lower courts could easily have concluded that it is certain that generic drug makers will file an ANDA for the various TAF drugs as soon as Gilead's NCE exclusivity period expires.

B. THE FEDERAL CIRCUIT'S RIGID RULE REQUIRING AN APPLICATION FOR FDA APPROVAL FOR DECLARATORY JUDGMENT STANDING IS IRRECONCILABLE WITH ARTICLE III AND ESTABLISHED PATENT POLICY.

Just as this Court in *MedImmune* rejected the Federal Circuit's holding that a contracting party to a license agreement must first breach the agreement before bringing suit, it should similarly reject the Federal Circuit's rigid rule here that a declaratory judgment action cannot be brought in the pharmaceutical context until an application for FDA approval is filed.

AHF has a real conflict with respondents. It is working to introduce generic TAF prodrugs and HAART therapies using TAF to its patients as soon as Respondents' drugs lose their NCE exclusivity at the end of 2019. It is prevented from doing so by Respondents' patents, which "serve as barriers to entry for any generic" drug maker. App. at 26. If Respondents' patents are invalidated, AHF can begin providing generic drugs to patients as soon as TAF's NCE exclusivity period ends.

This Court has repeatedly acknowledged the "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). *See also Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless

patents, as that the patentee of a really valuable invention should be protected in his monopoly. . . ."); *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58 (1973) (quoting *Pope Mfg.*); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993) (emphasizing "the importance to the public at large of resolving questions of patent validity"). The Federal Circuit's rigid rule works against this important public policy.

The Federal Circuit reinforced its view that no declaratory judgment action is available until FDA approval can be sought, saying that AHF's arguments "warrant legislative consideration, not departure from precedent." App. at 16. However, it is the Federal Circuit who departed from precedent by creating a rigid rule barring declaratory judgment suits before an application for FDA approval is filed. The Federal Circuit has cited nothing in the Hatch-Waxman Act that prohibits declaratory judgment lawsuits until an ANDA or other FDA submission is made. Nor did it make any attempt to square its rigid rule rejecting declaratory judgment actions until FDA approval is sought with this Court's decision in *MedImmune* or other Article III cases. Filing an ANDA that creates an "artificial infringement" certainly is one way of triggering a controversy sufficient to establish declaratory judgment standing, but nothing in the Hatch-Waxman Act or this Court's precedent says it is the *only* way.

Article III standing and declaratory judgment subject matter jurisdiction are not patent-specific issues, and this Court should continue to police the Federal Circuit's decisions applying basic federal statutes

and constitutional provisions – which apply in all judicial circuits – to ensure that the Federal Circuit's misinterpretations of the law do not lead other courts of appeals astray.

In the end, the main effect of the Federal Circuit's rigid rule on declaratory judgment standing in this case is delaying the inevitable by kicking AHF's dispute with Respondents down the road a few years. As discussed *supra*, § A.2, as soon as an ANDA can be filed on Respondents' TAF drugs, litigation will undoubtably occur.[3] Nothing will have changed about the content of the dispute between AHF and Gilead in those three years. Nonetheless, Gilead will be able to extract additional years of monopoly pricing for its products while a new lawsuit challenging Respondents' patents winds its way through the courts, and AHF and its patients will have to suffer an additional three years of either using a more toxic drug or paying monopoly prices for a drug that does not deserve patent protection.

Only this Court can remove the Federal Circuit's rigid, bright line test and restore the meaning of

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[3] Of course, Respondents are likely to try to delay that litigation by paying the first generic challenger to withdraw its challenge. "This delay will be compounded by the likelihood that the first generic manufacturer to challenge the patents [after filing an ANDA that states the patents are invalid] 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." App. at 31.

Article III standing and the Declaratory Judgment Act to their proper scope.

CONCLUSION

For the reasons stated, the petition for certiorari should be granted.

Respectfully submitted,

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