United States Court of Appeals for the Federal Circuit

06-1181

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS PHARMA AG
and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Defendants-Appellees.

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Appealed from: United States District Court for the District of New Jersey

Judge Jose L. Linares

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DECIDED: March 30, 2007

Before MAYER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and GAJARSA, Circuit Judge.

Opinion for the court filed by Circuit Judge GAJARSA. Concurring opinion filed by Senior Circuit Judge FRIEDMAN.

GAJARSA, Circuit Judge.

Teva Pharmaceuticals ("Teva") appeals from the dismissal of its declaratory judgment action by the United States District Court for the District of New Jersey. The district court, relying on our two-part declaratory judgment test for patent non-infringement as modified by our recent decision in Teva Pharmaceuticals USA, Inc., v. Pfizer, Inc., 395 F.3d 1324 (2005) ("Pfizer"), found that Teva failed to establish a reasonable apprehension of imminent suit and that it therefore lacked jurisdiction over the declaratory judgment action. In light of the Supreme Court's recent decision in MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007), which finds that our

declaratory judgment test for non-infringement or invalidity "conflicts" with its precedent, we reverse.

I. BACKGROUND

Novartis holds a New Drug Application ("NDA") for three strengths of the drug Famvir®. Upon filing its Famvir® NDA, Novartis listed five patents in the Food and Drug Administration's ("FDA") Orange Book, each of which covers and is directed to various aspects of Famvir®, including U.S Patent Nos: 5,246,937 ("'937 patent"); 5,840,763 ("'763 patent"); 5,866,581 ("'581 patent"); 5,916,893 ("'893 patent"); and 6,124,304 ("'304 patent"). The '937 patent is directed to the active ingredient in Famvir®, famciclovir, while the remaining Orange Book patents are directed to methods of therapeutic use ("method patents") of Famvir®. The '937 patent expires in 2010, but the related therapeutic use patents do not expire until 2014-15.

In 2004, Teva filed an Abbreviated New Drug Application ("ANDA") with the FDA for generic famciclovir tablets in which Teva certified under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) that its drug did not infringe any of the five Novartis Famvir® Orange Book patents or that the patents were invalid. Teva's paragraph IV certifications constitute technical infringement under 35 U.S.C. § 271(e)(1). Accordingly, Novartis had 45 days to sue on these patents in order to invoke a statutorily mandated 30-month stay to delay immediate FDA approval of Teva's famciclovir ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii).

Novartis brought an infringement suit against Teva on the '937 patent alone and did not include in the action the related therapeutic use patents. The infringement suit is pending in the United States District Court for the District of New Jersey. Novartis Pharm. Corp., v. Teva Pharm. USA, Inc., No. 05-1887 (D.N.J. 2005).

After Novartis filed suit, Teva brought this declaratory judgment action on the four remaining method patents under 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5) to establish "patent certainty." Title 21 U.S.C. § 355(j)(5)(C) is a 2003 amendment to the ANDA statute entitled "civil action to obtain patent certainty." Under this provision, if the patentee or NDA holder does not bring an infringement suit within 45 days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the ANDA was submitted. Id. Title 35 U.S.C. § 271(e)(5) is a 2003 amendment to the patent statute that works in conjunction with the 2003 amendment to the ANDA statute to provide that in a civil action to obtain patent certainty, federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under § 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." Teva argues that by bringing suit on the '937 patent alone in the first instance, "Novartis has sought to put Teva to the hard choice of either launching at risk of massive liability for patent infringement when the '937 patent expires or Teva prevails in the pending infringement action, or foregoing that opportunity and thereby effectively extending the term of the '937 patent." Appellant Br. 9 (footnotes omitted).

Novartis moved to dismiss for lack of subject matter jurisdiction, arguing that Teva had no reasonable apprehension that it would be sued by Novartis for infringing the four method patents. In response, Teva argued that: (1) Novartis had already sued Teva on the underlying composition patent; (2) listing patents in the Orange Book established infringement as a matter of law; (3) Novartis had a history of aggressively

suing generic drug companies; and (4) Novartis had declined to give Teva a covenant not to sue.

The district court dismissed Teva's declaratory judgment action requesting "patent certainty" on the four method patents. Teva Pharm., USA, Inc., v. Novartis Pharm. Corp., No. 05-2881, slip op. at 10 (D.N.J. Dec. 12, 2005). In so doing, the district court applied our two prong "reasonable-apprehension-of-imminent-suit" test from Pfizer.[1] 395 F.3d at 1332. After comparing the facts of this case to those in Pfizer, the district court found that Teva had failed to establish a reasonable apprehension of imminent suit and that the district court therefore lacked jurisdiction over the declaratory judgment action. Teva, slip op. at 10. Teva timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. See Pfizer, 395 F.3d at 1332 (citing Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1379 (Fed. Cir. 2004)). The determination of whether an actual controversy exists under the Declaratory Judgment Act in a patent case is a question of law that we review de novo. BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993). The district court's factual findings supporting its determination are reviewed for clear error. Id.

[1] Under this two prong test, the ANDA declaratory judgment plaintiff must show both: (1) a "reasonable apprehension" of "imminent" suit by the patentee; and (2) activity constituting infringement or the intent to infringe. See Pfizer, 395 F.3d at 1332.

II. ANALYSIS

A.

Our starting point in analyzing Teva's appeal is the Declaratory Judgment Act, 28 U.S.C. § 2201(a) under which Teva filed this suit. The relevant text of the Act reads:

> 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.

28 U.S.C. § 2201(a).

In the ANDA context, Congress explicitly extended federal court declaratory judgment jurisdiction under 28 U.S.C. § 2201 to ANDA paragraph IV disputes such as Teva's and did so "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).[2]

The Supreme Court recently re-affirmed that the Act's "actual controversy" requirement "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." MedImmune, 127 S. Ct. at 771 ("[T]he phrase 'case of actual controversy' in

[2] The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) "serve[] the policies underlying the patent laws by enabling a test of the validity and infringement of patents that are . . . being used only as . . . 'scarecrows.'" Arrowhead Indus. Water, Inc. v. Ecolochem, 845 F.2d 731, 735 (1988) (quoting Judge Learned Hand in Bresnick v. U.S. Vitamin Corp., 139 F.2d 239 (2d Cir. 1943)). Before the declaratory judgment provisions, competitors were "victimized" by patent owners who engaged in "extra-judicial patent enforcement with scare-the-customer-and-run tactics that infect[ed] the competitive environment of the business community with uncertainty and insecurity" and that rendered competitors "helpless and immobile so long as the patent owner refused to . . . sue." Id. at 735 (quoting Japan Gas Lighter Ass'n v. Ronson Corp., 257 F. Supp. 219, 237 (D.N.J. 1966)). After enactment of these provisions, competitors "were no longer restricted to [the hard] choice between incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a [declaratory] judgment." Id.

the Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III.") (citing Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937)).

In MedImmune, the Court found that its precedent "did not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not." Id. Instead of applying a bright line, the Court stated that its decisions required:

> that the dispute be "definite and concrete, touching the legal relations of the parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."

Id. (citing Aetna Life Ins. Co., 300 U.S. at 240-41).

Previously, the Court held that "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." Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). In MedImmune, the Court re-affirmed the correct standard for determining a justiciable declaratory judgment action: "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. (citing Md. Cas. Co., 312 U.S. at 273).

Thus, MedImmune teaches that in a declaratory judgment action, "all the circumstances" must demonstrate that a justiciable Article III "controversy" exists. A justiciable Article III controversy requires the party instituting the action to have standing

and the issue presented to the court to be ripe. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

Article III standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." Allen v. Wright, 468 U.S. 737, 751 (1984). Of the three standing requirements, injury-in-fact is the most determinative: "[W]hatever else the 'case or controversy' requirement embodie[s], its essence is a requirement of 'injury in fact.'" Schlesinger v. Reservists Comm. to Stop the War, 418 U.S. 208, 218 (1974) (citing Ass'n of Data Processing Serv. Org., Inc. v. Camp, 397 U.S. 150, 152 (1970)). An injury-in-fact must be "personal," "concrete and particularized," and "actual or imminent." Lujan, 504 U.S. at 560; Warth v. Seldin, 422 U.S. 490, 501 (1975).

Under the declaratory judgment standard, "all the circumstances" must demonstrate the Article III justiciability requirement that the case be ripe for judicial review. Abbott Labs. v. Gardner, 387 U.S. 136 (1967). The doctrine of ripeness focuses on the conduct of the defendant to determine whether the defendants actions have harmed, are harming, or are about to harm the plaintiff. Ripeness can be an issue in obtaining anticipatory relief like declaratory judgments. Id. at 149. A "controversy" is "ripe" if the question presented is "fit for judicial review," meaning it is entirely or substantially a question of law and postponing a decision would work a substantial hardship on the challenging party. Id. at 149-50 (applying the test and holding that a regulation requiring drug manufacturers to change labeling was ripe for review before it was enforced because the regulation had an immediate and expensive impact on the plaintiffs' operations and plaintiffs risked a substantial sanction for non-compliance).

Similar to the ripeness doctrine and based on the same constitutional "controversy" requirement is the Court's prohibition against advisory opinions. Under this doctrine, federal courts are to decide only "actual controversies by judgment which can be carried into effect, and not to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in the case before it." Local No. 8-6, Oil, Chem. & Atomic Workers Int'l Union v. Missouri, 361 U.S. 363, 367 (1960). Although there can be a fine line between declaratory judgments and advisory opinions, the Supreme Court maintains the necessity of avoiding issuing advisory opinions based upon hypothetical facts. Elec. Bond & Share Co. v. Sec. & Exch. Comm'n, 303 U.S. 419 (1938).

Notwithstanding the Court's justiciability precedent, it is well established that Congress by legislation "may expand standing to the full extent permitted by [A]rticle [III] of [the] Constitution, thus permitting litigation by one who otherwise would be barred." Gladstone Realtors v. Vill. of Bellwood, 441 U.S. 91, 100 (1979). Congress, however, cannot expand standing beyond the Article III jurisdiction of federal courts. Id. Thus, as long as Congress remains within constitutional limits, it may "enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute." Linda R.S. v. Richard D., 410 U.S. 614, 617 n.4 (1973) (citing Trafficante v. Metro. Life Ins. Co., 409 U.S. 205, 212 (1972) (White, J., concurring)).

The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) are examples of legislation that expand standing to constitutional limits and provide a way for plaintiffs to bring actions in federal court when they might otherwise be barred. The sole requirement for federal court jurisdiction under both provisions is an "actual controversy," 28 U.S.C. § 2201(a), which is the same as an Article III case or

controversy. See Aetna Life Ins., 300 U.S. at 239-41. This means that under both provisions, a declaratory judgment plaintiff is only required to satisfy Article III, which includes standing and ripeness, by showing under "all the circumstances" an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, 127 S. Ct. at 771 (internal citations omitted).[3]

In the instant case, we follow the Court's analysis in MedImmune in determining whether Teva has a justiciable controversy within the meaning of Article III. Id. By following MedImmune, we recognize that we are not relying on our two-part reasonable-apprehension-of-suit test. See, e.g., Pfizer, 395 F.3d at 1332-33. This court respects the principle of stare decisis and follows its own precedential decisions unless the decisions are "overruled by the court en banc, or by other controlling authority such as an intervening . . . Supreme Court decision." Tex. Am. Oil Co. v. U.S. Dep't of Energy, 44 F.3d 1557, 1561 (Fed. Cir. 1995) (en banc).

Under our patent jurisprudence, we developed a two-part test to determine if an "actual controversy" exists in a general declaratory judgment action for patent non-infringement or invalidity. See, e.g., Pfizer, 395 F.3d 1332-33. This test requires both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit

[3] However, unlike non-declaratory judgment actions, even if there is an actual controversy, the district court is not required to exercise jurisdiction to address the merits of the action, as it retains discretion under the Act to decline declaratory judgment jurisdiction. Public Serv. Comm'n v. Wycoff Co., 344 U.S. 237, 241 (1952); Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631, 634 (Fed. Cir. 1991) ("When there is no actual controversy, the court has no [jurisdiction and no] discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary.").

and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity. See, e.g., id.

In MedImmune, the Supreme Court in a detailed footnote stated that our two-prong "reasonable apprehension of suit" test "conflicts" and would "contradict" several cases in which the Supreme Court found that a declaratory judgment plaintiff had a justiciable controversy.[4] 127 S. Ct. at 774 n.11. In MedImmune, the Court disagreed with our "reasonable apprehension of imminent suit" test and re-affirmed that the "actual controversy" requirement in the Declaratory Judgment Act is the same as the "Cases" and "Controversies" requirement in Article III. Id. at 771. The Court further re-affirmed that an "actual controversy" requires only that a dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.'" Id. (quoting Aetna Life Ins. Co., 300 U.S. at 240-41). The Court summarized the declaratory judgment "actual controversy" requirement by quoting the "all the circumstances" test from Maryland Casualty. Id. Thus, because the Supreme Court in MedImmune cautioned that our declaratory judgment "reasonable-apprehension-of-suit" test "contradict[s]" and "conflicts" with its precedent, these Federal

[4] See, e.g., Md. Cas. Co., 312 U.S. at 273 (finding a justiciable controversy even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured); Aetna Life Ins. Co., 300 U.S. at 239 (finding a justiciable controversy even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit); Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 98 (1993) (holding that appellate affirmance of a judgment of non-infringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity).

Circuit tests have been "overruled by . . . an intervening . . . Supreme Court decision." Tex. Am. Oil Co., 44 F.3d at 1561; see also, SanDisk v. STMicroelectronics, --- F.3d ----, 2007 WL 881008 (Fed. Cir. Mar. 26, 2007). Therefore, we follow MedImmune's teaching to look at "all the circumstances" under Maryland Casualty to determine whether Teva has a justiciable Article III controversy.

B.

The district court was bound by our precedent in Pfizer to apply the "reasonable-apprehension-of-imminent-suit" test to Teva's declaratory judgment action. Teva, slip op. at 9. In applying this test, the district court considered Teva's standing and concluded that Teva had failed to establish the type of injury-in-fact that we required in Pfizer because Teva could not show a reasonable apprehension of imminent suit. Teva, slip op. at 9; see Pfizer, 395 F.3d at 1333 (requiring a showing of "imminent suit"). The district court found that because Teva could not establish an Article III controversy under our precedent, it did not have jurisdiction and dismissed Teva's declaratory judgment action.

We hold that MedImmune applies to Teva's declaratory judgment action and takes precedence over the district court's application of Pfizer, which required Teva to show a single type of Article III injury-in-fact, "a reasonable apprehension of imminent suit." 395 F.3d at 1333. The question in this case is whether Teva has a justiciable controversy within Article III, which is the only limitation on our jurisdiction under the Declaratory Judgment Act. See 28 U.S.C § 2201. An Article III controversy is found where a plaintiff has demonstrated an injury-in-fact caused by the defendant that can be redressed by the court. See Steel Co., 523 U.S. at 83. In the present case, only the concrete injury-in-fact requirement under Article III is in dispute.

We hold that under "all the circumstances" as found in this case, Teva has an injury-in-fact and therefore has a justiciable Article III controversy. Here, Novartis argues that there is no actual controversy between it and Teva on the four method patents in spite of Teva's paragraph IV certifications of the four method patents because Novartis has not filed suit nor threatened to sue Teva on the method patents. Moreover, Novartis contends that the suit on the '937 patent is an entirely different controversy. Novartis is incorrect. There is no question that Novartis has already filed suit based on Teva's act of infringement in submitting the ANDA. Under 35 U.S.C. § 271(e)(2)(A), submitting an ANDA, regardless of how many paragraph IV certifications it may contain, is a single act of infringement: "It shall be an act of infringement to submit—an [ANDA] application . . . for a drug claimed in a patent or for the use of which is claimed in a patent." (Emphasis added). While it is true that the suit on the '937 patent is a different "case" than Teva's declaratory judgment action, Novartis created a present and actual "controversy" by choosing to sue under 35 U.S.C. § 271(e)(2)(A) on Teva's single act of infringement, thereby placing into actual dispute the soundness of Teva's ANDA and Teva's ability to secure approval of the ANDA. Thus, while Teva's declaratory judgment action and the pending '937 suit are different "cases," they arise from the same controversy created when Novartis listed its Famvir® patents in the Orange Book, Teva submitted its ANDA certifying all five Famvir® patents under paragraph IV, and Novartis sued Teva challenging the submission of Teva's ANDA.[5]

[5] In analyzing Novartis' election not to sue on the four method patents, it appears from the greater part of the district court's analysis that the district court may have erred in explaining the purpose of the 45-day statutory "window" in 21 U.S.C. § 355(j)(5)(B)(iii). The provision provides an automatic 30-month stay of approval of an ANDA if an infringement action is brought by a patent holder within 45 days against the ANDA filer on a patent it has certified under paragraph IV; if no suit is brought the ANDA

Novartis' conduct raises the questions of if and how 35 U.S.C. § 271(e)(2) applies to multiple suits between the same parties on the submission of a single ANDA with more than one paragraph IV certification. It is clear from the statutory language that recovering damages for a 35 U.S.C. § 271(e)(2)(A) infringement action is only time barred by the statutory six-year statute of limitations. See 35 U.S.C. § 286 ("[N]o recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action."); see also, A.C. Aukerman Co. v. R.L. Chaides Const. Co., 960 F.2d 1020, 1030 (Fed. Cir. 1992) (explaining that § 286 is "not a statute of limitations in the sense of barring a suit for infringement" . . . but rather a "limit to recovery to damages for infringing acts committed within six years of the date of the filing of the infringement action."). Thus, Novartis has the right of an immediate action against Teva under 35 U.S.C. § 271(e)(2)(A) on any or all of the remaining Famvir® Orange Book patents.[6] These actions could be brought at any time until the patents expire and damages would be limited only by the six-year limitations period. While it is unclear whether Novartis would be prohibited from suing

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is immediately approved. Id. The district court seemed to incorrectly interpret this provision as a waiver, finding that Novartis had only a 45-day window in which to sue Teva on all the paragraph IV patents in Teva's ANDA, and because Novartis had allowed this window to expire, it could not bring suit on the four remaining method patents. Teva, slip op. at 7, 9-10. This is not what the statute provides. Novartis' selective action against Teva is an attempt by Novartis to limit the impact of Teva's ANDA under the Hatch-Waxman Act, while at the same time using it to forestall a challenge on all the remaining four method patents. By suing solely on the '937 patent, Novartis has not only invoked the 30-month stay, preventing Teva's entire ANDA from immediate approval, but Novartis is also selectively suing on the patent with the earliest expiration date leaving the remaining four method patents overhanging Teva for future litigation. This conduct prevents Teva's generic from entering the market until the expiration of the last patent and is directly contrary to the purpose of the 30-month stay. The stay is explicitly offered to patent holders who "reasonably cooperate in expediting [] action[s]" challenging their patents. 21 U.S.C. § 355(j)(5)(B)(iii).

under the doctrine of claim preclusion, Teva remains under the threat of an infringement suit because the 45-day statutory window does not preclude Novartis from pursuing additional infringement suits under 35 U.S.C. § 271(e)(2)(A). In light of Novartis' pending suit on the same ANDA, this threat of litigation is a present injury creating a justiciable controversy. Moreover, Novartis retains the right to sue Teva under the Famvir® patents pursuant to 35 U.S.C. § 271(a). Therefore, Novartis has numerous opportunities to bring an action at any time for patent infringement and is not precluded by the 45-day window.

The district court erred in finding that Teva did not demonstrate an Article III controversy. Teva, slip op. at 6-10. A justiciable controversy can arise from either an actual or an imminent injury. While it is true that several of Teva's grounds alleging an "actual controversy" when standing alone might not be sufficient, if taken as a whole these circumstances establish a justiciable controversy with Novartis that can be resolved by allowing Teva to bring a declaratory judgment.

First, Novartis listed its Famvir® patents in the Orange Book. By so doing, Novartis represents that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of generic famciclovir covered by the claims of its listed Famvir® patents. 21 U.S.C. § 355(b)(1); see Pfizer, 395 F.3d at 1341 (Mayer, J., dissenting). While this conduct on its own may not be sufficient to establish an Article III controversy, it is a circumstance to be considered in determining whether a justiciable controversy exists under the totality of the circumstances.

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[6] Teva filed its ANDA with the five paragraph IV certifications on December 28, 2004, resulting in the single act of infringement under 35 U.S.C. § 271(e)(2)(A).

A second circumstance that supports Teva's claim of a justiciable controversy is Teva's submission of its ANDA certifying that it did not infringe Novartis' Famvir® Orange Book patents or that the patents were invalid. The very act of submitting an ANDA is an act of infringement. 35 U.S.C. § 271(e)(2); see Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) (holding that the statute creates an "act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification"). There is no question that under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA; indeed, that is exactly what occurred in this case. It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party. In fact, the Supreme Court has stated: "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case." Md. Cas. Co., 312 U.S. at 273. This conclusion is supported in the legislative history of the 2003 "civil action to obtain patent certainty" amendment to the Hatch-Waxman Act:

> [T]he Hatch-Waxman Act has always provided that patent owners and brand drug companies can bring patent infringement suits against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent [by filing an ANDA]. The [ANDA] declaratory judgment provisions . . . simply level the playing field by making it clear that the generic applicant can also seek a prompt resolution of these patent issues by bringing a declaratory judgment action if [it is not sued] . . . within 45 days.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of the Senate HELP committee).

A third circumstance we find relevant in determining whether Teva has established an actual controversy is the combination of three statutory provisions: 1) the

"civil action to obtain patent certainty" under 21 U.S.C. § 355(j)(5)(C); 2) the ANDA declaratory judgment provision under 35 U.S.C § 271(e)(5); and 3) the purpose of the Hatch-Waxman Act. The "civil action to obtain patent certainty," which was enacted in 2003 is designed to prevent patentees from "gaming" the Hatch-Waxman Act.[7] See 21 U.S.C. § 355(j)(5)(C). This amendment specifically permits an ANDA applicant to file a declaratory judgment action under 28 U.S.C. § 2201 against the patent owner or the brand-name drug company "for a declaratory judgment that the patent [listed in the Orange Book] is invalid or will not be infringed by the drug" covered by the ANDA if the patentee has not brought an infringement action within 45 days. Id. By virtue of 35 U.S.C § 271(e)(5), Congress extended federal court jurisdiction over these ANDA declaratory judgment actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

By filing a lawsuit on only one its five patents certified under paragraph IV in Teva's ANDA, Novartis has tried to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities. Novartis' '937 patent suit against Teva has invoked the statutory automatic 30-month stay and is concurrently insulating the four method patents from a validity challenge. In the statute, Congress explicitly required that in exchange for the 30-month stay, patentees were to "reasonably cooperate in expediting the action" of

[7] "[I]n recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the [] Act . . . will stop these abuses." 149 Cong. Rec. S15882-03, S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of the Senate HELP committee).

whether the paragraph IV patents were invalid or not infringed.[8] 21 U.S.C. § 355(j)(5)(B)(iii). Novartis' action insulates it from any judicial determination of the metes and bounds of the scope of the claims of its four Famvir® method patents in relation to design-around, a determination that is central to the proper function of our patent system and is a central purpose of the Hatch-Waxman Act. Teva Pharm. USA, Inc. v. Pfizer Inc., 405 F.3d 990, 992 (Fed. Cir. 2005) (rehearing en banc denied) (Gajarsa, J., dissenting).

It is clear from the legislative history that Congress intended this "civil action" to adjudicate the very controversy that Novartis has created here:

> The provision [a "civil action to obtain patent certainty"] . . . is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.
>
> The mere fact that neither the patent owner nor the brand drug company has brought a patent infringement suit within 45 days against a generic applicant does not mean there is no "case or controversy." The sole purpose of requiring the passage of 45 days is to provide the patent owner and brand-name drug company the first opportunity to begin patent litigation. Inaction within the 45-day period proves nothing, as there are

[8] A patent owner who brings an infringement claim against an ANDA filer within the 45-day period invokes an automatic 30-month stay preventing the otherwise immediate approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The stay provides a safety net and an incentive to patentees who would otherwise not be inclined to bring a suit against the generic because at the time the ANDA is filed, the patentee has not suffered any economic loss. Where no commercial activity has yet taken place, a patentee becomes susceptible to having its patent found invalid or not infringed.

> tactical reasons why a patent owner or brand drug company might refrain from bringing suit on a patent within 45 days.
>
> For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.
>
> In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee) (emphasis added). A central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to that Act is "to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible." Id. Novartis' actions frustrate this purpose and create a basis for finding a justiciable controversy.

A fourth circumstance contributing to Teva's justiciable controversy is Novartis' pending infringement litigation. See Novartis Pharm. Corp., No. 05-1887. As stated previously, Novartis' suit against Teva on Teva's submitted ANDA is an Article III controversy. A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA

certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents. Our conclusion supports what we have already established in non-ANDA cases—that related litigation involving the same technology and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on other related patents. See Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1255 (Fed. Cir. 2005) (following Goodyear and finding a justiciable declaratory judgment controversy where the defendant had sued the declaratory judgment plaintiff for misappropriation of trade secrets thereby demonstrating "a willingness to protect [its] technology."); Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987) (finding a justiciable declaratory judgment controversy in a patent non-infringement and invalidity action where the defendant had sued the declaratory judgment plaintiff in state court for misappropriation of trade secrets involving the same technology, thereby engaging in "a course of conduct that shows a willingness to protect that technology.").

Novartis' selective '937 suit creates uncertainty as to Teva's legal rights under its ANDA. Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer in Teva's situation is not legally free to enter the market because federal statutes prohibit it. See 21 U.S.C § 355(j)(5)(B)(iii). Hence, Teva suffers a direct legal injury from the actions that Novartis has already taken—Novartis' listing of the five Famvir® patents in the Orange Book and Novartis' suit against Teva

challenging the validity of Teva's ANDA—which requires judicial relief. It is this exact type of uncertainty of legal rights that the ANDA declaratory judgment action was enacted to prevent. See id. § 355(j)(5)(C). Congress clearly has authority to give standing and create justiciable injuries through legislation for parties that might otherwise have no recourse as long as Congress does not exceed the limitations of Article III. Gladstone, 441 U.S. at 100 ("Congress may, by legislation, expand standing to the full extent permitted by Art. III, thus permitting litigation by one 'who otherwise would be barred . . . .'" (internal citations omitted)). Congress created the ANDA declaratory judgment action for generic drug companies specifically to avoid the type of legal uncertainty that Novartis has created. The legislative history of the ANDA declaratory judgment amendment explicitly states that the "uncertainty" caused by a brand-name company when it chooses to sue on only selective patents submitted in a single ANDA is an injury sufficient to support a justiciable controversy. See 149 Cong. Rec. S15885 (Nov. 25, 2003). The type of legal uncertainty as to the legal status of Teva's ANDA that Novartis has created by suing on only one of the five paragraph IV certified Famvir® patents listed in the Orange Book is a present injury sufficient for a justiciable controversy.

Finally, the possibility of future litigation that Novartis created by electing to challenge Teva's ANDA on only one of the five Orange Book listed Famvir® patents is a fifth circumstance contributing to finding that Teva has a justiciable declaratory judgment controversy. Novartis' suit on the '937 patent alone leaves open the possibility of future litigation regardless of whether Teva wins or loses the '937 infringement suit. The possibility that an ANDA filer will be subject to multiple infringement suits from the same patentee based on the submission of a single ANDA

containing several paragraph IV certifications is an injury relevant to finding a justiciable controversy. If Teva is successful in defending the pending '937 infringement suit, it remains subject to four additional infringement actions by Novartis under 35 U.S.C. § 271(e)(2) on the remaining Famvir® Orange Book patents certified in Teva's ANDA under paragraph IV. By its action, Novartis is insulating its Famvir® Orange Book patents from any challenge of invalidity or non-infringement until all the patents expire. This threat of protracted litigation creates a present and real harm that is a relevant circumstance in finding whether a justiciable controversy exists.

III. CONCLUSION

The Court re-affirmed in MedImmune the "all circumstances" analysis as the correct standard to use in determining whether a justiciable Article III controversy exists in a declaratory judgment action. Under this standard, we find that Teva has an injury-in-fact and a justiciable controversy that can be fully resolved by a declaratory judgment. Allowing Teva's declaratory judgment action is consistent with the "controversy" requirement in Article III and the Declaratory Judgment Act because the suit will achieve a final determination that resolves the entire dispute between Teva and Novartis. Teva has experienced real and actual injury. Consequently, Teva's injuries are traceable to Novartis' conduct and those injuries can be redressed by a favorable judicial decision. Therefore, Teva has established standing and an actual controversy sufficient to confer jurisdiction under the Declaratory Judgment Act.

For these reasons we reverse the district court's decision dismissing Teva's declaratory judgment action.

REVERSED

United States Court of Appeals for the Federal Circuit

06-1181

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION
NOVARTIS PHARMA AG
and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Defendants-Appellees.

FRIEDMAN, Senior Circuit Judge, concurring in the judgment.

I agree with the court that the appellant Teva Pharmaceuticals USA, Inc. ("Teva") has shown an "actual controversy" under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), and that the district court's judgment dismissing Teva's declaratory judgment action for lack of jurisdiction should be reversed. I write separately because I take a somewhat different, and shorter, path than the court does in reaching that conclusion.

In MedImmune, Inc., v. Genentech, Inc., 549 U.S. ___ (2007), the Supreme Court rejected this court's settled view that a patent licensee must "terminate or be in breach of its license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed." Id., slip op. at 1; see Gen-Probe Inc. v. Vysis, 359 F.3d 1376 (Fed. Cir. 2005). The Supreme Court ruled that the jurisdiction of the district court did not turn on whether the declaratory judgment plaintiff had stopped paying royalties under or otherwise terminated the license, but on the general broader principles governing declaratory judgment jurisdiction, namely, whether

the dispute between the parties is "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. . . . 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.'" MedImmune, slip op. at 7-8 (citation and footnote omitted).

In a somewhat detailed footnote, the Supreme Court stated that this court's "'reasonable apprehension of imminent suit' test" for determining declaratory judgment jurisdiction in patent cases (see Teva Pharms., USA, Inc. v. Pfizer, 395 F.3d 1324, 1333 (2005)) "would still contradict" a prior Supreme Court case and also "conflict[ ]" with another Supreme Court case, both of which that Court had relied on in its license breach ruling. Id., slip op. at 13 n.11. Although these footnote statements were dicta, the Court apparently was telling us that it rejected our "reasonable apprehension of imminent suit" test for determining declaratory judgment jurisdiction in patent cases, and that the broader general rules governing declaratory judgment jurisdiction also govern patent cases.

In these unusual circumstances, where the Supreme Court went out of its way to state its disagreement with our "reasonable apprehension of imminent suit" test, which was not an issue in the case before it, it appears incumbent on us to stop using that test and hereafter to apply the general declaratory judgment standards that the Supreme Court applied in Medimmune.

I agree with the court that under these general standards there was an "actual controversy" between Teva and Novartis about the infringement and validity of the four patents relating to the Famvir® technology. All five of Novartis' Famvir® patents are closely related. As this court here recognizes, by listing those five patents in the Orange Book, "Novartis represent[ed] that a 'claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale' of generic famciclovir covered by the claims of its listed Famvir® patents." Maj. Op. at 15. In its Abbreviated New Drug Application filed with the Food and Drug Administration, Teva certified under paragraph IV of 21 U.S.C. § 355(j)(2(A)(vii) that "its drug did not infringe" any of the five Novartis Famvir® Orange Book patents or that the patents were invalid. There thus is an existing controversy between the parties over whether Teva's generic version of Famvir® would infringe the four other Famvir® patents listed in the Orange Book, and whether these patents are valid. Novartis' filing of the suit charging that Teva has infringed one of those five patents and Teva's filing a declaratory judgment suit relating to the other four patents confirms that the controversy between the parties is continuing.