SAN FRANCISCO BAY AREA INTELLECTUAL PROPERTY
AMERICAN INN OF COURT

April 2007 Meeting Announcement:

Avoiding Litigation While Initiating Licensing Discussions

For the second consecutive meeting, we look at the impact of the recent Supreme Court decision in *Medimmune v. Genentech*. This month's pupilage group will focus on declaratory judgment jurisdiction, and in particular, the recent Federal Circuit opinions in *SanDisk v. STMicroelectronics* and *Teva v. Novartis*. In particular, the presentation will consider the challenges of initiating and responding to licensing discussions, and present practical considerations and strategies to consider in light of this substantial shift in declaratory judgment act jurisdiction.

Panelists:	**I. Neel Chatterjee**	*Orrick*
	Fabio Marino	*Orrick*
	Michael Schwartz	*DLA Piper*
	Julianne Sullivan	*Sheppard Mullin*
	Robert Taylor	*Howrey*
	Patrick Weston	*Bingham McCutchen*

Time and Location: April 18, 2007 at 6:00pm
Townsend and Townsend and Crew
379 Lytton Avenue (at Waverley Street)
Palo Alto
650.326.2400

Dinner to Follow at: Restaurant Zibibbo
430 Kipling Street
Palo Alto
650.614.9131

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United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.

Michael A. Ladra, Wilson Sonsini Goodrich & Rosati, of Palo Alto, California, argued for plaintiff-appellant. With him on the brief were James C. Yoon and Julie M. Holloway.

Edward V. Anderson, Sidley Austin Brown & Wood, LLP, of San Francisco, California, argued for defendant-appellee. With him on the brief were Russell L. Johnson, Georgia K. Van Zanten, Philip W. Woo, Matthew L. McCarthy, Peter Suen; and Kathi A. Cover, of Washington, DC.

Appealed from: United States District Court for the Northern District of California

Judge Jeremy Fogel

United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.

DECIDED: March 26, 2007

Before BRYSON, LINN, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge LINN. Opinion concurring in the result filed by Circuit Judge BRYSON.

LINN, Circuit Judge.

SanDisk Corporation ("SanDisk") appeals from a decision of the U.S. District Court for the Northern District of California granting STMicroelectronics' ("ST's") motion to dismiss SanDisk's second through twenty-ninth claims relating to declaratory judgment of noninfringement and invalidity for failure to present an actual controversy. See SanDisk Corp. v. STMicroelectronics, Inc., No. 04-CV-04379 (N.D. Cal. Jan. 20, 2005). Because the district court erred in dismissing the declaratory judgment claims

for lack of subject matter jurisdiction, we vacate the judgment and remand the case to the district court.

I. BACKGROUND

SanDisk is in the flash memory storage market and owns several patents related to flash memory storage products. ST, traditionally in the market of semiconductor integrated circuits, more recently entered the flash memory market and has a sizeable portfolio of patents related to flash memory storage products. On April 16, 2004, ST's vice president of intellectual property and licensing, Lisa Jorgenson ("Jorgenson"), sent a letter to SanDisk's chief executive officer requesting a meeting to discuss a cross-license agreement. The letter listed eight patents owned by ST that Jorgenson believed "may be of interest" to SanDisk. SanDisk, slip op. at 2; Letter from Jorgenson to SanDisk (Apr. 16, 2004). On April 28, 2004, SanDisk responded that it would need time to review the listed patents and would be in touch in several weeks to discuss the possibility of meeting in June.

On July 12, 2004, having heard nothing further from SanDisk, Jorgenson sent a letter to SanDisk reiterating her request to meet in July to discuss a cross-license agreement and listing four additional ST patents that "may also be of interest" to SanDisk. SanDisk, slip op. at 2; Letter from Jorgenson to SanDisk (July 12, 2004). On July 21, 2004, SanDisk's chief intellectual property counsel and senior director, E. Earle Thompson ("Thompson"), responded to ST's letter by informing Jorgenson of his "understanding that both sides wish to continue . . . friendly discussions" such as those between the business representatives in May and June. SanDisk, slip op. at 2-3; Letter from Thompson to Jorgenson (July 21, 2004). The discussions of May and June that

Thompson referred to were discussions among managers and vice presidents of SanDisk and ST at business meetings held on May 18, 2004, and June 9, 2004, to explore the possibility of ST's selling flash memory products to SanDisk. The business meetings were unrelated to any patents. Thompson also requested that Jorgenson join the next business meeting on August 5, 2005. On July 27, 2004, Jorgenson replied, again urging a meeting with Thompson, noting that it was "best to separate the business discussions from the patent license discussions." SanDisk, slip op. at 3; Letter from Jorgenson to Thompson (July 27, 2004).

On August 5, 2004, when the business representatives next met, SanDisk presented an analysis of three of its patents and orally offered ST a license. ST declined to present an analysis of any of its patents, stating instead that any patent and licensing issues should be discussed in a separate meeting with Jorgenson. Later that same day, Thompson wrote a letter to Jorgenson objecting to separating business and intellectual property issues and stating that "[i]t has been SanDisk's hope and desire to enter into a mutually beneficial discussion without the rattling of sabers." SanDisk, slip op. at 4; Letter from Thompson to Jorgenson (Aug. 5, 2004). On August 11, 2004, Jorgenson replied, stating that it was her understanding that the parties were going to have a licensing/intellectual property meeting later that month "to discuss the possibility for a patent cross-license." Letter from Jorgenson to Thompson (Aug. 11, 2004). She said that SanDisk should come to that meeting prepared to present an analysis of the three SanDisk patents it identified during the August 5th business meeting, as well as "any infringement analyses of an ST device or need for ST to have a license to these patents." Id. She also said that ST would be prepared at that meeting to discuss the

twelve patents identified in her prior letters. In closing, Jorgenson said that ST was "look[ing] forward to open and frank discussions with SanDisk concerning fair and reasonable terms for a broad cross-license agreement." Id.

On August 27, 2004, the licensing meeting was held. Jorgenson, two ST licensing attorneys, and three technical experts retained by ST to perform the infringement analyses of SanDisk's products, attended on behalf of ST. Thompson and an engineer attended on behalf of SanDisk. At the meeting, Jorgenson requested that the parties' discussions be treated as "settlement discussions" under Federal Rule of Evidence 408.[1] SanDisk, slip op. at 5. ST then presented a slide show which compared statistics regarding SanDisk's and ST's patent portfolios, revenue, and research and development expenses, and listed SanDisk's various "unlicensed activities." Id. This slide show was followed by a four- to five-hour presentation by ST's technical experts, during which they identified and discussed the specific claims of each patent and alleged that they were infringed by SanDisk. According to Thompson, the presentation by ST's technical experts included "mapp[ing] the elements of each of the allegedly infringed claims to the aspects of the accused SanDisk products alleged to practice the elements." Id. Thompson declares that "the experts liberally referred to

[1] To avoid the risk of a declaratory judgment action, ST could have sought SanDisk's agreement to the terms of a suitable confidentiality agreement. The record before us reflects that the parties did not enter into such an agreement. Rather, ST sought to condition its open licensing discussions and the infringement study on adherence to Federal Rule of Evidence 408. That rule expressly relates to evidence of efforts toward compromising or attempting to compromise a claim in litigation and does not prevent SanDisk from relying on the licensing discussions and infringement study to support its claims. See Fed. R. Evid. 408. Furthermore, ST's presentation was made outside the context of litigation, and there is nothing on the record to indicate that it could be properly considered an "offer" to settle a claim which was then in dispute. See, e.g., Deere & Co. v. Int'l Harvester Co., 710 F.2d 1551, 1556-57 (Fed. Cir. 1983).

SanDisk's (alleged) infringement of [ST's] products." Id., slip op. at 5-6. SanDisk's engineer then made a presentation, describing several of SanDisk's patents and analyzing how a semiconductor chip product sold by ST infringes. Id., slip op. at 6.

At the end of the meeting, Jorgenson handed Thompson a packet of materials containing, for each of ST's fourteen patents under discussion, a copy of the patent, reverse engineering reports for certain of SanDisk's products, and diagrams showing how elements of ST's patent claims cover SanDisk's products. According to SanDisk, Jorgenson indicated (in words to this effect):

> I know that this is material that would allow SanDisk to DJ [ST] on. We have had some internal discussions on whether I should be giving you a copy of these materials in light of that fact. But I have decided that I will go ahead and give you these materials.

Id. Jorgenson further told Thompson that "ST has absolutely no plan whatsoever to sue SanDisk." Id. Thompson responded to Jorgenson that "SanDisk is not going to sue you on Monday" and that another meeting might be appropriate. Id.

On September 1, 2004, Jorgenson wrote to Thompson, enclosing copies of ST's general slide presentation from the August meeting and also enclosing a hard copy booklet containing each of the engineering reports "for each claim on all products where ST demonstrated coverage by the 14 ST patents to-date [sic]." Id.; Letter from Jorgenson to Thompson (Sept. 1, 2004). Jorgenson requested that SanDisk provide ST with a copy of SanDisk's presentation and information about the three SanDisk patents presented. On September 8, 2004, Thompson replied by e-mail, confirming receipt of the package from ST, attaching a copy of SanDisk's presentation, indicating it was his "personal feeling . . . that we have got to trust one another during these negotiations," and seeking a non-disclosure agreement. SanDisk, slip op. at 6-7; E-mail from

Thompson to Jorgenson (Sept. 8, 2004). Thompson also wrote "I still owe you the rates quoted." Id.

On September 15, 2004, Thompson again corresponded with Jorgenson, this time by letter, enclosing a confidential version of SanDisk's cross licensing offer, which noted that the offer would expire on September 27, 2004. SanDisk, slip op. at 7; Letter from Thompson to Jorgenson (Sept. 15, 2004). Jorgenson destroyed this confidential offer and did not retain a copy, and, on September 16, 2004, sent Thompson an e-mail requesting that a non-confidential version be sent for ST's consideration. SanDisk, slip op. at 7; E-mail from Jorgenson to Thompson (Sept. 16, 2004). SanDisk refused to send a non-confidential version. Instead, on September 27, 2004, Thompson offered to send another confidential version, or to communicate the offer orally. E-mail from Thompson to Jorgenson (Sept. 27, 2004). Thompson also indicated that SanDisk did not need additional information regarding ST's patents because SanDisk was "quite comfortable with its position" and that it was "time to let our business people talk and see if a peaceful resolution is possible." Id. On September 28, 2004, Jorgenson repeated her request for a written non-confidential version of SanDisk's licensing offer. SanDisk, slip op. at 7-8; E-mail from Jorgenson to Thompson (Sept. 28, 2004). The following day, Thompson e-mailed Jorgenson another confidential version of SanDisk's offer. SanDisk, slip op. at 8.

On October 15, 2004, after several further e-mails and phone calls between the business representatives trying to establish another meeting, SanDisk filed the instant lawsuit. SanDisk alleged infringement of one of its patents and sought a declaratory judgment of noninfringement and invalidity of the fourteen ST patents that had been

discussed during the cross licensing negotiations. On December 3, 2004, ST filed a motion to dismiss SanDisk's declaratory judgment claims for lack of subject matter jurisdiction, maintaining that there was no actual controversy at the time SanDisk filed its complaint.

The district court granted ST's motion to dismiss, holding that no actual controversy existed for purposes of the Declaratory Judgment Act because SanDisk did not have an objectively reasonable apprehension of suit, even though it may have subjectively believed that ST would bring an infringement suit. See id., slip op. at 14. The district court reasoned that "SanDisk has presented no evidence that ST threatened it with litigation at any time during the parties' negotiations, nor has SanDisk shown other conduct by ST rising to a level sufficient to indicate an intent on the part of ST to initiate an infringement action." Id. The district court found that the studied and determined infringement analyses that ST presented to SanDisk did not constitute the requisite "express charges [of infringement] carrying with them the threat of enforcement." Id., slip op. at 14-15. The district court also found that the totality of the circumstances did not evince an actual controversy because ST told SanDisk that it did not intend to sue SanDisk for infringement. Id., slip op. at 15-16. In a footnote, the court indicated that, as an alternative basis for its ruling, even if it did have jurisdiction, it would exercise its discretion and decline to hear the case. Id., slip op. at 17 n.30.

SanDisk appealed the dismissal to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

II. DISCUSSION

A. Standard of Review

For purposes of Article III, this court reviews a dismissal of a patent claim for lack of an actual controversy upon a particular set of facts as a question of law subject to plenary appellate review. Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735 (Fed. Cir. 1988). This court reviews the underlying factual findings for clear error. Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1379 (Fed. Cir. 2004).

B. Analysis

SanDisk argues that the district court erred as a matter of law by requiring an express accusation of patent infringement coupled with an explicit threat of judicial enforcement to support declaratory judgment jurisdiction, and that, under the correct legal standard articulated by this court in Arrowhead, 846 F.2d at 736, the facts of this case illustrate that SanDisk's apprehension of an infringement suit was objectively reasonable. SanDisk asserts that the infringement analysis presented by ST and its experts at the August 27, 2004 licensing meeting constituted an allegation of infringement and that the totality of the circumstances shows that ST's conduct gave rise to an actual case or controversy. SanDisk further points out that negotiations regarding licensing had ceased by the time SanDisk filed its claims for declaratory judgment.

ST counters that the district court applied the correct legal standard and argues that SanDisk ignores the line of cases that have followed and interpreted Arrowhead. ST asserts that the cases following Arrowhead reveal that the bare mention of infringement, particularly during license negotiations, is not sufficient to meet the

standard set forth in Arrowhead. ST asserts that its conduct at the August 27, 2004 licensing meeting was to strengthen its position during licensing negotiations and that, under the totality of the circumstances, SanDisk has not shown that ST's conduct gave rise to declaratory judgment jurisdiction. Moreover, ST argues that the district court did not abuse its discretion when it concluded, as an alternative basis for its ruling, that it would exercise discretion to decline to decide SanDisk's claims.

1. Case or Controversy

The first question we address is whether the facts alleged in this case show that there is a case or controversy within the meaning of the Declaratory Judgment Act, 28 U.S.C. § 2201(a).

The Declaratory Judgment Act provides, in relevant part, that

> [i]n 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). The "actual controversy" requirement of the Declaratory Judgment Act is rooted in Article III of the Constitution, which provides for federal jurisdiction over only "cases and controversies." Thus, our jurisdiction extends only to matters that are Article III cases or controversies.

The Supreme Court, in the context of a patent license dispute, recently examined Article III's case or controversy requirement as it relates to the Declaratory Judgment Act. See MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007). In MedImmune, the Supreme Court considered "whether Article III's limitation of federal courts' jurisdiction to 'Cases' and 'Controversies,' reflected in the 'actual controversy' requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires a patent

licensee to 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. at 767.

The Supreme Court began its analysis

> with the recognition that, where threatened action by government is concerned, [the Court] do[es] not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat—for example, the constitutionality of a law threatened to be enforced. The plaintiff's own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction.

Id. at 772. The Supreme Court quoted its earlier decision in Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941), where the Court stated that "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, 127 S. Ct. at 771. The Supreme Court emphasized that Article III requires that the dispute at issue 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 state of facts.'" Id. (quoting Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240–41 (1937)). The Supreme Court stated that, when faced with a genuine threat of enforcement that the government will penalize a certain private action, Article III "d[oes] not require, as a prerequisite to testing the validity of the law in a suit for injunction, that the plaintiff bet the farm, so to speak, by taking the violative action." Id. at 772 (citations omitted). As the Supreme

Court noted, "the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity." Id. (quotation marks omitted). The Supreme Court clarified that, although a declaratory judgment plaintiff may eliminate an "imminent threat of harm by simply not doing what he claimed the right to do[,] . . . [t]hat did not preclude subject-matter jurisdiction [where] the threat-eliminating behavior was effectively coerced." Id. "The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." Id. at 773 (internal quotation marks omitted).

The Supreme Court then applied these principles to the facts of the case and remarked that "the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim." Id. (internal quotation marks omitted). The Supreme Court held that "[t]he rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III." Id. at 775.

With regard to patent disputes, prior to MedImmune, this court articulated a two-part test that first considers whether conduct by the patentee creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and second examines whether conduct by the declaratory judgment plaintiff amounts to infringing activity or demonstrates concrete steps taken with the

intent to conduct such activity. See Arrowhead, 846 F.2d at 736. The Supreme Court, in MedImmune, addressed the "reasonable apprehension of suit" aspect of this court's two-part test and concluded that it conflicts with Aetna Life Insurance and Maryland Casualty, and is in tension with Cardinal Chemical Co. v. Morton International, Inc., 508 U.S. 83, 98 (1993). See MedImmune, 127 S. Ct. at 774 n.11.

In Aetna Life Insurance, an insurer sought a declaratory judgment that the insured was not relieved of his duty to continue to pay insurance premiums and that, since the insured had stopped making the payments, the insurance policy had lapsed. In that case, the Supreme Court first upheld the constitutionality of the federal Declaratory Judgment Act. 300 U.S. at 240-41. The Supreme Court then held that, although the insured party gave no indication that he would file suit, id. at 239, the case nevertheless presented a controversy under Article III because the parties had taken adverse positions with regard to their obligations, each side presenting a concrete claim of a specific right—the insured claiming that he had become disabled and therefore was relieved of making insurance premium payments and the insurer claiming that the insured was not disabled and that the failure to make payments caused the policy to lapse, id. at 244. Similarly, in Maryland Casualty, the declaratory judgment plaintiff, an insurance company which had agreed to indemnify and defend the insured against actions brought by third parties against the insured, sought a declaration that it had no duty to defend or to indemnify the insured. 312 U.S. at 272. In that case, the insured could not have sued the declaratory judgment plaintiff without first obtaining a judgment against the third party and the underlying action against the third party "[a]pparently . . . ha[d] not proceeded to judgment." Id. at 271. Nevertheless, the Supreme Court held

that "[i]t is clear that there is an actual controversy between petitioner and the insured" since the insured was in the process of seeking a judgment and had a statutory right to proceed against the declaratory judgment plaintiff if such judgment were obtained and not satisfied. Id. at 274. Finally, in Cardinal Chemical, the Supreme Court held that this court's affirmance of a judgment of noninfringement does not necessarily moot a declaratory judgment counterclaim of patent invalidity. 508 U.S. at 98. The Supreme Court's rationale for holding that the declaratory judgment action can proceed consistent with Article III was that a contrary result would create the potential for relitigation or uncertainty with regard to the validity of patents and would be contrary to Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313 (1971).

The Supreme Court's opinion in MedImmune represents a rejection of our reasonable apprehension of suit test.[2] The Court first noted that "the continuation of royalty payments makes what would otherwise be an imminent threat at least remote, if not nonexistent. . . . Petitioner's own acts, in other words, eliminate the imminent threat of harm." MedImmune, 127 S. Ct. at 772. The Court nonetheless concluded that declaratory judgment jurisdiction existed relying in particular on its earlier decision in Altvater v. Freeman, 319 U.S. 359 (1943). There, the patentee brought suit to enjoin patent infringement, and the accused infringer filed declaratory judgment counterclaims of invalidity. The district court found that there was no infringement and that the patent was invalid. Id. at 362. The appellate court affirmed the finding of noninfringement but vacated the finding of invalidity as moot. Id. The Supreme Court held that the

[2] In this case, we address only the first prong of this court's two-part test. There is no dispute that the second prong is met. We therefore leave to another day the effect of MedImmune, if any, on the second prong.

declaratory judgment counterclaims were not mooted by the finding of noninfringement. Id. at 365-66. In finding declaratory judgment jurisdiction in MedImmune, the Court specifically addressed and rejected our reasonable apprehension test:

> [e]ven if Altvater could be distinguished as an "injunction" case, it would still contradict the Federal Circuit's "reasonable apprehension of suit" test (or, in its evolved form, the "reasonable apprehension of imminent suit" test, Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 239 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83, 98 (1993), which held that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.

MedImmune, 127 S. Ct. at 774 n.11.

The Supreme Court in MedImmune addressed declaratory judgment jurisdiction in the context of a signed license. In the context of conduct prior to the existence of a license, declaratory 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. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the

application of the principles of declaratory judgment jurisdiction to the facts and circumstances of each case. We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights. See id. Contra Cygnus Therapeutics Sys. v. ALZA Corp., 92 F.3d 1153 (Fed. Cir. 1996) (holding that declaratory judgment jurisdiction was not supported where the "patentee does nothing more than exercise its lawful commercial prerogatives and, in so doing, puts a competitor in the position of having to choose between abandoning a particular business venture or bringing matters to a head by engaging in arguably infringing activity").

Our holding is consistent with decisions of other courts in various cases unrelated to patent licensing. See, e.g., Bancroft & Masters, Inc. v. Augusta Nat'l Inc., 223 F.3d 1082, 1085 (9th Cir. 2000) (finding declaratory judgment jurisdiction based on trademark owner's cease and desist letter despite the fact that trademark owner offered to waive all trademark infringement and related claims); GNB Battery Tech., Inc. v. Gould, Inc., 65 F.3d 615, 620 (7th Cir. 1995) (finding declaratory judgment jurisdiction where declaratory judgment plaintiff filed action in anticipation of potential action by the defendant based on new legislation although the defendant had not indicated whether or when it may act); Kunkel v. Cont'l Cas. Co., 866 F.2d 1269, 1274 (10th Cir. 1989) (affirming exercise of declaratory judgment jurisdiction over suit seeking declaratory judgment for determination of value of insurance coverage even though existence of

coverage remained dependent upon the outcome of a collateral action and noting that "[t]he contingent nature of the right or obligation in controversy will not bar a litigant from seeking declaratory relief when the circumstances reveal a need for present adjudication"); see also IMS Health, Inc. v. Vality Tech. Inc., 59 F. Supp. 2d 454 (E.D. Pa. 1999) (holding that requirements for declaratory judgment jurisdiction were satisfied where copyright holder had not indicated it was going to file suit but had taken positions and made demands such that the declaratory judgment plaintiff justifiably believed that copyright holder might take such action in the future and noting that "[i]t is quite possible for two parties to simultaneously consider nonlitigious settlement of a dispute, while at the same time maintaining an awareness that either settlement is improbable or that litigation is equally likely"); N. Shore Gas Co. v. Salomon, Inc., 896 F. Supp. 786, 789-90 (N.D. Ill. 1995) (finding declaratory judgment jurisdiction where plaintiff, "rather than wait an indefinite time to be sued," filed suit after the settlement discussions came to an impasse); J. Lyons & Co. Ltd. v. Republic of Tea, Inc., 892 F. Supp. 486 (S.D.N.Y. 1995) (dismissing trademark holder's later-filed infringement action in favor of previously filed declaratory judgment actions where declaratory judgment plaintiffs had received cease and desist letters and no settlement appeared agreeable, despite the fact that trademark holder did not give actual notice of litigation); Kmart Corp. v. Key Indus., Inc., 877 F. Supp. 1048, 1055 (E.D. Mich. 1994) (holding that ongoing settlement negotiations did not require dismissal of declaratory judgment action where the evidence indicated that the trademark holder would accept no settlement short of total capitulation); Agridyne Tech., Inc. v. W.R. Grace & Co., 863 F. Supp. 1522 (D. Utah

1994) (refusing to dismiss declaratory judgment action where plaintiff justifiably believed that further settlement negotiations would be fruitless).

Under the facts alleged in this case, SanDisk has established an Article III case or controversy that gives rise to declaratory judgment jurisdiction. ST sought a right to a royalty under its patents based on specific, identified activity by SanDisk. For example, at the August 27, 2004 licensing meeting, ST presented, as part of the "license negotiations," a thorough infringement analysis presented by seasoned litigation experts, detailing that one or more claims of its patents read on one or more of SanDisk's identified products. At that meeting, ST presented SanDisk with a detailed presentation which identified, on an element-by-element basis, the manner in which ST believed each of SanDisk's products infringed the specific claims of each of ST's patents. During discussions, the experts liberally referred to SanDisk's present, ongoing infringement of ST's patents and the need for SanDisk to license those patents. ST also gave SanDisk a packet of materials, over 300 pages in length, containing, for each of ST's fourteen patents under discussion, a copy of the patent, reverse engineering reports for certain of SanDisk's products, and diagrams showing a detailed infringement analysis of SanDisk's products. ST communicated to SanDisk that it had made a studied and determined infringement determination and asserted the right to a royalty based on this determination. SanDisk, on the other hand, maintained that it could proceed in its conduct without the payment of royalties to ST. These facts evince that the conditions of creating "a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" were fulfilled. Md. Cas., 312 U.S. at 273. SanDisk need not "bet

the farm," so to speak, and risk a suit for infringement by cutting off licensing discussions[3] and continuing in the identified activity before seeking a declaration of its legal rights. See MedImmune, 127 S. Ct. at 774 n.11. Contra Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051 (Fed. Cir. 1995) ("When there are proposed or ongoing license negotiations, a litigation controversy normally does not arise until the negotiations have broken down.").

2. Promise Not to Sue

We next address whether Jorgenson's direct and unequivocal statement that "ST has absolutely no plan whatsoever to sue SanDisk" eliminates any actual controversy and renders SanDisk's declaratory judgment claims moot.

We decline to hold that Jorgenson's statement that ST would not sue SanDisk eliminates the justiciable controversy created by ST's actions, because ST has engaged in a course of conduct that shows a preparedness and willingness to enforce its patent rights despite Jorgenson's statement. Having approached SanDisk, having made a studied and considered determination of infringement by SanDisk, having communicated that determination to SanDisk, and then saying that it does not intend to sue, ST is engaging in the kinds of "extra-judicial patent enforcement with scare-the-customer-and-run tactics" that the Declaratory Judgment Act was intended to obviate. Arrowhead, 846 F.2d at 735. ST's statement that it does not intend to sue does not moot the actual controversy created by its acts. See Md. Cas., 312 U.S. at 273

[3] Although the district court found that licensing negotiations had not been terminated, we note that SanDisk in fact declined to participate in further negotiations, effectively bringing them to an end. Regardless, however, a party to licensing negotiations is of course within its rights to terminate negotiations when it appears that they will be unproductive.

(jurisdiction obtained even though the defendant could not have sued the declaratory judgment plaintiff).

3. District Court's Discretion

Although the district court is given the discretion, in declaratory judgment actions, to dismiss the case, there are boundaries to that discretion. See Wilton v. Seven Falls Co., 515 U.S. 277, 289 (1995). "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal." Genentech v. Eli Lilly & Co., 998 F.2d 931, 937 (Fed. Cir. 1993). Furthermore, the exercise of discretion must be supported by a sound basis for refusing to adjudicate an actual controversy. See Elecs. for Imaging, Inc. v. Coyle, 394 F.3d 1341, 1345 (Fed. Cir. 2005); Capo, Inc. v. Dioptics Med. Prod., Inc., 387 F.3d 1352, 1357 (Fed. Cir. 2004).

In this case, the district court noted, without explanation in a footnote, that "[a]s an alternative basis for its ruling, the Court concludes that even if it had subject matter jurisdiction over the instant claims, it would exercise its discretion and decline to decide them." SanDisk, slip op. at 17 n.30. That decision, however, was made in the context of our "reasonable apprehension" precedent without the benefit of the Supreme Court's views in MedImmune. Given the change reflected in MedImmune and our holding in this case, we discern little basis for the district court's refusal to hear the case and expect that in the absence of additional facts, the case will be entertained on the merits on remand.

CONCLUSION

For the above reasons, we conclude that the dismissal was improperly granted. The dismissal is vacated, and the case is remanded for further proceedings consistent with this opinion.

VACATED and REMANDED

COSTS

Costs are awarded to SanDisk.

United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.

BRYSON, Circuit Judge, concurring in the result.

Under our law, as things stood before the Supreme Court's decision in MedImmune, the district court's order in this case was correct. ST, the patentee, had offered a license to SanDisk, but had not threatened suit and had sought to continue licensing negotiations. Although ST had made a detailed showing as to why it believed SanDisk's products were within the scope of its patent rights, there is nothing exceptional in that. In the typical case, we would expect competent patent counsel who offers a license to another party to be prepared to demonstrate why such a license is required. By the time the suit was brought, ST had done nothing to give SanDisk cause to be in reasonable apprehension of suit, and in fact ST had expressly stated that it did not intend to sue SanDisk. In short, ST was simply availing itself of the safe haven our

cases had created for patentees to offer licenses without opening themselves up to expensive litigation. See, e.g., Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1054 (Fed. Cir. 1995); Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 888 (Fed. Cir. 1992).

The decision in MedImmune dealt with a narrow issue: whether a declaratory judgment action can be brought by a patent licensee without terminating the licensing agreement. Footnote 11 of the MedImmune opinion, however, went further and criticized this court's "reasonable apprehension of suit" test for declaratory judgment jurisdiction. I agree with the court that the footnote calls our case law into question and would appear to make declaratory judgments more readily available to parties who are approached by patentees seeking to license their patents. In particular, the reasoning of the MedImmune footnote seems to require us to hold that the district court in this case had jurisdiction to entertain SanDisk's declaratory judgment action. For that reason I concur in the judgment of the court in this case reversing the jurisdictional dismissal of the complaint.

I think it is important, however, to point out the implications of the footnote in MedImmune as applied here, because the implications are broader than one might suppose from reading the court's opinion in this case. While noting that it is not necessary to define the outer boundaries of declaratory judgment jurisdiction, the court holds that "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license," the party may bring a declaratory judgment action. Applying that principle, the court concludes that in this

case, where "ST sought a right to a royalty under its patents based on specific, identified activity by SanDisk," an Article III case or controversy has arisen.

In practical application, the new test will not be confined to cases with facts similar to this one. If a patentee offers a license for a fee, the offer typically will be accompanied by a suggestion that the other party's conduct is within the scope of the patentee's patent rights, or it will be apparent that the patentee believes that to be the case. Offers to license a patent are not requests for gratuitous contributions to the patentee; the rationale underlying a license offer is the patentee's express or implied suggestion that the other party's current or planned conduct falls within the scope of the patent. Therefore, it would appear that under the court's standard virtually any invitation to take a paid license relating to the prospective licensee's activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent. Indeed, as the court makes clear, even a representation by the patentee that it does not propose to file suit against the prospective licensee will not suffice to avoid the risk that the patentee will face a declaratory judgment action. And if there is any uncertainty on that score, all the prospective licensee has to do in order to dispel any doubt is to inquire of the patentee whether the patentee believes its activities are within the scope of the patent. If the patentee says "no," it will have made a damaging admission that will make it very hard ever to litigate the issue, and thus will effectively end its licensing efforts. If it says "yes" or equivocates, it will have satisfied the court's test and will have set itself up for a declaratory judgment lawsuit.

For these reasons, I see nothing about the particular facts surrounding this licensing negotiation in this case that triggers SanDisk's right to bring a declaratory judgment action under the new standard. The court emphasizes that ST made a "detailed presentation [to SanDisk] which identified, on an element-by-element basis, the manner in which ST believed each of SanDisk's products infringed the specific claims of each of ST's patents." The court summarizes ST's presentation by stating that "ST communicated to SanDisk that it had made a studied and determined infringement determination and asserted a right to a royalty based on this determination" and that SanDisk "maintained that it could proceed in its conduct without the payment of royalties to ST." Those facts, the court concludes, evinced a sufficient controversy to entitle SanDisk to institute its declaratory judgment suit.

But what is the significance of those facts? The court's legal test does not suggest that the case would come out differently if ST had been less forthcoming about why it believed SanDisk should take a license, or even if ST had simply contacted SanDisk, provided copies of its patents, and suggested that SanDisk consider taking a license. I doubt the court would hold that there was no controversy in that setting, as long as SanDisk was prepared to assert that it believed its products were not within the scope of ST's valid patent rights. If SanDisk's lawyers had any question about whether this court would permit them to seek a declaratory judgment under those circumstances, they could readily resolve that question by sending a "put up or shut up" response to ST's licensing offer—asking ST to state expressly whether it regarded SanDisk's products to be within the scope of ST's patents and to identify with particularity how

SanDisk's products read on particular claims of those patents. Any response by ST would either end its licensing efforts or expose it to a declaratory judgment action.[1]

In sum, the rule adopted by the court in this case will effect a sweeping change in our law regarding declaratory judgment jurisdiction. Despite the references in the court's opinion to the particular facts of this case, I see no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the patentee. Although I have reservations about the wisdom of embarking on such a course, I agree with the court that a fair reading of footnote 11 of the Supreme Court's opinion in MedImmune compels that result, and I therefore concur in the judgment reversing the district court's dismissal order in this case.[2]

---

[1] The court suggests that ST could have avoided the risk of a declaratory judgment action by obtaining a suitable confidentiality agreement. The problem with that suggestion is that it would normally work only when it was not needed—only a party that was not interested in bringing a declaratory judgment action would enter into such an agreement. A party that contemplates bringing a declaratory judgment action or at least keeping that option open would have no incentive to enter into such an agreement.

[2] Although I agree that the judgment must be reversed, I take issue with the scope of the remand insofar as it applies to the district court's exercise of its discretion to decline to entertain this action as a discretionary matter. I would allow the district court to reconsider that issue based on all the circumstances, not just "additional facts" not previously before the district court, as the terms of this court's remand seem to require. Thus, for example, the fact that the parties are engaged in a parallel infringement action in another district court is an important factor in the district court's decision on whether to allow SanDisk's declaratory suit to proceed at this time. See Intermedics Infusaid, Inc. v. Regents of Univ. of Minn., 804 F.2d 129 (Fed. Cir. 1986) (pending action in another jurisdiction is sufficient ground on which to stay declaratory suit). The district court should be free on remand to consider that factor in determining how to exercise its discretion, even though the pendency of that parallel action is not an "additional fact" that was not before the court at the time of its earlier decision.

Exhibit 1.

STMicroelectronics, Inc.
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Carrollton, TX 75006
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Lisa K. Jorgenson
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April 16, 2004

VIA FACSIMILE
408-542-0503

Dr. Eli Harari
SanDisk Corporation
140 Caspian Court
Sunnyvale, CA. 94089

Dear Dr. Harari,

Due to our respective activities in the field of semiconductor memory products, and STMicroelectronics' ("ST's") announced entry in the market for NAND Flash products, we believe that it is in the respective best interests of ST and SanDisk to negotiate a broad patent cross license agreement, to provide each of us the freedom to design and compete in the market place.

In this respect we would like to set up a meeting during the week of May 3rd to begin discussions concerning such a license.

In anticipation of such a meeting we would like to inform you that ST has started a review of its patent portfolio among which it has currently identified at least the following patents which we believe may be of interest to SanDisk:

4,839,768 – 5,073,816 – 5,175,706 – 5,455,954 – 5,589,762 – 5,793,679 – 6,100,581 – 6,163,487.

We fully expect that at our planned meeting you will also present certain SanDisk patents which you consider could be of interest to ST.

We look forward to open and frank discussions with SanDisk concerning fair and reasonable terms for a broad patent cross license agreement, and would like to agree on a date and location for such discussions as soon as possible.

Thank you in advance for your kind consideration of this matter and prompt response.

Sincerely,

Lisa K. Jorgenson

Lisa K. Jorgenson
Vice President
Intellectual Property and Licensing

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.

Henry C. Dinger, Goodwin Procter LLP, of Boston, Massachusetts, argued for plaintiff-appellant. With him on the brief were Shepard M. Remis and Roland H. Schwillinski. Of counsel on the brief were Allyn Z. Lite and Michael E. Patunas, of Lite Depalma Greenberg & Rivas, LLC, of Newark, New Jersey.

Hugh C. Barrett, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for defendants-appellees. With him on the brief were Robert L. Baechtold, Nicholas N. Kallas, and Simon D. Roberts.

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

Judge Jose L. Linares

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.

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.
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> 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.