IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD.	)	
Plaintiffs,	)	
v.	)	Civil Action No. 07-138 (JJF)
RANBAXY LABORATORIES LIMITED, and RANBAXY INC.	)	
Defendants.	)	

PFIZER'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1), RANBAXY'S COUNTERCLAIMS WITH RESPECT TO THE '995 PATENT

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I. INTRODUCTION

Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, C.P. Pharmaceuticals International C.V., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Limited, (collectively referred to as "Pfizer") have moved pursuant to Federal Rule of Civil Procedure 12(b)(1) to dismiss defendants/counterclaimants' Ranbaxy Laboratories Limited ("RLL") and Ranbaxy Inc. ("RI") (collectively "Ranbaxy") Fourth, Fifth, Sixth and Seventh Counterclaims with respect to United States Letters Patent No. 5,273,995 ("the '995 patent") for lack of subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Claim 6 of the '995 patent was held to be invalid by the Federal Circuit in prior litigation. Pfizer has provided a covenant not to sue to Ranbaxy on all remaining claims of the '995 patent. See Exhibit "A" hereto. Therefore, there is no justiciable case or controversy and no declaratory judgment jurisdiction over these counterclaims. They should be dismissed.

II. NATURE AND STAGE OF THESE PROCEEDINGS

In this patent infringement action, Pfizer sued Ranbaxy on two patents, United States Letters Patents Nos. 4,681,893 ("the '893 patent") and 6,455,574 ("the '574 patent"). The '893 patent issued on July 21, 1987, on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company. The '893 patent claims a genus of chemical compounds which embrace atorvastatin calcium. The '574 patent, entitled "Therapeutic Combination", issued on September 24, 2002, on an application filed by Jan Buch and assigned to Pfizer Inc.

Ranbaxy filed an amended answer and counterclaims (D.I. 10) (hereinafter "Ans.") seeking a declaration of invalidity of the '893 patent and its term extension, and a declaration

of invalidity and non-infringement of the '574 patent. Ranbaxy also counterclaimed seeking a declaration of non-infringement, invalidity and/or unenforceability of the '995 patent.

This is Pfizer's opening brief in support of its motion to dismiss Ranbaxy's counterclaims directed to the '995 patent.

III. STATEMENT OF FACTS[1]

A. Ranbaxy's New ANDA Directed To Caduet®

Pfizer is the owner of record of the '893, '574 and '995 patents. Pfizer, through Parke-Davis Pharmaceutical Research, a division of Warner-Lambert Company, holds an approved New Drug Application ("NDA") for a formulation containing atorvastatin calcium, which it sells in the United States under the registered name Lipitor®. Comp. ¶ 26. Pfizer also holds an approved NDA for a formulation containing the active ingredient amlodipine besylate which it sells in the United States under the registered name Norvasc®. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1352 (Fed. Cir. 2007); *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004). Additionally, Pfizer holds an approved NDA for a formulation containing both active ingredients amlodipine besylate and atorvastatin calcium, which it sells in the United States under the registered name Caduet®. Comp. ¶ 16; Orange Book, Patent and Exclusivity Addendum, ADA pp. 5-6.[2] The '893 and '574 patents are identified pursuant to 21 U.S.C. § 355(b)(1) by the United States Food and Drug Administration ("FDA") as covering

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[1] Unless otherwise indicated, all facts are taken from uncontested facts in the Complaint (D.I. 1) (hereinafter "Comp. ¶__") or as alleged in Ranbaxy's Amended Answer and Counterclaims (D.I. 10) (hereinafter "Ans. ¶__").

[2] U.S. Dept. of Health and Human Servs., Food and Drug Admin., Center for Drug Evaluation and Res., Office of Pharmaceutical Science, Office of Generic Drugs, Patent and Exclusivity Addendum, *Approved Drug Products with Therapeutic Equivalence Evaluations*, (27th ed. 2007) (the "Orange Book"), Patent and Exclusivity Addendum.

Pfizer's Caduet® product. Comp. ¶¶ 17, 18; Orange Book, Patent and Exclusivity Addendum, ADA pp. 6-8.

The present litigation was precipitated by Ranbaxy's letter notice dated January 24, 2007 to Pfizer stating that Ranbaxy had filed an Abbreviated New Drug Application ("ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing amlodipine besylate and atorvastatin calcium as the active ingredients ("Ranbaxy's New ANDA Product") prior to the expiration of the '893, '995 and '574 patents. Comp. ¶ 57; Ans. ¶ 57. RI is a wholly-owned subsidiary of RLL (Comp. ¶ 22; Ans. ¶ 22), as is Ranbaxy Pharmaceuticals, Inc ("RPI").

B. The Prior Litigation Involving Lipitor®

Pfizer received letters dated January 23, 2003 from RPI (the "January 23, 2003 letters") which notified Pfizer that RLL had filed ANDA No. 76-477, seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium as its active ingredient ("Ranbaxy's Atorvastatin Product") prior to the expiration of the '893 and '995 patents. Comp. ¶ 27; Ans. ¶ 27. Pursuant to 35 U.S.C. § 271(e)(2), Pfizer filed suits against RLL and RPI in this Court alleging that Ranbaxy's proposed ANDA product infringed the '893 and '995 patents. Ans. ¶ 95. Pfizer's Complaints were consolidated into Civil Action No. 03-209-JJF (collectively the "Lipitor® Litigation"). Ans. ¶ 95. In response to Pfizer's Complaints, Ranbaxy filed an answer and several counterclaims, which averred, *inter alia*, that it did not infringe the '995 patent, and which challenged the validity and enforceability of the '995 patent.

Ultimately, Pfizer granted to Ranbaxy a covenant not to sue with respect to **all** claims of the '995 patent except claim 6. Ans. ¶ 96. The covenant not to sue was

attached to the stipulation and order signed by the Court on November 17, 2004 (D.I. 255). That stipulation and order, *inter alia*, dismissed all of Ranbaxy's counterclaims relating to the '995 patent except claim 6. Thus, only the validity, enforceability and infringement of Claim 6 was at issue.

In an opinion dated December 16, 2005 in the Lipitor® Litigation (D.I. 327), this Court held that Claim 6 of the '995 patent was not invalid or unenforceable. The Court also held that Ranbaxy's Atorvastatin Product, the subject of ANDA No. 76-477, literally infringed claim 6 of the '995 patent. Ans. ¶ 97.

Ranbaxy appealed the decision in the Lipitor® Litigation to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") in Appeal No. 06-1179 (the "Lipitor® Appeal"). Comp. ¶ 46; Ans. ¶ 46. In the Lipitor® Appeal, the Federal Circuit determined that claim 6 of the '995 patent was invalid pursuant to the provisions of 35 U.S.C. § 112, ¶ 4. Ranbaxy filed a Petition for Rehearing and Rehearing En Banc and the Federal Circuit denied that petition. Comp. ¶ 49; Ans. ¶ 49. Ranbaxy then sought certiorari in the United States Supreme Court from the decision of the Federal Circuit in the Lipitor® Appeal. *Ranbaxy Laboratories Limited v. Pfizer Inc.*, No. 06-1016, 2007 WL 957312 (U.S. Apr. 2, 2007). On April 2, 2007, the Supreme Court denied Ranbaxy's petition. *Id.*

An amended final judgment was entered by the Court in the Lipitor Litigation, by Orders of the Court dated November 7, 2006 and November 30, 2006. Comp. ¶ 50; Ans. ¶ 50; (D.I. 338 and 344). The Judgment held claim 6 of the '995 patent invalid for failure to comply with 35 U.S.C. § 112, ¶ 4 and entered judgment in favor of Ranbaxy and against Pfizer on Ranbaxy's counterclaims alleging invalidity of claim 6 of the '995 Patent. *Id.*

Despite the fact that claim 6 was held invalid, that Ranbaxy has been provided a covenant not to sue on all remaining viable claims of the '995 patent, and that Ranbaxy itself recognizes that the '995 patent is in reissue before the PTO, it nonetheless now seeks a declaratory judgment that the '995 patent is not infringed, invalid and unenforceable.

IV. SUMMARY OF ARGUMENT

1. Because Pfizer has covenanted not to sue Ranbaxy on all claims of the '995 patent except claim 6, which has been held invalid, this Court has no jurisdiction over Ranbaxy's counterclaims relating to the '995 patent as there is no justiciable case or controversy.

2. The fact that Pfizer has filed an application for reissue of the '995 patent does not create a justiciable case or controversy permitting Ranbaxy to challenge the validity, enforceability and infringement of the '995 patent.

V. ARGUMENT

A. Legal Standards

1. Federal Rule of Civil Procedure 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter. Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to the Court's subject matter jurisdiction. In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. In this regard, the Court must accept all factual allegations in the Complaint as true, and the Court may only consider the complaint and documents referenced in or attached to the complaint. *Gould Electronics Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). However, the Court may consider "document[s] integral to or explicitly

relied upon in the complaint" without converting a motion to dismiss into a motion for summary judgment. *In re Rockefeller Center Properties, Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Judicial notice of public records outside the pleadings is also permitted on a motion to dismiss. *Adkins v. Rumsfeld,* 450 F. Supp. 2d 440, 444 (D. Del. 2006).

In reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to the allegations in the complaint. *Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997). Once the Court's subject matter jurisdiction over a complaint is challenged, the counterclaim plaintiff, here Ranbaxy, bears the burden of proving that jurisdiction exists. *Mortensen*, 549 F.2d at 891.

2. The Declaratory Judgment Act

The relevant text of the Declaratory Judgment 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).

Under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), jurisdiction over a declaratory judgment action exists only when there is an "actual controversy." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937) (declaratory judgment jurisdiction at any stage of litigation is limited to "the determination of controversies to which under the

Constitution the judicial power extends"). In other words, the "actual controversy" requirement refers to "Cases and Controversies" that are justiciable under Article III. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007). "Whether an actual controversy exists upon particular facts is a question of law...." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). The declaratory judgment plaintiff (or counterclaimant) carries the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy. *Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984); *Benitec Australia Ltd. v. Nucleonics, Inc.*, 2005 WL 2415959 at *3 (D. Del. 2005), *appeal pending*, No. 06-1122 (Fed. Cir. 2005). As the party seeking declaratory relief, Ranbaxy bears the burden to demonstrate that the court has jurisdiction over its declaratory judgment action. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991).

Within the context of ANDA litigation, Congress has enacted legislation granting subject matter jurisdiction, "to the extent consistent with the Constitution" in an action by an ANDA applicant who is not sued by the owner of a patent listed in the Orange Book or the NDA holder after a paragraph IV notice is given for that patent. 35 U.S.C. § 271(e)(5). Thus, the issue here is whether the exercise of jurisdiction over Ranbaxy's counterclaims relating to the '995 patent comports with Article III of the Constitution.

3. The *MedImmune* Decision

The test for a justiciable controversy enunciated by the Supreme Court in *MedImmune* and followed by the Federal Circuit in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, No. 06-1181, 2007 WL 942201 at *5 (Fed. Cir. Mar. 30, 2007) "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." Quoting *MedImmune,* 127 S. Ct. at 766; *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *Teva Pharms. USA, Inc. v. Novartis*, *supra* at *5.[3]

In *MedImmune*, the Supreme Court also stated that Article III requires:

> that the 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 state of the facts."

127 S. Ct. at 771 (citation omitted).

In *Sandisk Corp. v. STMicroelectronics, Inc.,* the Federal Circuit described the test for the existence of declaratory judgment jurisdiction as follows:

> [W]here 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.

480 F.3d 1372, 1381 (Fed. Cir. 2007).

This test looks for: (1) an assertion of patent rights; (2) based on identified

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[3] Under the long standing test for an actual controversy in the patent context, the Federal Circuit had previously established: "[t]here must be 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, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *BP*, 4 F.3d at 978; *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1373 (Fed. Cir. 2004). However, two recent panel decisions by the Federal Circuit have abrogated in whole or part this test, "[i]n light of the Supreme Court's recent decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007)." *Teva Pharms. USA, Inc. v. Novartis,* 2007 WL 942201, at *1; *Sandisk Corp. v. STMicroelectronics, Inc.,* 480 F.3d 1372 (Fed. Cir. 2007).

ongoing or planned activity; and (3) a contention of the right to engage in the accused activity without a license.

A justiciable controversy also requires that the party instituting the action have standing. 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." *Teva*, at *3 (*quoting Allen v. Wright*, 468 U.S. 737, 751 (1984)). Injury-in-fact is a widely-used test for standing, and such injury must be "personal", "concrete and particularized" and "actual or imminent". *Id.* (*citing Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560 (1992); *Warth v. Seldin*, 422 U.S. 490, 501 (1975)).

Additionally, under Article III the case must be ripe for judicial review. *Id.* The ripeness doctrine "focuses on the conduct of the defendant to determine whether the defendants actions have harmed, are harming, or are about to harm the plaintiff." *Id.* A controversy is ripe if the question is "fit for judicial review". *Id.*

Lastly, advisory opinions are prohibited. In other words, federal courts are "'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.'" *Id.* at *4 (*quoting Local No. 8-6, Oil, Chem. & Atomic Workers Int'l, Union v. Missouri*, 361 U.S. 363, 367 (1960).

B. The Court Lacks Subject Matter Jurisdiction Over Ranbaxy's Counterclaims Directed to the '995 Patent

Ranbaxy's counterclaims with respect to the '995 patent do not present a justiciable controversy under any of the foregoing requirements of Article III, and therefore, this Court lacks jurisdiction under the Declaratory Judgment Act. First, '995 Claim 6, which directly claims the active ingredient atorvastatin calcium, has been declared invalid, and the remaining claims of the '995 patent, to the extent they claim

Ranbaxy's New ANDA Product, are the subject of a covenant not to sue. See Exhibit "A". Second, the possibility that the '995 patent might reissue does not confer jurisdiction over a declaratory judgment claim of invalidity, unenforceability or non-infringement of the '995 patent.

1. Claim 6 Has Been Held Invalid And There Is No Case Or Controversy Over the Remaining '995 Claims

Further litigation over claim 6 is impossible. As Ranbaxy acknowledged in its counterclaims, the Federal Circuit has declared Claim 6 invalid. Ans. ¶ 98. This judgment is final and unappealable. Under the doctrine established by the Supreme Court in *Blonder-Tounge Labs., Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971), collateral estoppel bars any further enforcement of Claim 6 of the '995 patent. *Id.* at 350.

The claims of the '995 patent other than claim 6 are also not at issue between the parties. While Ranbaxy itself implies that these remaining claims are barred by Pfizer's prior covenant not to sue, contained in a stipulation and order in the prior Lipitor® Litigation (D.I. 255), Ans. ¶ 96, Pfizer has provided Ranbaxy with a new covenant not to sue making it quite clear that all remaining '995 claims will not be asserted against Ranbaxy's New ANDA Product. See Exhibit "A". Indeed, Pfizer has never asserted otherwise. And Pfizer has never threatened Ranbaxy with enforcement of the '995 patent against its New ANDA Product or any other product following the judgment of invalidity by the Federal Circuit. This is precisely the situation contemplated by the Federal Circuit in the *Teva* case in quoting from the legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which enacted 35 U.S.C. § 271(e)(5):

> "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."

Teva Pharms. USA, Inc. v. Novartis, 2007 WL 942201, at *9, *quoting* 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).

In short, there is no case or controversy between the parties relating to any of the claims of the '995 patent. *See, e.g., Microchip Technology Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 492 (Fed. Cir. 2006) (covenant-not-to-sue obviates declaratory judgment jurisdiction); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995) (same).

Moreover, Pfizer's listing of the '995 patent in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") "under all the circumstances", cannot create a present case or controversy over Ranbaxy's New ANDA Product. The Federal Circuit's decision in *Teva Pharmaceuticals USA, Inc. v. Novartis*, determined only that the initiation of a 35 U.S.C. § 271(e)(2) infringement action on a patent listed in the Orange Book could under the "all the circumstances" of that case establish declaratory judgment jurisdiction over additional patents listed in the Orange Book but upon which suit was not brought. However, the *Teva* decision cannot be read to establish declaratory judgment jurisdiction here, because a covenant not to sue has been granted on all claims but claim 6, and Claim 6 has been adjudicated invalid. In contrast, Novartis had refused to provide a covenant to Teva. *Id.* at *2.

Unlike the situation in *Teva*, it cannot be credibly argued that Pfizer has "tried to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities." *Id.* at *9. Pfizer has not chosen to postpone suit on the listed '995 patent for tactical reasons. Ranbaxy cannot be uncertain as to whether Pfizer could assert the listed '995 patent at some future time.

Pfizer has unequivocally and unambiguously covenanted not to sue Ranbaxy on the valid claims of the '995 patent.

2. Ranbaxy Cannot Manufacture A Case Or Controversy Based On A Possible Reissue Patent Derived From The '995 Patent

Ranbaxy alleges that: (1) Pfizer has publicly stated it will seek to correct a "technical defect" under which the Federal Circuit invalidated claim 6, Ans. ¶ 99; (2) Pfizer has filed an application seeking to reissue the '995 patent, *id.* ¶ 100; (3) Pfizer previously asserted the '995 patent against Ranbaxy in the Lipitor® Litigation and has asserted foreign counterparts to the '995 patent against Ranbaxy in several countries, *id.* ¶ 101; and (4) "Ranbaxy is under reasonable apprehension that Pfizer will sue Ranbaxy" based on Ranbaxy's New ANDA. *Id.* ¶ 103. These allegations do not alter the conclusion that Ranbaxy's '995 counterclaims must be dismissed.

Under current precedent, the fact that the '995 patent has been submitted for reissue does not create any justiciable issue between the parties. The Federal Circuit has repeatedly rejected the filing of a reissue application as a basis to establish current declaratory judgment jurisdiction. *See, e.g., Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d at 637; *Amana Refrigeration, Inc. v. Quadlux, Inc*, 172 F.3d at 856; *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d at 1058; *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479 (Fed. Cir. 1996); *see also Czarnik v. Illumina, Inc.* 437 F. Supp. 2d 252, 259 (D. Del. 2006).

As a corollary, litigating the '995 patent in light of all the circumstances would also entail litigation upon a purely hypothetical question. The gravamen of Ranbaxy's claim is a request for an advisory opinion that a '995 reissue patent, if allowed, would be invalid, unenforceable and not infringed. This is precisely the type of hypothetical that the Supreme Court has uniformly admonished is not a proper question for exercise of the

Federal judicial power. *See, e.g., Calderon v. Ashmus,* 523 U.S. 740, 747 (1998).

Moreover, any such challenge to the as yet to be allowed '995 reissue is hardly ripe. *Hoxha v. Levi*, 465 F.3d 554, 565 (3d Cir. 2006) ("the ripeness doctrine clearly precludes us from resolving questions that will have practical relevance to the parties only if a contingent event occurs at some future time."). The reissue patent is but a possibility, its issuance is uncertain, it has not been listed in the FDA Orange Book, and it cannot be listed in the FDA Orange Book until issued. *See* 21 U.S.C. § 355(c)(2) (providing for listing within 30 days of patent issuance where patent "could not be filed" with an NDA application because the patent had not yet issued). Nor has Ranbaxy had to certify against a '995 reissue patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Thus, under the Hatch Waxman Act, jurisdiction cannot be extended based on the possibility of reissue of a listed patent over which there is no present jurisdiction. Any Ranbaxy argument based on the objectives of the Hatch Waxman Act as somehow supporting the exercise of jurisdiction cannot be sustained in the face of the plain language of the Act's text.

Finally, Pfizer has no right to enforce a pending reissue application, and Ranbaxy has no standing to seek a declaratory judgment that a reissue patent would be invalid or unenforceable. *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d at 636 ("Before a patent issues, and during the pendency of a patent application in the PTO, the courts have no claims by which to gauge an alleged infringer's conduct."); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054. There can be no injury-in-fact based on an expectancy of a legal right. Analogically, this would be the equivalent to extending the federal judicial power to authorize attacks on pending legislation.

C. The Court Should In Any Event Decline To Exercise Jurisdiction, If Any, In Its Discretion

Even if the Court were to find subject matter jurisdiction under the Declaratory Judgment Act, the Court should decline to exercise that jurisdiction in its discretion. While the Declaratory Judgment Act grants the Court jurisdiction, the Act allows district courts to decline jurisdiction.

The Declaratory Judgment Act confers "unique and substantial discretion" upon district courts "in deciding whether to declare the rights of litigants." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995). The Act "provides that a court 'may declare the rights and other legal relations of any interested party,' 28 U.S.C. § 2201(a), not that it must do so." *MedImmune*, 127 S. Ct. at 776 (emphasis omitted). "When all is said and done ... 'the propriety of declaratory relief in a particular case will depend upon a circumspect sense of its fitness informed by the teachings and experience concerning the functions and extent of federal judicial power.'" *Wilton*, 515 U.S. at 287 (*quoting Public Serv. Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 243 (1952)). The Declaratory Judgment Act is "an enabling Act, which confers a discretion on the courts rather than an absolute right upon the litigant." *Wilton*, 515 U.S. 287.

The speculative nature of Ranbaxy's claims which are necessarily grounded on a possible '995 reissue patent, combined with the fact that Ranbaxy is prohibited from marketing its ANDA product until the expiration of the '893 patent in 2010, make this case one in which it is appropriate for the Court to decline jurisdiction. Here, Pfizer cannot sue Ranbaxy on any valid claim of the listed '995 patent and it has not threatened Ranbaxy with litigation on the possible '995 reissue. Ranbaxy therefore lacks any reasonable apprehension of being sued on the current or reissue claims of the '995 patent. Furthermore, Ranbaxy has not alleged that it is participating in any activity that could be

considered infringement of a listed patent, currently or in the future, given the new covenant not to sue.

VI. CONCLUSION

For the reasons stated above, defendants/counterclaimants' Fourth, Fifth, Sixth, and Seventh Counterclaims with respect to the '995 patent should be dismissed for lack of subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 or the Court should decline to exercise jurisdiction over the counterclaims in its discretion.

RESPECTFULLY SUBMITTED,

/s/ *Jeffrey B. Bove*
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CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2007, a true copy of the foregoing was hand delivered to the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and the document is available for viewing and downloading from CM/ECF:

Frederick L. Cottrell, III
Jameson A.L. Tweedie
Richards, Layton & Finger
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Wilmington, DE 19801

I hereby certify that on the May 3, 2007, I have sent by Electronic Mail the foregoing document to the following non-registered participants:

Joseph M. Reisman
William R. Zimmerman
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By: /s/ *Jeffrey B. Bove*
Jeffrey B. Bove (#998)
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EXHIBIT A

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REPLY TO Wilmington Office

April 25, 2007

Via Federal Express

William R. Zimmerman, Esquire
Knobbe Martens Olson & Bear LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

Re: Pfizer v. Ranbaxy (Caduet®), C.A. No. 07-138 (JJF)

Dear Bill:

I enclose the original of Pfizer's Covenant Not To Sue relating to ANDA No. 78-747.

Sincerely,

Jeffrey B. Bove

JBB/llw

Enclosure

523017_1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD.	)	
Plaintiffs,	)	
v.	)	Civil Action No. 07-138 (JJF)
RANBAXY LABORATORIES LIMITED, and RANBAXY INC.	)	
Defendants.	)	

PLAINTIFFS' NOTICE OF COVENANT NOT TO SUE DEFENDANTS FOR INFRINGEMENT OF CERTAIN CLAIMS OF THE '995 PATENT AND NOT TO INTERFERE WITH FDA APPROVAL OF ANDA 78-747

Plaintiffs, Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, C.P. Pharmaceuticals International C.V., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Limited, (collectively referred to as "Pfizer"), (collectively referred to as "Pfizer"), their successors in interest and successors in title to United States Letters Patent 5,273,995 ("the '995 patent") hereby covenant not to sue or otherwise hold liable (i) Defendants, Ranbaxy Laboratories Limited and Ranbaxy Inc.; (ii) Ranbaxy Pharmaceuticals, Inc., a wholly owned subsidiary of Defendants; (iii) the successors in interest of Defendants or Ranbaxy Pharmaceuticals Inc.; (iv) the parent companies, subsidiaries, and affiliated

companies of Defendants and/or Ranbaxy Pharmaceuticals, Inc. in which Ranbaxy Laboratories Limited, Ranbaxy Inc. or Ranbaxy Pharmaceuticals, Inc. have a controlling interest; and (v) any joint venture involving one of such identified companies in which the identified company has a controlling interest, (collectively referred to as "Ranbaxy"), for infringement of any of Claims 1, 2, 3, 4, 5, 7, 8, 9, 10, 11 and 12 of the '995 patent under any provision of 35 U.S.C. § 271 based upon: (1) activity reasonably related to seeking approval for Abbreviated New Drug Application ("ANDA") No. 78-747; (2) activity reasonably related to seeking approval for Drug Master File ("DMF") No. 16098 for Ranbaxy's DMF Product, as defined below; (3) the manufacture, use, sale, offer to sell, advertising, or importation of, or publishing of any usage or dosage guidelines or instructions for Ranbaxy's ANDA Product, as defined below; or (4) the importation of Ranbaxy's DMF Product, as defined below, into the United States for purposes of manufacturing Ranbaxy's ANDA Product.

"Ranbaxy's ANDA Product" refers to the formulation currently described in ANDA No. 78-747 (as set forth in the documents provided to Pfizer pursuant to the Offer of Confidential Access attached to the ANDA notice letter, dated January 24, 2007), which formulation contains the active pharmaceutical ingredients amlodipine besylate and amorphous atorvastatin calcium, and any other formulation that ANDA No. 78-747 may describe in the future by amendment, so long as the formulation contains the active ingredients amlodipine besylate and amorphous atorvastatin calcium and the other ingredients of the formulation remain substantially similar to those currently described in ANDA No. 78-747.

"Ranbaxy's DMF Product" refers to the product amorphous atorvastatin calcium currently described in DMF No. 16098 and any other product that DMF No. 16098 may describe in the future by amendment so long as the product described as a result of such amendment remains amorphous atorvastatin calcium. The definition of "Ranbaxy's DMF Product" is not contingent on the process by which the product is made, so long as the product remains amorphous atorvastatin calcium and the process is described in DMF No. 16098 now or by future amendment.

Pfizer, their successors in interest and successors in title to the '995 patent also hereby covenant not to sue or otherwise hold liable direct or indirect purchasers or users of Ranbaxy's ANDA Product for infringement of any of Claims 1, 2, 3, 4, 5, 7, 8, 9, 10, 11 and 12 of the '995 patent under any provision of 35 U.S.C. § 271 based upon the use, sale or resale, offer to sell or resell, or advertising of Ranbaxy's ANDA Product.

By reason of such withdrawal and covenant not to sue, no Claim of the '995 patent remains at issue in this suit.

These covenants shall estop the patentee, licensee, and any successors in interest of the '995 patent from asserting liability against Ranbaxy for infringement of Claims 1, 2, 3, 4, 5, 7, 8, 9, 10, 11 and 12 of the '995 patent based on ANDA No. 78-747, DMF No. 16098 for Ranbaxy's DMF Product, the identified activities involving Ranbaxy's ANDA Product, or importation of Ranbaxy's DMF Product into the United States for purposes of manufacturing Ranbaxy's ANDA Product. These covenants shall also estop the patentee, licensee, and any successors in interest of the '995 patent from asserting liability against

direct or indirect purchasers or users of Ranbaxy's ANDA Product for infringement of the '995 patent claims in question based on the identified activities involving Ranbaxy's ANDA Product.

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Assistant Secretary
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Dated: April 20, 2007

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Westlaw

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 2415959 (D.Del.)
(Cite as: Not Reported in F.Supp.2d)

H

Benitec Australia Ltd. v. Nucleonics, Inc.
D.Del.,2005.
Only the Westlaw citation is currently available.
United States District Court,D. Delaware.
BENITEC AUSTRALIA LTD., Plaintiff,
v.
NUCLEONICS, INC., Defendant.
No. Civ.A. 04-0174 JJF.

Sept. 29, 2005.

John W. Shaw, Glenn C. Mandalas, of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware, Marc R. Labgold, Kevin M. Bell, and Scott A.M. Changers, of Patton Boggs LLP, McLean, Virginia; Richard J. Oparil, of Patton Boggs LLP, Washington, District of Columbia, for Plaintiff, of counsel.
Paul E. Crawford, of Connolly, Bove, Lodge & Hutz, Wilmington, Delaware, Dennis J. Mondolino, and Jason A. Lief, of Morgan Lewis & Bockius LLP, New York, New York, for Defendant, of counsel.

MEMORANDUM OPINION

FARNAN, J.

***1** Pending before the Court is the Motion For Voluntary Dismissal Without Prejudice (D.I.108) filed by Plaintiff, Benitec Australia, Ltd. ("Benitec"). [FN1] For the reasons discussed, the Court will grant Benitec's motion.

FN1. Defendant Nucleonics, Inc. filed an Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I.117). The Court will grant the Motion, and the Surreply will be deemed filed.

BACKGROUND

The parties are engaged in conducting research and developing technologies to create therapeutics to treat disease using gene silencing technologies. On March 22, 2004, Benitec filed its Complaint (D.I.1), alleging that Defendant, Nucleonics, Inc. ("Nucleonics"), infringes U.S. Patent No. 6,573,099 ("the '099 patent").

On February 16, 2005, Nucleonics files a Motion To Amend Its Answer to add seven declaratory judgment counterclaims of non-infringement, patent invalidity under 35 U.S.C. § 102, patent invalidity under 35 U.S.C. § 103, patent invalidity under 35 U.S.C. § 112(1), patent invalidity under 35 U.S.C. § 112(2), patent invalidity under 35 U.S.C. § 116, and patent unenforceability. (D.I.91). On September 14, 2005, the Court issued an Order granting Nucleonics' Motion To Amend Its Answer (D.I.119).

The parties have not yet completed discovery.

PARTIES' CONTENTIONS

By its motion, Benitec contends that this case should be dismissed without prejudice pursuant to Federal Rule of Civil Procedure 41(a) because of a substantive change in the law with regard to the scope of the exemption set forth in 35 U.S.C. § 271(e)(1). Specifically, Benitec contends that the recent decision of the United States Supreme Court in *Merck KGAA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372 (2005), had the effect of negating the case or controversy before the Court with regard to infringement of Benitec's patents and, therefore, dismissal is warranted.

In response, Nucleonics contends that the Court retains jurisdiction to decide its counterclaims for invalidity, unenforceability, and non-infringement because Nucleonics has a reasonable apprehension of being sued by Benitec in the future. Nucleonics argues that, because Benitec filed a lawsuit for patent infringement against Nucleonics and Benitec has not provided Nucleonics with a covenant not to sue for past, present, and future acts, jurisdiction over the declaratory judgment counterclaims exists.

LEGAL STANDARD

When a plaintiff moves for a dismissal without prejudice under Rule 41(a)(2), the decision to dismiss with prejudice or without is left to the discretion of the court. *Buse v. Vanguard Group of Inv. Co.*, No. 91-3560, 1994 WL 111359, at *2 (E.D. Pa Apr. 1 1994). Specifically, Rule 41(a)(2) provides: "[A]n action shall not be dismissed at the plaintiff's instance

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save upon order of the court and upon such terms and conditions as the court deems proper. If a counterclaim has been pleaded by a defendant ... the action shall not be dismissed against the defendant's objection unless the counterclaim can remain pending for independent adjudication by the court. Unless otherwise specified in the order, a dismissal under this paragraph is without prejudice." Fed.R.Civ.P. 41(a)(2) (2004). A Rule 41(a)(2) motion "will be determined after attempting to secure substantial justice to both parties." *DuToit v. Strategic Minerals Corp.*, 136 F.R.D. 82 (D.Del.1991) *citing* *Lunn v. United Aircraft Corp.*, 26 F.R.D. 12, 14 (D.Del.1960). Moreover, while considering the legitimate interests of both parties, the Court must bear in mind that a plaintiff's motion should be granted absent substantial prejudice to the defendant. *Id.* at 10.

DISCUSSION

***2** The Court concludes that dismissing Benitec's action would not cause substantial prejudice to Nucleonics because no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonic's declaratory judgment claims against Benitec.

Nucleonics objects to dismissing Benitec's action without prejudice because Nucleonics contends that Benitec's action "brought a public cloud of uncertainty" over Nucleonics. (D.I. 110 at 2.) Thus, Nucleonics contends that Benitec should not now be allowed to leave the playing field, keeping its patent safe from scrutiny with regard to invalidity or unenforceability, while continuing to taint Nucleonic's current and future business and technology with the threat of another lawsuit. Nucleonics argues that the Declaratory Judgment Act, 28 U.S.C. § 2201, permits the Court to independently adjudicate Nucleonics' counterclaims.

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996). Nucleonics has the burden of establishing the existence of an actual case or controversy. *See* *Cardinal Chemical Co. v. Morton Intern., Inc.*, 508 U.S. 83, 95 (1993). When a party has actually been charged with infringement of a patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a counterclaim pursuant to the Declaratory Judgment Act. *Id.* at 96. Furthermore, a counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement. *Id.* The issue before the Court, then, is whether an actual controversy sufficient to support the Court's jurisdiction over Nucleonics' declaratory judgment counterclaims continues to exist if Benitec's patent infringement claim is dismissed.

Benitec contends that dismissing its infringement claim divests the Court of jurisdiction to hear the counterclaims. However, a number of courts have held that withdrawing a charge of infringement will not necessarily preclude the existence of an actual controversy, especially if, as here, the withdrawal occurs after the filing of the declaratory judgment action. *See, e.g.*, *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 881 (Fed.Cir.1983); *Societe de Conditionnement v. Hunter Eng'g*, 655 F.2d 938 (9th Cir.1981). In turn, Nucleonics contends that, because Benitec has refused to enter into a covenant not to sue for enforcement of the '099 patent against Nuceonics at a later time, an actual controversy necessarily exists. However, a patentee's refusal to promise not to enforce the patent, while "relevant to the [actual controversy] determination," is "not dispositive." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed.Cir.1993).

In the alternative, Nucleonics contends that it has a reasonable apprehension of suit because Benitec has already sued Nucleonics and others for patent infringement, Benitec has not promised not to assert the '099 patent against Nucleonics in the future, and Benitec has requested a voluntary dismissal of its action without prejudice. In reply, Benitec contends that Nucleonics has nothing to fear because Nucleonics' research activities are exempt from infringement liability pursuant to § 271(e)(1) and the Supreme Court's decision in *Integra.*

***3** The test for determining whether an actual case or controversy exists in a declaratory judgment action involving patents is two-pronged. First, the defendant's conduct must have created on the part of the plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the product or have prepared to produce that product. *Indium Corp. v. Semi-Alloys, Inc.*, 781 F.2d 879 (Fed.Cir.1985)

With regard to the first prong, the Court concludes that Nucleonics has demonstrated a reasonable apprehension of suit. The factual background in this

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case is such that Nucleonics could be concerned that Benitec would, at some time, file a patent infringement suit against it. By suing Nucleonics and alleging that Nucleonics' technology is now covered by the Benitec's patent, Benitec has engaged in a course of conduct that shows a willingness to protect that technology. *See, e.g.,* *C.R. Bard v. Schwartz*, 716 F.2d 874, 880-81 (Fed.Cir.1983); *Int'l Medical Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575, 229 U.S.P.Q. 278, 281 (Fed.Cir.1986)

With regard to the second prong, production or preparation of a product, Nucleonics contends that its entire research effort is devoted to the RNAi area of technology and its activities will ultimately leave the safe harbor created by *Integra.* Nucleonics further alleges that it anticipates beginning research on livestock diseases, which are unprotected by the safe harbor. In response, Benitec argues that future infringement is not ripe for adjudication because Benitec's product may never be approved by the FDA or may be approved in a form that does not implicate the claims of the '099 patent. (D.I. 115 at 18.)

The declaratory judgment plaintiff carries the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy. *Jervis B. Webb Co.*, 742 F.2d 1388, 1399 (Fed.Cir.1984). On the record before it, the Court concludes that Nucleonics has not demonstrated that it has produced or has prepared to produce a product that would be the target of an infringement lawsuit by Benitec. At the time this lawsuit was filed, Nucleonics was several years away from obtaining FDA approval. Further, as argued by Benitec, there is no certainty that any product approved by the FDA would be the same product that was in clinical trials at the time this lawsuit was filed. And finally, Nucleonics has adduced no evidence that it has undertaken sales or marketing activity with regard to any product. For these reasons, he Court concludes that any threat of litigation that may have existed now lacks sufficient immediacy and reality to support declaratory judgment jurisdiction.

CONCLUSION

In the circumstances presented here, the Court concludes that no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonic's declaratory judgement claims against Benitec with regard to the '099 patent. Accordingly, the Court will grant Benitec's Motion For Voluntary Dismissal Without Prejudice (D.I.108).

***4** An appropriate Order will be issued.

ORDER

At Wilmington, this 29th day of September 2005, for the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. The Motion For Voluntary Dismissal Without Prejudice (D.I.108) filed by Plaintiff, Benitec Australia, Ltd. is *GRANTED.*

2. Defendant Nucleonics, Inc.'s Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I.117) is *GRANTED.*

3. The Surreply attached as Exhibit 1 to the Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I.117) is deemed filed.

D.Del.,2005.
Benitec Australia Ltd. v. Nucleonics, Inc.
Not Reported in F.Supp.2d, 2005 WL 2415959 (D.Del.)

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H

Medimmune, Inc. v. Genentech, Inc.
C.A.Fed.,2007.
Only the Westlaw citation is currently available.This case was not selected for publication in the Federal Reporter.NOTE: This disposition is nonprecedential.
United States Court of Appeals,Federal Circuit.
MEDIMMUNE, INC., Plaintiff-Appellant,
v.
GENENTECH, INC., Defendant-Appellee,
andCity of Hope, Defendant-Appellee,
andCelltech R & D, Ltd., Defendant-Appellee.
No. 04-1300, 04-1384.

March 7, 2007.

Before NEWMAN and MAYER, Circuit Judges, and CLEVENGER, Senior Circuit Judge.

ON MOTION

PER CURIAM.

ORDER

***1** In *Medimmune, Inc. V. Genentech, Inc.*, 127 S.Ct. 764 (2007), the Supreme Court reversed this court's decision, reported at 427 F.3d 958 (Fed.Cir.2005), and remanded with instructions that the lower court consider the issues flowing from the Court's decision that Medimmune "was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed." The Court "express[ed] no opinion on ... the applicability of licensee estoppel under [the] circumstances" of the case at bar, *id.* at 769-70, and declined to affirm the dismissal of the declaratory judgment claims on discretionary grounds, the Court "leav[ing] the equitable, prudential, and policy arguments in favor of such a discretionary dismissal for the lower courts' consideration on remand." *Id.* at 777. The Court similarly left for consideration on remand any merits-based arguments for denial of declaratory relief in this case.

Genentech now moves for briefing and argument before this court, pointing to the potentially far-reaching impact of the Court's decision and the advantages of expeditious elaboration of the law and policy of patent licensing. We agree that the Court recognized that various issues may require further development. However, as Genentech recognizes in its motion, the Court's remand order is not amenable to determination upon the available record. The issues of law, equity, and policy, and their application to these parties, also require development of the relevant facts, and are not appropriately resolved in the first instance by an appellate tribunal. The Court so recognized, stating that "facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within the [district courts'] grasp." 127 S.Ct. at 776, quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995).

Accordingly,

IT IS ORDERED THAT:

(1) The mandate issued on November 8, 2005, is hereby recalled and these appeals are reinstated.

(2) The motion is denied.

(3) We remand to the district court for further proceedings consistent with the Court's opinion.

C.A.Fed.,2007.
Medimmune, Inc. v. Genentech, Inc.
Slip Copy, 2007 WL 930720 (C.A.Fed.)

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Westlaw.
--- F.3d ----
--- F.3d ----, 2007 WL 942201 (C.A.Fed. (N.J.)), 82 U.S.P.Q.2d 1225
(Cite as: --- F.3d ----)

H

Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.
C.A.Fed. (N.J.),2007.

United States Court of Appeals,Federal Circuit.
TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant,
v.
NOVARTIS PHARMACEUTICALS CORPORATION, Novartis Pharma AG and Novartis International Pharmaceutical Ltd., Defendants-Appellees.
No. 06-1181.

March 30, 2007.

Background: Competitor that had filed abbreviated new drug application (ANDA) for generic drug brought action against patent holder for declaratory judgment on validity or infringement of method patents not challenged in holder's suit alleging infringement of drug patent. The United States District Court for the District of New Jersey, Jose L. Linares, J., 2005 WL 3619389, dismissed suit for lack of jurisdiction. Competitor appealed.

Holdings: The Court of Appeals, Gajarsa, Circuit Judge, held that:

(1) actual controversy is the sole requirement for federal court jurisdiction under the Declaratory Judgment Act (DJA) and statute conferring subject matter jurisdiction over declaratory judgment action on infringement or validity of drug patent, and

(2) the competitor had an injury-in-fact and justiciable Article III controversy with holder.

Reversed.

Friedman, Senior Circuit Judge, concurred in the judgment and filed opinion.

[1] Declaratory Judgment 118A 393

118A Declaratory Judgment
118AIII Proceedings
118AIII(H) Appeal and Error
118Ak392 Appeal and Error
118Ak393 k. Scope and Extent of Review in General. Most Cited Cases

Federal Courts 170B 755

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)1 In General
170Bk754 Review Dependent on Whether Questions Are of Law or of Fact
170Bk755 k. Particular Cases. Most Cited Cases
Dismissal of declaratory judgment action for lack of jurisdiction presents a question of law reviewed without deference.

Dismissal of declaratory judgment action for lack of jurisdiction presents a question of law reviewed without deference.

[2] Declaratory Judgment 118A 393

118A Declaratory Judgment
118AIII Proceedings
118AIII(H) Appeal and Error
118Ak392 Appeal and Error
118Ak393 k. Scope and Extent of Review in General. Most Cited Cases

Federal Courts 170B 776

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)1 In General
170Bk776 k. Trial De Novo. Most Cited Cases
The determination of whether an actual controversy exists under the Declaratory Judgment Act (DJA) in a patent case is a question of law reviewed de novo. 28 U.S.C.A. § 2201.

The determination of whether an actual controversy exists under the Declaratory Judgment Act (DJA) in a patent case is a question of law reviewed de novo. 28

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U.S.C.A. § 2201.

[3] Declaratory Judgment 118A 393

118A Declaratory Judgment
118AIII Proceedings
118AIII(H) Appeal and Error
118Ak392 Appeal and Error
118Ak393 k. Scope and Extent of Review in General. Most Cited Cases

Federal Courts 170B 870.1

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)5 Questions of Fact, Verdicts and Findings
170Bk870 Particular Issues and Questions
170Bk870.1 k. In General. Most Cited Cases
District court's factual findings supporting its determination on questions of actual controversy and jurisdiction under the Declaratory Judgment Act (DJA) are reviewed for clear error. 28 U.S.C.A. § 2201.

District court's factual findings supporting its determination on questions of actual controversy and jurisdiction under the Declaratory Judgment Act (DJA) are reviewed for clear error. 28 U.S.C.A. § 2201.

[4] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases

Federal Courts 170B 12.1

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk12 Case or Controversy Requirement
170Bk12.1 k. In General. Most Cited Cases
A justiciable Article III controversy requires the party instituting the action to have standing and the issue presented to the court to be ripe. U.S.C.A. Const. Art. 3, § 2, cl. 1.

A justiciable Article III controversy requires the party instituting the action to have standing and the issue presented to the court to be ripe. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[5] Federal Civil Procedure 170A 103.3

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.3 k. Causation; Redressability. Most Cited Cases
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. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[6] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases

Federal Courts 170B 12.1

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk12 Case or Controversy Requirement
170Bk12.1 k. In General. Most Cited Cases
Of the three Article III standing requirements, injury-in-fact is the most determinative; whatever else the case or controversy requirement embodies, its essence is a requirement of injury in fact. U.S.C.A. Const. Art. 3, § 2, cl. 1.

Of the three Article III standing requirements, injury-in-fact is the most determinative; whatever else the case or controversy requirement embodies, its essence is a requirement of injury in fact. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[7] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties

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170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases
An injury-in-fact necessary for Article III standing must be personal, concrete, and particularized and actual or imminent. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[8] Declaratory Judgment 118A 62

118A Declaratory Judgment
118AI Nature and Grounds in General
118AI(D) Actual or Justiciable Controversy
118Ak62 k. Nature and Elements in General. Most Cited Cases
Under the declaratory judgment standard of an actual controversy, all the circumstances must demonstrate the Article III justiciability requirement that the case be ripe for judicial review. U.S.C.A. Const. Art. 3, § 2, cl. 1; 28 U.S.C.A. § 2201(a).

[9] Federal Courts 170B 12.1

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk12 Case or Controversy Requirement
170Bk12.1 k. In General. Most Cited Cases
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.

[10] Federal Courts 170B 12.1

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk12 Case or Controversy Requirement
170Bk12.1 k. In General. Most Cited Cases
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.

[11] Constitutional Law 92 69

92 Constitutional Law
92III Distribution of Governmental Powers and Functions
92III(B) Judicial Powers and Functions
92k69 k. Advisory Opinions. Most Cited Cases
Under the prohibition against advisory opinions, 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. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[12] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases
Congress by legislation may expand standing to the full extent permitted by Article III, thus permitting litigation by one who otherwise would be barred; Congress, however, cannot expand standing beyond the Article III jurisdiction of federal courts. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[13] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases
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. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[14] Declaratory Judgment 118A 232

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak232 k. Validity of Patents. Most Cited Cases

Declaratory Judgment 118A 233

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents

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118Ak231 Patents
118Ak233 k. Infringement of Patents. Most Cited Cases

Declaratory Judgment 118A 300

118A Declaratory Judgment
118AIII Proceedings
118AIII(C) Parties
118Ak299 Proper Parties
118Ak300 k. Subjects of Relief in General. Most Cited Cases
The Declaratory Judgment Act (DJA) and statute conferring subject matter jurisdiction over declaratory judgment action on infringement or validity of drug patent expand standing to constitutional limits and provide a way for plaintiffs to bring actions in federal court when they might otherwise be barred. 28 U.S.C.A. § 2201; 35 U.S.C.A. § 271(e)(5).

[15] Declaratory Judgment 118A 232

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak232 k. Validity of Patents. Most Cited Cases

Declaratory Judgment 118A 233

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak233 k. Infringement of Patents. Most Cited Cases
An actual controversy is the sole requirement for federal court jurisdiction under the Declaratory Judgment Act (DJA) and statute conferring subject matter jurisdiction over declaratory judgment action on infringement or validity of drug patent. 28U.S.C.A. § 2201; 35 U.S.C.A. § 271(e)(5).

[16] Declaratory Judgment 118A 62

118A Declaratory Judgment
118AI Nature and Grounds in General
118AI(D) Actual or Justiciable Controversy
118Ak62 k. Nature and Elements in General. Most Cited Cases
An "actual controversy" within the meaning of the Declaratory Judgment Act (DJA) is the same as an Article III case or controversy. U.S.C.A. Const. Art. 3, § 2, cl. 1; 28 U.S.C.A. § 2201(a).

[17] Declaratory Judgment 118A 232

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak232 k. Validity of Patents. Most Cited Cases

Declaratory Judgment 118A 233

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak233 k. Infringement of Patents. Most Cited Cases

Declaratory Judgment 118A 300

118A Declaratory Judgment
118AIII Proceedings
118AIII(C) Parties
118Ak299 Proper Parties
118Ak300 k. Subjects of Relief in General. Most Cited Cases
Under the Declaratory Judgment Act (DJA) and statute conferring subject matter jurisdiction over declaratory judgment action on infringement or validity of drug patent, a 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. U.S.C.A. Const. Art. 3, § 2, cl. 1; 28 U.S.C.A. § 2201(a); 35 U.S.C.A. § 271(e)(5).

[18] Declaratory Judgment 118A 5.1

118A Declaratory Judgment
118AI Nature and Grounds in General
118AI(A) In General
118Ak5 Discretion of Court
118Ak5.1 k. In General. Most Cited Cases
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 a declaratory judgment action, as it retains

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discretion under the Declaratory Judgment Act (DJA) to decline declaratory judgment jurisdiction. 28 U.S.C.A. § 2201.

[19] Courts 106 90(1)

106 Courts
106II Establishment, Organization, and Procedure
106II(G) Rules of Decision
106k88 Previous Decisions as Controlling or as Precedents
106k90 Decisions of Same Court or Co-Ordinate Court
106k90(1) k. In General. Most Cited Cases

Courts 106 90(2)

106 Courts
106II Establishment, Organization, and Procedure
106II(G) Rules of Decision
106k88 Previous Decisions as Controlling or as Precedents
106k90 Decisions of Same Court or Co-Ordinate Court
106k90(2) k. Number of Judges Concurring in Opinion, and Opinion by Divided Court. Most Cited Cases
The Court of Appeals 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.

[20] Declaratory Judgment 118A 61

118A Declaratory Judgment
118AI Nature and Grounds in General
118AI(D) Actual or Justiciable Controversy
118Ak61 k. Necessity. Most Cited Cases
A justiciable controversy within Article III is the only limitation on jurisdiction under the Declaratory Judgment Act (DJA). U.S.C.A. Const. Art. 3, § 2, cl. 1; 8 U.S.C.A. § 2201.

[21] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases

Federal Civil Procedure 170A 103.3

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.3 k. Causation; Redressability. Most Cited Cases
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. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[22] Declaratory Judgment 118A 234

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak234 k. Claim of Infringement as Condition Precedent. Most Cited Cases
Patent holder's competitor that had filed abbreviated new drug application (ANDA) for generic drug had an injury-in-fact and justiciable Article III controversy with holder and, therefore, could file action for declaratory judgment on validity or infringement of method patents listed in Orange Book, even though holder had not sued or threatened to sue competitor over those patents after its paragraph IV certification; the holder had sued competitor for infringement of the drug patent, that suit, although a different case, created a present and actual controversy, and the declaratory judgment arose from the same controversy. U.S.C.A. Const. Art. 3, § 2, cl. 1; Federal Food, Drug, and Cosmetic Act, § 505(j)(2)(A)(vii), (j)(5)(C), 21 U.S.C.A. § 355(j)(2)(A)(vii), (j)(5)(C); 28 U.S.C.A. § 2201(a); 35 U.S.C.A. § 271(a), (e)(2)(A), (e)(5).

[23] Health 198H 319

198H Health
198HI Regulation in General
198HI(E) Drugs; Medical Devices and Instruments
198Hk315 Applications and Approvals
198Hk319 k. Generic and Orphan Drugs; Market Exclusivity. Most Cited Cases
Patent holder's failure to sue for infringement of method patents when it sued for infringement of drug patent did not block holder from suing on the method patents, and the holder's suit on the patent expiring first invoked automatic thirty-month stay of competitor's abbreviated new drug application

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(ANDA) for generic drug, reserved option of future litigation on the method patents, and prevented the generic drug from entering the market until the expiration of the last patent. Federal Food, Drug, and Cosmetic Act, § 505(j)(5)(B)(iii), 21 U.S.C.A. § 355(j)(5)(B)(iii).

[24] Federal Courts 170B 12.1

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk12 Case or Controversy Requirement
170Bk12.1 k. In General. Most Cited Cases
A justiciable controversy under Article III can arise from either an actual or an imminent injury. U.S.C.A. Const. Art. 3, § 2, cl. 1.

[25] Declaratory Judgment 118A 231.1

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(L) Patents
118Ak231 Patents
118Ak231.1 k. In General. Most Cited Cases
A justiciable declaratory judgment controversy arises for the filer of an abbreviated new drug application (ANDA) 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. U.S.C.A. Const. Art. 3, § 2, cl. 1; Federal Food, Drug, and Cosmetic Act, § 505(j)(2)(A)(vii), (j)(5)(C), 21 U.S.C.A. § 355(j)(2)(A)(vii), (j)(5)(C); 28 U.S.C.A. § 2201(a); 35 U.S.C.A. § 271(a), (e)(2)(A), (e)(5).

[26] Federal Civil Procedure 170A 103.2

170A Federal Civil Procedure
170AII Parties
170AII(A) In General
170Ak103.1 Standing
170Ak103.2 k. In General; Injury or Interest. Most Cited Cases

Federal Courts 170B 12.1

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk12 Case or Controversy Requirement
170Bk12.1 k. In General. Most Cited Cases
Congress 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. U.S.C.A. Const. Art. 3, § 2, cl. 1.

Congress 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. U.S.C.A. Const. Art. 3, § 2, cl. 1.

Patents 291 328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original Utility. Most Cited Cases
5,246,937, 5,840,763, 5,866,581, 5,916,893, 6,124,304. Cited.

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.

Before MAYER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and GAJARSA, Circuit Judge.
GAJARSA, Circuit Judge.
***1** 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.*, --- U.S. ----, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007), which finds that our declaratory

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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, 2005 WL 3664014 (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).

***2** 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, 2005 WL 3619389 (D.N.J. Dec. 12, 2005). In so doing, the district court applied our two prong "reasonable-apprehension-of-imminent-suit" test from *Pfizer.*[FN1] 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).

[1][2][3] 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

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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.*

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).[FN2]

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 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, 57 S.Ct. 461, 81 L.Ed. 617 (1937)).

***3** 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, 57 S.Ct. 461).

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, 61 S.Ct. 510, 85 L.Ed. 826 (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, 61 S.Ct. 510).

[4] 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, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992).

[5][6][7] 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, 104 S.Ct. 3315, 82 L.Ed.2d 556 (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, 94 S.Ct. 2925, 41 L.Ed.2d 706 (1974) (citing *Ass'n of Data Processing Serv. Org., Inc. v. Camp*, 397 U.S. 150, 152, 90 S.Ct. 827, 25 L.Ed.2d 184 (1970)). An injury-in-fact must be "personal," "concrete and particularized," and "actual or imminent." *Lujan*, 504 U.S. at 560, 112 S.Ct. 2130; *Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975).

[8][9][10] 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, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967). The doctrine of ripeness focuses on the conduct of the defendant to determine whether the defendants

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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, 87 S.Ct. 1507. 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, 87 S.Ct. 1507 (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).

***4** [11] 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, 80 S.Ct. 391, 4 L.Ed.2d 373 (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, 58 S.Ct. 678, 82 L.Ed. 936 (1938).

[12][13] 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, 99 S.Ct. 1601, 60 L.Ed.2d 66 (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, 93 S.Ct. 1146, 35 L.Ed.2d 536 (1973) (citing *Trafficante v. Metro. Life Ins. Co.*, 409 U.S. 205, 212, 93 S.Ct. 364, 34 L.Ed.2d 415 (1972) (White, J., concurring)).

[14][15][16][17][18] 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, 57 S.Ct. 461. 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). [FN3]

[19] 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).

***5** 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 at 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 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.[FN4] 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

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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, 57 S.Ct. 461). 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 "reasonableapprehension-of-suit" test "contradict[s]" and "conflicts" with its precedent, these Federal 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*, 480 F.3d 1372 (Fed.Cir.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, 2005 WL 3619389. 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, 2005 WL 3619389; *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.

***6** [20][21] 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, 118 S.Ct. 1003. In the present case, only the concrete injury-in-fact requirement under Article III is in dispute.

[22][23] 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.[FN5]

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

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"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.[FN6] 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 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.

***7** [24] The district court erred in finding that *Teva* did not demonstrate an Article III controversy. *Teva*, slip op. at 6-10, 2005 WL 3619389. 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.

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, 110 S.Ct. 2683, 110 L.Ed.2d 605 (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, 61 S.Ct. 510. 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.

***8** 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.[FN7] *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

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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 whether the paragraph IV patents were invalid or not infringed.[FN8] 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.

***9** 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 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.

[25] A fourth circumstance contributing to Teva's justiciable controversy is Novartis' pending infringement litigation. *See* *Novartis Pharm. Corp.*, No. 05-1887, 2005 WL 3664014. 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

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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.2002) (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.").

***10** [26] 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, 99 S.Ct. 1601 ("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

***11** 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

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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

Concurring opinion filed by Senior Circuit Judge FRIEDMAN.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.*, --- U.S. ----, 127 S.Ct. 764, 166 L.Ed.2d 604 (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.*, 127 S.Ct. at 767; *see Gen-Probe Inc. v. Vysis*, 359 F.3d 1376 (Fed.Cir.2004). 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*, 127 S.Ct. at 771-72 (citation and footnote omitted).

***12** 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.*, 127 S.Ct. at 775 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 ----. 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.

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FN1. 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.

FN2. 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*, 846 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 "extrajudicial 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.*

FN3. 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, 73 S.Ct. 236, 97 L.Ed. 291 (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.").

FN4. *See, e.g.*, *Md. Cas. Co.*, 312 U.S. at 273, 61 S.Ct. 510 (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, 57 S.Ct. 461 (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, 113 S.Ct. 1967, 124 L.Ed.2d 1 (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).

FN5. 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 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, 2005 WL 3619389. 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

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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).

FN6. 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).

FN7. "[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).

FN8. 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.

C.A.Fed. (N.J.),2007.
Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.
--- F.3d ----, 2007 WL 942201 (C.A.Fed. (N.J.)), 82 U.S.P.Q.2d 1225

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