

DECLARATORY JUDGMENT ACTIONS IN PATENT CASES: THE FEDERAL CIRCUIT'S RESPONSE TO *MEDIMMUNE V. GENENTECH*

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I. INTRODUCTION

The Declaratory Judgment Act¹ provides federal courts with the authority to “declare the rights and other legal relations of any interested party” where an “actual controversy” exists.² The term “actual controversy” is rooted in the Constitution³ and requires that actions for declaratory judgment meet the same test for case or controversy as conventional suits under Article III federal jurisdiction.⁴ Declaratory judgment actions are intended to provide relief for a first party facing potential liability where a second party with standing to bring a conventional suit might delay taking action, thereby leaving the first party—the declaratory judgment plaintiff—in a state of legal risk.⁵

The Court of Appeals for the Federal Circuit, responsible for all appeals in cases involving patent claims,⁶ promulgated the two-part reason-

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1. Act of June 14, 1934, Pub. L. No. 73-343, 48 Stat. 955 (1934) (current version at 28 U.S.C. §§ 2201-2202 (2000)).

2. 28 U.S.C. § 2201(a) (2000).

3. U.S. CONST., art III, § 2.

4. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937) (“The Declaratory Judgment Act of 1934, in its limitation to ‘cases of actual controversy,’ manifestly has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense. The word ‘actual’ is one of emphasis rather than of definition.”).

5. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988) (comparing the interaction between the patent holder and the alleged infringer as a “*danse macabre*” where the patent holder “brandish[es] a Damoclean threat with a sheathed sword” and the Declaratory Judgment Act alleviates the “*in terrorem*” choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises”); *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 977 (Fed. Cir. 1993) (“The purpose of the Act is to enable a person who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side.”); *see also* Lisa A. Dolak, *Declaratory Judgment Jurisdiction in Patent Cases: Restoring the Balance Between the Patentee and the Accused Infringer*, 38 B.C. L. Rev 903, 910-11 (1997).

6. Since its establishment in 1982, the Federal Circuit has had sole jurisdiction over appeals from federal district court decisions in cases where patent claims form part

able apprehension of suit (“RAS”) test to determine whether a federal court has jurisdiction for a declaratory judgment action in patent cases.⁷ Under the RAS standard, there must be (1) action by the patent holder that creates a reasonable apprehension of an infringement suit against the declaratory judgment plaintiff and (2) activity by the declaratory judgment plaintiff that could constitute infringement.⁸ In *MedImmune, Inc. v. Genentech, Inc.*, the Supreme Court signaled the demise of the RAS test.⁹ The Court replaced the Federal Circuit’s formalistic approach with a totality of the circumstances approach that inquires into the parties’ legal interests.¹⁰

The Federal Circuit has responded by providing signposts for circumstances under which declaratory judgment of a party’s legal rights is appropriate. In *SanDisk Corp. v. STMicroelectronics*, the Federal Circuit found jurisdiction in a declaratory judgment action over a cross-licensing dispute where licensing negotiations had not yet broken down.¹¹ In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, the Federal Circuit found jurisdiction for a declaratory judgment action for noninfringement and invalidity by a generic pharmaceutical manufacturer where the branded drug manufacturer only sued for infringement on some of the patents relating to its product.¹²

The Federal Circuit’s RAS test focused on the legal connotations of the parties’ posturing.¹³ By returning to a declaratory judgment standard that requires inquiry into the actual legal interests of the parties, the Supreme Court set forth a standard for patent cases more in line with the purposes of the Declaratory Judgment Act. However, the Court also lowered the hurdle to establish jurisdiction in these cases, raising the question of whether a patent holder must take any affirmative action aside from obtaining the patent. The *MedImmune* opinion and the Federal Circuit’s ap-

of the well-pleaded complaint. See 28 U.S.C. §§ 1295(a)(1), (4), 1338 (2000). The Federal Circuit’s jurisdiction does not extend to cases where patent claims appear in a counterclaim, but not in the well-pleaded complaint. See *Holmes Group, Inc. v. Vornado Air Circulation Sys.*, 535 U.S. 826 (2002).

7. *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 879-880 (Fed. Cir. 1983).

8. See *infra* Section II.C.2.

9. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007).

10. *Id.* at 771.

11. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007).

12. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.* 482 F.3d 1330 (Fed. Cir. 2007).

13. Courts were instructed to look for objective indications that the patentee intended to sue. The courts attempted to differentiate between negotiation stances and threats of litigation. See *infra* Section II.C.2.

plication of it in *SanDisk* and *Novartis* suggest that little is required of the patent holder beyond providing notice of the patent. Constructive notice alone would perhaps suffice. Another question raised is whether the declaratory judgment plaintiff must take any action toward actual infringement of the patent to establish a justiciable controversy. Neither the Supreme Court nor the Federal Circuit has clearly indicated the lengths the alleged infringer must go toward actual infringement. However, the conduct by and legal interests of the alleged infringer may become the most significant part of determining a justiciable controversy.

Part II of this Note reviews the legal background for establishing controversy in federal declaratory judgment actions, in particular declaratory judgment actions in patent cases. Part III describes the facts, procedural histories, and rulings of *MedImmune*, *SanDisk*, and *Novartis*. Part IV analyzes the new standards for establishing declaratory judgment in patent cases as set out by the Supreme Court and interpreted by the Federal Circuit, arguing that while the previous Federal Circuit jurisprudence under the RAS test favored the patentee at the expense of the alleged infringer, the new standards for declaratory judgment actions favor the alleged infringer. Part V concludes that although the alleged infringer's interests are adequately covered by the *MedImmune* standard for establishing a justiciable controversy, the patent holder's interests are not. The inquiry into the alleged infringer's actual legal interests in the activities allegedly covered by the patent-in-suit should be rigorous: both to prevent parties from seeking to invalidate patents that are merely inconvenient and to adequately protect the patent holder's interests.

II. BACKGROUND

This Part provides the legal background for finding a justiciable controversy in declaratory judgment actions. Section II.A presents an overview of federal declaratory judgment actions. Section II.B traces the Supreme Court case law concerning the controversy requirement for all federal declaratory judgment actions. Section II.C surveys the Supreme Court and Federal Circuit jurisprudence pertaining to establishing a justiciable controversy for declaratory judgment actions in patent cases.

A. Declaratory Judgment Act

Congress enacted the Declaratory Judgment Act in 1934.¹⁴ The Act provides that a federal court may “declare the rights and other legal rela-

14. Act of June 14, 1934, Pub. L. No. 73-343, 48 Stat. 955 (1934) (current version at 28 U.S.C. §§ 2201-2202 (2000)).

tions of any interested party seeking such declaration.”¹⁵ The Act does not expand jurisdiction; it applies only if the requirements for federal jurisdiction are fulfilled.¹⁶ Courts do not have jurisdiction to deliver advisory opinions on questions that are abstract or hypothetical in nature.¹⁷ Rather, the facts must be sufficiently developed to give rise to a real legal dispute rising to the level of an Article III controversy.¹⁸ In a declaratory judgment suit, the positions of the parties as plaintiff or defendant are reversed from that of a “conventional” suit, but the character of the controversy is identical.¹⁹ The decision by a court to hear declaratory judgment actions is discretionary, but the district court must have a sound basis to refuse jurisdiction over a declaratory judgment action.²⁰

The patentee is generally the declaratory judgment defendant in disputes relating to patent infringement, enforcement, and validity. Prior to *MedImmune*, the Federal Circuit promulgated the reasonable apprehension of suit (“RAS”) test, a two-part conjunctive test that requires that (1) the declaratory judgment defendant’s actions indicate an “intent to enforce its patent” and (2) the plaintiff’s actions might “subject it or its customers to suit for patent infringement.”²¹ Under the first prong, the patent holder’s actions must create in the alleged infringer a reasonable apprehension of

15. 28 U.S.C. § 2201(a).

16. *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-72 (1950). The requirements applicable to conventional suits for entrance to federal courts also apply to declaratory judgment actions. The Supreme Court has defined the minimum constitutional requirements of standing:

[A] plaintiff must show (1) it has suffered an “injury in fact” that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs., (TOC) Inc., 528 U.S. 167, 180-81 (2000). *See also* *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

17. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937).

18. *See infra* note 34 and accompanying text.

19. *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

20. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289-90 (1995). *See also* *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345-46 (Fed. Cir. 2005); *Capo, Inc. v. Dioptrics Med. Prod., Inc.*, 387 F.3d 1352, 1357 (Fed. Cir. 2004) (“There must be a sound basis for refusing to adjudicate an actual controversy, for the policy of the [Declaratory Judgment] Act is to enable resolution of active disputes.”); *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993) (“When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory action is not subject to dismissal.”).

21. *Arrowhead Indus. Water, Inc. v. Ecolchem, Inc.*, 846 F.2d 731, 737 (Fed. Cir. 1988).

an infringement suit.²² Express charges of infringement by the patent holder are sufficient, but not necessary, to create a reasonable apprehension of suit.²³ Under the second prong, the declaratory judgment plaintiff must be engaged in an activity that would be subject to an infringement charge or have made “meaningful preparation” for such an activity.²⁴ In *MedImmune*, the Supreme Court indicated in a footnote that the RAS test was inconsistent with Supreme Court precedent, overruling the first prong of the RAS test and potentially overruling the second prong as well.²⁵ In the void left by the Court’s opinion, the Federal Circuit has begun to resolve what acts by a patentee create a justiciable controversy.²⁶

B. “Actual Controversy” in Declaratory Judgment Actions

The Supreme Court first established the meaning of “actual controversy” under the Declaratory Judgment Act in *Aetna Life Insurance Co. v. Haworth*.²⁷ In *Aetna*, the declaratory judgment defendant, Haworth, had purchased life insurance policies from Aetna Life Insurance Company.²⁸ The policies provided that upon proof of total and permanent disability, the insured was no longer required to pay additional premiums, yet the insurance policies would remain in force.²⁹ Haworth allegedly ceased payment of premiums and provided Aetna with documentation of disability.³⁰ Haworth did not initiate suit against Aetna nor make any threats to do so.³¹ He simply had a cause of action against Aetna.³² Aetna sued Ha-

22. See *infra* Section II.C.2.

23. *Goodyear Tire & Rubber Co. v. Relesomers, Inc.*, 824 F.2d 953, 956 (1987).

24. *Arrowhead*, 846 F.2d at 736.

25. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007). See *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380 n.2 (Fed. Cir. 2007) (stating that the court would “leave to another day the effect of *MedImmune*, if any, on the second prong”).

26. *Micron Tech., Inc. v. MOSAID Techs. Inc.*, No. 2007-1080, 2008 U.S. App. LEXIS 4387 (Fed. Cir. Feb. 29, 2008); *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007); *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007); *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.* 482 F.3d 1330 (Fed. Cir. 2007); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007).

27. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937).

28. *Id.* at 237.

29. *Id.*

30. *Id.* at 237-38.

31. *Aetna Life Ins. Co. v. Haworth*, 84 F.2d 695, 696-97 (8th Cir. 1936).

32. *Id.* Further, the statute of limitations would not lapse on Haworth’s cause of action for ten years after his death. *Id.* at 699 (Woodrough, J., dissenting).

worth under the Declaratory Judgment Act, seeking to have the policies declared null and void for nonpayment.³³

The *Aetna* Court defined the limitation of “actual controversy” in the text of the Declaratory Judgment Act to mean controversies appropriate for judicial determination by an Article III court.³⁴ The Court stated that the controversy must be “definite and concrete, touching the legal relations of parties having adverse legal interests.”³⁵

The Court held that the *Aetna* dispute was an actual controversy, concluding that the question before the Court was for a determination of a “present right” in the face of established, rather than hypothetical, facts.³⁶ The Court reasoned that if the insured had a clear cause of action, the opposing party also had a cause of action: “[i]t is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative.”³⁷

The Supreme Court further delineated the meaning of “actual controversy” in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*³⁸ The Court first noted the difficulty in defining an actual controversy because “the difference between an abstract question and a ‘controversy’ . . . is necessarily one of degree.”³⁹ The Court then restated the test for “actual controversy” as “whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse le-

33. *Aetna*, 300 U.S. at 239.

34. *Id.* at 239-40 (“The Declaratory Judgment Act of 1934, in its limitation to ‘cases of actual controversy,’ manifestly has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense. The word ‘actual’ is one of emphasis rather than of definition.”).

35. *Id.* at 240-41. The Court further specified:

A justiciable controversy is . . . distinguished from a difference or dispute of a hypothetical or abstract character; from one that is academic or moot. . . . It must be a real and substantial controversy admitting 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. (citations omitted)

36. *Id.* at 242.

37. *Id.* at 244.

38. *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270 (1941). The declaratory judgment plaintiff, Maryland Casualty Company, was an insurance company that had issued a policy insuring against injuries caused by automobiles hired by the insured. *Id.* at 271. After a collision between an automobile driven by an employee of the insured and a third party, suit was brought by the injured third party seeking damages. *Id.* Maryland Casualty brought a declaratory judgment action against the insured and the third party, seeking to establish that Maryland Casualty was not liable under the policy because the automobile was not owned by the insured. *Id.* at 271-72.

39. *Id.* at 273.

gal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”⁴⁰

C. Declaratory Judgment in Patent Cases

In its initial treatment of patent cases where declaratory judgment claims were brought, the Supreme Court established several benchmarks to guide lower courts as to what circumstances result in a justiciable controversy. The focus of the Supreme Court’s analyses, discussed in Section II.C.1, rested on the independence of declaratory judgment claims from infringement claims. The Court also emphasized the importance of looking into the actual relations between the parties to determine if a justiciable controversy exists. The Federal Circuit attempted to formalize the inquiry into the parties’ relations by developing the RAS test, discussed in Section II.C.2, to decide jurisdiction over declaratory judgment actions in patent cases.

1. *The Supreme Court Holds Declaratory Judgment Claims of Invalidity Justiciable Where the Patent is Found Noninfringed*

In *Altvater v. Freeman*, the Supreme Court held a justiciable controversy existed between a licensee and licensor on invalidity counterclaims.⁴¹ The Court held that the controversy still existed despite a district court’s ruling that the license was terminated and that a device manufactured and sold in violation of the license agreement did not infringe the licensor’s patents.⁴²

The licensor a decade earlier successfully sued for infringement of a different device, also in violation of the license, and the licensee was still subject to an injunction compelling royalty payments from that first suit.⁴³ After the first suit, the licensor surrendered the original patent and obtained reissue patents that the licensor contended substituted for the original patent in the license agreement.⁴⁴ On appeal from the later suit involv-

40. *Id.*

41. *Altvater v. Freeman*, 319 U.S. 359 (1943).

42. *Id.* at 365-66.

43. *Id.* at 361. The terms of the license agreement permitted *Altvater*, the licensee, to manufacture and sell parts for use with machines relating to shoe manufacture, but did not license manufacture or sale of the patented machine itself. *Freeman v. Altvater*, 66 F.2d 506, 506 (8th Cir. 1933). *Altvater* was held liable for infringement after manufacturing and selling a machine covered by the patent, in contravention of the license, and ordered to pay royalties on the machine. *Altvater*, 319 U.S. at 361.

44. *Id.* at 362. A few years after the first *Altvater* infringement suit, *Freeman* sued a different party for infringement of his patent, but the patent was held invalid. *Premier Mach. Co. v. Freeman*, 84 F.2d 425 (1st Cir. 1936). *Freeman* filed the disclaimer with the

ing the reissue patents, the Eighth Circuit affirmed the district court and held that the questions of patent validity were made moot by the district court's holdings of noninfringement and that the license was terminated by the original patent's surrender.⁴⁵

In reversing the Eighth Circuit, the Supreme Court determined that a "controversy was raging" around the validity of the patents.⁴⁶ The now-resolved patent infringement issue involved only one patent claim out of the many claims in the reissue patents owned by the licensor.⁴⁷ The licensees were commercializing products allegedly covered by the licensor's patents in addition to the product absolved of infringement.⁴⁸ The royalty payments compelled by the injunction did not make the dispute hypothetical,⁴⁹ but instead factored into the finding of controversy.⁵⁰ The Court characterized the demand and receipt of the royalty payments as a "heavy hand of . . . tribute" that the declaratory judgment counterclaim was intended to "lift" from the business.⁵¹ Furthermore, a justiciable controversy existed "where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim."⁵²

The Supreme Court more recently affirmed and clarified *Altvater* in *Cardinal Chemical Co. v. Morton International, Inc.*, in which it held that a court's finding of noninfringement does not make moot counterclaims for declaratory judgment of invalidity.⁵³ In *Cardinal Chemical*, the district court dismissed a suit for infringement, but granted the alleged infringer's

patent office covering all the invalidated claims. *Altvater*, 319 U.S. at 361-62. He then surrendered the patent and obtained the reissue patents. *Id.* at 362.

45. *Altvater*, 319 U.S. at 362. The district court held the royalties that Altvater had paid since the issuing of the reissue patents did not indicate acceptance of a new contract based on the reissue patents because the royalty payments were paid under protest and under the injunction for the first *Altvater* case. *Freeman v. Altvater*, 129 F.2d 494, 496 (8th Cir. 1942). The Eighth Circuit affirmed the district court's holding. *Id.* at 501. The Eighth Circuit's holdings of mootness were enunciated in a response to a petition for rehearing and motion to modify the opinion and decree. *Freeman v. Altvater*, 130 F.2d 763 (8th Cir. 1942).

46. *Altvater*, 319 U.S. at 364.

47. *Id.* at 364.

48. *Id.* at 364-65.

49. *Id.* at 364 ("The fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937))).

50. *Id.* at 364-65.

51. *Id.* at 365.

52. *Id.*

53. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993).

declaratory judgment counterclaims for invalidity.⁵⁴ The Federal Circuit affirmed the ruling of noninfringement on appeal, but vacated the declaratory judgment on the grounds that once a court finds noninfringement, then no controversy exists between the parties.⁵⁵ Unlike in *Altvater*, the entirety of the *Cardinal Chemicals* parties' dispute centered on allegations of infringement and invalidity.⁵⁶ However, the Supreme Court distinguished an "unnecessary ruling on an affirmative defense" from "the necessary resolution of a counterclaim for a declaratory judgment."⁵⁷ The Court underscored that jurisdiction for a counterclaim for declaratory judgment is established independently from the claim of infringement.⁵⁸

2. *The Federal Circuit Establishes the "Reasonable Apprehension of Suit" Test for Finding Jurisdiction for Declaratory Judgment Actions*

C.R. Bard, Inc. v. Schwartz was one of the first cases in which the Federal Circuit addressed declaratory judgment standing in patent cases.⁵⁹ The court held that where a patent licensee had a reasonable apprehension of an infringement suit, the license did not need to be terminated before the licensee could bring a declaratory judgment action.⁶⁰ Schwartz sued C.R. Bard, Inc. (Bard), its licensee, in state court for failing to adhere to the terms of a patent license agreement.⁶¹ Bard countered with a declaratory action in federal court alleging that Schwartz's patent was invalid and unenforceable and that the license was void and unenforceable.⁶² In reversing the lower court's dismissal for lack of jurisdiction, the Federal Circuit focused on the availability of legal challenges to both the licensor and the licensee.⁶³ Bard had materially breached the license agreement, thus allowing Schwartz, although he had not yet done so, to terminate the license and bring an action in federal court for infringement.⁶⁴ The court

54. *Id.* at 86-87.

55. *Id.* at 87.

56. *Id.* at 86-87.

57. *Id.* at 93-94.

58. *Id.* at 96.

59. 716 F.2d 874 (Fed. Cir. 1983).

60. *Id.* at 880.

61. *Id.* at 875-76.

62. *Id.* at 876.

63. *Id.* at 878-82. The court reiterated the holding from *Lear v. Atkins* that a licensee is not estopped from asserting that a patent under license is invalid. *Id.* at 878 (citing *Lear v. Atkins*, 395 U.S. 653 (1969)).

64. *Id.* at 881. The court noted that "Schwartz could at any time take action against Bard by bringing an infringement suit. There was no action Bard could take to prevent such a lawsuit." *Id.*

stated the requirement of controversy to mean that the declaratory judgment plaintiff must have “sufficient interest in the controversy and that there is a reasonable threat that the patentee or licensor will bring an infringement suit against the alleged infringer.”⁶⁵ While the court characterized its examination as “the totality of the circumstances” approach, it focused on whether Bard had a “reasonable apprehension of an infringement suit.”⁶⁶

In *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, the Federal Circuit emphasized the policy rationales behind the Declaratory Judgment Act, placing the inquiry into the existence of a controversy into the context of conducting business.⁶⁷ The Federal Circuit found that where a patent holder’s conduct compelled an apprehension of potential liability for substantial damages, a district court possesses jurisdiction over declaratory judgment claims.⁶⁸

The *Arrowhead* court applied the RAS test: “First, the defendant’s conduct must have created on the part of plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must have actually have produced the device or have prepared to produce that device.”⁶⁹ Ecolochem, a competitor of Arrowhead Industrial Water, had filed infringement suits against other competitors, informed Arrowhead’s customers of their potential liability for infringement, and initiated correspondence with Arrowhead demanding cessation of infringing practices.⁷⁰ The Federal Cir-

65. *Id.* at 879.

66. *Id.* at 880.

67. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35, 737 (Fed. Cir. 1988).

68. *Id.* at 739.

69. *Id.* at 736 (citing *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987)).

70. *Id.* at 733. The parties at suit were competing water treatment service providers. *Id.* Soon after filing suit against a third party competitor for infringement of an Ecolochem patent, Ecolochem advised an Arrowhead customer of its potential liability were it to make use of Arrowhead’s allegedly infringing services. *Id.* A month later, Ecolochem initiated correspondence with Arrowhead demanding that Arrowhead cease any current or future practices infringing the Ecolochem patent and referred to Ecolochem’s past actions of enforcing its patent rights via litigation. *Id.* Upon commencement of services to Arrowhead’s customer, Arrowhead brought a declaratory judgment action against Ecolochem. *Id.* The district court dismissed for lack of actual controversy and Arrowhead filed a second complaint that was also dismissed on the same basis. *Id.* at 733-34. Between the filing of the first and second complaint, Ecolochem proposed a finding in the suit against the third party that both the third party and Arrowhead had practiced a process that infringed the patent at suit. *Id.* at 734.

cuit found that Ecolochem's conduct indicated its intent to enforce its patent.⁷¹ The court observed that to find otherwise would allow Ecolochem to enforce its patent rights extra-judicially by way of intimidation and defeat the purpose of the Declaratory Judgment Act⁷²: to prevent "uncertainty and insecurity" and the "*in terrorem* choice between the incurrence of growing potential liability . . . and abandonment of [business] enterprises."⁷³ The Federal Circuit also found that Arrowhead's conduct fulfilled the second prong of the declaratory judgment test.⁷⁴ Although the district court indicated that Arrowhead must establish identity between its process and the patented process to satisfy this the second prong, the Federal Circuit opined that such a requirement prevents declaratory judgment actions for noninfringement and only allows those to establish invalidity or unenforceability.⁷⁵ The court stated that a declaratory judgment plaintiff instead need only show "a real interest in an activity that *may*, potentially, be enjoined."⁷⁶

In more recent cases applying the RAS test, the Federal Circuit has elaborated on the types of conduct that lead to a justiciable controversy. The court has held that threatening statements made by a patentee in the context of licensing negotiations do not fulfill the first prong of the test.⁷⁷ The court has also required objective evidence that patent licensing negotiations had broken down before exercising jurisdiction over an alleged infringer's declaratory judgment action.⁷⁸

3. *Generic Pharmaceutical Cases*

Patent infringement suits between generic and branded pharmaceutical manufacturers are governed not only by the patent laws, but also by the Federal Food, Drug, and Cosmetic Act (FDCA).⁷⁹ The FDCA regulates the manufacture and distribution of pharmaceutical drugs. The Hatch-

71. *Id.* at 737.

72. *Id.*

73. *Id.* at 735.

74. *Id.* at 737.

75. *Id.* at 738 n.10.

76. *Id.*

77. *See, e.g.,* Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 888-89 (Fed. Cir. 1992). Further, initiation of licensing negotiations by the alleged infringer was taken by the court as an indication that the patent holder might never have sued the alleged infringer. *Id.* at 889.

78. Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053-54 (Fed. Cir. 1995).

79. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-399 (2000 & Supp. IV 2004)).

Waxman Act Amendments to the FDCA provide generic pharmaceutical manufacturers a shortened approval process for marketing generic drugs.⁸⁰

The Abbreviated New Drug Application (ANDA) filed by generic manufacturers allows utilization of the safety and efficacy data submitted for the equivalent branded drug's previously filed New Drug Application (NDA).⁸¹ The ANDA process reduces both the time and cost of marketing generic pharmaceuticals. As an added incentive to produce generic drugs, the first company to file an ANDA for a particular drug is granted a 180-day period of market exclusivity before other generic manufacturers may enter the market.⁸² The 180-day period of market exclusivity begins to run either when the generic drug begins commercial marketing or when a court declares the patent covering the branded drug invalid.⁸³

An ANDA filing must include a certification concerning the status of patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.⁸⁴ The Orange Book contains a list of patents covering drugs approved by the FDA. Filing an ANDA with a certification that patents related to the branded drug are either invalid or will not be infringed constitutes a constructive act of infringement.⁸⁵ The patent owner then has forty-five days to bring a patent infringement suit against the would-be generic manufacturer.⁸⁶ By filing the patent infringement suit, the patent owner gains a thirty-month stay on the approval of the generic drug unless the patent is found invalid.⁸⁷ If the patent owner fails to file a timely action after a certification of invalidity and/or noninfringement is filed, then the FDA will begin the ANDA ap-

80. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant parts at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (2000 & Supp. III 2003)).

81. 21 U.S.C. § 355(j) (2000 & Supp. III 2003).

82. 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

83. *Id.*

84. 21 U.S.C. § 355(j)(2)(A)(vii) (2000 & Supp. III 2003). The ANDA may (i) certify that there is no patent listed for the relevant pioneer drug, (ii) certify that the patent relating to the pioneer drug is expired, (iii) list the date on which the patent relating to the pioneer drug will expire, or (iv) certify that the patent relating to the pioneer drug is invalid or not infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2000 & Supp. III 2003). The approval by the FDA of an ANDA that certifies that there is no patent or that the patent is expired is effective immediately. 21 U.S.C. § 355(j)(5)(B)(i) (2000). The approval by the FDA of an ANDA that certifies the date upon which the patent expires is effective on the date the patent expires. 21 U.S.C. § 355(j)(5)(B)(ii) (2000).

85. 35 U.S.C. § 271(e)(2)(A) (2000).

86. 21 U.S.C. § 355(j)(5)(B)(iii) (2000 & Supp. III 2003).

87. *Id.*

proval process⁸⁸ and the generic manufacturer gains standing to bring a declaratory judgment action with respect to the patent that is subject to the certification.⁸⁹

In *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, the Federal Circuit addressed declaratory judgment jurisdiction in the context of ANDA patent litigation.⁹⁰ In *Pfizer*, a generic manufacturer submitted an ANDA for a Pfizer product.⁹¹ Pfizer filed an infringement suit against the ANDA filer and the parties settled.⁹² Because the senior patent associated with the drug had not been challenged in the ANDA as invalid or noninfringed,⁹³ the ANDA filer's 180-day exclusivity period was tolled until the expiration of that patent.⁹⁴ Three years after the settlement, Teva Pharmaceuticals USA, Inc. filed an ANDA for the same product.⁹⁵ However, Pfizer neither filed an infringement suit nor agreed to grant Teva a covenant not to sue.⁹⁶ Teva filed a declaratory judgment action, seeking to invalidate the patent.⁹⁷ Invalidating the patent would trigger the first ANDA applicant's 180-day exclusivity period and hasten Teva's entry into the market.⁹⁸

The Federal Circuit concluded that even though the statute permitted an ANDA filer to bring a declaratory judgment action after the pioneer drug maker declined to sue for infringement, the statute did not independently confer subject matter standing on the ANDA filer.⁹⁹ Instead, the would-be declaratory judgment plaintiff must still show actual controversy between the parties.¹⁰⁰ Teva conceded that Pfizer would not bring suit

88. *Id.*

89. 21 U.S.C. § 355(j)(5)(C)(i) (2000 & Supp. III 2003); 35 U.S.C. § 271(e)(5) (2000 & Supp. III 2003). These provisions were part of the changes to the Hatch-Waxman Amendments made in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

90. *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

91. *Id.* at 1330. The first ANDA filer submitted a paragraph III certification for one patent and a paragraph IV certification for the other patent listed in the Orange Book. *Id.*

92. *Id.*

93. In addition, the patent did not expire for several more years. *Id.* at 1329.

94. *Id.* at 1330.

95. *Id.* Like the first ANDA filer, Teva filed a paragraph III certification for one patent and a paragraph IV certification for the other patent listed in the Orange Book. *Id.*

96. *Id.* at 1330.

97. *Id.* at 1327.

98. *See supra* text accompanying notes 81-83.

99. *Pfizer*, 395 F.3d at 1334.

100. *Id.* at 1334, 1337. The court based its finding, in part, on the plain language of statute: "[T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any [declaratory judgment] action brought [by an ANDA filer]." 35 U.S.C. 271(e)(5) (2000 & Supp. III 2003) (emphasis added).

against Teva because that would expose Pfizer's patent to the risk of an invalidity or noninfringement finding.¹⁰¹ Pfizer had no need to sue Teva immediately because Teva's ANDA would not be granted approval until after the expiration of the 180-day exclusivity period.¹⁰² The court held that Teva failed to show an "actual controversy" under the RAS test because there was no apprehension that Pfizer would bring suit.¹⁰³

III. CASE SUMMARY

This Part summarizes recent developments in establishing a justiciable controversy for declaratory judgment actions in patent cases. Section III.A discusses the facts, procedural history and ruling of *MedImmune*. Section III.B discusses the Federal Circuit's application of the *MedImmune* opinion in its *SanDisk* and *Novartis* decisions.

A. *MedImmune v. Genentech*

In *MedImmune*, the Supreme Court examined whether a patent licensee who paid royalties, thereby ensuring that the licensor could not sue for infringement or breach of contract, could still maintain an action for declaratory judgment to dispute the terms of the contract.¹⁰⁴

1. *Facts & Procedural History*

In 1997, MedImmune entered into a license agreement with Genentech.¹⁰⁵ The agreement licensed an issued patent and a pending patent application, hereinafter referred to as the Cabilly I¹⁰⁶ and Cabilly II¹⁰⁷ patents, respectively.¹⁰⁸ When the Cabilly II patent issued in late 2001, Genentech informed MedImmune in writing that Cabilly II covered MedImmune's Synagis product and asserted that royalties were thus owed under the 1997 license agreement.¹⁰⁹

MedImmune believed that the Cabilly II patent was invalid and unenforceable, and that the Synagis product did not infringe the Cabilly II patent's claims.¹¹⁰ Continuing to fulfill the stated royalty obligations of the license agreement, MedImmune filed a declaratory judgment action in the

101. *Pfizer*, 395 F.3d at 1333-34.

102. *Id.* at 1334.

103. *Id.*

104. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007).

105. *Id.* at 767-68.

106. U.S. Patent No. 4,816,567 (filed Apr. 8, 1983).

107. U.S. Patent No. 6,331,415 (filed June 10, 1988).

108. *MedImmune*, 127 S. Ct. at 768.

109. *Id.*

110. *Id.*

U.S. District Court for the Central District of California seeking a determination of invalidity and noninfringement of the Cabilly II patent.¹¹¹ MedImmune regarded Genentech's letter as a threat: if MedImmune did not pay the fees demanded for the Cabilly II patent, Genentech could terminate the license agreement and sue for infringement.¹¹² Loss in a patent litigation could result, in the worst-case scenario, in treble damages for willful infringement and an injunction against further sales of Synagis.¹¹³ Facing this risk, MedImmune continued to pay royalties under the license, thereby preventing Genentech from having an action for either breach of contract or infringement.

The district court granted Genentech's motion to dismiss the declaratory judgment claims for lack of subject-matter jurisdiction. The Federal Circuit affirmed.¹¹⁴ Both courts relied on the Federal Circuit's opinion in *Gen-Probe Inc. v. Vysis Inc.*, where the Federal Circuit held that there is no justiciable controversy where a licensee is in good standing because the licensee has no reasonable apprehension that the licensor will sue for infringement.¹¹⁵ The Federal Circuit held that a federal court does not have jurisdiction over a declaratory action for patent invalidity, unenforceability, or noninfringement where the plaintiff licensed the patents and is in full compliance with the license.¹¹⁶ Under these conditions, there is no apprehension of a suit for infringement.¹¹⁷

2. *The Supreme Court's Ruling*

The Supreme Court reversed the dismissal.¹¹⁸ The Court held that MedImmune could pay royalties to Genentech to eliminate the risk of an action for infringement, but still file suit for a declaratory judgment of noninfringement, invalidity, and unenforceability.¹¹⁹ The Court reasoned that Article III's justiciable controversy requirement did not support a standard that required an unwilling licensee to risk liability for infringe-

111. *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03-2567, 2004 U.S. Dist. LEXIS 28680 (C.D. Cal. Apr. 29, 2004).

112. *MedImmune*, 127 S. Ct. at 768.

113. *Id.*

114. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005).

115. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 768 (2007) (noting that both lower courts relied on *Gen-Probe Inc. v. Vysis Inc.*, 359 F.3d 1376 (Fed. Cir. 2004)).

116. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005).

117. *Id.* at 965.

118. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007).

119. *Id.*

ment, with potential treble damages, before it could obtain a declaration of actively contested legal rights.¹²⁰

The Court stated the standard for an actual controversy in the context of declaratory judgment as “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.”¹²¹ The Court noted that if MedImmune had ceased to pay the license fees, then there would have been no question that a justiciable controversy existed, but instead MedImmune’s “own acts . . . eliminate[d] the imminent threat of harm.”¹²² Thus, the Court considered whether the act of paying license fees prevented MedImmune from challenging the patents and the license agreement.

The Court first looked to cases where the adverse legal interests included a private party and the government. Where a declaratory judgment plaintiff seeks to challenge the constitutionality of a statute, the plaintiff is not required to violate the statute in question.¹²³ The Court characterized such a plaintiff’s conduct in avoiding prosecution and the risk of liability as eliminating a threat of harm.¹²⁴ The plaintiff does not have to choose between abandoning a claim of right or facing the threat of injury.¹²⁵

The Court next examined disputed legal claims between private parties. As above, the *MedImmune* Court stressed that a plaintiff should not be required to take actions that engender grave risks (to “bet the farm”) when such claims arise.¹²⁶ The Court’s reasoning relied on *Altwater*, where a licensee continued to pay royalties to the patent holder, but the requirements for a justiciable controversy were met for a dispute over the patents’ validity.¹²⁷ The Court interpreted *Altwater* to hold that a licensee retains the right to bring a declaratory judgment action when the licensee pays royalties under protest and because of injunction decree.¹²⁸ The Court pointed to the “involuntary” and “coercive” nature of the royalty payments

120. *Id.* at 775 (“The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.”).

121. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

122. *Id.* at 772.

123. *Id.* at 772-73.

124. *Id.* at 772.

125. *Id.* at 772-73.

126. *Id.* at 775.

127. *Id.* at 773. For discussion, see *supra* text accompanying notes 41-52.

128. *Id.* (citing *Altwater v. Freeman*, 319 U.S. 359 (1943)).

that the *Altvater* licensee made under the injunctive decree.¹²⁹ The Court reasoned that a party who makes royalty payments under an injunction, as in *Altvater*, is no different than a licensee in good standing who makes royalty payments based on fear of treble damages and injunctions.¹³⁰ However, in neither case would the party making royalty payments have standing to bring a declaratory judgment action under the Federal Circuit's RAS test.¹³¹

Ultimately, the Court never explicitly overruled the RAS test. Rather, the Court pronounced its death in a footnote by pointing out that the Federal Circuit's test conflicts with Supreme Court precedent,¹³² including *Aetna*,¹³³ *Maryland Casualty*,¹³⁴ and *Cardinal Chemical*.¹³⁵

B. The Federal Circuit's Response to *MedImmune*

Within three months of the *MedImmune* decision and the implicit overruling of the RAS test, the Federal Circuit began establishing new standards for declaratory judgment jurisdiction in patent cases. In *SanDisk Corp. v. STMicroelectronics, Inc.*, the Federal Circuit considered a dispute between competitors who had entered into negotiations over a cross-licensing agreement.¹³⁶ In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, the Federal Circuit addressed a dispute similar to that in *Pfizer* between generic and brand name pharmaceutical companies.¹³⁷ The Federal Circuit created signposts in these cases for future litigants regarding the actions of patent holders that establish declaratory judgment jurisdiction.

1. *SanDisk v. STMicroelectronics*

SanDisk Corp. brought a declaratory judgment action against STMicroelectronics, Inc. (ST) in the United States District Court for the Northern District of California. SanDisk sought a declaration of invalidity

129. *Id.* (citing *Altvater v. Freeman*, 319 U.S. 359, 365 (1943)).

130. *Id.* at 774 n.11 (2007). The Court failed to acknowledge that a party might voluntarily enter into a license to gain access to another party's technology. See Sean M. O'Connor, *Using Stock and Stock Options to Minimize Patent Royalty Payment Risks after MedImmune v. Genentech*, 3 N.Y.U. J.L. & BUS. 381, 387-88 (2007).

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

132. *Id.*

133. See *supra* text accompanying notes 27-37.

134. See *supra* text accompanying notes 38-40.

135. See *supra* text accompanying notes 53-58.

136. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007).

137. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007). See *supra* text accompanying notes 90-103 for discussion of *Pfizer*.

and noninfringement of patents held by ST.¹³⁸ The district court held that it had no subject matter jurisdiction under the RAS test.¹³⁹ The Federal Circuit reversed in view of the recently decided *MedImmune* case.¹⁴⁰

a) Facts & Procedural History

SanDisk, a manufacturer of flash memory storage devices, was initially approached by ST, a recent entrant into the flash memory storage market, to discuss a cross-licensing agreement.¹⁴¹ Over the next several months, SanDisk and ST met to discuss patent cross-licensing and other unrelated business transactions.¹⁴² During the meetings, ST presented infringement analyses of SanDisk activities in relation to ST patents.¹⁴³ SanDisk made an analogous presentation to ST.¹⁴⁴ At first, the parties maintained that they had no intention to sue each other.¹⁴⁵ However, SanDisk eventually filed an action for infringement of its own patent and for declaratory judgment of invalidity and noninfringement of the ST patents.¹⁴⁶ The district court granted ST's motion to dismiss SanDisk's declaratory judgment claims for lack of subject matter jurisdiction, holding that SanDisk did not have an objectively reasonable apprehension of suit by ST.¹⁴⁷

b) The Federal Circuit's Ruling

In light of the recently decided *MedImmune* case, the Federal Circuit vacated the district court's dismissal of SanDisk's declaratory judgment action for lack of subject matter jurisdiction.¹⁴⁸ Under *MedImmune*, a fed-

138. *SanDisk Corp. v. STMicroelectronics, Inc.*, No. C 04-04379 JF, 2005 U.S. Dist LEXIS 44870 (N.D. Cal. Jan. 20, 2005).

139. *Id.*

140. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007).

141. *Id.* at 1374.

142. *Id.*

143. *Id.* at 1375. ST also provided SanDisk with detailed reverse engineering reports for some of SanDisk's products and diagrams explaining how ST's patent claims covered SanDisk's products. *Id.*

144. *Id.*

145. *Id.* at 1376.

146. *SanDisk Corp. v. STMicroelectronics, Inc.*, No. C 04-04379 JF, 2005 U.S. Dist LEXIS 44870, *16 (N.D. Cal. Jan. 20, 2005).

147. *Id.* at *27. The district court also held, in a footnote, that as an alternative basis for dismissal, even if the court had subject matter jurisdiction, it would use its discretion to decline jurisdiction. *Id.* at *33 n.30.

148. *SanDisk*, 480 F.3d 1372. In reversing the district court's alternative basis for dismissal, discretion to decline declaratory judgment jurisdiction, the Federal Circuit concluded that because the dismissal relied on the now-overruled RAS test, there was "little basis" for the discretionary refusal. *Id.* at 1383. The court instructed the district

eral court has subject matter jurisdiction for a declaratory judgment action where the plaintiff disagrees with the defendant's claim of right, but would risk grave injury if they did not comply.¹⁴⁹ Unlike the parties in *MedImmune*, SanDisk was not a licensee of ST, but instead was in discussions with ST over cross-licensing. The Federal Circuit focused its decision on the acts by ST demonstrating its belief that SanDisk was infringing ST patents.¹⁵⁰

The court held that a party can bring a declaratory judgment action before it receives explicit threats of litigation.¹⁵¹

We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.¹⁵²

The court observed that this holding was consistent with *MedImmune* and other precedent regarding declaratory judgment jurisdiction in cases unconnected with patent licensing.¹⁵³ The Federal Circuit acknowledged that *MedImmune* thus overruled the first prong of the RAS test pertaining to acts by the patentee sufficient to confer jurisdiction.¹⁵⁴ However, the court observed that *MedImmune* did not address the second prong of the RAS test, concerning acts required by the declaratory judgment plaintiff, and stated that it would defer considering the effect of *MedImmune* on this prong.¹⁵⁵

court that, on remand, without additional facts in the record, the district court could not use its discretion to refuse jurisdiction. *Id.*

149. *Id.* at 1379 (citing *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 773 (2007)).

150. *Id.* at 1382.

151. *Id.* at 1381.

152. *Id.*

153. *Id.* at 1381-82.

154. *Id.* at 1380.

155. *Id.* at 1380 n.2 (“We therefore leave to another day the effect of *MedImmune*, if any, on the second prong.”). The second prong of the test asks whether declaratory judgment plaintiff has engaged in infringing activity or has meaningfully prepared to engage in infringing activity. See *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (defining the second prong).

In a concurring opinion, Judge Bryson agreed that *MedImmune* compelled the *SanDisk* outcome.¹⁵⁶ However, he believed nothing in the facts of the licensing negotiation between SanDisk and ST indicated any difference between their negotiation and any other licensing negotiation.¹⁵⁷ Judge Bryson also voiced his concerns that *MedImmune*'s broadening of declaratory judgment jurisdiction in patent cases implied "no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the patentee."¹⁵⁸

2. *Teva Pharmaceuticals v. Novartis Pharmaceuticals*

Teva Pharmaceuticals USA brought a declaratory judgment action against Novartis Pharmaceuticals Corp. in the United States District Court for the District of New Jersey for a declaration of invalidity and noninfringement of patents held by Novartis.¹⁵⁹ As in *SanDisk*, the district court found that Teva lacked standing to bring suit under the RAS test,¹⁶⁰ and the Federal Circuit reversed under *MedImmune*.¹⁶¹

a) Facts & Procedural History

Novartis held an NDA¹⁶² for Famvir, a drug used in the treatment of herpes infections.¹⁶³ Novartis listed five patents covering Famvir in the Orange Book: one related to the active ingredient composition and four directed to methods of therapeutic use.¹⁶⁴ The composition patent was set to expire four to five years before the method patents.¹⁶⁵ Teva submitted

156. Judge Bryson disagreed with the majority's remand that disallowed the district court to exercise discretion in declining jurisdiction. *SanDisk*, 480 F.3d at 1385 n.2 (Bryson, J., concurring). He noted that the engagement of the parties in a parallel infringement action was an important factor for deciding whether to allow a declaratory judgment action to proceed and suggested that there was no reason why the district court could not decide, on the present facts in the record, to refuse jurisdiction. *Id.*

157. *Id.* at 1385.

158. *Id.*

159. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007).

160. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, No. 05-2881 JLL, 2005 U.S. Dist. LEXIS 38649 (D.N.J. Dec. 12, 2005).

161. *Novartis*, 482 F.3d 1330.

162. *See supra* text accompanying notes 79-89.

163. *Novartis*, 482 F.3d at 1334.

164. *Id.*

165. *Id.*

an ANDA for a generic version of Famvir certifying that its drug did not infringe Novartis' patents or that the patents were invalid.¹⁶⁶

Novartis filed a timely suit against Teva for infringement of the composition patent, but not the method patents.¹⁶⁷ In a separate suit, Teva brought a declaratory judgment action for invalidity and noninfringement of the unasserted method patents.¹⁶⁸ Novartis filed a motion to dismiss, arguing that the district court lacked subject matter jurisdiction.¹⁶⁹ To determine whether it had jurisdiction, the district court applied the RAS test¹⁷⁰ with guidance from the Federal Circuit's opinion in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*¹⁷¹ Because Novartis had not taken any actions or made any threats to enforce the method patents, the district court held that no justiciable controversy existed and that the court lacked subject matter jurisdiction.¹⁷²

b) Federal Circuit's Ruling

The Federal Circuit reversed the district court and held that Teva had a justiciable controversy under the *MedImmune* standard.¹⁷³ Freed from the formalism of the RAS test, the court looked at the totality of the circumstances under which Teva had brought suit. The court cited several circumstances that factored into its finding of a controversy.

First, the court pointed to Novartis' Orange Book listing of the five patents related to Famvir. The listing signaled Novartis' claim of right to file a patent infringement suit against anyone who manufactured, used, or sold a generic version of the drug without license.¹⁷⁴ Second, Teva's ANDA submission with certification of noninfringement or invalidity was a statutory act of infringement that provided Novartis with grounds to sue.¹⁷⁵ The court reasoned that where an action creates a justiciable con-

166. *Id.* Teva filed paragraph IV certifications under 21 U.S.C. § 355(j)(2)(A)(vii) for all five Novartis patents. *Id.* Paragraph IV certifications constitute technical infringement under 35 U.S.C. § 271(e)(1) (2000 & Supp. III 2003).

167. *Novartis*, 483 F.3d at 1334-35.

168. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, No. 05-2881 JLL, 2005 U.S. Dist. LEXIS 38649 (D.N.J. Dec. 12, 2005).

169. *Id.* at *2-3.

170. *Id.* at *3.

171. *Id.* at *5-7 (comparing the facts to *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005)). *See supra* text accompanying notes 90-99.

172. *Id.* at *9.

173. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007).

174. *Id.* at 1341-42.

175. *Id.* at 1342 (applying *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941))

trover for one party, that action should likewise support declaratory judgment for the other party to the dispute.¹⁷⁶

Next, the Federal Circuit looked to the declaratory judgment provisions in the Hatch-Waxman Act¹⁷⁷ and the intent that motivated the Act.¹⁷⁸ Congress intended those provisions to facilitate prompt judicial resolution of patent issues between generic pharmaceutical manufactures and patent holders of the branded drug.¹⁷⁹ The intent behind both the Hatch-Waxman Act, in general, and the provisions, in particular, was to accelerate the time to market for generic drugs.¹⁸⁰ The court interpreted Novartis' selective suit for infringement on only one of its patents as an attempt to "simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities."¹⁸¹ By bringing a timely infringement action in response to Teva's ANDA filing, Novartis was granted a thirty-month stay on the approval of the ANDA under the Hatch-Waxman provisions.¹⁸² But, the statute requires that, in exchange for the stay, patentees must "reasonably cooperate in expediting" the underlying patent litigation.¹⁸³ Because Novartis selectively

176. *Id.* ("It logically follows that if [submitting an ANDA] creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party.").

177. The declaratory judgment provisions were added in the 2003 amendments to the Hatch-Waxman Act to allow an ANDA applicant to file a declaratory judgment action against the brand pharmaceutical manufacturer who had not brought an infringement action within 45 days. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

178. *Novartis*, 482 F.3d at 1342 (citing "the combination of . . . 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").

179. *Id.* The court observed that the declaratory judgment provisions were "designed to prevent patentees from 'gaming' the Hatch-Waxman Act." *Id.* Congress sought to prevent parties on both sides from exploiting loopholes in the Act to delay generic competition. *Id.* at 1343 n.7 (citing 149 CONG. REC. S15885 (Nov. 25, 2003) (remarks of Senator Kennedy, Ranking Member, Senate Committee on Health, Education, Labor, and Pensions ("Senate HELP committee"))).

180. *Id.* at 1344 ("A central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment [provisions] is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'" (alteration in original) (citing 149 CONG. REC. S15885 (Nov. 25, 2003) (remarks of Senator Kennedy, Ranking Member, Senate HELP committee))).

181. *Id.* at 1343.

182. *Id.* at 1343. The approval of an ANDA where the patent holder brings a timely infringement suit is effective at the earlier time point of 30 months or resolution of the litigation. *See* 21 U.S.C. 355(j)(5)(B)(iii) (2000 & Supp. III 2003).

183. *Novartis*, 482 F.3d at 1343 (quoting 21 U.S.C. 355(j)(5)(B)(iii)).

attempted to litigate only one of its listed patents, the Federal Circuit concluded that its actions “frustrate[d]” the purpose and intent of the Hatch-Waxman Act.¹⁸⁴

Finally, pending and potential future litigation supported the Federal Circuit’s decision to allow the declaratory judgment action to proceed. Novartis had already filed suit against Teva over the composition patent.¹⁸⁵ Litigation over the composition patent and the method patents necessarily involved the same technology, the same parties, and related patents. In non-ANDA actions, all of these factors are relevant to jurisdiction.¹⁸⁶ Moreover, the possibility of future litigation loomed because Novartis could sue Teva for infringement at a later time based on the method patents.¹⁸⁷ The Federal Circuit concluded that the possibility that a single ANDA application could initiate multiple infringement suits and lengthy litigation supported its finding of a justiciable controversy.¹⁸⁸

In his concurring opinion, Judge Friedman reached the same conclusion on simpler grounds.¹⁸⁹ He noted that all five of Novartis’ patents were related and that, by listing them in the Orange Book, Novartis had asserted that it could file an infringement action against any unlicensed entity manufacturing, selling, or using a generic version of its drug.¹⁹⁰ Furthermore, Teva had filed an ANDA with a certification of noninfringement/invalidity against all of Novartis’ Orange Book listed patents.¹⁹¹ As a result, a justiciable controversy existed between Teva and Novartis with respect to all of those patents.¹⁹²

184. *Id.* at 1343-44 (Fed. Cir. 2007). In support of its reasoning, the court quoted the legislative history:

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 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.

Id. at 1343 (alteration in original) (quoting 149 CONG. REC. S15885 (Nov. 25, 2003) (remarks of Senator Kennedy, Ranking Member, Senate HELP committee)).

185. *Id.* at 1344.

186. *Id.*

187. *Id.* at 1345.

188. *Id.*

189. *Id.* at 1346-47 (Friedman, J., concurring).

190. *Id.* at 1347.

191. *Id.*

192. *Id.*

IV. ANALYSIS

The *MedImmune* decision signaled the demise of the Federal Circuit's RAS test. The Supreme Court thus reversed years of Federal Circuit precedent that had established heightened requirements in patent cases for a justiciable controversy. In the wake of *MedImmune*, the Federal Circuit quickly established new standards for declaratory judgment jurisdiction in patent cases.¹⁹³ However, Judge Bryson's concurrence in *SanDisk* cautions that the new standard may set the bar too low; the mere offer of a license for a fee may trigger jurisdiction over a declaratory judgment action of noninfringement and invalidity.¹⁹⁴ The precedential void created by *MedImmune* raises two related issues. What are the outer boundaries of circumstances in which a party may bring declaratory judgment claims against a patent holder with regard to (1) actions taken by the patent holder and (2) conduct of the alleged infringer?

The Federal Circuit's now defunct RAS test provided guidelines for conduct that would trigger declaratory judgment jurisdiction. A patent holder had clear-cut courses of action for offering a license without risking a declaratory judgment action in response.¹⁹⁵ The alleged infringer was less fortunate, having little recourse to the courts when the patent holder made threats just below the level needed to establish a justiciable controversy.

The *MedImmune* decision corrected a course of action that the Federal Circuit had taken to an arguably unjust extreme. Rather than focusing on whether the patent holder had grounds to bring suit, the RAS standard required courts to focus on the imminence and likelihood of suit by the patent holder.¹⁹⁶ Under this query, parties facing an asserted patent could not obtain standing to challenge the patent even if the patent holder made it clear that they believed the patent infringed while the alleged infringer believed there was no liability under that patent.¹⁹⁷ *MedImmune* returned the

193. See *SanDisk Corp. v. STMicroelectronics, Inc.* 480 F.3d 1372 (Fed. Cir. 2007); *Novartis*, 482 F.3d 1330.

194. *SanDisk*, 480 F.3d at 1384 (Bryson, J., concurring).

195. See Lisa A. Dolak, *Power or Prudence: Toward a Better Standard for Evaluating Patent Litigants' Access to the Declaratory Judgment Remedy*, 41 U.S.F. L. REV. 407, 429-30 (2007) (detailing circumstances that have precluded a finding of declaratory judgment jurisdiction).

196. See *supra* II.C.2; see also Dolak, *supra* note 5, at 908, 923-937 (providing a history of the evolution of the Federal Circuit's declaratory judgment jurisprudence and critiquing the divergence of the declaratory judgment jurisdiction standard from the infringement liability standard).

197. See *supra* II.C.2; see also William S. Nabors, *A Reasonable Apprehension of Lawsuit: A Restrictive Threshold for Federal Court Jurisdiction in Patent Declaratory*

jurisdictional standard to where it was before the Federal Circuit established the RAS test. Reasonable apprehension of an infringement suit may remain a factor for determining if two parties have adverse interests sufficient for declaratory judgment, but the *MedImmune* Court held that such apprehension is not required to establish jurisdiction. Since *MedImmune*, the Federal Circuit has begun to reshape the bounds of declaratory judgment jurisprudence in patent cases.

A. Actions Required of the Patent Holder to Establish a Controversy

At present, the Federal Circuit appears to consider declaratory judgment jurisdiction established when an alleged infringer gains knowledge of potential liability. In the past, Professor Lisa Dolak criticized the RAS test because of inconsistency between its standard for declaratory judgment jurisdiction and the standard for notice of infringement.¹⁹⁸ The standard for notice, a requirement for damages to accrue and a possible precursor to a finding of willful infringement, is much looser than that for establishing reasonable apprehension of litigation.¹⁹⁹ This disparity allowed a patentee to provide notice of infringement without risking a declaratory judgment suit, thus producing considerable pressure on the alleged infringer to agree to a license, even when validity and infringement were uncertain. The new standard is more analogous to a liability standard.²⁰⁰ The focus of the inquiry going forward appears to be whether the patent holder's actions give the alleged infringer a reasonable basis to conclude potential infringement liability exists. As a result, the courts have leveled the playing field, in one respect, between the patent holder and the alleged infringer.

1. *Is a Patent Grant Sufficient to Establish a Controversy?*

In *Novartis*, the Federal Circuit suggested that constructive notice of infringement without any affirmative act by the patentee may suffice to

Judgments, 7 WAKE FOREST INTELL. PROP. L.J. 1, 31 (2006) (“It is likely that there are situations where a declaratory judgment plaintiff will suffer an actual injury cause by the patent owner’s acts or omissions, but where there is no apprehension of lawsuit.”).

198. Dolak, *supra* note 5.

199. See Dolak, *supra* note 5, at 938-44 (describing the standards for notice of infringement liability); *id.* at 944 (“[T]he accused infringer is potentially liable for damages but may be unable to bring a declaratory judgment action to challenge validity and infringement.”).

200. See Dolak, *supra* note 5, at 945 (arguing that “the courts should return to the view that a reasonable apprehension of *liability* on the part of the accused infringer is sufficient to satisfy the [Declaratory Judgment] Act’s requirement for an actual controversy”).

create an actual controversy. The court noted that Novartis' listing of patents in the Orange Book weighed toward the existence of a controversy.²⁰¹ Although it cautioned that the listing alone may be insufficient to establish a controversy, the court did not foreclose this possibility. Indeed, Judge Friedman's concurrence found that the only act required by Novartis was the Orange Book listing.²⁰² But the majority pointed to other conduct by Novartis in support of justiciability: the pending infringement litigation for infringement of the composition patent and the strategic nature of selecting the composition patent as the basis for the pending litigation.²⁰³ Regardless, it remains unclear whether these additional actions by Novartis were necessary in the majority's view to support a finding of an actual controversy.

The above reasoning is a far cry from that of the Federal Circuit in *Pfizer*, decided under the RAS test.²⁰⁴ There, the Orange Book listing was considered a statutory requirement and not indicative of intent to enforce the patent.²⁰⁵ Moreover, the *Pfizer* court did not show much sympathy for the generic manufacturer, explaining that "more is required for an actual controversy than the existence of an adversely held patent."²⁰⁶ The *Pfizer* court's reasoning possibly reflected the idea that a patent holder, having only rights to exclude, does not assert her rights until she takes steps to enforce the patent.²⁰⁷ But if Judge Friedman's view in *Novartis* carries the day, then affirmative steps are entirely unnecessary—all that is needed from the patent holder is an adversely held patent.²⁰⁸

2. *Should the Court Consider the Interests of the Patent Holder in Deciding Jurisdiction?*

A scheme that requires little or no action on the part of the patentee—other than holding a patent—shows little regard for the plight of the patentee at the mercy of litigious potential licensees. Prior to *MedImmune*, the Federal Circuit cited the protection of "quiescent patent owners against

201. See *supra* note 174 and accompanying text.

202. See *supra* note 190 and accompanying text.

203. See *supra* text accompanying notes 181-186.

204. *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005). See *supra* text accompanying notes 90-103.

205. *Id.* at 1333.

206. *Id.*

207. *Nabors*, *supra* note 197, at 21.

208. Granted, the *Novartis* and *Pfizer* cases involved patent litigation within the context of the Hatch-Waxman Act and its distinct statutory provisions and policy considerations. The Act is intended to encourage generic pharmaceutical companies to challenge drug patents. Minimizing the actions required by the patent holder to create a controversy thus aligns with the intent of the statute.

unwarranted litigation” as a rationale for placing weight on actions by the patentee that evince intent to sue for infringement.²⁰⁹ The court also concerned itself with the welfare of the patent licensors who had given up their statutory right to sue their licensees.²¹⁰ Professor Dolak argued that the Federal Circuit’s citing of protection of the patentee as one rationale for deciding declaratory judgment jurisdiction conflated policy concerns with constitutional concerns.²¹¹ She maintained that the protection of patent holders is a matter for legislative or judicial policy, not for jurisdictional issues that find their roots in the Constitution.²¹² Under *MedImmune*, concerns for protection of patentees may be considered as part of a district court’s discretion to hear the declaratory judgment action, rather than as part of the jurisdictional inquiry.

However, an effort to protect the patent holder may not actually prevent unnecessary litigation. In a case of actual controversy, the parties may land in court eventually, but under the RAS test there was bias towards the timing and venue of the patent holder’s choosing.²¹³ The RAS regime was not consistent with Supreme Court precedent that a controversy ripe for resolution via a conventional suit is appropriate for resolution by a declaratory judgment suit as well.²¹⁴

In *Micron Technology, Inc. v. MOSAID Technologies, Inc.*, a case decided after *MedImmune*, *SanDisk*, and *Novartis*, the Federal Circuit responded to the quandary of the competing interests of patent holders and alleged infringers where declaratory judgment jurisdiction is easily achieved.²¹⁵ In an opinion authored by Judge Rader, the Federal Circuit instructed courts to consider the convenience factors found in transfer

209. See Dolak, *supra* note 195, at 427 (citing *Arrowhead Indus. Water, Inc. v. Eco-lochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)). The court in *Arrowhead* had stated that, “[i]f, on the other hand, defendant has done nothing but obtain a patent, there can be no basis for the required apprehension, a rule that protects quiescent patent owners against unwarranted litigation.” *Arrowhead*, 846 F.2d at 736.

210. Dolak, *supra* note 195, at 423 (citing *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004)).

211. Dolak, *supra* note 195.

212. *Id.* at 429.

213. Nabors, *supra* note 197, at 7.

214. See *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 244 (1937) (stating that it is “the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative.”); *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (“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.”).

215. *Micron Tech., Inc. v. MOSAID Techs., Inc.*, No. 2007-1080, 2008 U.S. App. Lexis 4387 (Fed. Cir. Feb. 29, 2007).

analysis when deciding whether to exercise their discretion to accept a declaratory judgment action.²¹⁶ Accordingly, where both the alleged infringer and the patent holder file suit in separate forums, the first-filed action may not always be given priority.²¹⁷

B. Action Required by the Alleged Infringer to Establish Jurisdiction

The RAS regime did not solely examine the acts of the patent holder. It also required that the alleged infringer engage in infringing acts or make meaningful preparations to do so before jurisdiction was established.²¹⁸ In *MedImmune*, the Supreme Court did not make clear whether this second prong of the RAS test was also overruled. Each case the Court cited as contradicting the RAS test dealt with lack of apprehension that the patentee—the declaratory judgment defendant—would imminently sue.²¹⁹ Thus far, the Federal Circuit has forgone deciding the effect of *MedImmune* on the standard for the conduct of the alleged infringer.²²⁰

1. The Constitution and the Patent Statutes Mandate Demonstrable Interest in Allegedly Infringing Activities

The Constitution and policy rationales require that the alleged infringer show a real interest in activities that the patentee may attempt to exclude.²²¹ The Constitution prohibits advisory opinions and decisions based on hypothetical facts.²²² If the alleged infringer has not yet finalized the potentially infringing device, determining infringement is a counterfactual endeavor.²²³ Moreover, litigation over a theoretical device would waste judicial resources and squander the financial resources of both parties.²²⁴ These considerations should prevent a party from using a declara-

216. *Id.* at *12-13. See 28 U.S.C. § 1404(a) (2000); *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993).

217. *Micron*, 2008 U.S. App. LEXIS 4387, *16-18.

218. See *supra* text accompanying notes 21-24.

219. See *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007).

220. See *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380 n.2 (Fed. Cir. 2007) (“We therefore leave to another day the effect of *MedImmune*, if any, on the second prong.”).

221. See, e.g., *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992). Any declaratory judgment plaintiff must have suffered an injury to a “legally protected interest” that can be traced to the “challenged action” of the defendant. *Id.* at 560-61.

222. See *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937); see also *Muskrat v. United States*, 219 U.S. 346 (1911).

223. Dolak, *supra* note 195, at 435.

224. *Id.*

tory judgment action to attack a patent solely because it may impede a future business venture.

The patent statutes provide further basis for limiting a party's ability to challenge a patent via a declaratory judgment without a demonstrated interest in activities covered by the patent. Declaratory judgment challenges to patents can involve numerous claims, including noninfringement, invalidity, and unenforceability. Because a patentee will only bring a suit for infringement, invalidity and unenforceability are affirmative defenses, not freestanding actions.²²⁵ Thus, declaratory judgment actions cannot simply involve claims for invalidity or unenforceability, but must necessarily include a claim for noninfringement as the counterpart to the patentee's potential suit for infringement. If declaratory judgment actions could be brought solely on the basis of invalidity or unenforceability, the federal courts would effectively become tribunals for post-grant review, available at the whim of any party simply disgruntled by another party's patent.

In dissenting from the majority in *MedImmune*, Justice Thomas relied on the above arguments to contend that the courts had no jurisdiction over MedImmune's dispute with Genentech. He stated that "MedImmune's prayer for declaratory relief can be reasonably understood only as seeking an advisory opinion about an affirmative defense it might use in some future litigation."²²⁶ He also insisted that MedImmune's contract claim was simply a "repackag[ing]" of its invalidity claim and that invalidity is merely "an affirmative defense to patent infringement, not a freestanding cause of action."²²⁷

Justice Thomas' comments are more significant in the general context of patent disputes than within the context of *MedImmune* itself. Genentech's disagreement with MedImmune was complex, but it centered around the right of a licensee to challenge a licensed patent without first breaching the license agreement.²²⁸ Moreover, MedImmune was actually practicing the invention allegedly covered by the patent.²²⁹ But for the shield of the license, Genentech could have sued for infringement. Likewise, but for the un-breached license, MedImmune could have sought declaratory judgment, even under the high bar of the RAS test. But in cir-

225. Under the patent laws, patents are presumed valid. *See* 35 U.S.C. § 282(1)-(3) (2000).

226. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 780 (2007) (Thomas, J., dissenting).

227. *Id.* at 779, 780.

228. *See supra* Section III.A.

229. *MedImmune*, 127 S. Ct. at 768 (majority opinion). Genentech indicated that the Cabilly II patent covered MedImmune's product Synagis. *Id.*

cumstances where a potential declaratory judgment plaintiff is not yet practicing an allegedly infringing invention, Justice Thomas' admonition against issuing advisory opinions over affirmative defenses would carry more weight.

2. *The Federal Circuit may Require Evidence of a Real Interest in Activities Covered by the Patent at Issue*

The *MedImmune* majority signaled that an alleged infringer must come relatively close to infringement before bringing a declaratory judgment action. The Court stated that the facts of the case must have "sufficient immediacy and reality"²³⁰ and that the dispute must be "definite and concrete."²³¹ But conversely, the majority also stated that a party should not be required to engage in offending or illicit conduct in order to establish a justiciable controversy. These latter statements conflict with the second prong of the Federal Circuit's reasonable apprehension of suit test, thereby calling the viability of that prong into question.²³²

Although the Federal Circuit explicitly refused to address the validity of the second prong²³³ in *SanDisk*, its holding in *SanDisk* is consistent with overruling it. The Federal Circuit held in *SanDisk* that the alleged infringer must merely contend "that it has the *right* to engage in the accused activity without license [and] *need not risk a suit for infringement by engaging in the identified activity* before seeking a declaration of its legal rights."²³⁴

The Federal Circuit's view of the second prong remains murky as its application of *MedImmune* belies its statements in *SanDisk* against the second prong. In *Benitec Australia, Ltd. v. Nucleonics, Inc.*, a case decided after *MedImmune*, *SanDisk*, and *Novartis*, the court suggests that it may not entirely dispose of the requirement for some evidence of potential liability.²³⁵ Benitec, the patent holder, brought suit against Nucleonics for

230. *See id.* at 771 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

231. *See id.* (quoting *Aetna Life Inc. v. Haworth*, 300 U.S. 227, 240-41 (1937)). The Federal Circuit cited to this language from *Aetna* and *Maryland Casualty* in both the *SanDisk* and *Novartis* opinions, highlighting the significance of these considerations. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1378 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007).

232. *See MedImmune*, 127 S. Ct. at 775 ("The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.")

233. *See supra* Section II.C.2.

234. *SanDisk*, 480 F.3d at 1381 (emphasis added).

235. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007).

patent infringement.²³⁶ Nucleonics counterclaimed for a declaratory judgment of invalidity and noninfringement.²³⁷ The district court dismissed the case after an intervening change in precedent prevented Benitec from claiming Nucleonics' actions as infringing.²³⁸ The Federal Circuit reviewed whether the district court properly dismissed Nucleonics' declaratory judgment counterclaims for lack of jurisdiction.²³⁹ The inquiry focused on Nucleonics' stated desire to expand its activities into areas that would give rise to infringement liability.²⁴⁰ Without evidence that Nucleonics had already expanded its activities or made significant preparation to do so,²⁴¹ the court held that Nucleonics failed to fulfill the "immediacy and reality requirement of *MedImmune*."²⁴²

V. CONCLUSION

In *MedImmune*, the Supreme Court eased the requirements for establishing declaratory judgment standing in patent cases. The decision reduced the requirement for a justiciable controversy from that of a reasonable apprehension of litigation to a reasonable apprehension of liability. Post-*MedImmune*, the Federal Circuit has signaled that it may only require a patent holder to provide notice, actively or constructively, to the alleged infringer. But the Federal Circuit has yet to clarify how much liability the alleged infringer must risk to obtain standing for declaratory relief.

236. *Id.* at 1342.

237. *Id.*

238. *Id.* at 1343. Benitec first brought suit against Nucleonics for infringing a patent relating to RNA-based disease therapy. *Id.* at 1342. Several weeks before Benitec moved to dismiss its complaint, the Supreme Court decided *Merck KGaA v. Integra Lifesciences I, Ltd* where the Court read the 35 U.S.C. § 271(e)(1) pharmaceutical research exception broadly. 545 U.S. 193 (2005). See Daniel Wobbekind, Note, *Integra Lifesciences I, Ltd. v. Merck KGaA: Re-Examining the Broad Scope of the § 271(e)(1) Safe Harbor*, 23 BERKELEY TECH. L. J. 107 (2008) (discussing the background and the consequences of the *Merck* decision). Benitec claimed to seek the dismissal because, under the *Merck* decision, it could not obtain an infringement decision against Nucleonics. *Benitec*, 495 F.3d at 1343.

239. *Benitec*, 495 F.3d at 1343. The court's inquiry was focused not on whether jurisdiction was proper for Nucleonics' counterclaims for declaratory judgment at the time filed, but whether the court still had jurisdiction over the counterclaims.

240. *Id.* at 1348. Nucleonics' "present activities" were protected under 35 U.S.C. § 271(e)(1) and in light of the *Merck* decision. *Id.* at 1346 (referring to *Merck*). The activities would not become infringing until after an NDA filing with the U.S. Food and Drug Administration, which was not certain to happen. *Id.*

241. *Id.* at 1349.

242. *Id.* at 1348-49 (citing *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007)).

MedImmune's lower bar brings patent cases back to the standard used in other areas of law. Further, the enhanced ability of alleged infringers to gain access to the courts prevents patent holders from exploiting the differences between the infringement notice requirements and the declaratory judgment jurisdiction requirements. However, *MedImmune*'s lower bar also provides an incentive for potential licensors to file suit first and ask for a settlement license later. This scenario creates further risk that a patent holder—wishing to file first in a venue and at a time of its choosing—may not be able to conduct sufficient investigation into the allegedly infringing activities before filing an action for infringement.²⁴³ In addition, small entities wishing to initiate licensing discussions with larger entities having more resources run the risk of providing ammunition for a declaratory judgment action they cannot fund or withstand. Thus, the practical effect of the post-*MedImmune* legal regime may be to make it easier to practice the inventions of others without a license.

To prevent abuses by potential declaratory judgment plaintiffs seeking to initiate suits against inconvenient patent holders, courts should increase the rigor of the inquiry into the declaratory judgment plaintiff's legal interests in the activities covered by the patent at issue. Constitutional requirements for a justiciable controversy compel such an inquiry.²⁴⁴ The patent statutes upon which these declaratory judgment actions rely also compel such an inquiry.²⁴⁵ Courts may also prevent abuses by both parties by following Judge Rader's roadmap from *Micron* regarding the use of convenience factors and discretionary dismissals.²⁴⁶ Under *Micron*, while timing is still under the control of the first to file suit, venue may not be.

Ultimately, establishing a justiciable controversy is a factually dependent, case-by-case inquiry. Prior to *MedImmune*, the Federal Circuit went astray by losing sight of the fundamental principles of the analysis. It arguably conflated generalized policy concerns with jurisdictional requirements. In the future, courts should avoid repeating this mistake by remembering that at base the inquiry is constitutional.

243. See *Micromesh Tech. Corp. v. Am. Recreation Prods.*, No. C-06-6030 MHP, 2007 U.S. Dist. LEXIS 64241 (N.D. Cal. Aug. 30, 2007) (granting motion for attorney's fees for failure to conduct reasonable investigation, among other failings, prior to filing suit for infringement).

244. See *supra* text accompanying notes 14-20 and Section IV.B.1.

245. See *supra* Section IV.B.1.

246. See *Micron Tech., Inc. v. MOSAID Techs., Inc.*, No. 2007-1080, 2008 U.S. App. Lexis 4387, *12-13, *16-19 (Fed. Cir. Feb. 29, 2007).