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Note

Preparation to Infringe after *MedImmune v. Genentech*: Why the Federal Circuit's Declaratory Judgment Jurisdiction Test is Still Too Stringent

*Hugh D. Brown**

I. INTRODUCTION

*MedImmune v. Genentech*¹ significantly lowered the bar for patent declaratory judgment jurisdiction. Before *MedImmune*, the Federal Circuit's two-pronged reasonable apprehension of suit test² required a plaintiff (1) to have a reasonable basis for believing that it would be sued for infringement by a patentee, and (2) to have engaged in meaningful preparation to infringe. The Supreme Court's ruling removed the test's first prong, requiring a potential infringer to actually anticipate a suit for infringement.³ The case did not explicitly address the second prong of the test, which required declaratory judgment plaintiffs to show that their infringing products were at an advanced stage of development.

This Note argues that the Federal Circuit should lower the bar on the second prong of the reasonable apprehension of suit test, granting declaratory judgment jurisdiction on a lower showing of preparation to infringe. Section II describes the background to *MedImmune*, beginning with the Federal

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1. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).
2. See *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004), *overruled by MedImmune*, 549 U.S. at 133.
3. *MedImmune*, 549 U.S. at 132 n.11.

Circuit's reasonable apprehension of suit test. It then describes the *MedImmune* holding and the subsequent effect of the holding on Federal Circuit approaches to subject matter jurisdiction. Section III analyzes these effects in light of *MedImmune* and the purposes of the Declaratory Judgment Act⁴ itself. Based on the purposes behind the Declaratory Judgment Act, the influence of *MedImmune*, and good policy, this note concludes that the Federal Circuit's test is still too stringent and declaratory judgment plaintiffs ought to be able to sue to ascertain their rights in a broader range of circumstances.

II. THE IMPACT OF *MEDIMMUNE* ON DECLARATORY JUDGMENT JURISDICTION

A. THE DECLARATORY JUDGMENT ACT AND STANDING

Article III, Section 2 of the United States Constitution provides that the judicial power of the United States extends to cases and controversies.⁵ This provision prohibits federal courts from issuing advisory opinions or opinions on hypothetical facts.⁶ Therefore, for a plaintiff to have standing, he must allege an actual injury which is "fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief,"⁷ rather than a hypothetical future injury. Where the injury alleged is a prohibition on allegedly legal activity, such as an invalid patent or an unconstitutional law, this language presents litigants with an unpleasant choice: they can obey the unlawful prohibition and refrain from allegedly lawful behavior, in which case they would lack the injury necessary to avail themselves of relief in an Article III court, or they could disobey the prohibition and risk the consequences if the prohibition was later found to be lawful.

The Declaratory Judgment Act was designed to ameliorate the effects of this doctrine.⁸ It provides:

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4. 28 U.S.C. § 2201 (2006).
 5. U.S. CONST. art. III, § 2; *see also* U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc., 508 U.S. 439, 446 (1993).
 6. *U.S. Nat'l Bank*, 508 U.S. at 446.
 7. *Allen v. Wright*, 468 U.S. 737, 751 (1984).
 8. *See* *Willing v. Chi. Auditorium Ass'n*, 277 U.S. 274, 288–90 (1928), *superseded by statute*, 28 U.S.C. § 2201, *as recognized in* *Calderon v. Ashmus*,

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.⁹

Therefore, the Declaratory Judgment Act allows the courts to hear cases involving injuries which are merely threatened, rather than actually inflicted.

The Declaratory Judgment Act is particularly important for patent law. Patent infringement carries the threat of liability for treble damages.¹⁰ Without the ability to sue for a declaratory judgment, a potential infringer has no choice but to lose a business opportunity or indefinitely accrue potential liability for infringement in the course of that opportunity. This uncertainty allows patentees to put heavy pressure on potential infringers to pay license fees even in cases where a patentee has a questionable claim. The Federal Circuit described the resulting situation as a “*danse macabre*” where the patentee brandished a “Damoclean threat with a sheathed sword”:

Guerrilla-like, the patent owner attempts extra-judicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity. Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the patent owner refused to grasp the nettle and sue. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests.¹¹

Declaratory judgment removes this threat where there is a conflict between the patentee’s patent and the potential infringer’s product.

The Declaratory Judgment Act is a procedural tool, however, and only extends as far as the Constitution permits.¹² A case or controversy must still exist.¹³ As *Aetna v. Haworth* pointed out, Congress may provide for new procedures for the

523 U.S. 740, 745 (1998).

9. 28 U.S.C. § 2201(a).

10. 35 U.S.C. § 284 (2006); *see also* Biacore, AB v. Thermo Bioanalysis Corp., 79 F. Supp. 2d 422, 471 (D. Del. 1999).

11. *Arrowhead Indus. Water, Inc. v. Ecolchem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988) (internal citations removed).

12. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239–40 (1937).

13. *Id.*

adjudication and enforcement of rights, but it may not expand those rights beyond the limits of Article III.¹⁴ The constitutional requirements for declaratory judgment, therefore, are the same as those for standing in general.¹⁵ There must be a controversy that is appropriate for judicial determination, i.e. not “academic or moot.”¹⁶ The dispute must be “definite and concrete, touching the legal relations of parties having adverse legal interests.”¹⁷

B. FEDERAL CIRCUIT JURISDICTIONAL DOCTRINE

Article III limits the situations in which a potential infringer may challenge the validity of a patent via declaratory judgment. The Federal Circuit has developed a doctrine to determine when declaratory judgment jurisdiction exists for patent cases. Prior to *MedImmune*, the test, known as the reasonable apprehension of suit test, was two-pronged.¹⁸ The Federal Circuit first applied this test in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*¹⁹ First, the patentee must have given some indication to the potential infringer that the patentee would sue if the potentially infringing behavior continued.²⁰ Second, the potential infringer must have produced or prepared to produce the potentially infringing product.²¹

Most of the litigation in these cases has focused on the first prong of the reasonable apprehension of suit test, which regulates the actions of the patentee. However, the Federal Circuit has also mentioned the second prong in depth in, for example, *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.*²² In *Sierra*, the court consolidated the current language of “immediacy and reality” by focusing on its precedents in *Lang v. Pacific Marine and Supply Co.*²³ and

14. *Id.* at 240.

15. *See id.*

16. *Id.*

17. *Id.* at 240–41.

18. *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

19. 846 F.2d 731, 736 (Fed. Cir. 1988).

20. *Id.*

21. *Id.*

22. 363 F.3d 1361, 1378–80 (Fed. Cir. 2004).

23. 895 F.2d 761 (Fed. Cir. 1990).

*Teletronics Pacing Systems, Inc. v. Ventritex, Inc.*²⁴

In *Lang* we held that that immediacy was absent where the ship at issue would not be ready for at least nine months and the owners of the ship had not engaged in any marketing activities.

Teletronics implicitly tied the concept of “reality” to whether the design of the potentially infringing subject of the declaratory-judgment suit was substantially *fixed*, particularly with respect to its potentially-infringing characteristics, on the date the complaint was filed.²⁵

The Federal Circuit justified its approach by pointing out that variability in a potentially infringing product increased the chance that the product would change before release, rendering the opinion on the previous version purely advisory, in violation of Article III.²⁶ Because of this concern, the Federal Circuit has tended to require a high degree of product development before granting jurisdiction where the second prong is in issue. In *Lang*, the court held that jurisdictional immediacy requirements were not fulfilled when the “infringing ship’s hull was still nine months from completion when the complaint was filed.”²⁷ There was no indication that the design of the hull was susceptible to change or that the hull might not be finished. Yet the plaintiff was refused the chance to gain a determination of his rights before expending the resources necessary to complete the ship. *Lang* demonstrates the high degree of development the Federal Circuit requires before granting jurisdiction.

In several other cases, district courts, following the Federal Circuit’s lead, denied declaratory judgment jurisdiction in situations where potential infringers had incurred considerable cost in preparation of potentially infringing products. In *Duhn Oil Tool, Inc. v. Cooper Cameron Corp.*,²⁸ the court refused declaratory judgment jurisdiction to an alleged infringer whose product was still at the design stage.²⁹ The court stated, “Cameron asks the Court to determine that Cameron’s Patent Pending Design, whether in practice, or in theory, does not

24. 982 F.2d 1520 (Fed. Cir. 1992).

25. *Sierra*, 363 F.3d at 1379.

26. *Id.*

27. *Lang*, 895 F.2d at 765.

28. No. 1:05-cv-01411-OWW-GSA, 2007 WL 3335008 (E.D. Cal. Nov. 9, 2007).

29. *Id.* at *7.

infringe Duhn's '925 Patent. . . . No infringement is alleged. As yet, no adverse legal relationship exists."³⁰ Partially on this basis,³¹ the court refused to grant declaratory judgment jurisdiction, and the plaintiff was unable to determine whether its new design infringed an existing patent before proceeding to manufacture.

In *Shaunnessey v. Monteris Medical, Inc.*,³² the court held that a potential infringer who had not yet obtained approval on its medical device was not entitled to declaratory judgment since it was unclear whether the Food and Drug Administration (FDA) would require design change.³³ The potential infringer was several years away from submitting the device for FDA approval, however, and significant costs had been incurred in the development of the product.³⁴

In *Mega Lift Systems, LLC v. MGM Well Services, Inc.*,³⁵ the court granted the defendant's motion to dismiss the plaintiff's declaratory judgment suit where the plaintiff had substantially completed the design of the product, but had not yet finalized the design or begun to manufacture or sell the product. The court stated, "Under these facts, the Court cannot determine whether Mega Lift is ready to infringe tomorrow or next year."³⁶ The court decided that, under these circumstances, the dispute was neither "immediate" nor "real."³⁷ These cases demonstrate that in a large number of cases, both before and after *MedImmune*, district courts have adopted a restrictive approach to declaratory judgment jurisdiction.

C. THE EFFECT OF *MEDIMMUNE*.

MedImmune, decided January 9, 2007, lowered the bar established by the reasonable apprehension of suit test. *MedImmune*, manufacturer of Synagis, "a drug designed to prevent respiratory tract disease in young children," entered

30. *Id.* at *6.

31. The court also cited the fact that the USPTO had the power to alter the design, and, therefore, it was not necessarily fixed. *Id.*

32. 554 F. Supp. 2d 1321 (M.D. Fla. 2008).

33. *Id.* at 1324.

34. *See id.*

35. No. 6:08 CV 420, 2009 WL 1851919 (E.D. Tex. Jun. 29, 2009).

36. *Id.* at *4.

37. *Id.*

into a license agreement with Genentech, paying royalties to produce products covered by an existing patent and a pending patent.³⁸ MedImmune agreed to pay royalties on sales of “licensed products” in exchange for the right to make, use, and sell them.³⁹ In 2001, the pending patent matured, and Genentech sent a letter to MedImmune expressing its belief that Synagis was covered by the patent and requesting royalties under the license agreement.⁴⁰ MedImmune disagreed, but given the potential liability for treble damages and attorney’s fees, as well as for an injunction against selling Synagis (which had accounted for 80% of MedImmune’s revenue since 1999), MedImmune decided to pay under protest.⁴¹ MedImmune filed suit seeking a declaratory judgment of noninfringement of Genentech’s patent or invalidity of the patent.⁴² The district court granted Genentech’s motion to dismiss, and the Federal Circuit affirmed, reasoning that the license agreement had “obliterate[d] any reasonable apprehension that [MedImmune] will be sued for infringement.”⁴³

The Supreme Court reversed. It held that MedImmune was “not required, insofar as Article III [was] 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.”⁴⁴ The Court reviewed the history of the Declaratory Judgment Act in the context of its Article III roots.⁴⁵ The Court stated that the Act required a dispute that is “definite and concrete, touching the legal relations of parties having adverse legal interests; and that [is] real and substantial, and admit[s] 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.”⁴⁶ The fact that MedImmune’s own

38. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 121 (2007).

39. *Id.*

40. *Id.*

41. *Id.* at 122.

42. *Id.* at 123.

43. *Id.* at 122.

44. *Id.* at 137.

45. *Id.* at 120.

46. *Id.* at 127 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)).

actions eliminated the imminent threat of harm was irrelevant—the conflict was still real, and the fact that MedImmune was paying royalties was injury enough to provide a basis for declaratory judgment jurisdiction.⁴⁷ Arguably the most important part of the *MedImmune* opinion came in a footnote, which explained that the Federal Circuit’s reasonable apprehension of suit test was inconsistent with a previous Supreme Court case:

[*Altwater*]⁴⁸ . . . contradict[s] the Federal Circuit’s “reasonable apprehension of suit” test The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, . . . where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured. . . .⁴⁹

The Federal Circuit took the Supreme Court at its word and altered the reasonable apprehension of suit test in subsequent cases. The first prong was altered quickly. In *SanDisk Corp. v. STMicroelectronics Inc.*, the Federal Circuit recognized that *MedImmune* represented a rejection of the reasonable apprehension of suit test, and adopted the proposition that “Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do.”⁵⁰ The court declined to “define the outer boundaries” of

47. *Id.* at 123.

48. The Court described the *Altwater* opinion in more depth:

Altwater v. Freeman [319 U.S. 359 (1943)] held that a licensee’s failure to cease payment did not render non-justiciable a dispute over the validity of the patent. . . . “The fact that royalties were being paid did not make this a ‘difference or dispute of a hypothetical or abstract character.’” The royalties “were being paid under protest and under the compulsion of an injunction decree,” and “[u]nless the injunction decree were modified, the only other course [of action] was to defy it, and to risk not only actual but treble damages in infringement suits. [T]he requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim.”

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 130–31 (2007).

49. *Id.* at 132–33 n.11.

50. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

jurisdiction over declaratory judgment claims.⁵¹ *SanDisk* was a start, but left lower courts without much guidance. Four days later in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, the Federal Circuit suggested that an “all the circumstances” test was the appropriate test for declaratory judgment jurisdiction.⁵² Noting that an Article III controversy could be found where the plaintiff had demonstrated an injury in fact that could be redressed in court, the court held that the same standard applied in a declaratory judgment suit, and reversed the dismissal of the suit for lack of subject matter jurisdiction.⁵³ The case was an easy one, however, and the court would probably have reached the same result under its reasonable apprehension test prior to *MedImmune*.⁵⁴ The case established the importance of the Article III language. In subsequent cases, the court seems to have settled on a ‘standing-lite’ test, the court’s new relaxed standing requirement, which grants standing when the injury suffered by the plaintiff meets the test of “immediacy and reality”:⁵⁵

This “immediacy and reality” inquiry can be viewed through the lens of standing. To satisfy standing, the plaintiff must allege (1) an injury-in-fact, i.e., a harm that is “concrete’ and actual or imminent, not ‘conjectural’ or ‘hypothetical,’” (2) that is “fairly traceable” to the defendant’s conduct, and (3) redressable by a favorable decision.⁵⁶

MedImmune’s impact on the second prong of the reasonable apprehension of suit was less obvious. The Supreme Court had not explicitly indicated its disapproval, as it had with the first prong.⁵⁷ The Court’s indication that declaratory judgment ought to be available in a wider range of circumstances, however, was taken as a suggestion that the bar for fulfilling the second prong should be lowered too,

51. *Id.*

52. 482 F.3d 1330, 1339 (Fed. Cir. 2007).

53. *Id.* at 1345–46.

54. Teva Pharmaceuticals had already produced and marketed the potentially infringing product, and Novartis had brought an infringement suit against Teva on related products. *Id.* at 1334–35.

55. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008).

56. *Id.*

57. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132–33 n.11 (2007).

particularly in *Benitec Australia, Ltd. v. Nucleonics, Inc.*,⁵⁸ the first case to deal with the second prong. In *Benitec*, Nucleonics sued for a judgment of invalidity of Benitec's patent.⁵⁹ The Federal Circuit reversed the district court's dismissal of the declaratory judgment action on the basis that Nucleonics had "failed to show that its future plans meet the immediacy and reality . . . necessary to support a justiciable controversy."⁶⁰ First, Nucleonics had only talked with potential customers and executed a confidentiality agreement.⁶¹ The court stated that "to allow such a scant showing . . . would be to allow nearly anyone who so desired to challenge a patent."⁶² Second, "Nucleonics had provided insufficient information for a court to assess whether Nucleonics's future animal work would be infringing or not."⁶³ Third, the patentee had decided in the interim that the technology did not in fact infringe the patent.⁶⁴ The first and second rationales were the most important. The court recognized the overruling of the reasonable apprehension of suit test, and used the *SanDisk* test, stating that "Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do."⁶⁵ The court also used the "immediacy and reality" language of *Sierra*, applying it for the first time to a case where the party whose inaction deprived the court of jurisdiction was the plaintiff, not the defendant.⁶⁶ This touched on the second prong of the reasonable apprehension of suit test and suggested that *MedImmune* might have affected this aspect of declaratory judgment jurisdiction too.

The Federal Circuit more explicitly explored the second prong of the reasonable apprehension of suit test in *Cat Tech*

58. 495 F.3d 1340 (Fed. Cir. 2007).

59. *Id.* at 1342. The court's opinion does not give sufficient information to determine how far Nucleonics had progressed with its potentially infringing products.

60. *Id.* at 1348–49.

61. *Id.* at 1349.

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.* at 1344 (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007)).

66. *Id.* at 1348 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

LLC v. TubeMaster. Noting that it had yet to consider the effect of *MedImmune* on the second prong,⁶⁷ the court stated:

[A]lthough *MedImmune* articulated a “more lenient legal standard” for the availability of declaratory relief in patent cases the issue of whether there has been meaningful preparation to conduct potentially infringing activity remains an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate.⁶⁸

Following *Benitec*, the court decided that the immediacy and reality tests were appropriate for the second prong.⁶⁹ Analyzing “immediacy,” it found that “[c]onstitutionally mandated immediacy requirements have been satisfied because once the threat of liability . . . has been lifted, it appears likely that TubeMaster can . . . solicit and fill orders.”⁷⁰ Analyzing “reality,” it found that the potentially infringing product was “substantially fixed,” and that “TubeMaster does not expect to make substantial modifications.”⁷¹ Therefore, the dispute was “real.”⁷² *Cat Tech* was ambiguous on the effect of *MedImmune* on the second prong of the reasonable apprehension of suit test. While the court did not rule out the possibility that *MedImmune* was a factor, *Cat Tech* would most likely have been decided as it was regardless of *MedImmune*.⁷³

A recent Colorado district court decision provides more guidance on the effect of *MedImmune* on the second prong. In

67. *Cat Tech LLC v. TubeMaster*, 528 F.3d 871, 880 (Fed. Cir. 2008). The court acknowledged that it had addressed the actions of a potential infringer in *Benitec*, but maintained that it had not directly addressed the “continued viability of the second prong of this court’s pre-*MedImmune* test.” *Id.* at 880 n.3.

68. *Id.* (citations omitted).

69. *Id.* at 880 (“If a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither ‘immediate’ nor ‘real’ and the requirements for justiciability have not been met.”) (citing *Lang v. Pac. Marine and Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990)).

70. *Id.* at 882.

71. *Id.*

72. *Id.*

73. The court compared the stage of development to the technology in *Sierra*, decided prior to *MedImmune*, and decided on that basis that the technology in *Cat Tech* was sufficiently advanced to merit jurisdiction. *Id.* at 882–83 (“Unlike the technology involved in . . . *Sierra* . . . TubeMaster’s technology is ‘substantially fixed’. . . . The dispute with *Cat Tech* is ‘real,’ not hypothetical, because it appears likely that, once the cloud of liability for infringement is eliminated, the accused products can be produced without significant design change.”).

City of Aurora, Colo. v. PS Systems,⁷⁴ the court held that cases decided prior to *MedImmune* were no longer valid on the second prong of the reasonable apprehension test.⁷⁵ As this case and others show, the effect of *MedImmune* on the requirement of preparation to infringe is still an open question.

III. THE BAR TO DECLARATORY JUDGMENT JURISDICTION IS STILL TOO HIGH.

A. CRITICISM OF THE REASONABLE APPREHENSION OF SUIT TEST PRE-MEDIMMUNE

Before *MedImmune*, the Federal Circuit's approach had been criticized on several grounds. First, the test was applied with unreasonable formalism.⁷⁶ The Federal Circuit has too often applied the letter of the reasonable apprehension of suit test, with too little consideration for its normative purposes. In *Shell Oil Co. v. Amoco Corp.*, for example, the Federal Circuit affirmed the 12(b)(1) dismissal of a declaratory judgment suit against Amoco.⁷⁷ Shell initiated licensing discussions when deciding whether to pursue a course of conduct which might arguably have fallen under Amoco's patent.⁷⁸ When the discussions broke down, Amoco suggested that Shell consider a declaratory judgment action.⁷⁹ However, Amoco filed a 12(b)(1) motion in response to the action when it was filed.⁸⁰ Despite the breakdown of the licensing discussions, the Federal Circuit affirmed the lower court's grant of the motion on the basis that "Amoco *might* never have sued, either because the validity of its patent was doubtful or its infringement argument was too weak."⁸¹ The conflict in *Shell Oil* was real enough for the parties to begin licensing discussions and abandon them on the basis of inability to agree over their rights regarding a certain

74. No. 07-CV-02371-WYD-BNB, 2008 WL 4377505 (D. Colo. 2008).

75. *Id.* at *10 ("Finally, I note that those cases were decided under the 'reasonable apprehension' test which appears to be no longer valid in light of the more lenient standard articulated in *MedImmune*.").

76. Lorelei Ritchie de Larena, *Re-evaluating Declaratory Judgment Jurisdiction in Intellectual Property Disputes*, 83 IND. L.J. 957, 979 (2008).

77. 970 F.2d 885, 886 (Fed. Cir. 1992) (quoted in de Larena, *supra* note 76, at 979).

78. *Id.* at 886.

79. *Id.* at 887.

80. *Id.*

81. *Id.* at 889 (emphasis added).

patent. Despite this clearly concrete legal dispute between the parties, which would have been solved by a judgment on the merits, the Federal Circuit denied jurisdiction by a rigid application of the reasonable apprehension of suit test.⁸²

Second, the test has been inconsistent. Before *MedImmune*, the Federal Circuit usually used the reasonable apprehension of suit test. However, it has also used a “totality of the circumstances” test.⁸³ Accordingly, “[the Federal Circuit applied] the standard(s) formalistically, but at the same time mix[ed] in other tests and versions without clearly articulating or applying a single test that would settle the reasonable expectations of parties. Unfortunately, this goes against the normative values of consistency and reliability of jurisprudence.”⁸⁴ Also, more importantly, the court used its test to block parties like Shell from settling their rights and responsibilities vis-à-vis potentially infringed patents.

B. THE FEDERAL CIRCUIT’S ANALYSIS POST-*MEDIMMUNE*.

The court’s analysis in *Cat Tech* was much more similar to its pre-*MedImmune* analysis in *Sierra* than it was different. *Sierra* focused on immediacy and reality, and suggested that the plaintiff’s infringing conduct must not be forthcoming too far in the future,⁸⁵ and must not be susceptible to much change before taking its final form.⁸⁶ *Cat Tech* had similar requirements. It required that a plaintiff have taken significant, concrete steps to conduct infringing activity, and it also required immediacy.⁸⁷ While there was language that suggested that the court might be open to an easier standard,⁸⁸ no such standard was explicitly articulated.

Such an adherence to the old standard is inappropriate for many reasons. First, the unreasonably high bar is contrary to

82. *See id.*

83. de Larena, *supra* note 76, at 977–78.

84. *Id.*

85. *Sierra Applied Sci., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1378–79 (Fed. Cir. 2004).

86. *Id.* at 1379.

87. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881–82 (Fed. Cir. 2008).

88. “[A]lthough a party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement, there must be a showing of ‘meaningful preparation.’” *Id.* at 881.

the spirit, if not the explicit language, of *MedImmune*. Second, it is also contrary to the traditional standing doctrine which forms the basis for declaratory judgment jurisdiction.⁸⁹ Finally, good policy suggests that the bar should be lower.

MedImmune only explicitly challenged the first prong of the reasonable apprehension of suit test.⁹⁰ The Supreme Court's decision in the circumstances, however, supports lowering the bar for the second prong, too. The *MedImmune* plaintiff's own actions (i.e., complying with his license agreement) rendered suit against him impossible. Despite this, the Court allowed him to seek a declaration of his rights before he risked such a suit by taking the action which would have allowed the suit to proceed. In other words, the Court did not force the plaintiff to subject himself to the possibility of suit before it allowed him to sue for a declaration of his rights.⁹¹

Declaratory judgment plaintiffs whose suits are dismissed under the immediacy and reality requirements contained in the second prong of the reasonable apprehension of suit test⁹² have a similar quandary, and so they seek a declaration of their rights before their product reaches a point of development where they may be sued for infringement. The *MedImmune* Court stated strongly that this should be allowed: "There is no dispute that [the declaratory judgment requirements] would have been satisfied if petitioner had taken the final step of refusing to make royalty payments [and thereby subjecting himself to suit]."⁹³ The plaintiff's failure to subject himself to suit did not defeat this exercise of jurisdiction. Where an action of the plaintiff was the only thing preventing the suit for infringement, the Supreme Court stated "[W]e do not require a

89. See *supra* notes 10–11 and accompanying text.

90. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132 n.11 (2007) ("*Altwater* . . . contradict[s] the Federal Circuit's 'reasonable apprehension of suit' test.>").

91. The Supreme Court, of course, did not analyze this point under the reasonable apprehension of suit test. However, it allowed jurisdiction even when the plaintiff had not taken action to reach the point where it was infringing a patent.

92. See, e.g., *Shaunnessey v. Monteris Med., Inc.*, 554 F. Supp. 2d 1321 (M.D. Fla. 2008) (dismissing patentee's declaratory judgment action for lack of immediacy and ruling that where defendant had not yet obtained approval on its class III medical device, the "immediacy" requirement of an actual controversy was not satisfied, since it was speculative as to whether the FDA would require design changes).

93. *MedImmune*, 549 U.S. at 128.

plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat.”⁹⁴ However, this is exactly what the Federal Circuit requires when it forces a potential infringer to develop a product to the point where he may be sued before it allows a court to declare his rights vis-à-vis the patent. *MedImmune* allows a plaintiff to be sure of his rights before subjecting himself to suit. It should make no difference whether he is protected from suit by payment of license fees or by a product which has not yet reached the point where an infringement suit may be brought. Article III standing requirements, rather than those imposed by the Federal Circuit’s patent declaratory judgment jurisdiction, ought to be the only requirements.

The language used in *MedImmune* supports this conclusion. The Supreme Court describes declaratory judgment in terms of traditional standing doctrine, rather than traditional Federal Circuit patent analysis.⁹⁵ It reiterates that “the phrase ‘case of actual controversy’ in the Act refers to the type of ‘Cases’ and ‘Controversies’ that are justiciable under Article III.”⁹⁶ While the Supreme Court does use a patent case (*Altwater*) to demonstrate the final proposition, the cases that lead up to this proposition are not patent cases. This suggests that the Supreme Court is promulgating a patent declaratory judgment standard that more closely follows traditional standing doctrine than the Federal Circuit has been doing so far.

MedImmune’s implicit suggestion that the Federal Circuit should follow Article III’s standing doctrine more closely is welcome, but the reminder should not have been necessary. Patent rights have historically been problematic and uncertainty surrounding them was an issue even in 1934.⁹⁷ The Declaratory Judgment Act was partially intended to alleviate this uncertainty.⁹⁸ The Supreme Court had repeatedly decided

94. *Id.* at 128–29. While the court was referring to government enforcement, it is clear that this was the relevant question regardless of where the threat of force came from.

95. *Id.* at 127.

96. *Id.*

97. See *supra* notes 10–11 and accompanying text.

98. 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, 408 n.6 (2007). Dolak discusses congressional hearings on previous declaratory judgment bills. Bills were intended to remove

that the Declaratory Judgment Act should be interpreted to grant jurisdiction to the extent allowed by the Constitution.⁹⁹ This suggests that the requirements for declaratory judgment jurisdiction in patent cases should parallel the requirements for Article III standing.

C. THE JURISDICTIONAL GAP

Exactly how wide is the gap between Federal Circuit declaratory judgment jurisdiction, and traditional Article III standing doctrine as applied to declaratory judgment actions in general? *Aetna's* formulation of the declaratory judgment standard is difficult to apply in a concrete and consistent manner.¹⁰⁰ Rather, the Supreme Court has stated that whether specific facts constitute an actual controversy must be determined on a case by case basis.¹⁰¹ Therefore it is impossible to draw a bright line distinction between the practices of the Federal Circuit in patent cases and courts who interpret Article III standing in other kinds of cases. It is possible, however, to show some general distinctions.

First, the Constitution does not mandate the reasonable apprehension of suit test.¹⁰² “The Federal Circuit has

uncertainty, and patents were explicitly referred to in Senate testimony regarding a previous bill:

In his senate testimony, Professor Sunderland described the plight of the alleged patent infringer, as follows: I assert that I have a right to use a certain patent. You claim that you have a patent. What am I going to do about it? There is no way I can litigate my right, which I claim, to use that device, except by going ahead and using it, and you [the patent holder] can sit back as long as you please and let me run up just as high a bill of damages as you wish to have me run up, and then you may sue me for the damages, and I am ruined, having acted all the time in good faith and on my best judgment, but having no way in the world to find out whether I had a right to use that device or not.

Id. (quoting *1928 Hearings on H.R. 5623 Before a Subcomm. of the Senate Comm. on the Judiciary*, 70th Cong., 34–35 (1928) (testimony of Professor Edson R. Sunderland)).

99. *MedImmune*, 549 U.S. at 126 (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937)).

100. *McCahill v. Borough of Fox Chapel*, 438 F.2d 213, 215 (3d Cir. 1971) (“The considerations, while catholic, are not concrete.”).

101. *Simmonds Aerocessories, Ltd. v. Elastic Stop Nut Corp. of America*, 257 F.2d 485, 489 (3d Cir. 1958) (“Whether there is an actual controversy within the meaning of the Act is a question which turns on the facts of each individual case.”).

102. Dolak, *supra* note 98, at 421.

recognized that the Act's actual controversy requirement is constitutionally mandated and that the Act neither confers jurisdiction on the federal courts nor imposes jurisdictional *requirements* above and beyond those compelled by the Constitution."¹⁰³ As Dolak also points out, however, the Federal Circuit has repeatedly used its reasonable apprehension of suit test to determine whether an actual controversy exists, "thus effectively equating its test with the constitutional minimum requirements."¹⁰⁴ This conclusion is reinforced by the fact that many Federal Circuit members have disclaimed the jurisdictional underpinning of the reasonable apprehension of suit test.¹⁰⁵ Judge Gajarsa wrote: "Article III does not compel [the reasonable apprehension test]."¹⁰⁶

Second, the reasonable apprehension of suit test confuses the jurisdictional and discretionary prongs of declaratory judgment.¹⁰⁷ The Federal Circuit has recognized that there is a discretionary element to the declaratory judgment jurisdictional question.¹⁰⁸ Much more frequently, however, it has taken policy considerations into account when deciding the jurisdictional elements of declaratory judgment, rather than the discretionary element. As Dolak says:

[T]he problem is not that the Federal Circuit has taken policy into account in evaluating declaratory judgment justiciability. The problem is the extent to which it has permitted policy to influence the first step—the constitutional or jurisdictional analysis—as evidenced by its justifications for, and application of, its two-step reasonable apprehension/infringer activity test.¹⁰⁹

Dolak also points out several instances in which the court has "unequivocally linked its test to both the language of the Act and to the applicable constitutional constraints."¹¹⁰ In *Teva*, the court stated:

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of

103. *Id.* at 420 (emphasis added).

104. *Id.* at 421.

105. *Id.*

106. *Id.*

107. *See id.* at 422.

108. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 883 (Fed. Cir. 2008) ("Even assuming that the immediacy and reality prerequisites for declaratory judgment relief have been met, the district court's exercise of its declaratory judgment authority is discretionary.").

109. Dolak, *supra* note 98, at 425.

110. *Id.* at 423.

imminent suit. Whether there is an “actual controversy” between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties of “sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” This requirement of imminence reflects the Article III mandate that the injury in fact be “concrete,” and “actual or imminent, not conjectural or hypothetical.” . . . *We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement.*¹¹¹

Such conflation of jurisdictional and prudential considerations has developed a test that has been applied under the assumption that it is mandated by the Constitution. Not only has the test achieved quasi-constitutional force, it has become unnecessarily strict by formulating it not just on the basis of Article III, but also on the basis of every possible policy argument which can be made against easy declaratory judgment jurisdiction.¹¹² While making decisions on the basis of these policy considerations is appropriate in some cases, it is not appropriate in every case.¹¹³ This conflation of policy and jurisdiction arguments has not only resulted in an unnecessarily high bar to declaratory judgment for potential infringers, it has also made this high bar more difficult to overcome with jurisdictional arguments. If the discretionary prong is separated from the jurisdictional prong, plaintiffs can respond to each with appropriate arguments. As it is, the waters have been muddied. Conflation of the prudential and

111. *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333–35 (Fed. Cir. 2005) (second emphasis added) (internal citations omitted).

112. The three arguments Dolak raises in favor of a narrow declaratory judgment jurisdiction standard are (1) respect for the patent system, (2) encouragement to design around patents, (3) encouragement to negotiate. *See Dolak, supra* note 98, at 434–35 (“[R]eadily subjecting patents to declaratory judgment attack would tend to undermine the respect Congress created the Federal Circuit to engender, for litigation raises questions about, and potentially impairs, a patent’s validity.”). *See also Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991) (“Designing around patents is . . . one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose. Inherent in our claim-based patent system is also the principle that the protected invention is what the claims say it is, and thus that infringement can be avoided by avoiding the language of the claims.”); *Century Indus., Inc. v. Wenter Corp.*, 851 F. Supp. 1260, 1264–65 (S.D. Ind. 1994) (dismissing declaratory judgment claim in part because the parties were “still engaged in discussions aimed at resolving the potential dispute”).

113. *Dolak, supra* note 98, at 435–36.

jurisdictional prongs also destroys predictability¹¹⁴ and is contrary to the language of the Declaratory Judgment Act.¹¹⁵

It is clear that a controversy as described in Article III can exist between the parties even when the conduct is not as immediate and certain as mandated by the Federal Circuit. In cases outside the patent realm, preparation to engage in the prohibited conduct is enough to get jurisdiction over the declaratory judgment action challenging the prohibition.¹¹⁶ A plaintiff challenging a criminal statute does not even have to show that he has prepared to commit the prohibited behavior before he may mount a challenge to the act.¹¹⁷ While there are certainly differences between criminal and patent cases, these differences affect the policy rationales behind granting jurisdiction, not the constitutional underpinnings of jurisdiction. The language of federal decisions has repeatedly said that plaintiffs should not have to infringe in order to get an adjudication of their rights.¹¹⁸ The necessity of meaningful preparation, which may frequently expose a plaintiff to an infringement suit, renders this protection useless. In *Shaunnessey*, the district court declined to exercise jurisdiction prior to submission of the FDA device approval, which the court argued could have required changes to the device.¹¹⁹ As the plaintiffs argued, however, no potential change would have rendered the challenged device non-infringing.¹²⁰ Therefore, there was a high practical likelihood that the controversy was real. Under Article III analysis, this is sufficient to grant jurisdiction.¹²¹

114. *Id.* at 433 (“[T]o the extent that the courts inconsistently assign jurisdictional . . . weight to the same or similar facts in declaratory judgment justiciability determinations, outcomes are less predictable.”).

115. *Id.* (“[T]he Declaratory Judgment Act on its face precludes the consideration of prudential factors in the jurisdictional calculus, as the language of Congress made distinct the Act’s jurisdictional and discretionary aspects.”).

116. *Hertzog, Calamari & Gleason v. Prudential Ins. Co. of Am.*, 933 F. Supp. 246, 250 (S.D.N.Y. 1996).

117. *See Terrace v. Thompson*, 263 U.S. 197 (1923) (allowing an immigrant to challenge an anti-alien land owning statute before any attempts were made to actually own land).

118. *See, e.g., id.*

119. *Shaunnessey v. Monteris Med., Inc.*, 554 F. Supp. 2d 1321, 1324 (M.D. Fla. 2008).

120. *Id.*

121. *See* 10B CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE &

D. POLICY AND THE REASONABLE APPREHENSION OF SUIT TEST.

While there are policy reasons to restrict declaratory judgment actions,¹²² there are also significant policy reasons to encourage them. The most compelling of these reasons is that the declaratory judgment remedy was *designed* to prevent plaintiffs from suffering significant injuries before gaining an adjudication of their rights.¹²³ The traditional formulation says that these injuries constitute judicially awarded damages for infringement.¹²⁴ However, an examination of the cases in which the courts have denied jurisdiction on the basis of the Federal Circuit's test shows that declaratory judgment plaintiffs can often be forced to develop an infringing product to the point of near completion before gaining an adjudication of their rights, which process may ultimately find their product to be infringing. In this case, there is an argument to be made that the injury suffered constitutes the investment made between the period a party first asserts its right to a determination and the time that its product is found to be infringing.

*Lang, Duhn Oil Tool, and Shaunnessey*¹²⁵ demonstrate the costs of denying declaratory judgment in situations where plaintiffs may have products into which they have already put substantial resources, and which will require substantial further resources to finish. Such a decision denies the plaintiff the chance to (1) cease production of the infringing device and use the resources for another purpose, (2) design around the patent, or (3) evaluate the costs of getting a license before deciding whether to accept these costs or not as part of the entire cost of bringing the product to market. This wastes the resources needed to complete the product when an ultimately infringing product is completed, and the resources used to begin the product when an actually non-infringing product is

PROCEDURE § 2757 (3d ed. 2004) (“[T]he practical likelihood that the contingencies will occur and that the controversy is a real one should be decisive in determining whether an actual controversy exists.”). The imminence issue remains. However, the continuing expenditure of funds on a project which may turn out to be unusable should satisfy this requirement, as this Note argues later.

122. See *supra* note 115.

123. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 878 (Fed. Cir. 2008).

124. *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991).

125. See *supra* notes 23–34 and accompanying text for a description of these cases.

abandoned. This is not a social benefit.

It is true that to take jurisdiction too far in the opposite direction would run afoul of Article III standing. As the Third Circuit stated, “[i]t is obvious that a person not now engaged in possible infringing conduct, and having no immediate intention of doing so, but having an academic interest in the law of patents, could not obtain a declaratory judgment against a patentee as to the validity or scope of the patent.”¹²⁶ It is not socially desirable for a competitor to be able to challenge patents at will without having a financial or business interest in the result. However, *Lang*, *Duhn Oil Tool*, and *Shaunnessey* do not involve the problem of a gratuitous challenge to a competitor’s patent. In all three of the above examples, a significant investment had been made in the potentially infringing product. In *Lang*, a ship’s hull had been substantially finished.¹²⁷ In *Duhn Oil Tool*, design had been completed.¹²⁸ In *Shaunnessey*, design had been begun, and the product had been shown to potential customers.¹²⁹ When a plaintiff has put a substantial investment into a product and finds his way blocked by the uncertain legal rights of others, he should not be prevented from clarifying his position by an overly restrictive jurisdictional doctrine.

Another consideration weighing in favor of an easier declaratory judgment jurisdictional standard is what some claim is a proliferation of questionable patents. The FTC has highlighted this development as one of the more significant concerns surrounding the patent system.¹³⁰ Patents may be questionable for one of two reasons: either because they are invalid or because they are overly broad.¹³¹ Such patents represent a social cost insofar as they “reduce competition in the covered market [because licensing fees may present an

126. *Dewey & Almy Chem. Co. v. Am. Anode, Inc.*, 137 F.2d 68, 70 (3d Cir. 1943).

127. *Lang v. Pac. Marine and Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990).

128. *Duhn Oil Tool, Inc. v. Cooper Cameron Corp.*, No. 1:05-cv-01411-OWW-GSA, 2007 WL 3335008, at *2 (E.D. Cal. Nov. 9, 2007).

129. *Shaunnessey v. Monteris Med., Inc.*, 554 F. Supp. 2d 1321, 1326–27 (M.D. Fla. 2008).

130. Rachel Krevans & Daniel P. Munio, *Restoring the Balance: The Supreme Court Joins the Patent Reform Movement*, 9 SEDONA CONF. J. 15, 25 (2008).

131. *Id.* at 24.

unreasonable barrier to entry] and [deter] follow-on innovation [because development of products which build on and enhance the technology covered by a patent will probably involve the covered technology itself].¹³² Allowing plaintiffs to challenge the validity or breadth of patents more easily will provide another avenue for the removal of these questionable patents from the system.¹³³

This argument is bolstered by the fact that a large proportion of the patents challenged turn out to be invalid or non-infringed.¹³⁴ As one commentator states: “[T]he owners of invalid patents can capture supracompetitive profits during the time before their patents are invalidated, profits made at the expense of consumers and that they will never have to disgorge. That extra profit, in turn, would create significant incentives to obtain and enforce dubious patents.”¹³⁵ Thus, there is a powerful incentive to patent, even if the patent turns out to be weak, and such an incentive poses a social cost. Allowing a plaintiff to easily challenge patents before the patents hinder the plaintiff’s work significantly reduces this cost.

E. A REASONABLE ALTERNATIVE.

How should courts decide when to grant declaratory judgment in these cases? Any alternative standard will, of course, still have to respect the basic tenets of Article III standing, which require an actual case or controversy.¹³⁶ A standard which minimizes lost investment in ultimately

132. *Id.*

133. Krevans & Munio mention the possibility that *MedImmune* will have the following effect:

[T]he Court’s decision in *MedImmune* may also help to reduce the volume of questionable patents in effect. *MedImmune* clears the way, on a jurisdictional level, for use of the “pay and sue” strategy by licensees. Under this approach, a licensee eliminates the risk of being sued for infringement by paying royalties under the license, while simultaneously attacking the underlying patent’s validity. . . . *MedImmune* makes it easier for interested parties to challenge questionable patents. Removing such patents from circulation, if indeed they are invalid, benefits the industry to which they pertain and the economy at large.

Id. at 28.

134. See Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV 19, 27 (2008).

135. *Id.* at 28.

136. U.S. CONST. art III, § 2.

infringing products, however, can still accomplish this. Instead of requiring the heretofore narrowly defined “immediacy” and “reality” test, courts should simply look at whether all the circumstances indicate that the declaratory judgment plaintiff has made a prima facie showing that he intends to produce a product which may be accused of infringement by the declaratory judgment defendant. Such an approach will allow courts to determine when a party has expended sufficient resources in the development of the product to render the dispute non-hypothetical. Also, it will not shut the courthouse door to plaintiffs who are being forced to choose between “pursuing arguably illegal behavior or abandoning that which [they claim] a right to do.”¹³⁷

IV. CONCLUSION

The second prong of the Federal Circuit’s reasonable apprehension of suit test suffered from unreasonable formalism, an overly restrictive view of Article III standing, and a conflation of jurisdictional and discretionary analyses. This led to undesirable effects, and plaintiffs were precluded from litigating their rights before making a substantial investment in questionable products. In addition, the difficulty of getting into court to litigate potentially invalid patents led to an incentive to apply for and enforce these patents. After the *MedImmune* decision, there is reason to hope that the Federal Circuit will lower this standard.

If this occurs, it will have the effect of bringing cases into the system sooner, and may increase the number of patent cases adjudicated by federal courts. It may also provide a less clear guide concerning whether an actual case or controversy is presented. In the vast majority of circumstances, however, the fact that a party will shortly be offering for sale a product that may infringe another’s patent will more than satisfy the standing criteria. Courts should easily be able to spot those that do not. The end result will be fairer and will strengthen, not weaken, the patent system.

137. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).