

MEDTRONIC V. BOSTON SCIENTIFIC: ALLOCATING THE BURDEN OF PROOF IN DECLARATORY JUDGMENT ACTIONS FOR PATENT NON- INFRINGEMENT

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I. INTRODUCTION

The U.S. Patent & Trademark Office granted 276,788 patents in 2012,¹ creating 276,788 new opportunities to license patent rights and 276,788 new chances for patent infringement. Aware of the notoriously high costs of patent litigation² and the significance of patents to company profitability,³ the Supreme Court granted certiorari in *Medtronic, Inc. v. Boston Scientific Corporation*.⁴

* J.D. Candidate, 2015, Duke University School of Law. Thank you to Professor Arti Rai for her guidance and to the *Duke Journal of Constitutional Law and Public Policy* editors, especially Ravi Patel and Tara McGrath, for all of their help and feedback.

1. PATENT TECHNOLOGY MONITORY TEAM, U.S. PATENT STATISTICS, CALENDAR YEARS 1963-2012, U.S. PATENT AND TRADEMARK OFFICE, (2013), http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf.

2. See James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 2 (2005) (“Patent litigation has been called the sport of kings; it is complex, uncertain, and expensive.”); Shawn P. Miller, *What’s the Connection Between Repeat Litigation and Patent Quality? A (Partial) Defense of the Most Litigated Patents*, 16 STAN. TECH. L. REV. 313, 313 (2013) (“Patent litigation is notoriously expensive.”).

3. See Ted Sichelman & Stuart J.H. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111, 115 (2010) (“[W]e find—consistent with anecdotal reports—that many startups rely heavily on patents as signals to the market to improve their chances of raising financing, being acquired, and going public.”). Additionally, some commentators believe Twitter’s “dearth” of patents will deter investors. Leslie Picker, *Twitter’s Lack of Patents Seen as a Risk to Investors*, BLOOMBERG NEWS (Oct. 18, 2013), <http://www.businessweek.com/news/2013-10-18/twitter-pre-ipo-patent-paucity-seen-posing-investor-risk-tech>.

4. *Medtronic, Inc. v. Bos. Scientific Corp.*, 133 S. Ct. 2393 (argued Nov. 5, 2013).

Patent holders grant licensees permission to use patents in exchange for payment of royalties on any products manufactured by the licensee that utilize the licensed patent.⁵ However, patent holders and licensees sometimes disagree about which products utilize the patent.⁶ The patent holder will request royalties on a product, and the licensee will contend the product does not utilize the patent and therefore that no royalties are owed for that product. The Supreme Court held in *MedImmune, Inc. v. Genentech, Inc.*⁷ that a licensee can seek a declaratory judgment of patent invalidity or non-infringement to clarify whether it owes royalties on specific products without first breaking its license agreement.⁸ The Court has not addressed which party bears the burden of proof on infringement in such an action.

In *Medtronic*, the Court will address whether a licensee has the burden of proving non-infringement in a declaratory judgment action brought by the licensee.⁹ The patent holder has the burden of proving infringement “in all other patent litigation, including other declaratory judgment actions.”¹⁰ The Court of Appeals for the Federal Circuit allocated the burden of proving non-infringement to the declaratory judgment plaintiff-licensee, *Medtronic*.¹¹ If the plaintiff-licensee did not have the burden, the court determined, licensees like *Medtronic* could “use *MedImmune*’s shield as a sword.”¹²

The Supreme Court will likely reverse the Federal Circuit ruling. Declaratory judgments are procedural only, and in declaratory judgment actions the substantive burden of proof should not shift from the patent holder to the patent licensee. By shifting the burden to the patent holder, the Federal Circuit impermissibly established a presumption of infringement that is contrary to congressional intent. Further, considerations of policy and fairness weigh in favor of keeping the burden of proving infringement with the patent holder.

5. See 5 JOHN G. MILLS ET AL., PATENT LAW FUNDAMENTALS § 19:16 (2d ed. 2013), available at Westlaw PATLAWAPP.

6. *Id.*

7. 549 U.S. 118 (2007).

8. *Id.* at 137.

9. Brief for Petitioner at i, *Medtronic, Inc. v. Bos. Scientific Corp.*, No. 12-1128 (U.S. July 26, 2013).

10. *Id.*

11. *Medtronic, Inc. v. Bos. Scientific Corp.*, 695 F.3d 1266 (Fed. Cir. 2012), cert. granted, 133 S. Ct. 2393 (May 20, 2013).

12. *Id.*

II. FACTUAL BACKGROUND

Mirowski Family Ventures (MFV) owns the patents for the biventricular pacer,¹³ a device that corrects the heartbeats of patients with congestive heart failure.¹⁴ MFV licensed these patents exclusively to Guidant Corporation, a wholly-owned subsidiary of Boston Scientific Corporation.¹⁵ Guidant's predecessor-in-interest, Eli Lilly & Co., entered a sublicense agreement with Medtronic.¹⁶ Under the terms of the sublicense agreement, Medtronic was free to use the patent in its products as long as Medtronic paid MFV royalties on the sales of those products.¹⁷ Although Medtronic paid royalties on some of its products, MFV believed that additional products used the patent and that Medtronic should have paid royalties on those products as well.¹⁸

In 2006, MFV, the patent holder,¹⁹ and Medtronic, the licensee, entered into a Litigation Tolling Agreement.²⁰ The agreement required MFV to identify which of Medtronic's products MFV believed used licensed patents.²¹ Medtronic could then either pay royalties on those products or seek a declaratory judgment that the patent had not been infringed or was invalid.²² Medtronic chose to file for a declaratory judgment of non-infringement and invalidity.²³ Because the license agreement remained in effect when Medtronic brought its declaratory judgment action, MFV was barred from counterclaiming for infringement.²⁴

13. *Medtronic, Inc. v. Bos. Scientific Corp.*, 777 F. Supp. 2d 750, 758 (D. Del. 2011), *rev'd*, 695 F.3d 1266 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 2393 (May 20, 2013). The pacer, now referred to as cardiac resynchronization therapy (CRT), forces a patient's left and right heart ventricles to contract simultaneously, thereby increasing the efficacy of each heartbeat. *Id.* at 761. CRT is covered under U.S. Reissue Patents No. RE 38,119 (RE'119 patent) and No. RE 39,897 (RE'897 patent). *Id.* The RE'897 patent is a continuation of the RE'119 patent. *Id.*

14. *Id.* at 758.

15. *Id.* Hereinafter, MFV will refer to both MFV and Guidant unless otherwise noted.

16. *Id.* The sublicense agreement permitted Medtronic to challenge allegations of infringement through declaratory judgment actions. *Id.* In 2003, Medtronic began paying royalties into an escrow account for certain of its products that allegedly infringed the sublicensed patents while simultaneously challenging the validity of the patents. *Id.* at 758–59.

17. *Id.* at 759.

18. *Id.*

19. *Id.*

20. *Id.* The Litigation Tolling Agreement suspended litigious action between the parties until the resolution of litigation between Guidant and St. Jude over the RE'119 patent at issue in this case or October 1, 2007, whichever came later. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *See Medtronic, Inc. v. Bos. Scientific Corp.* 695 F.3d 1266, 1273 (Fed. Cir. 2012), *cert.*

Throughout the district court proceedings, both parties disputed who carried the burden of proof²⁵ on infringement.²⁶ Relying on *Under Sea Industries, Inc. v. Dacor Corp.*,²⁷ the district court held that MFV, as the patent holder, had the burden of proving infringement.²⁸ On appeal, the Federal Circuit addressed whether MFV had the burden of proving infringement or Medtronic had the burden of proving non-infringement in a declaratory judgment action where the continued existence of the license²⁹ prevented MFV from counterclaiming for infringement.³⁰

III. LEGAL BACKGROUND

A. Patent Licensees Do Not Need to Break Their License Agreement Before Seeking Declaratory Judgment

The license agreement was still in effect when Medtronic brought the declaratory judgment action, and the continued existence of the license prevented MFV from counterclaiming for infringement.³¹ This situation differs from declaratory judgment actions where the accused infringer does not have a license. Where there is no license, the patent holder is required to counterclaim for infringement or else the claim is lost.³²

The Supreme Court in *MedImmune* held that licensees can seek declaratory judgment of non-infringement or invalidity without having to first breach their license.³³ There, Genentech and MedImmune entered into a license agreement requiring MedImmune to pay royalties on the sales of its products that incorporated Genentech's patents.³⁴ Genentech notified MedImmune that one of

granted, 133 S. Ct. 2393 (May 20, 2013).

25. Brief for Petitioner, *supra* note 9, at 12 (“The ‘burden of proof’ at issue in this case is the ‘burden of persuasion,’ which lies with ‘the party who must persuade the [trier of fact] in its favor to prevail.’” (quoting *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2254 n.1 (2011))).

26. *Medtronic, Inc.*, 777 F. Supp. 2d at 765.

27. 833 F.2d 1551, 1557 (Fed. Cir. 1987) (“The burden is always on the patentee to show infringement.” (citing *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984))).

28. *Medtronic, Inc.*, 777 F. Supp. 2d at 765. The court further held that the defendants did not “prove literal infringement by a preponderance of the evidence.” *Id.* at 769.

29. See *Medtronic, Inc.*, 695 F.3d at 1272 (“[T]he declaratory judgment defendant is foreclosed from counterclaiming for infringement by the continued existence of that license.”).

30. *Id.* at 1270.

31. See *id.* at 1273.

32. *Id.*

33. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007).

34. *Id.* at 121–22.

MedImmune's products used the licensed patent and asked MedImmune to pay royalties.³⁵ MedImmune paid the applicable royalties "under protest" and filed for declaratory judgment of non-infringement or invalidity.³⁶

The Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires a party seeking declaratory judgment to establish the existence of an "actual controversy."³⁷ Genetech argued that MedImmune failed to establish an actual controversy and lacked standing because the license was not being breached while MedImmune willingly paid royalties.³⁸ The Court held that MedImmune did not have to break or terminate its license agreement before seeking declaratory judgment of patent invalidity or non-infringement.³⁹ Preventing non-repudiating licensees from seeking declaratory judgment would force the licensee to essentially "bet the farm" by terminating its license agreement in order to challenge the patent.⁴⁰ By terminating the license agreement, the licensee faces traditional infringement litigation that could destroy the business built upon the patent at issue.⁴¹

Justice Thomas dissented, concluding no actual controversy could exist when any threat of an infringement suit is eliminated by the continued existence of the license and royalties are voluntarily paid.⁴² The continued existence of the license prevents the patent holder from suing the licensee for infringement, and Thomas determined the royalties were paid voluntarily, thereby eliminating any type of coercion that would create an actual controversy.⁴³ Thomas focused on the lack of controversy where "the complaint at issue [is] 'but a request for an advisory opinion as to the validity of a defense to a suit for recovery of the royalties.'"⁴⁴ He would have held that the relief sought by MedImmune amounted to an advisory opinion, as a patent invalidity claim is raised as an affirmative defense to patent

35. *Id.*

36. *Id.* at 122 (internal quotation marks omitted).

37. 28 U.S.C.A. § 2201(a) (West 2013) (establishing that a declaratory judgment may be sought only "[i]n a case of actual controversy").

38. *MedImmune, Inc.*, 549 U.S. at 128.

39. *Id.* at 137.

40. *Id.* at 134.

41. *Id.* "The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80% of its business before seeking declaratory judgment of its actively contested legal rights finds no support in Article III." *Id.*

42. *Id.* at 146 (Thomas, J., dissenting)..

43. *Id.*

44. *Id.* at 139 (quoting *Coffman v. Breeze Corps.*, 323 U.S. 316, 324 (1945)).

infringement and is not a freestanding cause of action.⁴⁵ In Thomas's view, declaratory judgments may be appropriate when a patent holder threatens a competitor with an infringement suit, but not where a license is in place, as the licensee is not forced "either to cease the otherwise protected activity . . . or to continue in that activity and face the threat of a lawsuit."⁴⁶

B. Burdens of Proof in Declaratory Judgment

In *Aetna Life Insurance Co. v. Haworth*,⁴⁷ the Supreme Court upheld the constitutionality of declaratory judgments and reiterated that "the operation of the Declaratory Judgment Act is procedural only."⁴⁸ Due to the procedural nature of declaratory judgments, "the substantive burden of proof normally does not shift."⁴⁹ With patent infringement cases, "courts have generally recognized that any role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit."⁵⁰

There is, however, no hard and fast rule for which party has the burden of proof in declaratory judgment actions.⁵¹ In *Schaffer ex rel. Schaffer v. Weast*,⁵² a student was denied educational services under the Individuals with Disabilities Act (IDEA) and initiated a due process hearing, as permitted by IDEA, to seek compensation for the cost of subsequent schooling.⁵³ The Supreme Court found the "plain text of IDEA [wa]s silent on the allocation of the burden of persuasion."⁵⁴ Therefore, the burden of persuasion should be determined by the "ordinary default rule that plaintiffs bear the risk of failing to prove their claims."⁵⁵

45. *Id.* at 142 (citing 35 U.S.C. § 282(2)–(3) (2006)).

46. *Id.* at 146.

47. 300 U.S. 227 (1937).

48. *Id.* at 240.

49. *Medtronic, Inc. v. Bos. Scientific Corp.*, 695 F.3d 1266, 1272 (Fed. Cir. 2012) (citing *In re Tech. Licensing Corp.*, 423 F.3d 1286, 1288–89 (Fed. Cir. 2005)), *cert. granted*, 133 S. Ct. 2393 (May 20, 2013).

50. *Id.* at 1273 (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g., Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999)).

51. *Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 56 (2005) ("The term 'burden of proof' is one of the 'slipperiest member[s] of the family of legal terms.'" (quoting 2 J. STRONG, MCCORMICK ON EVIDENCE § 342 (5th ed. 1999))).

52. 546 U.S. 49 (2005).

53. *Id.* at 55.

54. *Id.* at 56.

55. *Id.*

The Court highlighted an exception to the default rule, permitting the burden to shift to defendants when elements of a plaintiff's claim "can be fairly characterized as affirmative defenses or exceptions."⁵⁶ By asking the Court to shift the burden, the plaintiffs effectively asked the Court "to assume that every [Individualized Education Program] is invalid until the school district demonstrates that is not. The Act d[id] not support this conclusion."⁵⁷

In his concurrence, Justice Stevens disagreed with the majority's opinion in that it failed to consider policy, convenience, and fairness.⁵⁸ Justice Ginsburg dissented, determining that the school district was in the best position to carry the burden due to their "better access to information, greater expertise, and an affirmative obligation to provide the contested services."⁵⁹ Although *Schaffer* settled the burden of proof issue in the particular setting of IDEA, the opinion left open the question of whether policy should play a role in determining burden allocation. Moreover, the decision did not address whether the defendant's inability to counterclaim should be considered.

C. Patent Infringement & Non-Infringement

Under 35 U.S.C. § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent therefor, infringes the patent." The Federal Circuit in *Under Sea Industries, Inc.* declared the burden for proving infringement "always is on the patent[] [holder]."⁶⁰ Patents are presumed valid, and the party asserting invalidity has the burden of proving invalidity.⁶¹ Non-infringement and invalidity are listed as a defenses "in any action involving the validity or infringement of a patent" under 35 U.S.C. § 282(b).

Process patents are different from patents on machines or compositions of matter. Process patents are presumptively infringed

56. *Id.* at 57 (citing *FTC v. Morton Salt Co.*, 334 U.S. 37, 44–45 (1948)).

57. *Id.* at 59.

58. *Id.* at 62 ("It is common ground that no single principle or rule solves all cases by setting forth a general test for ascertaining the incidence of proof burdens when both a statute and its legislative history are silent on the question.").

59. *Id.* at 67 (quoting *Weast v. Schaffer ex rel. Schaffer*, 377 F.3d 449, 458 (4th Cir. 2004) (Luttig, J., dissenting)).

60. *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (citing *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984)).

61. 35 U.S.C.A. § 282(a) (West 2013) ("The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.").

when a product is offered for sale that could not plausibly be made without use of the patented process.⁶² The party accused of infringing the process patent is statutorily required to bear the burden of establishing that the product was not made using the patented process.⁶³ But the patent at issue in *Medtronic* is not a process patent and is not subject to this statutory presumption of infringement.⁶⁴

IV. HOLDING

The Court of Appeals for the Federal Circuit reversed the district court on the burden of proof issue.⁶⁵ The appellate court held that “in the limited circumstance when an infringement counterclaim by a patent[] [holder] is foreclosed by the continued existence of a license,” the licensee has the burden of proof when seeking a declaratory judgment of non-infringement.⁶⁶

The court framed the burden of proof question as one arising “as a consequence of the Supreme Court’s decision in *MedImmune*.”⁶⁷ The court’s analysis began with an acknowledgement of the general rule that declaratory judgment actions do not shift the substantive burden of proof.⁶⁸ In a customary declaratory judgment case, the defendant patent holder is required to bring an infringement counterclaim or else the claim is lost, and this infringement counterclaim effectively shifts the burden to the patent holder.⁶⁹ But in the post-*MedImmune* world, MFV, the patent holder, is precluded from asserting an infringement counterclaim because the license is still in force.⁷⁰ It is only Medtronic asking the court to disturb the parties’ status while, “in contrast, MFV seeks nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract.”⁷¹ Under the default rule, Medtronic must carry the burden because it is the party requesting relief.⁷² The court

62. *See id.* § 295.

63. *Id.*

64. *See* U.S. Patent No. RE 39,897 (filed Aug. 8, 2002) (describing the patent as one for the “[m]ethod and apparatus for treating hemodynamic disfunction”).

65. *Medtronic, Inc. v. Bos. Scientific Corp.*, 695 F.3d 1266, 1276 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 2393 (May 20, 2013).

66. *Id.* at 1274.

67. *Id.* at 1271.

68. *Id.* at 1273.

69. *Id.*

70. *Id.*

71. *Id.*

72. The court highlighted that Medtronic sought relief from paying royalties, and this type of relief is not “the sort[] of relief generally sought when a party seeks relief for patent

determined that requiring MFV to prove infringement when MFV is prevented from counterclaiming for infringement “would allow licensees to use *MedImmune*’s shield as a sword—haling licensors into court and forcing them to assert and prove what had already been resolved by license.”⁷³

V. ARGUMENTS

A. Arguments for Petitioner, *Medtronic, Inc.*

Medtronic focuses its argument primarily on the substantive law’s allocation of the burden of proof. The Declaratory Judgment Act “is a purely procedural statute that neither enlarges the jurisdiction of the federal courts nor alters substantive rights.”⁷⁴ Because the statute is purely procedural, “the nominal reversal of traditional party status in a declaratory judgment action does not alter the substantive law’s allocation of the burden of proof.”⁷⁵ Medtronic cites *Aetna* for evidence that the Supreme Court “has also emphasized the substantive equivalence of a declaratory action and the corresponding coercive suit in holding that declaratory judgment cases can satisfy Article III’s case-or-controversy requirement.”⁷⁶ The substantive burden in declaratory actions should not shift because altering the burden necessarily alters what should be the substantive equivalent of a coercive suit.⁷⁷ Additionally, upholding the Federal Circuit ruling would undermine both “the [Declaratory Judgment] Act’s utility in avoiding uncertainty and disruption”⁷⁸ and “the finality of declaratory judgments.”⁷⁹

Medtronic argues there is no precedent to support the Federal Circuit’s ruling.⁸⁰ According to Medtronic, prior to the Federal Circuit decision, every court had correctly determined that “the burden of proof in a declaratory judgment action involving patent infringement is on the defendant owner of the patents at issue . . . just as if he were

infringement.” *Id.* at 1274.

73. *Id.*

74. Brief for Petitioner, *supra* note 9, at 15.

75. *Id.* at 18.

76. *Id.* at 22 (“It is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative.” (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 244 (1937))).

77. *See id.*

78. *Id.* at 29.

79. *Id.* at 31.

80. *See id.* at 36.

the plaintiff suing for infringement of those patents.”⁸¹ Neither MFV nor the Federal Circuit cited “any prior decision in which a court has charged an accused infringer with the burden of *disproving* patent infringement.”⁸² On the other hand, in 35 U.S.C. § 295⁸³ Congress expressly created a rebuttable presumption of infringement for process patents, thus indicating that patent law does not support the Federal Circuit decision.⁸⁴

The Federal Circuit also erred by viewing MFV as “a passive participant that merely s[ought] to be discharged from the suit.”⁸⁵ MFV initiated the controversy by demanding royalty payments.⁸⁶ Addressing the Federal Circuit’s concern that licensees will use *MedImmune* as a sword against patent holders, Medtronic argues *MedImmune* cannot be used as a sword to unfairly hail patent holders into court because a potential declaratory judgment defendant has ample notice due to the nature of the action.⁸⁷ The declaratory judgment suit is brought, regardless of the license, because there is a “substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”⁸⁸ The existence of a “substantial controversy,” which rises from the accusations of patent infringement, gives the patent holder notice of impending litigation.⁸⁹

By requiring licensees in *MedImmune*-type actions to prove non-infringement, the Federal Circuit rejected “repeated admonitions about the difficulty of proving a negative.”⁹⁰ Medtronic adds that the difficulty of proving a negative is exacerbated in the infringement context, “because patents regularly contain dozens (even hundreds) of claims, infringement of any one of which triggers liability.”⁹¹ The licensee proving non-infringement would have to show its product does not incorporate any of the claims, while the patent holder

81. *Id.* (quoting *Deere & Co. v. Sperry Rand Corp.*, 322 F. Supp. 397, 398 (E.D. Cal. 1970)).

82. *Id.* at 37.

83. “In actions alleging infringement of a process patent . . . the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.” 35 U.S.C.A. § 295 (West 2013).

84. Brief for petitioner, *supra* note 9, at 37.

85. *Id.* at 41 (internal quotation marks omitted).

86. *Id.*

87. *Id.*

88. *Id.* at 42 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

89. *Id.*

90. *Id.* at 43 (citing *Vieth v. Jubelirer*, 541 U.S. 267, 311 (2004)).

91. *Id.* at 44.

asserting infringement needs to show only that the product does infringe specific claims.⁹²

B. Arguments for Respondent, MFV

MFV frames the question as one involving claim coverage as opposed to infringement.⁹³ In a patent licensing agreement, infringement “means ‘claim coverage’ because the licensee cannot be an infringer.”⁹⁴ The license effectively protects the licensee from being sued for infringement.⁹⁵ Therefore, MFV could not accuse Medtronic of infringement. Whether Medtronic owes royalties is an issue of claim coverage,⁹⁶ and any cases Medtronic cites that do not involve claim coverage are inapposite.⁹⁷

MFV cites *Schaffer* for the default rule that the party seeking relief bears the burden of proof.⁹⁸ The license agreement “provided that Medtronic could file a [declaratory judgment] action if it wanted to seek relief from its license.”⁹⁹ Medtronic did file for declaratory judgment, and, “since the normal default rule is that the plaintiff bears the burden . . . Medtronic agreed that Medtronic would bear the burden on claim coverage (if it wanted relief from its license).”¹⁰⁰ In response to Medtronic’s claim that MFV sought relief first by asking for royalties, MFV clarifies that “to seek relief in a suit means to file a claim or counterclaim.”¹⁰¹

The fact that patent holders carry the burden of proof in traditional infringement actions has no bearing on whether MFV has the burden of proof on claim coverage in declaratory judgment.¹⁰² Patent holders normally have the infringement burden only because they are typically the party asserting infringement and seeking relief.¹⁰³ If the patent holder does not seek relief, the patent holder

92. *Id.*

93. *Id.* at i.

94. Brief for Respondent at 6–7, *Medtronic, Inc. v. Bos. Scientific Corp.*, No. 12-1128 (U.S. Sep. 16, 2013).

95. *Id.* at 48.

96. *Id.*

97. *Id.* at 37.

98. *Id.* at 25.

99. *Id.* at 36.

100. *Id.*

101. *Id.* at 47.

102. *Id.* at 35.

103. *Id.*

should not have to prove infringement.¹⁰⁴

MFV poses a hypothetical wherein a patent holder accuses a competitor of infringement, and the parties agree to settle their dispute through a licensing agreement, rather than litigation.¹⁰⁵ An adoption of Medtronic's proposed rule, however, would give patent holders a disincentive to settle disputes with infringers.¹⁰⁶ The patent holder cannot seek an injunction, damages, or willful infringement damages if a license exists, but nevertheless bears the burden of proof in declaratory judgment.¹⁰⁷ In this situation patent holders will "be quite reluctant to settle on such a basis since the patent[] [holder] gives up a lot and receives very little."¹⁰⁸

Regarding *MedImmune*, MFV notes that in the license agreement, the parties stipulated that either had the right to bring a declaratory judgment action.¹⁰⁹ Consequently, "[n]either party relied upon *MedImmune* for this right."¹¹⁰

VI. ANALYSIS

The Court should hold that patent holders have the burden of proving infringement in declaratory judgment regardless of the existence of a license. Determining which party bears the burden of proof is critical for patent-holding companies that may face substantial losses when a patent is held to be invalid or not infringed.¹¹¹ This decision also impacts the licensee who will no longer have to pay royalties to the patent holder. But the outcome of *Medtronic* will reach far past the two parties embroiled in litigation, influencing both future inventors and future licensing agreements.

Several factors weigh against shifting the burden to licensees. First, considerations of fairness, convenience, and policy weigh in favor of imposing the burden on the patent holder. Second, the Federal Circuit ruling creates a presumption of infringement at odds with congressional intent. Third, *MedImmune* will not become a sword if

104. *Id.*

105. *Id.*

106. *Id.* at 39.

107. *Id.* at 40.

108. *Id.*

109. *Id.* at 42.

110. *Id.*

111. Patents may be especially relevant to pharmaceutical company profitability. See Bessen & Meurer, *supra* note 2, at 10. In one case involving a finding of patent invalidity, "Eli Lilly lost nearly 30% of its stock market value." *Id.*

the Court reverses the Federal Circuit.

A. Considerations of Fairness, Convenience, and Policy

Justice Stevens and Justice Ginsburg did not join the majority in *Schaffer* partly because the majority failed to consider fairness, convenience, and policy in determining which party carried the burden of proof.¹¹² The Court should consider these factors in *Medtronic*, especially because Congress has invoked considerations of fairness, convenience, and policy in recent debates about the patent system's effectiveness in promoting innovation.¹¹³ Deciding which party bears the burden of proof in patent infringement without considering these factors would exacerbate fairness concerns with the patent system as a whole. If the Court considers these factors in *Medtronic*, the factors will weigh in favor of keeping the burden of proving infringement with the patent holder.

Fairness to future inventors suggests the Court should not require declaratory judgment plaintiffs to prove non-infringement. The Court's 2011 decision in *Microsoft Corp. v. i4i Ltd. Partnership*¹¹⁴ upheld a clear and convincing evidence standard for proving patent invalidity.¹¹⁵ Critics of the Court's decision focus on the importance of invalidating bad patents¹¹⁶ in order to justify the "embarrassment of an exclusive patent."¹¹⁷ By maintaining the "clear and convincing" evidence standard, the Court creates a tough barrier for any litigant seeking to invalidate a patent. Through this decision, the Court may have inadvertently "clear[ed] the way for holders of bad patents to stifle innovation and business growth."¹¹⁸

112. *Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 62 (2005) (Stevens, J., concurring) ("I do not understand the majority to disagree with the proposition that a court, taking into account policy considerations, convenience, and fairness could conclude the purpose of a statute is best effectuated by placing the burden of persuasion on the defendant." (internal quotation marks omitted)); *id.* at 63 (Ginsburg, J., dissenting) ("As the Fourth Circuit recognized, however, 'other factors,' prime among them 'policy considerations, convenience, and fairness' may warrant a different allocation." (citation omitted)).

113. See WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV. REPORT, R41638, PATENT REFORM IN THE 112TH CONGRESS: INNOVATION ISSUES 1 (2011).

114. 131 S. Ct. 2238 (2011).

115. *Id.* at 2242.

116. Kristen Dietly, Note, *Lightening the Load: Whether the Burden of Proof for Overcoming a Patent's Presumption of Validity Should be Lowered*, 78 *FORDHAM L. REV.* 2615, 2656-57 (2010).

117. Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 *THE WRITINGS OF THOMAS JEFFERSON* 326-35 (Andrew A. Lipscomb ed., 1903).

118. Irina Oberman, *Maintaining the Clear and Convincing Evidence Standard for Patent Invalidity Challenges in Microsoft Corp. v. i4i Limited Partnership*, 131 S. Ct. 2238, (2011), 35

Similar to the criticisms of *Microsoft*, the Federal Circuit's burden allocation could stifle innovation by raising the bar for proving a product does not infringe a certain patent. The declaratory judgment licensee facing infringement liability is at a disadvantage when two essential defenses to patent infringement—invalidity and non-infringement—require “clear and convincing” evidence and proof of a negative,¹¹⁹ respectively. In order to prove non-infringement, the licensee must show that they did not infringe the patent, whereas the patent holder proving infringement would have to show the licensee did infringe the patent.¹²⁰ *MedImmune* aided licensees by permitting them to bring declaratory judgment actions without being subject to liability through coercive patent infringement suits.¹²¹ The Federal Circuit decision would reduce this benefit to licensees in a “potentially outcome-determinative respect.”¹²²

HARV. J.L. & PUB. POL'Y 439, 441 (2012). *But see* Joshua L. Sohn, *Can't the PTO Get a Little Respect?*, 26 BERKELEY TECH. L.J. 1603, 1605 (2011) (“Yet, a judicial decision to invalidate a patent is essentially a judicial overturning of the PTO's decision to grant the patent. . . . '[C]lear and convincing evidence' is a significantly lower standard of proof than the normal standard that a litigant must satisfy before a court will overturn an administrative decision.”).

119. Proof of non-infringement requires proof of a negative, and the difficulty of proving a negative in the patent context is substantial. Brief for Petitioner, *supra* note 9, at 12.

120. The *Schaffer* Court specifically said the burden of proof could shift to defendants in declaratory judgment actions where the plaintiff asserts an affirmative defense. *Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 57 (2005). Both non-infringement and invalidity are listed under 35 U.S.C. § 282(b) as “defenses in any action involving the validity or infringement of a patent.” Infringement is not an “affirmative defense[] in the traditional sense, because the defendant asserting the defense does not take on the burden[] of production or persuasion.” Roger Allan Ford, *Patent Invalidity Versus Non-infringement*, 99 CORNELL L. REV. 71 (forthcoming 2013) (manuscript at 73 n.5); *see also* Certain Programmable Digital Clock Thermostats, Inv. No. 337-TA-278, USITC Pub. 1 (Apr. 12, 1988) (Final) (finding defendant “pleaded non-infringement, but this is not an affirmative defense”). Justice Thomas's *MedImmune* dissent rightly characterized patent invalidity as an affirmative defense. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (Thomas, J., dissenting). If Thomas similarly characterizes non-infringement as an affirmative defense, the exception created in *Schaffer* would permit the burden to shift to the defendant.

121. *MedImmune, Inc.*, 549 U.S. at 129.

122. Brief for Petitioner, *supra* note 9, at 3.

Burden of proof allocation is often outcome-determinative.¹²³ Accordingly, the Federal Circuit rule directly impacts whether patent licensees in declaratory judgment actions will be found liable for infringement. Forcing the declaratory judgment plaintiff to prove non-infringement increases the likelihood of finding infringement relative to the corresponding coercive suit. Whether a product infringes the underlying patent, in declaratory judgment or otherwise, has critical ramifications not just in terms of royalty payments, but also for future inventors.¹²⁴ It is better for the future inventor if the licensee “bets the farm” and enters into a coercive patent suit where the patent holder has the burden of proof; when a product is found not to infringe a patent, inventors may build off the product without fearing subsequent infringement litigation brought by the same patent holder. Shifting the burden of proof increases the likelihood of finding infringement, which may disrupt innovation and deprive the public of potential scientific and technological breakthroughs.

B. Presumption of Infringement

The Federal Circuit presumed Medtronic’s products infringed the underlying patent. The court determined Medtronic, as the plaintiff, should bear the burden because Medtronic sought declaratory judgment as stipulated by the license agreement. The court characterized MFV as merely wanting to enjoy its contract and to be discharged from the suit.¹²⁵ However, without the presumption of infringement, MFV would properly be characterized as the party who disturbed the parties’ status by asking Medtronic to pay royalties. This

123. Rochelle Cooper Dreyfuss & Lawrence S. Pope, *Dethroning Lear? Incentives to Innovation After MedImmune*, 24 Berkeley Tech. L.J. 971, 974 (2009) (“[P]atentability law tends to be so highly unsettled that it is easy to mount credible challenges.”); Thomas A. Mayes et al., *Allocating the Burden of Proof in Administrative and Judicial Proceedings Under the Individuals with Disabilities Education Act*, 108 W. VA. L. REV. 27, 80 (2005) (“In areas of law characterized by indeterminacy, a shift in the burden of proof is often outcome-determinative.”); Sandra M. Di Iorio, Comment, *Breaking IDEA’s Silence: Assigning the Burden of Proof at Due Process Hearings and Judicial Proceedings Brought by Parents Against a School District*, 78 TEMP. L. REV. 719, 726 (2005) (“Allocation of the burden of proof is often outcome-determinative.”).

124. E.g., Howard F. Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. ECON. 34, 34 (1995) (“Theses [infringement] decisions have important effects on the pace of technological progress through the incentives to invent not only the first invention but also later inventions that build upon the first.”).

125. *Medtronic, Inc. v. Bos. Scientific Corp.*, 695 F.3d 1266, 1273 (Fed. Cir. 2012) (“Medtronic and not MFV . . . is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear.”), *cert. granted*, 133 S. Ct. 2393 (May 20, 2013).

presumption of infringement conflicts with congressional intent, as evidenced by the express presumption of validity created under 35 U.S.C. § 282(a).¹²⁶

Congress placed the “burden of establishing invalidity of a patent or any claim thereof . . . on the party asserting such invalidity.”¹²⁷ Courts have held accordingly.¹²⁸ Under § 282(a) Congress declined to create a presumption of infringement while clearly creating a presumption of validity. As petitioners observe, Congress also expressly created a rebuttable presumption of infringement for process patents,¹²⁹ but this presumption is conspicuously absent from § 271.¹³⁰ By creating a presumption of infringement the Federal Circuit’s ruling conflicts with congressional intent.

C. *MedImmune’s Shield as a Sword*

MedImmune will not become a proverbial sword against patent holders if the Federal Circuit ruling is reversed. The Federal Circuit expressed concern that forcing MFV to carry the burden of proof “would allow licensees to use *MedImmune*’s shield as a sword—haling licensors into court and forcing them to assert and prove what had already been resolved by license.”¹³¹ *MedImmune* permitted licensees to seek declaratory judgment without breaching their license because the situation qualified as “a case of actual controversy.”¹³² If the license resolved the infringement issue, no controversy would exist and declaratory judgment would not be permitted.¹³³ Further, the nature of declaratory judgment oftentimes means “the injury-in-fact that gives a declaratory judgment plaintiff Article III standing is the

126. 35 U.S.C.A. § 282(a) (West 2013) (“In General. A patent shall be presumed valid.”).

127. *Id.*

128. *See, e.g.,* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1573 (Fed. Cir. 1984) (“[T]he one attacking validity has the burden of proving invalidity by clear and convincing evidence.” (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

129. Brief for Petitioner, *supra* note 9, at 37. “Through § 295, Congress imposed a rebuttable presumption of infringement that shifts the burden of production in certain carefully defined circumstances.” *Id.* (quoting S. REP. NO. 100-83, at 57 (1987)) (internal quotation marks omitted).

130. *See* 35 U.S.C.A. § 271.

131. *Medtronic, Inc. v. Bos. Scientific Corp.*, 695 F.3d 1266, 1274 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 2393 (May 20, 2013).

132. *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 133–34 (2007).

133. District Courts are vested with discretion to dismiss declaratory judgment actions “because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp.” *Id.* at 136 (quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995)).

threat of legal liability in an enforcement suit that could be, but has not been, brought against it by the declaratory judgment defendant.”¹³⁴ The assumption is that the defendant threatens infringement—as MFV did by notifying Medtronic of the products that allegedly infringed the patents¹³⁵—otherwise the plaintiff lacks standing. Therefore, defendants are not forced to assert infringement; the assertion is implied because plaintiffs have standing.

The sword concern is further diminished in the current case by the parties’ contractual agreement.¹³⁶ MFV must have some proof of infringement in order to identify which of Medtronic’s products infringe the patent. It is hard to see how MFV is being “forced” to assert and prove infringement when the assertions were made willingly, and those assertions required MFV to have some quantum of proof. Essentially, “[a]ny general fairness concerns in favor of placing the burden of persuasion on the plaintiff are muted where, as here, the parties’ agreements explicitly provide for the bringing of a licensee declaratory judgment action.”¹³⁷

VII. CONCLUSION

The Federal Circuit’s decision in *Medtronic* improperly gives the declaratory judgment plaintiff-licensee Medtronic the burden of proving non-infringement. In a declaratory judgment action for non-infringement, the plaintiff-licensee is necessarily at risk for infringement liability. The plaintiff in this instance should not bear the burden of disproving what they are impliedly accused of doing because this allocation of the burden does not comport with congressional intent or the procedural nature of declaratory judgments. To remedy the situation, the Supreme Court will likely reverse the Federal Circuit and hold the burden of proving infringement remains with the patent holder.

134. Brief for the United States as Amicus Curiae Supporting Petitioner at 22, *Medtronic, Inc. v. Bos. Scientific Corp.*, No. 12-1128 (U.S. Aug. 2, 2013).

135. *See supra* Section II.

136. *See supra* text accompanying note 21.

137. Brief of Legal Scholars as Amici Curiae in Support of Petitioner at 30, *Medtronic, Inc. v. Bos. Scientific Corp.*, No. 12-1128 (U.S. Aug. 2, 2013).