

BURDEN OF PROOF IN *MEDTRONIC*: THE FEDERAL CIRCUIT'S IDIOSYNCRATIC PATENT JURISPRUDENCE VETOED, AGAIN

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*Ei incumbit probatio qui dicit, non qui negat.*¹

In line with this time-honored maxim, the United States Supreme Court held in *Medtronic, Inc. v. Mirowski Family Ventures, LLC* that in a declaratory judgment action filed by a licensee denying infringement, the patent owner (the nominal defendant) retains the burden of proof for showing infringement.² The opinion, reversing the Federal Circuit's ruling that the burden shifts to the licensee,³ is a natural continuation of the Court's 2007 *MedImmune, Inc. v. Genentech, Inc.* decision, which struck down the Federal Circuit's stringent standard for when a licensee could file a declaratory judgment action.⁴

In *MedImmune*, a patent licensee filed suit seeking a declaratory judgment that the patent was invalid or not infringed.⁵ At the same time, the licensee continued paying royalties to preclude treble damages if the patent were to be found valid and infringed.⁶ The Federal Circuit ruled that since the licensee continued the royalty payments there was no constitutional case or controversy before the court, meaning the licensee had no standing.⁷ The Federal Circuit's rule clashed with established precedent for non-patent declaratory judgment cases⁸ and was overturned

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1. The burden of the proof lies upon him who affirms, not he who denies.

2. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 846 (2014).

3. *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266 (Fed. Cir. 2012), *rev'd sub nom. Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014).

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

5. *Id.* at 122–23.

6. *Id.* at 122.

7. *Id.*

8. As aptly indicated by an amicus before the *MedImmune* court. See Brief of Amicus Curiae Medtronic, Inc. in Support of Petitioner at 9, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (No. 05-608), 2006 WL 1355598, at *9 (pointing

by the Supreme Court.⁹ The Court ruled that a licensee could file a declaratory judgment action while continuing to pay royalties, thus bringing patent law back into the normative civil procedure fold.¹⁰

The dispute in *MedImmune* settled on remand¹¹ and therefore did not address who bore the burden of proof regarding infringement (or lack thereof) where the licensee's royalty payments foreclosed a counterclaim of infringement by the patent holder. Seven years later in *Medtronic*, the Court analyzed this issue on similar facts, rejected yet another patent-specific declaratory judgment rule from the Federal Circuit, and unanimously held that the burden was always on the patentee, a decision dictated by "simple legal logic" as well as multiple practical and policy considerations.¹²

Through Justice Breyer's well-reasoned opinion, the *Medtronic* Court again admonished the Federal Circuit for constructing, for patent cases alone, a legally unsound rule divorced from long-established precedent.¹³ As the *Medtronic* and *MedImmune* fact patterns are similar, the Court likely granted certiorari in *Medtronic* because the Justices felt the need to finish the job begun in *MedImmune* and continue to bring patent law within the fold of mainstream jurisprudence.

Yet *Medtronic* itself, like *MedImmune*, is a narrow ruling, making it likely that declaratory judgments in patent cases will reappear on the Supreme Court's docket in the near future. *MedImmune* did not address the issue of whether a declaratory judgment action could be prevented by licensee estoppel—in other words whether a no-challenge clause in the contract would be enforceable.¹⁴ On the other hand, licensee estoppel did not even come up in *Medtronic*, as the license agreement specifically

out legal precedent, going back seventy years, that was erroneously distinguished by the Federal Circuit).

9. *See MedImmune*, 549 U.S. at 137.

10. *See id.*

11. Marilyn Chase, *Genentech, MedImmune Settle Patent Dispute*, WALL ST. J., June 12, 2008, at B7.

12. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849 (2014).

13. *See id.* ("[S]ettled case law[] strongly supports [overruling the Federal Circuit.]; *see also id.* at 851 ("[T]he fact that [Federal Circuit's] rule's scope is limited cannot, by itself, show that the rule is legally justified.")).

14. *See MedImmune*, 549 U.S. at 124 ("We express no opinion on whether a nonrepudiating licensee is similarly relieved of its contract obligation during a successful challenge to a patent's validity—that is, on the applicability of licensee estoppel under these circumstances.").

permitted the declaratory judgment action.¹⁵ Yet issues related to licensee estoppel, at the heart of many patent disputes leading to declaratory judgments, form another area where the Federal Circuit has read established Supreme Court precedent narrowly¹⁶ and perhaps even idiosyncratically. The impact of *Medtronic* in the context of both present and future patent disputes will depend on how courts interpret “nonrepudiating” licensee estoppel.¹⁷

This Note examines the legal soundness, policy aspects, and practical impact of the *Medtronic* decision. The Note proceeds as follows: Part I describes the background of the declaratory judgment, including its historical and constitutional basis, as well as its application in patent cases. A significant portion is devoted to declaratory judgments in the context of a license relationship, with a particularly detailed discussion of the *MedImmune* case. The conflict between contract law and federal patent policy, as decided in the seminal *Lear, Inc. v. Adkins* case,¹⁸ is also analyzed, as is the Federal Circuit caselaw in view of the *Lear* doctrine, before and after *MedImmune*. Part II focuses on the *Medtronic* case, its factual background, the special rule established by the Federal Circuit, and a comprehensive account of the Supreme Court’s decision. Then, Part III provides a detailed analysis of the *Medtronic* decision, a comparison with other fields of law, a discussion of the public policy concerns at play, as well as a description of the opinion’s impact in the practice field. In the context of the latter, the Note includes advice for both patent holders and potential licensees in view of the decision. At the same time, it points out that while *Medtronic* and its predecessor *MedImmune* are steps forward, the Court has still not fully decided the issue of licensee estoppel, which is crucial for ascertaining the framework and the limits of permissibility in the interaction between contract law and federal patent policy. Part IV briefly summarizes and concludes the Note.

15. *Medtronic*, 134 S. Ct. at 846.

16. *See* *Studiengesellschaft Kohle M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997) (narrowing the circumstances in which licensee estoppel is precluded by *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969)).

17. *See MedImmune*, 549 U.S. at 124.

18. 395 U.S. at 674.

I. DECLARATORY JUDGMENT

The declaratory judgment action has emerged as a tool enabling licensees and other users of technology to determine whether their technology infringes a patent, without having to risk the high damages of willful infringement.¹⁹

A. CONSTITUTIONAL AND STATUTORY BASIS

Declaratory judgments are preventive adjudications, allowed in federal courts by the Declaratory Judgment Act (“DJA”) of 1934, which states (as amended):

(a) 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. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.²⁰

By instituting an “actual controversy” prerequisite, Congress ensured that the DJA adhered to the constitutional requirement that federal courts only adjudicate “case[s] or controvers[ies].”²¹ The Supreme Court upheld the constitutionality of the DJA three years after its enactment, in *Aetna Life Insurance Co. v. Haworth*,²² a cornerstone case in declaratory judgment jurisprudence. While declaratory judgments are not unique to patent law,²³ they are common in the patent context when there is an “actual controversy”²⁴ as to whether one’s commercial products infringe another’s patents.

B. DECLARATORY JUDGMENTS IN PATENT LICENSE DISPUTES AND THE STANDARD FOR “ACTUAL CONTROVERSY”

Declaratory judgments are relatively common in patent cases—indeed, the DJA was enacted with a view toward patent disputes.²⁵ The availability of a declaratory action is particularly appropriate in the patent context, in

19. See *MedImmune*, 549 U.S. at 134 (holding that a party does not have to risk treble damages and the loss of a significant percent of its business before seeking a declaration that its products do not infringe).

20. 28 U.S.C. § 2201 (2012).

21. U.S. CONST. art. III, § 2, cl. 1.

22. 300 U.S. 227 (1937).

23. Indeed, some of its earlier uses were in insurance cases; see, e.g., *id.*

24. 28 U.S.C. § 2201(a).

25. See *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95–96 (1993).

view of the significant damages available for infringement.²⁶ A declaratory judgment action allows one challenging a patent's scope to remove the cloud of litigation and avoid the dilemma between whether to continue his activities (and thus continue accruing damages if he is infringing) or to stop his economic undertaking.²⁷ Without the option of a declaratory judgment, he would be at the mercy of the patentee, as damages could accrue significantly²⁸ if the patentee delayed bringing an infringement suit.²⁹

In the context of a patent license agreement, an "actual controversy" clearly exists if a party to the contract breaches it, but the exact legal threshold for an "actual controversy" in the absence of a breach is more blurred.

1. *Lear v. Adkins: Freedom of Contract vs. Federal Patent Policy*

Many patent disputes arise in the context of patent license agreements, whereby patent owners contract the use of their patents in exchange for royalties. At one time it was deemed that by purchasing a license, the licensee was precluded from contesting the validity of the patent in court, even in the case of an "actual controversy," as reflected for example by the licensee stopping royalty payments (repudiating the contract).³⁰ This led to a conflict between the freedom of contract and federal patent policy. Taking a stand on the issue, in 1969 the Supreme Court partially struck down the common-law doctrine of licensee estoppel³¹ in *Lear v. Adkins*.³² *Lear* held that a licensee who repudiates the license agreement cannot be forbidden, in defending against infringement contentions, from arguing that the patent is invalid.³³ To reach this conclusion, the Court applied a

26. See 35 U.S.C. § 284 (2012) (authorizing a court to "increase the damages up to three times the amount found or assessed." Courts usually do this if they find infringement to have been "willful." See *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996)).

27. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 850 (2014) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007)).

28. Under the statute of limitations, damages can be recovered for acts of infringement that occurred as far back as six years prior to filing the lawsuit. See 35 U.S.C. § 286 (2012).

29. See *Medtronic*, 134 S. Ct. at 850.

30. *Automatic Radio Mfg. Co., Inc. v. Hazeltine Research, Inc.*, 339 U.S. 827, 836 (1950) ("The general rule is that the licensee under a patent license agreement may not challenge the validity of the licensed patent in a suit for royalties due under the contract.") (citing *United States v. Harvey Steel Co.*, 196 U.S. 310 (1905)).

31. See, e.g., *Automatic Radio*, 339 U.S. at 836.

32. *Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969).

33. *Id.*

balancing test between the patent owner's interests and the public policy of having invalid patents struck down, finding the latter to be countervailing.³⁴ It is important to note that the *Lear* decision was narrow on its facts: it did not address nonrepudiating licensees, nor did it explicitly address "no challenge" clauses (provisions in a written contract that would bar legal challenges to the patent). Those unaddressed issues would come to the fore in subsequent years.

2. *Narrowing of Lear by the Federal Circuit; the Reasonable Apprehension of Suit ("RAS") Standard*

In subsequent years the Federal Circuit applied *Lear* narrowly, attempting to limit its impact and generally the ability of licensees to challenge patents when a license agreement was in place.³⁵ Because *Lear* involved a repudiating licensee, it did not address the case where the licensee has not stopped making royalty payments, yet does not agree that his products are infringing. A potent tool in the licensee's arsenal is the declaratory judgment action, which has the purpose of deciding such controversies. So an important question before the courts concerned justiciability, whether a licensee who was still paying royalties under an agreement even had standing to file a declaratory judgment action, that is, whether there was an "actual controversy." In *Gen-Probe, Inc. v. Vysis, Inc.*, the Federal Circuit sided with the patent owner and ruled that there was no "actual controversy" if the licensee did not repudiate the contract and continued to make payments; lack of standing meant that the court did not even need to invoke licensee estoppel to throw the licensee out of court.³⁶ In *Gen-Probe* the Federal Circuit established the so-called "reasonable apprehension of suit" ("RAS") standard for when a licensee would have standing to file a declaratory judgment action.³⁷ A Federal Circuit panel was bound by the RAS standard³⁸ when it dismissed another nonrepudiating licensee's declaratory judgment suit in *MedImmune*.³⁹

34. *Id.* at 670.

35. *See Studiengesellschaft Kohle M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997) (holding that a condition for a licensee to invoke the *Lear* doctrine is to cease payment of royalties).

36. *See Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379–80 (Fed. Cir. 2004).

37. *Id.*

38. A Federal Circuit panel "is bound by prior precedential decisions unless and until overturned *in banc*." *Gen. Dynamics Corp. v. United States*, 773 F.2d 1224, 1225 n. 2 (Fed. Cir. 1985), *rev'd on other grounds*, 481 U.S. 239 (1987).

39. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 964–65 (Fed. Cir. 2005), *rev'd*, 549 U.S. 118, 137 (2007).

3. *MedImmune: The Supreme Court Rules that “Actual Controversy” Does Not Require that Licensee Repudiate Contract*

The Supreme Court granted certiorari in *Medimmune* and reversed the Federal Circuit 8–1.⁴⁰ In an opinion written by Justice Scalia, the Court found that a potential infringer did not have to “bet the farm” and risk treble damages before filing a declaratory judgment action.⁴¹ The Court found that an actual controversy existed where the declaratory judgment plaintiff was making the royalty payments practically under coercion and therefore the constitutional requirements of Article III were satisfied.⁴² The Federal Circuit’s RAS standard died in a footnote.⁴³ The *MedImmune* Court found the meaning of an “actual controversy” much broader than the Federal Circuit’s view.⁴⁴ In the Court’s opinion, “actual controversy” meant the existence of a “substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality.”⁴⁵

Notably, however, the *MedImmune* Court emphasized that it was not deciding the licensee estoppel issue.⁴⁶ Because *MedImmune* was a “nonrepudiating” licensee (i.e., still paying royalties), the case did not expressly involve the *Lear* doctrine (which struck down licensee estoppel in the case of “repudiating” licensees).⁴⁷ Neither did the case address who had the burden of proof regarding infringement.

4. *Post-MedImmune: The Unanswered Question of the Burden of Proof*

Following *MedImmune*, the Federal Circuit applied the broader “actual controversy” standard in declaratory judgment cases.⁴⁸ Yet aside from the issue of licensee estoppel, *MedImmune* failed to address another important matter. While *MedImmune* made it possible for a licensee to file a declaratory judgment action without “betting the farm,” the case was

40. *MedImmune*, 549 U.S. at 137.

41. *Id.* at 129.

42. *See id.* at 131–32.

43. *Id.* at 132 n.11 (finding that the Federal Circuit’s RAS standard conflicted with Supreme Court precedent, including *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937) and *Cardinal Chemical Co. v. Morton Int’l*, 508 U.S. 83 (1993)).

44. *See MedImmune*, 549 U.S. at 127.

45. *Id.*

46. *See id.* at 124.

47. *Id.*

48. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1377 (Fed. Cir. 2007); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1334 (Fed. Cir. 2007).

mostly about patent validity.⁴⁹ Obviously, the licensee has to prove invalidity as the patent comes with a presumption of validity from the U.S. Patent Office.⁵⁰ Moreover, the case settled on remand;⁵¹ the Federal Circuit did not have the opportunity to iron out the mechanics of an action for declaratory judgment of non-infringement filed by a non-repudiating licensee. Notably, *MedImmune* did not address the issue of who has the burden of proof in an suit seeking a declaration of non-infringement. Does the alleged infringer (the plaintiff in the declaratory judgment action) need to prove non-infringement, or does the patentee (the defendant) need to prove infringement instead, as would be the case in an ordinary patent infringement suit?⁵² If the patentee could counter-claim for infringement, that would be a compulsory counter-claim⁵³ and the patentee would bear the burden of proof. But what if the patentee cannot counter-claim, for example if the licensee continues making royalty payments? This question had to wait seven years to be answered, again by the Supreme Court, in *Medtronic*.⁵⁴

II. *MEDTRONIC* CASE SUMMARY: THE UNFINISHED BUSINESS OF *MEDIMMUNE*

Because the *MedImmune* case settled on remand, there was no chance to answer the question of who bears the burden of proof when the licensee continues paying royalties. Instead, the Federal Circuit provided an answer in *Medtronic, Inc. v. Boston Scientific Corp.*, holding that the burden of proof shifted to the licensee if the patent owner could not assert infringement.⁵⁵ This was yet another special rule crafted by the Federal Circuit for patent cases, a rule that the Supreme Court abrogated shortly after granting certiorari.⁵⁶

49. See *MedImmune*, 549 U.S. at 124.

50. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011).

51. *Chase*, *supra* note 11.

52. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 851 (2014).

53. See FED. R. CIV. P. 13(a)(1).

54. *Medtronic*, 134 S. Ct. at 846.

55. *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266 (Fed. Cir. 2012), *rev'd sub nom. Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014).

56. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014).

A. FACTUAL BACKGROUND AND DISTRICT COURT JUDGMENT

Mirowski Family Ventures (“Mirowski”), owner of patents related to cardiac stimulation devices,⁵⁷ had a license agreement with Medtronic, Inc., a medical device manufacturer, by which Medtronic was allowed to practice certain Mirowski patents in return for royalties.⁵⁸ The agreement, which the parties entered into in 1991, also spelled out a procedure whereby Medtronic could challenge allegations of infringement by Mirowski by seeking a declaratory judgment, while at the same time paying disputed royalties into escrow, to be distributed to the prevailing party.⁵⁹

After Mirowski sent letters to Medtronic in 2003 claiming that several new Medtronic products infringed Mirowski patent claims and demanding royalties,⁶⁰ Medtronic filed a suit in the U.S. District Court for the District of Delaware, asking for a declaratory judgment of non-infringement and patent invalidity.⁶¹ At the same time, as provided by the license agreement, Medtronic started paying royalties into the escrow account for its new products that Mirowski claimed were infringing.⁶² Because Medtronic was paying royalties (even though into escrow) as specified by the agreement and thus remained Mirowski’s licensee, Medtronic was not making and selling its products “without authority” and thus was not technically infringing.⁶³ Therefore, Mirowski could not file a counterclaim of patent infringement under 35 U.S.C. § 271.⁶⁴

The district court held that Mirowski held the burden of proving infringement, since Mirowski as the patentee claimed that Medtronic’s

57. *Id.* at 846.

58. *Id.* In reality, Medtronic’s agreement was with two other companies (Eli Lilly and Boston Scientific) to which Mirowski had licensed its patents. For the sake of simplicity, this Note follows the Court and uses “Mirowski” to refer to all entities that licensed the Mirowski patents to Medtronic.

59. *See id.* at 846–47.

60. *Id.* at 847.

61. *Id.* The parties delayed the action until 2007, under timing provided in a “Litigation Tolling Agreement” (“LTA”), which spelled out that an actual controversy existed as to whether one of Mirowski’s patents was valid and whether Medtronic’s new products were infringing its claims. The LTA provided for a “DJ Suspension Period.” Once that period ended, Medtronic sued for a declaratory judgment. *See Medtronic, Inc. v. Boston Scientific Corp.*, 777 F. Supp. 2d 750, 759 (D. Del. 2011).

62. *Medtronic*, 134 S. Ct. at 847.

63. *See* 35 U.S.C. § 271 (2012) (“[W]hoever *without authority* makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.” (emphasis added)).

64. *See Medtronic*, 134 S. Ct. at 847.

new products read on its patent claims.⁶⁵ The court further found after a bench trial that Mirowski had failed to prove infringement and entered judgment for Medtronic.⁶⁶ Mirowski appealed on the burden of proof issue, which had been a constant point of disagreement between the parties throughout the trial.⁶⁷

B. THE FEDERAL CIRCUIT'S SPECIAL RULE ON THE BURDEN OF PROOF

The Federal Circuit reversed on appeal, finding that Medtronic, as the plaintiff in the declaratory action, bore the burden of proof.⁶⁸ While it agreed that ordinarily the burden would stay with the patentee even in a declaratory judgment action, the Federal Circuit held that in this particular case, where the patent holder was precluded by an existing license agreement from asserting an infringement counterclaim, the burden shifted to the licensee.⁶⁹

In arriving at this conclusion, the Federal Circuit described the burden-shifting rule as arising by necessity from the Supreme Court's *MedImmune* decision.⁷⁰ The Federal Circuit started by admitting that generally the burden of proof lies with the "party seeking relief" and that that party was the patentee in a regular infringement action or a counterclaim.⁷¹ Notably, the court reiterated its holding in a pre-*MedImmune* case that the evidentiary burdens are the same "whether or not the counterclaim [is] permitted."⁷² However, the court held that this was not a regular case, and in its view the major difference was that this particular instance involved a patent license in a "post-*MedImmune*" world.⁷³ Post-*MedImmune*, Medtronic was able to file its declaratory judgment action, but the Federal Circuit found that it was the only party seeking relief, as in the court's view Mirowski was seeking nothing but "to

65. *Medtronic*, 777 F. Supp. 2d at 765 (quoting *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) for the proposition that "[t]he burden is always on the patentee to show infringement.").

66. *Medtronic*, 134 S. Ct. at 847.

67. *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1270 (Fed. Cir. 2012), *rev'd sub nom. Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014).

68. *Medtronic*, 134 S. Ct. at 847.

69. *Id.*

70. *Medtronic*, 695 F.3d at 1272.

71. *Id.*

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

73. *Id.*

be discharged from the suit and be permitted to continue the quiet enjoyment of its contract.”⁷⁴

In holding that Medtronic bore the burden of proof, the Federal Circuit described its ruling as consistent with other areas of law, and mentioned insurance cases as an example.⁷⁵ While usually the insured has the burden of proof regarding coverage, if the insurer files for a declaratory judgment of non-liability the burden shifts because, in the Federal Circuit’s words, the insured “is not seeking affirmative relief.”⁷⁶

The Federal Circuit thus found that Medtronic was the party seeking relief.⁷⁷ In announcing the rule that where a licensor could not assert a counterclaim the licensee bore the burden of proving non-infringement, the Federal Circuit declared that a contrary result would transform *MedImmune*’s “shield” for licensees into a sword, by allowing licensees to “hal[e] licensors into court and forc[e] them to . . . prove what had already been resolved by license.”⁷⁸ In May 2013 the Supreme Court granted certiorari on the question of who had the burden of proof.⁷⁹

C. THE SUPREME COURT’S REVERSAL IN *MEDTRONIC V. MIROWSKI*:
MEDIMMUNE REDUX

Seven years after *MedImmune*, the Supreme Court revisited declaratory actions in the patent context in *Medtronic v. Mirowski*, which again overturned the Federal Circuit (this time unanimously) and held that in a declaratory judgment suit the burden of proof of patent infringement always stays with the patent owner.⁸⁰

The 9–0 opinion⁸¹ written by Justice Breyer was based on “simple legal logic,” case precedent in both patent and non-patent cases, and several practical considerations.⁸²

74. *Id.*

75. *Id.* at 1273–74.

76. *See id.* at 1274 (citing *Reliance Life Ins. Co. v. Burgess*, 112 F.2d 234, 237 (8th Cir. 1940)).

77. *Id.*

78. *Id.*

79. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 846 (2014).

80. *Id.* at 849.

81. Even Justice Thomas, the sole dissenter in *MedImmune*, signed on.

82. *Medtronic*, 134 S. Ct. at 849.

1. *The Jurisdictional Issue: “Actual Controversy” Under a Straightforward Application of MedImmune*

The Court pointed first to *Medimmune* and its very similar facts, and found that the “case or controversy” constitutional justiciability requirement was satisfied.⁸³ Like in *MedImmune*, the Court held in *Medtronic* that an “actual controversy” does not require an actual likelihood of suit—rather it only necessitates a likelihood of suit if the royalty payments were to stop.⁸⁴

2. *The Court’s Main Legal Argument: “Simple Legal Logic”*

Turning to the burden of proof, the Court found that it cannot shift in a declaratory judgment action, based on a “simple legal logic” syllogism.⁸⁵ The burden of proof in patent infringement cases is on the patentee, a proposition established more than a hundred years ago.⁸⁶ The Court noted that the DJA was only “procedural⁸⁷ and neither expanded courts’ jurisdiction nor created substantive rights.⁸⁸ The burden of proof, being a substantive characteristic of a claim,⁸⁹ could not thus be shifted in a declaratory judgment action.⁹⁰ Therefore, a declaratory judgment suit deviated from the “default rule” that usually placed the burden of proof on the nominal plaintiff.⁹¹

3. *Three Additional Practical Considerations Mandating the Same Result*

In addition, the Court also noted three “practical considerations” leading to the same conclusion.⁹² First, the Court found that the Federal Circuit’s rule would have created significant post-litigation uncertainty,

83. *See id.* at 848–49.

84. *Id.*; *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128 (2007). In fact, the action in *Medtronic* started pursuant to a “Litigation Tolling Agreement” through which the parties expressly recognized their dispute as to whether the patent covered *Medtronic*’s new products. *See Medtronic, Inc. v. Boston Scientific Corp.*, 777 F. Supp. 2d 750, 759 (D. Del. 2011).

85. *Medtronic*, 134 S. Ct. at 849.

86. *See id.* (citing *Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1880)); *see also Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987).

87. *Medtronic*, 134 S. Ct. at 849 (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)).

88. *Id.*

89. *Id.* (quoting *Raleigh v. Ill. Dept. of Revenue*, 530 U.S. 15, 20–21 (2000)).

90. *Id.*

91. *See Schaffer v. Weast*, 546 U.S. 49, 56 (2005) (“We therefore begin with the ordinary default rule that plaintiffs bear the risk of failing to prove their claims.”).

92. *Medtronic*, 134 S. Ct. at 849–50.

because a burden of proof different than in a regular infringement lawsuit would have eliminated the preclusive effect of the declaratory judgment action.⁹³ Destroying its preclusive effect would have defeated the very object of the declaratory judgment, that of providing a definitive legal determination of the parties' legal rights.⁹⁴

Second, the Court reasoned that a shifted burden of proof would be onerous to the licensee, who would have to prove a negative, seeking to "negate every conceivable infringement theory."⁹⁵ The Court found that the patentee was in a better position to know and point out exactly how a given product infringes the patent's claims.⁹⁶

Third, the Justices found that a shifting burden would be hard to reconcile with the "very purpose" of the DJA.⁹⁷ The Court found that by making the declaratory judgment procedure so onerous for the licensee, the Federal Circuit's rule would have eviscerated the very objective of the DJA, that is, ameliorating the dilemma of the licensee between abandoning his rights and risking a lawsuit and potential treble damages ("bet[ting] the farm" in Justice Scalia's *MedImmune* words).⁹⁸ The significant drawbacks of shifting the burden were not counterbalanced by any notable advantages.⁹⁹

4. *The Supreme Court Finds that the Public Interest Does Not Warrant a Shift in the Burden*

Finally, the *Medtronic* Court found, in the spirit of *Lear*, that the public interest did not warrant a shift in the burden of proof in declaratory judgment actions of patent non-infringement.¹⁰⁰ As the public has a "paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope,"¹⁰¹ patent owners should not be allowed to extract royalties for use of ideas beyond the limited patent monopoly grant.¹⁰² The

93. *Id.*

94. *Id.* (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937) and pointing out that a shifting burden of proof would invalidate any preclusive effect of the first judgment, per the RESTATEMENT (SECOND) OF JUDGMENTS § 28(4) (1980)).

95. *Id.* at 850.

96. *Id.*

97. *Id.* (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128 (2007)).

98. *See Medtronic*, 134 S. Ct. at 850.

99. *See id.*

100. *Id.* at 851–52.

101. *Id.* (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)).

102. *Id.* at 852 (quoting *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349–50 (1971)).

Supreme Court noted again, quoting *Lear*, that the public's interest is furthered by cases involving a licensee and licensor, because licensees might be "the only individuals with enough economic incentive to litigate questions of a patent's scope."¹⁰³

III. DISCUSSION

Before looking at the practical impact and the still unsettled questions in the wake of *Medtronic*, it is helpful to analyze the legal soundness and the policy aspects of the decision.

A. LEGAL SOUNDNESS—HOW "SIMPLE" IS THE COURT'S "SIMPLE LEGAL LOGIC"?

The issue of who bears the burden of proof in patent infringement cases is not a mandatory rule,¹⁰⁴ proven, for example, by the Court's discussion of whether it could be shifted.¹⁰⁵ The Court's ruling that the burden stays with the patentee relies on the burden's being a substantive aspect, an issue that is settled law¹⁰⁶ even though it started as a historical quirk in this context. Equally importantly, the Court gives a strong message that it does not want the Federal Circuit to construct idiosyncratic rules for patent cases divorced from general jurisprudence.

1. *Burden of Proof as a Substantive Aspect—The Impact of Erie*

The Court dealt rather quickly with a crucial prong of its "simple legal logic" syllogism, that is, the proposition that the burden of proof is a substantive issue.¹⁰⁷ In fact, while this appears to be long-settled precedent,¹⁰⁸ it hasn't always been the case, and it is to some extent a historical quirk. At one point in the early twentieth century, the burden of

103. *Id.* (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

104. An example of a mandatory burden of proof rule is in criminal cases, where a "beyond a reasonable doubt" burden is constitutionally mandated as a matter of due process to always lie with the prosecution. *See In re Winship*, 397 U.S. 358, 364 (1970).

105. *Medtronic*, 134 S. Ct. at 851–52. Also, in one instance in U.S. patent law, the burden of proof can be statutorily shifted from the patentee: in process patents, the burden shifts to the accused infringer if the patentee cannot determine through reasonable efforts the process used, because the alleged infringer is in a better position to know the actual process utilized to manufacture its products. *See* 35 U.S.C. § 295 (2012).

106. *Medtronic*, 134 S. Ct. at 849.

107. *See id.*

108. *See id.* (citing an admiralty action, *Garrett v. Moore-Cormack Co., Inc.*, 317 U.S. 239, 249 (1942), for the proposition that the burden of proof is "part of the very substance of [the plaintiff's] claim and cannot be considered a mere incident of a form of procedure.").

proof was mostly regarded as procedural.¹⁰⁹ At the same time, it was recognized that whether a rule was substantive or procedural might depend on the purpose for which it was applied.¹¹⁰

It was only after the landmark decision in *Erie v. Tompkins* that federal courts became compelled, in the context of diversity jurisdiction cases, to decide whether something was a matter of substance or procedure.¹¹¹ Federal courts in diversity cases had to apply substantive state law even while using federal procedural rules, with the main difference between substance and procedure being whether the choice of a particular rule dictated the outcome of the case, which had to be under *Erie* and its progeny “substantially the same” in federal as in state courts.¹¹² In view of this requirement, the courts categorized the burden of proof as a matter of substance rather than procedure, due to its significant impact on a case’s outcome.¹¹³ From there, it was an easy leap for federal courts to hold the burden of proof as substantive in all cases, including those involving federal questions, such as admiralty¹¹⁴ or bankruptcy law.¹¹⁵

Does this mean that whether the burden of proof is substantive in federal question cases, including patent cases, is not settled? Not at all. While not as long-established as other federal jurisprudence, it is certainly old by many standards—in fact, fifty years older than the Federal Circuit itself.¹¹⁶ From a pragmatic viewpoint, if the criterion of whether something is a matter of substance versus procedure is strongly tied to the outcome, it makes sense that the burden of proof should be substantive in a declaratory judgment suit. The Declaratory Judgment Act¹¹⁷ envisioned such an action to be solely a procedural vehicle speeding up the resolution of a controversy, with the outcome the same as in a full infringement suit. To paraphrase *Guaranty Trust*, a well-known case in the wake of *Erie*,

109. See, e.g., *Levy v. Steiger*, 124 N.E. 477 (Mass. 1919); RESTATEMENT OF CONFLICT OF LAWS § 595 (1934); Case Comment, *Is the Incidence of the Burden of Proof a Matter of Substantive or Procedural Law?*, 29 HARV. L. REV. 1, 95–97 (1915).

110. See Case Comment, *Procedure or Substance – Burden of Proof – Erie v. Tompkins and the New Federal Rules*, 15 IND. L.J. 4, 329 (1940).

111. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938).

112. See *Guaranty Trust Co. v. York*, 326 U.S. 99, 109 (1945).

113. See *Cities Serv. Oil Co. v. Dunlap*, 308 U.S. 208, 212 (1939).

114. See *Garrett v. Moore-McCormack Co.*, 317 U.S. 239, 249 (1942) (quoted by the Supreme Court in *Medtronic* and holding that the burden of proof was “part of the very substance of [the] claim and cannot be considered a mere incident of a form of procedure.”).

115. See *Raleigh v. Ill. Dept. of Revenue*, 530 U.S. 15, 20–21 (2000).

116. The Court of Appeals for the Federal Circuit was created in 1982, through the Federal Courts Improvement Act, Pub. L. No. 97-164, 96 Stat. 25 (1982).

117. 28 U.S.C. § 2201 (2012).

through the Declaratory Judgment Act Congress afforded litigants another means to resolve their patent disputes, not another body of patent law.¹¹⁸ Finally, the Court's message about settled legal precedent resonates not only in *Medtronic*, but in other recent cases as well.

2. *Bringing Patent Law into the Mainstream*

The *Medtronic* Court, by shooting down the Federal Circuit's rule, promulgated the same message that it repeatedly announced throughout the past decade: patent cases do not warrant special rules regarding trans-substantive aspects of the litigation that are not in the patent statutes themselves. The Supreme Court admonished the Federal Circuit for adopting such a rule, and noted that the fact that the Federal Circuit meant for the rule to apply only in "limited circumstances" was irrelevant to its soundness.¹¹⁹ This message is in line with previous Court decisions that rejected the Federal Circuit's special rules for patent cases, such as *eBay v. MercExchange*,¹²⁰ *Medimmune v. Genentech*¹²¹ and *Teva v. Sandoz*.¹²²

The Court made a salient point, as it did in *MedImmune*, that there is substantial legal precedent to rely on, not unique to patent law.¹²³ Like *MedImmune*, the *Medtronic* opinion is replete with jurisprudence going back to the nineteenth century.¹²⁴ For example, as Justice Scalia emphasized at oral argument, in most declaratory judgment actions the defendant cannot counterclaim either, so a patent declaratory action is not special because of the impossibility of a counterclaim.¹²⁵ The Federal Circuit had created a special rule in patent cases solely due to the subject matter. This rule was similar to the pre-*MedImmune* rule it created in *Gen-Probe*, where it distinguished *Aetna* basically on the ground that it was

118. *See Guaranty Trust Co. v. York*, 326 U.S. 99, 112 (1945) (holding that "Congress afforded out-of-State litigants another tribunal, not another body of law.")

119. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 851 (2014).

120. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 390 (2006) (finding no special injunction rule in patent cases).

121. *MedImmune v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (finding no special rule about what constitutes an "actual controversy" in a declaratory judgment action).

122. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015) (no special rule on the standard of appellate review of a district court's factual conclusions).

123. *See Medtronic*, 134 S. Ct. at 849.

124. *See id.* (discussing "settled case law," dating as far back as 1880, that "strongly supports" the Court's opinion). Note however that, as discussed above, the Court's syllogism actually relies on slightly more recent precedent, going back to the 1930s.

125. Transcript of Oral Argument at 28, *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014) (No. 12-1128).

not a patent case. As a prescient amicus in *MedImmune* put it, this was a “distinction without a difference.”¹²⁶

The *Medtronic* ruling was an easy decision involving settled aspects of civil procedure rather than technical patent expertise. Its civil procedure underpinnings should shield it from the usual dismissive criticisms of the Supreme Court’s lack of technical expertise.¹²⁷ And a deeper look into those fundamentals highlights even better the problems with the Federal Circuit’s burden-shifting rule.

B. A UNIFORM VIEW OF DECLARATORY JUDGMENTS: THE FURTHER CASE AGAINST A SPECIAL RULE FOR THE BURDEN OF PROOF IN PATENT CASES

Besides the reasons discussed by the Supreme Court in overturning the Federal Circuit, two other points work against the Federal Circuit’s special rule. First, a comparison with insurance industry cases actually works against the rule, contrary to the Federal Circuit’s reliance on one insurance case taken out of context. Second, even the basic assumptions of the Federal Circuit, such as that *Mirowski* could not counterclaim, were perhaps unwarranted.

1. *A One-to-One Comparison with Insurance Industry Cases*

In fact, other areas of law posit clear analogies to the patent context, and in all of them the defendant in a declaratory judgment action needs to be the first to establish a claim. One example is insurance disputes, an area the Federal Circuit noted, but erroneously interpreted a case as warranting

126. Brief of Amicus Curiae Medtronic, Inc. in Support of Petitioner at 9, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (No. 05-608).

127. See, e.g., Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus*, IPWATCHDOG (Mar. 20, 2012, 1:44 PM), <http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/>, where Quinn discussed the Court’s holding and stated:

If a student were to write such nonsense in a patent law paper or on a patent law final exam they would receive little, if any, credit. It is shocking that all 9 Justices of the Supreme Court know so little about patent law, yet the collective fate of the industry rests on those with only a cursory understanding of patent law.

Id. But there is a counter argument that even in very technical areas, lack of specialized expertise can help someone when experts are lost in the minutiae. See Timothy Lee, *The Supreme Court’s Technical Cluelessness Makes Them Better Justices*, VOX (Apr. 23, 2014, 6:00 PM), <http://www.vox.com/2014/4/23/5644154/the-supreme-courts-technical-cluelessness-makes-them-better-justices>.

its burden-shifting rule.¹²⁸ In insurance disputes, when an insurer files a declaratory judgment action asking for a declaration that it does not owe coverage of a claim, the burden of proof is initially on the insured, who needs to establish a claim within the scope of the insurance coverage.¹²⁹ This situation is similar to the patent context in *Medtronic*, where Mirowski, as the analogue of the insured, had the burden of showing a positive claim that Medtronic's products read on its patents.¹³⁰ The very language Mirowski used in briefing and at oral argument,¹³¹ trying to distinguish the suit as being about "claim coverage" rather than infringement,¹³² rang hollow and in fact shows why it had to bear the burden of proof. "Claim coverage" does not exist in a vacuum¹³³—what Mirowski really was claiming was that Medtronic's new products were infringing its patents. Just as the insured needs to establish first a claim within the scope of coverage in an insurance case, so too the patentee must establish an activity of the licensee falling within the scope of its patents' claims. In other words, infringement.

The Federal Circuit partly based its new rule on an incorrect interpretation of *Burgess*, an insurance case where the burden was shifted to the insurer, by reading the rationale as that the insured "asked no

128. See *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1273–74 (Fed. Cir. 2012), *rev'd sub nom. Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014) (citing *Am. Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) for the general proposition that in a declaratory judgment the burden is on the party seeking recovery under a policy, i.e. the insured, yet reading the placing of the burden on the insurance company in *Reliance Life Ins. Co. v. Burgess*, 112 F.2d 234, 237 (8th Cir. 1940) as a burden shift due to the insured not asking for any "affirmative relief.").

129. See, e.g., *Am. Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) (cited by the Federal Circuit in *Medtronic*); *Harken Exploration Co. v. Sphere Drake Ins., PLC*, 261 F.3d 466, 471 (5th Cir. 2001).

130. The burden of showing that the products read on the patents is higher than the weak requirement that "it believed were covered by the contract" that satisfied the Federal Circuit. See *Medtronic*, 695 F.3d at 1273. Similarly, in an insurance case it is not sufficient that the insured "believes" that he suffered, for example, a loss covered by the policy—some substantiation is required, e.g., that the loss was of the type covered by the insurance contract. Obviously, this substantiation is technically much easier there (e.g. a police report of an accident might suffice) than in the patent context, but that does not remove the similarity.

131. Transcript of Oral Argument at 27, *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014) (No. 12-1128).

132. See *id.* at 37 (noting "claim coverage" is itself part of the infringement analysis).

133. There is no "claim coverage" cause of action in the federal patent statutes.

affirmative relief.”¹³⁴ That is not the complete reason. In *Burgess*, the insured, who had several life insurance policies in his name, died of gunshot wounds, which the insurer claimed were self-inflicted while the insured was sane.¹³⁵ The court did place the burden on the insurer, but not only because the insured “asked [for] no affirmative relief.” As stated in another case cited by the Federal Circuit, the burden was shifted in *Burgess* because the insurer “disputed coverage by asserting an affirmative defense of exclusion” of coverage in case of intentional or suicidal death.¹³⁶ That fact pattern is distinguishable from the context here, because Medtronic’s claim of non-infringement is not an “affirmative defense,” but just the negative of infringement.¹³⁷ *Burgess* was taken out of context by the Federal Circuit in trying to rationalize its new rule—insurance cases where the insurer is not trying to prove a particular exclusion of coverage as an affirmative defense, but just claiming that the insured did not show coverage to begin with, are the correct analogue of Medtronic’s claiming “non-infringement.”

Further showing that insurance cases do not justify the Federal Circuit’s rationale, in those cases the insured also cannot generally counterclaim if the insurer is making payments under the claim. As long as the insurer continues to provide coverage, even “under protest,”¹³⁸ there is no breach of the insurance contract¹³⁹ and the insured cannot countersue

134. See *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1274 (Fed. Cir. 2012).

135. *Reliance Life Ins. Co. v. Burgess*, 112 F.2d 234, 236 (8th Cir. 1940).

136. *Fireman’s Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1175 (3d Cir. 1976) (discussing *Burgess*).

137. An affirmative defense accepts all allegations of the other party, but then goes on to show other facts proving lack of liability. See, e.g., *Tech. Licensing Corp. v. Pelco, Inc.*, No. 11 C 8544, 2012 U.S. Dist. LEXIS 28673, at *2 (N.D. Ill. Mar. 5, 2012) (taking issue with the alleged infringer’s listing “noninfringement” as an affirmative defense in their answer, as “violat[ing] the fundamental nature of an [affirmative defense]”).

138. For example, an insurer may do this through a reservation of rights. A reservation of rights is issued by an insurer who feels unsure about whether it owes coverage, but does not want to risk punitive damages if a court decides that it wrongfully denied a claim. The reservation of rights spells out that while the insurer is paying (for example paying to defend the insured in a lawsuit) for the time being, it is still investigating coverage and reserves the right to stop its payments in the future and recover monies already paid.

139. There might be, in the insurance context, a breach of the covenant of good faith and fair dealing, but that issue is separate from the breach of contract issue, and in most jurisdictions is dependent on the existence of a breach of the underlying contract.

for any such breach.¹⁴⁰ The wise insurer who has questions of coverage does not have to “bet the farm,” that is, open itself to high punitive damages, by breaching the contract. Similarly, the patent licensee should not be forced to open himself to treble damages for willful infringement.¹⁴¹ Besides insurance cases not justifying a burden-shifting rule, a few premises behind the Federal Circuit’s reasoning might also have been faulty.

2. *Even the Underlying Assumptions of the Federal Circuit Might Have Been Wrong*

The Federal Circuit’s rule did not agree with established jurisprudence, because a declaratory judgment action is not supposed to change the rules of the game. Indeed, the declaratory judgment considers the future action that would be brought by the defendant. The fact that the future action has not yet been taken does not make the controversy “hypothetical.”¹⁴²

Further making the case against a special rule, it is very possible that the Federal Circuit erred when it found that the patent owner could not file any counterclaim. Some claim that Mirowski, the patent owner, might have been able to file its own action, a “reverse” declaratory judgment counterclaim of future infringement, and thus the Federal Circuit could have been reversed on this ground alone.¹⁴³ This is an interesting idea, and the record shows that Mirowski did initially counterclaim for the right to obtain the money deposited by Medtronic in escrow.¹⁴⁴ However, it is not clear how far from anticipatory breach one needs to be for a court to find such an option viable.

140. Again, in some jurisdictions the insured, while not being able to sue for breach of the underlying contract, can countersue on a bad faith cause of action, if the reservation of rights was issued in bad faith. But in the majority of jurisdictions, continuous payment by the insurer precludes any counterclaim.

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

142. *See* *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 242 (1937) (holding that because the parties had “taken adverse positions with respect to their existing obligations” the controversy was real and concrete, rather than hypothetical).

143. Megan M. La Belle, “Reverse” Patent Declaratory Judgment Actions: A Proposed Solution for Medtronic, 162 U. PENN. L.R. 43, 45 (2013).

144. *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1273 n.2 (Fed. Cir. 2012), *rev’d sub nom.* *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014) (showing that Mirowski initially counterclaimed for a declaratory judgment of its right to recover the money paid into escrow, and that the counterclaim “was dismissed without prejudice pursuant to joint stipulation by the parties”). While the dismissed counterclaim was not at issue for the appeal, the proven possibility of such a claim showed that Medtronic was not the only party seeking relief.

In a similar vein, an even stronger argument is that the Federal Circuit was wrong to hold that only Medtronic was “seeking relief.”¹⁴⁵ The patentee itself was also seeking relief, in the form of receiving the royalties paid into the escrow account. The existence of the escrow account provision shows that Medtronic was truly paying the royalties under protest¹⁴⁶ and undermines the Federal Circuit’s finding that Medtronic was the one asking the court to “disturb the status quo ante” and that the only thing Medtronic wanted was the “quiet enjoyment of its contract.”¹⁴⁷

C. *MEDIMMUNE AND MEDTRONIC ARE GOOD PUBLIC POLICY*

As the rule about who shoulders the burden of proof is not mandatory, a discussion is in order as to whether there are sound policy arguments for shifting it. A shift is not warranted, for two reasons. First, licensees are best equipped and motivated to litigate a patent’s scope. Second, critics’ contentions that letting the patentee shoulder the burden would increase licensing costs and decrease innovation are mostly unsupported.

1. *A Change in the Default Rule is Not Warranted in the Patent Context, as the Licensee Has the Strongest Incentive to Challenge a Dubious Patent*

As shown above,¹⁴⁸ there is ample legal precedent for the default rule that the patentee should bear the burden of proving infringement in any action before a court. However, every rule has an exception.¹⁴⁹ While well settled, the burden of proof rule is not a mandatory one, at least not constitutionally mandatory, as in a choice of law¹⁵⁰ or a criminal case.¹⁵¹ Therefore, it is fair to ask whether, for example, public policy would warrant or even dictate a change of this rule in the patent context, in a

145. *See id.*

146. It might also have helped with justiciability, by showing that the parties were clearly engaged in an “actual controversy.”

147. *See Medtronic*, 695 F.3d at 1273.

148. *See supra* Section III.A.

149. As mentioned above, there is a statutory exception in the case of products manufactured using process patent techniques. 35 U.S.C. § 295 (2012). The statute makes this one-time exception because an accused infringer would be in a better position to know how his products were manufactured.

150. In a choice of law case, changing a (state) substantive issue in federal court would be unconstitutional under *Erie*. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938).

151. *See supra* note 104. The burden of proof in criminal cases is constitutionally mandated as a matter of due process to be always on the prosecution and to reach the “beyond a reasonable doubt” level.

situation where the patentee cannot countersue for infringement and apparently only wants to “continue the quiet enjoyment of its contract.”¹⁵²

The answer is no. In *Lear*, the Supreme Court has recognized that invalidating bad patents is in the public interest, and that a licensee is in the strongest position to invalidate a dubious patent. The message of the *Medtronic* opinion is that public policy is well served by the current rules, and there is no rationale for creating a special burden-of-proof rule for patent declaratory judgment actions.¹⁵³ The Court rightly believes that keeping the patent monopoly in check is important, and it might well be that for many patents the licensees, being the ones with a direct “economic incentive,” are the only ones who would be interested in litigating issues related to the patent.¹⁵⁴

In disregarding the licensee’s unique position as having an incentive to challenge a patent, proponents of very strong “contract rights” place excessive confidence on the motivations of third-parties to challenge patents and on the reliability of examinations at the patent office.¹⁵⁵ Further, invalidating bad patents has distinct advantages. For example, there is empirical proof that invalidating patents does in fact spur so-called “cumulative” or “follow-on” innovation, at least in some fields.¹⁵⁶

2. *Making It Harder for Licensees to Challenge Patents Is Not Justified*

Critics of “diluting patent rights” unleash a bevy of arguments, though not fully persuasive. Some critics of the *Medtronic* decision argue that here, unlike in *MedImmune*, “helping” the licensee does not have similar public benefits, because *Medtronic* did not concern invalidity (which is good against the world)¹⁵⁷ but rather non-infringement, which is a private affair between licensor and licensee. This is not a truly germane argument. The

152. *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1273 (Fed. Cir. 2012).

153. *See Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 851–52 (2014).

154. *See id.* at 852.

155. *See* Peter S. Menell, *Governance of Intellectual Resources and Disintegration of Intellectual Property in the Digital Age*, 26 BERKELEY TECH. L.J. 1523, 1554 n.129 (2011).

156. Alberto Galasso & Mark Schankerman, *Patents and Cumulative Innovation: Causal Evidence from the Courts*, 130 QUARTERLY J. ECON. 317 (2015) (finding that invalidating patents has a positive effect on cumulative, or follow-on, innovation in the fields of computers and communications, electrical and electronics, and medical instruments, as measured by the number of scientific citations).

157. *See Blonder-Tongue Labs. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

Federal Circuit's inverted standard was making it harder for the licensee to file a declaratory judgment in the first place, and many licensees contest both validity and infringement. A higher threshold for proving non-infringement would have had a chilling effect on many declaratory judgment plaintiffs. It would have dissuaded many licensees who still wished to argue patent invalidity, but did not want to concede infringement, from bringing a declaratory judgment action altogether.

Another argument against *Medtronic* is that it will increase licensing costs, since licensors will be wary of licensing their patents for fear of being found invalid.¹⁵⁸ This argument is not totally without merit, as it appears that bargaining failure is more rampant with large firm patents and small potential licensees.¹⁵⁹ However, licensees now have cheaper and easier avenues—namely the new post-grant proceedings such as *inter partes* review (“IPR”) available under the America Invents Act (“AIA”)¹⁶⁰—for invalidating dubious patents.

Yet another argument is that allowing “easy” declaratory judgment suits would lead to forum shopping. However, a study has shown that the party filing a declaratory judgment is not at a particular advantage if the forum is contested, as courts are much more likely to transfer declaratory judgment cases compared to non-declaratory judgment suits.¹⁶¹

Finally, critics claim that *MedImmune* and *Medtronic* will decrease innovation by decreasing the value of a patent.¹⁶² Proponents of this argument fail to bring any hard evidence for this assertion. In fact, factual evidence suggests no such decrease in innovation. Obviously, one cannot just rely on the total number of patent filings, as filings alone are not a good measure of innovation, in view of the various reasons one might file a patent application, from government incentives to “padding” a curriculum vitae. A better yardstick is the number and percentage of the total patent applications filed concurrently in two or more countries (signifying at least

158. See, e.g., Brief of Intellectual Prop. Owners Ass'n in Support of Respondents, *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014) (No. 12-1128).

159. See Galasso & Schankerman, *supra* note 156. The invalidation of large firm patents is the one most likely to lead to strong follow-on innovation, but only in selected fields.

160. See 35 U.S.C. § 311 (2013).

161. Chester S. Chuang, *Offensive Venue: The Curious Use of Declaratory Judgment to Forum Shop in Patent Litigation*, 80 GEO. WASH. L. REV. 1065 (2012).

162. See, e.g., Nicholas G. Smith, *Medimmune v. Genentech: A Game-Theoretic Analysis of the Supreme Court's Continued Assault on the Patentee*, 15 MARQUETTE INTELL. PROP. L. REV. 503 (2011).

the perceived heightened value of the invention, in view of the applicant's expending significant effort and money in applying abroad).¹⁶³ This percentage can serve as a rough normalizing factor that, while not perfect, is better at gauging innovation than the raw number of patent applications. In any case, it does not appear that the Supreme Court's many so-called "patentee-unfriendly" decisions in the last decade have had a significant effect on the explosion in the number of patent applications.¹⁶⁴ The number of applications has continued to increase almost exponentially with time, with the only blip seen across all world regions during the great economic recession of 2008.¹⁶⁵

In conclusion, invalidating bad patents is likely to provide significant benefits—while the putative drawbacks (a claimed "devaluation" of the patents) have not been proven to adversely affect innovation in a significant fashion. The value of invalidating bad patents and breaking abusive patent monopolies has been noted in other recent court decisions, including in antitrust scrutiny of the so-called "reverse payment" or "pay for delay" settlements that keep generic medicines off the market.¹⁶⁶ Indeed, recently in *FTC v. Actavis, Inc.*,¹⁶⁷ the Supreme Court again brought echoes of *Lear* and the bane of bad patents, in ruling that reverse payment settlements, in which big pharmaceutical companies pay off would-be generic producers to not enter the market, can be scrutinized in court under antitrust rationales.¹⁶⁸ In analyzing the impact of the *Medtronic* decision, the broader policy message espoused in *Lear* and in recent cases such as *Actavis*, should play center stage.

163. See *How Innovative is China? Valuing Patents*, ECONOMIST, Jan. 5, 2013, at 52 (finding that only 5% of Chinese patent filers seek to patent their ideas abroad, compared to 27% of American patent applicants and 40% of the Europeans). This could also show that different countries grant patents at very different rates, with the result that potential applicants might not want to waste their efforts in filing for a weak patent in the face of long odds of a grant. This aspect also normalizes the raw number of patents to better reflect actual innovation.

164. See *id.* (showing in a figure the global number of patent applications growing from 400,000 in 2000 to almost 1.2 million in 2011).

165. See *id.*

166. See, e.g., FTC, PAY-FOR-DELAY: WHEN DRUG COMPANIES AGREE NOT TO COMPETE, <http://www.ftc.gov/news-events/media-resources/mergers-and-competition/pay-delay> (last visited Mar. 15, 2015).

167. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). For a recent review of the doctrine surrounding this decision, see Allison A. Schmitt, Note, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.*, 29 BERKELEY TECH L.J. 493, 533 (2014) (discussing that one of the policy goals behind the Hatch-Waxman Act is to invalidate "bad" patents).

168. *Actavis*, 133 S. Ct. at 2233.

D. PRACTICAL IMPACT OF *MEDTRONIC* AND ADVICE FOR DRAFTING LICENSES

Medtronic is arguably a narrow decision on its facts. It applies only in the licensor/licensee context, where the licensee does not repudiate the license (otherwise, the patentee could always have asserted, in fact would have had to assert, a compulsory counterclaim for infringement and thus bear the burden of proof, even in the eyes of the Federal Circuit). Due to its apparent narrowness, many commentators paid little attention to *Medtronic*, some calling it just a “blip.”¹⁶⁹ Nevertheless, practitioners predicted that the number of declaratory judgment cases would rise in the wake of the decision, as licensees would be more emboldened to file actions for declaratory judgment.¹⁷⁰ A few commentators even ventured as far as to imply that *Medtronic* was a potentially quite significant decision.¹⁷¹ This Part analyzes the practical impact of the decision and provides advice for parties in an existing or prospective patent license relationship.

1. *Practical Impact*

As a practical impact, the *Medtronic* decision, like *MedImmune*, will likely make it easier for licensees to bring declaratory judgment suits. The special burden of proof rule created by the Federal Circuit would have worked to the detriment of licensees and made them think twice before filing a declaratory judgment action because, among others, it is indeed hard to prove a negative.¹⁷²

Yet, unlike *MedImmune*, which applied to many more cases, touching upon the central issue of whether a declaratory judgment action could be filed in the first place, *Medtronic* is not likely to be as significant in immediate, measurable impact. So far, its actual influence has been limited but perceptible. And in a related context in *Ferring B.V. v. Watson Labs., Inc.*, the Federal Circuit ruled that there was no presumption of

169. See, e.g., Supreme Court IP Review (SCIPR) IIT Chicago-Kent College of Law, <http://www.kentlaw.iit.edu/scipr> (last visited Feb. 9, 2015).

170. See, e.g., Brian G. Arnold et al., *KEEPING CURRENT: Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014), BUS. LAW TODAY, May 2014, available at http://www.americanbar.org/publications/blt/2014/05/keeping_current_arnold.html (last visited Feb. 9, 2015).

171. *IP Professors Q&A: GW Law's Roger Schechter*, LAW360 (Oct. 3, 2014, 3:09 PM), <http://www.law360.com/articles/583169/ip-professors-q-a-gw-law-s-roger-schechter>.

172. See *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 850 (2014).

infringement on an ANDA filer.¹⁷³ While not a declaratory judgment action, the *Ferring* decision may have been influenced by *Medtronic* and its message that the patentee holds the burden of proving infringement.

Thus, *Medtronic* should not be relegated to a narrow holding on its facts, but viewed in light of its implications and its *Lear*-based discussion of public policy. *Medtronic* makes not only the statement that patent law needs to pay heed to settled civil procedure,¹⁷⁴ but also that *Lear* is very much alive,¹⁷⁵ and that its precepts will continue to affect the relationship between patent holders and licensees (or prospective licensees) in the future.

2. *Advice for Parties in a Patent License Relationship*

Predicting the *exact* impact of *Medtronic* is nevertheless hard. As general advice for patent holders and licensees, it is obvious that *Medtronic* goes in the same direction as *MedImmune* and provides similar incentives to licensees to file actions for declaratory judgment (even though as discussed¹⁷⁶ the *MedImmune* decision is probably weightier). As such, some of the general advice given post-*MedImmune* also applies to a large extent here.¹⁷⁷ The advice that follows is for patent holders (obviously, the converse applies to licensees).

For existing license agreements, a patent holder wary of litigation should be careful of change in terms (or the appearance of new products of the licensee) that could lead to an adverse legal relationship. This could be sufficient to establish the “actual controversy” necessary for declaratory judgment jurisdiction.¹⁷⁸ Patent holders would also do well to have a mechanism for being able to inspect their licensee’s new products in the agreement,¹⁷⁹ as that would help them objectively assess whether the

173. See *Ferring B.V. v. Watson Labs., Inc.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014).

174. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849–52 (2014); see also *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007).

175. The reference to *Lear* in *Medtronic* shows that reports of its possible death have been exaggerated. See, e.g., Rochelle Cooper Dreyfuss & Lawrence S. Pope, *Dethroning Lear? Incentives to Innovate after MedImmune*, 24 BERKELEY TECH. L.J. 971, 991–1006 (2009).

176. See *supra* Section III.D.1.

177. See, e.g., Dreyfuss & Pope, *supra* note 175.

178. See, e.g., Mark Henry, *Patent Licensing After Medimmune v. Genentech*, IPTODAY (Apr. 2007), <http://www.iptoday.com/pdf/2007/4/Henry-Apr2007.pdf>.

179. Adrian Mollo, *Licensing Law Alert: Patent Owners Retain Burden of Proof When Licensees Challenge Infringement*, BNA BLOOMBERG LAW (Feb. 21, 2014), <http://www.bna.com/licensing-law-alert-patent-owners-retain-burden-of-proof-when-licensees-challenge-infringement/>.

licensee's products infringe their patents, an assessment they are solely responsible for under *Medtronic*.

Regarding prospective license agreements, again, much of the excellent advice provided by several scholars¹⁸⁰ post-*MedImmune* applies, with even stronger relevance. In reading Dreyfuss and Pope's advice¹⁸¹ one needs to keep in mind the *Lear* decision, and the fact that, despite assertions to the contrary, *Lear, Brulotte v. Thys Co.*,¹⁸² and the other cases asserting the strong federal patent policy of needing to keep patent monopoly in check are not dead, as shown by *Medtronic*.¹⁸³ Thus, no challenge clauses in licensing agreements, while obviously topping the list of what a patent holder might want, are still unlikely to be enforceable.¹⁸⁴ Less extreme measures, that are likely enforceable, are provisions that the license agreement be automatically terminated in the event the licensee files a declaratory judgment suit.¹⁸⁵ Arbitration provisions would also be likely enforceable, in view of the federal policy of favoring arbitration.¹⁸⁶ Another helpful license clause for patent owners is permitting inspection of the licensee's products, both old and new. In the event the parties are competitors or proprietary issues exist, a manageable solution would be a neutral party performing the inspection.¹⁸⁷ Much of this advice is still uncertain at least in part, because the Court has still not resolved the issue of licensee estoppel.

E. THE ELEPHANT IN THE ROOM: LICENSEE ESTOPPEL

The biggest issue of all is still in the air. *Medtronic* left unanswered the question of licensee estoppel for nonrepudiating licensees, and the closely related non-challenge clause, which Justice Scalia noted might still be fair

180. Dreyfuss & Pope, *supra* note 175, at 991–1006.

181. *Id.*

182. *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).

183. *See* *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1327 (Fed. Cir. 2010) (citing *Brulotte* for the proposition that trying to extend royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly and a misuse of the patent). However, the Supreme Court has granted certiorari and is reconsidering the *Brulotte* rule in 2015, in a decision that will have important ramifications in the freedom of contract vs. federal patent policy battle landscape. *See* Ryan Davis, *High Court To Reconsider Ban On Expired-Patent Royalties*, LAW360 (Dec. 12, 2014, 6:13 PM), <http://0-www.law360.com.texsl.iii.com/appellate/articles/604392/high-court-to-reconsider-ban-on-expired-patent-royalties>.

184. *See infra* Section III.E (providing a more detailed discussion).

185. *See, e.g.*, Arnold, *supra* note 170.

186. *See, e.g.*, *AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740 (2011).

187. *See* Dreyfuss & Pope, *supra* note 175, at 991–1006.

game in a contract for nonrepudiating licensees.¹⁸⁸ The outcome of a declaratory judgment action will strongly depend on how courts treat this matter, an issue relevant to many license agreements. Could parties contract around this issue, and is a non-challenge clause enforceable? Some commentators read *MedImmune* as providing an affirmative answer, arguing that Justice Scalia was open to a prohibition spelled in the terms of the contract.¹⁸⁹ Following *MedImmune*, scholars have put forth many arguments trying to explain Justice Scalia's apparent dicta, ranging from simply stating that the Court was not aware that licensee estoppel had been dead for four decades, to a conscious effort to revive it, in spite of other cases in the late 1960s affirming a federal policy of not allowing contract law to expand the narrow patent monopoly.¹⁹⁰

Again, *Medtronic's* explicit mentioning of *Lear* hints that the Court is not going to overrule that case anytime soon. Although neither the *MedImmune* nor the *Medtronic* Court ruled on the applicability of the *Lear* doctrine when a licensee is still making payments, the tone of the *Medtronic* opinion and stress on the public's "paramount interest" of seeing patent monopolies "kept within their legitimate scope"¹⁹¹ is more than a clue that the Court would likely rule that *Lear* applies to such situations. Thus, a patentee cannot through contract prevent a licensee from suing, at least if claiming invalidity of the patent. *FTC v. Actavis* is another instance in which the policy arguments in *Lear* were brought to the fore, even though in an antitrust context.¹⁹² It is safe to say that the Court would not cite *Lear* approvingly if it were ready to overrule it and hold that "freedom of contract" trumps federal patent policy in this area.¹⁹³ Also, other courts as well continue to view *Lear* as a strong doctrine.¹⁹⁴ It is thus very likely that a contractual no-challenge clause would be unenforceable.

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

189. See *id.*

190. See Dreyfuss & Pope, *supra* note 175, at 984–86.

191. See *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 852 (2014).

192. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

193. *But see Kimble v. Marvel Enters., Inc.*, 727 F.3d 856 (9th Cir. 2013), *cert. granted*, 135 S. Ct. 781 (2014). While *Kimble* involves the ability to extract royalty payments after patent expiration (as opposed to patent validity in *Lear*), it will nevertheless provide another window into how the Court regards the conflict between freedom of contract and patent policy.

194. See *Rates Tech., Inc. v. Speakeasy, Inc.*, 685 F.3d 163 (2d Cir. 2012) (holding that a no-challenge clause in a license agreement was void for public policy based on *Lear*, and that only after being afforded discovery could a licensee be bound by an ulterior no-challenge agreement, e.g., a settlement).

However, a no-challenge clause in a consent decree, after the licensee has had at least the opportunity to do some discovery, may be enforceable.¹⁹⁵ While not ideal for a patent holder, who will still have to engage in litigation, it could offer peace of mind that he does not need to go through litigation again to forestall a similar challenge in the future.

Assuming, however, that a no-challenge clause were, against all odds, found enforceable by the courts, the toolbox that patent owners have to protect their monopoly would expand significantly. In addition to provisions calling for higher royalties if the licensee files a declaratory judgment action or even upfront royalties, a patent owner could insist in the license terms on an outright prohibition of a licensee filing a declaratory judgment suit, for either non-infringement or invalidity, while still paying royalties.

While the *Medtronic* opinion will certainly affect the dynamics of the patent owner-licensee equation, and in particular how license agreements are drafted, only time and a future ruling on licensee estoppel/no-challenge clauses in the context of nonrepudiating licensees will tell the full effect of this decision. The *Kimble v. Marvel Enterprises* case, in which the Supreme Court recently granted certiorari to revisit the *Brulotte* rule barring royalty payments after a patent's expiration, will hopefully help clarify the current Court's view of the conflict between freedom of contract and federal patent policy.¹⁹⁶

IV. CONCLUSION

*Ei incumbit probatio qui dicit, non qui negat.*¹⁹⁷ The Supreme Court's *Medtronic* opinion is proof that this maxim is as true today as it was thousands of years ago, and not only in criminal cases. Declaratory judgment is but a procedural vehicle allowing the dispute between the parties to be settled earlier, rather than changing the main duties of the actors in court. In *Medtronic*, the high Court continued the task begun in *MedImmune* in bringing patent law declaratory judgments into line with other legal fields, in spite of the Federal Circuit's efforts to the contrary. While the Court's "simple legal logic" partly relies on a historical quirk, the result in *Medtronic* was unavoidable in view of eighty years of legal precedent, practical considerations, and public policy. However,

195. *See id.* (distinguishing a clause in a consent decree, after the licensee has had the benefit of discovery).

196. *See Kimble v. Marvel Enters., Inc.*, 135 S. Ct. 781 (2014) (granting certiorari to review the Ninth Circuit's decision); *see also Davis, supra* note 183.

197. The burden of the proof lies upon him who affirms, not he who denies.

Medtronic's true impact will only be seen when and if the Court finally settles the tug-of-war between contract law and federal patent policy, in particular the issue of nonrepudiating licensee estoppel, which it brought to the fore but punted on in the earlier *MedImmune* case. The outcome in *Kimble v. Marvel Enterprises*,¹⁹⁸ a case on a related issue in the freedom of contract vs. patent policy clash that the Court will decide in 2015, will hopefully provide at least a partial clarification of who the winner is of this legal battle in the twenty-first century.

198. *Kimble v. Marvel Enters., Inc.*, 727 F.3d 856 (9th Cir. 2013), *cert. granted*, 135 S. Ct. 781 (2014).