

No. 12-1128

In the Supreme Court of the United States

MEDTRONIC INC., PETITIONER

v.

BOSTON SCIENTIFIC CORPORATION, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE SUPPORTING PETITIONER**

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QUESTION PRESENTED

Whether the burden of proof regarding patent infringement shifts from a patent holder to its licensee when the licensee sues the patent holder for a declaratory judgment that the licensee is not obligated to make royalty payments under the license because its products do not practice the patent.

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INTEREST OF THE UNITED STATES

This case presents a question regarding the allocation of the burden of proof in a declaratory-judgment action in which a licensee seeks a declaration that royalties are not owed under a patent licensing agreement because the licensee's product does not practice the licensed patent. The United States Patent and Trademark Office (PTO) is responsible for "the granting and issuing of patents," 35 U.S.C. 2(a)(1), as well as for advising the President on domestic and international issues of patent policy and advising federal departments and agencies on matters of intellectual-property policy, 35 U.S.C. 2(b)(8) and (9). Several federal agencies are extensively engaged in the licensing of patented inventions to private entities, and the United States is also a licensee of various patents. The government according-

ly has a substantial interest in this Court's resolution of the question presented.

STATEMENT

1. Under the federal Declaratory Judgment Act, ch. 512, 48 Stat. 955, a court of the United States is authorized, “[i]n a case of actual controversy within its jurisdiction” and “upon the filing of an appropriate pleading,” to “declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. 2201(a); see Fed. R. Civ. P. 57. A principal purpose of that procedural mechanism is “to afford one threatened with liability an early adjudication without waiting until an adversary should see fit to begin an action after the damage has accrued.” 10B Charles Alan Wright et al., *Federal Practice and Procedure* § 2751, at 457 (3d ed. 1998). The potential availability of declaratory relief enables the declaratory-judgment plaintiff “to minimize the danger of avoidable loss and the unnecessary accrual of damages.” *Ibid.*; see S. Rep. No. 1005, 73d Cong., 2d Sess. 2-3 (1934).

When disagreements arise concerning the scope or validity of an issued patent, the Declaratory Judgment Act enables a party who has been “charged with infringement of [a] patent” to establish an actual controversy with the patentee and “seek a declaratory judgment, even if the patentee has not filed an infringement action.” *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95-96 (1993). Declaratory-judgment actions are “frequently” brought in the patent context, where they are recognized as being “useful to establish the rights of licensees and other interested persons.” 10B *Federal Practice and Procedure* § 2761, at 572. Such actions “most common[ly]” take the form of “a suit by one

thought to be an infringer for a declaration that he is not infringing the patent or that the patent is invalid.” *Id.* at 572-573; see 12 James Wm. Moore et al., *Moore’s Federal Practice* § 57.83[1], at 57-148 (3d ed. 2013).

2. The dispute in this case involves two patents that are owned by respondent Mirowski Family Ventures, LLC (Mirowski or respondent), and exclusively licensed to Guidant Corporation (which is a subsidiary of Boston Scientific Corporation). Pet. App. 2a, 22a.¹ The patents relate to “cardiac resynchronization therapy” devices, which stimulate portions of a patient’s heart to ensure that the chambers of the heart are working in a coordinated way. *Id.* at 29a.

In 1991, petitioner Medtronic entered into a cross-licensing agreement with Guidant’s predecessor-in-interest, Eli Lilly & Co. See J.A. 7-18. That agreement granted Medtronic a sublicense as to certain patents owned by Mirowski (including subsequently reissued patents), under which Medtronic agreed to pay royalties for practicing the patents. J.A. 12. The agreement also established a structured process for identifying and resolving disputes about Medtronic’s obligations to pay royalties under that sublicense. J.A. 13-14. If Lilly or Mirowski believed that any new Medtronic device “infringe[d]” a covered patent, Lilly was to “notify Medtronic of such infringement,” triggering a 90-day period to cure nonpayment of royalties or risk having the sublicense terminated. J.A. 13. If Medtronic chose to pay the royalty, it still retained “the right to challenge the

¹ Although Boston Scientific and Guidant are listed as respondents in the caption in this Court, they were not parties to the appeal below (Pet. App. 1a) and did not file a brief in this Court at the certiorari stage. Accordingly, this brief uses the term “respondent” to refer to Mirowski Family Ventures.

validity and enforceability of [certain] patent[s] under the Mirowski license” and “the right to challenge Lilly’s assertion of infringement of any of the Mirowski patents through a Declaratory Judgment action.” *Ibid.*

In 2003, a patent covered by the sublicense was issued, followed shortly by litigation in which Medtronic challenged the patent’s enforceability and validity. Pet. App. 23a. In 2006, Medtronic, Guidant, and Mirowski entered into a litigation tolling agreement, J.A. 19-29, which acknowledged the parties’ dispute about “the scope, validity and enforceability” of the patent, J.A. 20, and again provided a process under which Guidant or Mirowski “may notify Medtronic” of any claims in the patent “that Guidant or Mirowski asserts are infringed by [Medtronic products].” J.A. 23-24. Upon a “timely written notice of infringement,” Medtronic would be permitted to initiate the “Final [Declaratory Judgment] Action challenging infringement, unenforceability and/or validity of the asserted claims of the [patents].” J.A. 24. Medtronic was required to “accumulate disputed royalties and future disputed royalties” in an escrow account. J.A. 27. After the conclusion of the declaratory-judgment action, Medtronic would be required to “cause distribution of the total amount in the [escrow] account to Mirowski or to Medtronic in a manner consistent with the [declaratory-judgment] decision.” J.A. 28.

In October 2007, Mirowski’s counsel, acting pursuant to the tolling agreement, “provide[d] notice” of Mirowski’s contention that seven Medtronic products “infringe at least one of” 12 specified claims of the patent that had been issued in 2003. J.A. 30-31. A few weeks later, another patent issued, Pet. App. 30a, and Mirowski’s counsel provided an amended notice, contending that the

seven Medtronic products “infringe at least one of” four claims of the first patent and 25 claims of the second patent. J.A. 32-33.

3. a. As the parties’ licensing arrangement contemplated, Medtronic responded to the notice of infringement by filing this declaratory-judgment action in the United States District Court for the District of Delaware, seeking a determination that its devices do not infringe the two patents and that the asserted claims of the two patents are invalid and unenforceable. J.A. 40-46. With respect to the noninfringement counts, Mirowski’s answer to the declaratory-judgment complaint “admit[ted] that [Mirowski] has asserted” that several Medtronic devices “infringe at least one of” several claims in the two patents (though its answer identified a different set of infringed claims than had its two prior letters). J.A. 48-49.

In the district court, petitioner and respondent disagreed about who bore the burden of proving infringement at trial. Pet. App. 39a; J.A. 37-38. Petitioner contended that the burden remained on respondent, as the patent holder, while respondent contended that the burden of proof was on petitioner, as the plaintiff in the declaratory-judgment action. Pet. App. 39a-40a.

b. After a bench trial and post-trial briefing, the district court held, as relevant here, that, although respondent was the defendant in the declaratory-judgment action, it was the “part[y] asserting infringement” and therefore bore “the burden of proof by a preponderance of the evidence.” Pet. App. 41a. The court’s discussion of the burden-of-proof question relied on several Federal Circuit precedents, which had endorsed the proposition that “[t]he burden is always on the patentee to show infringement.” *Id.* at 40a (citation omitted).

Applying that burden of proof to the evidence before it, the district court found that respondent's expert report lacked a "sufficient foundation" because respondent had failed to demonstrate that its expert had "considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions." Pet. App. 49a. The court held that respondent had failed to meet its burden of proving infringement by a preponderance of the evidence. *Id.* at 49a-52a. The district court also held that petitioner had failed to prove by clear and convincing evidence that the patent claims are invalid or unenforceable. *Id.* at 52a-83a; see *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2244-2252 (2011) (holding that, in order to prevail on an invalidity defense, the defendant in a patent-infringement suit must establish the invalidity of the patent by clear and convincing evidence). The court accordingly entered declaratory judgment in favor of petitioner "as to noninfringement" and declaratory judgment in favor of respondent (and its licensees) as to the "validity and enforceability" of the patents. J.A. 3.

4. Respondent appealed, petitioner cross-appealed, and the Federal Circuit vacated and remanded. Pet. App. 1a-18a. As relevant here, the court held that the district court had erred in placing the burden of proof with respect to infringement on respondent. *Id.* at 15a.

The court of appeals acknowledged that "a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement." Pet. App. 10a (citing *Under Sea Indus. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987)). The court also acknowledged that, when infringement claims are asserted as mandatory counterclaims in declaratory-judgment actions brought by accused infringers, "[t]he

substantive burden of proof normally does not shift simply because the party seeking relief is a counterclaiming defendant in a declaratory judgment action.” *Ibid.* (citing *Vivid Techs., Inc. v. American Sci. & Eng’g, Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999); *In re Technology Licensing Corp.*, 423 F.3d 1286, 1288-1289 (Fed. Cir. 2005), cert. denied, 547 U.S. 1178 (2006)).

The court of appeals held, however, that when the declaratory-judgment plaintiff is a licensee, the burden of proof regarding infringement (or the absence thereof) should shift from the patent holder to the licensee. The court stated that the question regarding the burden of proof in such a case “arises as a consequence of the Supreme Court’s decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).” Pet. App. 8a. In *MedImmune*, this Court “found declaratory judgment jurisdiction notwithstanding the fact that the declaratory judgment plaintiff licensee continued to make royalty payments pursuant to a license.” *Id.* at 8a-9a. The court of appeals viewed this case as involving “the proper allocation of the burden of persuasion in the post-*MedImmune* world,” in a case where “a declaratory judgment plaintiff licensee seeks a judicial decree absolving it of its responsibilities under its license while at the same time the declaratory judgment defendant is foreclosed from counterclaiming for infringement by the continued existence of that license.” *Id.* at 9a.

The court of appeals held that, “in the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.” Pet. App. 14a. In reaching that conclusion, the court observed

that, as a general matter, “the party seeking relief [from a court] bears the burden of proving the allegations in his complaint.” *Id.* at 9a (citing *Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005)). The court stated that, in this case, petitioner “is unquestionably the party now requesting relief from the court: it already has a license; it cannot be sued for infringement; it is paying money into escrow; and it wants to stop.” *Id.* at 12a.

The court of appeals described respondent, by contrast, as “seek[ing] nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract.” Pet. App. 12a. The court concluded that, because petitioner “is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear,” petitioner “must present evidence showing that it is entitled to such relief.” *Id.* at 13a. The court stated that, if the rule were otherwise, licensees would be “allow[ed] * * * 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.” *Id.* at 14a.

The court of appeals vacated the declaratory judgment of noninfringement and remanded the case for further proceedings, in which the district court might exercise its discretion to permit petitioner to make “additional noninfringement contentions” in light of its burden of proof. Pet. App. 15a.²

² The court of appeals also held, on petitioner’s cross-appeal, that “the district court erred by restricting the claimed invention to the treatment of congestive heart failure.” Pet. App. 18a. The court of appeals vacated the district court’s determination with respect to validity, and it remanded to allow petitioner to “press its invalidity contention based upon the correct claim construction.” *Ibid.* Those aspects of the court of appeals’ decision are beyond the scope of the

SUMMARY OF ARGUMENT

A. It is well established that, although an issued patent is presumed valid, and an accused infringer must prove invalidity by clear and convincing evidence, the patent holder in an infringement suit bears the burden of proving that the accused product infringes the patent. Before the decision below, courts had consistently held that the burden of proving infringement remains with the patent holder even in a declaratory-judgment action initiated by the accused infringer. That allocation of the burden of proof is justified in part by the fact that a single patent may contain many claims, and there may be more than one potential rationale for asserting that a particular product infringes a particular claim. It would be unwieldy to require the alleged infringer to anticipate and negate every potential theory of infringement that the patent holder might assert.

B. The court of appeals held that the burden of disproving patent coverage should shift to petitioner because petitioner had initiated this declaratory-judgment action and respondent had not counterclaimed for infringement. That reasoning was erroneous. Although the plaintiff typically bears the burden of proof on the essential elements of its claims, that rule is subject to exceptions. Where, as here, the injury that a declaratory-judgment suit seeks to prevent is the imposition of legal liability in alternative proceedings that might otherwise be instituted by the declaratory-judgment defendant, the Declaratory Judgment Act allows the court to determine how the correlative enforcement suit would

questions presented in this case, but are implicated by the petition for a writ of certiorari in *Mirowski Family Ventures, LLC v. Medtronic, Inc.*, No. 12-1116 (filed Mar. 14, 2013), which is currently pending before this Court.

be resolved, without requiring the declaratory-judgment plaintiff to expose itself to potential retrospective liability as a precondition to judicial resolution. When the declaratory-judgment mechanism is used in that manner, it is generally appropriate to apply the same burdens of proof that would govern in those alternative enforcement proceedings.

That approach reflects the procedural character of the Declaratory Judgment Act and the purposes the statute is intended to serve in this context. In order to determine how an infringement suit filed by a patent holder would have been resolved, the declaratory-judgment court must conduct the same factual inquiries, and apply the same body of law, that the court in an infringement suit would conduct and apply. The allocation of burdens of proof is a matter of substantive law, and there is no sound reason that a putative infringer's use of the declaratory-judgment mechanism should, without more, trigger a different allocation. That is particularly so because the practical justifications for requiring the patent holder to prove infringement apply equally in the declaratory-judgment context.

C. Contrary to the Federal Circuit's conclusion, the licensing arrangement between the parties here provides no sound basis for requiring petitioner to disprove patent coverage. The arrangement recognizes that disputes concerning patent coverage may arise, and it establishes a structured mechanism, culminating if necessary in a declaratory-judgment action filed by petitioner, for resolving those disputes. Nothing in the licensing and tolling agreements suggests that the parties intended the courts in such suits to do anything other than apply the same legal rules that would govern

a similar declaratory-judgment action between parties with no prior course of dealing.

Besides being untethered to the terms of the parties' license and tolling agreements, the court of appeals' approach would deter licensees' use of the declaratory-judgment mechanism and would disserve sound patent policy. The Declaratory Judgment Act alleviates the dilemma that one in petitioner's position might otherwise face, between forgoing conduct it believes to be lawful and risking onerous retrospective penalties. The statute cannot fully vindicate that purpose if licensees who file declaratory-judgment suits must litigate questions of patent coverage on terms less favorable than defendants in infringement actions. And by deterring use of the declaratory-judgment mechanism to resolve disputed questions of patent scope, the court of appeals' approach would impede the public interest in prompt and dispositive judicial resolution of such issues.

ARGUMENT

A PATENT HOLDER BEARS THE BURDEN OF PROVING INFRINGEMENT OF ITS PATENT IN AN ACTION FOR A DECLARATORY JUDGMENT OF NONINFRINGEMENT BROUGHT BY A PATENT LICENSEE

The parties in this case disagree about whether some of petitioner's devices practice respondent's patents and therefore trigger petitioner's obligation to pay royalties under the terms of their license. Because infringement of a patent occurs when the patent is practiced "without authority" from the patent holder, 35 U.S.C. 271(a), and petitioner has been authorized to practice the patents at issue here so long as it fulfills its obligations under the licensing and tolling agreements, a judicial determination that petitioner's devices practice the patent would not subject petitioner to the remedies (including injunc-

tive relief and treble damages, see 35 U.S.C. 283, 284) that the Patent Act authorizes in suits for infringement. See generally 35 U.S.C. 281-285. The parties' agreements nevertheless establish a structured dispute-resolution process, potentially culminating in a declaratory-judgment action filed by petitioner, that is triggered by respondent's assertion that some of petitioner's products "infringe" respondent's patents. The parties' evident intent was to allow a court to determine whether the manufacture and sale of petitioner's devices *would infringe* the patents if petitioner did not pay royalties it believes it does not owe.

The court of appeals recognized that, in almost every context, a patent holder has the burden of proof (*i.e.*, the burden of persuasion) with respect to whether its patent is infringed.³ The court nevertheless concluded that, in the context of an action brought by a licensee for a declaration of noninfringement, that burden of proof should be imposed on the licensee. That result is not supported by the Declaratory Judgment Act, which (as applied to cases like this one) simply furnishes a procedural mechanism for securing a conclusive judicial resolution of the same legal issue that could arise in a different procedural posture. Nor is the altered burden of proof justified by the presence of a license (either in general or in this case). Petitioner's exercise of its right to employ the

³ This Court has often observed that the phrase "burden of proof" has been used to mean different things. See, *e.g.*, *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 n.4 (2011); *Schaffer v. Weast*, 546 U.S. 49, 56 (2005). As relevant here, it means the "burden of persuasion," which specifies "which party loses if the evidence is balanced." *Microsoft*, 131 S. Ct. at 2245 n.4. See Pet. App. 14a (equating "burden of proof" with "burden of persuasion"); Pet. Br. 12 n.5; Br. in Opp. 25-26.

declaratory-judgment mechanism to clarify its rights and responsibilities, as contemplated by the license and authorized in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), should not come at the cost of assuming the burden of proof on the issue of infringement, which falls on the patent holder in every other context.

A. The Burden of Proving Patent Infringement Generally Rests With The Patent Holder

1. As the court of appeals recognized, “[i]t is, of course, well settled that a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement.” Pet. App. 10a. This Court explained long ago that patent “[i]nfringement must * * * be shown by satisfactory proof; it cannot be presumed.” *Railroad Co. v. Mellon*, 104 U.S. 112, 119 (1881).

In that regard, the question of infringement differs from another recurring issue in patent litigation: the question of patent validity. Congress has codified a presumption of validity for a patent that has been issued by the PTO. See 35 U.S.C. 282. Congress has “explicitly specific[d],” moreover, that “the burden of proof” on that question is to be borne by the party who asserts the *invalidity* of an issued patent and attempts to overcome the statutory presumption. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2245 (2011); see *id.* at 2242 (holding that invalidity must “be proved by clear and convincing evidence”); 35 U.S.C. 282 (“The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”). With respect to infringement, by contrast, Congress has not enacted any similar presumption, but instead has left in place

the established rule that the party asserting infringement bears the burden of proving it.⁴

Based on this Court's holding that "the burden to prove infringement never shifts [to the alleged infringer] if the charge is denied in the plea or answer," *Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1880), it had been universally understood—until the exception created by the decision below—that "the burden of proof on factual issues relating to infringement rests upon the patent owner." 5B Donald S. Chisum, *Chisum on Patents* § 18.06[1][a], at 18-1180 (2007). As the Federal Circuit explained in 2008: "Neither [the patentee's] burden to prove infringement nor [the accused infringer's] burden to prove invalidity, both ultimate burdens of persuasion, ever shifts to the other party[.]" *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327; see, e.g., *Under Sea Indus. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) ("The burden always is on the patentee to show infringement.")⁵

⁴ Under 35 U.S.C. 295, there is a rebuttable presumption that a product was made from a process patented in the United States when the court finds a "substantial likelihood" that it was made in that way and the patent holder has, despite "a reasonable effort," been unable to "determine the process actually used in the production of the product." See Pet. Br. 37-38. Section 295 might be viewed as establishing a rebuttable presumption of infringement in certain narrow circumstances once a predicate showing has been made. Section 295 is not at issue in this case.

⁵ Congress has included "[n]oninfringement, absence of liability" in a list of "defenses in any action involving the validity or infringement of a patent [that] shall be pleaded." 35 U.S.C. 282(1). That statutory requirement, however, "has never been deemed to alter the basic rule that a patentee bears the burden of proving infringement." 5B *Chisum on Patents* § 18.06[1][a], at 18-1181. Accordingly, an "accused infringer" may meet that "pleading burden with either a denial of a patentee's infringement allegation or by a positive asser-

2. Because this Court’s decisions in *Railroad Co.* and *Imhaeuser* long predated the federal Declaratory Judgment Act, they did not contemplate or address the now-commonplace situation in which questions of patent coverage arise in a declaratory-judgment action commenced by the alleged infringer, rather than in an infringement suit initiated by the patent holder. Until the decision below, however, the relatively few lower-court decisions to address the question had recognized that an accused infringer does not assume the burden of proving noninfringement merely because it is a declaratory-judgment plaintiff. See 12 *Moore’s Federal Practice* § 57.62[2][d], at 57-137 (“In patent, copyright, and trademark cases, courts have generally recognized that

tion of noninfringement.” *Ibid.* In certain circumstances, noninfringement might be treated as an affirmative defense. See 6 R. Carl Moy, *Moy’s Walker on Patents* § 17:14, at 17-47 (4th ed. 2012) (“[A]llegations of noninfringement [under Section 282] can be denials of various assertions in the patent owner’s complaint. They can also be various affirmative defenses, such as when the defendant alleges that the patent owner’s recourse to the Doctrine of Equivalents has been barred by Prosecution History Estoppel.”) (footnotes omitted); but see 5B *Chisum on Patents* § 18.06[1][a], at 18-1184.2 (noting that prosecution-history estoppel “presents a special problem,” and that, although a defendant should be required to introduce evidence of the prosecution history and make “a prima facie showing,” “[a]rguably, the ultimate burden of persuasion * * * should remain on the plaintiff”). When the relevant argument for noninfringement would take the form of an affirmative defense, the burden of proving that defense would likely be borne by the defendant. See *Schaffer*, 546 U.S. at 57 (“the burden of persuasion as to certain elements of a plaintiff’s claim may be shifted to defendants, when such elements can fairly be characterized as affirmative defenses or exemptions”). But neither the Federal Circuit nor respondent has suggested that a noninfringement argument of the sort asserted by petitioner in this case would be treated as an affirmative defense outside the declaratory-judgment context.

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.”); 5B *Chisum on Patents* § 18.06[1][a], at 18-1182 to 18-1183 (“Courts apply the burden of proof to the patent owner” “in a declaratory judgment action initiated by the accused infringer.”); Pet. Br. 36 & n.15 (citing cases). The courts had recognized that principle applied even in the absence of a counterclaim for infringement. See, e.g., *Vivid Techs., Inc. v. American Sci. & Eng’g, Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999) (noting that “the parties bore the same evidentiary burdens whether or not the counterclaim [for infringement] was permitted”); Pet. Br. 36 n.16 (citing cases).

3. To prove infringement of a patent, the patent holder must make an affirmative showing that “every limitation set forth in a claim [is] found in an accused product or process exactly or by a substantial equivalent.” *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 796 (Fed. Cir. 1990). Accordingly, regardless of whether the patent holder asserts literal infringement or relies on the doctrine of equivalents, it must demonstrate how each limitation of the relevant claim maps onto the accused product. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) (“[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.”); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir.) (for literal infringement, “every limitation set forth in a claim must be found in an accused product, exactly”), cert. denied, 516 U.S. 987 (1995).

A patent may include many claims. See Pet. Br. 44 (noting that “the two patents at issue here comprised more than 300 claims”). And, in some cases, there may

be more than one way in which the limitations may be mapped (or may be claimed to map) onto the accused product. See, e.g., *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1358 (Fed. Cir. 2006) (discussing three separate theories for which portion of the accused product constitutes a “feedback control loop”); *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1252 (Fed. Cir. 2010) (noting that patentee had impermissibly changed theories at trial regarding how the accused product employed a “spring means”). It makes sense to assign to the party alleging infringement the burden of demonstrating how the claim limitations map onto the accused product, because infringement may be found only when the product falls within the scope of the asserted claim or claims in every respect.

A contrary rule—under which the party denying infringement bears the burden of proof—would require that party to identify and negate every conceivable theory on which the product could infringe. In other words, “the alleged infringer would be forced to prove a negative, that no conceivable activity could infringe on any of the holder’s rights.” 12 *Moore’s Federal Practice* § 57.62[2][d], at 57-137. “[P]racticality therefore favors placing the burden on the party asserting” infringement, rather than on the party attempting to disprove it. *NLRB v. Kentucky River Community Care, Inc.*, 532 U.S. 706, 711 (2001); *ibid.* (finding it reasonable to place the burden of proving supervisory status under the National Labor Relations Act on the party asserting that status, in part because “it is easier to prove an employee’s authority to exercise 1 of the 12 listed supervisory functions than to disprove an employee’s authority to exercise any of those functions”). That allocation

of the burden of proof facilitates the orderly presentation of evidence and enables the parties and the court to focus on the theory of infringement asserted by the patent holder.

B. The Declaratory-Judgment Posture Does Not Require Shifting The Burden Of Proof Otherwise Associated With The Parties' Underlying Substantive Dispute

The court of appeals recognized the “general proposition that mere role reversal in a declaratory judgment action does not shift the burden” of proof on an issue from one party to the other. Pet. App. 11a. It observed, however, that “the burden of proving the allegations in [a] complaint” is “[g]enerally” borne by “the party seeking relief.” *Id.* at 9a. On the basis of declaratory-judgment cases from the insurance context, the court concluded that it would be “fully consistent with other areas of the law” to require the burden in this case to “shift to the declaratory judgment plaintiff where the [defendant] is not seeking affirmative relief.” *Id.* at 13a. That cursory analysis failed to account for several reasons why the declaratory-judgment posture does not support shifting the burden of proof in this case.

1. Declaratory-judgment plaintiffs do not invariably assume the burden of proof simply because they are plaintiffs

a. The court of appeals cited this Court’s decision in *Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005), for the proposition that “the party seeking relief”—*i.e.*, the plaintiff—generally “bears the burden of proving the allegations in his complaint.” Pet. App. 9a. *Schaffer* was not a declaratory-judgment case, however, and the Court recognized that “[t]he ordinary default rule * * * admits of exceptions.” 546 U.S. at 57. “[T]he

burden of persuasion” sometimes will be placed on the defendant for “elements of a plaintiff’s claim” that “can fairly be characterized as affirmative defenses or exemptions,” and in some circumstances “this Court has even placed the burden of persuasion over an entire claim on the defendant.” *Ibid.*

b. Like any other party invoking the jurisdiction of a federal court, a declaratory-judgment plaintiff must establish the constitutional and statutory prerequisites for such jurisdiction. See *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95 (1993); see generally *Daimler-Chrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006). This Court has not otherwise addressed the allocation of the burden of proof in the declaratory-judgment context. See, e.g., *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 244 (1937). The Court has repeatedly observed, however, that “the operation of the Declaratory Judgment Act is procedural only.” *Id.* at 240; see, e.g., *Vaden v. Discover Bank*, 556 U.S. 49, 70 n.19 (2009); *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950); see also *MedImmune*, 549 U.S. at 138 (Thomas, J., dissenting) (“[T]he Act merely provides a different procedure for bringing an actual case or controversy before a federal court.”). As petitioner explains (Br. 23-24), the purely procedural nature of the Declaratory Judgment Act strongly implies that it does not alter the burden of proof associated with an underlying claim, because this Court has “long held the burden of proof to be a ‘substantive’ aspect of a claim.” *Raleigh v. Illinois Dep’t of Revenue*, 530 U.S. 15, 20-21 (2000). Moreover, looking to the nature of the underlying dispute between the parties is consistent with the approach the Court has taken in determining whether a declaratory-judgment

action implicates the right to a jury trial. See *Simler v. Conner*, 372 U.S. 221, 223 (1963) (per curiam).⁶

c. The court of appeals invoked cases from the insurance context to support its conclusion that a declaratory-judgment plaintiff should bear the burden of proof on a claim “where the [declaratory-judgment defendant] is not seeking affirmative relief.” Pet. App. 13a. Two of the three insurance cases cited by the court of appeals, however, ultimately placed the burden of proof on the declaratory-judgment defendant (an insured), rather than on the insurance company that sought a declaratory judgment of non-coverage. The courts of appeals in those cases found that allocation of the burden appropriate because the substance of the underlying dispute turned on whether the insured was covered—a question on which, as a matter of applicable state insurance law, the insured bore the burden of proof.⁷

⁶ Petitioner also invokes (Br. 20-21) the application of the well-pleaded-complaint rule in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). This Court has noted in dictum, however, that it “is not clear” whether “a declaratory-judgment complaint raising a *nonfederal* defense to an anticipated *federal* claim * * * would confer [federal-question] jurisdiction” under 28 U.S.C. 1331. *Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace & Agric. Implement Workers of Am.*, 523 U.S. 653, 659 (1998).

⁷ See *American Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) (finding “no reason to deviate from Arkansas [state-law] burden of proof principles [which place the burden of proving coverage on the person seeking insurance coverage] simply because this action was brought by the insurer under the federal Declaratory Judgment Act”); *Fireman’s Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1174, 1176 (3d Cir. 1976) (“The burden of proof which usually accompanies the affirmative of the issue of coverage should not be shifted merely due to the [declaratory-judgment] form of the

In the third case, *Reliance Life Insurance Co. v. Burgess*, 112 F.2d 234 (8th Cir.), cert. denied, 311 U.S. 699 (1940), the court apparently placed the burden of proof on the insurance company, which was the declaratory-judgment plaintiff. That decision has been understood, however, as resting on the fact that the insurance company was asserting “an affirmative defense” stemming from a policy exclusion.⁸ Because defendants often bear the burden of proving affirmative defenses, see *Schaffer*, 546 U.S. at 57, the insurer in *Burgess* therefore might have borne the burden of proof regarding the exclusion even if the suit had been commenced by the insured to obtain benefits alleged to be due. Thus, even if *Burgess* is assumed to have been correctly decided, it does not follow that petitioner’s invocation of the declaratory-judgment mechanism should shift the burden of proof on the issue of infringement.

2. A basic purpose of the Declaratory Judgment Act is disserved if the parties’ nominal status as plaintiff or defendant is enough to alter the burden of proof in this context

The Declaratory Judgment Act authorizes a court to provide “specific relief through a decree of a conclusive character” that adjudicates “the rights of the litigants” and thus resolves “a real and substantial controversy” between the parties.” *Aetna*, 300 U.S. at 241. In many cases, including suits brought by alleged patent infringers to determine the scope or validity of a contested patent, the injury-in-fact that gives a declaratory-judgment plaintiff Article III standing is the threat of

action”; applying “general law” in the absence of controlling Virgin Islands declaratory-judgment law), cert. denied, 429 U.S. 1053 (1977).

⁸ *American Eagle Ins. Co.*, 85 F.3d at 331 (describing *Burgess*).

legal liability in an enforcement suit that could be, but has not been, brought against it by the declaratory-judgment defendant. See pp. 2-3, *supra*.

In such circumstances, the basic purpose and great utility of the Declaratory Judgment Act is to provide a mechanism for determining how *that enforcement suit* would be resolved without requiring, as a precondition to judicial resolution, that the declaratory-judgment plaintiff subject itself to retrospective liability. It would make little sense to require the declaratory-judgment plaintiff to bear the burden of proof on an issue as to which its adversary would have borne the burden in the correlative enforcement suit. That would detract from the understanding that the Declaratory Judgment Act was intended to provide an alternative procedural mechanism for “the same court, the same jurisdiction, the same procedure, the same parties and the same question.” S. Rep. No. 1005, 73d Cong., 2d Sess. 3 (1934).⁹

⁹ In many suits where the plaintiff seeks declaratory relief pursuant to the Declaratory Judgment Act, his asserted injury has nothing to do with the possibility that suit might be filed against him. For example, a plaintiff might seek (perhaps in combination with other forms of relief) a declaration that the defendant’s ongoing or impending conduct was violating or would violate federal or state environmental laws. To establish standing to sue, the plaintiff in such a case would need to show that he would personally be injured by the allegedly unlawful conduct. If a dispute arose concerning the applicable burden of proof on some subsidiary question, it would be arbitrary and perhaps incoherent to attempt to resolve that dispute by hypothesizing a coercive suit between the same parties in which the parties’ alignment (as plaintiff and defendant) was reversed, and then asking who would bear the burden of proof on the issue in that context. That approach provides a useful guide, however, when the injury that the declaratory-judgment suit seeks to prevent is the imposition of legal liability in proceedings that might otherwise be instituted by the declaratory-judgment defendant.

In determining whether an accused device practices a particular patent, a court will undertake the same factual inquiry and apply the same rules of law, regardless of whether the question of patent coverage arises in a declaratory-judgment suit brought by the alleged infringer or in an infringement suit brought by the patent holder. The Declaratory Judgment Act would not retain its “procedural” character, see *Aetna*, 300 U.S. at 240, or fulfill its intended purpose of determining how an infringement suit brought by the patent holder would have been resolved, if the putative infringer’s use of the declaratory-judgment mechanism triggered the application of a different body of substantive law. There is no sound reason to treat the rule that a patent holder bears the burden of proof on infringement, alone among the substantive legal rules that the court in an infringement suit would apply, as inapplicable to suits under the Declaratory Judgment Act.

That is particularly so because the practical justifications for requiring the patent holder to prove infringement apply equally in the declaratory-judgment context. As explained above (pp. 16-17, *supra*), a patent may contain many claims, and there may be more than one potential basis for alleging that a particular product infringes a particular claim. It would be just as unwieldy for a declaratory-judgment plaintiff to attempt to anticipate and disprove every potential theory of patent coverage as for an infringement defendant to do so.¹⁰

¹⁰ Moreover, to the extent that a different burden of proof would threaten the issue-preclusive effect of a proceeding in which the declaratory-judgment plaintiff loses its case (see Pet. Br. 32-33), that would detract from the ability of the Declaratory Judgment Act to provide for a “conclusive” resolution of the litigants’ “rights.” *Aetna*, 300 U.S. at 241; cf. *MedImmune*, 549 U.S. at 127-128 n.7 (“[A] litigant

C. The Existence Of A License Does Not Shift The Burden Of Proving Patent Infringement From A Patent Holder To Its Licensee

The court of appeals acknowledged both of the propositions discussed above: that a patentee generally bears the burden of proving infringement (Pet. App. 10a), and that, as a “general proposition,” the “mere role reversal [of the parties] in a declaratory judgment action does not shift the burden” of proof (*id.* at 11a). The court found those usual principles inapplicable here, however, because it believed that, as a result of the parties’ licensing arrangements, petitioner is “the only party seeking the aid of the court.” *Id.* at 14a. The Federal Circuit’s factual premises were incorrect, and its conclusion runs counter both to this Court’s decision in *MedImmune* and to broader patent-law policies.

1. The parties’ licensing arrangement does not resolve the dispute or alter the legal rules for determining whether petitioner’s devices practice respondent’s patents

The Federal Circuit stated that, when petitioner initiated this declaratory-judgment action, respondent was “foreclosed from counterclaiming for infringement by the continued existence of that license.” Pet. App. 9a. The court further observed that “neither party here seeks money damages or an injunction based on patent infringement, which are the sorts of relief generally sought when a party seeks relief for patent infringement.” *Id.* at 14a. The court viewed the licensing arrangement as a sound basis for re-allocating the burden

may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve the underlying controversy.*”).

of proof on the issue of patent coverage, and it characterized petitioner as “seek[ing] a judicial decree absolving it of its responsibilities under its license.” *Id.* at 9a.

The court of appeals was correct that, so long as petitioner complies with its obligations under the licensing and tolling agreements, it cannot be held liable for infringement, and petitioner cannot obtain damages or injunctive relief. The court erred, however, in treating that fact as a ground for requiring petitioner to prove that its devices do not practice respondent’s patents.

a. This is not a case in which petitioner conceded (or promised not to contest) that a particular product practiced one of respondent’s patents, but then attempted to litigate an issue that had been resolved by the parties’ prior agreement. The 1991 license agreement does not require petitioner to acquiesce in respondent’s assessment that particular devices practice respondent’s patents. To the contrary, the agreement specifically contemplates that disputes regarding patent coverage may arise, and it establishes a structured process for resolving them. J.A. 13. Accordingly, the question that petitioner seeks to have answered (*i.e.*, whether its accused devices practice either of respondent’s patents) is the very question that the license left open to be resolved by a court’s declaratory judgment. As the Court said in *MedImmune*: “Petitioner is not repudiating or impugning the contract * * *. Rather, it is asserting that the contract, properly interpreted * * * does not require the payment of royalties *because the patents do not cover its products.*” 549 U.S. at 135 (emphasis added).

b. Because the licensing and tolling agreements authorized petitioner to practice respondent’s patents so long as petitioner complied with the agreement’s terms (*e.g.*, by paying the contractually-specified royalties into

a segregated fund), respondent could not succeed on any counterclaim for infringement damages even if it established that petitioner's devices were within the patent's scope. See 35 U.S.C. 271(a); J.A. 13 (licensing agreement provides that, so long as contractually-specified royalties are paid, respondent "shall not make claims for wilful infringement or punitive damages" and shall not "seek injunctive relief"); Br. in Opp. 16 (stating that respondent "did not assert infringement, and could not do so because [petitioner] was a licensee who had not breached its license"); pp. 11-12, *supra*. But while the agreement protected petitioner from potential liability for *infringement*, it did not pretermitt judicial consideration of the question whether petitioner's devices *practice* respondent's patents.

Nor did the licensing arrangement suggest that the coverage question would be resolved under legal rules different from those that would apply in an infringement suit. To the contrary, the agreements between the parties, and respondent's own filings and communications, repeatedly use variants of the word "infringe" to refer to respondent's assertions that petitioner's devices practice the patents at issue here.¹¹ By stating that petition-

¹¹ See J.A. 13 (license agreement provides that, when "Lilly or the Mirowski family believes that [a Medtronic] device infringes one or more of the Mirowski patent(s), Lilly shall notify Medtronic of such infringement"); J.A. 23 (tolling agreement states that litigation is tolled for a period "after receipt by Medtronic of a notice of infringement from Guidant or Mirowski"); J.A. 28 (tolling agreement specifies that respondent will be "entitled to recover" royalties from the escrow account to the extent that petitioner's products are "held to infringe" respondent's patents); J.A. 48, 49 (respondent's answer to petitioner's declaratory-judgment complaint "admits that [respondent] has asserted that [several of petitioner's] products infringe at least one of [various claims in respondent's patents]").

er “shall have the right to challenge Lilly’s assertion of infringement * * * through a Declaratory Judgment action,” J.A. 13, the license agreement clearly authorized petitioner to contest respondent’s assertions regarding patent *coverage*. And the terminology in the licensing and tolling agreements belies any inference that the parties viewed the concepts of patent infringement and patent coverage as meaningfully distinct.

c. The Federal Circuit also erred in concluding that petitioner—which “is paying money into escrow” and “wants to stop,” Pet. App. 12a—“is the only party seeking the aid of the court,” *id.* at 14a. In the court’s view, petitioner needs to satisfy its burden of proof in order for “the court to disturb the status quo.” *Id.* at 13a.

In fact, both parties are seeking to alter the status quo. The disputed royalties are currently in a segregated account established by petitioner. J.A. 22, 27. Once this case has been finally resolved, petitioner will be required under the terms of the tolling agreement to “cause distribution of the total amount in [that] account to [respondent] or to [petitioner] in a manner consistent with” the outcome of this case. J.A. 28. Respondent therefore has not yet received the royalties to which it believes it is entitled, and it (like petitioner) seeks a judicial decision that will cause money currently outside its control to be transferred to its possession.

That aspect of the parties’ agreement further undermines the court of appeals’ conclusion that petitioner should bear the burden of disproving patent coverage because respondent cannot counterclaim for infringement. The practical effect of the licensing and tolling agreements is to substitute one form of monetary relief (accumulated royalties in an amount agreed to by the parties) for another (infringement damages as deter-

mined by the court) if respondent ultimately prevails on the issues of patent coverage and validity. There is no sound reason to treat that remedial choice as a basis for altering the legal rules under which the merits of the suit will be adjudicated.

Thus, even assuming that the burden of proof generally should belong to the party that requests judicial relief, that proposition does no meaningful work in this case. The parties' licensing arrangement reflects their mutual agreement to have the scope of respondent's patents (and the extent of petitioner's royalty obligations) resolved in this declaratory-judgment action. The final decision in this case cannot possibly result in preservation of the status quo, but will necessarily produce affirmative relief for one side or the other.

2. *MedImmune and broader patent policy concerns counsel against the Federal Circuit's exception for licensees*

a. In *MedImmune*, this Court held that the existence of a patent-licensing agreement (and a licensee's failure to breach the agreement) did not preclude the licensee from having an actual controversy with patent assignees that was sufficient, for purposes of Article III and the Declaratory Judgment Act, to support the licensee's request for a declaratory judgment that the underlying patent was invalid, unenforceable, or not infringed. 549 U.S. at 120, 137. The Court recognized that the licensee's continuing payment of royalties under the agreement eliminated any imminent risk that an infringement suit would be filed against it. *Id.* at 128. The Court concluded, however, that the licensee nevertheless had Article III standing to seek the declaratory judgment "because the threat-eliminating behavior was effectively coerced," *id.* at 129, by the prospect that the

licensee's sales might be enjoined, and that the licensee might be subject to treble damages and attorney's fees, if it ceased making royalty payments, see *id.* at 122, 128.

The Court in *MedImmune* canvassed several of its declaratory-judgment precedents and concluded that “the very purpose of the Declaratory Judgment Act [was] to ameliorate” a recurring “dilemma.” 549 U.S. at 129 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967)). If the declaratory-judgment mechanism were not available, a person who believed particular conduct to be lawful, but who recognized that a court might ultimately reach a different conclusion, would be forced to choose “between abandoning his rights or risking” injurious consequences. *Ibid.*; see *id.* at 130-134. By continuing to make royalty payments under its license agreement, the licensee in *MedImmune* avoided the risk of a potential adverse judgment in a patent-infringement action, which could have resulted in an “order[] to pay treble damages and attorney’s fees” and an injunction against selling a product that had “accounted for more than 80 percent” of its sales revenue for several years. *Id.* at 122.¹² The Court held that a justiciable controversy between the parties existed regarding the licensee’s request for a declaratory judgment that the license agreement “does not require the payment of royalties because the patents do not cover its products and are invalid.” *Id.* at 135.

¹² Here, the license agreement authorized “terminat[ion of] the sublicense as to” respondent’s patents if petitioner failed to pay royalties. J.A. 13. Like the licensee in *MedImmune*, petitioner would then have been forced to choose between withdrawing its allegedly-infringing products from the market and being exposed to treble damages and attorney’s fees in a potential infringement action. See 35 U.S.C. 284, 285.

The Court in *MedImmune* had no occasion to discuss the proper allocation of burdens of proof in a declaratory-judgment action. The primary thrust of the Court’s decision, however, was that the parties’ agreement did not prevent the licensee from initiating suit because the declaratory-judgment mechanism would still serve its core purpose of ameliorating the dilemma that a potential infringer would otherwise face. Nothing in the decision suggests that, although a licensing agreement of this sort does not prevent a declaratory-judgment action from going forward *at all*, it alters the substantive rules that govern the suit’s disposition.

In the decision below, the Federal Circuit expressed concern about transforming *MedImmune*’s “shield” into a “sword” that licensees could use to “hal[e] licensors into court.” Pet. App. 14a. But the Declaratory Judgment Act’s very purpose in this context is to give the alleged infringer access to a court, “even if the patentee has not filed an infringement action” against him. *Cardinal Chem.*, 508 U.S. at 95. And the prospect of being haled into court is precisely what the license agreement told respondent to expect when it gave notice that it believed petitioner’s products infringed its patent.

b. By reducing the likelihood that the licensee will prevail, the Federal Circuit’s burden-shifting rule would deter licensees’ use of the declaratory-judgment mechanism, disserving the public interest in definitive judicial resolution of disputed issues of patent scope.

“The far-reaching social and economic consequences of a patent * * * give the public a paramount interest in seeing * * * that such monopolies are kept within their legitimate scope.” *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). In overturning the prior doctrine of licensee

estoppel, this Court explained that a rule precluding licensees from contesting the validity of the licensed patents would conflict with the strong federal policy favoring “full and free competition in the use of ideas which are in reality a part of the public domain.” *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). Although the dispute presently before this Court involves the scope rather than the validity of the relevant patents, it is equally important that “the holder of a patent should not be * * * allowed to exact royalties for the use of an idea * * * that is beyond the scope of the patent monopoly granted.” *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 349-350 (1971); see *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) (“[T]he public policy which includes inventions within the granted monopoly excludes from it all that is not embraced in the invention.”); cf. *Treemond Co. v. Schering Corp.*, 122 F.2d 702, 705 (3d Cir. 1941) (“Manifestly, the threat is as unjust if the [declaratory-judgment] plaintiff is not infringing a valid patent as it is if he is infringing an invalid one.”).

To be sure, the court below did not treat the licensing agreement in this case as a ground for outright dismissal of petitioner’s declaratory-judgment suit. By shifting to the licensee a burden of proof that the patent holder would otherwise have borne, however, the court impeded licensees’ use of the Declaratory Judgment Act to obtain definitive judicial resolution of issues of patent scope. Accordingly, the same kinds of policy concerns that encouraged this Court to overturn the doctrine of licensee estoppel (see *Lear, supra*) and to permit patent licensees to seek declaratory judgments without violating their licenses (see *MedImmune, supra*) warrant reversal of the Federal Circuit’s judgment here.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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