No. 12-1128

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

MIROWSKI FAMILY VENTURES, LLC.

Respondent,

and

BOSTON SCIENTIFIC CORPORATION and GUIDANT CORPORATION

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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CORPORATE DISCLOSURE STATEMENT

Mirowski Family Ventures, LLC is a limited liability company that is not publicly traded. It has no parent corporation and no publicly held company owns 10% or more of its stock.

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BRIEF IN OPPOSITION

Respondent Mirowski Family Ventures, LLC ("MFV") respectfully submits this brief in opposition to Medtronic's petition for a writ of certiorari.

OVERVIEW

Medtronic asserts that the Federal Circuit's decision is inconsistent with this Court's decision in *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118 (2007) and that this supposed inconsistency will result in a parade of horribles. However, there is no inconsistency, nor is there any parade of horribles.

MedImmune dealt with the not uncommon situation where the patent licensee (MedImmune) wished to challenge its liability to pay royalties for particular products, but it could not do so without running the risk that the patentee (Genentech) would regard the challenge as a breach of the license, and counterclaim for an injunction and damages. Accordingly, MedImmune continued to pay royalties. Because MedImmune continued to pay royalties, Genentech asserted that there was no justiciable controversy necessary to support declaratory judgment ("DJ") jurisdiction. The Federal Circuit agreed, but this Court disagreed, holding that MedImmune did not have to "bet the farm" to challenge its liability to pay royalties for particular products under the license. *Id.* at 134.

In the case at bar, Medtronic never had any *MedImmune* problem because the 1991 MFV-Medtronic license gave Medtronic the specific right to file a DJ action to challenge its obligation to pay royalties for particular products. Thus, unlike the situation in *MedImmune*, Medtronic never had to "bet the farm" to challenge its obligation to pay royalties under the license.

Pursuant to the license, Medtronic did file a DJ action asserting non-infringement (non-claim coverage since Medtronic remained a licensee and, therefore, could not be an infringer).[1] In the suit, Medtronic asserted that MFV had the burden to prove infringement (claim coverage). The district court agreed but the Federal Circuit reversed, holding that under the terms of the license, Medtronic had the responsibility of filing the declaratory judgment action, and it had the burden of proof because it was the only party in the suit requesting any relief. The Federal Circuit specifically noted that MFV merely desired to have the suit dismissed.

> The contract at issue here required MFV to identify products it believed were covered

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[1] 35 U.S.C. § 271(a) defines infringement as acting "without authority." As a licensee, Medtronic did not act "without authority." Similarly, both Medtronic and MFV agreed to the term in the pretrial order that - "the term 'infringement' is used in the LTA [litigation tolling agreement] to indicate claim coverage. Since Medtronic is a licensee, it cannot be an infringer." A2303. ("A___" refers to the joint appendix in the Federal Circuit appeal).

> by the contract [license]. After MFV identified those products, Medtronic was required to either pay royalties on them, or sue for declaratory judgment that the products were not covered. *Medtronic 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*. In contrast, regarding the patents at issue here, MFV seeks nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract. (footnote omitted) *In other words, it is Medtronic and not MFV that is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear*. Consistent with the above, for the court to disturb the status quo ante, Medtronic must present evidence showing that it is entitled to such relief. *If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.*

App. 12a-13a (emphasis added).

Thus, the Federal Circuit's decision is in no way inconsistent with *MedImmune*. It was the specific terms of the 1991 license that controlled and dictated the result. These terms permitted Medtronic to file

the DJ action and precluded MFV from counterclaiming for an injunction and damages since Medtronic remained a licensee. The Federal Circuit's decision that Medtronic *under these specific terms* had the burden of proof is unremarkable and consistent with applicable precedent.

STATEMENT

A. Factual Background

The patents in suit, RE38,119 ("the '119 patent") and RE39,897 ("the '897 patent"), are directed to the field of cardiology and, more particularly, to cardiac resynchronization therapy ("CRT") for treating congestive heart failure. CRT was invented by Morton M. Mower, M.D.

Dr. Mower, a practicing cardiologist for many years, is as the district court stated "a renowned researcher in the cardiology field." A107. In the 1970s and while he was a practicing cardiologist, Dr. Mower worked with Dr. Mieczyslaw Mirowski at the Sinai Hospital of Baltimore to invent the first implantable cardioverter defibrillator ("ICD") which, since its introduction, has saved countless lives. A1479-81. For this work, Dr. Mower was inducted into the National Inventors Hall of Fame. A107; A1481. After his work on the ICD, and in the 1980s while still a practicing cardiologist, Dr. Mower turned his attention to the treatment of congestive heart failure, a condition more widespread than ventricular fibrillation for which the ICD was invented. Dr. Mower recognized that the ICD, despite its

overwhelming success in saving lives, did not address the many lives lost each year from congestive heart failure. Dr. Mower also recognized that a patient could be saved by an ICD only to subsequently succumb to more prevalent chronic congestive heart failure. A1481-82.

In the late 1980s, Dr. Mower devised his cardiac resynchronization therapy for treating congestive heart failure. A1488-91. In the early 1990s, looking to have Guidant Corporation obtain FDA approval for his CRT treatment, Dr. Mower arranged for investigators to conduct trials of his treatment on patients suffering from congestive heart failure. A1491-93; A1496. Dr. Mower supplied modified pacemakers for use in the trials and they were subsequently implanted in eighteen patients.[2] A1493-97. The results of the trials were "excellent," even "amazing."

> [I]mmediately upon implanting the device, the patient starts to do very well. They feel better. They lose that ashen color. They were able to -- whereas before, they were confined to bed and a chair, they were able to walk and actually do exercise tests and things like that. And they mobilize fluid on their own. We have to cut back on the

[2] Dr. Mower arranged for these trials to be done by Dr. Patricia Bakker, a cardiac surgeon in the Netherlands (15 patients), Dr. Leslie Saxon at UCLA (one patient) and Dr. Michael Gold at the University of Maryland (two patients). As a result of the trials, Guidant began an FDA trial that resulted in a market release for Guidant's CRT device. A1492-98.

> diuretic medicine so they don't get dehydrated. And echo[e]s of the heart show an improvement in the function.

A1495; A1498.

Dr. Mower's CRT treatment for congestive heart failure uses an implanted pacemaker to continuously coordinate the contractions of the left and right ventricles of the heart. A1488-89. Dr. Mower was familiar with pacemakers and their operation from his work as a practicing cardiologist. He determined that a conventional pacemaker could be modified so as to ensure a coordinated contraction of the left and right ventricles for each heartbeat. The modification involved adding a lead and electrode from the pacemaker to the left ventricle. A1494. Dr. Mower's treatment is so effective and beneficial that it has today become the standard of care for the treatment of advanced heart failure. A1499; A1525-26.

Medtronic's statements to physicians, prospective patients, and the public speak in no uncertain terms to the remarkable effectiveness of Dr. Mower's invention. Medtronic describes CRT as "*a revolutionary new approach* to managing heart failure," "*a proven treatment* for selected patients with … ventricular dyssynchrony," and "designed to reduce symptoms and *improve cardiac function*." A2801 (emphasis added).

Medtronic also describes the benefits of Dr. Mower's CRT treatment as follows:

> Following a sensed atrial contraction or atrial-paced event, both ventricles are stimulated to synchronize their contraction. *The resulting ventricular resynchronization reduces mitral regurgitation and optimizes left ventricular filling, thereby improving cardiac function*.

A2702 (emphasis added).

> For those patients with heart failure who have electrical conduction problems of the heart, resynchronization therapy is intended to improve the heart's efficiency and increase blood flow to the body. Blood ejected from the heart is decreased in people who have heart failure, which is the reason they often experience symptoms such as fatigue, shortness of breath, and swelling (or edema) of the feet and ankles. *By improving blood flow, heart resynchronization therapy may reduce heart failure symptoms, improve quality of life and increase patients' ability to perform the tasks of daily living*.

A2902 (emphasis added).

B. The District Court's Decision

Pursuant to the 1991 license, Medtronic filed a DJ action against MFV in 2007. Medtronic asserted non-infringement (claim coverage since Medtronic was a licensee and could not infringe), invalidity and

unenforceability. In accordance with the 1991 license, MFV filed no counterclaim for injunction or damages.

The trial was to the court and not to a jury. After a five day trial and post-trial briefing, the district court held against Medtronic on validity and enforceability, but against MFV on infringement (claim coverage), holding that MFV had the burden of proof on this issue and had not sustained this burden.

As to infringement (claim coverage), Medtronic asserted that MFV's expert Dr. Berger had not covered in his expert report each of the elements of the patent claims at issue. However, Medtronic declined to identify any element that Dr. Berger had supposedly not covered in his report. After post-trial briefing, and presumably reluctant to rule against MFV on this issue without identifying any missing element, the district court *sua sponte* made its own review, and concluded that Dr. Berger's report did not cover the "sense amplifier." On this basis, the district court then held that MFV had not sustained its supposed burden of proof.

This district court erred on this point for a number of reasons. First, Dr. Berger's report did include the sense amplifier. Second, most of the claims at issue in both the '119 and '897 patents did not recite a sense amplifier and, therefore, did not require its presence. Third, Medtronic's engineer Ms. Kleckner, who had helped design its CRT device testified at trial that Medtronic's devices did include the sense amplifier. Fourth, Medtronic had limited

the infringement issues through discovery so as not to include the sense amplifier. Fifth, since MFV did not (and could not) counterclaim for infringement, Medtronic was the only party requesting any relief and, therefore, had the burden of proof.[3] Sixth, contrary to Medtronic's assertion (at 7) that "MFV did not offer any affirmative evidence of infringement," Dr. Berger's testimony at trial (and his expert report) applied each element of each claim at issue including the sense amplifier to each Medtronic CRT device.[4]

C. The Federal Circuit's Decision

The Federal Circuit addressed only the burden of proof issue as to infringement (claim coverage) and held that Medtronic, not MFV, had the burden of proof because Medtronic was the only party requesting relief.

> Medtronic 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*. In contrast, regarding the patents at issue here, *MFV seeks nothing more than to be discharged from the suit* and be permitted to continue the quiet enjoyment of its contract.

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[3] See MFV's opening (blue) brief before the Federal Circuit (filed July 13, 2011) at 39-60.

[4] *Id.* at 13-27

> (footnote omitted)"

App. 12a (emphasis added).

The Federal Circuit further held that it was Medtronic, not MFV, that sought to disturb the status quo.

> In other words, *it is Medtronic and not MFV that is asking the court to disturb the status quo ante* and to relieve it from a royalty obligation it believes it does not bear. Consistent with the above, *for the court to disturb the status quo ante, Medtronic must present evidence showing that it is entitled to such relief. If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.*

Id. at 12a-13a (emphasis added).

The Federal Circuit relied upon this Court's precedent in holding that the party seeking relief, Medtronic, bears the burden of proving the allegations in its DJ complaint.

> Generally, *the party seeking relief bears the burden of proving the allegations in his complaint. See Schaffer ex reI. Schaffer v. Weast,* 546 U.S. 49, 56-57 (2005). "Perhaps the broadest and most accepted idea is that

> the person who seeks court action should justify the request ...." *Schaffer,* 546 U.S. at 56 (quoting C. Mueller & L. Kirkpatrick, *Evidence* § 3.1, p. 104 (3d ed. 2003)). "*The burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion*." *Id.* (quoting 2 J. Strong, *McCormick on Evidence* § 337, p. 412 (5th ed. 1999)).

Id. at 9a-10a (emphasis added).

The Federal Circuit further held that MFV did not have the burden of proof because it did not (and could not) counterclaim for infringement

> And in the customary declaratory judgment case, ... the declaratory judgment defendant must assert a counterclaim for infringement to avoid risking the loss of that claim forever. *See id. But this is not such a case. In this case, ... the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee. Here, Medtronic is shielded from any liability for infringement by its license. And MFV has not asserted a claim of infringement, nor could it because of the license.*

Id. at 12a (emphasis added).

The Federal Circuit further held that "the one claim for relief sought in this case" was the claim sought by Medtronic and it, not MFV, should bear the burden of proof on this claim.

> As noted, 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. *Instead, the one claim for relief sought in this case is the claim Medtronic asserts to be relieved from liability under the license by having a court declare the products in question to be noninfringing. Medtronic is the party seeking this relief and Medtronic must bear the burden of proving it is entitled to such relief.*

Id. at 14a (emphasis added).

To hold otherwise would allow licensees "to use *MedImmune's* shield as a sword."

> *A contrary result would allow licensees to use MedImmune's shield as a sword -- haling licensors into court and forcing them to assert and prove what had already been resolved by license.* Because the declaratory judgment plaintiff is the only party seeking the aid of the court in the circumstances presented here, that party

must bear the burden of persuasion.

Id. (emphasis added).

The Federal Circuit pointed out that the result in this case was highly dependent upon "the limited circumstance" of the specific terms in the MFV-Medtronic license.

> Therefore, this court holds 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.

Id. (emphasis added).

REASONS FOR DENYING THE PETITION

I. Contrary to Medtronic's Assertion, the Federal Circuit's Decision is Consistent with this Court's Precedent and the Principles of Federal Civil Procedure.

Medtronic asserts (at 4) that MFV "accused products first marketed in 2004 of infringing patent claims first issued in 2003 and 2007, over a decade after the license was signed in 1991." However, Medtronic's chronology omits Medtronic's first DJ action against MFV in Delaware filed in 2003. The current case involves Medtronic's second generation

CRT products. The 2003 suit involved Medtronic's first generation CRT products. After a three-day bench trial in 2004, the district court held for MFV. *Medtronic, Inc. v Guidant Corp.*, 378 F.Supp.2d 503 (D. Del. 2005). The Federal Circuit affirmed. 465 F.3d 1360 (Fed. Cir. 2006). Medtronic then paid the royalties due for its first generation CRT products.

Throughout its petition, Medtronic assiduously ignores the dispositive fact that the 1991 license required Medtronic to file the DJ action (to be the plaintiff in the suit) and precluded MFV from counter-claiming for infringement (or requesting other relief) because Medtronic was still its licensee. Nowhere is this more apparent than in Medtronic's Question Presented (at i) where it fails to acknowledge that the terms of the license effectively controlled who had the burden of proof on claim coverage.

> The question presented is whether ... the licensee has the burden to prove that its products do not infringe the patent, or whether (as is the case in all other patent litigation, including other declaratory judgment actions), the patentee must prove infringement.

Medtronic's Question Presented is also incorrect in asserting that a patentee must prove infringement "in all ... patent litigation, including ... declaratory judgment actions." A patentee not asserting infringement has no obligation to prove what it does not assert.

Medtronic asserts (at 10) that there is supposedly a "fundamental principle of patent litigation that a patentee must prove infringement." However, a patentee need prove infringement only when it asserts it. There is no requirement for a patentee to prove infringement if it does not assert it, as is the case here.

Rather, the fundamental principle is as this Court held in *Schaffer v Weast*, 546 U.S. 49 (2005),

> We hold that *the burden lies, as it typically does, on the party seeking relief.*

Id. at 51 (emphasis added).

> [P]etitioners offered no persuasive reason to "depart from *the normal rule of allocating the burden to the party seeking relief*." 377 F.3d 449, 453 (2004).

Id. at 55 (emphasis added).

> We therefore begin with *the ordinary default rule that plaintiffs bear the risk of failing to prove their claims*. McCormick § 337, at 412 ("The *burdens* of pleading and *proof* with regard to most facts have been and should be *assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion*"); C. Mueller & L. Kirkpatrick, Evidence § 3.1, p 104 (3d

> ed. 2003) ("Perhaps the broadest and most accepted idea is that *the person who seeks court action should justify the request, which means that the plaintiffs bear the burdens on the elements in their claims*").

Id. at 56 (emphasis added).

> [W]e have usually assumed without comment that *plaintiffs bear the burden of persuasion regarding the essential aspects of their claims*.

Id. at 57 (emphasis added).

> [W]e will conclude that *the burden of persuasion lies where it usually falls, upon the party seeking relief*.

Id. at 57-58 (emphasis added).

Medtronic asserts (at 10) that supposedly "[t]his Court has long held that when an issue of patent infringement is contested, it is the patentee, not the accused infringer, that bears the burden of proving infringement." Medtronic cites *R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1891) and *Cammeyer v. Newton*, 94 U.S. 225, 231 (1877). However, in each case, the patentee asserted infringement against an accused infringer and, of course, had the burden of proof unlike in this case, where MFV did not assert infringement, and could not do so because Medtronic was a licensee who had not breached its license.

Medtronic asserts (at 12) that "this court has held (and the Federal Circuit recognized) that 'mere role reversal in a declaratory judgment action does not shift the burden.'" However, Medtronic is referring to a DJ action in which the patentee counterclaims for infringement. In such an instance, the patentee has the burden to prove infringement since it has asserted it. This is to be distinguished from the case at bar where MFV did not, and could not, assert infringement.

Medtronic asserts (at 13) that the Federal Circuit's decision "create[s] a gaping exception." However, the decision creates no such exception. Rather, Medtronic had the burden of proof on infringement (claim coverage) because, as held by the Federal Circuit,

> *[I]n 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.

Id. at 14a (emphasis added).

Medtronic also asserts (at 13) that "[t]his case does not meaningfully differ from a traditional declaratory judgment action for noninfringement in response to a patentee's assertion of infringement" because MFV, pursuant to the license, advised Medtronic that there was claim coverage for

Medtronic's products. However, advising Medtronic as to infringement (claim coverage) does not amount to filing a counterclaim for infringement, as would be required for MFV to have any burden of proof. Medtronic is simply railing against the terms of its license, which it sought so that it could challenge liability without running the risk of breaching its license.

Medtronic also asserts (at 13) that it "began this action" because it did not want to "risk such serious consequences" as being "'ordered to pay treble damages and attorney's fees and ... enjoined from selling' its products." However, this belies the fact that Medtronic was a licensee, who had no such risk under the 1991 license, which permitted it to challenge liability without breaching its license.

Medtronic asserts (at 14) that the Federal Circuit was wrong when it said that MFV did not seek money damages because, according to Medtronic, "MFV seeks royalties from Medtronic." However, the Federal Circuit's statement that MFV did not seek money damages refers to the fact that MFV did not seek money damages *in this suit*, *i.e.*, it did not counterclaim for infringement. Again, Medtronic is simply railing against the terms of its license, which it sought so that it could challenge liability without risking breaching its license.

Medtronic also asserts (at 14) that "the only difference between this case and a traditional infringement suit is that the parties have, through their license agreement, already fixed the measure of

damages to be paid in the event of an adjudication of infringement. (footnote omitted)" However, in a traditional infringement suit, the patentee seeks an injunction and past damages. In contrast, in this suit, the terms of the license preclude MFV from seeking an injunction and past damages because Medtronic's filing of a DJ action is in accordance with, and not a breach of, the 1991 license.

Medtronic asserts (at 15) that "[n]or was the Federal Circuit correct that the controversy over infringement 'had already been resolved by the license'" because, according to Medtronic, the license was entered into in 1991, and the patent claims were not issued until 2003 and 2007. However, Medtronic does not dispute that the license agreement covered subsequently issued patents. The Federal Circuit was simply referring to the fact that MFV could not assert infringement against Medtronic under the 1991 license because Medtronic had the right under the license to challenge liability.

Medtronic asserts (at 15) that "the matter in controversy is whether the patentee is entitled to take the licensee's money as compensation for infringement." However, MFV did not, and could not, counterclaim for infringement. Again, Medtronic is simply railing against the terms of the 1991 license, which it sought so that it could challenge liability without breaching the license.

Medtronic asserts (at 15, n.5) that "[c]ontrary to the Federal Circuit's suggestion, nothing in the license 'foreclosed' MFV from counterclaiming for

infringement. App. 14a." However, this was not a "suggestion" by the Federal Circuit, it was a specific holding, and Medtronic does not disagree that the 1991 license permitted Medtronic to challenge liability without risking its status as a licensee and that Medtronic could not be an infringer because it was a licensee.

Medtronic also asserts (at 15) that the Federal Circuit presumed that Medtronic's products at issue were covered by the license. However, the Federal Circuit made no such presumption. Rather, the Federal Circuit merely held that Medtronic, as the only party seeking relief had the burden to prove its entitlement to such relief.

Medtronic asserts (at 17) that the Federal Circuit's decision "sharply undercut[s] the value of this Court's holding in *MedImmune*." However, the Federal Circuit's decision does not undercut *MedImmune* in any way. *MedImmune* holds that a licensee need not breach its license ("bet the farm") in order to create a justiciable controversy as to its liability under the license. Medtronic already had the right to file a DJ action against MFV without breaching the 1991 license, some 16 years before *MedImmune*. Further, the Federal Circuit's decision pertains only to "the limited circumstance" (App. 14a) of the 1991 license. Also, *MedImmune* did not consider or decide who would bear the burden of proof on claim coverage if the patentee did not counterclaim for infringement or seek any other relief.

II. Contrary to Medtronic's Assertion, the Federal Circuit's Decision Has No Far-Reaching or Negative Effect.

Medtronic asserts (at 18) that the Federal Circuit's decision will "fundamentally change the law governing relationships among licensees and licensors" because it supposedly "creates a legal presumption of infringement" "by placing the burden on a licensee to prove a negative - the absence of infringement." Medtronic further asserts that this burden is "particularly difficult in a patent infringement case." Medtronic's assertion makes no sense whatsoever.

Infringement (or non-infringement) is proved by the presence (or absence) of claimed elements. The claim elements are construed by the court if the parties cannot agree to their meaning. The accused product or method is known, and can be observed and understood. Contrary to Medtronic's assertion, there is no general rule or understanding that non-infringement is always difficult to prove because non-infringement is the negative of infringement. In fact, just the opposite is true as is apparent from the many motions for summary judgment of non-infringement considered by the Federal Circuit each year.

Further, the fact of the matter is that in many cases, non-infringement may be easier to prove than infringement because unlike the case where the patentee has to prove the presence of *all* claim elements in the device at issue, the accused infringer only need show that any *one* of the claimed elements

(and any equivalent) is absent to prove non-infringement.[5]

Medtronic is also wrong in asserting (at 18) that the Federal Circuit's decision creates "a legal presumption of infringement." The Federal Circuit only held that, under the terms of the 1991 license, Medtronic had the burden of proof, not that Medtronic had this burden because infringement was presumed.

Medtronic also asserts (at 18) that "[p]atents typically contain dozens, often hundreds of individual claims, infringement of any one of which triggers liability." Medtronic also asserts (at 3) that in this case "the asserted patents include hundreds of individual claims." However, Medtronic acknowledges (at 6) that in this case, only 29 claims were involved (from two patents), not hundreds of claims as implied by Medtronic (at 3, 5 and 18).

Medtronic asserts (at 19) with reference to the doctrine of equivalents ("DOE") that "[r]equiring a licensee to prove noninfringement would require it to anticipate and refute all theories under which the accused products could [be] said to perform in 'substantially the same way' as the claimed invention." Medtronic's assertion is baseless. The licensee need only address DOE for any claim limitation(s) it is asserting is not present in the device(s) at issue.

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[5] This is the familiar "all elements rule" used to prove the presence or absence of infringement.

Further with respect to DOE, Medtronic states (at 8) that the district court held that MFV "fail[ed] to execute a proper doctrine of equivalents analysis." However, the district court erred in this regard because it did not appear to recognize that such an analysis is not restricted to the "function-way-result" test, but instead, can employ the "insubstantial differences" test which Dr. Berger used in his analysis.[6]

Medtronic also asserts (at 19-20) that the Federal Circuit's decision will "increase the frequency of patent litigation, because it undermines the utility of several means by which parties have heretofore avoided disputes over products not yet in existence" and "will be particularly problematic in situations where industry participants pool their collective resources in a standards-setting organization ... ." However, Medtronic offers no reason why the Federal Circuit's decision will have any such effect and, indeed, there will be no such effect. As the Federal Circuit specifically held, its ruling applies only to "the limited circumstance" of the 1991 license. App. 14a.

Medtronic asserts (at 20) that "[u]nder *MedImmune,* licensees faced with this type of dispute should be able to file declaratory judgment actions in order to force the patentee to prove its assertion of infringement (and of essentiality)." However, *MedImmune* did not hold that in a DJ action by a licensee, that the patentee has the burden of proof on

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[6] See MFV's opening (blue) brief before the Federal Circuit (filed July 13, 2011) at 55-60.

claim coverage. Rather, *MedImmune* held that there was a justiciable controversy even if the licensee continued to pay royalties to the patentee to avoid breaching the license. *MedImmune* did not hold that the patentee has the burden of proof where it does not counterclaim for infringement and the only party requesting relief is the licensee.

Similarly, Medtronic asserts (at 21) that "[a] party accused of infringing a patent falling within the scope of such a cross-license could, under *Medlmmune,* file a declaratory judgment action and force the patentee to prove its infringement allegations." However, as noted above, *MedImmune* did not hold that the patentee has the burden of proof where it does not counterclaim for infringement and the only party requesting relief is the licensee.

Medtronic also asserts (at 21) that "[t]he Federal Circuit's new regime, however, will require the cross-licensee to prove that it is not an infringer, thereby decreasing incentives for parties to resolve actual and prospective disputes via broad cross-licenses to each other's patent portfolios." However, there is no "new regime." The Federal Circuit merely ruled as to the terms of the 1991 license. Parties are free to agree in any "broad cross-licenses to each other's patent portfolios" who will have any burden of proof. Medtronic had the burden of proof under the terms of the 1991 license because MFV did not, and could not, counterclaim for infringement, and Medtronic was the only party seeking relief.

Medtronic asserts (at 21-22) that "[t]he Federal Circuit's decision in this case improperly encumbers the protection afforded by *Medlmmune,* by requiring the licensee to assume the burden of proof on the issue of infringement as a price of filing a declaratory judgment action." However, as noted above, *MedImmune* did not hold that the patentee has the burden of proof where it does not counterclaim for infringement and the only party requesting relief is the licensee.

Medtronic asserts (at 22) that "[t]he Federal Circuit also unnecessarily imposed a cost on licensees who attempt, in good faith, to develop products that are *not* covered by a licensed patent; such products would nonetheless be *presumed* to infringe simply upon the patentee's assertion." (Emphasis by Medtronic.) However, the Federal Circuit's decision creates no presumption of infringement. The Federal Circuit merely held that, under "the limited circumstance" (App. 14a) of the 1991 license, Medtronic had the burden of proof because MFV was precluded from counterclaiming for infringement, and Medtronic was the only party seeking relief.

Medtronic also asserts (at 22) that "[t]he Federal Circuit's ruling also rewards licensors who make out-of-court demands for royalties based on general assertions that the licensee's products infringe any of the licensed patents, knowing that the licensor has no requirement actually to prove those infringement allegations." Medtronic's assertion is baseless. If Medtronic is able to prove a *prima facie* case of non-infringement, MFV will have to disprove Medtronic's

prima facie case, even through Medtronic will have to bear the ultimate burden of proof because it is the only party requesting relief.

Lastly, Medtronic asserts (at 22) that there is a supposed "settled principle that the patentee always bears the burden of proving its infringement allegations." However, there is no such settled principle, and Medtronic is unable to cite any case for such a principle. Rather, as held by the Federal Circuit,

> As noted, 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. *Instead, the one claim for relief sought in this case is the claim Medtronic asserts to be relieved from liability under the license by having a court declare the products in question to be noninfringing. Medtronic is the party seeking this relief and Medtronic must bear the burden of proving it is entitled to such relief.*

App. 14a (emphasis added).

CONCLUSION

For the foregoing reasons, Medtronic's petition should be denied.

Respectfully submitted,

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