No. 12-_____

IN THE
Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

Mark C. Fleming
Wilmer Cutler Pickering
Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Martin R. Lueck
Counsel of Record
Jan M. Conlin
Stacie E. Oberts
Robins, Kaplan, Miller & Ciresi LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500

Attorneys for Petitioner

March 14, 2013

QUESTION PRESENTED

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007), this Court ruled that a patent licensee that believes that its products do not infringe the patent and accordingly are not subject to royalty payments is "not required … to break or terminate its … license agreement before seeking a declaratory judgment in federal court that the underlying patent is … not infringed."

The question presented is whether, in such a declaratory judgment action brought by a licensee under *MedImmune,* 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.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

There are no parties to the proceedings other than those listed in the caption.

Petitioner Medtronic, Inc. has no parent corporations and no publicly held company owns 10% or more of its stock.

Page

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Page

Page

Statutes

Page

Other Authorities

PETITION FOR A WRIT OF CERTIORARI

Petitioner Medtronic, Inc. ("Medtronic") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-18a) is reported at 695 F.3d 1266. The order of the court of appeals denying rehearing and rehearing *en banc* (App. 84a) is unreported. The opinion of the United States District Court for the District of Delaware (App. 19a-83a) is reported at 777 F. Supp. 2d 750.

JURISDICTION

The Federal Circuit entered judgment on September 18, 2012 and denied rehearing on December 14, 2012. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 281: "A patentee shall have remedy by civil action for infringement of his patent."

28 U.S.C. § 2201(a):

> In a case of actual controversy within its jurisdiction … any court of the

> United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall the force and effect of a final judgment or decree and shall be reviewable as such.

INTRODUCTION

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), this Court confirmed that a patent licensee that believes that its licensor is improperly demanding royalties for noninfringing products is not required to breach the license and risk infringement litigation, but may instead bring a declaratory judgment action asserting that "the agreement does not call for royalties because their product does not infringe the patent." *Id.* at 135. After Respondents asserted that certain of Medtronic's products were subject to the parties' license, Medtronic filed just such an action, while continuing to pay royalties under protest in a set aside account.

The Federal Circuit, however, significantly undermined the value of such an action by adopting a novel requirement that, in a declaratory judgment action under *MedImmune*, the accused infringer bears the burden of proving that its products *do not* infringe the patent. The court reached this conclusion while recognizing that, in traditional

infringement litigation—whether a coercive claim by a patentee or a declaratory judgment claim by an accused infringer—the patentee has the burden of proving infringement and bears the risk of any failure of proof.

The Federal Circuit's unprecedented ruling is contrary to the settled principle that infringement must "be shown by satisfactory proof; it cannot be presumed." *R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881). Nor does the procedural realignment of parties in a declaratory judgment action reallocate the burden of proof—a principle the Federal Circuit acknowledged. App. 10a. The Federal Circuit's conclusion that the presence of a patent license justified a fundamental departure from these principles is unsupported and deserves this Court's review.

If not reversed, the Federal Circuit's decision will have numerous undesirable consequences. First and foremost, it dramatically undercuts the holdings in *MedImmune* and the remedies it provided. Under the Federal Circuit's new regime, a declaratory judgment under *MedImmune* comes with a significant price: the duty to prove the *negative* proposition that the involved products do *not* infringe—a formidable task where, as here, the asserted patents include hundreds of individual claims and liability could rest on any one of several infringement theories. The only way a licensee could ensure that the burden of proof remains with the patentee would be to repudiate the license and invite the patentee to sue for infringement, thereby

"risk[ing] such serious consequences" as treble damages and attorney's fees—the very outcome the Court allowed licensees to avoid in *MedImmune*. 549 U.S. at 122.

The Federal Circuit's decision also effectively allows patentees to trigger a judicial presumption of infringement simply by *asserting* to their licensees that particular products are covered by the licensed patents. Such a doctrine is unsupported by anything in *MedImmune*, the Declaratory Judgment Act, the Patent Act, or this Court's patent jurisprudence. There is certainly no basis to conclude that, simply because parties sign a license agreeing to royalty payments for infringing products, the patentee's assertion that certain newly-developed products infringe should be taken as correct unless the licensee proves otherwise. Rather, the risk of nonpersuasion on the patentee's claim of infringement should be allocated identically, regardless of whether the patentee claims that the infringement is to be compensated by a royalty found by a jury (in the case of a coercive litigation) or a royalty previously determined by the parties' license agreement (in the case of a *MedImmune*-type declaratory judgment).

Here, Respondents 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. Yet, the Federal Circuit's ruling *presumes* that those products infringe the patents and *presumes* that royalties are due based simply on the patentee's vague assertion of

infringement. Under this standard, patent licensors could demand royalties from licensees for every product they make due to asserted infringement of every licensed patent, knowing that they will have no affirmative burden to prove their assertions.

The petition for a writ of certiorari should be granted.

STATEMENT

A. Factual Background

Petitioner Medtronic, one of the world's largest medical device companies, manufactures and sells thousands of products for use in various medical fields, including cardiac rhythm disease management, spinal and biologics, cardiovascular disease, neuromodulation, diabetes, surgical technologies, and emergency response systems. Medtronic's cardiovascular products include implantable cardiac stimulation devices, which help a patient maintain a normal heart rate or rhythm.

Respondent Mirowski Family Ventures, LLC ("MFV") is the owner of U.S. Reissue Patent Nos. RE38,119 and RE39,897. The patents together contain over 300 individual claims, and are generally directed to a "cardiac resynchronization therapy" device, which detects a cardiac signal resulting from a contraction of a first ventricle, and then sends an immediate and unconditional signal to stimulate contraction of a second ventricle. MFV has exclusively licensed the patents to Respondent Guidant, which is a wholly-owned subsidiary of Respondent Boston Scientific. App. 22a.

In 1991, following prior litigation, Medtronic entered into a license agreement with Respondents' predecessor-in-interest. App. 4a. The license agreement gave Medtronic the right to practice certain patents, including the predecessor to the two patents-in-suit, RE38,119 and RE39,897. App. 23a. The agreement provides that Medtronic will pay royalties for any products subject the license.

The agreement set out a procedure for determining whether new products developed by Medtronic were subject to royalty payments. If MFV believed that a new Medtronic product infringed a licensed patent, it was specifically required to identify the product and those patent claims it believed were infringed. Medtronic would then have the option of either paying royalties on the new devices or initiating a declaratory judgment action to challenge the alleged infringement and/or validity of the asserted MFV patents. App. 23a.

On October 3, 2007, and November 20, 2007, MFV sent letters to Medtronic accusing seven Medtronic devices of infringing 29 claims of the two patents-in-suit, and demanding royalties for those devices. Those products did not exist at the time of the 1991 license agreement, but rather were first marketed beginning in 2004. The claims MFV asserted also were only issued by the Patent Office in 2003 and 2007.

Because Medtronic did not believe that its products infringed MFV's patents, Medtronic filed this action on December 17, 2007. Medtronic's

complaint sought a declaration of noninfringement and invalidity of the asserted claims.[1]

B. District Court Proceedings

Before the district court, the parties disputed who had the burden of proof regarding infringement. MFV argued that Medtronic should bear the burden because: (1) "the plaintiff usually has the burden of proof"; (2) cases placing the burden of proving infringement on the patentee were "inapposite"; and (3) the district court's guidelines provided that "the party having the burden of proof on an issue is usually permitted both an opening brief and a reply brief," and Medtronic had submitted a reply brief on the issue of infringement. App. 40a.

Due to its position, MFV did not offer any affirmative evidence of infringement. Indeed, MFV served a contention interrogatory on Medtronic, demanding that Medtronic "identify each *non-infringement* assertion." App. 44a n.10 (emphasis added).

The district court rejected MFV's argument regarding the burden of proof, noting that "'[t]he burden is always on the patentee to show infringement'" and that that burden never "'shifts to the other party—the risk of decisional uncertainty stays on the proponent of the proposition.'" App. 40a (quoting *Under Sea Indus., Inc. v. Dacor Corp.,* 833

---

[1] This petition is limited to the issue of the burden of proof regarding noninfringement. Other litigated issues, such as validity and claim construction, are accordingly not summarized.

F.2d 1551, 1557 (Fed. Cir. 1987) and *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)).

The district court held that Respondents had failed to prove that Medtronic's products infringed the patents either literally or under the doctrine of equivalents. App. 44a-52a. Respondents had submitted an expert report that, as the district court found, did not show that the expert "considered each limitation of each asserted claim in comparison to each accused product." App. 49a. The expert's report and testimony regarding infringement under the doctrine of equivalents, *see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), likewise "fail[ed] to execute a proper doctrine of equivalents analysis." App. 52a.

The court accordingly concluded that Respondents failed to show, by a preponderance of the evidence, that the accused products infringe the asserted claims of the reissue patents either literally or under the doctrine of equivalents. App. 49a, 52a. The court accordingly entered judgment for Medtronic as to noninfringement.

C. The Federal Circuit's Decision

A panel of the United States Court of Appeals for the Federal Circuit reversed the district court's ruling regarding the burden of proof, vacated the judgment, and remanded for further proceedings. App. 15a, 187a.

The Federal Circuit began with the "well-settled" rule that a "patentee who files a complaint or

counterclaim alleging patent infringement bears the burden of proving that infringement," App. 10a, as well as the "general proposition that mere role reversal in a declaratory judgment does not shift the burden" of proof, App. 10a. In an ordinary patent declaratory-judgment action, these principles produce a scenario in which "a declaratory judgment action of invalidity with an infringement counterclaim is nothing more than an inverted infringement suit," and the patentee retains the burden of proof on infringement. App. 11a.

The Federal Circuit departed from those settled principles, however, ruling that they did not apply in the "post-*MedImmune* world." App. 9a. The Federal Circuit ruled that, in this case, "as sanctioned by *MedImmune*, the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee." App. 12a. Although the Federal Circuit recognized that "Medtronic's suit for declaratory judgment undoubtedly rests upon the infringement provisions laid out in [35 U.S.C.] § 271," the fact that "the relief it seeks relates directly to its obligations under the license" changed the burden of proof, because in the court's view "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." App. 12a-13a. In that context, the Federal Circuit ruled, courts should presume that the accused products infringe unless proven otherwise. App. 13a ("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.").

The Federal Circuit summarized its holding as follows: "[W]hen 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." App. 14a.

The Federal Circuit denied Medtronic's petition for rehearing and rehearing *en banc*. App. 84a-85a.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Decision Conflicts with this Court's Precedent and Settled Principles of Federal Civil Procedure.

The Federal Circuit's decision conflicts with the fundamental principle of patent litigation that a patentee must prove infringement—a principle that the court acknowledged, but erroneously concluded was inapplicable to a declaratory judgment brought under *MedImmune*.

This 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. App. 10a; *see also R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881) ("Infringement must … be shown by satisfactory proof; it cannot be presumed."); *Cammeyer v. Newton,* 94 U.S. 225, 231 (1877) ("Infringement is alleged by the complainants,

and the burden is upon them to prove the allegation, as it imputes a wrongful act to the respondents.").

Assignment of the burden of proof is a substantive, and not merely procedural, rule of law. *See, e.g., Raleigh v. Illinois Dep't of Revenue,* 530 U.S. 15, 20-21 (2000) ("Given its importance to the outcome of cases, we have long held the burden of proof to be a 'substantive' aspect of a claim." (emphasis supplied)); *Dir., Office of Workers' Comp. Programs v. Greenwich Collieries,* 512 U.S. 267, 271 (1994) ("[T]he assignment of the burden of proof is a rule of substantive law …."); *Dick v. New York Life Ins. Co.,* 359 U.S. 437, 446 (1959) ("[P]resumptions (and their effects) and burden of proof are 'substantive' …."). Such substantive rights are unaffected by the declaratory nature of a proceeding, and do not vary simply because a party brings an action for declaratory judgment. *See Beacon Theatres, Inc. v. Westover,* 359 U.S. 500, 508-509 (1959) ("the plan of … the Declaratory Judgment Act [was] to effect substantial procedural reform while … leaving substantive rights unchanged"); *see id.* at 514 (Stewart, J., dissenting) ("[T]he Declaratory Judgment Act did not 'expand' the substantive law."); *United States v. West Virginia,* 295 U.S. 463, 475 (1935) ("[The Declaratory Judgment Act] does not purport to alter the character of the controversies which are the subject of the judicial power under the Constitution.").[2]

---

[2] *See also CGM, LLC v. BellSouth Telecommunications, Inc.,* 664 F.3d 46, 55 (4th Cir. 2011) ("[The Declaratory Judgment Act] is remedial only and neither extends federal courts' jurisdiction nor creates any substantive rights.");

Consistent with these principles, this court has held (and the Federal Circuit recognized) that "mere role reversal in a declaratory judgment action does not shift the burden." App. 11a; *see also Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1880) ("[T]he burden to prove infringement never shifts."); 3D Moore's Federal Practice § 57.62[2][d] ("In patent, copyright, and trademark cases, courts have generally recognized that any role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit.") (collecting cases); *cf. Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (finding it "immaterial" to a determination of whether an Article III controversy exists that "in the declaratory judgment suit, the position of the parties in the conventional suit are reversed; the inquiry is the same in either case"); *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 244 (1937) ("But the

---

Medical Assur. Co. v. Hellman, 610 F.3d 371, 377 (7th Cir. 2010) ("[The Declaratory Judgment Act] does not, and arguably could not, affect the underlying substantive state and federal laws that define the rights of the parties. A federal court applying the Declaratory Judgment Act must evaluate the parties' rights based on the same body of substantive law that would apply in a conventional action."); *Hanson v. Wyatt,* 552 F.3d 1148, 1157 (10th Cir. 2008) ("The Declaratory Judgment Act does not create substantive rights." (alterations omitted)); *B. Braun Med. Inc. v. Abbott Labs.,* 124 F.3d 1419, 1428 (Fed. Cir. 1997) ("Given that the Act merely provides a new noncoercive remedy, it should come as no surprise that the practice in declaratory judgment actions is, on almost every point, the same as in any civil action." (internal quotation marks omitted)).

character of the controversy and of the issue to be determined is essentially the same whether it is presented by the insured or by the insurer…. It is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative.").

Despite recognizing these principles, the Federal Circuit created a gaping exception to them in what it called "the post-*MedImmune* world." App. 9a. But nothing in *MedImmune* or the nature of the declaratory judgment action it permitted envisions that a licensee will be required to shoulder the burden of proving *noninfringement*, contrary to the ordinary procedure in a patent infringement case (including most declaratory judgment cases).

This case does not meaningfully differ from a traditional declaratory judgment action for noninfringement in response to a patentee's assertion of infringement. The controversy began not with any assertion by Medtronic, but with MFV's assertion that Medtronic's products infringed its patents and demand for royalties in the amount fixed by the license agreement. MFV's assertion amounted to a contention that, unless Medtronic paid, it would be in breach of the license and subject to a patent infringement suit, in which Medtronic "could be ordered to pay treble damages and attorney's fees, and could be enjoined from selling" its products. *MedImmune*, 549 U.S. at 122. Rather than "risk such serious consequences," Medtronic paid the demanded royalties into a set aside account and began this action. *Id.*

The Federal Circuit misinterpreted this situation as one in which MFV did not "seek[] money damages … based on patent infringement" (App. 14a), but rather sought "nothing more than to be discharged from the suit" (App. 12a). MFV of course seeks more than that; it seeks the royalties that it initially demanded for the products that *it asserted* infringed its patents. Although Medtronic was the party that initiated this action after MFV asserted infringement (as this Court envisioned in *MedImmune*), that does not alter the fact that MFV seeks royalties from Medtronic, nor should it affect the allocation of the burden of proof.[3]

Indeed, the only difference between this case and a traditional infringement suit is that the parties have, through the license agreement, already fixed the measure of damages to be paid in the event of an adjudication of infringement.[4] There is no reason to think that that agreement about *damages*,

---

[3] Medtronic does not demy its obligation to pay royalties on products actually covered by the license; indeed, it has already paid millions in royalties to MFV under the license. The breadth of the license is yet another reason Medtronic did not wish to repudiate it, as the consequences would have extended more broadly than the products at issue in this case. Instead, it sought to do just as the licensee in *MedImmune* did: to put the patentee's infringement contention before the district court for adjudication.

[4] There is nothing unusual about parties stipulating to the amount a patentee will recover if infringement is found. *E.g.*, Brief for Respondents 11, *Microsoft Corp.* v. *AT&T Corp.*, No. 05-1056 (reporting that the parties entered into an agreement that preserved Microsoft's challenge to liability for infringement and "prescribe[d] different dollar amounts that Microsoft must pay AT&T depending on the outcome").

without more, alters the burden of proof with respect to *liability*.

Nor was the Federal Circuit correct that the controversy over infringement "had already been resolved by the license" (App. 14a); nothing in a *1991* license agreement resolved, or could have resolved, the question whether products Medtronic began marketing in 2004 infringed patent claims that were issued in 2003 and 2007. Rather, the license expressly provided that a disagreement over such a matter would be adjudicated in the way this Court envisioned in *MedImmune*: through a declaratory judgment action.

In such a situation, there is certainly a "principled reason" (App. 13a) for requiring the patentee to prove its entitlement to royalties. Although the licensee is nominally the declaratory judgment plaintiff, the matter in controversy is whether the patentee is entitled to take the licensee's money as compensation for infringement. There is, by contrast, no principled reason for presuming, as the Federal Circuit did, that products not identified in the license agreement and that did not exist at the time of the agreement infringe patent claims that likewise were not issued at the time of the agreement.[5]

---

[5] Contrary to the Federal Circuit's suggestion, nothing in the license "foreclosed" MFV from counterclaiming for infringement. App. 14a. MFV had no *need* to do so, because Medtronic was continuing to pay royalties under protest on the disputed products into a set-aside account, but it was not precluded from doing so.

The Federal Circuit sought to rely on insurance coverage decisions, which it believed were "consistent" with its shifting of the burden of proof. App. 13a-14a. Contrary to the Federal Circuit's view, however, the lower courts are at best divided on allocating the burden of proof in the insurance context. "[S]ome courts believe that the insurer should bear the burden of proof when the insurer is the declaratory relief plaintiff," while "other courts argue that if the insured would have to prove entitlement to coverage or benefits in a coercive suit on the policy, the insured must still bear the burden of proof in a declaratory relief action initiated by the insurer." 3D *Moore's Federal Practice* § 57.62[2][d]; *see, e.g.*, *Am. Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) (placing burden of proof on declaratory judgment defendant because he "asserted the affirmative of the question asked of the jury and … would lose in the absence of any evidence on the issue"). The division among lower courts on this issue in the insurance context would be reason enough to grant certiorari; the Federal Circuit's importation of that disagreement into the patent context is all the more reason to do so, particularly given the consequences that the ruling below will have if left undisturbed. *See infra* Part II.

Moreover, courts that shift the burden from the insured to the insurer as a declaratory judgment plaintiff often do so based on a concern that an unsuspecting insured should not be hauled into court and then required to bear a burden of proof. *See, e.g.*, *Am. Eagle*, 85 F.3d at 331; *Fireman's Fund*

Ins. Co. v. Videfreeze Corp., 540 F.2d 1171, 1175 (3d Cir. 1976). That concern does not arise in declaratory judgment actions under *MedImmune*, where the patentee/declaratory judgment defendant begins the controversy by demanding royalties based on an assertion of patent infringement—and particularly where, as here, the parties' agreement *expressly envisions* that the licensee may seek adjudication of that demand through a declaratory judgment action like this one. App. 23a-24a.

By shifting the burden of proof, the Federal Circuit sharply undercut the value of this Court's holding in *MedImmune*, which envisioned that a licensee could place a patentee's demand for royalty payments before a federal court without having to breach the license and invite a coercive infringement suit from the patentee. Under the Federal Circuit's rule, a licensee who wishes to pursue that route must incur a significant cost, namely a *presumption* that its products infringe and the concomitant risk of loss if the evidence is in equipoise. A licensee who wishes to force the patentee to prove the infringement contentions that the patentee first raised by demanding royalties must apparently follow the disfavored course of baiting the patentee into assuming the role of infringement plaintiff—thereby assuming for itself the risk of multiple damages and an injunction. There is no basis for requiring that state of affairs, which (as this Court recognized in *MedImmune*) is contrary to the very purpose of the declaratory judgment remedy. *See* 549 U.S. at 122. At the very least, this Court should review the case

to determine whether *MedImmune* truly meant so little.

II. Unless Reversed, The Federal Circuit's Decision Will Have Far-Reaching Negative Effects.

The Federal Circuit's decision would fundamentally change the law governing relationships among licensees and licensors, to the detriment of innovation and dispute resolution, and with no evident benefit. The Federal Circuit's decision effectively creates a legal presumption of infringement in any *MedImmune*-type declaratory judgment action between a licensee and a patent licensor by placing the burden on a licensee to prove a negative—the absence of infringement.

While proving a negative is always difficult and rarely required (*see, e.g.*, *Miller* v. *California*, 413 U.S. 15, 22 (1973) (requiring prosecution "to prove a negative" imposed "a burden virtually impossible to discharge")), it is particularly difficult in a patent infringement case. Patents typically contain dozens, often hundreds of individual claims, infringement of any one of which triggers liability. *See, e.g.*, *Bio–Technology Gen. Corp.* v. *Genentech, Inc.*, 80 F.3d 1553, 1562 n.8 (Fed. Cir. 1996) ("Infringement of one valid and enforceable patent claim is all that is required for liability to arise.")

Moreover, a patent may be infringed not only literally—if every limitation of a claim is present in the accused product (*see Cross Med. Prods., Inc.* v. *Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310

(Fed. Cir. 2005))—but also under the doctrine of equivalents, if the accused product "'performs substantially the same function in substantially the same way to obtain the same result.'" *Warner-Jenkinson*, 520 U.S. at 38 (quoting *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877)). But infringement under the doctrine of equivalents may turn on many different theories of equivalence that are not evident on the face of the patent, but are only developed through expert testimony in litigation. *See, e.g.*, *AquaTex Industries, Inc.* v. *Techniche Solutions*, 479 F.3d 1320, 1329 (Fed. Cir. 2007) ("[T]he difficulties and complexities of the doctrine [of equivalents] require that evidence be presented to the jury or other fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert, who (on a limitation-by-limitation basis) describes the claim limitations and establishes that those skilled in the art would recognize the equivalents.")

Requiring a licensee to prove noninfringement would require it to anticipate and refute all theories under which the accused products could said to perform in "substantially the same way" as the claimed invention. Indeed, in this very case, Respondents tried to require Medtronic to do just that, submitting what the district called "vague perfunctory testimony" on the issue because they believed that it was Medtronic's duty to dispel a presumption of infringement.

The Federal Circuit's rule will also 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. The Federal Circuit's rule will be particularly problematic in situations where industry participants pool their collective resources in a standards-setting organization, which this Court has recognized creates "significant procompetitive advantages." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988). To prevent patentees from claiming ownership of widely-applicable standards (known as "patent hold-up"), standards organizations typically require members to identify all of their patents that are "essential" to the collectively-developed standard and to license the declared-essential patents on reasonable terms. *See Apple, Inc.* v. *Motorola, Inc.*, 869 F. Supp. 2d 901, 911-912 (N.D. Ill. 2012) (Posner, J., sitting by designation); Lemley & Shapiro, *Patent Holdup and Royalty Stacking*, 85 Tex. L. Rev. 1991, 2025-2029 (2007)

But most standards-setting organizations allow members to decide *unilaterally* whether one of their patents is "essential" to a standard. It is accordingly not uncommon for a licensee to dispute whether such a patent (i) is actually essential, and (ii) covers one or more of the licensee's standard-compliant products. Under *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).

Under the Federal Circuit's new burden-shifting scheme, however, a licensee to a standards-essential patent who launches a declaratory judgment action will be presumed to infringe, merely because the patentee unilaterally declared the patent to be "essential" and agreed to a license. This drastic change will upset settled expectations and chill the willingness of parties to enter into future licenses involving standards-essential patents.

The same holds true with respect to the broad patent cross-licenses that allow industry participants to promote innovation and protect freedom to operate by securing mutual "patent peace." See *United States v. Line Material Co.,* 333 U.S. 287, 291 (1948) ("Only when both patents could be lawfully used by a single maker could the public or the patentees obtain the full benefit of the efficiency and economy of the inventions."). A party accused of infringing a patent falling within the scope of such a cross-license could, under *MedImmune*, file a declaratory judgment action and force the patentee to prove its infringement allegations. The 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.

This Court has long recognized that patent licensees should not face undue obstacles in their efforts to resolve disputes regarding their obligations to licensors. *See Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). The Federal Circuit's decision in this case

improperly encumbers the protection afforded by *MedImmune*, by requiring the licensee to assume the burden of proof on the issue of infringement as a price of filing a declaratory judgment action. The 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.

The 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. Nothing in *MedImmune* requires or recommends such a drastic departure from the settled principle that the patentee always bears the burden of proving its infringement allegations.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Mark C. Fleming
Wilmer Cutler Pickering
Hale and Dorr LLP
60 State Street

Martin R. Lueck
Counsel of record
Jan M. Conlin
Stacie E. Oberts

Boston, MA 02109
(617) 526-6000

Robins, Kaplan,
Miller &
Ciresi LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN
55402
(612) 349-8500

Attorneys for
Petitioner
March 14, 2013

TABLE OF CONTENTS

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MEDTRONIC INC.,
Plaintiff-Cross Appellant,

v.

BOSTON SCIENTIFIC CORPORATION
AND GUIDANT CORPORATION,
Defendants,

AND
MIROWSKI FAMILY VENTURES, LLC,
Defendant-Appellant.

2011-1313, -1372

Appeals from the United States District Court for the District of Delaware in No. 07-CV-0823, Judge Sue L. Robinson.

Decided: September 18, 2012

MARTIN R. LUECK, Robins, Kaplan, Miller & Ciresi L.L.P., of Minneapolis, Minnesota, argued for plaintiff-cross appellant. With him on the brief were JAN M. CONLIN and STACIE E. OBERTS.

ARTHUR I. NEUSTADT, Oblon, Spivak, McClelland, Maier & Neustadt, LLP, of Alexandria, Virginia, argued for defendant-appellant. With him on the brief were THOMAS J. FISHER and JOHN F. PRESPER.

Before LOURIE, LINN, and PROST, Circuit Judges.

LINN, Circuit Judge.

Medtronic, Inc. ("Medtronic") filed a complaint in the United States District Court for the District of Delaware seeking declaratory judgment of noninfringement and invalidity of Mirowski Family Ventures, LLC's ("MFV") U.S. Reissue Patents No. RE'38,119 ("RE'119 Patent") and No. RE 39,897 ("RE'897 Patent"). The district court entered judgment of noninfringement in favor of Medtronic and judgment of validity and enforceability in favor of MFV. *Medtronic, Inc. v. Boston Scientific Corp.,* 777 F. Supp. 2d 750 (D. Del. 2011). MFV appeals the district court's judgment of noninfringement and Medtronic cross appeals the district court's claim construction on which its judgment of validity is based.[1] Because the district court relied on a legally incorrect allocation of the burden of proof to find noninfringement in the limited circumstances of this case and incorrectly construed the claim terms in question, this court vacates and remands.

[1] Medtronic has not appealed the district court's enforceability ruling and that issue is therefore not considered in this appeal.

I. BACKGROUND

Between 1969 and 1980, Dr. Morton Mower ("Mower") worked with Dr. Mieczyslaw Mirowski to develop the first implantable cardioverter defibrillator ("ICD"). An ICD is a device that is implanted into a patient's chest to monitor the patient's heartbeat. When the ICD detects a very rapid heartbeat that could cause cardiac arrest, it shocks the heart causing all muscle fibers to contract and resynchronize with the sinus node. Thus, the ICD is intended to prevent sudden death from heart attack, but is not designed to improve the general efficacy of the heart. The ICD is therefore not effective for treating heart conditions like congestive heart failure, where the underlying problem is the heart's decreasing ability to pump enough blood.

Between the 1960's and 1980's, Mower also analyzed EKG readings from congestive heart failure patients. Mower realized that slow conduction from one side of the heart to the other might be the cause of the incoordinate contractions that play a role in heart failure. Based on this observation, Mower developed what he called a biventricular pacer, a device that ultimately became known as a cardiac resynchronization therapy ("CRT") device. Mower's CRT device increases the heart's efficacy by causing both the patient's left and right ventricles to contract simultaneously as the heart beats. Mower ultimately patented the CRT device in what are now the RE'119 and RE'897 Patents, both assigned to MFV. MFV exclusively licenses both patents to Guidant Corp.

Medtronic is a leading manufacturer of medical devices and equipment. In 1991, Medtronic entered into a sublicense agreement covering the RE'119 Patent with Eli Lilly & Co., Guidant's predecessor-in-interest of the patents-in-suit. That agreement allowed Medtronic to challenge the RE'119 Patent's validity, enforceability, and scope via a declaratory judgment action. In 2003, as required by the sublicense, Medtronic began paying royalties into escrow while challenging the validity of the RE'119 Patent. Ultimately the parties entered into a Litigation Tolling Agreement ("LTA") that tolled litigation and obligated MFV to inform Medtronic of which Medtronic products MFV deemed were covered by the RE'119 Patent, or subsequent reissue patents claiming priority from the RE'119 Patent (here, the RE'897 Patent), and subject to royalty payments. If Medtronic disagreed, the LTA gave Medtronic the right to retain its license and obligated Medtronic to seek a declaratory judgment of noninfringement in the United States District Court for the District of Delaware. In October and November of 2007, MFV identified several Medtronic products that MFV thought practiced its patents. Pursuant to the LTA, on December 17, 2007, Medtronic filed the complaint giving rise to this declaratory judgment action. Because Medtronic remained MFV's licensee, MFV could not counterclaim for infringement of either patent.

Throughout this litigation the parties have disagreed over whether MFV, the patentee, bore the burden of proving infringement, or whether Medtronic, the declaratory judgment plaintiff, bore the

burden of proving noninfringement. During discovery, MFV propounded an interrogatory requesting Medtronic to state the basis for its allegation in paragraph twenty-four of its complaint that "Medtronic's Accused Devices do not infringe any valid claim of the '119 Reissue Patent or the '897 Reissue Patent." Complaint at 6, *Medtronic, Inc. v. Boston Scientific Corp.*, No. 07-CV-0823 (D. Del. Mar. 30, 2011), ECF No. 1. Medtronic objected to MFV's interrogatory, maintaining that the burden to prove infringement rested on MFV and that MFV had failed to provide its infringement contentions. Medtronic ultimately responded to the interrogatory with reasons why it felt that its products do not infringe MFV's patents. On the date expert reports were due, Medtronic served the report of its expert, Dr. Charles Love ("Love"). MFV subsequently served the report of its expert, Dr. Ronald Berger ("Berger"). Consistent with MFV's contention that Medtronic bore the burden to prove noninfringement as it alleged in its complaint, Berger's report was largely responsive to Love's report, and Berger admitted that he did not expressly map the products in question to every limitation of the relevant claims. *Medtronic, Inc. v. Boston Scientific Corp.,* No. 07-CV-0823, slip op. at 22-23 (D. Del. Mar. 30, 2011) ("*Opinion*").

The district court held a bench trial on January 25-28, 2010, and March 13, 2010. The court relied on *Under Sea Industries, Inc. v. Dacor Corp.,* 833 F.2d 1551, 1557 (Fed. Cir. 1987), which states that "[t]he burden always is on the patentee to show infringement," and thus held that "[a]s the parties asserting infringement, defendants bear the burden of proof by

a preponderance of the evidence." *Opinion* at 17. "Having determined that defendants, as patentees, have the burden to prove infringement," *id.* at 20, the court found that Berger's testimony lacked sufficient foundation because of his failure to consider "each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions," and that defendants "failed to prove literal infringement by a preponderance of the evidence," *id.* at 24. The court also found Berger's report and testimony conclusory and insufficient to show that the products infringe the patents under the doctrine of equivalents. *Id.* at 25-26.

Finally, the district court, in conducting its claim construction, relied on portions of the specification that describe the invention in the context of treating congestive heart failure to construe the preamble terms "improving the hemodynamic efficiency of a heart," RE'119 Patent col. 10 ll. 1-2, 25-26, and "bi-ventricular pacemaker," RE'119 Patent col. 11 l. 1, col. 12 l. 1, as limited to the treatment of congestive heart failure. *Opinion* at 12-14; *see, e.g.*, RE'119 Patent col. 1 ll. 18-22 (stating in the specification that "[t]his invention pertains to . . . a method for increasing the cardiac output of a patient suffering from congestive heart failure by stimulating the heart of the patient at multiple sites simultaneously"), col. 3 ll. 13-15 (stating in the specification that "an objective of the present invention is to provide a cardiac pacer for increasing hemodynamic efficiency of a heart experiencing a conduction deficiency.").

MFV appeals the district court's grant of declaratory judgment of no literal infringement and no in-

fringement under the doctrine of equivalents. Medtronic cross appeals the district court's claim construction ruling. This court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

Claim construction is a question of law that this court reviews de novo. *Cybor Corp. v. FAS Techs.,* 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc). This court also reviews a district court's other legal conclusions, such as who bears the burden of proof, de novo. *Madey v. Duke Univ.,* 307 F.3d 1351, 1358 (Fed. Cir. 2002).

B. Burden of Proof

MFV argues that because Medtronic is the declaratory judgment plaintiff--the party seeking court action--Medtronic bore the burden of proving noninfringement, a burden it failed to carry. MFV further explains that because of the parties' licensing agreement, it could not have filed a counterclaim for infringement and the court erred by viewing MFV as a party "asserting infringement." *Opinion* at 17. MFV points out that all of the cases the district court relied on to conclude that MFV bore the burden to prove infringement are conventional claims for patent infringement by the patentee as contrasted with declaratory judgment actions by licensees. MFV also points out that the parties' agreement requires Medtronic to initiate litigation by filing a declaratory judgment action, as it has done in this case, making

Medtronic the party seeking relief from the court. Thus, according to MFV, because Medtronic filed a complaint seeking a judgment that its products do not infringe MFV's patents, Medtronic should have to prove that at least one limitation of each claim of MFV's patents is not met by Medtronic's products.

Medtronic counters that, as the district court held, the burden of proving patent infringement always lies with the patentee; that burden never shifts to the accused infringer. *Opinion* at 17. Medtronic cites *Under Sea Industries,* 833 F.2d at 1557 ("The burden always is on the patentee to show infringement."), *Technology Licensing Corp. v. Videotek, Inc.,* 545 F.3d 1316, 1327 (Fed. Cir. 2008) (burden never shifts to an accused infringer), and *Laitram Corp. v. Rexnord, Inc.,* 939 F.2d 1533, 1535 (Fed. Cir. 1991) (patentee must demonstrate every element of the claim), as support for its position. Medtronic also finds the District of Maryland's reasoning persuasive in *MedImmune, Inc. v. Centocor, Inc.,* 271 F. Supp. 2d 762 (D. Md. 2003), where, on similar facts, the court placed the burden on the patentee. Finally, Medtronic argues that because MFV complied with the requirement of the LTA to first notify Medtronic of the products accused to infringe before Medtronic filed the declaratory judgment action, MFV was in fact the party to "assert infringement" notwithstanding that it did not and could not file an infringement counterclaim.

The question before us arises as a consequence of the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118 (2007). In *MedImmune* the Court found declaratory judgment jurisdiction

notwithstanding the fact that the declaratory judgment plaintiff licensee continued to make royalty payments pursuant to a license. The Court reasoned that a licensee should not be forced to cease royalty payments and risk infringement liability before the licensee can challenge the extent of coverage of the license. *MedImmune,* 549 U.S. at 134. Thus, *MedImmune* provided licensees with a shield from the economic consequences of challenging their licensors' patents while enabling those licensees to file declaratory judgment suits to clarify the rights and obligations of the parties under their license agreements. This case requires us to determine the proper allocation of the burden of persuasion in the post-*MedImmune* world, under circumstances in which 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.

Generally, the party seeking relief bears the burden of proving the allegations in his complaint. *See Schaffer ex rel. 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 fail-

ure of proof or persuasion." *Id.* (quoting 2 J. Strong, *McCormick on Evidence* § 337, p. 412 (5th ed. 1999)). In *Schaffer*, a school district denied a student educational services under the Individuals with Disabilities Education Act. *Id.* at 54-55. The student filed suit against the school district and the Court considered which party bore the burden of proving the student was entitled to the services. After finding no guidance in the statute the Court applied "the ordinary default rule that plaintiffs bear the risk of failing to prove their claims," *id.* at 56-57, and placed the burden on the student, "where it usually falls, upon the party seeking relief," *id.* at 58.

It is, of course, well settled that a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement. *See Under Sea Indus.,* 833 F.2d at 1557; *In re Tech. Licensing Corp., 4*23 F.3d 1286, 1288-89 (Fed. Cir. 2005); *see also Tech. Licensing Corp. v. Videotek, Inc.,* 545 F.3d 1316, 1327 (Fed. Cir. 2007); *Laitram Corp. v. Rexnord, Inc.,* 939 F.2d 1533, 1535 (Fed. Cir. 1991). In the absence of a license, this court has recognized "that when the same patent is at issue in an action for declaration of non-infringement, a counterclaim for patent infringement is compulsory and if not made is deemed waived." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.,* 200 F.3d 795, 802 (Fed. Cir. 1999).

The substantive burden of proof normally does not shift simply because the party seeking relief is a counterclaiming defendant in a declaratory judgment action. *See In re Tech. Licensing Corp.,* 423 F.3d at 1288-89 (citing *In re Lockwood,* 50 F.3d 966, 976

(Fed. Cir. 1995) and recognizing that a declaratory judgment action of invalidity with an infringement counterclaim is nothing more than an inverted infringement suit); *Ranbaxy Pharms. Inc. v. Apotex, Inc.,* 350 F.3d 1235, 1237, 1239-40 (Fed. Cir. 2003) (requiring patentee seeking preliminary injunction on infringement counterclaim to show *inter alia* a likelihood of proving infringement). In *Vivid Technologies*, this court explained that "the parties bore the same evidentiary burdens whether or not the counterclaim was permitted," but did not further discuss what those burdens were. 200 F.3d at 802. Moreover, that statement was made before the Supreme Court's *MedImmune* decision and was based on the general proposition that mere role reversal in a declaratory judgment action does not shift the burden. *Id*. Specifically, *Vivid Technologies* quoted *Moore's Federal Practice* that "in patent cases 'courts have generally recognized that any role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit.'" *Id.* (quoting 12 James Wm. Moore et al., *Moore's Federal Practice* 57.62[2][d] (3d ed. 1997)). But *Moore's Federal Practice* did not consider allocating the burden of proof post-*MedImmune*, when "a coercive infringement suit" was not possible and therefore did not address Medtronic's simple role reversal argument at issue here.

These cases only stand for the rote proposition that when there is a direct claim for infringement, in a complaint or by way of counterclaim, the patentee cannot prevail without proving all the elements of

infringement under 35 U.S.C. § 271. And in the customary declaratory judgment case, like *Vivid Technologies*, 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, as sanctioned by *MedImmune*, 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. Thus, while Medtronic's suit for declaratory judgment undoubtedly rests upon the infringement provisions laid out in § 271, the relief it seeks relates directly to its obligations under the license.

The contract at issue here required MFV to identify products it believed were covered by the contract. 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.[2] In other words, it is Medtronic and not

[2] MFV initially counterclaimed for declaratory judgment of its right to recover money paid into escrow under the 2003 escrow agreement regarding U.S. Patent No. 4,407,288. This counter-

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.

This analysis is fully consistent with other areas of the law. In insurance cases, courts generally place the burden on the party seeking recovery under a policy. This is true even when the insured is the declaratory judgment defendant. *See Am. Eagle Ins. Co. v. Thompson,* 85 F.3d 327, 331 (8th Cir. 1996) ("Stripped of its procedural posture, this action is, at base, a claim by Thompson [the insured who ultimately bore the burden] that he is covered under an insurance policy and a denial by the insurer [declaratory judgment plaintiff] that coverage properly exists."). But the burden can shift to the declaratory judgment plaintiff where the insured is not seeking affirmative relief. *See Reliance Life Ins. Co. v. Burgess,* 112 F.2d 234, 237 (8th Cir. 1940) (holding that when the declaratory judgment defendant insureds "asked no affirmative relief [and] prayed only to be discharged with their costs," the burden fell on the declaratory judgment plaintiff insurance company). The Third Circuit cited Burgess as "[t]he leading case which expounded the[] guiding principles" for allocating the burden of proof in a declaratory judg-

---

claim was dismissed without prejudice pursuant to joint stipulation by the parties and is not at issue in this appeal.

ment action. *Fireman's Fund Ins. Co. v. Videfreeze Corp.,* 540 F.2d 1171, 1175 (3d Cir. 1974) (also noting that the burden often falls on the insurer in personal disability insurance cases where the issue is whether the insured is able to return to work and the insurer may cease making payments).

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. 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. 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.

In view of the above holding, the district court's finding that Berger's expert testimony lacked sufficient foundation because his report "fail[ed] to

demonstrate that [he] considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions" was clearly erroneous. *Opinion* at 24. MFV did not bear that burden of proof and its expert was therefore not obliged to do more than rebut Medtronic's contentions. The district court's conclusion that "[d]efendants have failed to prove literal infringement by a preponderance of the evidence" can not stand. *Id.* Because we reverse on this basis we need not reach the district court's conclusion regarding Berger's opinions on infringement by equivalents. We also need not address MFV's argument that Medtronic's interrogatory responses effectively conceded that all unaddressed claim limitations were satisfied. Because Medtronic, and ultimately the district court, did not appreciate the appropriate allocation of the burden of proof and how the burden affected the parties' conduct during discovery, it is within the district court's discretion on remand whether to limit Medtronic to its current interrogatory answer, or to allow Medtronic to amend its interrogatory answer to include any additional noninfringement contentions it may wish to assert.

C. Claim Construction

In its cross-appeal, Medtronic contends that the district court based its refusal to find the patents invalid on an erroneous claim construction. Medtronic argues that the district court improperly restricted the asserted claims of the RE'119 patent to treating congestive heart failure based only on the specification's disclosure of such treatment; nothing in the

specification disclaims using the invention to treat other conditions. According to Medtronic, the specification is very broad and provides examples of treating many conditions caused by conduction deficiency--some unrelated to heart failure (e.g., bundle branch blocks). Medtronic argues that the patentee did not expressly narrow or clearly disavow a broader claim scope. Finally, Medtronic notes that claim 171 of the RE'897 Patent specifically recites the limitation of "improv[ing] the pumping ability of the heart suffering from heart failure," while the other, broader claims do not. RE'897 Patent col. 21 ll. 34-35.

MFV argues that the patentee expressly defined his invention for use only in congestive heart failure. MFV also stresses that the inventor described the invention's use for treating congestive heart failure as a way to distinguish this invention from a prior art reference ("Funke"). *See* RE'119 Patent col. 2 ll. 28-33. Finally, MFV cites *SafeTCare Manufacturing, Inc. v Tele-Made, Inc.,* 497 F.3d 1262 (Fed. Cir. 2007), to argue that it is only trying to understand what the patentee has claimed and disclaimed, not to import limitations from the specification into the claims.

"[T]he words of a claim 'are generally given their ordinary and customary meaning' . . . that the term would have to a person of ordinary skill in the art in question at the time of the invention . . . ." *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (citations omitted). That person of ordinary skill in the art is deemed to understand the terms in the context of the entire patent, including the speci-

fication, *id.* at 1313, but the claim terms should not be limited to the disclosed embodiments, *id.* at 1323. Rather, claim terms should generally be given their ordinary and customary meaning unless "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC,* 669 F.3d 1362, 1365 (Fed. Cir. 2012). "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term . . . .'" *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.,* 288 F.3d 1359, 1366 (Fed. Cir. 2002)). And "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside . . . the patent," even if the terms might otherwise be broad enough to cover that feature. *Id.* at 1366 (internal citation omitted).

Here, the district court did nothing more than append the limitation "for the treatment of congestive heart failure," onto the ends of the disputed claim terms. *Opinion* at 12-14. This unquestionably added a limitation. This would only have been proper if the patentee specifically defined the terms to include that limitation, or disavowed their otherwise broad scope. While the specification explains the use of the invention to treat congestive heart failure, it also discloses the invention's value in treating other diseases. *See, e.g.*, RE'119 Patent col. 3 ll. 13-15 ("an objective of the present invention is to . . . [treat] a heart experiencing a conduction deficiency."). As for

the prior art Funke reference, the prosecution history reveals that the patentee distinguished Funke based on the placement of electrodes to stimulate only the ventricles, not based on any express use of the disclosed device to treat any particular condition. The statement in the specification that Funke does not disclose his invention's "specific use as a method of improving the cardiac output of patients suffering from congestive heart failure," RE'119 Patent col. 2 ll. 30-32, is a far cry from the clear disavowal needed to limit the claims of the RE'119 Patent. Moreover, inclusion of the express limitation "to improve the pumping ability of the heart suffering from heart failure," RE'897 Patent col. 21 ll. 33-35, in claim 171 of the RE'897 Patent, a continuation of the RE'119 Patent, suggests that the other claims that do not recite such a limitation should not be so limited. We therefore conclude that the district court erred by restricting the claimed invention to the treatment of congestive heart failure. The district court's determination of no invalidity predicated on its improper claim construction is vacated. On remand, Medtronic may press its invalidity contention based upon the correct claim construction.

CONCLUSION

For the foregoing reasons, the judgment of the district court is vacated, and the case is remanded for additional proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

Each of the parties shall bear its own costs.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC, INC. Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, and MIROWSKI FAMILY VENTURES L.L.C. Defendants.	)	Civ. No. 07-823-SLR

Arthur G. Connolly III, Esquire of Connolly Bove Lodge & Hutz LLP, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Martin R. Lueck, Esquire, Jan M. Conlin, Esquire and Stacie E. Oberts, Esquire of Robins, Kaplan, Miller & Ciresi L.L.P., Minneapolis, Minnesota.

Richard L. Horowitz, Esquire, David Ellis Moore, Esquire of Potter Anderson & Corroon, LLP, Wilmington, Delaware. Counsel for Defendant Mirowski Family Ventures, L.L.C. Of Counsel: Arthur J. Neustadt, Esquire, Thomas J. Fisher, Esquire and John F. Presper, Esquire of Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P., Alexandria, Virginia.

Frederick L. Cottrell, III, Esquire and Anne Shea Gaza, Esquire of Richards, Layton & Finger, Wilmington, Delaware. Counsel for Defendants Boston Scientific Corporation and Guidant Corporation. Of Counsel: J. Michael Jakes, Esquire and Naveen Modi, Esquire of Finnegan Henderson Farabow Garrett & Dunner LLP, Washington, District of Columbia.

OPINION

Dated: March 30, 2011
Wilmington, Delaware

I. INTRODUCTION

Plaintiff Medtronic, Inc. ("Medtronic" or "plaintiff") filed this complaint on December 17, 2007, against Boston Scientific Corporation ("BSC"), Guidant Corporation ("Guidant"), and Mirowski Family Ventures LLC ("MFV," collectively "defendants") for declaratory judgment of non-infringement and invalidity of United States Reissued Patent Nos. RE 38,119 ("the '119 patent") and RE 39,897 ("the '897 patent," collectively "the reissue patents"). (D.I. 1) Thereafter, plaintiff amended its complaint twice, first to add a defense of prosecution laches, and then to assert non-infringement of two new products. (D.I. 84; D.I. 108) BSC and Guidant filed an answer on February 2, 2008, and thereafter amended it twice. (D.I. 18; D.I. 88; D.I. 115) MFV also filed an answer on February 2, 2008 and amended it twice. (D.I. 20; D.I. 89; D.I. 114) On December 2, 2009, the parties submitted their joint claim construction chart. (D.I. 144) The court conducted a *Markman* hearing on January 7, 2010.

A bench trial was held January 25-28 and March 13, 2010 on validity and enforceability of the reissue patents and whether any of the accused products infringe any valid asserted claim. On March 30, 2010, the parties stipulated that in post-trial briefing, plaintiff would file opening and reply briefs, and defendants would file only an answering brief. (D.I. 187) On February 7, 2011, the court ordered that defendants may file a sur-reply brief addressing only the issue of infringement as

discussed in plaintiff's reply post-trial brief. (D.I. 253) Pursuant to the court's order, defendants filed a sur-reply brief on February 22, 2011. (D.I. 254) The issues at bar have been fully briefed post-trial. The court has jurisdiction pursuant to 35 U.S.C. §§ 1 et seq. and 28 U.S.C. §§ 1331, 1338(a), 1400(b) and 2201. Having considered the documentary evidence and testimony, the court makes the following findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Background

1. The parties and litigation history

1. Medtronic, BSC, and Guidant are all leading manufacturers and sellers of medical devices. (D.I. 86 at 2) Medtronic is a Minnesota corporation with a principal place of business in Minneapolis, Minnesota. (D.I. 115 at 1) Medtronic is engaged in the business of manufacturing, promoting, offering for sale, and selling certain implantable cardiac stimulation devices that are capable of providing cardiac resynchronization therapy ("CRT"). (D.I. 114 at 1; D.I. 115 at 1) BSC is a Delaware corporation with a principal place of business in Natick, Massachusetts. (D.I. 115 at 1) Guidant is an Indiana corporation with a principal place of business in Carmel, Indiana, and is a wholly-owned subsidiary of BSC. *(Id.)* Guidant is the exclusive licensee of the reissue patents. *(Id.)* MFV is a Maryland limited

liability company which holds the patent rights of Michel Mirowski, M.D., inventor of the implantable cardiac defibrillator ("ICD"), and is the assignee of the reissue patents. (D.I. 86 at 2; D.I. 114 at 1)

2. There is a long history of litigation involving the parties in the case at bar. (See D.I. 86 at 1-8) Ely Lilly & Co. ("Lilly"), Guidant's predecessor-in-interest to the reissue patents, entered into a sublicense agreement ("Lilly agreement") with Medtronic in 1991 covering, inter alia, the '119 patent. (DTX-87 at 1) The Lilly agreement gave Medtronic the right to challenge allegations of infringement of the '119 patent as well as the validity and enforceability of the '119 patent through one or more declaratory judgment actions. (*Id.*)

3. In 2003, by agreement of the parties, Medtronic began paying royalties into escrow on sales of certain products, while at the same time challenging the validity of the '119 patent ("2003 litigation").[1] (*Id.*) In 2004, the validity and enforceability of the '119 patent was also placed at issue in litigation between Guidant and St. Jude Medical, Inc. ("St. Jude litigation").[2] (*Id.*)

4. In 2006, Medtronic, Guidant, and MFV entered into a "Litigation Tolling Agreement"

---

[1] *Medtronic, Inc. v. Guidant Corp.*, No. 03-848-SLR (D. Del.)
[2] *St. Jude Medical, Inc. v. Guidant Corp.*, No. 04-0067-SLR (D. Del.)

("LTA"). (DTX-87) The LTA recognized that "an actual controversy exists . . . as to the scope, validity and enforceability of the '119 patent, and whether or not any valid and enforceable claims thereof cover Medtronic products, and consequently the proper distribution of substantial monies residing in or to be paid into various escrow accounts." (*Id.* at 2) The LTA tolled and suspended various litigation and defenses thereto pending the conclusion of the "DJ Suspension Period" and for ninety (90) days after receipt by Medtronic of a notice of infringement from Guidant or MFV. (*Id.* at 5) The "DJ Suspension Period" was defined to be "the later of: (a) final resolution of the St. Jude Litigation (including settlement thereof), or (b) October 1, 2007." (*Id.* at 2) The LTA provided that, within 60 days after the DJ Suspension Period, defendants could provide written notice to Medtronic of infringement of the '119 patent or subsequent reissue patents claiming priority to the '119 patent. (*Id.* at 5) The LTA further provided that, within 90 days after such notice, Medtronic could initiate a final declaratory judgment, in this court, challenging infringement, unenforceability and/or validity of the asserted claims of the '119 patent and any asserted claims of any subsequent reissue patent(s). (*Id.* at 6) The declaratory judgment complaint in the present action was filed pursuant to the LTA. (D.I. 1)

2. The heart, its maladies and treatment

5. The human heart is divided into four chambers. (D.I. 154, ex. 1 at ¶ 22; 0.1.146 at 3) The two upper chambers of the heart are called the left

and right atria and receive blood from the body or lungs. (D.I. 154, ex. 1 at ¶¶ 22, 23; D.I. 146 at 3) "One upper chamber is called an 'atrium,' while both upper chambers together are called the 'atria.'" (D.I. 154, ex. 1 at ¶ 22) The two lower chambers in the heart are called the left and right ventricles and are the pumping chambers of the heart. (*Id.*; D.I. 146 at 3) When the ventricles contract, blood is pumped out of the heart with enough force to push blood through the lungs and entire body. (*Id.*)

6. The left and right sides of the heart are separated by a wall, called the septum. (D.I. 154, ex. 1 at ¶ 23; D.I. 146 at 3) Deoxygenated blood (blood with no oxygen) returning to the heart from the body moves through the right side of the heart. (*Id.*) Oxygenated blood (blood with oxygen) returning from the lungs moves through the left side of the heart. (*Id.*)

7. The right atrium receives deoxygenated blood from the body. (D.I. 154, ex. 1 at ¶ 22; D.I. 146 at 3) When the right atrium contracts, blood is pushed into the right ventricle. (*Id.*) Once the right ventricle has filled, it contracts and pumps blood to both lungs. (*Id.*) Blood is circulated through the lungs where carbon dioxide is removed and oxygen is absorbed. (D.I. 146 at 3)

8. Oxygenated blood returns to the heart into the left atrium. (*Id.*) When the left atrium contracts, blood is pushed into the left ventricle. (*Id.*) When the left ventricle contracts, blood is pushed on

to the rest of the body. (*Id.*) The circulatory cycle then begins again. (*Id.*)

9. A variety of problems can cause the heart to behave abnormally. (D.I. 148, ex. 1 at 5-6) One problem involves the heart's electrical system, which can affect the timing of the heart, resulting in arrhythmias (rhythm disorders). (*Id.*) One such disorder is bradycardia, a condition in which the heart beats too slowly. (*Id.*) Tachycardia, on the other hand, is a condition in which the heart beats too rapidly. (*Id.* at 7) Fibrillation is a condition in which the heartbeat is chaotic, or irregular, and the heart may skip beats. (*Id.*)

10. Treatment of these electrical disorders usually involves an implantable electronic device for stimulating the heart. (*Id.*) Bradycardia is treated using a pacemaker, a device that sends electrical impulses to the heart through electrical leads (wires) in the right atrium and right ventricle to maintain a suitable heart rate. (*Id.* at 6-7) Tachycardia and fibrillation are usually treated using an implantable cardioverter defibrillator ("ICD"). (*Id.* at 7) Compared to pacemakers, ICDs deliver a massive high- energy pulse (shock) to the heart through electrical leads to stop the arrhythmias. (*Id.*)

11. Separate from the timing problem of arrhythmias, a heart may also suffer from structural problems that affect its pumping ability, such as heart failure. (*Id.* at 8) Heart failure is a disease in which the heart progressively loses its ability to effectively pump blood. (*Id.*)

12. Pacing of the heart, using a pacemaker, is performed in various modes described by a shorthand positional notation according to at least the following three parameters: (1) the chamber(s) where pacing occurs; (2) the chamber(s) where sensing occurs; and (3) the response to sensing. (D.I. 188 at 80:23-86:10) In this notation, the chambers paced and sensed are designated by characters, where "O" represents zero or none, "A" represents atrium, "V" represents ventricle, and "D" represents dual (A+V). (*Id.*) The response to sensing is designated by the characters "O" representing zero or none, "T" representing triggered output in response to a sensed event, "I" representing inhibited output in response to a sensed event, and "D" representing dual (T+I). (*Id.*)

13. The modes relevant to the reissue patents are: VOO, VVI, VDI, VVT, VAT, and VDD. VOO mode, also known as "Fixed-rate Ventricular pacing," describes ventricular pacing with no sensing. (D.I. 188 at 82:6-21; D.I. 193 at 42) VVI mode indicates activity is sensed in the ventricle, and stimulation of one ventricle is inhibited if intrinsic electrical activity is sensed. (D.I. 188 at 83:2-24; D.I. 193 at 42) VDI mode indicates activity is sensed in the ventricle and/or atrial chambers. and stimulation of one ventricle is inhibited if intrinsic electrical activity is sensed. (D.I. 188 at 83:2-24; D.I. 193 at 42) VVT mode, or "Triggered pacing," indicates stimulation of one ventricle is triggered upon the sensing of an electrical signal in another ventricle. (D.I. 188 at 83:25-84:3; D.I. 193 at 42) VAT

mode, or "atrial-triggered, ventricular pacing," indicates that the ventricle is paced if electrical activity is sensed in an upper (atrial) chamber of the heart. (D.I. 188 at 84:19-85:4; D.I. 193 at 42) Finally, in VDD mode, stimulation of the ventricle can be inhibited or triggered if intrinsic activity in the atrial or ventricular chambers is sensed. (D.I.188 at 85:23-86:9; D.I. 193 at 42)

3. Dr. Mower's invention

14. Dr. Mower is a renowned researcher in the cardiology field, having been inducted into the National Inventors Hall of Fame for his invention, in the 1970s with Dr. Mirowski, of the first ICD. (D.I. 189 at 479:7-481:10) As a practicing cardiologist in the 1980s, Dr. Mower concerned himself with the treatment of congestive heart failure, a condition more widespread than ventricular fibrillation for which the ICD was invented. (*Id.* at 481:20-482:8) At the time, Dr. Mower was practicing at Sinai Hospital in Baltimore, Maryland, where he "ran the heart station, which . . . did most of the EKG reading." (*Id.*) Dr. Mower noticed that "those patients who were diagnosed [with] congestive heart failure generally had widened QRSs," from which he inferred that "there was a slow conduction from one side of the heart to the other, and [] realized that there might be incoordinate contraction playing at least some role in the heart failure." (*Id.* at 488:7-22) This insight led to the invention that is the subject of the reissue patents. (*Id.* at 488:12-489:2)

15. Dr. Mower's invention is directed to a device to treat ventricular asynchrony. *Medtronic v. Guidant Corp.*, Civ. No. 03-848-SLR, 2004 WL 5501181 at *3-4 (D. Del. July 19, 2005). Ventricular asynchrony is a condition in which the patient has a conduction defect in his ventricles causing the ventricles to contract at different times. *Id.* Dr. Mower's invention addresses this defect by pacing the heart so as to cause substantially simultaneous ventricular contractions. *Id.* Unlike treating an arrhythmia (where the concern is the quantity of heartbeats), because the patient is suffering from heart failure, continuous bi-ventricular pacing improves the output of the heart and, therefore, the quality of the heartbeats. (D.I. 190 at 528:13-25) "Bi-ventricular pacing (or pacer/pacemaker)," a term used in the reissue patents, is now referred to as cardiac resynchronization therapy. ('119 patent at col. 3:56-57, col. 6:3-14, col. 7:17-20, and claims 9-13, 22-26; '897 patent, claims 132-133; D.I. 146, ex. 2 at 17)

4. The reissue patents

16. The reissue patents are both reissues of U.S. Patent No. 4,928,688 ("the '688 patent"). (Reissue patents at [64]) The '688, '119 and '897 patents are directed to a method and apparatus for treating hemodynamic dysfunction by using electrodes to simultaneously stimulate the ventricles of the heart. ('688, '119 and '897 patents, Abstract) The reissue patents share the specification and priority date of the '688 patent. (D.I. 147 at 2 n.2) The '688 patent issued on May 29,1990 from

application No. 07/299,895 ("the '895 application"), filed on January 23, 1989. ('688 patent at [21, 22, 45])

17. The '119 patent issued on May 20, 2003 from application No. 08/547,691 ("the '691 application"), filed on October 19, 1995. ('119 patent at [21, 22, 45]) The '691 application was a continuation of application No. 10/214,474, ("the '474 application") filed Aug. 8, 2002, which in turn was a continuation of application No. 07/890,280, ("the '280 application") filed May 29, 1992, which was later abandoned. ('119 patent at [63])

18. The '897 patent issued on October 23, 2007 from application No. 10/214,474, filed on August 8, 2002. ('897 patent at [21, 22, 45]) The '897 patent is a continuation of the '119 patent. ('897 patent at [63])

19. The named inventor of the reissue patents is Morton M. Mower. (Reissue patents at [75]) Since a reissued patent is valid only for the "unexpired term of the original patent," the reissue patents each expired on January 23, 2009. See 35 U.S.C. 251.

20. Defendants allege that plaintiff infringed one or more of claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 120, 144, 172,201, 217, 233, 248, 273, 288, 303, 308, 311, 315

and 324-328 of the '897 patent. (D.I. 188 at 4:22-25, 137:22-138:13; PTX-515[3])

5. Accused devices

21. Defendants accuse plaintiff's InSync, InSync ICD, InSync II Marquis, InSync Maximo, InSync II Protect, InSync Sentry, Concerto, Maximo II and Consulta devices (collectively "accused devices") of infringing the reissue patents. (D.I. 192 at 868:8-17; PTX-567) The accused devices are all cardiac resynchronization therapy devices. (D.I. 189 at 334:11-335:4) Although similar, slight differences exist among the accused products. (*Id.*) The InSync device does not provide defibrillation therapy, whereas the remaining accused devices are all CRT devices coupled with defibrillators. (*Id.*) Additionally, the InSync pacemaker does not have separate sensing and pacing circuitry for the two ventricular leads; instead, the leads are coupled together. (*Id.*) Some modes available in the other devices are not found in the InSync ICD. (*Id.*)

B. Claim Construction

22. The parties dispute construction of ten different terms of the asserted claims of the '119 patent. For the reasons discussed below, the court finds that only two terms, involving claim preambles, are dispositive of the issues at bar.

---

[3] Claims 184 and 309 of the '897 patent were originally asserted and are shown in PTX-515, but were later withdrawn. (D.I. 188 at 4:22-24)

1. Legal standard

23. Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The words of a claim "are generally given their ordinary and customary meaning," as understood by a person of ordinary skill in the art in question, read in the context of the particular claim and that of the entire patent, at the time of the invention. *Phillips v. AVVH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (*quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317 "[A] court 'should also consider the patent's prosecution history, if it is in evidence.'" *Id.* (quoting *Markman*, 52 F.3d at 980).

24. "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bell Commc'ns Research, Inc. v. VitaLink Commc'ns Corp.*, 55 F.3d 615 (Fed. Cir. 1995) (citations omitted). "[T]erms appearing in a preamble may be deemed limitations of a claim when they give

meaning to the claim and properly define the invention." *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994).

25. "Although no 'litmus test' exists as to what effect should be accorded to words contained in a preamble, review of a patent in its entirety should be made to determine whether the inventors intended such language to represent an additional structural limitation or mere introductory language." *Id.* "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (holding that a preamble reciting "an optical waveguide" was limiting as to the specific type of waveguide taught by the specification, and not to any type, as would be the case without construing the preamble as a limitation). "Whether a preamble of intended purpose constitutes a limitation to the claim is, as has long been established, a matter to be determined on the facts of each case in view of the claimed invention as a whole." *In re Stencel*, 828 F.2d 751,754 (Fed. Cir. 1987).

26. "'In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim.'" *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed.

Cir. 2008) (*quoting On Demand Mach. Corp. v. Ingram Indus.*, 442 F.3d 1331, 1343 (Fed. Cir. 2006)). "(W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d at 808. Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention," the preamble is not limiting. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

27. Having heard oral argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction, the court construes the disputed claim language consistent with the tenets of claim construction set forth by the Unites States Court of Appeals for the Federal Circuit in *Phillips*, as follows:

2. Improving the hemodynamic efficiency of a heart

28. The parties dispute whether the preambles of independent claims 15 and 19 of the '119 patent constitute limitations and, if so, their proper construction. The preambles of claims 15 and 19 are identical and recite: "A method for improving the hemodynamic efficiency of a heart comprising the steps of: . . . ." At the very outset, the specification of the '119 patent defines an objective of the invention as "a method for increasing the cardiac output of a patient suffering from congestive heart failure," and

points to this objective to distinguish over the prior art.[4] ('119 patent at col. 1:18-22) It is evident from the specification that the invention exists in the context of improving the pumping ability of a heart that is in a state of (congestive) heart failure[5] and,

---

[4] Although Funke does teach the concept of simultaneous stimulation of a plurality of spaced electrodes, he **does not disclose** its specific use as a method of **improving the cardiac output of patients suffering from congestive heart failure**."('119 patent at col. 2:28-33) (emphasis added)

[5] The specification teaches:

> The method of the present invention involves a procedure for pacing of the heart in a particular way so as to improve its contraction pattern, and thereby **augment the movement of blood through the heart**. Patients suffering from severe congestive **heart failure**, which is found not to respond well to conventional drug therapy and to have a conduction defect in the ventricle resulting in a widen [sic] Q-R-S complex have been aided by a pacing regimen in which stimulating pulses are simultaneously applied to both ventricles by way of a demand pacemaker or asynchronous pacemaker.
>
> It is theorized that a considerable part of the **hemodynamic impairment** in refractory congestive **heart failure** with conduction defects is due to an incoordinate contraction of the heart, so that a part of the heart muscle contracts and balloons out the part that is not contracting. When the latter area of the heart muscle does finally contract, the former has relaxed, so that a large part of the blood volume is merely shunted back and forth within the heart rather than being ejected as would happen with a more coordinate contraction pattern.

('119 patent at col. 3:32-51) (emphasis added)

thus, the preambles give meaning to the claims and properly define the invention. The court concludes that the preambles of claims 15 and 19 are limiting, and mean improving the heart's pumping ability for treatment of congestive heart failure. This construction is consistent with the specification: col. 1:18-22; col. 2:28-33; col. 3:12-15, 32-51; col. 4:23-27.

3. Bi-ventricular pacemaker

29. The preambles of independent claim 25 and of dependent claim 26 of the '119 patent recite, "[a] bi-ventricular pacemaker . . . ." Plaintiff argues that this phrase "merely describes the purpose of claims 25 and 26." (D.I. 147 at 10) Although admitting that these claims require the capability to stimulate two ventricles, plaintiff argues that the language of the claim body alone, without consideration of the preamble, expressly creates this limitation.[6] Claim 25 recites:

> A bi-ventricular pacemaker comprising:
> **detecting means for detecting** a cardiac signal resulting from a **contraction of a first ventricle**;
> **stimulating means for effecting** immediate and unconditional **contraction of a second ventricle** in response to the

[6] "[T]he express language of the claims (without consideration of the preamble) calls for an apparatus for stimulating or pacing the two ventricles." (D.I. 147 at 10)

> detected cardiac signal, thereby effecting simultaneous contraction of both ventricles.

('119 patent at 11:1-7) (emphasis added)

30. Excluding the preamble, claim 25 discloses stimulating means for only one ventricle, the second. It is the preamble, with its term "bi-ventricular pacemaker," that describes structure capable of stimulating two ventricles. ('119 patent at col. 3:39-55, 6:13-22) Therefore, the court finds that the preamble of claim 25 contains a structural limitation that is not present in the body of the claim and concludes that the preamble of claim 25 constitutes a limitation. A bi-ventricular pacemaker, as used in the preamble of claim 25, means a device capable of providing stimulation to either one or both ventricles to effect a coordinated contraction thereof for the treatment of congestive heart failure. This construction is consistent with the specification: col. 3:32-4:26, col. 6:3-14, col. 7:17-20. Due to its dependency on claim 25, the preamble to claim 26 is similarly construed.

C. Infringement

1. Legal standard

31. To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. *See Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336

(Fed. Cir. 2001). To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). Significant to the case at bar, if an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989).

32. To prove infringement by the doctrine of equivalents, a patentee must provide "particularized testimony and linking argument" as to the "insubstantiality of the differences" between the claimed invention and the accused product, or with respect to the function/way/result test. *See Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996).

33. Establishing the literal infringement of a means-plus-function limitation "requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999). A patentee may show structural equivalence "if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the

corresponding structure described in the specification." *Id.* The *Odetics* court differentiated between the "similar analysis" of equivalents under the doctrine of equivalents and 35 U.S.C. § 112, ¶ 6, noting that a component by component analysis is not required to establish structural equivalence in the latter. *Id.* Indeed, such an analysis would be improper to the extent that

> [t]he individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function.
> . . . The appropriate degree of specificity is provided by the statute itself; the relevant structure is that which "corresponds" to the claimed function. Further deconstruction or parsing is incorrect.

Id. at 1268 (internal citations omitted). Conversely, the relevant structure does not include "structure 'unrelated to the recited function' disclosed in the patent . . . ." *Id.* (*citing Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998)).

2. Burden of proof

34. The parties dispute which side has the burden to prove infringement at trial. Plaintiff argues that the burden is always on the patentee (defendants). (D.I. 193 at 7-9) Defendants assert that

the burden of proof was always on Medtronic as plaintiff, and argue three theories in support thereof. First, defendants argue that the Lilly agreement and the LTA provide that Medtronic must file a declaratory judgment action in order to challenge infringement, and that "the plaintiff usually has the burden of proof." (D.I. 247 at 38) Second, defendants argue that, due to these provisions, the case law cited by plaintiff is inapposite. (*Id.* at 38-39) Finally, defendants point to this court's guidelines as to post-trial briefing, establishing that the party having the burden of proof on an issue is usually permitted both an opening brief and a reply brief, whereas the opposing party is usually limited to an answering brief. (*Id.* at 39) Defendants allege that "Medtronic has taken the unusual position that it does not have the burden of proof but it is entitled to both open and reply on [the issue of infringement]." (*Id.*)

35. "The burden is always on the patentee to show infringement." *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (*citing Envirotech Corp. v. AI George, Inc.*, 730 F.2d 753, 758 (Fed. Cir.1984)). "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 - the risk of decisional uncertainty stays on the proponent of the proposition." *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (*citing Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1574 (Fed. Cir.

1985); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

36. As the parties asserting infringement, defendants bear the burden of proof by a preponderance of the evidence. *See Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991) (*citing Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983)).

3. Sufficiency of evidence

37. Plaintiff asserts that defendants' evidence of infringement is insufficient. (D.I. 193 at 9-10) During pre-trial proceedings, plaintiff requested that the court preclude Dr. Berger, defendants' expert on infringement, from testifying because "he failed to map every element of each asserted claim against the accused Medtronic devices in his expert report." (D.I. 189 at 327:4-5; D.I. 193 at 9) (*citing* D.I. 177-2 at 25; D.I. 255 at 116:11-120:3) Pursuant to the court's order of January 22, 2010 (D.I. 185), plaintiff again raised this issue during trial. (D.I. 189 at 472:2-474:11) The court, at the behest of the parties, reserved judgment on this issue pending post-trial briefing, allowing supplementation of the record. (*Id.*) In essence, plaintiff has raised a *Daubert* challenge, claiming that, in opining on infringement, Dr. Berger failed to apply reliable principles and methods to the facts of the case. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

a. Legal standard

38. The Supreme Court in *Daubert* made clear that courts have to play a gatekeeping role with respect to experts. *Daubert*, 509 U.S. at 113. According to the Supreme Court, Rule 702 of the Federal Rules of Evidence[7] is the primary locus of the gatekeeping role. Pursuant to Rule 702, a party can offer testimony of an expert witness at trial so long as the expert is qualified, the methodology the expert uses is reliable, and the opinion fits the facts of the case. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). A trial judge, then, is tasked with being a "'gatekeeper' to ensure that 'any and all expert testimony is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

39. As recognized by the United States Court of Appeals for the Third Circuit, while an expert's methodology is required to pass muster under Rule 702, the data underlying the expert's

---

[7] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. § 702.

opinion must pass muster under Rules 104[8] and 703.[9] More specifically, the Third Circuit in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994), made clear "that it is the judge who makes the determination of reasonable reliance, and that for the judge to make the factual determination under Rule 104(a) that an expert is basing his or her opinion on a type of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness." *Id.* at 748. The Third Circuit concluded in *In re Paoli* that, because the policy considerations underlying the rules of

---

[8] Rule 104 provides:

> (a) **Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) . . . .
>
> (b) **Relevance conditioned on fact.** When the relevance of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

Fed. R. Evid. § 104.

[9] Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted[.]

Fed. R. Evid. § 703.

evidence are the same, the "reliability requirement" for admission under Rules 104, 702 and 703 should be the same - "there must be good grounds on which to find the data reliable." *Id.*

b. Literal infringement

40. Having determined that defendants, as patentees, have the burden to prove infringement, the court recognizes at the outset of its discussion that there are litigation efficiencies in narrowing the issues to be resolved at trial. Therefore, if only certain limitations are in dispute, it makes sense to limit the presentation of evidence to such limitations. In this case, however, it is unclear from the record that there was an agreement among the parties to narrow the issues for trial. Aside from citing to an interrogatory response (DTX-71), it would appear that defendants relied primarily on their burden-shifting view of the case,[10] thus leaving the court

---

[10] Defendants assert that they served an interrogatory on plaintiff, requiring plaintiff to identify each non-infringement assertion. (D.I. 247 at 35-36) Continuing their position that plaintiff had the burden of proof, defendants argue that,

> [s]ince Medtronic is the plaintiff in this action, Dr. Love's non-infringement expert report came before Dr. Berger's responsive infringement expert report. While Dr. Berger's expert report was primarily directed to each of Dr. Love's non-infringement assertions, Dr. Berger did cover all the elements of the asserted claims even though he did not repeatedly point out for each claim the undisputed presence of an element such as a pulse generator or a sense amplifier.

Footnote continued on next page . . .

between a rock (the way the parties chose to litigate this case) and a hard place (the court's responsibility to make an infringement determination based on appropriate evidence). Because plaintiff has asserted consistently that Dr. Berger failed to conduct an appropriate infringement analysis in his expert report, through his deposition and at trial, and because there is no affirmative evidence excusing Dr. Berger from this responsibility, the court will review the record to test the sufficiency of defendants' infringement analysis in this regard.

41. In its post-trial brief, plaintiff points to Dr. Berger's deposition testimony in support of its argument that "his expert report did not map every element of each asserted claim against each accused product."

> Q. Okay. And you understand that in undertaking an infringement analysis what you do is map each element of the asserted claim against the accused products; right?
> A. Correct.
> Q. Okay. In this case you did not do that for each limitation of the asserted claims; correct?
> A. I believe I did do that.

. . . *footnote continued from prior page*

> Also, after Medtronic had identified its non-infringement assertions which formed the basis for its declaratory judgment complaint, there was no need for Dr. Berger to concentrate on claim elements that Medtronic did not dispute.

(*Id*. at 36).

> Q. Okay. Well let's take a look at your report. As an example if we could turn to page 56, and section O of your report is dealing with the '897 patent, Claim 217. Do you see that?
> A. Yes.
> Q. Okay. And what follows is your analysis with respect to that claim; correct?
> A. I believe so, yes.
> Q. Okay. And in fact there are certain limitations in Claim 217 for which you did not map it to the accused products; correct, doctor?
> A. Let me read the -
> Q. Sure.
> A. - section. (Witness reviewing exhibit.) Well in this section here in the - in the area of this report it does not list my opinions on each of the claims limitations, correct.
> Q. And in fact what you did, doctor, was respond to certain limitations that were addressed in the report of Dr. Love; correct?
> A. I believe that's -- I believe that was the philosophy that I took here, yes.
> Q. Okay. So you didn't in fact independently map each asserted limitation onto the accused devices; correct, doctor?
> A. In this - In this report that's correct

(D.I. 193 at 910) (*citing* D.I. 193, ex. A at 7:11-8:21)

42. Plaintiff supplemented the record with a video clip on CD media (*id.*, ex. B) purporting to show that "Dr. Berger's admissions were not 'off the cuff' or made under time restraints. Dr. Berger carefully and deliberately reviewed his expert report

for seven minutes before admitting that he failed to map the claims to the products." (D.I. 193 at 10) Plaintiff further asserts that, "[i]n addition, in their original pre-trial submission of Exhibit 5 to the Joint Pretrial Order to Medtronic, [d]efendants admitted that Dr. Berger did not address each claim limitation, stating that 'Dr. Berger was not required to map every element of each claim.'" (*Id.*) (*citing id.*, ex. C at 2)

43. Dr. Berger's expert report on infringement (D.I. 148, ex. 2, "Berger report") covers combinations of 27 claims of two patents asserted against nine accused products, and comprises 72 pages. The Berger report does not contain or reference a typical infringement analysis chart whereby each element of each asserted claim is individually compared with each accused product. Plaintiff does not assert that such a chart is required to prove infringement, although it would have certainly aided the court's determination of whether Dr. Berger's analysis met the required standard. Instead, Dr. Berger provides only a narrative discussion of various claim limitations, organized to be responsive to Dr. Love's expert report on non-infringement. (D.I. 148, ex. 1)[11]

44. Dr. Berger's analysis of claim 15 of the '897 patent serves as an example of the issue at bar. That claim recites, as the first of three limitations

[11] As can be observed by comparing the table of contents of each of the two reports.

after the preamble, "a sense amplifier to receive ventricular depolarization signals originating from a first ventricle." Dr. Berger's analysis of the entire claim is limited to a recitation of the full claim language, followed by:

> It is my opinion that each of Medtronic's cardiac resynchronization systems marketed under the names InSync, InSync II Marquis, InSync II Protect, InSync Sentry, InSync Maximo, Concerto, Consulta and Maximo II delivers a stimulating pulse to the ventricles in response to a ventricular sense for the reasons discussed above in Section V(A)(3) [sic], or does not operate substantially differently than a device that operates in this manner.

(D.I. 148, ex. 2 at 47-48, § VI(G)) Section VI(A)(3) (*id.* at 30-31), in turn, is a narrative analysis of claim 15 of the '119 patent relating to the limitation, "stimulating both ventricles . . . when a cardiac depolarization signal originating from a first ventricle is detected." The court is unable to locate any reference to the term "sense amplifier" in section VI(A)(3). Section VI(A)(3) has a further reference to unspecified preceding sections relating to the VVT mode and VSR feature. The court is also unable to locate any consideration of the "sense amplifier" limitation in preceding sections. Moreover, it is not incumbent on the court to do so.

45. Dr. Berger similarly performs his analysis of claims 54, 84, 86, 120, and 144 of the '897

patent and others. Only vague perfunctory language potentially covers the remaining elements of asserted claims. Defendants' argument that they need only address elements identified in plaintiff's response to its interrogatories or in Dr. Love's non-infringement report (collectively "non-infringement defense") is inapposite as it does not address the issue at bar, whether Dr. Berger's testimony lacks sufficient foundation.

46. The Berger report fails to demonstrate that Dr. Berger considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions.[12] Plaintiffs non-infringement defense, even if considered an admission, would not relieve Dr. Berger of this requirement absent affirmative evidence to this effect. There is no way to determine if "every limitation set forth in a claim is found in an accused product, exactly," without accounting for each limitation. Any such admission would merely render that task easier to accomplish. Defendants have failed to prove literal infringement by a preponderance of the evidence.

c. Doctrine of equivalents

47. Plaintiff contends that Dr. Berger's doctrine of equivalents analysis consists solely of

[12] The court notes in this regard that an expert cannot testify at trial beyond the opinions offered in his/her expert report. In this case, Dr. Berger's trial testimony is no more illuminating than his report and lacks a proper foundation.

conclusory statements, and fails to provide particularized testimony and linking arguments required to sufficiently prove infringement under this doctrine. (D.I. 193 at 27-28) (*citing id.*, ex. D at 19-23, 23-26, 31-33, 34-35, 36-39)

48. Defendants' argument regarding doctrine of equivalents is subsumed in their term-by-term rebuttal to plaintiff's non-infringement defenses. (D.I. 247 at 34, ¶ 9) Defendants argue, for example, with respect to the term "contractions" and the doctrine of equivalents that

> Dr. Mower's invention is directed to resynchronization of the ventricles and not to any particular manner in which a contraction is sensed (by electrical or mechanical sensing). Therefore, the resynchronization would take place using either form of sensing. Accordingly, the difference would be "insubstantial." As explained by Dr. Berger, "[t]he difference would not be substantial at all. The purpose is the same, to detect when the atria are activated."

(D.I. 247 at 24) (*citing* D.I. 189 at 342:9-13; D.I. 192 at 983:7-18; D.I. 246, ex. D, D.I. 148, ex. 2, at 31-33)

49. The Federal Circuit has explained that its "prior cases stand for the proposition that mere generalized testimony as to equivalence is insufficient as a matter of law to support a [] verdict finding infringement under the doctrine of equivalents." *Comark Commc'ns, Inc. v. Harris*

Corp., 156 F.3d 1182 (Fed. Cir. 1998). "'Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice [to show infringement under the doctrine of equivalents].'" *Id.* (*quoting Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)) (brackets retained) The Federal Circuit has also previously stated that "[t]he evidence and argument on the doctrine of equivalents cannot be merely subsumed in plaintiff's case of literal infringement. Rather, 'a patentee must prove substantial identity as to each of the function, way and result prongs of the doctrine of equivalents.'" *Id.* (*quoting Lear Siegler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422, 1425 (Fed. Cir.1989); *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1327 (Fed. Cir. 1991)) (brackets retained). "The thrust of these cases is to ensure that a [finder of fact] is provided with the proper evidentiary foundation from which it may permissibly conclude that a claim limitation has been met by an equivalent." *Id.*

50. "[W]hile infringement under the doctrine requires 'only' substantial identity, substantial identity must be proven with regard to all three elements of the doctrine specified in *Graver Tank*: function performed, means by which function is performed, and result achieved." *Lear Siegler*, 873 F.2d at 1425 (*citing Universal Gym Equip., Inc. v. ERWA Exercise Equip. Ltd.*, 827 F.2d 1542, 1548 (Fed. Cir. 1987)). "Absent the proper *Graver Tank* context, i.e., a showing of how plaintiff compares the

function, means, and result of its claimed invention with those of the accused device, a [finder of fact] is more or less put to sea without guiding charts when called upon to determine infringement under the doctrine." *Id.* at 1425-26.

51. There are numerous instances in his testimony where Dr. Berger declares equivalent structure by simply stating "[t]he difference would not be substantial at all. The purpose is the same . . . ,"or words of a very similar nature. (D.I. 189 at 342:9-13) (*see also id.* at 345:1-7, 348:3-5, 372:3-24, 373:13-17) Dr. Berger's testimony lacks sufficient foundation; his expert report reflects the same failure to execute a proper doctrine of equivalents analysis as his testimony. (*See, e.g.*, D.I. 148, ex. 2 at 19, 31, 33, 35, 48-50) Defendants have failed to show, by a preponderance of the evidence, that the accused products infringe the asserted claims of the reissue patents under the doctrine of equivalents.

D. Invalidity

52. Plaintiff frames its arguments regarding anticipation and obviousness by grouping claims according to pacemaker operational modes as follows: VOO - claim 308 of the '897 patent; VVI and VDI - claims 120, 217, 233, 288, 303, 315, 324-328 of the '897 patent; VVT - claims 15, 25, and 26 of the '119 patent and claims 15, 54, 84, 86, 144, 172, 201, and 311 of the '897 patent; VAT- claims 19 and 20 of the '119 patent; and VDD- claims 248 and 273 of the '897 patent.

1. Prior art

53. Plaintiff asserts that four alleged prior art references, either alone or in combination with each other or the state of the art, either anticipate or make obvious the asserted claims of the reissue patents: "Tyers"[13] (PTX-216); "Gibson"[14] (PTX-219); "Silva"[15] (PTX-269); and "Curtiss"[16] (PTX-217). Each of the four asserted prior art references ("asserted references") were before the examiner during prosecution of the '897 patent. (PTX-5 at MEDMIR0023011, 23017, 23018, 23148; '897 patent at [56]) Plaintiff argues that Silva renders VAT and VVT claims anticipated and/or obvious; that Gibson renders VVI and VDI claims anticipated and/or obvious; that Tyers renders VOO, VDD, and VAT claims obvious; and that Curtiss renders VVT claims obvious. (D.I. 193 at 42; D.I. 188 at 4:22-24; PTX-515)

---

[13] Tyers, G. F. O., *Comparison of the effect on cardiac function of single-site and simultaneous multiple-site ventricular stimulation after A-V block*, The Journal of Thoracic and Cardiovascular Surgery, 59(2):211-217 (1970).

[14] Gibson, D. G., et al., *Effect of Changes in Ventricular Activation on Cardiac Haemodynamics in Man*, British Heart Journal 33:397-400 (1971).

[15] *Influence of the Location of Ventricular Electrical Stimulation on Cardiac Efficiency*, Experimental and Clinical Study, Doctoral Dissertation, Lorenzo Silva Melchor, Autonomous University of Madrid School of Medicine, Madrid (1987).

[16] Curtiss, E. I., et al., *Electrocardiographically Discrete Right and Left Ventricular QRS Complexes: A Case Report*, Journal of Electrocardiology, 20(2): 162-168 (1987)

a. The state of the art

54. Plaintiff argues that "the treatment of heart failure was not a 'new' use for biventricular pacing," and that "[p]acing for heart failure was known at least as early as the late 1950s." (D.I. 193 at 36) As proof of these statements, plaintiff proffers the testimony of its expert, Dr. Benditt, in this regard. In addition to the asserted references discussed below, Dr. Benditt recounts various disclosures of atrial-(uni-)ventricular pacing for complete heart block and for heart failure, permanent pacemaking for treatment of bradycardia, and uni-ventricular pacing to treat heart failure. (D.I. 188 at 87:5-109:6) One of Dr. Benditt's state of the art references did explore the use of bi-ventricular pacing to treat certain arrhthymias, not heart failure; even then the study concluded right atrial and right ventricular pacing was preferable to bi-ventricular pacing to correct the arrhythmias. (*Id.* at 109:24-110:4, 237:2-239:17) Dr. Benditt testified that persons of skill in the art were "aware of the difficulty of treating heart failure and that while single chamber ventricular pacing was helpful in some patients, it failed to be adequate in many other patients." (D.I. 188 at 107:5-9) Indeed, Dr. Benditt's testimony does establish that there was a long-felt need to better address heart failure, even with the then available single ventricle pacing. (D.I. 188 at 87:5-109:6) The court finds that, excluding the asserted references, which are discussed in more detail below, Dr. Benditt's testimony fails to establish that bi-ventricular pacing

for heart failure was known, or even that uni-ventricular pacing was particularly successful in treating congestive heart failure.

b. Tyers

55. Tyers is a 1970 study of multi-site pacing in dogs with induced heart block (profound bradycardia) but normal ventricles. (D.I. 190 at 561:14-24, 563:9-10, 15-16) Tyers induced heart block by crushing the A-V node, eliminating intrinsic electrical stimulation of the ventricles, and making the dogs dependent on extrinsic stimulation to sustain life. (*Id.* at 561:16-19) Tyers experimented with using 1, 2, 3, and 4 simultaneous ventricular pacing sites. (PTX-216 at MEDMIR0007199) The results showed that "tri-site" stimulation, with one electrode on the left ventricle and two on the right ventricle, provided a highly significant increase over stimulation of the left ventricle alone. (*Id.*) In contrast, stimulation of two sites, with one electrode on each ventricle, provided "no significant alteration of cardiac function." (*Id.* at MEDMIR0007199-200)

c. Gibson

56. Gibson is a 1971 study of the impact of various pacing locations in postoperative patients having undergone valve replacement. (PTX-219 at MEDMIR0001055). Of the six patients included in the study, five were in sinus rhythm and one was in atrial fibrillation. (*Id.* at 398, table I) The particular device implanted was a Starr-Edwards prosthesis, an early valve that would allow one way flow of blood,

comprising a birdcage-like container enclosing a ball. (D.I. 190 at 550:6-10) With the ball seated at the inlet end of the cage, the valve is sealed and back flow is prevented. (*Id.*) A characteristic property of the Starr-Edwards valve is that the ball makes a loud clicking sound as it contacts the end of the cage. (*Id.*) Gibson discloses a shortened ball travel time, based on timing of the clicks, when pacing is done to both ventricles as opposed to a single ventricle. (*Id.* at 550:20-23) Notwithstanding the shortened ball travel time, Gibson concluded that "the change . . . from single to bi-ventricular pacing was associated with no consistent alteration in either arterial pressure or cardiac output." (PTX-219 at MEDMIR0001058) Instead, Gibson suggests that "it is possible that more conspicuous changes could be obtained by variation in the numbers, position, or sequence of activation of ventricular electrodes" (*Id.*)

d. Silva

57. Silva is a 1987 doctoral dissertation written at the Autonomous University of Madrid. Medtronic and defendants dispute whether Silva meets the requirements of a "printed publication" under 35 U.S.C. § 102.

(1) Legal standard

58. Whether a reference is a "printed publication," under 35 U.S.C. § 102, is a "legal determination based on underlying issues of fact." *In re Hall*, 781 F.2d 897, 898 (Fed. Cir. 1986). "A reference is a 'printed publication' within the

meaning of section 102(b) if it was 'available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, [could] locate it.'" *Am. Stock Exch., LLC v. Mopex, Inc.*, 250 F. Supp. 2d 323, 328 (S.D.N.Y. 2003) (*citing In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568 (Fed. Cir. 1988)) (brackets retained). "'Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to. If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Id.* at 328-29. "[C]ompetent evidence of [] general library practice may be relied upon to establish an approximate time when a thesis became accessible." *In re Hall*, 781 F.2d at 897.

(2) Public access to Silva

59. To support their respective positions, both parties point to deposition testimony of the librarian who indexed, catalogued and shelved the thesis, Ms. Barredo-Sobrino ("librarian"). (D.I. 246, ex. I at 37:20-40:5) The librarian was originally deposed on June 30, 2007 ("2007 deposition"), during the St. Jude litigation, to which Medtronic was not a party. (D.I. 246, ex. J) She was again deposed on December 14, 2009 ("2009 deposition"). (D.I. 246, ex. I) Both depositions required the services of an interpreter.

60. Plaintiff argues that the librarian's testimony establishes that, based on the library's

normal business procedures, Silva was submitted to the library, cataloged, and available to the public no later than Apri11988. (D.I. 193 at 59) (*citing* 2007 deposition at 61, 64-78, 142-143)

61. Defendants assert that, while "[t]he reading room where the card catalogue was located was apparently open to the public . . . the thesis was located in the stacks, which were not open to the public, [that required one] to pass through a 'control point' to access doctoral theses." (D.I. 247 at 59) (*citing* 2007 deposition at 17:5-14) Defendants further assert that individuals permitted to pass through this control point were members of the university community, whereas other doctors could request access to a doctoral thesis only by first providing "accreditation" and a reason for consulting the thesis. (*Id.*) (*citing* 2007 deposition at 16:14-22, 39:16-40:11)

62. The librarian testified that a doctor not affiliated with the university who desired access to a doctoral thesis would have to "[first] identify himself with his official medical identification as a doctor of Spain [and then] fill out a form indicating the reason for his consultation." (2007 deposition at 39:16-40:3) It was possible for a non-Spanish doctor to "consult" a doctoral thesis by showing a passport in addition to the other requirements. (*Id.* at 40:4-8) Such consultation was restricted to the confines of the public reading room; the thesis could not be loaned out. (*Id.* at 40:8-11) Under such circumstances, provision was made for appropriate time to review the thesis and take notes. (*Id.* at 40:8-15) Non-

Spanish doctors had, in fact, consulted doctoral theses in the reading room in this manner. (*Id.* at 40:16-18) The librarian **did not testify** that any group or person was or would have been denied the opportunity to consult any doctoral thesis, including Silva.

63. Defendants argue that there is no clear and convincing evidence that "anyone not a member of the university family had access to the stacks where the doctoral theses were located." (D.I. 247 at 59) Defendants conflate access to the room where a doctoral thesis was kept with access to the thesis itself. Only access to the thesis is required. Moreover, it is not necessary to show that the thesis was actually accessed by anyone. *See Am. Stock Exch., LLC*, 250 F. Supp. 2d at 328. Although defendants argue there was no proof that either the reason for consultation or the accreditation of a Spanish or foreign doctor would be approved, there is no evidence of record that approval was required. (D.I. 247 at 59) Instead, the record shows that sufficient access was granted to Spanish and non-Spanish doctors, as well as to the university community. The court concludes that Silva qualifies as a printed publication under 35 U.S.C. § 102, and was publicly available no later than April1988. The '688 patent issued from an application filed on January 23, 1989, and no earlier priority date is claimed. ('688 patent at [22]) Silva qualifies as prior art to the '688 patent and the reissue patents.

(3) Silva as prior art

64. Silva disclosed a study of the impact of various pacing locations in the hearts of healthy dogs and postoperative patients. (D.I. 190 at 556:21-560:24; PTX-269 at MEDMIR0006892) The selection criteria for patients included in the study were: (1) a stable (normal) sinus rhythm; (2) no atrioventricular conduction disorders or bundle branch blocks on the 12-lead peripheral electrocardiogram; (3) an ejection fraction greater than 0.50 (normal left ventricular function), evaluated by angiogram; and (4) no akinetic, dyskinetic or hypokinetic areas after performance of the angiogram. (PTX 269 at MEDMIR0006953; D.I. 190 at 630:18-632:13) In the actual study populations, both the dogs and patients were in sinus rhythm. (PTX-269 at MEDMIR0006937, 6953) All ten patients were without bundle branch blocks or conduction abnormalities. (*Id.* at MEDMIR0006953) Of the ten patients, seven had "coronary artery disease and maintained ventricular function," and three "suffered from valve disease." *Id.* "Coronary patients with prior myocardial necrosis were rejected even if ventricular function had been maintained." *Id.* Silva concluded that "[b]i-ventricular electrical stimulation in post-operative patients (VAT mode) is hemodynamically more favorable than that obtained from univentricular stimulation." (*Id.* at MEDMIR000702)

e. Curtiss

65. Curtiss is a 1987 case report of a single patient that presented with the extraordinarily unique condition of having two separate QRS complexes resulting in separate mechanical contractions of the left and right ventricles. (PTX-217 at MEDMIR0008797, 8802) The patient in Curtiss was treated experimentally by pacing the left ventricle, triggered by sensing the right ventricle, wherein "[a] sense to pace interval of 50 msec. was selected since a therapeutic alternative was implantation of a modified universal pacemaker and the shortest sense to pace interval in the available units was 50 msec." (*Id.* at MEDMIR0008801) Curtiss reported that, hemodynamically, triggered left ventricular pacing was associated with a 24% rise in cardiac output. (*Id.*) In notational terms, triggered left ventricular pacing would be classified as VVT mode.

2. Anticipation

a. Legal standard

66. Under 35 U.S.C. § 102(a), "a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

67. A claim is anticipated only if each and every limitation as set forth in the claim is found,

either expressly or inherently described, in a single prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

> [A]nticipation requires that each limitation of a claim must be found in a single reference. Although [the Federal Circuit has] permitted the use of additional references to confirm the contents of the allegedly anticipating reference, . . . we have made clear that anticipation does not permit an additional reference to supply a missing claim limitation.

Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1335 (Fed. Cir. 2002). That is, additional references may be used only to shed light on what a prior art reference would have meant to those skilled in the art at that time, not for a specific teaching, as this would be indicative of an attempt to improperly "combine the teachings of the references to build an anticipation." *Studiengesellschaft Kohle, m.b.H. v. Dart Industries, Inc.*, 726 F.2d 724, 727 (Fed. Cir. 1984).

68. A single prior art reference may expressly anticipate a claim where the reference explicitly discloses each and every claim limitation. However, the prior art need not be *ipsissimis verbis* (i.e., use identical words as those recited in the claims) to be expressly anticipating. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

69. A single prior art reference also may anticipate a claim where one of ordinary skill in the art would have understood each and every claim limitation to have been disclosed inherently in the reference. *Continental Can Co. USA Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. *Id.* That is, "the mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* "[I]nherency operates to anticipate entire inventions as well as single limitations within an invention." *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). The recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. *Id.* at 1377.

70. An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. *Key Pharms. v. Hercon Lab. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art to determine whether the prior art discloses the claimed invention. *Id.*

b. Silva and the VAT and VVT claims[9]

71. Each of the VAT and VVT claims[10] require either: (1) "improving the pumping ability of a heart that is in a state of congestive heart failure," by "effecting a coordinated contraction of both ventricles;"[11] (2) "a device capable of providing stimulation to both ventricles to effect a coordinated contraction thereof for the treatment of congestive heart failure;"[12] or (3) are directed to devices for treating heart failure and methods for improving the pumping ability of a heart suffering from heart failure.[13]

72. Plaintiff argues that Silva anticipates the VAT and VVT claims of the reissue patents, both triggered modes, by disclosing triggered, bi-ventricular pacing. (D.I. 193 at 51; PTX-515) Plaintiff further argues that Silva "clearly teaches that pacing both ventricles would be beneficial to patients in heart failure." (D.I. 193 at 40) (*citing* D.I. 188 at

---

[9] Claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 144, 172, 201 and 311 of the '897 patent.

[10] As construed by the court with respect to asserted claims of the '119 patent.

[11] Claims 15, 19, and 20 of the '119 patent.

[12] Claims 25 and 26 of the '119 patent.

[13] Claims 15, 54, 84, 86, 144, 172, 201 and 311 of the '897 patent.

146:22-147:6; PTX-269 at 126; PTX-529 at 10; D.I. 188 at 145:4-14; PTX-269 at 120; PTX-529 at 8)

73. The parties disagree as to the nature of the patients included in the Silva study and as to the results. Plaintiff, relying on the testimony of its expert, Dr. Benditt, asserts "in 1988, Silva reported that bi-ventricular pacing was a better way to treat postoperative patients" and that the patients included those with "class II heart failure symptoms." (D.I. 193 at 39; D.I. 188 at 123:17-19). Defendants argue that Silva did not address any subjects that were in heart failure or had uncoordinated contraction of the ventricles. (D.I. 247 at 50) Instead, defendants assert that Silva was an attempt "to see which [pacing] site might be best and most closely approach that during sinus rhythm." (D.I. 190 at 557:8-9) Defendants further argue that "Silva determined that the patients would have been better off, hemodynamically, with no pacing at all." (D.I. 247 at 50) (*citing* D.I. 190 at 559:16-560:9; DTX-203 at DDX-115, DDX-11)

74. To anticipate the VAT and VVT claims, each and every limitation must be expressly or inherently described in a single prior art reference. Plaintiff argues that treatment of heart failure is an inherent property of bi-ventricular pacing. (D.I. 193 at 35) Inherency may not be established by probabilities or possibilities. *See Continental Can*, 948 F.2d at 1268. In its non-infringement argument, plaintiff argued that "approximately 30% of patients with CRT devices are 'non-responders,' meaning their hearts do not respond to the devices, and their

hemodynamic efficiency is not improved." (D.I. 193 at 12 n.8) Plaintiff proffers no evidence that treatment of heart failure using bi-ventricular pacing, as construed by the court, is inherently disclosed in the prior art. Silva itself distinguishes the apparatus and method used in the study from implantable devices which are more highly constrained as to ventricular pacing sites, and further identifies these constraints as the probable reason that earlier studies did not focus on bi-ventricular stimulation. The court finds that Silva did not address patients who were in (congestive) heart failure, a limitation shared by all of the VAT and VVT claims; therefore, the court concludes that Silva does not anticipate the VAT and VVT claims.

c. Gibson and the VVI and VDI claims[14]

75. Each of the VVI and VDI claims include one of three forms of preamble: a "heart stimulating device for treating heart failure;" a "method for improving the pumping ability of a heart suffering from heart failure;" a "heart failure treatment device for improving the pumping ability of a heart suffering from heart failure." The record shows that the examiner considered these preambles to be limitations and a means for distinguishing the claims over the prior art. (PTX-5 at MEDMIR0023137, "Notice of Allowance") ("[T]he

[14] Claims 120, 217 233, 288, 303, 315, and 324-28 of the '897 patent.

prior art does not show a heart stimulating device for treating heart failure, or improving hemodynamics, as set forth in the claims.")

76. Plaintiff does not dispute that these preambles constitute limitations. Instead, plaintiff argues that Gibson renders VVI and VDI claims of the '897 patent anticipated by disclosing a commercial pacemaker capable of bi-ventricular pacing in a demand or inhibited mode; a lead placed in the atrium; a Y adapter used to allow electrodes to be placed in the left and right ventricles; and a predetermined A-V delay period. (D.I. 193 at 46) Plaintiff admits that "the experimental conditions in Gibson did not require atrial sensing," and instead argues that "one skilled in the art knew that the pacemaker Gibson used had the capability for atrial sensing and for an A-V delay period." (*Id.*) Presumably, this is in regard to VDI mode, which requires atrial sensing in addition to ventricular sensing. Finally, plaintiff asserts that Gibson further taught that bi-ventricular pacing effected a coordinated contraction, and that defendants' expert, Dr. Platia, "admitted that the improvement Gibson observed was due to a more synchronous contraction because of bi-ventricular pacing." (D.I. 193 at 47) The improvement admitted to by Dr. Platia, however, was with reference to shortened ball travel time of the valve, at the onset of systole, and not to improvement in hemodynamic efficiency over the entire cardiac cycle. (D.I. 190 at 599:19-25; 600:16-601:9)

77. Relying on the testimony of its expert, Dr. Benditt, plaintiff further asserts that the patients in the Gibson study were suffering from heart failure. (D.I. 193, ex. E at ¶ 120) (*citing* D.I. 188 at 97:1-14, 99:2-100:9, 184:16-187:5). The referenced portions of Dr. Benditt's testimony show that his assertions of heart failure in the Gibson study were often tentative: "[Gibson] was dealing with abnormal hearts. These had all had aortic valve surgery, and their cardiac outputs were all low . . . . So these are not just normal hearts that he's playing around with. These were sick hearts who got aortic valve replacements for **presumably** failing to thrive." (D.I. 188 at 99:9-15) (emphasis added) "That's **typically** a heart failure scenario, and **he's implying** that this new pacing mode, biventricular pacing that he observed, **may be of value** there. But he's also appropriately saying that **more study is needed**." (D.I. 188 at 100:2-6) (emphasis added)

78. Defendants argue that Gibson does not address patients in heart failure, but rather valve disease. (D.I. 247 at 44-45) Defendants further argue that, while Gibson may disclose shortened ball travel time resulting from bi-ventricular pacing, it also discloses that there was no associated gain in hemodynamic efficiency. (D.I. 190 at 552:7-13; D.I. 247 at 45)

79. The court finds defendants' characterization of Gibson to be the more credible. Plaintiff has failed to prove, by clear and convincing evidence, that each and every limitation as set forth in the VVI and VDI claims is found, either expressly

or inherently described, in Gibson. Gibson does not disclose a "heart stimulating device for treating heart failure;" a "method for improving the pumping ability of a heart suffering from heart failure;" or a "heart failure treatment device for improving the pumping ability of a heart suffering from heart failure." Therefore, the court concludes that Gibson does not anticipate the VVI and VDI claims of the '897 patent.

3. Obviousness

a. Legal standard

80. "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Obviousness is a question of law, which depends on several underlying factual inquiries.

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding

> the origin of the subject matter sought to be patented.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

81. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Likewise, a defendant asserting obviousness in view of a combination of references has the burden to show that a person of ordinary skill in the relevant field had a reason to combine the elements in the manner claimed. *Id.* at 418-19. The Supreme Court has emphasized the need for courts to value "common sense" over "rigid preventative rules" in determining whether a motivation to combine existed. *Id.* at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. In addition to showing that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, a defendant must also demonstrate that "such a person would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007). "Because patents are presumed to be valid, see 35 U.S.C. § 282, an alleged infringer seeking to invalidate a patent on obviousness grounds must establish its obviousness

by facts supported by clear and convincing evidence." *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 968 (Fed. Cir. 2006) (citation omitted).

b. Tyers and the VAT[15], VOO[16] and VDD[17] claims

82. Plaintiff argues that the VAT claims are rendered obvious by Tyers, asserting that "Tyers disclosed all of the limitations of claim 19--including sensing the atrium and stimulating both ventricles for effecting a coordinated contraction of the ventricles following an A-V delay period." (D.I. 193 at 53) To complete the argument, plaintiff points to Dr. Benditt's testimony that, "this is all standard pacemaker stuff even in 1989." (*Id.*) Plaintiff further asserts that "it was well known that a coronary sinus pacing lead could be placed to pace the left ventricle, as required by claim 20." (*Id.*) Plaintiff concludes by arguing that "[f]or all of these reasons, Tyers also anticipates and/or renders obvious claims 19 and 20 of the '119 patent." (*Id.*)

83. Defendants respond that "the dogs in the Tyers study did not have heart failure or weak contractions, they had complete heart block." Plaintiff's expert, Dr. Benditt, agrees:

> Q. And A-V block, is that a form of heart failure?

---

[15] Claims 19 and 20 of the '119 patent.
[16] Claim 308 of the '897 patent.
[17] Claims 248 and 273 of the '897 patent.

> A. A-V block is actually just interruption of the depolarization sequence between the atria and the ventricle, also previously talked of as heart block.

(D.I. 188 at 92:19-22)

84. The '119 patent, as discussed earlier, involved pacing of "both the right and left [ventricles] to thereby increase the hemodynamic efficiency of a patient experiencing congestive heart failure or weak contractions." The court construed claims 15 and 19 to include the limitation, "improving the heart's pumping ability for treatment of congestive heart failure." Claim 20 depends from claim 19 and, therefore, must include the same limitation. The dogs in Tyers did not have congestive heart failure or ventricles that were contracting in an incoordinate manner. Instead, the dogs had an induced total heart block. The court finds that Tyers lacks the above stated limitations, and concludes that Tyers does not anticipate the VAT claims.

85. Plaintiff argues that "Tyers taught that pacing both ventricles simultaneously resulted in a significant increase in blood pressure and cardiac output." In fact, Tyers did not find an improvement with bi-ventricular pacing when using only two leads. Improvement was not shown except with the addition of a third lead. Bi-ventricular pacing, in and of itself, did not result in an improvement.

86. The VOO and VDD claims each require pacing the left and right ventricles for "effecting of a

coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure." Plaintiff argues that Tyers, in combination with the knowledge of one of ordinary skill in the art, renders the VOO and VDD claims obvious. Here, plaintiff goes into more detail, identifying background references that contribute to the comparison of the limitations with the claims. Most of these references are to known pacing modes. Plaintiff also asserts that coronary sinus electrodes, for pacing the left ventricle, were well known. Plaintiff fails to address the limitations directed to heart failure, coordinated contraction of ventricles, and the reason to combine the references.

c. Gibson and the VVI[18] and VDI[19] claims

87. Plaintiff argues that Gibson, "along with the knowledge of one of skill in the art," renders the VVI and VDI claims obvious. (D.I. 193 at 47-48) Plaintiff points to the availability of the various pacing modes as proof of obviousness. (*Id.*) The court's discussion above, with respect to anticipation by Gibson, informs its analysis of obviousness in light of Gibson. Gibson is not directed toward treating patients with heart failure or discoordinate ventricles. Bi-ventricular stimulation, as tested by Gibson, did not result in improved hemodynamic

[18] Claims 217, 233, 288, 303, 325, and 328 of the '897

[19] Claims 120, 315, 324, 326, and 327 of the '897 patent.

efficiency, thus teaching away from bi-ventricular pacing to improve hemodynamic efficiency.

d. Curtiss and the VVT claims[20]

88. All of the asserted claims of the '119 patent, as construed by the court, require both ventricles to be paced to effect coordinated or simultaneous contraction of both ventricles.[21] The specification of the '119 patent teaches that "ventricular contractions which occur with [sic] 5-10 milliseconds of each other result in sufficient hemodynamic efficiency so as to not require treatment. Hence, the delay window may be of this order of magnitude." ('119 patent at 6:23-26)

89. Plaintiff argues that "Curtiss disclosed detecting a depolarization of the right ventricle and immediately stimulating the left ventricle." In its non-infringement argument, plaintiff asserts that a delay of 1.25 msec. is not immediate as used within the context of the reissue patents. (D.I. 193 at 17) Plaintiff admits that Curtiss discloses only single ventricle pacing, but argues that "pacing both ventricles was well known and standard in the art, as described, for example, in Tyers." (D.I. 193 at 54) Plaintiff further argues that "Curtiss provides the

---

[20] Claims 15, 25 and 26 of the '119 patent.

[21] Claims 15 and 19 require "stimulating both ventricles for effecting a coordinated contraction of both ventricles." Claim 20 depends from claim 19. Claim 25 requires a "bi-ventricular pacemaker" for "effecting simultaneous contraction of both ventricles." Claim 26 depends from claim 25.

motivation for one skilled in the art to use bi-ventricular pacing in conjunction with the teachings of Curtiss." (D.I. 193 at 54) Dr. Benditt testified that "[Curtiss] could have stimulated both ventricles, but it's kind of a waste of energy to stimulate both," thereby suggesting that Curtiss teaches away from bi-ventricular pacing. (D.I. 188 at 172:5-8)

90. Plaintiff also argues that Curtiss in light of Tyers renders claims 25 and 26 obvious. (*Id.* at 54) That two or more prior art references disclose, in combination, all limitations of a claim does not, by itself, establish obviousness. Plaintiff fails to show any reason why a person of skill in the art would combine Curtiss, an extraordinary case involving one patient with dual QRS complexes, and Tyers, a study in dogs with complete heart block.

91. Defendants argue that the patient in Curtiss did not exhibit the "broadened QRS complex associated with heart failure" but, rather, "two distinct QRS complexes" that had never been seen before, nor since. (D.I. 190 at 541:16-24) Defendants' validity expert, Dr. Platia, opined that "[i]t certainly wouldn't occur to me that pacing in such a heart would give us any useful information to be interpreted broadly," and that this unique case was unrelated to the reissue patents. (D.I. 190 at 541:25-542:4)

92. Plaintiff again fails to provide motivation to combine Curtiss with any other reference or the knowledge of one of ordinary skill in the art. Curtiss involved single ventricle pacing of a

single unique case, with a sense to pace interval of 50 msec. The reissue patents are directed to stimulating both ventricles effecting a coordinated contraction of the ventricles (within 5-10 msec.) for treating heart failure. The court finds that plaintiff has failed to show Curtiss, in combination with any other reference, renders the VVT claims obvious.

e. Silva and the VAT and VVT claims

93. As previously discussed, Silva does not anticipate the asserted claims of the '119 patent as it did not address patients in heart failure. Plaintiff argues that, "in 1988, Silva reported that bi-ventricular pacing was a better way to treat postoperative patients." (D.I. 193 at 39) Silva itself distinguished the post-operative context as being less restrictive than using an implantable device. (PTX-269 at MEDMIR0006936) ("[I]t is not possible to select the point(s) of ventricular stimulation due to the limitations imposed by the implantation technique.") Defendants argue that, "[a]s with the Tyers and Gibson studies, the Silva thesis was directed to determining the least bad place to pace the heart." (D.I. 247 at 50) (*citing* D.I. 190 at 557:10-13)

94. Under *KSR*, it is not necessary that the prior art be directed to solving the same problem. *KSR*, 550 U.S. at 402, 418. The case at bar is not one, however, where "one of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution

encompassed by the patent's claims." *Id.* at 419-20. There was unquestionably a problem, one of long-felt need. Plaintiff has failed, however, to demonstrate an obvious solution. The field of the reissue patents is a complex one, involving the highest level of skill, incremental experimentation, uncertainty, and concerns over efficacy and safety. Even plaintiff admits that the patented devices and methods have far less than a 100% chance of success in treating heart failure. Experimentation in this field is time consuming, difficult, expensive, and poses some level of risk.

95. While Silva disclosed that bi-ventricular stimulation was more favorable, hemodynamically, than single ventricle pacing, this does not necessarily suggest hemodynamic improvement in heart failure. The base ejection fraction of the patients in Silva was 0.555 ± 0.018 whereas, with bi-ventricular pacing, it decreased to 0.535 ± 0.018. (PTX-269 at MEDMIR000699) Although the ejection fraction was even lower for single ventricle pacing, it supports defendants' conclusion that Silva demonstrated bi-ventricular pacing was the least bad solution under the circumstances. (*Id.*) Further supporting defendants' position, Silva also found that, with all three experimental positions, there was "a widening of the QRS" although it was less pronounced in bi-ventricular pacing. (*Id.* at MEDMIR0006987)

96. The court finds defendants' characterization of the results of Silva to be the more persuasive. Plaintiff has failed to show, by clear and convincing evidence, that Silva, in view of the

knowledge of one of ordinary skill in the art or in combination with any other reference, renders the VAT and VVT claims obvious.

f. Secondary considerations

97. As discussed earlier, Dr. Benditt pointed to the long-felt unfulfilled need to treat heart failure. (D.I. 247 at 57) Plaintiff admits that Dr. Mower's invention is successful in treating heart failure in more than 60% of cases. (D.I. 189 at 301:10-11, 23-24, 302:2-4) While arguing that all of the components of a bi-ventricular pace maker were available prior to Dr. Mower's invention, and such combination was obvious, Plaintiff fails to adequately account for the lack of success in addressing this long-felt need. Based on the foregoing, the court finds that, taken as a whole, the secondary considerations favor defendants and do not change the obviousness determination discussed above.

g. Conclusion

98. Plaintiffs arguments regarding obviousness are less than compelling, attempting only to demonstrate that limitations of the asserted claims can be found as disparate pieces in various combinations of the prior art. Dr. Benditt, plaintiff's invalidity expert, admitted that he failed to consider any apparent reason to combine references in

forming his opinions.[22] Moreover, many of the asserted references teach away from bi-ventricular pacing. Plaintiff has not demonstrated, by clear and convincing evidence, that the asserted claims of the reissue patents are invalidated on obviousness grounds.

E. Prosecution Laches

1. Legal standard

99. The doctrine of prosecution laches is an equitable defense to a charge of patent infringement that "'may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution' that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 422 F.3d 1378, 1384-85 (Fed. Cir. 2005) ("Symbol Techs. II") (citation omitted). "[T]here are no strict time limitations for determining whether continued refiling of patent applications is a legitimate utilization of statutory provisions or an abuse of those provisions. The matter is to be decided as a matter of equity, subject to the discretion of a district court before which the issue is raised." *Id.* at 1385. A

[22] Dr. Benditt in his deposition stated, "it would be obvious to somebody who was working in the field who was familiar with the literature that this would not be a particular stretch of the imagination. . . . what would lead me to . . . say, 'Oh, I'm going to combine X and Y,' I don't think we can give you an answer here." (D.I. 188 at 225:17-226:9)

finding of prosecution laches further requires " a finding of prejudice, as does any laches defense." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010).

100. An applicant may attempt to obtain new claims directed to inventions that he or she believes are fully disclosed and supported in an earlier application. *See In re Bogese*, 303 F.3d 1362, 1369 (Fed Cir. 2002). This is distinguished from an applicant failing to further the prosecution of his or her application toward the issuance of any claims. *Id.* The Federal Circuit has made clear that

> there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988}.

2. Discussion

101. The original '688 patent, on which the reissue patents are based, was filed on January 23, 1989 and issued on May 29, 1990. The '119 patent resulted from a series of three continuation applications, the first of which was filed on May 29,

1992, and issued May 20, 2003. The '897 patent was filed on August 8, 2002 and issued on October 23, 2007.

102. Plaintiff argues that the claims of the '897 patent are unenforceable for prosecution laches. (D.I. 193 at 2) In support of this argument, plaintiff asserts that the application for the '119 patent "lingered in the patent office until 2003, over 14 years after the filing of [the] original '688 patent application." (*Id.* at 3) Plaintiff further asserts that during those 14 years, the market developed for CRT devices. (*Id.*) Plaintiff introduced its first CRT product in 2001. (*Id.*)

103. The evidence of record demonstrates that the delays in prosecution of the '119 patent were reasonable. (D.I. 247 at 10-11; PTX-7; PTX-8) The delays are documented in the file history as being caused by a withdrawal of allowability by the PTO and the PTO's twice losing the file. (*Id.*) Meanwhile, defendants diligently prosecuted the '119 patent seeking repeated status updates. (*Id.*)

104. Plaintiff further argues that, since the '119 patent did not cover commercially available devices, defendants filed a new reissue application a year after plaintiff's InSync product was released in 2001, in an attempt to obtain new claims to assert against their competitors. (*Id.*) This new reissue application resulted in issuance of the '897 patent. (*Id.*) Finally, plaintiff asserts that "Dr. Mower did nothing for over a decade after he first noticed the alleged errors in the '688 patent to ensure that these

additional 300 claims [of the '897 patent] were prosecuted."

105. Defendants counter that the '897 application was filed on August 8, 2002 after the PTO stated that the '119 claims were allowable. (D.I. 247 at 12; PTX-5) Prosecution consisted of three rejections and three responses, all within the statutory period. *Id.*

106. Plaintiff, relying on *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 301 F. Supp. 2d 1147, 1157 (D. Nev. 2004) ("Symbol Techs. I") argues that the failure to prosecute all claims of a patent (or reissue patent) as soon as they are known constitutes prosecution laches. *In Symbol Techs. I*, the patentee had "effectively extended his patent monopoly by maintaining co-pendency for nearly forty years through continuation practice, and added new claims to cover commercial inventions in the market place years after his original patents had expired." *Id.* The court finds no such unreasonable or unexplained delay with respect to the reissue patents.

III. CONCLUSION

For the reasons discussed above, the court concludes that defendants have not proven, by a preponderance of the evidence, that plaintiff Medtronic infringes claims 15, 19, 20, 25, or 26 of the '119 patent, or claims 15, 54, 84, 86, 120, 144, 172, 201, 217, 233, 248, 273, 288, 303, 308, 311, 315, or 324-328 of the '897 patent. Plaintiff has failed to

prove, by clear and convincing evidence, that the aforesaid claims are invalid as anticipated. Plaintiff has not demonstrated, by clear and convincing evidence, that the aforesaid claims are invalid as obvious. Plaintiff likewise has failed to establish, by clear and convincing evidence, that the reissue patents are unenforceable by reason of prosecution laches. An appropriate order shall issue.

APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2011-1313, -1372

MEDTRONIC INC.,

Plaintiff-Cross Appellant,

v.

BOSTON SCIENTIFIC CORPORATION and GUIDANT CORPORATION,

Defendants,

and

MIROWSKI FAMILY VENTURES, LLC,

Defendant-Appellant.

Appeals from the United States District Court for the District of Delaware
in case no. 07-CV-0823, Judge Sue L. Robinson.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Cross-Appellant, and a response thereto having been invited by the court and filed by the Appellant, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 21, 2012.

FOR THE COURT

/s/ Jan Horbaly
Jan Horbaly, Clerk

Dated: 12/14/2012

cc: Arthur I. Neustadt
Martin R. Lueck

MEDTRONIC V BOSTON SCIENTIFIC, 2011-1313, -1372
(DCT - 07-CV-0823)