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. RE38,119 ("RE'119 Patent") and No. RE39,897 ("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.*, No. 07-CV-0823 (D. Del. Mar. 30, 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.

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

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

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 re-synchronize 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 Med-

tronic 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 infringement 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 failure 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.*, 423 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, 39-40 (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 in-

fringement; 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 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 dis-

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

charged 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 judgment 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 specification, *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.