IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CARDIAC PACEMAKERS, INC. AND GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

AND

MIROWSKI FAMILY VENTURES, LLC AND ANNA MIROWSKI,

Plaintiffs-Appellants,

V.

ST. JUDE MEDICAL, INC. AND PACESETTER, INC.,

Defendants-Cross Appellants.

On Appeal From The United States District Court For The Southern District of Indiana In No. 96-CV-1718, Judge David F. Hamilton

PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to this Court's Rule 47.4, counsel for St. Jude Medical, Inc., *et al.* certify the following:

- 1. The full name of every party represented is: St. Jude Medical, Inc., and Pacesetter, Inc.
- 2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: Not applicable.
- 3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by me are: Pacesetter, Inc. is (and has been since September 29, 1994) a wholly owned subsidiary of St. Jude Medical, Inc. St. Jude Medical, Inc. is a publicly traded company and no publicly held company owns 10 percent or more of its shares.
- 4. The names of all the law firms and the partners or associates who appeared for the parties now represented by me in the trial court or are expected to appear in this Court are:

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RULE 35(b)(2) STATEMENT

Based on my professional judgment, I believe that:

- 1. The panel's decision that 35 U.S.C. § 271(f) reaches the extraterritorial practice of method claims conflicts with *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746 (2007), *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360 (Fed. Cir. 1992), and *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005).
- 2. The panel's decision that a verdict of nonobviousness precludes a subsequent determination of anticipation conflicts with *Cohesive Technologies, Inc. v.*Waters Corp., 543 F.3d 1351 (Fed. Cir. 2008), as well as statutory and decisional differences between the obviousness and anticipation defenses.

Denis R. Salmon

GIBSON, DUNN & CRUTCHER LLP Attorney of Record for St. Jude Medical, Inc. and Pacesetter, Inc.

STATEMENT OF THE CASE

The parties are competitors in the market for implantable cardiac defibrillators (ICDs). CPI now accuses St. Jude's devices of infringing claim 4 of U.S. Patent No. 4,407,288, which claims a method for cardioverting the heart.

After a trial, the jury found that the sole method claim now in issue was not invalid for obviousness, and that it was not infringed by the accused devices. In a previous appeal, a panel of this Court affirmed the validity verdict but vacated the

verdict of non-infringement because it was based on an incorrect claim construction. A158, A163; Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 381 F.3d 1371, 1379, 1382 (Fed. Cir. 2004).

On remand, the district court re-construed the disputed claim limitation (the "determining" step) and then ruled that all elements of the claim, as re-construed, were anticipated by two prior art references (Duggan and Denniston). A26. The district court also rejected St. Jude's argument that 35 U.S.C. § 271(f)—which imposes liability for certain acts of patent infringement occurring overseas—does not apply to method or process claims. A76-77.

In the most recent appeal, the panel reversed the district court's determination of invalidity by anticipation, reasoning that the Duggan and Denniston references "were presented to the jury" in connection with St. Jude's obviousness defense. Slip op. 11. The panel also "affirm[ed] the district court's ruling on the application of 35 U.S.C. 271(f) to this case" on the basis of *Union Carbide Chems*. & *Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d 1366 (Fed. Cir. 2005), which applied § 271(f) to method claims, explaining that "[a]s a panel, we cannot reverse the holding of another panel of this court." Slip op. 16 (emphasis added).

ARGUMENT

This case directly presents the important and recurring question whether the extraterritorial prohibitions of 35 U.S.C. § 271(f) apply to method or process

claims, as opposed to apparatus or product claims. See Union Carbide Chems. & Plastic Tech. Corp. v. Shell Oil Co., 434 F.3d 1357, 1358-59 (Fed. Cir. 2006) (dissenting opinion of Lourie, Michel, and Linn, JJ.) (identifying this issue as warranting en banc review). The Supreme Court's intervening decision in Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746 (2007), confirms that the panel in Shell Oil wrongly applied § 271(f) to process claims.

A secondary question here is whether a jury's verdict of nonobviousness forecloses a subsequent determination of anticipation. The panel's affirmative answer to that question is irreconcilable with the recent decision in *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351 (Fed. Cir. 2008), as well as settled law concerning the difference between obviousness and anticipation.

I. Section 271(f) Does Not Apply To Method Claims

In three (and only three) cases, this Court has suggested that 35 U.S.C. § 271(f) can be applied to process claims. *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005); *AT&T Corp. v. Microsoft Corp.*, 414 F.3d 1366 (Fed. Cir. 2005); and *Shell Oil*, 425 F.3d 1366. While this appeal was pending, the Supreme Court reversed this Court's decision in *AT&T*, and expressly abrogated *Eolas*. 127 S. Ct. at 1754 n.10. That leaves *Shell Oil* as the only surviving precedent of this Court applying § 271(f) to a method claim; but *Shell Oil* itself conflicted with earlier precedents from this Court. *Standard Havens Prods., Inc. v.*

Gencor Indus., Inc., 953 F.2d 1360, 1374 (Fed. Cir. 1992) (holding § 271(f) not implicated by method claim); NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1321-23 (Fed. Cir. 2005) ("it is difficult to conceive of how one might supply or cause to be supplied all or a substantial portion of the steps of a patented method in the sense contemplated by the phrase 'components of a patented invention' in section 271(f)"). The Supreme Court's subsequent decision in AT&T confirms that Shell Oil is on the wrong side of this conflict.

1. Shell Oil is based on the premise that "every component of every form of invention deserves the protection of 35 U.S.C. § 271(f)." 425 F.3d at 1379 (emphasis added). In AT&T, the Supreme Court addressed two questions: (1) "when, or in what form, does software qualify as a 'component' under § 271(f)?" and (2) "were 'components' of the foreign-made computers involved in this case 'supplie[d]' by Microsoft 'from the United States?" 127 S. Ct. at 1753-54. The Court's analysis of the first question obliterates the premise of Shell Oil.

Construing the plain terms in § 271(f), the AT&T Court explained that "components" must be capable of combination to form the patented invention at issue in order for the provision to apply. 127 S. Ct. at 1755. The Court reasoned that "[u]ntil it is expressed as a computer-readable 'copy,' e.g., on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable.... Abstract software code is an idea without a physical

embodiment, and as such, it does not match § 271(f)'s categorization: 'components' amenable to 'combination.'" *Id*.

The AT&T Court reinforced its interpretation of the text of § 271(f) by observing that the decision in Deepsouth Packing Co., Inc. v. Laitram Corp., 406 U.S. 518 (1972), directly led Congress to enact § 271(f). 127 S. Ct. at 1752. In Deepsouth, the Court had held that nothing in U.S. patent law prevented a company from making in the United States the parts of a machine, as opposed to the machine itself, and selling those parts to foreign buyers for assembly and use abroad. Id. at 1751. In response, Congress enacted § 271(f) to expand the definition of infringement to include supplying from the United States a patented invention's components. *Id.* at 1752. Consistent with its focus on the tangibility of the patented invention at issue, the AT&T Court emphasized that the problem Congress sought to remedy in enacting § 271(f) involved "kits containing all the physical, readily assemblable parts of a shrimp deveining machine (not an intangible set of instructions), and those parts themselves (not foreign-made copies of them) would be combined abroad by foreign buyers." *Id.* at 1759.

In light of AT&T, Shell Oil's extension of § 271(f) to process claims cannot survive. To be sure, the AT&T Court did not resolve this precise issue:

We need not address whether software in the abstract, or any other intangible, can ever be a component under § 271(f). If an intangible method or process, for instance, qualifies as a "patented invention" under § 271(f) (a question as to which we express no opinion), the

combinable components of that invention might be intangible as well.

127 S. Ct. at 1756 n.13. But the *AT&T* Court's holding that "components" under § 271(f) must be "combinable" and otherwise susceptible of being "supplied from the United States" necessarily rejected the incorrect premise in *Shell Oil* that "every component of every form of invention" deserves the protection of 35 U.S.C. § 271(f). *See also Shell Oil*, 434 F.3d at 1358 (Lourie, J., dissenting).

2. The structure of the Patent Act confirms that § 271(f) does not apply to method claims. In § 271(f), Congress adopted certain language directly from 35 U.S.C. § 271(c), which defines liability for contributory infringement. *See* S. Rep. No. 98-663, at 7 (1984). It is instructive to examine the language of § 271(c) that was *not* incorporated by Congress into § 271(f):

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, ... shall be liable as a contributory infringer.

35 U.S.C. § 271(c) (emphasis added).

Thus, § 271(c) distinguishes between "a component of a patented machine, manufacture, combination, or composition" and "a material or apparatus for use in practicing a patented process." On its face, the statutory language illustrates that Congress did not treat processes as having "components" and did not intend "component" to include "a material or apparatus for use in practicing a patented process." Indeed, any other interpretation would render the phrase "material or appara-

tus for use in practicing a patented process" meaningless, a result which should be avoided. See, e.g., TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001); Connecticut Nat'l. Bank v. Germain, 503 U.S. 249, 253 (1992). Similarly, the fact that Congress incorporated the concept of "component" into § 271(f) but did not include the "material or apparatus for use in practicing a patented process" language supports an interpretation of the text that does not include method or process claims. See also Shell Oil, 434 F.3d at 1358 (Lourie, J., dissenting) (noting that text used in § 271(c) indicates Congress' recognition of the distinction between components of a machine and material for use in practicing a process).

The text of 35 U.S.C. § 271(g), which expressly imposes liability for importing products made overseas using a patented process, further strengthens an interpretation of § 271(f) that does not include protection for method patents. Section 271(g) illustrates that Congress knew how to protect against foreign use of process patents, and chose to limit such protection only to uses which result in products introduced back into the United States. Its decision not to reach such claims in § 271(f) must be respected. *See Enpat, Inc. v. Microsoft Corp.*, 6 F. Supp. 2d 537, 539 (E.D. Va. 1998).

Indeed, the conclusion that § 271(f) does not protect U.S. process patents is confirmed by the legislative history of § 271(g):

The bill does not attempt to prevent the use of the [patented] process in another country. If the U.S. process patentholder has not obtained a

similar patent in the other country, he has and should have no right by virtue of his U.S. patent to prevent anyone from using the process in that country.

132 Cong. Rec. S17, 386-02, at 6 (1986); see also 132 Cong. Rec. S15, 049-01, at 5 (1986) ("Simply using the process in a foreign country where the U.S. inventor does not have a patent is perfectly legitimate; the measure we are considering prohibits only the subsequent importation, use and sale of the resulting products in this country"). If § 271(f) precluded the use of method patents in foreign countries in 1984, as CPI now contends, Congress would not have stated only two years later that existing law contained no such prohibition. The *only* protection against use of patented processes in foreign countries is that set forth in § 271(g).

3. The AT&T Court noted that its conclusions concerning the clear limits of the text of § 271(f) were reinforced by the presumption against extraterritoriality. 127 S. Ct. at 1758. The Court explained that "§ 271(f) is an exception to the general rule that our patent law does not apply extraterritorially" and stated that it would not give the language of § 271(f) an "expansive interpretation." Id. at 1751, 1758. Applying that presumption to the facts presented in AT&T, the Court concluded that "the presumption tugs strongly against construction of § 271(f) to encompass as a 'component' not only a physical copy of software, but also software's intangible code, and to render 'supplie[d] . . . from the United States' not only exported copies of software, but also duplicates made abroad." Id. at 1758.

The Court rejected AT&T's argument that the presumption was inapplicable because Congress enacted § 271(f) specifically to extend the reach of United States patent law to cover certain activity abroad, noting that the presumption "remains instructive in determining the *extent* of the statutory exception." *Id*.

The presumption against extraterritorial application of § 271(f) is vital because the contrary interpretation would improperly interfere with the ability of many countries to regulate their own commercial affairs. Under the *Shell Oil* interpretation of § 271(f), a foreign company using, in Europe, a business method developed and patented in the United States could be liable for infringing a U.S. patent. The European Patent Convention, however, does not allow patent protection of business methods. *See* http://www.european-patent-office.org/legal/epc/e/ar52.html#A52. As this example illustrates, *Shell Oil*'s expansive interpretation of § 271(f) transgresses the principle that "an act of Congress ought never to be construed to violate the law of nations if any other possible construction remains." *Murray v. Schooner Charming Betsy*, 6 U.S. 64, 118 (1804).

When St. Jude's ICDs are shipped from the U.S., they are not programmed to deliver any form of therapy. A5998; A6556. The ICD must be configured by a physician using an external programmer before it will deliver any form of therapy to a patient. Moreover, the most common setting of the ICD by physicians is for delivery of defibrillation therapy *only*, which renders the device incapable of exe-

cuting a separate cardioversion method, as required for any potential infringement of claim 4. A66; A5998; A6556-6557. Nevertheless, the panel's approach to the interpretation of § 271(f) would invoke U.S. patent law whenever a German physician in Germany prescribes a particular combination of therapies for her patient, even though (1) the ICD device itself is not patented under U.S. or German law and (2) the prescribed method of therapy is not patented in Germany. This result would render meaningless the presumption against extraterritoriality that underlies all of U.S. patent law, as recently reaffirmed by the Supreme Court in *AT&T*.

4. The applicability of § 271(f) to process claims is an important question that should be resolved by the en banc Court one way or the other to give all participants in the patent system—and the district court judges who must resolve most of these issues—clear guidance on whether overseas activities can result in infringement of process claims. If nothing else, the Supreme Court's decision in AT&T is a clear indication that the scope of liability for extraterritorial infringement under § 271(f) is a matter of significant national and international concern. Indeed, the amicus briefs filed in that case—from corporations, inventors, and trade associations (both foreign and domestic)—reflect the wide interest in the appropriate reach of § 271(f). Since then, the national and world economies have experienced increased volatility, heightening the need for clear rules with respect to the scope of the U.S. patent laws.

The panel in this case was bound by the *Shell Oil* precedent, but its decision can be read as an invitation for the en banc Court to revisit the applicability of § 271(f) to process claims. The Court should accept that invitation.

II. A Jury Verdict Of Nonobviousness Does Not Preclude A Finding Of Anticipation

After this case was briefed and argued, this Court issued a significant decision addressing the interplay between the anticipation and obviousness defenses. *Cohesive Technologies*, 543 F.3d 1351. There, the district court had rejected an anticipation defense on the ground, among others, that "the jury had the opportunity to consider the same references for obviousness." *Id.* at 1363. This Court ruled that the jury should have been allowed to resolve *both* defenses, stressing that "novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103 are separate conditions of patentability and therefore separate defenses available in an infringement action." *Id.* The Court emphasized that "[t]he tests for anticipation and obviousness are different" (*id.* at 1364), explaining:

Obviousness can be proven by combining existing prior art references, while anticipation requires all elements of a claim to be disclosed within a single reference. Moreover, obviousness requires analysis of secondary considerations of nonobviousness, while secondary considerations are not an element of a claim of anticipation. And although anticipation can be proven inherently, proof of inherent anticipation is not the same as proof of obviousness.

Id. (citations omitted).

Cohesive Technologies noted that "[w]e have expressly upheld a jury verdict of anticipation under § 102(b), even when the same jury found the patent nonobvi-

ous under § 103." 543 F.3d at 1364 n.2 (citing *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1563 (Fed. Cir. 1993)). Therefore, the Court held that "[a] court cannot refuse to submit the issue of anticipation to the jury simply because the accused infringer has also asserted an obviousness defense"; rather, "[a]n accused infringer that introduces a prior art reference and makes a non-frivolous argument that each and every limitation of a claim is found, expressly or inherently, in that single prior art reference generally is entitled to have anticipation decided by the finder of fact." *Id.* at 1364-65 (internal quotation and alteration omitted).

The panel in this case rendered a decision on anticipation that is flatly inconsistent with *Cohesive Technologies*, creating a square conflict that warrants resolution by the en banc Court. The panel in this case, like the district court in *Cohesive Technologies*, rejected the anticipation defense on the ground that the jury had considered the same references en route to finding the patent nonobvious. *See* slip op. 11 ("both references were presented to the jury," which "found that those references did not invalidate the patent" as obvious under § 103).

In this case, the construction of one of the claim elements (the "determining" step) changed between the jury's verdict of nonobvious and St. Jude's assertion of its anticipation defense. Based on the previous claim construction—which required the use of PDF circuitry—there was a difference between the prior art and the claimed invention, which rendered the anticipation defense unavailable to St.

Jude at trial. See, e.g., Net MoneyIN, Inc. v. Verisign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008) ("differences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation").

On remand, the district court re-construed the claim element in a way that allowed St. Jude to assert, for the first time, that a single reference (indeed, two separate references) anticipated every element of the sole asserted claim. The panel did not disagree with the district court that the claim was, in undisputed fact, anticipated by the prior art; rather, the panel recited that "the jury's verdict of validity [i.e., nonobviousness] could not have depended upon the erroneous construction of 'determining' because it was uncontested during trial that that term was present in the prior art." Slip op. 11. This confuses obviousness with anticipation in precisely the way that the *Cohesive Technologies* Court rejected.

CPI has previously attempted to avoid the anticipation defense by arguing that St. Jude could have urged a different construction of the "determining" step to the jury in the first trial. This argument borders on the preposterous—the original claim construction was the law binding both the parties and the jury. *Markman v. Westview Investments*, 517 U.S. 370, 372 (1996). A party may not urge a contrary view of the law to a jury. Although this Court ultimately determined that the construction was wrong, that is an *appellate* court's prerogative; and it gave rise, as such rulings frequently do, to previously unavailable invalidity defenses. *Exxon*

Chem. Patents, Inc. v. Lubrizol Corp., 137 F.3d 1475, 1477-1480 (Fed. Cir. 1998); Turbocare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1113 (Fed. Cir. 2001); Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1376 (Fed. Cir. 1998).

Moreover, the jury that considered the obviousness defense *could* have found that all claim elements were present in the prior art, but that the invention was nonobvious based, for instance, on "secondary considerations." *See Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966). Indeed, that is precisely what CPI urged at trial, and again in the first appeal. A5851-5855. Such secondary considerations, of course, are irrelevant to an anticipation defense; accordingly, the same references can lead to a finding of anticipation even in the face of a verdict of nonobviousness—as *Cohesive Technologies* held.

The panel in this case held that the jury's verdict of nonobviousness precluded consideration of St. Jude's anticipation defense. The *Cohesive Technologies* majority held exactly the opposite. This square intracircuit conflict warrants review and resolution by the en banc Court.

CONCLUSION

The case should be reheard en banc.

Respectfully submitted this 21st day of January, 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of January, 2009, I caused two copies of the foregoing brief to be served on the following counsel for appellants by United States Mail, with a courtesy copy by hand to Mr. Jakes:

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REQUIRED ADDENDUM

Opinion sought to be reheard (Fed. Cir. R. 35(c)(3)):

Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., Nos. 2007-1296, -1347 (Dec. 18, 2008)

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2007-1296, -1347

CARDIAC PACEMAKERS, INC. and GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

and

MIROWSKI FAMILY VENTURES, LLC and ANNA MIROWSKI,

Plaintiffs-Appellants,

٧.

ST. JUDE MEDICAL, INC. and PACESETTER, INC.,

Defendants-Cross Appellants.

Arthur I. Neustadt, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Alexandria, Virginia, argued for all plaintiffs-appellants. With him on the brief for Mirowski Family Ventures, LLC, et al. was <u>Barry J. Herman</u>. On the brief for Cardiac Pacemakers, Inc., et al. were <u>J. Michael Jakes</u>, <u>Kara F. Stoll</u>, <u>Michael V. O'Shaughnessy</u>, and <u>Molly R. Silfen</u>, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC.

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Appealed from: United States District Court for the Southern District of Indiana

Judge David F. Hamilton

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2007-1296, -1347

CARDIAC PACEMAKERS, INC. and GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

and

MIROWSKI FAMILY VENTURES, LLC and ANNA MIROWSKI,

Plaintiffs-Appellants,

٧.

ST. JUDE MEDICAL, INC. and PACESETTER, INC.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the Southern District of Indiana in 96-CV-1718, Judge David F. Hamilton.

DECIDED: December 18, 2008

Before NEWMAN, MAYER, and LOURIE, Circuit Judges.

LOURIE, Circuit Judge.

Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively "Cardiac" or "appellants") appeal from the decision of the United States District Court for the Southern District of Indiana

granting summary judgment of invalidity of claim 4 of U.S. Patent 4,407,288 ("the '288 patent"). See Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 483 F. Supp. 2d 734 (S.D. Ind. 2007) ("Invalidity Decision"). St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "St. Jude") cross-appeal the district court's decision permitting damages under 35 U.S.C. § 271(f). See Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 418 F. Supp. 2d 1021, 1027-30 (S.D. Ind. 2006) ("Damages Decision"). Because the district court erred in concluding that it could find the '288 patent anticipated, we reverse on invalidity. As infringement has already been decided by the court, we remand the case for a determination of the damages award. Such a determination should be made in accordance with the district court's prior rulings, which we affirm, limiting damages to those devices that can be shown to have executed the steps comprising claim 4 of the '288 patent.

BACKGROUND

This is a patent dispute relating to implantable cardioverter defibrillators that has been before us on four previous occasions. See Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 296 F.3d 1106 (Fed. Cir. 2002); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371 (Fed. Cir. 2004) ("2004 Opinion"); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 144 Fed. Appx. 106 (Fed. Cir. 2005) ("2005 Reassignment Order"); In re Cardiac Pacemakers, Inc., 183 Fed. Appx. 967 (Fed. Cir. 2006) ("2006 Writ Order"). Three of our prior decisions, the 2004 Opinion, the 2005 Reassignment Order, and the 2006 Writ Order, are at issue in this appeal.

Implantable cardioverter defibrillators ("ICDs") are small devices that detect and correct abnormal heart rhythms that can be fatal if left untreated. Defibrillators work by

administering electrical shocks to the heart, those shocks being calibrated to restore normal heart functioning. There are different types of electrical shocks that defibrillators can be programmed to administer, including pacing shocks (which are relatively low power shocks), defibrillation (relatively high power shocks), and cardioversion, the definition of which has been a source of dispute throughout the protracted litigation of this case.

Cardiac owns various patents relating to cardiac defibrillators, including the '288 patent. The '288 patent claims a method of heart stimulation using an implantable heart stimulator that is capable of detecting heart arrhythmias, or irregular heart rhythms, and of being programmed to treat the arrhythmia through either single or "multimode" operation. Multimode operation allows defibrillators to respond to arrhythmias by applying first one type of shock and then, if unsuccessful, administering a second type of shock. Multimode allows an implantable cardioverter defibrillator to administer various types of shocks consecutively until the normal heart rhythm is restored.

Cardiac brought an infringement action against St. Jude, accusing St. Jude of selling ICDs that infringed Cardiac's patents. In 2001 the case went to trial, and a jury returned a verdict awarding Cardiac \$140 million in royalties for infringement of U.S. Patent 4,316,472 ("the '472 patent"). As for the '288 patent, the jury found the patent valid and enforceable, but not infringed by St. Jude's ICDs. The jury rejected St. Jude's arguments that the invention of the '288 patent was obvious in light of various prior art references, including U.S. Patent 3,805,795 ("Denniston") and United Kingdom Patent Application 2,026,870 ("Duggan"). The jury also rejected St. Jude's argument that the

'288 patent was unenforceable for inequitable conduct.1

Following the trial, the district court granted several post-verdict motions that overturned the jury verdict and conditionally granted a new trial on several issues that St. Jude had lost at trial. The court granted St Jude's JMOL motions holding the '472 patent not infringed and invalid, as well as St. Jude's motion for a conditional new trial on damages. That decision vacated the damages awarded by the jury. Cardiac has not appealed any of the court's decisions regarding the '472 patent.

Regarding the '288 patent, the district court denied Cardiac's request for a new trial on infringement. Cardiac had claimed that it had been denied a fair trial on the '288 patent due to St. Jude's opening statement and presentation about the inconsistent reports of Dr. Joseph Bourland, one of Cardiac's primary experts. The court also granted St. Jude's JMOL motion and request for a new trial, finding that the '288 patent was invalid on the grounds of obviousness and lack of best mode. The court denied St. Jude's JMOL motion of unenforceability in which St. Jude argued that the '288 patent was unenforceable due to Cardiac's alleged failure to pay proper maintenance fees.

Following the district court's decisions, Cardiac appealed the court's grant of JMOL of invalidity of the '288 patent as well as the court's rejection of JMOL of infringement of claim 4 of that patent. On appeal, we reversed on both issues. Regarding validity, we held that there was "substantial evidence whereby a reasonable jury could have reached the verdict that it would not have been obvious in March 1981 to provide an ICD that includes cardioversion," and therefore reinstated the jury verdict

The jury also rejected St. Jude's argument that the '288 patent failed to comply with the best mode requirement of 35 U.S.C. § 112 ¶ 1. St. Jude has not appealed any decisions relating to 35 U.S.C. § 112 in this appeal.

that the "'288 patent is not invalid for obviousness." <u>2004 Opinion</u> 381 F.3d at 1378-80. We also found that the district court's conditional grant of a new trial on obviousness "exceeded the court's discretionary authority." <u>Id.</u> at 1380.

Regarding infringement, we reversed the court's claim construction and therefore vacated the jury's finding of non-infringement. We held that the district court had erred in finding that the "determining" step of claim 4 was a "step-plus-function" limitation under 35 U.S.C. § 112 ¶ 6 and remanded the case to the district court to modify the claim construction of the "determining" step in accordance with our opinion. Id. at 1382. Lastly, we agreed with St. Jude that our reversal of the district court's claim construction entitled St. Jude to a "jury determination on the question of infringement." Id. at 1383.

We summarized our holding as follows:

We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial on infringement and reassessment of damages.

Id. at 1374.

On remand, the case was returned to Judge Hamilton. Cardiac challenged the assignment, claiming that Seventh Circuit Rule 36 required automatic reassignment of a case remanded for a new trial to a new judge. Judge Hamilton ultimately agreed with Cardiac and agreed to reassign the case. He then certified the issue for an interlocutory appeal. St. Jude appealed the reassignment decision to this court, and we reversed, finding that reassignment to Judge Hamilton would best conserve judicial resources. 2005 Reassignment Order, 144 Fed. Appx. at 106. We also noted that the case had been remanded for "a new trial on literal infringement of one claim of one patent and for any damages determination." Id. at 107.

After this remand, both sides submitted to the district court proposed claim constructions for the disputed "determining" limitation in claim 4 of the '288 patent, and the district court adopted Cardiac's definition of "determining" with one minor change (which is not challenged on appeal). Damages Decision, 418 F. Supp. 2d at 1027-30. Cardiac also moved for summary judgment on St. Jude's invalidity and unenforceability defenses, arguing that such defenses were precluded by our 2004 Opinion and the mandate rule. The district court disagreed and denied the motion. The court found that "[t]he Federal Circuit's remand left open the possibility of new invalidity and unenforceability defenses." Id. at 1031. According to the district court, while the mandate rule precluded assertion of the same obviousness argument raised and lost previously, "St. Jude's other theories of invalidity were not within the scope of the appealed judgment and therefore may be asserted on remand." Id. at 1032. In arriving at that conclusion, the district court relied on three points. First, the court found that our remand instructions "suggested" that a new claim construction might give rise to new invalidity defenses, particularly with regard to the adequacy of the written description requirement. Id. Second, the court found that because St. Jude had no obligation on appeal to present alternative arguments for invalidity, those alternative arguments were not precluded on remand. Id. at 1032-33. Third, and most importantly, the court found that St. Jude did not abandon or waive its invalidity defenses that became relevant only on remand; that is, due to the court's new claim construction of "determining," certain prior art that was not invalidating under the erroneous claim construction may have become invalidating under the new claim construction. <u>Id.</u> at 1033.

The district court also rejected Cardiac's motion for summary judgment on St.

Jude's affirmative defenses and related counterclaims. The court found that "all of St. Jude's arguments concerning unenforceability" could be asserted on remand. <u>Id.</u> The district court found that this court's mandate "did not even suggest, let alone require," that the issue of inequitable conduct be precluded from adjudication on remand. <u>Id.</u> at 1034.

Finally, the district court granted in part and denied in part St. Jude's motion for summary judgment limiting damages. The court granted St. Jude's motion to limit damages to ICDs that actually performed the claimed steps. <u>Id.</u> at 1040. The court held that because claim 4 is a method claim, only those devices that "can be shown to have executed" the claimed method were to be used in the damages calculation. <u>Id.</u> at 1042. However, the court rejected St. Jude's motion to limit damages to U.S. sales of ICDs. The court held that, according to Federal Circuit case law on 35 U.S.C. § 271(f), Cardiac was not limited in its potential damages award to infringing devices that were sold in the United States. <u>Id.</u> at 1042-44.

Following the district court's ruling on claim construction and summary judgment, Cardiac petitioned this court for a writ of mandamus directing the district court to vacate its order allowing St. Jude to assert invalidity and inequitable conduct defenses on remand. We denied the petition. In doing so, we stated:

[W]e repeat that we "remand[ed] for a new trial of infringement and reassessment of damages," including re-construction by the district court of the "determining" provision in light of our ruling that section 112 ¶ 6 did not apply. We also recognized that a new claim construction may raise directly related new issues, "such as whether the now-asserted scope of the claims is supported by the specification."

All of the other issues on remand were finally decided, and are not subject to reopening on remand.

<u>2006 Writ Order</u>, 183 Fed. Appx. at 967 (citations omitted) (emphasis added). The case was once more remanded to the district court.

On March 26, 2007, the district court granted Cardiac's motion for summary judgment of infringement, while also granting St. Jude's motion for summary judgment of anticipation. As a threshold matter, the district court found that because of the new, broader claim construction, the anticipation defense was, in the words of this court, a "directly related new issue," and therefore not precluded by our previous decisions. Invalidity Decision, 483 F. Supp. 2d at 738-739. The court then turned to the prior art and found that the '288 patent was anticipated by two references that had been previously presented to the jury: Denniston and Duggan. Final judgment was entered by the district court.

Cardiac timely appealed and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review the district court's grant of summary judgment <u>de novo</u>, "applying the same criteria used by the district court in the first instance." <u>Rothe Dev. Corp. v. Dep't of Defense</u>, 545 F.3d 1023, 1035 (Fed. Cir. 2008) (quoting <u>W.H. Scott Constr. Co. v. City of Jackson</u>, 199 F.3d 206, 211 (5th Cir. 1999)). Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). We review the interpretation of our own mandates <u>de novo</u>. <u>Engel Indus.</u>, <u>Inc. v. Lockformer Co.</u>, 166 F.3d 1379, 1382 (Fed. Cir. 1999).

A. <u>Invalidity</u>

On appeal, Cardiac argues that the district court erred in granting summary judgment of invalidity. Preliminarily, Cardiac argues that invalidity was not at issue on remand because the mandate rule precluded St. Jude's anticipation defense. If we find that anticipation was still at issue on remand, Cardiac argues that we should also find that the district court erred in finding that genuine issues of material fact did not exist as to whether Duggan and Denniston were anticipating references, particularly with respect to whether Duggan teaches cardioversion and whether Denniston teaches programming.

In response, St. Jude argues that while the mandate rule bars consideration of obviousness on remand, it does not bar an anticipation defense. According to St. Jude, our reversal of the "determining" construction in the <u>2004 Opinion</u> created new validity defenses due to the changed claim scope. St. Jude also claims that the '288 patent was anticipated by both Denniston and Duggan, as the district court found.

We agree with Cardiac that anticipation was not properly before the district court on remand. In the <u>2004 Opinion</u>, we clearly stated that the purpose of the remand was "for a new trial of infringement and reassessment of damages." <u>2004 Opinion</u>, 381 F.3d at 1374. Furthermore, we explicitly "reinstate[d] the jury verdict of validity." <u>Id.</u> The mandate rule requires that the district court follow an appellate decree as the law of the case. <u>See Sibbald v. United States</u>, 37 U.S. 488, 492 (1838). Therefore, according to our explicit instructions, any new trial on remand was limited to an assessment of infringement and a calculation of any damages.

Of course, as St. Jude rightly notes throughout its briefs, our 2004 Opinion

altered the district court's claim construction, and in the <u>2006 Writ Order</u> we left open the possibility that a new claim construction ruling "may raise directly related new issues." <u>2006 Writ Order</u>, 183 Fed. Appx. at 967. As one example of a directly related new issue, we noted the question whether the scope of the claims under the new claim construction was supported by the specification. <u>Id.</u> We did not explicitly include or exclude anticipation from the list of possible new issues raised by a new construction of "determining."

Thus, the question before us today is whether anticipation is a "directly related new issue," or whether our reinstatement of the jury's validity verdict precludes raising anticipation on remand. In this case, a jury found that the '288 patent was nonobvious in light of numerous prior art references, including both Duggan and Denniston. At trial, Cardiac did not dispute that the "determining" step was in the prior art and did not raise that step as a distinguishing feature between the '288 patent and Duggan or Denniston. See Reply Brief of Plaintiffs-Appellants at 12-14, 2004 Opinion (arguing that Duggan and Denniston do not teach cardioversion); Brief of Plaintiffs-Appellants at 21-24, 2004 Opinion, 381 F.3d 1371 (Fed. Cir. 2004) (arguing that the jury heard evidence that the prior art did not teach "cardioversion," "multi-mode operation," and "programmability"); but see id. at 22 (noting evidence that the Baker reference does not perform, among other things, the determining step). In fact, the evidence of obviousness during the trial primarily focused on whether the prior art taught multi-mode with cardioversion. See Brief for Defendants-Cross Appellants at 7-8, 2004 Opinion (stating that with regard to obviousness, the only disputed limitations were the claimed invention's ability to perform multimode operation and the use of cardioversion). In finding the claims of the '288

patent nonobvious, the jury reached the conclusion that some element necessary to prove obviousness had not been demonstrated. For St. Jude to succeed in this appeal, that missing element would have to have been the "determining" limitation.

In allowing St. Jude's anticipation defense on remand, the district court stated that due to the erroneous claim construction, "St. Jude may have chosen not to pursue some invalidity defenses, including anticipation, at trial." Damages Decision, 418 F. Supp. 2d at 1033. While it is true that new anticipation arguments may arise under a change in claim construction, that cannot be the case here because the "determining" limitation never served as a basis for distinguishing the prior art from the '288 patent. Duggan and Denniston were not only known to St. Jude before trial, but both references were presented to the jury. The jury found that those references did not invalidate the patent even though Cardiac did not dispute that the "determining" construction was known in the prior art. Thus, it cannot be said that the jury's decision hinged on the erroneous construction of that claim. Stated differently, the jury's verdict of validity could not have depended upon the erroneous construction of "determining" because it was uncontested during trial that that term was present in the prior art.

The initial, erroneous construction of "determining" was appealed by Cardiac in order to challenge the jury's verdict of non-infringement. While a change in claim construction often may affect a jury's validity determination, in this case it does not. Therefore, St. Jude cannot now be allowed to claim that its anticipation arguments involving Duggan and Denniston are "directly related" to the change in the construction of "determining," because the jury's validity determination, which we reinstated, did not depend upon that erroneous definition.

We therefore reverse the district court's summary judgment of invalidity and reinstate the jury's verdict that the '288 patent has not been shown to be invalid.

B. Inequitable Conduct

Cardiac asks this court to instruct the district court that enforceability defenses are precluded from any remand order. According to Cardiac, the mandate rule requires such a determination. St. Jude counters that inequitable conduct is still at issue on remand because of the district court's explicit ruling that "in the event of a new trial . . . the inequitable conduct defense shall be part of the trial." Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., No. IP-96-1718-C, 2002 U.S. Dist. LEXIS 14767, at *143 (S.D. Ind. July 5, 2002). Because Cardiac failed to appeal this ruling, St. Jude contends, that decision is final.

The district court characterized St. Jude's inequitable conduct arguments as falling into three broad categories. The first category involved misrepresentations made before the PTO. <u>Damages Decision</u>, 418 F. Supp. 2d at 1033-34. Some of these arguments were raised by St. Jude at trial and rejected by the jury. <u>Id.</u> at 1034. Others were raised and abandoned at trial. <u>Id.</u> The second category of arguments involved three patents that are no longer at issue in this case. St. Jude alleges that they were asserted even though Cardiac knew that they were invalid. <u>Id.</u> The district court granted Cardiac's motion for summary judgment on these arguments, and St. Jude did not appeal that decision. <u>Id.</u>

We conclude that St. Jude has waived both categories of the arguments above. St. Jude either failed to pursue those arguments at trial, thereby waiving the arguments, or failed to appeal the arguments to this court. <u>Id.</u> St. Jude cannot now be heard to

raise those arguments again on remand.

A third category of inequitable conduct arguments relates to misrepresentations made by Cardiac's expert, Dr. Bourland. The jury rejected many of St. Jude's inequitable conduct arguments based on Dr. Bourland's conduct, and the district court declined to reverse the jury's decision. However, due to revelations that came to light after trial, the court found that Dr. Bourland's conduct entitled St. Jude to a new trial. Cardiac, 2002 U.S. Dist. LEXIS 14767, at *143. In September 2006, the parties filed a stipulation stating that St. Jude would not pursue any defense based in whole or in part on Dr. Bourland's conduct. Following this stipulation, Cardiac filed a renewed motion for summary judgment on inequitable conduct. The district court never ruled on Cardiac's renewed motion because it entered a final judgment on anticipation on March 26, 2007.

With the stipulation removing Dr. Bourland's conduct as a basis for an inequitable conduct defense, St. Jude cannot now be heard to raise inequitable conduct on remand. Any language from the district court's opinion indicating otherwise would be an abuse of the court's discretion to grant a new trial. We therefore reinstate the jury's verdict of enforceability of the '288 patent and hold that enforceability should not form part of any new trial on remand.

C. <u>Damages</u>

Cardiac argues that the district court erred by limiting damages to those ICDs that actually performed cardioversion during the infringement period. According to Cardiac, St. Jude waived its damages argument by not raising it at trial. Furthermore, Cardiac argues, Stryker Corp. v. Intermedics Orthopedics, Inc., 96 F.3d 1409 (Fed. Cir. 1996), and other cases have held that it is appropriate for patentees to recover

damages based on sales of products with the mere capability to practice the invention.

St. Jude responds that it is not precluded from arguing for limited damages because the remanded damages assessment was significantly altered from the assessment that occurred at trial. Because Cardiac is now asserting only a method claim, St. Jude contends, any damages claim must be limited accordingly. Furthermore, in a cross-appeal, St. Jude argues that the district court erred in concluding that Cardiac could recover damages for overseas sales of St. Jude's ICDs under 35 U.S.C. § 271(f).

We agree with St. Jude that damages must be limited to those devices that were shown to infringe the '288 patent, but we reject St. Jude's cross-appeal seeking to limit overseas damages. As a preliminary matter, we find that St. Jude has not waived its argument to limit damages. The jury was presented with a damages decision regarding two claims of the '288 patent: an apparatus claim that has since been abandoned by Cardiac and the method claim (claim 4) that is at issue on appeal. While both patent claims were at issue during trial, St. Jude would not have benefited if it had moved to limit damages because the damages on the apparatus claims would have covered any sale of an apparatus that could execute the elements of the claims. However, now only a method claim is at issue; thus, St. Jude stands to benefit from limiting damages to devices that actually practice the method. As the district court noted, the purpose of the waiver rule is to prevent a party from arguing on remand what it should have argued at trial or on appeal. Damages Decision, 418 F. Supp. 2d at 1035 (citing Tronzo v. Biomet, Inc., 236 F.3d 1342, 1347-48 (Fed. Cir. 2001)). St. Jude cannot have been expected to raise at trial an argument that would not have reduced damages until after

Cardiac abandoned its apparatus claim on remand.

The district court was also correct in limiting damages to sales of ICDs that performed the steps of the claimed method. Cardiac disputes the district court's ruling by pointing this court to Stryker, in which we affirmed a district court's decision awarding damages on sales of an infringing prosthesis, even in cases in which a distal sleeve, a required element of the claim, was not included. See Stryker, 96 F.3d at 1416-17. The holding in Stryker is distinguishable from this case by the type of damages being sought and the type of patent being asserted. In Stryker, the patentee was seeking lost profits on an apparatus claim. We held, based on the particular facts of that case, that the patentee was entitled to profits on the sale of all devices, with or without the required distal sleeve because the sale of the device robbed the patentee of "the opportunity to make the sale." Id. at 1417. This was true because the sleeve, while not included in every sale, was available to the surgeon during surgery. Id.

In the present case, however, Cardiac is not seeking lost profits on an apparatus and therefore cannot rely on the reasoning in Stryker. Here, Cardiac seeks royalties on its patented method. "A method claim is directly infringed only by one practicing the patented method." Joy Tech. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993). Thus, regarding claim 4 of the '288 patent, infringement can only occur in cases in which the patented method is practiced. In Stryker, the court found that because the entire patented apparatus was "supplied" during surgery, the patent was infringed by any sale of the device. Stryker, 96 F.3d at 1416-17. In this case it cannot be said that St. Jude has somehow "supplied" all of the elements of Cardiac's patented method through its devices unless those devices actually performed all of the steps required by the claims.

"The law is unequivocal that the sale of equipment to perform a process is not a sale of the process." <u>Joy Tech.</u>, 6 F.3d at 773. Therefore, Cardiac can only receive infringement damages on those devices that actually performed the patented method during the relevant infringement period. We thus affirm the district court's ruling.

We also affirm the district court's ruling on the application of 35 U.S.C. § 271(f) to this case. St. Jude urges us to hold that the Supreme Court's decision in Microsoft Corp. v. AT&T Corp., 550 U.S. 437 (2007) overturns this court's prior precedents that have held that § 271(f) applies to method claims. We do not agree. As St. Jude admits, the Supreme Court "left open the question of whether Section 271(f) applies to method claims." Appellees' Brief at 62. St. Jude would have us extend the reasoning behind the Supreme Court's decision in AT&T to overturn this court's decision in Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005) (holding that Section 271(f) applies to components used in the performance of patented methods and processes). We decline to do so. While this court was not unanimous in its approval of the holding in Union Carbide, see Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 434 F.3d 1357, 1358-59 (Fed. Cir. 2006) (Lourie, J., Michel, J., and Linn, J., dissenting from order denying rehearing en banc), the Supreme Court's decision does not alter that holding. As a panel, we cannot reverse the holding of another panel of this court. We thus affirm the district court's decisions relating to damages.

D. Reassignment

Finally, Cardiac urges this court to reassign the case to a different judge on remand. However, there is no evidence of, and Cardiac does not appear to allege, that

Judge Hamilton has been impartial or biased in any way during the proceedings. We therefore refuse to designate the proper judge to preside over the remand. As an appellate court, we must review decisions stemming from the internal procedures of district courts around the country. We should not, however, be in the habit of dictating to those district courts how they should conduct their internal affairs prior to any decision being made in a particular case. We see no reason to interfere with the internal operations of the Seventh Circuit, and leave the determination of assignment on remand to that circuit's internal rules and procedures.

CONCLUSION

For the foregoing reasons, we <u>reverse</u> the district court's grant of summary judgment of invalidity of the '288 patent and reinstate the jury verdict that the patent has not been shown to be invalid. We also reinstate the jury's verdict that the '288 patent is not unenforceable for inequitable conduct and <u>reverse</u> the district court's grant of a conditional new trial on that issue. We <u>remand</u> to the district court for a determination of damages. We <u>affirm</u> the district court's rulings limiting damages to instances in which the patented method has been performed and permitting the application of 35 U.S.C. § 271(f).

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED