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,

v.

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 Barry J. Herman. On the brief for Cardiac Pacemakers, Inc., et al., were J. Michael Jakes, Kara F. Stoll, Michael V. O'Shaughnessy and Molly R. Silfen, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC.

Mark A. Perry, Gibson, Dunn & Crutcher LLP, of Washington, DC, argued for defendants-cross appellants. With him on the brief was Denis R. Salmon, and H. Mark Lyon, of Palo Alto, California. Of counsel on the brief was Jeffrey M. Olson, Sidley Austin LLP, of Los Angeles, California.

Mark M. Supko, Crowell & Moring LLP, of Washington, DC, for amici curiae Federal Circuit Bar Association, et al., on petition for rehearing en banc. With him on the brief were Michael I. Coe; and Alyson G. Barker, Howrey LLP, of Irvine, California. Of counsel on the brief were Joseph R. Re, Federal Circuit Bar Association, of Washington, DC, and Teresa Stanek Rea, American Intellectual Property Law Association, of Arlington, Virginia.

Jamie H. McDole, Kirkland & Ellis LLP, of Chicago, Illinois, for amicus curiae Research in Motion Limited, on petition for rehearing en banc.

Edward R. Reines, Weil, Gotshal & Manges LLP, of Redwood Shores, California, for amici curiae Cisco Systems, Inc., et al., on petition for rehearing en banc. With him on the brief were Melanie P. Sarwal, of Austin, Texas, and Rebecca Fett, of New York, New York.

Lance A. Lawson, Alston & Bird LLP, of Charlotte, North Carolina, for amici curiae AGA Medical Corporation, et al., on petition for rehearing en banc. With him on the brief were Michael S. Connor, Kirk T. Bradley and Brian F. McMahon.

R. Carl Moy, William Mitchell College of Law, of St. Paul, Minnesota, for amicus curiae William Mitchell College of Law, on petition for rehearing en banc. With him on the brief was Jay Erstling.

Daryl Joseffer, of McLean, Virginia, for amicus curiae Ormco Corporation, on petition for rehearing en banc. With him on the brief was David L. DeBruin, Michael Best & Friedrich LLP, of Milwaukee, Wisconsin.

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

Judge David F. Hamilton

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,

v.

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: August 19, 2009

Before NEWMAN, MAYER, and LOURIE, Circuit Judges. Opinion for the court filed by Circuit Judge LOURIE, in which Circuit Judge MAYER joins and Circuit Judge NEWMAN joins parts A, B, C.1, and D.

Part C.2 was heard en banc before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges. Opinion for the court filed by Circuit Judge LOURIE, in which Chief Judge MICHEL and Circuit Judges MAYER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE join. Dissenting opinion filed by Circuit Judge NEWMAN.

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 Med., Inc., 483 F. Supp. 2d 734 (S.D. Ind. 2007) ("Invalidity Decision"). Cardiac also appeals aspects of the district court's decision concerning damages. See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 418 F. Supp. 2d 1021, 1027-30 (S.D. Ind. 2006) ("Damages Decision"). Because the district court erred in concluding in light of our prior mandates that it could find the '288 patent anticipated, we reverse on invalidity. In light of the fact that infringement has already been decided by the district court, we remand the case solely for a determination of damages. We affirm the court's decision limiting damages to those devices that can be shown to have executed the steps of claim 4 of the '288 patent.

St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "St. Jude") cross-appeal from the district court's decision permitting damages under 35 U.S.C. § 271(f). See Id. at 1027-30. The en banc court reverses the district court's determination that 35 U.S.C. § 271(f) applies to method claims and hence permits damages in this case on devices exported where the claimed method is carried out in countries other than the United States (see Section C.2 of this opinion).

BACKGROUND

This patent dispute concerning implantable cardioverter defibrillators ("ICDs"), has been before us on four previous occasions. See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106 (Fed. Cir. 2002); Cardiac Pacemakers, Inc. v. St. Jude

Med., Inc., 381 F.3d 1371 (Fed. Cir. 2004) ("2004 Opinion"); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 144 F. App'x 106 (Fed. Cir. 2005) ("2005 Reassignment Order"); In re Cardiac Pacemakers, Inc., 183 F. App'x 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 relevant to this appeal.

ICDs are small devices that detect and correct abnormal heart rhythms that can be fatal if left untreated. The ICDs in this case work by administering electrical shocks to the heart, those shocks being calibrated to restore normal heart functioning. Implantable cardiac devices can be programmed to administer different types of electrical shocks, 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 a heart stimulator to respond to arrhythmias by applying first one type of shock and then, if unsuccessful, administering a second type of shock. Claim 4 of the '288 patent, the only claim at issue on appeal, is dependent on claim 1:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising:
> (a) determining a heart condition of the heart from among a plurality of conditions of the heart;

(b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition;
(c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

* * *

4. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion.

The litigation history of this case is complicated and protracted, but for clarity's sake we will recite the portion of that history that is relevant to this appeal. Cardiac brought an infringement action against St. Jude on November 26, 1996, accusing St. Jude of selling ICDs that infringed a number of Cardiac's patents. In 2001 the case was tried before a jury. The jury returned a verdict awarding Cardiac $140 million in royalties for infringement of U.S. Patent 4,316,472 ("the '472 patent"). Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., No. IP-96-1718-C, 2002 U.S Dist. LEXIS 14767, at *7 (S.D. Ind. July 5, 2002). The jury found the '288 patent valid and enforceable, but not infringed by St. Jude's ICDs. Id. at *6-*7. In doing so, the jury rejected St. Jude's argument 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"). Id. at *117, *120. The jury also rejected St. Jude's argument that the '288 patent was unenforceable for inequitable conduct.[1] Id. at *7.

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

[1] 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.

St. Jude had lost at trial. First, the court granted St. Jude judgment as a matter of law ("JMOL") on invalidity and noninfringement of the '472 patent, thereby vacating the jury's $140 million damage award. Id. at *100. Cardiac has not appealed any of the district court's decisions regarding the '472 patent.

Regarding the '288 patent, which the jury found valid and not infringed, the district court granted St. Jude's JMOL motions for invalidity due to obviousness and lack of best mode. Id. at *100-*133. The court denied St. Jude's JMOL motion of unenforceability, in which St. Jude alleged that Cardiac had failed to pay proper maintenance fees. Id. at *133-*143. Finally, the court further denied Cardiac's motion for a new trial on infringement. Id. at *195-*196. The court granted a conditional new trial on the obviousness issue and the inequitable conduct issue in the event that the JMOL decision finding the '288 patent obvious was reversed on appeal. Id. at *114, *143.

Following the district court's post-trial decisions, Cardiac appealed the district court's grant of St. Jude's motion for JMOL of invalidity of the '288 patent as well as the court's rejection of Cardiac's motion for JMOL of infringement of claim 4 of the '288 patent. On appeal, we reversed on both issues. 2004 Opinion, 381 F.3d at 1378-80. 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 that the "'288 patent is not invalid for obviousness. Id. We also found that the district court's conditional grant of a new trial on obviousness "exceeded the court's discretionary authority." Id. at 1380.

Regarding infringement, we reversed the court's claim construction and therefore vacated the jury's finding of noninfringement. 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 its 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 that 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 to reassign the case to another judge. He then certified the issue for an interlocutory appeal. St. Jude appealed the reassignment decision to this court, and we reversed, finding that further assignment to Judge Hamilton would best conserve judicial resources. 2005 Reassignment Order, 144 F. App'x 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.

With that background in mind, we now turn to the decisions of the district court that are at issue on appeal. After that 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. Id. at 1031. 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 our 2004 Opinion precluded assertion of the same obviousness argument that St. Jude had 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 in the 2004 Opinion “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; in other words, 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. Id. at 1033.

The district court also rejected Cardiac’s motion for summary judgment on St. Jude’s affirmative defense of inequitable conduct. The court found that “all of St. Jude’s

arguments concerning unenforceability" could be asserted on remand. Id. 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. Id. 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. Id. 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. Id. 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 regarding 35 U.S.C. § 271(f), Cardiac's potential damages included the sale of infringing devices supplied from the United States to other countries. Id. at 1042-44.

Following the district court's rulings on claim construction and the various summary judgment motions, 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. 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.

2006 Writ Order, 183 F. App'x 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. Invalidity Decision, 483 F. Supp. 2d at 745. 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. Id. at 738-39 (quoting 2006 Writ Order, 183 F. App'x at 967). The court then examined the prior art and found that the '288 patent was anticipated by two references that had been presented to the jury: Denniston and Duggan. Id. at 740-45. Final judgment of invalidity 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 de novo, "applying the same criteria used by the district court in the first instance." Rothe Dev. Corp. v. Dep't of Defense, 545 F.3d 1023, 1035 (Fed. Cir. 2008) (quoting W.H. Scott Constr. Co. v. City of Jackson, 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 de novo. Engel Indus., Inc. v. Lockformer Co., 166 F.3d 1379, 1382 (Fed. Cir. 1999).

A. Invalidity

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. Alternatively, Cardiac argues that if we find that anticipation was still at issue on remand, then we should also find that the district court erred in finding that no genuine issues of material fact existed 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 our 2004 Opinion and the mandate rule bar consideration of obviousness on remand, St. Jude is permitted to bring an anticipation defense. According to St. Jude, our reversal of the "determining" construction in the 2004 Opinion 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 2004 Opinion, we clearly stated that the purpose of the remand was "for a new trial of infringement and reassessment of damages." 2004 Opinion, 381 F.3d at 1374. Furthermore, we explicitly "reinstate[d] the jury verdict of validity." Id. The mandate rule requires that the district court follow an appellate decree as the law of the case. Sibbald v. United States, 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 brief, our 2004 Opinion altered the district court's claim construction, and in the 2006 Writ Order we left open the

possibility that a new claim construction ruling "may raise directly related new issues." 2006 Writ Order, 183 F. App'x at 967. As one example of a directly related new issue, we suggested that written description may be challenged under a new, broader claim construction. Id. 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 now is whether anticipation is a "directly related new issue" in this case, or whether our reinstatement of the jury's validity verdict precludes raising anticipation on remand. The jury found the claims of the '288 patent nonobvious in light of numerous prior art references, including both Duggan and Denniston. In overturning the jury's validity verdict, the district court permitted St. Jude to raise anticipation arguments on remand that St. Jude did not raise at trial. The court based its decision on the fact that "St. Jude may have chosen not to pursue some invalidity defenses, including anticipation, at trial," due to the erroneous claim construction of "determining" used at trial. Damages Decision, 418 F. Supp. 2d at 1033. In finding the claims of the '288 patent nonobvious, the jury necessarily 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.

While it is true that a changed claim construction may permit new anticipation arguments, that cannot be the case here because the "determining" limitation never served as a basis for distinguishing the prior art from the '288 patent and is therefore not a "directly related new issue."

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 Br. of Plaintiffs-Appellants at 12-14, 2004 Opinion (arguing that Duggan and Denniston do not teach cardioversion); Br. of Plaintiffs-Appellants at 21-24, 2004 Opinion (arguing that the jury heard evidence that the prior art did not teach "cardioversion," "multi-mode operation," and "programmability"); cf. id. at 22 (noting evidence that the Baker reference does not perform, among other things, the determining step). The evidence of obviousness during the trial primarily focused on whether the prior art taught multi-mode with cardioversion. See Br. 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). 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 noninfringement. 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. Thus, in light of the jury's verdict and our previous mandates unique to this case, we 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, 2002 U.S. Dist. LEXIS 14767, at *143. Because Cardiac failed to appeal that 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. Damages Decision, 418 F. Supp. 2d at 1033-34. Some of those arguments were raised by St. Jude at trial and rejected by the jury. Id. at 1034. Others were raised and abandoned at trial. Id. The second category of arguments involved three patents that are no longer at issue in this case. St. Jude alleges that those patents were asserted by Cardiac even though Cardiac knew that they were invalid. Id. The district court granted Cardiac's motion for summary judgment on those arguments, and St. Jude did not appeal that decision. Id.

We conclude that St. Jude has waived the first two categories of inequitable

conduct arguments. St. Jude either failed to pursue those arguments at trial, thereby waiving the arguments, or failed to appeal the arguments to this court. Id. 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 Pacemakers, 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 that 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. Damages

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).

1. Damages Limited to Devices Performing Claimed Method

We agree with St. Jude that the district court correctly limited damages to those devices that were shown to infringe the '288 patent. 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." Joy Tech., 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.

2. Section 271(f)

The court hears this section C(2) en banc. The district court, following our decision in Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), found that 35 U.S.C. § 271(f) applied to method claims and that St. Jude's shipment of ICDs abroad could result in a violation of that section. Damages Decision, 418 F. Supp. 2d at 1042-44. On cross-appeal to this court, St. Jude challenged the court's decision. The panel affirmed the court's decision on the basis of Union Carbide. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 303 F. App'x 884 (Fed. Cir. 2008). St. Jude filed a petition for rehearing en banc, which we granted, thus vacating the panel decision. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., No. 07-1296, -1347, 2009 U.S. LEXIS 4379 (Mar. 6, 2009). The en banc court heard oral argument on this issue on May 29, 2009. For the reasons stated below, we reverse and hold that Section 271(f) does not cover method claims and is therefore not implicated in this case.[2]

[2] The court has received a number of briefs amicus curiae on the Section

a. Background on 35 U.S.C. § 271(f)

Before analyzing the merits of St. Jude's cross-appeal, some background on Section 271(f) is in order. In Deepsouth Packing Co., Inc. v. Laitram Corp., 406 U.S. 518 (1972), the Supreme Court held that a manufacturer who shipped unassembled parts of a patented shrimp deveining machine abroad was not liable for patent infringement. Because "it is not an infringement to make or use a patented product outside of the United States," the Court held that the shipment of unassembled components of the deveining machine did not constitute patent infringement. Id. at 527, 531.

In response to Deepsouth, Congress enacted Section 271(f). See, e.g., Patent Law Amendments of 1984, S. Rep. No. 98-663, pp 2-3 (1984) (describing Section 271(f) as a response to the "Deepsouth decision which interpreted the patent law not to make it infringement where the final assembly and sale is abroad"); see also Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 444 & n.3 (2007) (AT&T II) (stating that Section 271(f) was enacted with Congress "[f]ocusing its attention on Deepsouth").

Section 271(f) provides in full as follows:

> (1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
>
> (2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not

---

271(f) issue that we are reviewing en banc. The court is appreciative of these contributions.

> a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

35 U.S.C. § 271(f).[3]

This court first dealt with Section 271(f) in Standard Havens Products, Inc. v. Gencor Industries, Inc., 953 F.2d 1360 (Fed. Cir. 1991). Standard Havens involved patent claims directed to methods of producing asphalt compositions. Id. at 1363. We held simply that a "sale to a foreign customer" of an asphalt plant did not implicate the provisions of Section 271(f). Id. at 1372-74. Our opinion on that issue did not elaborate further.

We more fully addressed Section 271(f) in Eolas Technolgies, Inc. v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005). In that case, we held that Microsoft could not avoid Section 271(f) liability by exporting golden master disks containing software code that were subsequently copied onto computer hard drives and sold outside of the United States. Id. at 1331, 1341. Eolas involved both a product and a method claim. In holding that Microsoft was liable under Section 271(f), we held that the software code included on Microsoft's master disks was a "component" of a patented invention under Section 271(f), id. at 1339, and that the relevant "component" referred to a part of the product claim. See id. at 1339 (holding that the "computer readable code claimed in claim 6," the product claim, was "a part or component of that invention"). We rejected

[3] Our analysis here focuses on 271(f)(1), but is equally applicable to 271(f)(2). While the two paragraphs differ in some respects, neither party argues that the differences are relevant in this case. Indeed, both paragraphs require the "supply" of "components" that are capable of being "combined outside of the United States." Compare 35 U.S.C. § 271(f)(1) & (2); see also AT&T II, 550 U.S. 437, 454 n.16. The definition of those terms guides our analysis on this issue.

Microsoft's argument that the term "component" was limited to physical items, id. at 1340, and held that "section 271(f)'s 'components' include software code on golden master disks," id. at 1341. No specific mention was made in Eolas concerning the relationship between Section 271(f) and the method claims. See id. at 1339 (citing the patent specification, not the claims, as evidence that the patented invention was a software product).

Shortly after Eolas issued, we decided a similar issue in AT&T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed. Cir. 2005) (AT&T I). AT&T I involved a factual scenario similar to that in Eolas: Microsoft exported golden master disks containing software that was covered by a patent held by AT&T. The software, once shipped abroad, was copied onto hard drives and sold to foreign customers. In our holding in AT&T I, we relied on the holding in Eolas that intangible software code was capable of being a component of a patented invention. Id. at 1369. We further held that such software was "supplied" for purposes of Section 271(f) when "a single copy [was sent] abroad with the intent that it be replicated." Id. at 1370.

In the same year that we decided Eolas and AT&T I, we decided a third case dealing with the scope of Section 271(f). Our discussion of Section 271(f) in NTP, Inc. v. Research in Motion, Ltd. was limited to the question whether infringement liability was somehow proper under Section 271(f) where RIM supplied BlackBerry handheld devices to customers in the United States, and use of those devices (in concert with a relay of the Blackberry network located in Canada) would infringe NTP's patented method if all steps were performed in the United States. 418 F.3d. 1282, 1321 (Fed. Cir. 2005). We held that it was not. In doing so, we held that "[w]hile it is difficult to

conceive of how one might supply or cause to be supplied . . . the steps of a patented method," the supply of BlackBerry devices to customers in the United States did not constitute the supply step required by Section 271(f). Id. at 1322.

In 2006, a panel of this court explicitly held that Section 271(f) applied to method claims. In Union Carbide, the court was presented with a case in which a catalyst, which was necessary to perform a patented method for producing ethylene oxide, was exported from the United States. 425 F.3d 1366, 1369 (Fed. Cir. 2006). The court held that Section 271(f) was applicable to the exportation of the catalyst and use of the patented method abroad. In doing so, the court referred to the catalyst as the "component" referred to in Section 271(f). It distinguished NTP by noting that the catalyst at issue in Union Carbide was directly supplied to foreign affiliates whereas the device in NTP was sold domestically and then used in a foreign country. Id. at 1380. It found that Eolas, which supported a finding of infringement under Section 271(f), expressly under a product claim and impliedly under a method claim, was more factually analogous and earlier in time than NTP, and therefore governed the case. Id. Indeed, the court considered that the shipment of the chemical catalyst was an even stronger candidate for the application of Section 271(f) than the shipment of master disks in Eolas because, unlike Eolas, Shell used the shipped components directly in its process instead of using copies of the exported components. Id. at 1379. Thus, the court held that "because § 271(f) governs method/process inventions, Shell's exportation of catalysts may result in liability" under that section. Id. at 1380.

The Supreme Court subsequently examined Section 271(f) when it granted certiorari and reversed our decision in AT&T I. AT&T II, 550 U.S. 437 (2007). The

Court held that Microsoft did not supply combinable components of a patented invention when it shipped master disks abroad to be copied. Because the foreign-made copies of Windows that were installed on computers were supplied "from places outside of the United States," the Court held that Microsoft had not supplied components from the United States. Id. at 452. The court reserved judgment on whether "an intangible method or process . . . qualifies as a 'patented invention' under § 271(f)," but noted that if so, the "combinable components of that invention might be intangible." Id. at n.13. The Court sent a clear message that the territorial limits of patents should not be lightly breached. Id. at 454-56.

b. Analysis

In construing the terms of Section 271(f), we do so "in accordance with [their] ordinary or natural meaning." Id. at 449 (alteration in original) (quoting FDIC v. Meyer, 510 U.S. 471, 476 (1994)). Section 271(f)(1) provides that one who "supplies . . . in or from the United States, all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components" shall be liable as an infringer. 35 U.S.C. § 271(f)(1). Section 271(f)(2) contains similar language.

Cardiac argues that the use of the term "patented invention" in 271(f) indicates Congress's intent to include all classes of invention within that statute's reach. Cardiac rightly notes that "invention" is defined in the U.S. Code to include "any new and useful process, machine, manufacture or composition of matter," 35 U.S.C. § 101, and thus is broad enough to include method patents. However, examination of the statute before us is not quite so simple. While the isolated "patented invention" language in Section

271(f) by itself might seem to extend to all inventions within the definition of "invention," we cannot disregard all the other language of that section, which, as we shall demonstrate, makes it clear that it does not extend to method patents. We also cannot ignore the context of the statute and its legislative history, which lead us to the same conclusion, which is that Section 271(f) does not encompass method patents.

In interpreting the terms of Section 271(f), it is critical to recall what a "patented invention" consists of when method patents are at issue. We have noted "the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps." In re Kollar, 286 F.3d 1326, 1332 (Fed. Cir. 2002); see also NTP, 418 F.3d at 1322 ("The invention recited in a method claim is the performance of the recited steps."). Thus, a component of a tangible product, device, or apparatus is a tangible part of the product, device, or apparatus, whereas a component of a method or process is a step in that method or process. As we demonstrate herein, this fundamental distinction between claims to a product, device, or apparatus on one hand and claims to a process or method on the other, is critical to the meaning of the statute and dooms Cardiac's argument on this issue.

Cardiac relies on the Supreme Court's language in Quanta Computer, Inc. v. LG Electronics, Inc., 128 S. Ct. 2109 (2008), in which the Court stated: "Apparatus and method claims may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus." Id. at 2118 (citation and internal quotations omitted). However, the Court's language throughout the Quanta opinion is focused on the similarities between method and apparatus patents in the unique context

of patent exhaustion. See, e.g., id. at 2117-18 (noting that a method may be "embodied" in devices for purposes of a "sale"); id. (method patents may be "exhausted by the sale of an item"). Moreover, in an exhaustion context, which considers whether a patent owner has been fully compensated when a sale or license of his invention has occurred, it matters little whether the patent involved claims to a product (apparatus) or a method. If a patent owner sells or licenses a product, it is not unreasonable to hold that the patent owner has received his due compensation under the patent, whether it is a product or a method patent. Thus, as the Supreme Court stated, for purposes of exhaustion, it may "be difficult to distinguish the process from the function of the apparatus." Quanta, 128 S. Ct. at 2118 (citation and internal quotations omitted). The Supreme Court's statement in an exhaustion context has no application here.

Our precedents draw a clear distinction between method and apparatus claims for purposes of infringement liability, which is what Section 271 is directed to. See, e.g., Joy Tech., 6 F.3d at 773-75 (stating that method claims are infringed only by practicing the steps of the method); NTP, 418 F.3d 1282, 1318 ("[A] patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized."). Section 271(f) "applies only to 'such components' as are combined to form the 'patented invention' at issue." AT&T II, 550 U.S. at 449 (footnote omitted). "Component" is defined as "a constituent part," "element," or "ingredient." Webster's Third New International Dictionary of the English Language 466 (1981); see also AT&T II, 550 U.S. at 449 n.11 (adopting same definition in Section 271(f) case). As we have seen, the patented invention at issue when a method patent is implicated consists of a "series of acts or steps." In re Kollar, 286 F.3d at 1332. The elements of a method are the steps

that comprise the method. Thus, method patents do have "components," viz., the steps that comprise the method, and thus they meet that definitional requirement of Section 271(f), but the steps are not the physical components used in performance of the method.

Cardiac disagrees that a component of a patented method is a step of that method. Instead, Cardiac urges us to adopt a definition of "component" that would encompass "the apparatus that performed the process." Appellants' Br. 15. That position is clearly contrary to the text of Section 271(f). It is not even supported by the lone amicus brief we have received in favor of including method patents within Section 271(f)'s reach. Br. for Ormco Corp. as Amicus Curiae Supporting Application of Section 271(f) to Method Claims, No. 07-1296,-1347 at 11 (Fed. Cir. Apr. 13, 2009) ("Ormco Br.") ("[T]he components of a method are the steps or acts that comprise the method.").[4]

Another subsection of Section 271 further undercuts Cardiac's proposed definition of "component." It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." Davis v. Mich. Dept. of Treasury, 489 U.S. 803, 809 (1989). Section 271(c) illustrates the contrasting treatment that Section 271 gives to tangible inventions and method inventions and the meaning of the term "component." Section 271(c) contrasts "a component of a patented machine, manufacture, combination, or composition" with a "material or apparatus for use in practicing a patented process." 35 U.S.C. § 271(c). Congress clearly believed that a "component" was separate and

[4] Aside from Ormco's brief, all other amicus briefs we have received support our conclusion that Section 271(f) does not apply to method patents.

distinct from a "material or apparatus for use in practicing a patented process." Thus, a material or apparatus for use in practicing a patented process is not a component of that process. The components of the process are the steps of the process.

Although such patented methods do have components, as indicated, Section 271(f) further requires that those components be "supplied." That requirement eliminates method patents from Section 271(f)'s reach. The ordinary meaning of "supply" is to "provide that which is required," or "to furnish with . . . supplies, provisions, or equipment." Webster's Third New International Dictionary of the English Language 2297 (1981). These meanings imply the transfer of a physical object. Supplying an intangible step is thus a physical impossibility, a position that not even Cardiac seems to dispute. See Appellants' Br. 15 (arguing that steps of a patented process, "which conceptually could not be supplied from the United States," were not the components of the process). As we have noted before, "it is difficult to conceive how one might supply or cause to be supplied all or a substantial portion of the steps in a patented method in the sense contemplated by" Section 271(f). NTP, 418 F.3d at 1322.

One amicus curiae brief has argued that one might supply a physical object that is the result of one of the steps of a patented process and combine that object with the remaining steps abroad. Ormco Br. at 12-14. That argument, however, confuses the result of a method step with the step itself. See id. (arguing that one who "supplies the results of" patented steps meets the requirements of Section 271(f)) (emphasis added). Section 271(f) does not forbid the supplying of products that are the result of steps of the patented method; rather it forbids the supply of the components themselves. 35 U.S.C. § 271(f) (imposing liability on one who "supplies or causes to be supplied in or

from the United States all or a substantial portion of the components of a patented invention"). Thus, because one cannot supply the step of a method, Section 271(f) cannot apply to method or process patents.

Our holding today is fully consistent with the legislative history of Section 271(f). As discussed above, in enacting Section 271(f), Congress intended to overturn the holding in Deepsouth. AT&T II, 550 U.S. at 457-58. Deepsouth dealt with an apparatus patent, a shrimp deveining machine, and the exportation of the physical components of that machine. Deepsouth 406 U.S. at 519. Congress was clearly focused on closing the loophole presented in Deepsouth, viz., that shipping an unassembled patented product abroad for later assembly avoids patent infringement. Congress's focus on patented products is apparent from an examination of the legislative history. See, e.g., S. Rep. No. 98-663 at 6 (1984) (stating that Section 271(f) will "prevent copiers from avoiding U.S. patents by shipping overseas the components of a product patented in this country so that assembly of the components will be completed abroad." (emphasis added)); 130 Cong. Rec. H10,525 (daily ed. Oct. 1 1984) (same). The legislative history of Section 271(f) is almost completely devoid of any reference to the protection of method patents and the Supreme Court has advised us that it is Congress's right, not the courts', to extend the statute beyond the Deepsouth problem it was designed to fix. See AT&T II, 550 U.S. at 457-58 (explaining that Congress designed 271(f) to close the Deepsouth loophole and that another loophole should be left in "Congress' court").

Cardiac argues that a single statement by former Commissioner of Patents, Donald Banner, indicates that Congress understood "components" to apply also to method patents. In a prepared statement, Mr. Banner stated that Section 271(f) "makes

it infringement to supply components of a patented process for final assembly abroad, if supplied for the purpose of avoiding the patent." S. 1535 – A Bill To Amend Title 35, United States Code, To Increase The Effectiveness Of The Patent Laws And For Other Purposes: Hearing Before The Subcommittee On Patents, Copyrights And Trademarks of the Committee On The Judiciary, United States Senate, 98th Cong. 46 (1984) (prepared statement of Donald W. Banner, President, Intellectual Property Owners, Inc.). Cardiac argues that this statement proves that a method can have components, Appellants' Br. 17, a statement with which we do not disagree. What we do disagree with is the argument that Section 271(f) encompasses method patents. In any event, the impact of the Banner statement is limited at best. That statement, while apparently reflecting an interested party's views of the effect of a pending bill, is not persuasive regarding the meaning of the enacted language. A statement by one private proponent of a pending bill in Congress, even if his testimony was that the bill was intended to encompass methods as well as apparatus patents, a matter not entirely clear from its language, cannot override the clear language of the statute and the context in which it was enacted. See McCaughn v. Hershey Chocolate Co., 283 U.S. 488, 493-94 (1931) (stating that "individual expressions are without weight in the interpretation of a statute"). Certainly in light of the statutory language and the overwhelming evidence of Congress's focus on patented products, that lone statement cannot carry the day for Cardiac.

Any ambiguity as to Congress's intent in enacting Section 271(f) is further resolved by the presumption against extraterritoriality. The Supreme Court took a narrow view of Section 271(f) by stating that the presumption against extraterritoriality

still applies to Section 271(f), even though that section specifically extends the reach of U.S. patent law in a limited manner. AT&T II, 550 U.S. at 454-56. In light of the near complete absence of any Congressional intent to protect patented methods under Section 271(f) and the explicit Congressional purpose of overruling Deepsouth's holding, the presumption compels us not to extend the reach of Section 271(f) to method patents.

In sum, the language of Section 271(f), its legislative history, and the provision's place in the overall statutory scheme all support the conclusion that Section 271(f) does not apply to method patents. We therefore overrule, to the extent that it conflicts with our holding today, our decision in Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), as well as any implication in Eolas or other decisions that Section 271(f) applies to method patents.

We now turn to the facts of this case. Cardiac alleges that St. Jude violates Section 271(f) when it ships its ICDs outside of the United States. We disagree. Claim 4 of the '288 patent is comprised of the steps of determining a heart condition, selecting cardioversion as the appropriate therapy, and executing a cardioverting shock. Cardiac does not allege that all of those steps are carried out in the United States with respect to certain of the ICDs. Moreover, it cannot allege that the steps of the method are supplied, a contradiction in terms. Rather, Cardiac alleges that St. Jude's shipment of a device that is capable of performing the method is sufficient to fall within the scope of Section 271(f). Although the ICD that St. Jude produces can be used to perform the steps of the method, as we have demonstrated, Section 271(f) does not apply to method or process patents. As Section 271(f) does not encompass devices that may

be used to practice a patented method, St. Jude is therefore not liable for infringement of claim 4 of the '288 patent under Section 271(f) for ICDs exported abroad.

D. Reassignment

Finally, Cardiac urges us to reassign this 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 partial or biased in any way during the proceedings. We therefore decline to designate a judge to preside over the remand. We see no reason to interfere with the internal operations of the Seventh Circuit, and we leave the determination of assignment on remand to that circuit's internal rules and procedures.

CONCLUSION

For the foregoing reasons, we reverse 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 reverse the district court's grant of a conditional new trial on that issue. We remand to the district court for a determination of damages. We affirm the district court's rulings limiting damages to instances in which the patented method has been performed. Finally, we reverse the court's decision that 35 U.S.C. § 271(f) is applicable to this case and hold that St. Jude's ICDs that practice the method of claim 4 outside the United States do not infringe that claim under Section 271(f).

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

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,

v.

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

Defendants-Cross Appellants.

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

NEWMAN, Circuit Judge, concurring in parts A, B, C.1, and D, dissenting from part C.2.

I concur in the court's opinion except for the en banc ruling in part C.2. I respectfully dissent from the court's interpretation of 35 U.S.C. §271(f) as excluding all process inventions. The statutory term "patented invention" in §271(f) has the same meaning in this subsection as in every other part of Title 35: it is the general term embracing all of the statutory classes of patentable invention. The court's interpretation

of §271(f) to exclude all process inventions is contrary to the text of the statute, ignores the legislative history, is without support in precedent, and defeats the statutory purpose.

35 U.S.C. §271(f) was enacted to provide remedy to patentees for certain activity conducted outside of the United States, when that activity would be infringing if conducted within the nation's borders. Section 271(f) specifically concerns offshore activity where practice of a patented invention is "actively induced" by the supply of defined components from the United States, in which situation the supplier is deemed an infringer under §271(f). The statute is aimed at evasion of United States patents, and is not limited to any particular class of patentable subject matter. The court now holds, sitting en banc for the purpose, that the statutory term "patented invention" excludes process inventions in §271(f). That ruling, placing a different definition on "patented invention" in §271(f) than in any other provision of Title 35, is incorrect.

The statute is unambiguous

Section 271(f) contains two subsections. The court today holds that both parts exclude all process inventions from the "patented invention" of the statutory text, without discrimination or exception; the court imposes this reading despite the plain text of the statute, as follows (with emphases added):

> §271(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a **patented invention**, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
>
> §271(f)(2) Whoever without authority supplies or causes to be supplied in

> or from the United States any component of a **patented invention** that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

Title 35 defines "inventions patentable" as including all patent-eligible subject matter, including processes:

> §101. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirement of this title.

Many sections of Title 35 use "invention" or "patented invention" or "patentable invention" when referring to all of the statutory classes of invention set forth in §101. E.g., §§102, 103, 104, 105, 181, 201, 286, etc.[1] When a specific statutory class is intended it is explicitly stated, as for example in §271(c) and (g), as explained post. The text of §271(f) states no such limitation, and presents no ambiguity in its use of "patented invention." The extreme redefinition here proffered for this subsection, unique within the entire statute, cannot be inferred from the use of "patented invention," without qualification, in §271(f).

The Supreme Court has stressed that "in interpreting a statute a court should always turn first to one, cardinal canon before all others. We have stated time and

[1] E.g., §102 (use of the term "invention" to refer to statutory subject matter); §103(a) (use of "invention" as synonymous with "subject matter sought to be patented"); §104 (describing rights in an "invention made abroad"); §105 ("invention made, used or sold in outer space"); §181(d) (defining "invention" as "any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act"); §286 (time limit on damages for infringement of a "patented invention").

again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-254 (1992). "When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'" Id. at 254 (quoting Rubin v. United States, 449 U.S. 424, 430 (1981)). The Federal Circuit, too, has recognized that "[i]f the statute is unambiguous, our inquiry is at an end; we must enforce the congressional intent embodied in that plain wording." Chamberlain Group, Inc. v. Skylink Techs., Inc., 381 F.3d 1178, 1192 (Fed. Cir. 2004). The meaning of "patented invention" is unambiguously stated in 35 U.S.C. §101, for the entire statute.

The Supreme Court has previously so held. In Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) the Court addressed the term "patented invention" as it appears in §271(e), an infringement provision enacted six weeks before §271(f). The Court rejected the argument that the term "patented invention" in §271(e) was limited by other language in the provision to mean only drug patents, holding that "[t]he phrase 'patented invention' in §271(e)(1) is defined to include all inventions, not drug-related inventions alone." Id. at 665. The Court stated that if the statute had been intended to apply only to drug-related inventions, "there were available such infinitely more clear and simple ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected." Id. at 667.

My colleagues reach the opposite conclusion today, without mentioning the use of the identical words "patented invention" by the same Congress that enacted §271(e) and soon thereafter enacted §271(f). It is not reasonable now to rule that the same words used in two adjacent subsections of the same statute, enacted by the same

Congress in close temporal proximity, were intended to diverge radically from the statutory definition of "patented invention" and from each other.

The context of §271(f)

The statutory meaning of "patented invention" is reinforced upon observation of those sections of the Patent Act that are directed to particular categories of invention, as illustrated in §271 itself. The relationships and balance of the several provisions in subsections of this section demonstrate the statutory use of "patented invention" as the umbrella term for the forms of invention subject to the Patent Act, with narrower terminology used in those provisions that have narrower application. The §271 subsections deal with the various legislative remedies for various forms of infringement, as Congress acted to plug the loopholes that had arisen or were foreseen.

Reviewing the context of §271, we start with §271(a), the general infringement statute, directed to "any patented invention." Section 271(b) is directed to inducement of infringement of "a patent." All agree that subsections (a) and (b) apply to all statutory subject matter. Section 271(c) recites contributory infringement by a "component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process"; Congress thus specified how contributory infringement occurs for the statutory categories. Section 271(d) relates to misuse of "a patent," citing specific commercial practices. Section 271(e) concerns "a patented invention" and although the statute refers to the drug regulatory context, the court in Eli Lilly, supra, explained that this term incorporates the entire subject matter of §101. Section 271(f) concerns the supply of components of "a patented invention" for use outside of the United States, again incorporating the subject matter of §101. Section

271(g), in contrast, is specific to the importation or sale of "a product which is made by a process patented in the United States." Each subsection is directed to different circumstances of infringement, and each recites its subject matter with generality or specificity, as appropriate.

Some amici curiae in this appeal suggested that since §271(g) specifically mentions practice of a patented process, then "patented invention" in §271(f) must exclude processes. That thesis is devoid of support. Subsections (g) and (f) are directed to distinct situations, for §271(g) requires importation or sale of the product of a patented process practiced abroad, before infringement can be established under that provision, while §271(f) does not require importation or sale, but instead requires that a component of the "patented invention" practiced abroad comes from the United States. Subsections 271(f) and (g) address quite different acts, and their subject matter is defined in accordance with the action that the specific statute is designed to remedy.

Section 271(c) is relied upon by the court as somehow requiring that §271(f) excludes processes. Section 271(c) defines as "contributory infringement" acts that include the sale or importation into the United States of a non-staple article of commerce that is a "component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process," where the non-staple article constitutes a "material part of the invention" and is known to be made or adapted for the purpose of infringing, within the United States, a patented product or process. The text of §271(c) illuminates the text of §271(f), for §271(c) mentions the statutory classes in terms of how "contributory infringement" works, whereas §271(f)(1) is directed to inducement, and in the usage "patented invention" in

both subparts, §271(f) states its independent scope. This is not an inadvertent distinction, in view of these heavily scrutinized provisions and their years of legislative consideration. My colleagues appear to have misinterpreted these distinct usages, for the different subsections reinforce that the legislators carefully structured each for a distinct purpose. See Russello v. United States, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion.").

The various subsections of §271 reflect the considered legislative approach to plug loopholes in the infringement statute, in the interest of United States patentees and in support of United States innovation. The close relationship among these and all sections of the Patent Act "presents a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." Sullivan v. Stroop, 496 U.S. 478, 484 (1990) (quoting Sorenson v. Sec'y of Treasury, 475 U.S. 851, 860 (1986)). Nonetheless, the court today discards this rule, and holds that despite its consistent usage throughout the Patent Act, "patented invention" in §271(f) was intended to have a unique meaning, applicable only to this subsection, to exclude all processes from "patented invention."

The new loophole here created under §271(f) will outshine the simple evasion that led Congress and the innovation community to the carefully written texts of sections 271(c), (e), (f), and (g). These texts show that when legislation specific to one or another class of invention was intended, it was explicitly stated in those subsections of §271. "'It is not uncommon to refer to other, related legislative enactments when

interpreting specialized statutory terms,' since Congress is presumed to have 'legislated with reference to' those terms." Reno v. Koray, 515 U.S. 50, 57 (1995) (quoting Gozlon-Peretz v. United States, 498 U.S. 395, 407-408 (1991)).

Legislative history and congressional intent

This congressional intent is confirmed by the legislative history. Various proposals were considered over many years before selecting the text that was enacted as §271(f). Beginning with the statutory loophole exposed in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), legislative activity proceeded for a decade as new pitfalls were foreseen, new bills introduced, new hearings held, and new provisions written. For example, the early proposals suggested adapting the language in existing statutory provisions. See, e.g., Hearings Before the Subcomm. on Patents, Trademarks, and Copyrights of the Sen. Comm. on the Judiciary, 93rd Cong. 2871-74 (1973) (statement of Guy W. Shoup) (proposing amendment to overturn Deepsouth and stating that an "attempt has been made to track present statutory language as closely as possible, specifically 35 U.S.C. §271(b) and §271(c)"). The early bills borrowed directly from §271(c), as for instance in S. 2504, initially introduced on October 1, 1973. A committee print of that bill, as amended, shows the following text, with the relevant language emphasized:

> (f) Whoever, without authority, makes or sells, within the United States, all of the components of a patented machine, manufacture, or composition of matter, uncombined, intending that such components will be combined outside the United States to constitute the patented subject matter, knowing that if such components were combined within the United States, the combination would be an infringement of the patent, shall be liable as an infringer.

S. 2504, 93d Cong., 2d Sess. (comm. print dated May 8, 1974); see also S. 473, 94th

Cong., 1st Sess., §271(e) (1975) (same text); S. 23, 94th Cong., 1st Sess., §271(f) (1975) (same text); S. 2255, 94th Cong., 1st Sess., §271(f) (1975) (same text). Reprinted in Hearings Before the Subcomm. of Courts, Civil Liberties, and the Administration of Justice of the H.R. Comm. on the Judiciary, 98th Cong. 2859-69 (1984) ("Hearing Review"). It is seen that these early bills did not include processes, but were specific to "a patented machine, manufacture, or composition of matter."

Subsequent bills, including S.1535, 98th Cong., 1st Sess. (1983), replaced this specific text with the encompassing term "patented invention." The published record in the Hearing Review shows the understanding that the effect of this change is to cover processes as well as the other statutory categories. Contrary to the majority's suggestion, the legislative history is not limited to an ambiguous private statement by an "interested party," see maj. op. at 28, for the Hearing Review demonstrates that the executive branch considered it important that the statute cover process inventions. The Hearing Review contains a report prepared by the Patent and Trademark Office for the Justice Department, observing that the Deepsouth holding had been applied to process patents in John Mohr & Sons v. Vacudyne Corp., 354 F. Supp. 1113 (N.D. Ill. 1973), and stating that "[n]o reasons exist for treating process patents differently from product patents in this regard, and therefore, the Mohr case should also be overturned." Hearing Review at 2897. The majority has not controverted the clear evidence that the change in statutory language was for the purpose of encompassing processes.

The ensuing change in legislative language, embodied in S.1535, demonstrates the purposeful action to include processes in §271(f), instead of the more limited scope of earlier versions of the legislation. "Where Congress includes limiting language in an

earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." Russello, 464 U.S. at 23-24 (citing Arizona v. California, 373 U.S. 546, 580-81 (1963)). This broadening of statutory protection, over the decade of hearings and review that followed the Deepsouth decision, reflects a careful and deliberative process, as additional concerns were exposed and additional subsections proffered, in a collaborative legislative effort to reinforce the value of the patent statute as an innovation incentive. As the Court observed in Oncale v. Sundowner Offshore Serv., Inc., 523 U.S. 75, 79 (1998), "statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." Here, in plugging the Deepsouth loophole, Congress eventually enacted a statute directed to all classes of patentable invention. Yet this court curiously returns to the precise words that were initially proposed and then explicitly superceded.

Plain language and contemporary context

It is a canon of statutory construction that the statute must be understood in its contemporary context. The Court stated in Cannon v. University of Chicago, 441 U.S. 677, 696-97 (1979), that "it is always appropriate to assume that our elected representatives, like other citizens, know the law . . . and that an evaluation of congressional action taken at a particular time must take into account its contemporary legal context." Despite the clarity of "patented invention" in §271(f), and the context of concern for statutory loopholes inimical to the interest of innovators in the United States, this court now rules that the legislators intended to preserve a large loophole for patented processes, and never intended to cover more than the narrow Deepsouth

loophole for machinery.

Despite the multiple manifestations of legislative intent, in the plain language, the statutory context, and the evolution of §271(f), my colleagues now rule that in one and only one subsection of Title 35, "patented invention" excludes process inventions. My colleagues state that they agree that the plain meaning of "patented invention" is fixed by §101, yet they decide that Congress cannot have meant what it said, and that this plain meaning is defeated by hidden meaning in §271(f). The Court has cautioned that such a statutory interpretation can arise only in "rare and exceptional circumstances," Crooks v. Harrelson, 282 U.S. 55, 58 (1930) (rejecting argument to ignore literal meaning of a statute based on Holy Trinity Church v. United States, 143 U.S. 457 (1892), and stating that a court may "override the literal terms of a statute only under rare and exceptional circumstances"). Such circumstances are not present here.

My colleagues seek support in the statutory words "components" and "supply." The en banc court concedes that processes have "components," but argues that process components cannot be "supplied" from the United States to a foreign operation, because the steps of a process are intangible. However, process information, as well as the results of process steps, are readily supplied from one entity to another. The Court recently noted, in a case under §271(f) involving products, that "[i]f an intangible method or process . . . 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." Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 452 n.13 (2007). My colleagues' opinion mentions tangibles and intangibles, but does not apply §271(f) to the claimed process.

Although the facts of infringement are not developed on the en banc record, enough is before this court to show that the claim is not for an abstract, disembodied process. In addition, the claims include both method and structural aspects. See '288 patent, Claim 1 (reciting method "using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia"); Claim 4 (reciting "mode of operation of said implantable heart stimulator").

It appears that the heart stimulator is supplied from the United States and combined with process steps that are taught from the United States and performed abroad. Although both product and process aspects are involved, the court presents no findings concerning the nature of the components supplied from the United States. It may also be relevant that in Quanta Computer, Inc. v. LG Electronics, Inc., 128 S. Ct. 2109, 2117-18 (2008), the Court reminded us that: "Apparatus and method claims 'may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus.'" (quoting United States ex rel. Steinmetz v. Allen, 192 U.S. 543, 559 (1904)). Such complex issues have not been brought out on this appeal, because they were not presented in the winner-take-all question presented for en banc briefing.[2] The court's new statutory interpretation is far more sweeping than is needed to decide this case, and far simpler than today's technology deserves. The challenge of applying important and complex law to new facts is poorly met by holding that no law applies to any facts.

[2] The court invited briefing limited to the question "Does 35 U.S.C. §271(f) apply to method claims, as well as product claims? Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., No. 07-1296 (order granting rehearing en banc) (Fed. Cir. March 6, 2009).

It is well recognized that a process has parts, or "components"; this is a general term applicable to all inventions. In Microsoft, 550 U.S. at 449 n.11, the Court, in discussing §271(f), noted that "component" is defined as "a constituent part," "element," or "ingredient," quoting Webster's Third New International Dictionary of the English Language; and as the majority acknowledges, the Court stated that for a process invention, the "combinable components of that invention might be intangible," id. at 452 n.13. In a discussion of process claims in Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997), where the patent was for a purification process, the Court stated the inquiry as: "Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" Id. at 40. Throughout our own precedent this court has, without quibble, described a step in a process or method as an element of the process or method. See, e.g., Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1328 (Fed. Cir. 2009) ("In summary, during the 1989 demonstration, all elements of the repair method in claim 1 of the '307 Patent were performed."); Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1214 (Fed. Cir. 2008) ("This court has consistently interpreted 'including' and 'comprising' to have the same meaning, namely, that the listed elements (i.e., method steps) are essential but other elements may be added.").

Each step of a process is a component thereof, which, when combined with the other steps, performs the process. In BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (2007), this court held that process claims are infringed when some steps are practiced by one entity and other steps are practiced by another, provided that the charged entity controls or directs the conduct of the other, the court explaining that: "A

party cannot avoid infringement, however, simply by contracting out steps of a patented process to another entity." Id. at 1381. The court concluded that the practice of steps of the patented method can be combined, whereby the party that performs earlier steps "supplies" this component to the party that performs the later steps. This principle is commensurate with the application of §271(f) to processes that are partly performed in the United States. Surely there is no cause to conclude, as the majority concludes, that it is a "physical impossibility" to read §271(f) as applying to processes. Maj. op. at 26.

On the established understanding of how processes are performed, it cannot be ruled that the words "component" and "supply" in §271(f)(1) impart a unique meaning that defeats the plain text of the statute. It cannot be ruled that Congress, along with all of the contributors to this legislation, who understood and intended the use of general terms to embrace all forms of patented invention in Title 35, nonetheless silently eliminated patented processes from "patented invention" in §271(f).

Sovereignty Issues

I share every court's concern about legislatively impinging upon sovereign foreign rights. In this case, however, the statutory purpose is to reach the evasion of United States rights by actions that are taken within the United States by entities subject to United States law. The practice in foreign countries of United States–origin technology without any contribution of components from the United States is untouched by §271(f), whether of process or product. Liability under §271(f) is based on domestic conduct and intent.

Although protection in foreign countries can sometimes be had by obtaining and

enforcing foreign patents, as mentioned in Microsoft, 550 U.S. at 456, that expensive alternative may not be available. When a patented process is practiced so that some steps are performed in the United States and other steps are performed offshore, the purloiner of the patented process may escape liability everywhere, for United States infringement is avoided if all of the process steps are not practiced in the United States, and infringement of foreign patents is avoided for the same reason. It cannot be that the legislators intended to enable avoidance of process patents by this ploy, while correcting it for machine patents. A statutory interpretation that results in all process inventions being seriously devalued, is not free of the charge of "absurd result." See Dewsnup v. Timm, 502 U.S. 410, 427 (1992) (the interpretation of a statute should "avoid absurd results").

St. Jude and several amici curiae observe that some countries do not permit patenting of medical procedures, and cite this as a reason for refusing all remedy under §271(f) for any practice abroad of any infringing process in any aspect of technology. This reasoning is insupportable in the broad thesis proposed by the amici. And as to the specific patent in suit, as Cardiac points out, a medical device such as a defibrillator and its method of use are generally viewed as patentable in most countries.

Concerns of amici curiae

Several amicus curiae briefs expressed concern that a broad construction of §271(f) could lead to unfair liability for United States providers of computer-based systems. Thus these amici proposed that blanket removal of all process inventions—the yes-or-no question here posed by this court—would best meet the needs of their industries. True, this court's inquiry was insufficiently nuanced, for such a blunderbuss

attack on all process technologies is not needed to serve the asserted special needs of information industries. However, my colleagues have over-reacted as well as over-reached, for it is not necessary (nor is it our prerogative) to destroy the statute for all process industries, in order to avert potential abuses in unknown circumstances. I agree that for ever more complex technologic facts, vigilance is required to preserve the statutory purpose. As in all areas of evolving interests and policy, if statutory change is warranted, it should be achieved with the participation of all those affected. It is not the judicial role to dump the statute entirely, as overreaction to the facts of one case. The court's decision today is as unnecessary as it is incorrect.

The simple purpose of §271(f) is that, for patented inventions, a United States patent cannot be avoided by providing substantial components from the United States while performing some aspect offshore to avoid a technical act of infringement under §271(a). Section 271(f) draws no distinction between process and product inventions, and such distinction is unrelated to the legislative purpose. As Judge Learned Hand reminds us, "statutes always have some purpose or object to accomplish:"

> "[I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning."

Cabell v. Markham, 148 F.2d 737, 739 (2d Cir.), aff'd, 326 U.S. 404 (1945).

The court's ruling reopens, for process inventions, the loophole that was plugged by §271(f) for all patented inventions. The extensive legislative record shows consideration of equity, economics, innovation incentive, and international concerns, in

the evolution of the text of §271(f). The en banc court makes no mention of any of these concerns, and does not discuss the consequences of today's holding in negating the legislative purpose. I respectfully dissent from the court's statutory interpretation and the decision based thereon.