United States District Court,
S.D. Indiana, Indianapolis Division.

**CARDIAC PACEMAKERS, INC., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski,**
Plaintiffs.
v.
**ST. JUDE MEDICAL, INC., and Pacesetter, Inc,**
Defendants.

No. IP961718DFHTAB

**March 1, 2006.**

**Background:** Owner of patent for implantable cardiac defibrillator sued competitor for infringement. The District Court for the Southern District of Indiana, 2002 WL 1801525, entered judgment in favor of competitor on issues of validity and infringement, and owner appealed. The Court of Appeals, 381 F.3d 1371, affirmed in part, reversed in part, and remanded. Certiorari was denied, 544 U.S. 1032, 125 S.Ct. 2254, 161 L.Ed.2d 1058. On remand, parties cross-moved for summary judgment.

**Holdings:** The District Court, Hamilton, J., held that:
(1) "determining" heart condition step merely required detection of whether one of several heart arrhythmias existed;
(2) competitor was not precluded from asserting invalidity or unenforceability defenses;
(3) owner did not waive claim for lost profits damages; and
(4) owner could recover damages only for accused devices that were programmed to practice claimed method.

See also 144 Fed.Appx. 106.

4,407,288. Construed.

J. Michael Jakes, Kara Farnandez Stoll, Michael Andre Morin, Michael Vincent O'Shaughnessy, Finnegan Henderson Farabow Garrett & Dunner, LLP, Washington, DC, John R. Schaibley, III, Robert K. Stanley, Baker & Daniels, Indianapolis, IN, for Plaintiffs.

Daniel Pierre Muino, Frederick Brown, Gibson Dunn & Crutcher LLP, San Francisco, CA, David A. Segal, Gibson Dunn & Crutcher LLP, Irvine, CA, Denis R. Salmon, H. Mark Lyon, Y. Ernest Hsin, Gibson Dunn & Crutcher LLP, Palo Alto, CA, Jay G. Taylor, Michael T. McNally, Philip A. Whistler, Thomas Eugene Mixdorf, Ice Miller LLP, Indianapolis, IN, Jeffrey M. Olson, Sidley Austin Brown & Wood LLP, Los Angeles, CA, for Defendants.

**ENTRY AFTER REMAND ON CLAIM CONSTRUCTION AND MOTIONS FOR PARTIAL SUMMARY JUDGMENT**

HAMILTON**, District Judge.**

## *Introduction*

This patent infringement action was filed more than nine years ago. At the outset, plaintiffs asserted infringement of numerous claims under four patents relating to implantable cardiac defibrillators. A trial in 2001 on claims for infringement of four claims of two patents resulted in a verdict awarding plaintiffs $140 million in royalties for infringement of two claims of one patent, United States Patent No. 4,316,472. Following trial, this court resolved various post-trial motions and entered judgment for defendants on all claims. Both sides appealed to the United States Court of Appeals for the Federal Circuit. The Federal Circuit affirmed in part and remanded in part for reconsideration of the court's construction of the "determining" step limitation of Claim 4 of a different patent, United States Patent No. 4,407,288, and for a possible new trial of that one claim. Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371 (Fed.Cir.2004).

Claim 4 of the '288 patent is a method patent. A trial on that one remaining claim is scheduled for later this year. The parties have submitted proposed claim constructions for the disputed "determining" step limitation of Claim 4. Defendants have also asked the court to reinterpret the other limitations of Claim 4 in light of the revised claim construction of the "determining" step. In addition, both sides have filed several motions for summary judgment, only some of which are resolved by this Entry. The motions addressed here seek to narrow the scope of any new trial in terms of the defenses that would be available to defendants and the damages that could be pursued by plaintiffs.

As explained below, the court intends to adopt plaintiffs' proposed claim construction of the "determining" step limitation of Claim 4 of the '288 patent, with one minor change. The court denies plaintiffs' motion for summary judgment on defendants' affirmative defenses and counterclaims. The court denies defendants' motion as to plaintiffs' claim for lost profits, and grants in part and denies in part defendants' motion to limit damages to implantable cardiac defibrillators shown to have used the claimed method in the United States.

## *Background*

### I. *Factual History*

Plaintiffs in this case are Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively, "CPI"). Defendants are St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "St.Jude").

CPI's sole remaining claim in this case alleges that St. Jude infringed its patent for a method used to evaluate and treat abnormal rhythms of a patient's heart. The relevant patent is United States Patent No. 4,407,288 ("the '288 patent"), which expired in December 2003, after the first trial in this case. In general, the '288 patent claims improvements enabling "multimode" operation by implantable cardiac defibrillators ("ICDs"). ICDs are small, powerful devices implanted under the skin of a heart patient. They can detect abnormal heart rhythms, including ventricular fibrillation, which renders a person unconscious in seconds

and is fatal within a few minutes unless corrected. Upon detecting an abnormal heart rhythm, an ICD can administer different types of electrical shocks to restore a normal rhythm to the heart. The '288 patent addresses "multimode" operation, meaning that the device can respond to an arrhythmia first with one type of electrical therapy and then, if the first therapy is not successful, can proceed automatically to administer other types or modes of electrical therapy until the heart resumes a normal rhythm. Modes of electrical therapy carried out by the ICDs may include cardiac pacing (low power) and automatic defibrillation (with very powerful shocks), as well as "cardioversion," an intermediate form of therapy discussed below. A more detailed discussion of the technology is available in the court's numerous prior written decisions, including the original Entry on Claim Construction Issues, Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 2000 WL 1765358 (S.D.Ind. Nov. 29, 2000) (Docket No. 365), and the Amended Entry on Post-Verdict Motions, Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 2002 WL 1801525 (S.D.Ind. July 5, 2002) (Docket No. 960).

The only remaining claim at issue here is Claim 4 of the '288 patent. Claim 4, including Claim 1 on which it depends, claims:

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 the steps of:

(a) determining a 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; and

(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.

'288 patent, col. 21, *ll*. 9-32.

**II.** ***Procedural History***

**A.** ***Jury Trial***

An overview of this case's procedural history is essential to understand the current motions. In June 2001, a jury heard CPI's claims for patent infringement against St. Jude on two claims in the '472 patent and two in the '288 patent. The jury rendered a mixed verdict. It found that St. Jude had infringed the '472 patent, and it rejected St. Jude's defenses that the '472 patent was invalid for failure to comply with the written description requirement of 35 U.S.C. s. 112 para. 1, for obviousness, and for obviousness-type double patenting. The jury also found that St. Jude's infringement was not willful.

With regard to the '288 patent, the jury found that St. Jude had not infringed. The jury also rejected St. Jude's defenses that the '288 patent was invalid for failure to comply with the best mode requirement of 35 U.S.C. s. 112 para. 1 and for obviousness, and that the '288 patent should be unenforceable because of CPI's allegedly inequitable conduct.

The jury found that CPI had not proved any lost profits, but the jury awarded royalties for infringement of the '472 patent in the amount of $140 million.

**B.** ***Post-Verdict Motions***

Following trial, the court resolved numerous post-verdict motions that essentially decided for St. Jude on both patents and conditionally granted a new trial on several issues on which it did not prevail at trial. With respect to the '472 patent, the court granted St. Jude's motion for judgment as a matter of law, finding that neither one of the two claims of the '472 patent had been infringed. The court granted a conditional new trial on that issue with respect to Claim 18, but not for Claim 1. The court also addressed several of St. Jude's defenses relating to the '472 patent. First, the court found that the two claims of the '472 patent were invalid for failure to satisfy the written description requirement and granted St. Jude's JMOL motion and, alternatively, granted a conditional new trial on this defense. The court also found the two claims of the '472 patent invalid for obviousness-type double patenting, and granted St. Jude's JMOL motion, but denied its alternative request for a new trial. Finally, the court denied both St. Jude's JMOL motion and its alternative motion for a new trial on its obviousness defense to the two claims of the '472 patent.

With regard to the '288 patent, CPI requested a new trial on infringement, alleging that it had been denied a fair trial because of St. Jude's opening statement and its presentation to the jury to discuss the inconsistent reports of one of CPI's experts. By way of background, the court and St. Jude learned during the trial that CPI's primary expert, Dr. Joseph Bourland, gave incorrect testimony in his pre-trial deposition and on the witness stand about his involvement in another pending ICD patent infringement action. The court therefore permitted St. Jude to point out to the jury the inconsistencies between the reports Dr. Bourland had authored for each of the two cases. After trial, the court allowed St. Jude to conduct discovery on Dr. Bourland's actions and testimony. Dr. Bourland admitted after trial that he had not been just honestly mistaken, but had deliberately lied in his trial testimony. Finding that CPI had not been denied a fair trial on this (or any other) basis, the court denied CPI's request for a new trial. The court also granted St. Jude's motion for sanctions and for a conditional new trial as a result of Dr. Bourland's conduct and CPI's related failure to comply with discovery obligations.

The court resolved other post-verdict issues related to the '288 patent. First, the court granted St. Jude's JMOL motion and alternative request for a new trial, finding that Claims 4 and 13 of the '288 patent were invalid for violating the best mode requirement of 35 U.S.C. s. 112 para. 1. The court also granted St. Jude's JMOL motion and alternative request for a new trial, finding that Claims 4 and 13 of the '288 patent were invalid for obviousness. The court denied, however, St. Jude's JMOL motion and alternative request for a new trial on its defense that the '288 patent should be unenforceable because of CPI's inequitable conduct, relating to its failure to pay appropriate maintenance fees for the patent.

Finally, with respect to damages awarded for infringement of the '472 patent, the court granted St. Jude's motion for a conditional new trial on the issue of royalties, and denied CPI's contingent motion for a new trial on the issue of lost profits. This court entered an amended final judgment on July 5, 2002. FN1

FN1. The court also denied St. Jude's JMOL motion on whether any lump sum initial royalty payment would be proper and did not reach CPI's motion for an award of prejudgment interest.

**C.** ***Federal Circuit Review***

CPI did not try to revive the $140 million verdict under the '472 patent, but it appealed the judgment as to the '288 patent. St. Jude cross-appealed on certain issues. The Federal Circuit reversed the court's grant of JMOL on the '288 patent and reinstated the jury verdict that the patent was not invalid for obviousness or for failure to satisfy the best mode requirement. See 381 F.3d at 1378, 1379. The Federal Circuit also reversed the court's conditional grant of a new trial on these issues. Id. at 1380.

CPI appealed the finding of non-infringement as to only Claim 4 of the '288 patent. The Federal Circuit held that this court had erred by construing the "determining" step element of Claim 4 as a "step-plus-function" limitation under 35 U.S.C. s. 112 para. 6. The Federal Circuit did not, however, actually determine the proper construction of Claim 4. Nor did it grant CPI's request to find infringement as a matter of law. Instead, the Federal Circuit ordered this court to re-construe the "determining" step "in light of the specification and the prosecution history." 381 F.3d at 1382. The Federal Circuit concluded that a new trial of infringement was required because of the need for a new claim construction. Id. at 1383.

Next, the Federal Circuit vacated the court's conditional sanction that CPI would pay St. Jude's attorneys fees if a new trial for infringement was required. The court reasoned that the new trial ordered in this case would not have resulted from Dr. Bourland's deception and CPI's complicity in it. See id. at 1383.

Finally, the Federal Circuit considered CPI's request that the jury's $140 million damage award on the '472 patent simply be shifted by the court to the '288 patent. The court did not shift the damage award, stating that "damages for infringement of the '288 patent, should infringement be found on remand, requires determination on remand." Id. at 1383. The Federal Circuit summarized its rulings on the '288 patent 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 of infringement and reassessment of damages. We affirm the district court's decision upholding the patent term extension.

381 F.3d at 1374. FN2

FN2. Though not raised as issues here, St. Jude cross-appealed a previous ruling by this court that the '288 patent's term was properly extended and had not expired. The Federal Circuit affirmed this ruling.

The case is now before the court for claim construction and to resolve several motions for partial summary judgment.

***Discussion***

**I.** ***Claim Construction of*** the '288 Patent

**A.** ***Standards for Claim Construction***

[1] The court must construe ambiguous terms in a patent as a matter of law. Markman v. Westview

Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995) ( *en banc* ), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In Phillips v. AWH Corp., 415 F.3d 1303 (Fed.Cir.2005) ( *en banc* ), the Federal Circuit restated the principles to be applied in claim construction. *Phillips* reaffirmed the importance of intrinsic evidence, *i.e.,* the claim language, specification, and prosecution history of a patent, for claim construction.

[2] In considering the claim language, words are generally to be given their ordinary and customary meanings. Phillips, 415 F.3d at 1312. That is, the words of a claim are to be construed to have the meanings they would have for "a person of ordinary skill in the art in question at the time of the invention." Id. at 1313. The starting point for applying this standard is understanding that "patents are addressed to and intended to be read by others of skill in the pertinent art," and not the public generally, or lawyers and judges. *Id.*

[3] [4] A patent's specification is highly relevant to the claim construction analysis. "Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996), quoted in Phillips, 415 F.3d at 1315. The court also may consider the patent's prosecution history, which consists of the complete record of proceedings before the Patent and Trademark Office ("PTO") and the prior art cited during the patent's examination. Like the specification, the prosecution history provides evidence of how the PTO and inventor understood the patent. However, it often lacks the same clarity and is "less useful" than the specification for claim construction. Phillips, 415 F.3d at 1317. Nevertheless, the prosecution history can sometimes demonstrate whether the inventor limited the invention in the course of prosecution, thereby narrowing the scope of a claim. *Id.,* citing Vitronics, 90 F.3d at 1582-83.

[5] [6] *Phillips* also pointed out that extrinsic evidence (such as expert testimony, dictionaries, and learned treatises) is generally less helpful than intrinsic evidence and is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." 415 F.3d at 1319. The Federal Circuit acknowledged, however, that one proper use for extrinsic evidence can be to avoid the danger of reading limitations from the specification into the claim. *Id.* at 1323. *Phillips* reaffirmed the critical distinction between using the specification to interpret the meaning of a claim and improperly importing limitations from the specification into the claim. *Id.* With these standards in mind, the court addresses the proper construction of Claim 4.

**B. '*288 Claim 1 and 4: "determining a condition of the heart from among a plurality of conditions of the heart*"**

[7] Claim 1 is incorporated by reference into Claim 4 of the '288 patent. Before the first trial, the court construed the "determining" step as a step-plus-function element that was illuminated by the patent's specification. The specification describedthe use of a combination of circuitry that measured the heart's rate and that used a technique known as probability density function, or "PDF." Using the step-plus-function approach, the court held before the first trial that the "determining" step was limited to methods using PDF as part of the process. The use of the step-plus-function approach was the reversible error at the heart of the Federal Circuit's remand.

Without using the mistaken step-plus-function mode of interpretation, the "determining" step is straightforward. The court intends to define "determining a condition of the heart from among a plurality of conditions of the heart" from Claim 1 for the jury as follows:

Detecting which one of a number of heart arrhythmias exists, *i.e.*, whether there exists, *e.g.*, tachycardia, fibrillation, or bradycardia, or whether there exists a normal sinus rhythm. This step of "determining" may merely analyze heart rate to determine the condition of the heart.

This construction very nearly reflects the claim construction proposed by CPI. FN3

FN3. The heart's condition should usually be determined as "normal," so the court has revised CPI's proposed construction to account for this happy circumstance.

CPI's proposed construction is well-supported by the claim language. The "determining" step is the first step of a method for treating arrhythmias, rhythm disorders that typically result from problems with the heart's electrical system. The claim preamble calls for a device "capable of detecting a plurality of arrhythmias." The "determining" step is the only step in the claim that could address that basic requirement for the ICD. The "determining" step itself is not novel-it merely represents the initial step where one learns whether anything is wrong with the heart's rhythm, and if so what the problem is.

St. Jude argues that CPI's construction equates "determining a condition of the heart" with "detecting an arrhythmia," and that this is contrary to the claim language, specification, and prosecution history of the '288 patent. St. Jude argues that a "condition," as opposed to an "arrhythmia," can be determined only by logically analyzing both rate and PDF inputs.

St. Jude's proposed construction tries to complicate a simple element of the claim. Although the use of different claim terms can create a presumption of different meanings, see CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1317 (Fed.Cir.2000), this principle does not dictate the outcome here. The ordinary meaning of an "arrhythmia" is an irregular heartbeat. Remand Docket No. 107, CPI Ex. 13 at 7 (Dr. Berger's report: to one of ordinary skill in the art, "the only difference between an arrhythmia and a condition of the heart is that the term 'condition of the heart' would include a normal condition"). At the time of invention, several methods for detecting arrhthymias were well-known, and prior art had disclosed the use of rate circuitry alone. See Remand Docket No. 107, CPI Ex. 13 at 8-10 (Dr. Berger's report); Remand Docket No. 120, CPI Ex. 15 at 51-55 (Dr. Mihran's testimony that rate detector circuitry can detect conditions of bradycardia, tachycardia, and fibrillation).

[8] The specification also supports CPI's proposed construction. The specification repeatedly refers to an "arrythmia" as a "heart disorder." See '288 patent, col. 1, *ll*. 23-28, 38, 53-54, 62-63; col. 4, *ll*. 8-10; col. 7, *ll*. 23-33 (describing object of invention to provide device and method capable of electrical heart stimulation "in response to detection of the occurrence of various heart disorders or arrhythmias"). Most important, CPI's proposed construction avoids, and St. Jude's invites, "one of the cardinal sins of patent law"-reading specific limitations in a specification's disclosed embodiment into the broader claim. See Phillips, 415 F.3d at 1320, 1323. The '288 specification discloses an embodiment that uses both rate and PDF detection circuitry to determine a heart's condition. See '288 patent, col. 9, *l*. 59-col. 10, *l*. 28. However, apart from the rejected step-plus-function mode of interpretation, there is no indication that this disclosed embodiment was meant to exclude or disclaim devices that use rate circuitry alone. As CPI points out, no particular circuitry is discussed in the patent's abstract, background of the invention, summary of the invention, or objects of the invention.

This case is readily distinguishable from both SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed.Cir.2001), and Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377 (Fed.Cir.1999), where the court held that the patentees intended to claim only the preferred embodiments disclosed in their respective specifications. In *SciMed,* the patent specification criticized a dual lumen structure for catheters and stated that a coaxial lumen structure, the only alternative, was "the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." 242 F.3d at 1339. Based on this language in the specification, the Federal Circuit held that SciMed had disclaimed dual lumen catheters. Id. at 1343-44. Similarly, in *Wang Laboratories,* the court held that only the specified protocol was claimed, since the specification would not be understood by a person skilled in the field of the invention as including the other possible embodiment. 197 F.3d at 1382. Although the parties in *Wang Laboratories* agreed that the term "frame" could theoretically apply to either character-based or bit-mapped display systems, the specification's consistent illustration of "frame" using character-based protocol and the patent's prosecution history indicated that the claim referred only to character-based systems. *Id*. at 1382-84.

[9] In this case, the '288 patent's claim language, specification, and prosecution history do not disclaim detection methods that are not "rate plus PDF." See, *e.g.,* '288 patent, col. 10, *ll*. 19-23 (stating that "conventional logic circuitry can be provided for determining, based on the previously discussed inputs, the existence of various medical conditions, for example, ventricular tachycardia, ventricular fibrillation and super-ventricular tachycardia"). Absent specific reasons dictating a narrow claim construction, a particular embodiment in a specification will not limit broader claim language. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 907 (Fed.Cir.2004).

[10] St. Jude also contends that CPI's proposed construction of Claim 4 would render it invalid, and St. Jude points out that a claim ordinarily should not be construed in a manner that would render it invalid. See Phillips, 415 F.3d at 1327; Carman Indus., Inc. v. Wahl, 724 F.2d 932 (Fed.Cir.1983). St. Jude argues that CPI's construction places no limit on how a heart condition is determined and therefore poses a host of invalidity problems, such as indefiniteness, failure to meet written description requirements, failure to enable, and anticipation. St. Jude argues that acceptance of CPI's construction for the "determining" step would allow non-ICD devices such as pressure monitors, stethoscopes, and oxygen monitors to fall within the claim.

[11] The claim language and specification strongly support CPI's broader construction of the "determining" step elementof Claim 4. Moreover, it is not clear at this point that CPI's construction will lead to invalidity of the claim. The preference for claim constructions supporting validity is essentially a last resort, to be used only when the other tools for interpreting ambiguous claims have been exhausted. See Phillips, 415 F.3d at 1327-28 (noting that the doctrine of construing claims to preserve their validity is of "limited utility" and applies only when claim is ambiguous after applying all other tools of claim construction); see also Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1356 (Fed.Cir.1999) (doctrine not applicable where claim is reasonably susceptible of only one meaning). The consequences of the court's adopted construction are best addressed in the context of St. Jude's pending motion for summary judgment of invalidity or at trial.

**C. *Remaining Limitations***

St. Jude contends that the new construction of the "determining" step directly affects other elements of Claim 4, requiring the court to revisit the interpretations of those elements as well. See Remand Docket No. 92, St. Jude Ex. H at 7 (Dr. Mihran's report). St. Jude also asks the court to interpret phrases from the preamble of Claim 1.

The Federal Circuit did not address whether other claim elements should be construed on remand. Its statement that "the 'determining' step must be construed, *as for all claim steps,* in light of the specification and the prosecution history" does not require that the court revisit the other elements in Claim 4. See 381 F.3d at 1382 (emphasis added). The statement merely highlights the appellate court's recognition that its instructions for construing the "determining" step on remand in this case fit with its generally applicable standards for claim construction.

[12] While the district court may not grant relief beyond the scope of the Federal Circuit's mandate, it may act on matters left open by the mandate. Laitram Corp. v. NEC Corp., 115 F.3d 947, 951 (Fed.Cir.1997); see also Exxon Corp. v. United States, 931 F.2d 874, 877 (Fed.Cir.1991) (law-of-the-case doctrine does not constrain the trial court with respect to issues it previously decided that were not also decided by the appellate court's judgment). It is doubtful that the Federal Circuit's single statement that it was affirming in part and modifying in part this court's claim construction, see 381 F.3d at 1374, meant that its judgment decided all claim construction issues, since these issues were not appealed by the parties nor discussed by the court. Also, this court's construction of Claim 4's other limitations could be subject to *de novo* review by the Federal Circuit if this case were to return to the appellate court. See Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1456 (Fed.Cir.1998) ( *en banc* ).

However, both parties fully briefed and argued these issues for the initial *Markman* hearing. St. Jude did not dispute this court's constructions either at trial or on appeal. Most important, St. Jude has not presented any convincing argument as to how the broader interpretation of the "determining" step affects the other claim elements. Because the court adopts CPI's proposed construction for the "determining" step, it is unnecessary to reconstrue "detecting an arrhythmia" to highlight the differences between those two phrases. When asked in his deposition, St. Jude's own expert could not articulate what effect the broader interpretation of the "determining" step might have on the "cardioversion" limitation of the claim. See Remand Docket No. 120, CPI Ex. 15 at 104-05 (Dr. Mihran). Because St. Jude offers no persuasive reason for this court to reconstrue the other limitations, the court declines to do so.

To address several of the specific issues: First, "cardioversion," as it is used in "wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion" in Claim 4, is not limited to manual cardioversion. The patent specification clearly uses the term "cardioversion" generically to encompass both manual and automatic cardioversion. See, *e.g.,* '288 patent, col. 12, *ll.* 49-65 (using "cardioversion" in describing automatic operation of claimed device).

Second, St. Jude's argument for reinterpreting the "selecting" step is not persuasive. The "selecting" step states that operation of the implantable heart stimulator includes "a unique sequence of events corresponding to said determined condition." The court has previously construed the "unique sequence" language to involve "matching the currently determined heart condition to the unique set of instructions that have been programmed to treat the detected condition." See 2000 WL 1765358, at *35-36. St. Jude now asks the court to modify this instruction by adding that the device is incapable of "learning," *i.e.,* it will execute the same electrical stimulation sequence each time a particular heart condition occurs.

This court previously found that the '288 patent did not claim a learning functionality. See 2000 WL 1765358, at *35 ("The court agrees with St. Jude's contention that the currently determined condition of the heart is the only variable that affects the step of 'selecting' "). However, the '288 patent's preferred embodiment does allow *physicians* to reprogram the ICD depending on the patient's reaction to treatment.

See '288 patent, col. 5, *ll*. 27-45. Therefore, St. Jude's proposed construction, which requires that the same sequence of electrical stimulation occur *every* time a particular condition occurs, would not cover the '288 patent's preferred embodiment. Such an interpretation is unlikely to be correct. Vitronics, 90 F.3d at 1583.

Third, St. Jude's proposed changes to the court's construction of the "executing" step are minimal and unnecessary. The court addresses St. Jude's argument concerning infringement and the execution of all claimed method steps in Part IV of this Entry.

In sum, the court sees no need to revisit the elements of Claims 1 and 4 other than the "determining" step, and intends to use the constructions from its previous Entry on Claim Construction Issues (Docket No. 365).

**II.** ***CPI's Motion for Summary Judgment on St. Jude's Second, Fourth, Fifth, Sixth, and Seventh Affirmative Defenses and Related Counterclaims***

CPI has moved for summary judgment on St. Jude's invalidity and unenforceability defenses and related counterclaims. CPI contends the Federal Circuit rejected those defenses conclusively. The motion is denied. The Federal Circuit's remand left open the possibility of new invalidity and unenforceability defenses. The Federal Circuit wrote: "We ... reinstate the jury verdict of validity, and remand for a new trial of infringement and reassessment of damages." 381 F.3d at 1374. The court also wrote that a "new trial is required so [St. Jude] can present evidence and argument that were not needed under the district court's original claim construction, such as whether the now-asserted scope of the claims is supported by the specification." Id. at 1382-83. That language plainly leaves open the possibility of affirmative defenses.

**A.** ***Invalidity***

St. Jude has asserted as affirmative defenses that the '288 patent is invalid and unenforceable. See Remand Docket No. 40 at 3, para. 2. CPI points out that the jury previously found against St. Jude on the issues of obviousness and best mode for the '288 patent. Although this court granted JMOL and a conditional new trial to St. Jude on these issues, the Federal Circuit reinstated the jury's findings that (1) the '288 patent was not invalid for obviousness under 35 U.S.C. s. 103 and (2) the '288 patent had not violated the best mode requirement in 35 U.S.C. s. 112. 381 F.3d at 1378, 1379. The Federal Circuit also vacated this court's conditional grant of a new trial on these issues. Id. at 1380.

CPI argues that a different construction of the "determining" step does not affect either obviousness or the best mode issue. With respect to obviousness, CPI concedes that the "determining" step limitation, however it is construed, was present in prior art. CPI Br. at 5. CPI argues that the parties' obviousness debate focused on other features in the claimed invention ( *e.g.,* multimode operation), and that these features are not affected by the court's new construction. With respect to best mode, this court had held the '288 patent invalid for failure to disclose use of the Honeywell battery. CPI contends that St. Jude never made a best mode argument relating to Claim 4's "determining" step. Based on the failure of these defenses before the Federal Circuit, CPI argues that St. Jude should be foreclosed from raising any invalidity defenses on remand.

[13] The Federal Circuit's decision does not generally bar St. Jude from asserting invalidity defenses and related counterclaims on remand. When a new trial on infringement is ordered, a defendant is generally entitled to present any defenses to infringement that may be available and that are not foreclosed by the appellate court's mandate. In this case, the Federal Circuit's mandate, including its reinstatement of the jury's

verdict on obviousness and best mode, did not foreclose all of St. Jude's validity defenses under a new claim construction in a new trial for infringement. Of course, the mandate rule precludes St. Jude from asserting the same obviousness and best mode arguments it raised and lost earlier in the litigation. See Ins. Group Committee v. Denver & R.G.W.R. Co., 329 U.S. 607, 612, 67 S.Ct. 583, 91 L.Ed. 547 (1947) (mandate rule requires that a lower court "refuse to permit the relitigation of matters or issues previously determined on a former review"). However, St. Jude's other theories of invalidity were not within the scope of the appealed judgment and therefore may be asserted on remand. See Exxon Chemical Patents, Inc. v. Lubrizol Corp., 137 F.3d 1475, 1478 (Fed.Cir.1998) ( "Even without the express disclaimer in the court's opinion, it would be incorrect to conclude that the court's mandate encompassed an issue that was not presented to the court.").

Three points support this conclusion. First, the Federal Circuit suggested that a new claim construction might give rise to new invalidity defenses when it noted that St. Jude could present evidence and argument on remand, "such as whether the now-asserted scope of the claims is supported by the specification." 381 F.3d at 1382-83. Clearly implicit in this language is the invalidity defense based on the written description requirement of 35 U.S.C. s. 112.

Second, St. Jude had no obligation on appeal to present alternative arguments for invalidity since it had succeeded on its obviousness and best mode points in this court. See Lubrizol, 137 F.3d at 1482 (vacating district court's denial of new trial on infringement under doctrine of equivalents;patentee could not be held to have abandoned theory that was moot until appellate court reversed jury verdict on literal infringement; finding of waiver "would require an appellee to anticipate every possible claim construction that the appellate court might adopt and put forth grounds for a new trial under each possible claim construction"); Laitram, 115 F.3d at 951-55 (issues made moot by district court's resolution of separate issue later reversed on appeal were not foreclosed on remand either by mandate rule or doctrine of waiver); Cordis Corp. v. Medtronic Ave, Inc., 2005 WL 283525, at (D.Del. Jan. 27, 2005) (invalidity defense that theoretically could have been asserted at trial but might have resulted in jury confusion was not waived under new claim construction). Even if St. Jude could have made invalidity arguments contingent on the success of CPI's appeal on the claim construction, it was not required to do so. If the law were otherwise, complex appeals in cases like this would become even more complex and difficult to manage.

Most important, because of the court's previous claim construction, St. Jude may have chosen not to pursue some invalidity defenses, including anticipation, at trial. But because anticipation requires specific reference to all claim elements, it is possible, for example, that the court's previously adopted claim construction steered St. Jude away from other art that would be relevant to this defense under a revised claim construction. It is also possible that the first trial's primary focus on apparatus claims, as opposed to the lone method claim that now remains, led St. Jude to focus on different invalidity defenses than it might assert now. See, *e.g.,* TI Group Automotive Systems (North America), Inc. v. VDO North America, LLC, 375 F.3d 1126, 1139 (Fed.Cir.2004) (remanding invalidity question because "jury could only have compared the prior art to the erroneously narrowly construed claims"); Cordis Corp., 2005 WL 283525, at *2 (denying plaintiff's motion for summary judgment that defendants had waived obviousness argument on remand; issue had changed as a result of revised claim construction). St. Jude did not abandon or waive invalidity defenses that became relevant only on remand, where the court's new claim construction is broader than the original. Cf. Cordis, 2005 WL 283525, at *2 ("it is unrealistic to have expected Medtronic to present invalidity arguments in the original trial if it thought such arguments were futile based on the narrower claim construction at issue"). St. Jude's motions for summary judgment of invalidity of Claims 1 and 4 (Remand Docket Nos. 80 & 81) raise more than a mere theoretical possibility that different invalidity defenses are

now available.

**B.** ***Unenforceability***

[14] CPI also seeks to exclude St. Jude's defenses and counterclaims relating to CPI's alleged misconduct before the Patent and Trademark Office and during the first trial. St. Jude argues that the '288 patent is unenforceable on the grounds of unclean hands, estoppel, inequitable conduct, and fraud. The court holds that *all* of St. Jude's arguments concerning unenforceability may be asserted on remand as well.

St. Jude's unenforceability arguments on remand fall into three broad categories. First, St. Jude alleges that CPI engaged in several types of misconduct before the PTO. At trial, St. Jude alleged that CPI made misrepresentations to the PTO in 1994 to secure extension of its '288 patent and in 1998 by claiming that its failure to pay correct maintenance fees was a filing error. The jury rejected St. Jude's inequitable conduct defense on these issues, and the court denied St. Jude's motion for JMOL. Also, prior to trial, St. Jude alleged that CPI had engaged in inequitable conduct by failing to disclose material information to the PTO during the original prosecution and reexamination of the '288 patent, but it did not pursue either theory at trial. St. Jude also had alleged that CPI misrepresented another patent during reexamination of the '288 patent, but it did not pursue that theory at trial. On remand, St. Jude seeks to revive each of these arguments. See Remand Docket No. 40 at 8-9, para.para. 18-23; at 4, para.para. 6-7; at 6-7, para. 14; and at 7, para. 17.

Second, St. Jude previously alleged that CPI had asserted three patents against St. Jude that it knew were invalid. The court granted summary judgment for CPI on St. Jude's counterclaim. Docket No. 559. St. Jude did not appeal the order. St. Jude raises this issue again on remand. See Remand Docket No. 40 at 9, para. 24.

Third, St. Jude seeks to introduce evidence concerning Dr. Bourland's misconduct at the first trial. See Remand Docket No. 40 at 10, para. 25 to 15, para. 44. At the end of the first trial, the full extent of Dr. Bourland's misconduct and CPI's involvement was not known. In the post-verdict entry, this court stated that "if any claim by CPI that was tried to the jury survives an appeal, Dr. Bourland's deception entitles St. Jude to a new trial." 2002 WL 1801525, at *64. The court also ordered a conditional sanction requiring CPI to pay St. Jude's attorneys fees on retrial. *Id*. at *64-65.

On appeal, the Federal Circuit vacated the court's conditional sanction because the new trial it ordered as a result of the erroneous claim construction was "unrelated to the witness' deception." 381 F.3d at 1383. The Federal Circuit did not address this court's findings concerning Dr. Bourland's conduct or St. Jude's inequitable conduct defense.

The Federal Circuit's mandate only vacated the court's conditional sanction of attorneys fees against CPI. The opinion and mandate did not even suggest, let alone require, that the issue of Dr. Bourland's misconduct be removed from this case for all purposes. See Laitram, 115 F.3d at 951 (appellate court's mandate extends only to matters decided explicitly or by necessary implication). This court's entry clearly stated that Dr. Bourland's conduct could be litigated in a new trial. CPI and the Federal Circuit did not address this ruling on appeal. The court's opinion emphasized that the information known at the end of trial might not have been a complete account of Dr. Bourland's misconduct or CPI's and its attorneys' involvement, and that it might not have fully accounted for the ways in which CPI's misconduct had affected St. Jude's success at trial. The court concluded that, if its reasons for finding against CPI on its infringement claims were rejected on appeal, the remedy should be "tailored more closely to the harm caused, which would be the need for a

new trial." 2002 WL 1801525, at *63. Accordingly, St. Jude is entitled to raise the issue of Dr. Bourland's misconduct at a new trial, whether asserted as inequitable conduct or some other legal theory.

In addition, the court believes that St. Jude is entitled to put in evidence relevant to CPI's *entire pattern* of allegedly inequitable conduct. As a question of law, a defense of inequitable conduct requires consideration of the totality of the circumstances, both those that support the defense and those that weigh against it. See, *e.g.,* Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1259 (Fed.Cir.1997) (finding inequitable conduct as a matter of law based on pattern of conduct); Consolidated Aluminum Corp. v. Foseco International Ltd., 910 F.2d 804, 809 (Fed.Cir.1990) (affirming finding of inequitable conduct based on totality of circumstances); Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1562 (Fed.Cir.1989) (stating that inference of intent to mislead PTO "depends upon the totality of the circumstances, including the nature and level of culpability of the conduct and the absence or presence of affirmative evidence of good faith").

Second, new post-trial information on CPI's conduct sheds additional light on CPI's efforts to enforce the patents in suit. For example, CPI's counsel told the jury that Dr. Bourland's false testimony was the product of an honest but mistaken memory. It is now clear that Dr. Bourland lied deliberately, and that CPI's trial attorneys made no reasonable effort to address the problem when it arose during trial. There is an interesting parallel with the evidence of the fee issue that was the basis of the inequitable conduct defense at trial: CPI explained away its actions as honest mistakes, though there was certainly some additional circumstantial evidence that would have permitted, though not required, a finding of deliberate deception. A trier of fact who was aware of both patterns of activity, as well as such matters as the double-patenting in the '472 patent and other topics, might be less willing to give CPI the benefit of the doubt on the explanation that it had simply made honest mistakes.

After the first trial, this court stated: "in the event of a new trial on the '288 patent, based on Dr. Bourland's conduct, discussed next, *or for other reasons,* the inequitable conduct defense shall be part of the trial." 2002 WL 1801525, at *48 (emphasis added). St. Jude is entitled to raise its allegations of inequitable conduct, fraud, or unclean hands in a second trial. CPI's motion for summary judgment on St. Jude's affirmative defenses and related counterclaims is denied in all respects.

## III. *St. Jude's Motion for Summary Judgment on CPI's Claim for Lost Profits*

### A. *Waiver*

[15] St. Jude first argues that CPI has waived its lost profits claim on the '288 patent because it chose not to appeal either the jury verdict or this court's denial of a new trial for lost profits on the '472 patent. Because lost profits are merely a function of how many infringing products are sold, CPI's expert acknowledged that the measure of lost profits would not differ depending on which patent is found infringed. See Remand Docket No. 84, St. Jude Ex. 6 at 1175-76 (Britven's testimony). Nonetheless, CPI argues that it was not required to challenge lost profits for the '288 patent on appeal because the jury did not find infringement on that patent.

[16] The doctrine of waiver prevents a party from raising an issue on remand that it should have raised previously on appeal. See, *e.g.,* Tronzo v. Biomet, Inc., 236 F.3d 1342, 1347-48 (Fed.Cir.2001). In this case, the jury did not find infringement of the '288 patent. It never reached the issue of damages under that patent. In addition, this court's order denying CPI's contingent motion for a new trial on lost profits related only to the '472 patent because the motion depended on a reviewing court finding that the '472 patent was not

invalid. See 2002 WL 1801525, at *76-77. Accordingly, for purposes of deciding waiver, the lost profits issue, as it applies to the '288 patent, cannot be considered within the scope of the judgment that was appealed. Cf. Engel Indus., Inc. v. Lockformer Co., 166 F.3d 1379, 1382 (Fed.Cir.1999) ("The scope of the issues presented to this court on appeal must be measured by the scope of the judgment appealed from, not by the arguments advanced by the appellant.") (internal citations omitted). Argument on lost profits for the '288 patentwas unnecessary, and indeed hypothetical, until the Federal Circuit reversed the court's construction of Claim 4 and remanded for a new trial on infringement. See Laitram, 115 F.3d at 954 (no waiver on remand for failure to appeal issue that was moot until appellate court reversed judgment on appeal).

This analysis is not changed even though there may be no practical difference in the measure of lost profits between the '472 and the '288 patents. The Federal Circuit's actions and words caution this court to treat the two patents independently, at least with respect to damages. On appeal, the Federal Circuit refused to shift CPI's damages award from the '472 patent to the '288 patent, stating only that "damages for infringement of the '288 patent, should infringement be found on remand, requires determination on remand." 381 F.3d at 1383. Although St. Jude argues that this decision can be explained by the fact that royalty damages depend in part on the value of the particular patent that has been found infringed, the court hesitates to read this unstated rationale into the Federal Circuit's decision so as to prevent a party from litigating an issue that the jury did not decide directly before. If a new trial results in a finding of infringement of the '288 patent, a new determination of damages must occur.

This case is distinguishable from *Tronzo v. Biomet, Inc.,* which St. Jude cites as an example of waiver in the district court following an appeal. 236 F.3d 1342 (Fed.Cir.2001). In *Tronzo,* a jury found defendant Biomet liable for patent infringement and other state law claims, and it awarded both compensatory and punitive damages. The trial court entered a judgment for $7.1 million in compensatory damages and $20 million in punitive damages. It also denied Biomet's post-trial motion to set aside the jury award of punitive damages. On appeal, Biomet challenged its liability and the amount of compensatory damages, but it did not challenge the punitive damages award. The Federal Circuit reversed the finding of infringement, upheld liability on the state law claims, and remanded for a new determination of compensatory damages.

On remand, the district court reduced both the compensatory and punitive damages awards. The patent holder then appealed, arguing that Biomet had waived its right to challenge the punitive damages award by not appealing the award the first time around. The Federal Circuit agreed and reinstated the original $20 million punitive damages judgment.

The outcome in *Tronzo* depended on the fact that the punitive damages award was within the scope of the initial judgment. Biomet had an opportunity to challenge it in the first appeal, and it waived its opportunity to do so when it did not use that opportunity. See *id.* at 1348-49 (noting that district court had considered the issue below). In this case, neither the jury nor the court made any finding on lost profits for the '288 patent. The issue simply was not within the scope of the appealable judgment, and CPI was not required to raise it on appeal. Cf. Engel Industries, 166 F.3d at 1383 (no argument permitted on remand for issue within scope of judgment appealed from where appellate court did not order remand on any issues). Accordingly, this court cannot conclude that CPI has waived its claim to lost profits on the '288 patent.

**B.** ***Merits***

[17] Alternatively, St. Jude asks the court to find that CPI's claim for lost profits fails as a matter of law

because CPI cannot establish that it lost any sales it would have made but for St. Jude's alleged infringement. A patentee claiming lost profits must prove that but for the infringement, it would have made a portion of the defendant's sales and made profits on those sales. Grain Processing Corp. v. American Maize-Prods. Co., 185 F.3d 1341, 1349 (Fed.Cir.1999). The relevant facts here are unusual. The alleged infringement occurred in this case when St. Jude acquired Ventritex, an existing market competitor. Ventritex had a license to practice the '288 patent. The license expired with the change of corporate control. St. Jude had made arrangements with another business to acquire a comparable license in a separate but simultaneous transaction. An arbitrator eventually ruled that the separate transaction did not provide St. Jude with a valid license, thus exposing it to claims for infringement. See Telectronics Pacing Systems, Inc. v. Guidant Corp., 143 F.3d 428 (8th Cir.1998) (compelling arbitration); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 149 F.Supp.2d 610 (S.D.Ind.2001) (finding that arbitrator's ruling was binding on parties to this lawsuit).

St. Jude argues that in the hypothetical "but for" market, St. Jude would not have closed its merger with Ventritex, and therefore Ventritex's ICDs would have remained on the market as a non-infringing alternative to CPI's products. St. Jude claims that it is undisputed that Ventritex had an established market share and a license to the '288 patent. Remand Docket No. 84, St. Jude Ex. 6 at 1230, 1241 (Britven's testimony). St. Jude also claims that CPI's own market share actually increased following St. Jude's merger with Ventritex. *Id*. at 1228. Based on this evidence, St. Jude argues that CPI cannot prove any lost profits as a matter of law.

[18] Genuine issues of material fact prevent the court from finding that CPI's claim for lost profits should fail as a matter of law. The court could grant St. Jude's motion for summary judgment only if no reasonable jury could find in favor of CPI, the non-moving party, based on the evidence in the record. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); American Airlines, Inc. v. United States, 204 F.3d 1103, 1108 (Fed.Cir.2000). At the first trial, CPI failed on its claim for lost profits under the (invalid) '472 patent. However, CPI presented evidence from which a reasonable jury could have concluded that it suffered lost profits on sales of ICDs following St. Jude's merger with Ventritex, despite Ventitrex's pre-merger license to its patents.

[19] On remand, CPI again can come forward with evidence to support a prima facie case for lost profits under the *Panduit* test. See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152 (6th Cir.1978); Micro Chemical, Inc. v. Lextron, Inc., 318 F.3d 1119, 1122 (Fed.Cir.2003) (recognizing *Panduit* test as one way to demonstrate entitlement to lost profits "but for" infringement); Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1373 (Fed.Cir.1991) (approving jury instruction on *Panduit* test in case for infringement of only method claims). Under the *Panduit* test, a patentee must show: (1) demand for the patented product; (2) the absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of profit it would have made. Panduit Corp., 575 F.2d at 1156. In a multi-supplier market, the patentee may substitute proof of market share for the second factor. State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1578 (Fed.Cir.1989).

CPI has presented evidence of demand for its patented products. CPI can present evidence of market share, and an increase in CPI's market share during the alleged infringement period is not necessarily inconsistent with lost profits if the overall market was expanding. For the third *Panduit* factor, CPI has presented evidence of its capacity to manufacture additional ICDs. Finally, CPI can offer evidence on the amount of lost profits through expert testimony as in the first trial.

The court intends to provide essentially the same jury instructions on lost profits that it gave at the first trial. After setting forth the *Panduit* test, the court explained in part:

As you know, Ventritex was licensed to practice the '472 and '288 patents before it merged with St. Jude and Pacesetter. Because the merger caused the termination of that license, any infringement began with the merger. If that merger had not occurred (that is, if the infringement had not occurred), the license would have allowed Ventritex to continue manufacturing and selling its products as an independent company. When reconstructing the market in the absence of the infringement, you may take this possibility into account.

Remand Docket No. 84, St. Jude Ex. 3 at 122 (Court's Final Instruction No. 60).

CPI argues, as it did at trial, that the court's instruction misstated the law. CPI contends that the Federal Circuit's decision in *Grain Processing* and its progeny permit a fact-finder to consider only alternative products that were available to the alleged infringer. CPI argues that the jury may not consider more broadly the alternative actions that the alleged infringer might have taken had it not infringed. In the context of this case, CPI claims that it was improper for the jury to consider the possibility that St. Jude might not have merged with Ventritex, so that Ventritex could have continued to sell ICDs with a license on CPI's patents.

CPI raised this same objection prior to the first trial and in its contingent motion for a new trial. The court declined to adopt CPI's interpretation of the law and denied its post-trial motion on this issue. CPI did not appeal that denial.

On remand, CPI argues that more recent case law demonstrates that *Grain Processing* cannot be read so broadly as to include alternative actions by alleged infringers, such as a decision by St. Jude not to merge with Ventritex. CPI cites the Federal Circuit's decision in Micro Chemical, Inc. v. Lextron, Inc., 318 F.3d 1119 (Fed.Cir.2003), and several district court decisions. It argues that these cases show that the "but for" infringement inquiry must be narrower.

The cases cited by CPI do not require a change in this court's interpretation of *Grain Processing* or its application to this case. Recent cases have focused only on the speculation surrounding the substitute product itself, *i.e.*, whether the infringer could establish that the product was both available and acceptable in the market during the relevant accounting period. For example, *Micro Chemical* simply reaffirmed the *Grain Processing* conclusion that the mere possession of material goods and know-how for making a substitute product may not be sufficient for finding that the alleged infringer could have brought the product to the market. In *Micro Chemical,* the Federal Circuit held that the defendant's product could not be considered available as a substitute because it took over four months to be converted into a non-infringing form. 318 F.3d at 1123; see also McGinley v. Franklin Sports, Inc., 192 F.Supp.2d 1214, 1220-22 (D.Kan.2002) (denying infringer's motion for summary judgment on lost profits where evidence conflicted as to market acceptability of substitute product); Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp., 166 F.Supp.2d 1008, 1030 (D.Del.2001) (denying JMOL to cap damages award against defendant where non-infringing substitute had not been "finalized, approved, or implemented" during relevant accounting period), *aff'd in part, vacated in part, remanded on other grounds,* 370 F.3d 1131 (Fed.Cir.2004); Bose Corp. v. JBL, Inc., 112 F.Supp.2d 138, 160 (D.Mass.2000) (finding record was "too scant on the availability of 'acceptable' substitutes to be persuasive"); Cordis Corp. v. Boston Scientific Corp., 2005 WL 1322953, at (D.Del. June 3, 2005) (ability to make non-infringing substitute alone is insufficient to render product "available" for lost profits purposes).

[20] CPI cannot dispute that Ventritex's ICD was identical to the accused product and available for market at the time of the alleged infringement. Moreover, the cases cited by CPI do not speak more generally to the debate over whether the hypothetical "but for" market can include other non-infringing actions by the defendant. *Grain Processing* instructs that the court's reconstruction of the market "take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed," without the restrictions CPI proposes. 185 F.3d at 1350-51. Applying this principle here, one non-infringing alternative available to St. Jude was a decision not to close on its merger with Ventritex, leaving Ventritex with a valid license to compete independently in the market.

Because there is a genuine factual dispute as to whether this available alternative meant that CPI suffered no lost profits, St. Jude's motion for summary judgment on CPI's claim for lost profits is denied.

**IV.** ***St. Jude's Motion for Summary Judgment Limiting CPI's Damages***

**A.** ***Waiver***

[21] St. Jude seeks to limit CPI's damages claim to only those devices that actually executed CPI's claimed method of cardioversion in the United States during the relevant infringement period. As an initial matter, CPI argues that St. Jude has waived this argument by raising it for the first time on remand. The court finds no waiver of this issue.

CPI has now narrowed its claims against St. Jude to a single method claim. CPI originally asserted both a method claim (Claim 4) and an apparatus claim (Claim 13) under the '288 patent. On the apparatus claim, a finding of infringement would have made St. Jude liable for *all* device sales. The method claim did not add to the scope of the infringement claim based on the apparatus claim. St. Jude therefore had no strong incentive to try to limit its damages with respect to the method claim in particular. After this court upheld the jury's verdict of non-infringement of the '288 patent, CPI abandoned the apparatus claim when it chose not to appeal any findings on the apparatus claim. In other words, St. Jude had no reason to present its present damages argument until the remand. Under the reasoning of the cases cited above at pages 1035-36, there was no waiver.

**B.** ***Actual Use of Claimed Method***

[22] St. Jude argues that CPI can prove infringement of Claim 4 of the '288 patent only by showing that St. Jude's devices were actually programmed to execute the claimed method of cardioversion or that they actually executed cardioversion. St. Jude contends that the method claimed in Claim 4 was not practiced in a large number of its ICDs. The point is critical here because CPI, to avoid problems of obviousness, chose not to pursue claims of infringement of Claims 3 and 5. Claim 3 is for: "The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes a cardiac pacer mode of operation."Claim 5 is for: "The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes automatic defibrillation." Cardiac pacing and automatic defibrillation are the most common forms of therapy administered by ICDs.

St. Jude's ICDs must be programmed before they can deliver any therapy to the patient. See Remand Docket No. 84, St. Jude Exs. 8 & 9 (Shipman Decl. para. 4; Kadish Decl. para. 3). St. Jude has presented evidence that a number of its devices implanted during the relevant infringement period were programmed by implanting physicians to "DEFIB ONLY" mode, making them incapable of executing a separate

"cardioversion" therapy unless and until they were reprogrammed. See Remand Docket No. 84, St. Jude Exs. 8 & 9 (Shipman Decl. para.para. 5-6; Kadish Decl. para. 4); Hearing Tr. at 118 (discussing availability of statistical data as to how St. Jude devices were programmed and used in clinical trials).

St. Jude cannot be held liable for infringement of Claim 4 on a device that was not programmed to execute the claimed method of cardioversion and/or that has not executed the claimed method of cardioversion. This issue previously arose with respect to infringement of Claim 18 of the '472 patent. In the post-verdict entry, this court stated:

To hold St. Jude liable for infringement on this method claim-whether for inducing infringement or contributory infringement or direct infringement-CPI was required to come forward with some evidence of actual use of the infringing method by someone. See Met-Coil Systems Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 687 (Fed.Cir.1986) (absent direct infringement of the patent claims, there can be neither contributory infringement nor inducement of infringement). A method claim is not infringed by the sale of a device that is merely capable of being used in an infringing manner. Actual infringing use must be shown. Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 773-75 (Fed.Cir.1993) (reversing finding of infringement of method claims where no actual infringing use was shown); Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1374 (Fed.Cir.1991) (method claims held not directly infringed by the mere sale of an apparatus capable of performing the claimed process).

2002 WL 1801525, at *29 (granting JMOL on non-infringement because of absence of evidence of actual infringing use). Recent cases reaffirm this requirement. See, *e.g.,* NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1318 (Fed.Cir.2005) ("well-established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized"), quoting Roberts Dairy Co. v. United States, 208 Ct.Cl. 830, 530 F.2d 1342, 1354 (1976); see also Imagexpo, LLC v. Microsoft Corp., 284 F.Supp.2d 365, 369-70 (E.D.Va.2003) (holding that patent holder could recover on only those devices distributed by alleged infringer and employed by the end user to use the patented method). Absent proof that St. Jude's devices were programmed for and actually executed the claimed method, CPI may not recover damages for the sales of devices merely capable of infringing. See 35 U.S.C. s. 284 (damages available for "use made of the invention by the infringer").

CPI emphasizes that all of St. Jude's devices were capable of executing cardioversion therapy, and CPI contends that St. Jude even instructed physicians how to program its devices to execute this therapy. See Remand Docket No. 84, St. Jude Exs. 9 (Ex. A) & 11 (Reiss Aff. para.para. 24-27). CPI also argues that devices incapable of multimode operation would not have been marketed or implanted after the mid-1990s because physicians wanted the flexibility to later reprogram for cardioversion therapy. Remand Docket No. 125, CPI Ex. 1 at 281 (Dr. Tacker's testimony) and 1068 (Verrastro's testimony); CPI Ex. 2 (Berger Aff. para.para. 5-9).

None of these facts are sufficient to impose liability (and therefore damages) for every device sold. The case law cited above draws a clear distinction between method and apparatus claims for purposes of infringement liability. An apparatus claim is infringed when a product containing the patented invention is made, used, offered for sale, or sold in the United States. See 35 U.S.C. s. 271(a). But a method claim, like CPI's remaining claim in this case, is not infringed unless the patented method is *actually practiced*. St. Jude cannot be held liable for infringement of the '288 patent unless its ICDs were used by others to practice each step of the patented method. FN4

FN4. St. Jude does not concede that CPI has proven all of the other elements for contributory infringement or inducement of infringement, see St. Jude Br. at 2 n. 1, but the court need not resolve those issues here.

This important distinction between apparatus claims and method claims explains why the cases cited by CPI are not persuasive here. CPI argues that a patentee may recover damages for all sales when the ability to practice the patented feature is fundamental to the product's value. For example, in *Stryker Corp. v. Intermedics Orthopedics, Inc.,* the Federal Circuit affirmed a damages award based on all of the defendant's sales even though the components comprising the patented invention were used together only about 20 percent of the time. 96 F.3d 1409 (Fed.Cir.1996). Stryker's patent covered a femoral prosthesis device. The patent required that the prosthesis include a distal sleeve. The defendant sold over 20,000 "APR II" prostheses but fewer than 5,000 sleeves. The Federal Circuit permitted Stryker to recover damages for all 20,000 prostheses sold, concluding that it was the availability of distal sleeves that was important to physicians, regardless of whether they were ultimately used in surgery. The court reasoned that "by supplying the APR II to surgeons, [Intermedics] kept [Stryker] out of the operating room." Id. at 1417.

CPI argues that St. Jude similarly kept it out of the operating room by selling ICD devices that were capable of cardioversion, regardless of whether this mode was actually programmed or executed for a particular patient. CPI's argument overlooks the fundamental fact that *Stryker* involved an apparatus claim and not a method claim. The basis for the *Stryker* court's decision was its recognition that Stryker was damaged by the defendant "each time [Intermedics] supplied an APR II system, complete with a distal sleeve, to a surgeon." Id. at 1417. That is, the apparatus patent was directly infringed by each sale of the device, whether it was used or not. As explained above, however, the method of Claim 4 is infringed only when every step of the claimed method is executed. The reasoning of *Stryker* does not apply to CPI's remaining method claim. See also Oak Indus., Inc. v. Zenith Electronics Corp., 726 F.Supp. 1525, 1543 (N.D.Ill.1989) (granting summary judgment for defendant to limit plaintiff's damages to cable converters shown to have practiced the patented method, rather than all converters that were capable of performing the method).

CPI points to other cases holding that a product may be found to infringe when it sometimes, but not always, practices the claimed method. See Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 622-23 (Fed.Cir.1995) (vacating summary judgment of non-infringement of patented method and cautioning that product only sometimes performing patented method may nonetheless infringe); see also Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1343 (Fed.Cir.2001) (vacating summary judgment of non-infringement but noting that operation of accused device under unusual conditions may not establish infringement). These cases are also inapposite. CPI's argument confuses the distinction between all devices sometimes practicing the patented method and the very different situation of some devices never practicing the patented method. St. Jude contends that its devices, similar to the cable converters in *Oak Industries,* fall into the latter category.

By abandoning its apparatus claim, CPI has radically altered the relevant considerations for potential damages. As a matter of law, CPI's damages for infringement of Claim 4 of the '288 patent are limited to only those devices that can be shown to have executed the claimed method of cardioversion during the relevant infringement period.

**C. *Applicability of*** Section 271(f)

St. Jude seeks another limit on CPI's available damages. St. Jude argues that CPI may recover damages only

on devices it sold in the United States. Devices sold outside of the United States that do not practice the claimed method domestically cannot create infringement liability under 35 U.S.C. s. 271(a). See NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1318 (Fed.Cir.2005). However, CPI argues that it is entitled to recover damages for St. Jude's foreign sales under 35 U.S.C. s. 271(f).

Section 271(f) was adopted in 1984 to close a loophole exposed by Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 92 S.Ct. 1700, 32 L.Ed.2d 273 (1972), that allowed parties to avoid infringement liability by manufacturing components of a patented product in the United States and then shipping those components abroad for assembly. Section 271(f)(1) reads:

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.

35 U.S.C. s. 271(f)(1). CPI argues that this provision applies to St. Jude because St. Jude supplied its ICD "components" abroad, thereby actively inducing the combination of its devices with the steps of CPI's patented method to infringe Claim 4 of the '288 patent. FN5

FN5. CPI does not appear to suggest that St. Jude would be liable under 35 U.S.C. s. 271(f)(2), which creates liability for entities supplying "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 ... knowing that such a 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." See CPI Br. at 6.

CPI points to several recent decisions by the Federal Circuit that it argues demonstrate the applicability of section 271(f) to method claims. First, in Eolas Technologies Inc. v. Microsoft Corp., 399 F.3d 1325 (Fed.Cir.2005), the specific issue was whether software code developed in the United States, shipped abroad on master disks, and then downloaded onto computer hard drives for foreign sales constituted "components" of an infringing product for combination outside of the United States under section 271(f). The patentee had sued Microsoft for allegedly infringing its internet browsing software through domestic and foreign sales of Internet Explorer. The district court held that section 271(f) applied to the software code shipped abroad, and the Federal Circuit agreed. The Federal Circuit emphasized that "every component of every form of invention deserves the protection of section 271(f)." *Id*. at 1339.

In *AT* & T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed.Cir.2005), the Federal Circuit again confronted Microsoft, exported software code, and section 271(f). The court held that sending a master version of software abroad with the intent of replication fell within section 271(f) liability for foreign-made copies. 414 F.3d at 1370. While the court did not discuss section 271(f) in detail outside of the software context, it once again noted that the statute "should be construed broadly to effectuate its purposes." *Id*. at 1371, citing Tcherepnin v. Knight, 389 U.S. 332, 336, 88 S.Ct. 548, 19 L.Ed.2d 564 (1967).

St. Jude correctly points out that the plaintiffs in *Eolas* and *AT & T Corp*. had asserted both product and method claims. St. Jude argues that because the product claims embodied the method claims in those cases,

the court's discussion of section 271(f)'s application to method claims was mere dicta. St. Jude contends that the plain language and legislative history of section 271(f) show that the statute was intended only to prevent companies from avoiding liability by assembling components of a patented physical product outside of the United States. St. Jude also argues that use of the word "component" in reference to a method step would be inconsistent with the use of that term in other provisions of section 271, and that the notions of "combining" or "supply" make no sense in the context of method claims. Finally, St. Jude points out that if section 271(f) were applied as CPI suggests, St. Jude could be liable for more damages on its foreign sales of ICDs than on its domestic sales of the same devices.

St. Jude's arguments have considerable weight, especially in light of the statutory language: "in a manner that would infringe the patent if such combination occurred within the United States." The mere assembly of an ICD that is capable of infringing the method of Claim 4 simply does not infringe Claim 4 within the United States. Only infringing use of the method infringes the method claim.

[23] Nevertheless, the Federal Circuit's even more recent decision in Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed.Cir.2005), seems to point in the opposite direction. In *Shell Oil,* the plaintiff's patent claimed a more efficient process for producing ethylene oxide gas by using certain types of catalysts. The district court had ruled that section 271(f) did not apply to process claims. On that basis, it excluded evidence that Shell Oil exported catalysts abroad.

The Federal Circuit held that the district court had erred by excluding the evidence, and it remanded for additional findings on section 271(f) liability. The court analogized the case to *Eolas,* noting that both involved the exportation of a component used in the performance of a patented process. 425 F.3d at 1379. It also noted that the case presented an even stronger basis for applying section 271(f) than *AT & T v. Microsoft* since Shell Oil's foreign affiliates did not copy the catalysts for use abroad but used the catalysts supplied directly by Shell. *Id.* In addition, the court explicitly asked and answered the basic question:

In other words, does this phrase ["any component of a patented invention"] apply to components used in the performance of patented process/method inventions? Eolas Techs. v. Microsoft Corp., 399 F.3d 1325, 1339 (Fed.Cir.2005) recently answered this question in the affirmative, holding that *every* component of *every* form of invention deserves the protection of 35 U.S.C. s. 271(f); *i.e.,* that "components" and "patented inventions" under s. 271(f) are not limited to physical machines.

*Id.* at 1378-79 (emphases in original). The court distinguished its earlier decision in *NTP, Inc. v. Research in Motion, Ltd.,* where it had held that section 271(f) did not apply to infringement of a method claim by devices that were domestically manufactured and sold even though their systems operated partially abroad. See 418 F.3d 1282. The *Shell Oil* court reasoned that the infringer in *NTP* had not supplied or combined any components abroad, while Shell Oil had.

St. Jude argues that the *Shell Oil* panel simply erred or, at the very least, that the case is distinguishable on its facts. Several patent law associations and at least three Federal Circuit judges believe that section 271(f) was not intended to apply to method claims. See Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 434 F.3d 1357, 1358-59 (Fed.Cir.2006) (Lourie, J., Michel, C.J., and Linn, J., dissenting from order denying rehearing *en banc* ); Remand Docket No. 138, St. Jude Exs. 36 & 37 ( *amicus* briefs in support of petition for rehearing, filed by American Intellectual Property Law Association, Federal Circuit Bar Association, and Federation Internationale des Conseils en Propriete Industrielle). As the court noted in *NTP,* "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)." 418 F.3d at 1322. In addition, Shell Oil had combined its exported catalysts with gases in executing the claimed process. St. Jude's ICDs sold abroad are not combined with other physical components to practice the claimed method.

Nevertheless, on the authority of *Eolas, AT & T Corp*., and especially *Shell Oil,* this court cannot conclude as a matter of law that section 271(f) does not apply to the method claim at issue here. St. Jude's devices are sold directly to foreign customers for (the court must assume) use of the patented method abroad. The court denies St. Jude's motion for summary judgment on the issue, but remains open to considering the issue again if addressed by subsequent case law. Also, if the question remains open at the time of trial, the court will attempt to use procedures that would require the jury to identify specifically any damages attributable to such foreign sales of devices that were capable of infringing use, so that it would be easy to correct any such error.

***Conclusion***

For the foregoing reasons, the court intends to interpret the disputed elements of Claim 4 of the '288 patent as indicated in this Entry. The court denies CPI's motion for summary judgment on St. Jude's second, fourth, fifth, sixth, and seventh affirmative defenses and its related counterclaims (Remand Docket No. 57). The court denies St. Jude's motion as to CPI's claim for lost profits (Remand Docket No. 77), and grants in part and denies in part its motion to limit CPI's damages to ICDs shown to have used the claimed method in the United States (Remand Docket No. 79).

So ordered.