UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

BOSTON SCIENTIFIC CORPORATION, *et al.*,	)	
Plaintiffs,	)	
vs.	)	**Cause No. 1:11-cv-736-WTL-DKL**
MIROWSKI FAMILY VENTURES, LLC,	)	
Defendant.	)	

ENTRY ON MOTIONS REGARDING EXPERT TESTIMONY

This cause is before the Court on Plaintiff Boston Scientific Corporation's Motion in Limine to Preclude Certain Testimony Based on Estoppel (Dkt. No. 195) and Defendant Mirowski Family Venture's Motion in Limine to Exclude Testimony that Contradicts This Court's Construction of "Cardioversion" (Dkt. No. 205). The motions are fully briefed and the Court, being duly advised, rules as follows.

I. BACKGROUND[1]

This is not the first time at the rodeo for either party. In 1996, Mirowski and Boston Scientific's predecessors jointly sued St. Jude Medical, Inc., for infringement of Mirowski's '288 patent, which was licensed to Boston Scientific's predecessors.[2] The case was tried to a jury in 2001. The jury found claims 4 and 13 of the'288 patent valid but not infringed by St. Jude. Following trial, the presiding judge, the Honorable David F. Hamilton, granted judgment as a

[1] A more detailed background of this case can be found in the Court's November 30, 2012, entry on summary judgment at Docket No. 235.

[2] In the interest of accuracy, the Court notes that Mirowski was not actually added as a plaintiff until 2001.

matter of law to St. Jude, finding the patent invalid for obviousness.[3] Judge Hamilton also denied Boston Scientific and Mirowski's motion for a new trial on infringement of the patent.

Mirowski and Boston Scientific jointly appealed Judge Hamilton's ruling of invalidity as to claims 4 and 13 of the patent and infringement as to claim 4 only. On appeal, the Federal Circuit reversed Judge Hamilton's invalidity ruling and reinstated the jury verdict that the '288 patent was not invalid for obviousness. The Federal Circuit concluded that the district court had erred regarding a portion of the claim construction not relevant here (the "determining step") and it remanded the case for reconsideration of this part of the claim construction and, if necessary, a new trial of that claim.

The case continued on a long and windy path until, in 2006, Boston Scientific and St. Jude, and eventually Mirowski, agreed to a narrowing of certain claims. In 2010, the parties settled the remaining claims and the case was dismissed.

What was once united is now divided. Among other claims, Mirowski now seeks to recover from Boston Scientific for actions it took during and after the St. Jude litigation that it argues breached certain of its agreements with Boston Scientific. First, Mirowski argues that Boston Scientific breached its agreement to pay royalties on ICDs it sold. Second, Mirowski argues that Boston Scientific breached another of the parties' agreements when it settled portions of its claims with St. Jude without first notifying Mirowski and obtaining its approval.

The inquiry now before the Court concerns whether and how, under the doctrine of judicial estoppel, certain representations the parties jointly made to the Federal Circuit and the district court preclude testimony now offered by Mirowski's or Boston Scientific's experts in

[3] This is just one aspect of the opinion. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 2002 WL 1801525 (S.D. Ind. 2002).

this case. This dispute is relevant to both the first and second issues described above, as it may shed light on (1) the percentage of Boston Scientific's ICDs that actually performed the method of claim 4 (that is, cardioversion) and therefore accrued royalties in favor of Mirowski,[4] and (2) the percentage of St. Jude's ICDs that actually performed the method of claim 4 and therefore would yield damages for infringement in favor of Boston Scientific and Mirowski, had the case not settled.

A. Claim 4 and the District Court Opinion

Claim 4 of the '288 patent, and claim 1 from which it depends, states:

> 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 at least one mode of operation of said implantable heart stimulator includes cardioversion.

At the conclusion of the evidence in the 2001 jury trial, Judge Hamilton instructed the jury that the term "cardioversion," as used in claim 4, meant "the application of non-pacing electrical pulses designed to stimulate sufficient heart tissue to correct an arrhythmia, with energy levels generally below those used for defibrillation." June 28, 2001, Tr. of Final Inst. at

[4] Of course, as this Court's summary judgment entry explained, this is not the only way that Boston Scientific ICDs accrue royalties in favor of Mirowski.

3278:8-13, Ex. 1 to No. 206; *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 2002 WL 1801525 at *38 (S.D. Ind. 2002). The jury returned a verdict that the '288 patent was not invalid for obviousness, but St. Jude had not infringed the '288 patent for multimode programming for ICDs. 2002 WL 1801525 at 2. However, on post-verdict motions, Judge Hamilton held that the jury's verdict on validity was not supported by substantial evidence. He granted St. Jude judgment as a matter of law, holding that the '288 patent was invalid for obviousness. 2002 WL 1801525 at *38-44. Mirowski and Boston Scientific appealed.

B. Federal Circuit Appeal

The Federal Circuit paraphrased the district court's holding as follows:

> The district court, granting St. Jude's motion for judgment as a matter of law, found that each of the elements of claims 4 and 13 was previously known. The court cited references that described implanted cardiac devices that provided multimode therapy, although none included cardioversion therapy. The court found that cardioversion therapy was known, and found that "compelling motivation" to combine therapies in a single implanted device was provided by an article by Haft, wherein Haft explained that pacing therapy may trigger ventricular fibrillation. The district court found that Haft identified the problem solved by the '288 patent, and concluded that it would have been obvious to design a pacing device that could defibrillate if necessary. That is, the court found that there was a known need to treat mixtures of arrhythmias, and that it would have been obvious to combine known methods of separate treatment.
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> Among the cited references, the district court placed weight on a British patent 2,026,870 to Duggan, as providing the motivation to combine treatments of different arrhythmias. Duggan discusses cardioversion achieved by application not of a single large shock, as in the '288 patent, but by a combination of small pacing shocks delivered simultaneously to multiple sites on the heart. CPI's expert explained that what Duggan taught was a form of pacing and not true cardioversion, and concluded that Duggan does not propose the combination of therapies provided by the '288 patent, or teach how to achieve a device that produces this combination.

Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371, 1376-77 (Fed. Cir. 2004). The Federal Circuit went on to find that the particular solution at issue here was not rendered obvious merely because the problem had been identified:

> We think that the district court, in granting JMOL, applied an incorrect standard to the ultimate question. Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure.
>
> There can of course arise situations wherein identification of the problem is itself the invention. But in the case at bar the problem was well-recognized: the problem of treating complex cardiac arrhythmias. The solution of this problem, according to the trial proceedings, had not previously been achieved. It was undisputed that before the work of Dr. Mirowski and his team there was no implantable device that was capable of treating the combination of abnormal arrhythmias including cardioversion.[5] Recognition of an unsolved problem does not render the solution obvious.

Id. at 1377. Having found that the district court had applied the wrong standard, the Federal Circuit then assessed the sufficiency of the underlying jury verdict that claim 4 of the '288 patent was not invalid for obviousness. *Id.* at 1376. The Federal Circuit first reviewed the evidence heard by the jury.

> Expert witnesses for each side presented opposing opinions as to the unobviousness of the Mirowski invention. St. Jude's expert testified that in his opinion persons of ordinary skill in the relevant field would have been motivated to modify Duggan "if one felt it [cardioversion] would be better accomplished with a single high energy shock." CPI's expert testified that the Duggan reference teaches away from use of high-energy shock because Duggan is concerned only with power consumption in ICDs. St. Jude stressed the obviousness of high energy cardioversion or defibrillation shocks due to the statement in the Haft article that "antitachycardia pacing could induce fibrillation." CPI presented contrary expert opinion, stressing that no reference teaches combining cardioversion with other cardiac therapies in a single device, or states that it is feasible to do so.

Id. at 1378. In their brief to the Federal Circuit, the parties argued that this evidence was sufficient to support the jury verdict of validity.

> As an alternative ground for obviousness, St. Jude's expert opined that one of ordinary skill in the art would have been motivated to combine prior art

[5] The use of the term here is puzzling, as cardioversion is a form of treatment, not an arrhythmia.

> pacemakers that use multiple pacing modes, like Haft and Pequignot with "high energy cardioversion or defibrillating shocks" due to the alleged teaching in Haft that "antitachycardia pacing could induce fibrillation." But, as noted above, claim 4 requires "cardioversion," not "defibrillation." It is claim 5, which CPI did not assert, that requires "defibrillation." And the jury heard substantial testimony that defibrillation shocks, not cardioversion shocks, revert fibrillation. In addition, the jury heard testimony that, at least at the time of the invention, defibrillation energy levels were different than cardioversion energy levels. Accordingly, substantial evidence supports the jury's finding that one of ordinary skill would not have been motivated in March 1981 to add cardioversion to a pacing device to revert fibrillation induced by pacing because cardioversion, unlike defibrillation, would not necessarily revert fibrillation.

2002 Br. to Fed. Cir. at 48-49, Ex. 3 to No. 196. The Federal Circuit agreed and adopted the parties' argument:

> It was not disputed that before the '288 invention this combination of modes of treatment had not been achieved. CPI pointed out that claim 4 requires cardioversion, not defibrillation, and that the Haft article is concerned with fibrillation. The jury heard testimony that defibrillation shocks, not cardioversion shocks, revert fibrillation. The jury also heard testimony that defibrillation energy levels are different from cardioversion energy levels. While the jury also heard testimony that "cardioversion and defibrillation are so similar to practically be the same therapy," other witnesses disputed this position.
>
> Whether the prior art provides the suggestion or motivation or teaching to select from prior knowledge and combine it in a way that would produce the invention at issue is a question of fact. *Winner Int'l Royalty Corp. v. Wang,* 202 F.3d 1340, 1348 (Fed.Cir.2000). These issues were extensively explored at the trial, including evidence of the commercial success and the interest of others in licensing the Mirowski inventions. The record contains 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. In view of this evidentiary support, the district court's grant of JMOL cannot stand. *See Continental Air Lines, Inc. v. Wagner-Morehouse, Inc.,* 401 F.2d 23, 30 (7th Cir.1968) (the jury verdict must be sustained, even if the judge would have reached a different conclusion, if the verdict is supported by substantial evidence). The grant of JMOL is reversed, and the jury verdict is reinstated that the '288 patent is not invalid for obviousness.

381 F.3d at 1378. While reinstating the jury's verdict on validity, the Federal Circuit reversed and remanded to the district court for a new claim construction on an unrelated issue and, if necessary, a new trial.

C. Remand to Judge Hamilton

On remand to the district court, St. Jude attempted to raise new claim construction arguments that were unrelated to the claim limitation reversed on appeal. Boston Scientific and Mirowski objected to St. Jude's attempts to relitigate other parts of the court's claim construction:

> [A]lmost a decade into the case, St. Jude now advances six *brand new* claim construction arguments relating to *other* limitations in claim 4. In so doing, St. Jude essentially asks this Court to start over from scratch, as if it had never construed the claims in the first place and as if there had been no appeal. But St. Jude cannot erase history. The fact is that this Court already construed claim 4 of the '288 patent, St. Jude did not dispute the presence of any limitation other than "determining a condition" at trial, and St. Jude did not raise this Court's claim construction on appeal. Accordingly, the Court's prior constructions are law of the case and this Court should reject St. Jude's attempts to reconstrue any other claim limitations.

Nov. 4, 2005, Br. on Construction of Claim 4 at 2, Ex. 9 to No. 207. In a related brief, Boston Scientific and Mirowski went on:

> [T]he Court already interpreted the term "cardioversion" in its jury instruction and St. Jude never objected or appealed from that instruction. In particular, the Court instructed the jury that "for purposes of claim 4, the term 'cardioversion' applies to the application of non-pacing electrical pulses designed to stimulate sufficient heart tissue to correct an arrhythmia, with energy levels generally below those used for defibrillation." . . . Nothing in the Court's construction limits cardioversion to "manual cardioversion" and, rightly so, as St. Jude never previously suggested as much.

Dec. 2, 2005, Br. on Construction of Claim 4 at 17-18, Ex. 7 to No. 207. Judge Hamilton agreed, noting that "St. Jude did not dispute [the] court's constructions either at trial or on appeal." *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 418 F. Supp. 2d 1021, 1030 (S.D. Ind. 2006). Ultimately, Judge Hamilton saw "no need to revisit the elements of Claims 1 and 4 other than the one issue raised on appeal." *Id*. at 1031.

D. The Present Conflict

The present dispute concerns whether representations made by the parties during the Federal Circuit appeal and remand described above preclude or require characterizing testing done at implantation of an ICD as "cardioversion" under Judge Hamilton's definition. If so, the parties argue, then certain expert witnesses may not testify at trial.

A brief overview of cardiac arrhythmias and their treatment is necessary to understand the present dispute. At the risk of oversimplification, arrhythmias can be characterized by their speed and regularity: a beat that is too slow (bradycardia), a beat that is too fast, but regular (tachycardia), and a beat that is too fast and irregular (fibrillation). Such arrhythmias can afflict the atria of the heart (the smaller, upper chambers that fill with blood) or the ventricles (the larger, lower chambers that pump blood into the body), and are characterized accordingly (e.g., atrial fibrillation, ventricular fibrillation, etc.).

At implantation, the implanting physician induces an arrhythmia in the patient. Testing shocks are then delivered and their effect – success or failure at correcting the arrhythmia – is noted. Depending on the result, the physician may go through several rounds of testing. Two facets of implantation testing are pivotal here: (1) the arrhythmia induced by the physician is often ventricular fibrillation; and (2) the shocks delivered during testing (and that may successfully revert the induced fibrillation) are administered at an energy level less than the energy at which the device is ultimately programmed to defibrillate.[6] Mirowski seizes on the latter fact, and argues that, because the device is ultimately programmed to defibrillate at a higher (often, the maximum) energy level than that used during testing, testing is cardioversion.

[6] The parties explain that this procedure, which appears curious to the layman, ensures that, if the patient goes into cardiac arrest after implantation, the device is sure to succeed in reverting an arrhythmia. Better safe than sorry, they say.

Boston Scientific seizes on the former, urging that, because cardioversion treats tachycardia and defibrillation treats fibrillation, testing is defibrillation, not cardioversion. Each party asserts that the other's position is precluded by judicial estoppel and accordingly seeks the exclusion of the other's expert witnesses who are poised to testify to the parties' respective positions.

II. STANDARD

Judicial estoppel is an equitable concept providing that a party who prevails on one ground in a lawsuit cannot turn around and in another lawsuit repudiate that ground. *United States v. Hook,* 195 F.3d 299, 306 (7th Cir. 1999). In other words, judicial estoppel protects this Court from manipulation by "chameleonic litigants" who seek to prevail, twice, on opposite theories. *In re Airadigm Comm'ns, Inc.*, 616 F.3d 642, 661 (7th Cir. 2010). Although the doctrine has no precise bounds, certain prerequisites exist for its application: (1) the facts at issue should be the same in both cases; (2) the latter position must be clearly inconsistent with the earlier position; (3) the party to be estopped must have convinced the first court to adopt its position; and (4) the party to be estopped will derive an unfair advantage if not estopped. *See id.*; *Hook*, 195 F.3d at 306.

III. DISCUSSION

Boston Scientific argues that Mirowski's current position is inconsistent with its arguments before the Federal Circuit. At its core, Mirowski's position before this Court is that cardioversion may revert fibrillation. In order to determine whether this position conflicts with its position before the Federal Circuit, the Court turns now to the parties' briefs. In its brief before the Federal Circuit, Boston Scientific and Mirowski wrote,

> As an alternative ground for obviousness, St. Jude's expert opined that one of ordinary skill in the art would have been motivated to combine prior art pacemakers that use multiple pacing modes, like Haft and Pequignot with "high energy cardioversion or defibrillating shocks" due to the alleged teaching in Haft

> that "antitachycardia pacing could induce fibrillation." But, as noted above, claim 4 requires "cardioversion," not "defibrillation." It is claim 5, which CPI did not assert, that requires "defibrillation." And the jury heard substantial testimony that defibrillation shocks, not cardioversion shocks, revert fibrillation. In addition, the jury heard testimony that, at least at the time of the invention, defibrillation energy levels were different than cardioversion energy levels. Accordingly, substantial evidence supports the jury's finding that one of ordinary skill would not have been motivated in March 1981 to add cardioversion to a pacing device to revert fibrillation induced by pacing because cardioversion, unlike defibrillation, would not necessarily revert fibrillation.

2002 Br. to Fed. Cir. at 48-49, Ex. 3 to No. 196. Boston Scientific argues that Mirowski's position conflicts with its prior representation to the Federal Circuit that "defibrillation shocks, not cardioversion shocks, revert fibrillation." Mirowski argues, however, that its representation must be viewed in context and points to the last sentence of this paragraph – "cardioversion, unlike defibrillation, would not *necessarily* revert fibrillation." The Court agrees with Mirowski that its representation must be read as a whole. When read as a whole, Mirowski's representation to the Federal Circuit that cardioversion would not necessarily revert fibrillation is not inconsistent with its position before this Court that cardioversion may revert fibrillation.

As Mirowski's current position is not inconsistent with its representation to the Federal Circuit, judicial estoppel is not warranted. The Court turns now to Mirowski's motion on the same issue.

According to Mirowski, Boston Scientific is estopped from offering expert testimony not based on Judge Hamilton's construction of "cardioversion." Boston Scientific asserted the finality of the claim construction on appeal, Mirowski argues, and therefore Boston Scientific cannot now be heard to argue that the claim construction is anything other than that held by Judge Hamilton.

The Court does not read Boston Scientific's current position to be that Judge Hamilton's claim construction is invalid or no longer applicable. Its position is that, "to apply the Court's

definition, one must understand defibrillation," Boston Scientific's Resp. at 9, No. 238, and its experts provide that explanation. This statement makes clear that Boston Scientific does not seek to throw out Judge Hamilton's claim construction. *See also* Expert Rep. of Dr. Zipes at ¶ 20 ("It is my opinion that the court's definition of cardioversion inherently requires that the shock be delivered during the QRS complex to treat ventricular tachycardia, and that cardioversion is not a shock to treat ventricular fibrillation."). As such, there is no conflict with its prior position before Judge Hamilton on remand, and judicial estoppel is not warranted.

One additional point bears mention. Mirowski is correct in its assertion that, on its face, Judge Hamilton's definition does not depend on the type of arrhythmia it treats. However, Judge Hamilton's claim construction does depend on the meaning of defibrillation, a determination that neither party has shown this Court was made by Judge Hamilton. One must know what energy levels are generally used for defibrillation before one can apply Judge Hamilton's claim construction. Yet as Mirowski points out, "the terms are not absolute and the appropriate energy level for a shock may vary by patient, as the Court recognized through its reliance on the word 'generally.'" Mirowski's Reply at 7, No. 245. The issue is thus not whether Judge Hamilton's construction of claim 4 should be used – the parties agree that Judge Hamilton's claim construction is final, non-appealable, and should be applied – but what the term "defibrillation" means as used in that construction. There is precedent to suggest that this Court may construe the term "defibrillation" in order to permit application of the claim construction, although the inquiry before the Court would be complicated by the fact that the term "defibrillation" occurs elsewhere in the patent. *Adv. Fiber Techs. (AFT) Trust v. J & L Fiber Servs.*, 674 F.3d 1365, 1373(Fed. Cir. 2012) ("In those cases in which the correct construction of a claim term necessitates a derivative construction of a non-claim term, a court may perform the derivative construction in order to

elucidate the claim's meaning."). However, in the course of preparing this case for trial, the parties have repeatedly represented to the Court that this is not a patent case and that the patents are only marginally relevant to the issues in this case. More to the point, the parties disavowed the need for a *Markman* hearing in this case from the beginning and have not wavered from that position. *See* Case Management Plan at 4 n.1 ("Although this case does require resolution of substantive issues of patent law . . . the parties do not allege infringement and invalidity claims that would make the Case Management Plan for Patent Cases appropriate. Nor do the parties anticipate the need for a *Markman* hearing."); *see also* Boston Scientific's Mot. to Preclude Mirowski from Presenting Case-Within-a-Case Evidence for the Underlying Delaware Case Without Proper Claim Construction, No. 275 (filed January 10, 2013); Mirowski's Resp., No. 300 (filed January 17, 2013). Furthermore, the parties have not provided to the Court the evidence and argument it would need to construe this term. The instant motions present the dispute to the Court in the sole context of judicial estoppel and the Court has found that judicial estoppel is not applicable. Accordingly, the Court declines to preclude either party's experts on this ground and declines to preclude either party's experts on the ground that their testimony is inconsistent with "defibrillation" as used in Judge Hamilton's claim construction.

IV. CONCLUSION

Boston Scientific's motion is **DENIED**. Mirowski's motion is also **DENIED**.

SO ORDERED: 02/13/2013

Hon. William T. Lawrence, Judge
United States District Court
Southern District of Indiana

Copies to all counsel of record via electronic communication.