IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC VASCULAR, INC., BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC., Defendants.	)	Civ. No. 97-550-SLR (Consolidated)
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Plaintiffs, v. ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., Defendants.	)	Civ. No. 98-19-SLR

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MEMORANDUM OPINION

Dated: September 15, 2008
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Cordis Corporation ("Cordis") is the owner of United States Patent No. 4,739,762 ("the '762 patent"). The '762 patent discloses a coronary stent that can be mounted on an angioplasty balloon and delivered to a target location intraluminally (i.e., through the vascular system) by a catheter. Once the stent and balloon reach the targeted location, the balloon is inflated to expand the stent to a desired size. The use of coronary stents has become the primary intervention for coronary artery disease and has generated a multi-billion dollar industry.

Cordis filed its first lawsuit involving the '762 patent in 1997. Since then, this court has presided over four liability trials and two damages trials against the defendants at bar, Medtronic Vascular, Inc. ("Medtronic") and Boston Scientific Corporation ("BSC"). The decades-long history of the litigation, replete with ever-evolving claim construction and theories of liability, will not be repeated here. Suffice it to say that the United States Court of Appeals for the Federal Circuit, in *Cordis Corp. v. Medtronic AVE, Inc. and Boston Scientific Corp.*, 511 F.3d 1157 (Fed. Cir. 2008), affirmed the entry of judgment against Medtronic but remanded the case once more to this court to resolve three issues: (1) with respect to claim 23 of the '762 patent, is BSC entitled to a new trial on obviousness based on the Federal Circuit's revised claim construction for the "smooth surface" limitation; (2) with respect to claim 44 of the '762 patent, has BSC waived its defense of obviousness and, if not, what further proceedings are appropriate in light of the Federal Circuit's revised claim construction for the "slots formed therein" limitation; and (3) with respect to damages asserted

against both Medtronic and BSC, does a new trial need to be conducted to determine whether other stents can be considered noninfringing alternatives under the Federal Circuit's revised claim construction of the "substantially uniform thickness" limitation? In response to the Federal Circuit's mandate, Cordis filed a motion for entry of final judgment[1] (D.I. 1455) and BSC has filed a motion to defer further proceedings and for a new trial (D.I. 1461). Also pending before the court is an unresolved motion for JMOL on lost profits damages filed by Medtronic following the 2000 trial. Medtronic has also filed a brief in opposition to Cordis' motion for entry of final judgment; however, to the extent Medtronic seeks to reopen its case of invalidity through such papers, the court declines to do so.

The court has jurisdiction over these matters pursuant to 28 U.S.C. § 1338. For the reasons that follow, Cordis' motion for entry of final judgment shall be granted, BSC's motion to defer proceedings and for a new trial shall be denied, and Medtronic's motion for JMOL is denied.

II. STANDARD OF REVIEW

The "harmless error" standard of Federal Rule of Civil Procedure 61 is the applicable standard for determining, after a jury trial, whether an error in claim construction requires a new trial. Rule 61 states:

> Unless justice requires otherwise, no error in admitting or excluding evidence - or any other error by the court or a party - is ground for granting a new trial, for setting aside a verdict, or for vacating, modifying or otherwise disturbing a judgment or order. At every stage of the proceeding, the court must disregard all errors and defects that do not affect

[1]The references to the docket are from Civ. No. 97-550, unless otherwise noted.

> any party's substantial rights.

The "salutary policy" embodied in Rule 61, as explained by the United States Supreme Court in *McDonough Power Equipment., Inc. v. Greenwood*, 464 U.S. 548 (1984), is that courts should "ignore errors that do not affect the essential fairness of the trial" and "should exercise judgment in preference to the automatic reversal for 'error.'" *Id.* at 553 (citations omitted).

> Trials are costly, not only for the parties, but also for the jurors performing their civic duty and for society which pays the judges and support personnel who manage the trials. It seems doubtful that our judicial system would have the resources to provide litigants with perfect trials, were they possible, and still keep abreast of its constantly increasing case load.

Id. at 553.

The standard for determining whether an error is prejudicial or harmless under Rule 61 is well settled:

> Prejudicial error is an error that . . . "appears to the court inconsistent with substantial justice." . . . If an asserted error did not prejudice any substantial interest of a party, that error is deemed harmless and the jury verdict is not disturbed.

Environ Prods., Inc. v. Furon Co., 215 F.3d 1261, 1265 (Fed. Cir. 2000) (citations omitted). A court "need not disprove every reasonable possibility of prejudice" to find that an error was harmless. *General Motors Corp. v. New A.C. Chevrolet, Inc.,* 263 F.3d 296, 329 (3d Cir. 2001) (citations omitted). In deciding whether an error was prejudicial, "[t]he entire record must be considered and the probable effect of the error determined in light of all the evidence." Vol. 11, Wright, Miller & Kane, *Federal Practice*

& Procedure, § 2883. For instance, in the context at bar, the Federal Circuit has held an error in claim construction to be harmless where there was substantial evidence of nonobviousness in the record. *Teleflex, Inc. v. Ficosa N. Am. Corp.,* 299 F.3d 1313, 1334 (Fed. Cir. 2002).

III. ANALYSIS

The '762 patent, entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft," includes both apparatus and method claims. The apparatus claims are directed to an expandable tubular member that serves as vascular scaffolding. The method claims of the '762 patent describe the process of implanting the stent into a diseased vessel.

Claim 23 of the '762 patent is an apparatus claim which is dependent upon claim 13.[2] The claims read:

> 13. An expandable intraluminal vascular graft, comprising:
> a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
> the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and
> the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

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[2]Claim 13 was cancelled during reexamination of the '762 patent. ('762 reexamination certificate, col. 1, l. 34)

> 23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

('762 patent, col. 11, l. 63 - col. 12, l. 14; col. 12, ll. 56-59)

Claim 44 of the '762 patent, a method claim added during reexamination, reads:

> 44. A method for implanting a balloon expandable stent prosthesis within a passageway of a coronary artery having an area of stenosis, comprising the steps of:
> utilizing a thin-walled, tubular member as the stent prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
> disposing the stent prosthesis and catheter having an inflatable balloon portion;
> inserting the stent prosthesis and catheter within the passageway by percutaneous catheterization;
> delivering the catheter and stent prosthesis to the area of stenosis without surgically exposing the area of the passageway; and
> expanding and deforming the stent prosthesis at the area of stenosis within the coronary artery passageway by expanding the inflatable balloon portion of the catheter associated with the stent prosthesis to force the stent prosthesis radially outwardly into contact with the area of stenosis in the passageway, the stent prosthesis being controllably deformed beyond its elastic limit.

('762 reexamination certificate, col. 3, ll. 22-44)

A. "Smooth Surface" Limitation

BSC argues on remand that a new invalidity trial is warranted for claim 23 because the changed construction of "smooth surface"[3] broadens the claim scope and

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[3]This court had construed the limitation to mean a "continuously even surface, without roughness, points, bumps or ridges, especially to the touch." The Federal Circuit concluded that this construction was too narrow and, instead, construed the limitation functionally, "so that a stent would be considered 'smooth' if it was smooth

makes it closer to the prior art, identified by BSC as the fixation sleeve disclosed in United States Patent No. 3,657,744 issued to Robert A. Ersek ("Ersek") and an abstract written by Dr. Julio Palmaz, the named inventor of the '762 patent ("the Palmaz Abstract"). The court agrees with Cordis that the proof of nonobviousness offered to the jury in 2005 was so substantial as to not be affected by the Federal Circuit's change in claim construction.

With respect to Ersek,[4] there is no credible evidence of record that supports BSC's contention that Ersek disclosed a graft that is smooth enough to deliver intraluminally, or that there was a motivation to make the Ersek device so deliverable. Indeed, the record is replete with evidence that Ersek disclosed a "fixation sleeve" which - by its name, its purpose, its design, and its operation - was not meant to be, nor could it be, delivered intraluminally.[5] To argue otherwise defies the common sense approach to the question of obviousness explained by the Supreme Court in *KSR International Co. v. Teleflex, Inc.,* 127 S. Ct. 1727, 1742 (2007).

The Palmaz Abstract, a one-paragraph review of an eight-minute talk given by Dr. Palmaz in 1984,[6] is entitled "Expandable Intruluminal Graft: A Preliminary Study." Despite its descriptive title, the body of the reference does not disclose a critical element of the invention, that is, that the expansion is controllable or achieved by

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enough to be capable of intraluminal delivery." *Cordis Corp. v. Medtronic AVE, Inc.,* 511 F.3d at 1180.

[4](D.I. 1456, ex. C)

[5]*(See, e.g.,* D.I. 1467 at 19-20, and the record citations identified therein)

[6](D.I. 1467 at 21-22)

plastic deformation. Consequently, although the Federal Circuit's broader construction of "smooth surface" now arguably includes within its scope the woven wire embodiment described in the Palmaz Abstract, that fact does not remedy (nor is it even relevant to) the absence of any evidence relating to the controllable expansion/plastic deformation limitation of claim 23.

B. "Slots Formed Therein" Limitation

By way of background, prior to the trial in 2000, this court construed the claim limitation "slots formed therein"[7] to "require[ ] that the slots be manufactured by removing material from a pre-existing wall surface." (D.I. 1171 at 7-8) On appeal, the Federal Circuit reversed this construction, holding that "[s]lots can be 'formed' in a wall surface by means other than removing material, such as by constructing the wall with openings built into it." (*Id.* at 8) On remand, this court held that the modified construction of "slots formed therein" warranted a new invalidity trial for claim 23 because it broadened the claim scope and arguably changed the invalidity analysis. (D.I. 1295 at 4) The validity of claim 23 was retried in the 2005 trial. Because claim 44 had been adjudicated to be invalid under 35 U.S.C. § 305 prior to trial (D.I. 1127 at 51-56), the issue of whether claim 44 was invalid over the prior art was moot and not justiciable.

Claim 44 was added to the '762 patent during reexamination, pursuant to 35 U.S.C. § 305. Section 305 permits the owner of a patent that is in reexamination "to propose any amendment to his patent and a new claim or claims thereof, in order to

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[7]This limitation is found in both claims 23 and 44.

distinguish the invention as claimed from the prior art cited under provision of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent." Section 305 also provides a limitation on a patent owner's ability to add or amend claims: "No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding."

This court invalidated claim 44 on the ground that claim 44 had been added "solely to cover competitors' stents, and not for a permissible reason under § 305." The Federal Circuit reversed this determination, concluding that claim 44 does not broaden the scope of coverage of the '762 patent" and, therefore, was permissibly added pursuant to § 305. The Federal Circuit remanded this issue, however, for this court to resolve the question of whether BSC's defense of obviousness with respect to claim 44 has been waived and, if not, what further proceedings are appropriate. (D.I. 1454 at 2-3)

BSC argues in this regard that a new invalidity trial is warranted for claim 44 because the changed construction of "slots formed therein" broadens the claim scope and makes it closer to the prior art and to the alleged inventive contribution of one Dr. Stanley Carson. The prior art identified by BSC once again is Ersek and the Palmaz Abstract. Even assuming that these prior art references newly satisfy the "slots formed therein" limitation, nevertheless, for the reasons stated above in connection with the analysis of claim 23, these prior art references fail to disclose other critical limitations of claim 44.

More specifically, claim 44 clearly requires the use of a stent "having a plurality of slots formed therein" that is capable of (1) being delivered intraluminally ("to the

stenosis without surgically exposing the area of the passageway") and (2) of "being controllably deformed beyond its elastic limit." ('762 reexamination certificate, col. 3, ll. 22-44) Although the court certainly understands the difference between an apparatus claim (claim 23) and a method claim (claim 44), nevertheless, the claim limitations are essentially the same, a substantial record of nonobviousness has been amassed with respect to claim 23, and the court has already concluded that Ersek and the Palmaz Abstract are not invalidating prior art as to claim 23. Given that claim 23 is nonobvious, then the claim 44 method, with its additional limitations, is necessarily not obvious, no matter how the "slots formed therein" limitation is construed.[8]

With respect to BSC's theory that Dr. Carson is a co-inventor of the '762 patent, BSC has twice waived this issue, and its waiver is unaffected by any change in claim construction.[9] More specifically, Dr. Carson claimed to have invented the general concept of intraluminally delivering and expanding a stent on a balloon in an artery, attributing to Dr. Palmaz the specific design of the slotted-tube stent. (D.I. 1462 at 26) Given the history of Dr. Carson's anticipated testimony, the change in scope of the

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[8]Given this conclusion on the merits, the court does not address Cordis' waiver argument. However, the court notes that, at the 2005 trial, BSC made a strategic decision to try to bolster its obviousness arguments for apparatus claim 23 by telling the jury that the really novel aspect of Dr. Palmaz's work was his method of delivering the supposedly obvious apparatus intraluminally, on a balloon catheter. More specifically, BSC's counsel told the jury at trial in 2005 that "[Dr. Palmaz's] idea of putting the stent on a balloon, delivering it intraluminally" was a "great idea," one for which Dr. Palmaz is entitled to credit. (D.I. 1369 at 126-133) This trial strategy is in stark contrast to BSC's current litigation strategy regarding the validity of method claim 44.

[9]Despite presenting evidence regarding Dr. Carson at the 2000 trial, BSC chose not to seek a verdict on the issue. BSC did not seek to offer any evidence of co-inventorship at the 2005 trial.

"slots formed therein" limitation is unrelated to BSC's ability to claim that Dr. Carson was a co-inventor.

C. Damages

1. Prejudgment interest[10]

Medtronic and BSC dispute the method of calculating prejudgment interest. Medtronic first argues that prejudgment interest should be calculated using the United States Treasury Bill rate, compounded quarterly, rather than awarding prejudgment interest at the prime rate, compounded monthly. The latter method of calculation was utilized against Cordis in litigation with BSC; in that litigation, the court admonished "that prejudgment interest shall be calculated consistently in all cases involving these parties," referring to Cordis and BSC. (D.I. 1456, ex. L) Medtronic argues that, since it has not had the benefit of the higher prime rate of interest, as has BSC, the court should decline to impose on it the burden of the higher prime rate of interest. However, the court has held generally that "the prime rate best serves" the purpose of compensating a patentee for lost revenues during the period of infringement, albeit compounded quarterly, not monthly. *See C.R. Bard, Inc. v. Medtronic, Inc.,* No. Civ. A. 96-589, 1999 WL 458305 at *15 (D. Del. June 15, 1999) (Robinson, J.), *aff'd in part, rev'd in part on other grds.,* 250 F.3d 760 (Fed. Cir. 2000). Therefore, the damages award shall include prejudgment interest calculated at the prime rate of interest, compounded quarterly.

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[10]Medtronic argues that Cordis is not entitled to prejudgment interest at all due to Cordis' alleged prosecutorial delay. Having lived with this litigation for decades, Medtronic's argument deserves no further analysis.

With respect to the issue of whether prejudgment interest should be based on the "pre-tax" rate, versus calculating prejudgment interest based on "after-tax" damages, there is case law supporting both methods. *See, e.g., Hughes Aircraft Co. v. U.S.,* 86 F.3d 1566, 1574-75 (Fed. Cir. 1996); *Electro Scientific Indus., Inc. v. Gen. Scanning,* 247 F.3d 1341, 1354 (Fed. Cir. 2001). The court agrees with defendants that taking into account the tax consequences of a damages award best reflects reality. Therefore, the court will require the parties to submit a final prejudgment interest claculation based on an after-tax amount of damages.

2. BSC's motion for a new trial on damages

BSC argues that a new damages trial should be conducted because, *inter alia,* Medtronic's S-Series and Driver stents are now non-infringing stents as a result of a 2006 arbitration decision that they are licensed under the '762 patent. However, in 2000, BSC stipulated that Medtronic's stents - including the S-Series stents - "infringe claim 23 of the '762 patent and, therefore, are not non-infringing substitutes." (Civ. No. 98-197, D.I. 209 at 3890-91) The court declines to allow BSC out of its agreement based on later, business-related proceedings of which it was not a part.

BSC next asserts that it is entitled to a new trial on whether ACS stents are non-infringing alternatives. There is no record evidence to support this proposition,[11] however, and the court will not prolong this litigation further based on mere

[11]The jury verdict in 2000 constituted a determination that the ACS stents literally infringed the substantially uniform thickness limitation, at that time a more narrow construction.

speculation.[12]

Finally, there is no need for a new trial on damages relating to claim 44. If the damages verdict on claim 23 is entered, Cordis has represented that it will not seek additional damages associated with BSC's infringement of claim 44 of the '762 patent.

3. Medtronic's JMOL on lost profits damages

Following the 2000 trial, Medtronic filed a JMOL on damages, arguing that Cordis had failed to carry its burden of proving, by a preponderance of the evidence, a prerequisite to proving entitlement to lost profits. (D.I. 1063; D.I. 1064 at 30-34)

The fundamental purpose of lost profits recovery is that the patent owner must demonstrate that there was "a reasonable probability that, but for the infringement, it would have made the sales that were made by the infringer." *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 826 (Fed. Cir. 1989) (citations omitted). In support of its position, Cordis offered evidence at trial that: (1) Johnson & Johnson had created the stent market in the United States by, *inter alia*, developing training programs to teach physicians how to implant stents; (2) Johnson & Johnson had acquired Cordis in order to expand its range of angioplasty products; (3) Cordis sold over $1.3 billion in coronary stents in 1995-97 in the United States alone; (4) Cordis increased its market share in 2000 when it introduced its BX Velocity stent; and (5) Cordis had access to substantial capital resources through Johnson & Johnson, the world's largest health care manufacturer. The court concludes that the jury's verdict was based on substantial

[12]Likewise, BSC's theory that "a slightly modified NIR stent with slightly thicker welds would be a non-infringing alternative" under the modified, broader construction of the "substantially uniform thickness" limitation is nothing more than speculation, as such a stent has never been actually made or sold by BSC. (D.I. 1462 at 31)

evidence.

IV. CONCLUSION

The history of this venerable litigation has been well documented. The issues of infringement and validity have been vetted on multiple occasions. It is time to give Dr. Palmaz his due and to bring this litigation to a close. For the reasons stated, therefore, Cordis' motion for entry of final judgment is granted. BSC's motion to defer further proceedings and for a new trial, as well as Medtronic's motion for JMOL on lost profits damages are denied. An order consistent with this memorandum opinion shall issue.

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ORDER

At Wilmington this 15th day of September, 2008, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. The motion for entry of final judgment filed by Cordis Corporation (D.I. 1455) is granted.

2. The motion to defer further proceedings and for a new trial filed by Boston Scientific Corporation (D.I. 1461) is denied.

3. The motion for JMOL on lost profits damages filed by Medtronic Vascular, Inc. (D.I. 1063) is denied.

IT IS FURTHER ORDERED that the parties shall confer and, on or before **September 29, 2008,** shall submit either an agreed-upon form of order of final judgment or their various proposed versions of said order. Please note that the court intends to enter final judgment on September 30, 2008 and will not postpone its consideration of the various forms of order by reason of any intervening motions, such as for reconsideration. Therefore, any party who fails to timely submit a proposed form of order risks waiver of any input into such order.

United States District Judge