

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC SCIMED, )  
INC. and BOSTON SCIENTIFIC )  
CORPORATION, )  
 )  
Plaintiffs, )  
 )  
v. ) Civ. No. 03-283-SLR  
 )  
CORDIS CORPORATION and )  
JOHNSON & JOHNSON, INC., )  
 )  
Defendants. )

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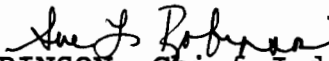
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**MEMORANDUM OPINION**

Dated: June 16, 2006  
Wilmington, Delaware

  
ROBINSON, Chief Judge

## I. INTRODUCTION

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Incorporated (collectively "BSC") filed this action against defendants Cordis Corporation and Johnson & Johnson, Incorporated (collectively "Cordis") alleging, inter alia, that Cordis' Cypher stent infringes claim 8 of U.S. Patent No. 6,120,536 ("the '536 patent"). (D.I. 1)

A jury trial was held on this matter from June 21, 2005 to July 1, 2005. The jury entered a verdict on July 1, 2005, finding that BSC had shown by a preponderance of evidence that the Cypher stent infringes claim 8 of the '536 patent. (D.I. 400) The jury also found that Cordis failed to show by clear and convincing evidence that claim 8 of the '536 patent is invalid due to obviousness. (Id.)

Pending before the court are Cordis' renewed motion for judgment as a matter of law or, in the alternative, a new trial on infringement and invalidity of the '536 patent (D.I. 440); and BSC's motion to strike portions of Cordis' reply brief (D.I. 465). The court has jurisdiction over these matters pursuant to 28 U.S.C. § 1338.

## II. BACKGROUND

The '536 patent generally relates to a stent with a drug-eluting coating. Claim 8<sup>1</sup> of the '536 patent, which depends from claim 1 and claim 6,<sup>2</sup> discloses a drug-eluting balloon expandable stent. The court has construed the disputed limitations of this claim. (D.I. 368)

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<sup>1</sup>Claim 8 states: "The device of claim 6 wherein the stent comprises a tubular body having open ends and an open lattice sidewall structure and wherein the coating conforms to said sidewall structure in a manner that preserves said open lattice." ('536 patent, col. 14, ll. 1-4)

<sup>2</sup>Claim 1 reads:

A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material, wherein said coating comprises an undercoat comprising a hydrophobic elastomeric material incorporating an amount of biologically active material therein for timed release therefrom, and wherein said coating further comprises a topcoat which at least partially covers the undercoat, said topcoat comprising a biostable, non-thrombogenic material which provides long term non-thrombogenicity to the device portion during and after release of the biologically active material, and wherein said topcoat is substantially free of an elutable material.

'536 patent, col. 13, ll. 13-26.

Claim 6 reads: "The device of claim 1 wherein the medical device is an expandable stent." '536 patent, col. 13, ll. 37-38.

The accused device, the Cypher stent, is a drug-eluting BX Velocity balloon expandable stent.

### III. STANDARD OF REVIEW

#### A. Renewed Motion for Judgment as a Matter of Law

Cordis has renewed its motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b) on the infringement claims of BSC. To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial'" evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893.

The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Perkin-Elmer Corp., 732 F.2d at 893. In sum, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

**B. Motion for a New Trial**

Cordis has moved, pursuant to Fed. R. Civ. P. 59(a), for a new trial on the issues of infringement and validity. Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

Fed. R. Civ. P. 59(a). The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See Allied Chem. Corp. v. Darflon, Inc., 449 U.S. 33, 36 (1980); Olefins Trading, Inc. v. Han Yang Chem. Corp., 9 F.3d 282 (1993); LifeScan Inc. v. Home Diagnostics, Inc., 103 F. Supp.2d 345, 350 (D. Del. 2000) (citations omitted). See also 9A Wright & Miller, Federal Practice and Procedure § 2531 (2d ed. 1994) ("On a motion for new trial the court may

consider the credibility of witnesses and the weight of the evidence.”). Among the most common reasons for granting a new trial are: (1) the jury’s verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury’s verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584-85 (D.N.J. 1997) (citations omitted). The court must proceed cautiously, mindful that it should not simply substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. Rather, in order to promote finality after trial, as well as to preserve the historical function of the jury as the trier of facts, the court should grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand. See Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1352 (3d Cir. 1991); EEOC v. State of Del. Dep’t of Health and Soc. Servs., 865 F.2d 1408, 1413 (3d Cir. 1989).

#### **IV. DISCUSSION**

##### **A. BSC’s Motion to Strike Portions of Cordis’ Reply Brief**

Before discussing Cordis’ motion, the court shall consider BSC’s motion to strike portions of Cordis’ reply brief. In its

motion to strike, BSC argues that the sections of Cordis' reply brief which allege the "legal irrelevance" of Dr. Hopfenberg's testimony, by including material that could have and should have been included in its opening brief, violates D. Del. LR 7.1.3(c)(2).<sup>3</sup> (D.I. 465 at 1-2) BSC argues that "Cordis never objected to the admissibility of Dr. Hopfenberg's testimony at trial, nor did it argue the issue to the jury at the close of the evidence, nor raise it in its JMOL motion at trial." (D.I. 465 at 2) While these observations by BSC are correct based on the record, much of the analysis of Cordis which appears to be at issue<sup>4</sup> is responsive to the arguments in BSC's opposition brief regarding how persons of ordinary skill in the art would have understood the teachings of the Wolff '208 and Domb '055 patents.

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<sup>3</sup>Rule 7.1.3 addresses the form and content of briefs in the District of Delaware. Subsection (c) discusses the contents of opening, answering, and reply briefs. Rule 7.1.3(c)(2) states, "The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief . . . ." D. Del. LR 7.1.3(c)(2).

<sup>4</sup>In its motion to strike, BSC argues that "Cordis for the first time contends that Dr. Hopfenberg's testimony was legally irrelevant because he did not apply the same level of skill in the art to his non-obviousness analysis as that instructed to the jury. (Reply Brief at 1, 14-19)." (D.I. 465 at 1) While several of these cited pages refer to the "legal irrelevance" of Dr. Hopfenberg's testimony, the rest of the pages discuss the appropriate qualifications of one having ordinary skill in the art independent of any consideration of Dr. Hopfenberg's testimony. Therefore, it is not clear precisely what portions of Cordis' reply brief BSC seeks to have stricken, but the court will address the content of pages 1 and 14 through 19 of Cordis' reply brief in considering BSC's motion to strike.

As noted above, Cordis argued in its opening brief that the teachings of those patents would have rendered the claimed invention obvious to a person having ordinary skill in the art. (D.I. 440 at 29-38) Cordis offered specific analysis of the particular knowledge of one having ordinary skill in the art. (D.I. 440 at 36-37) Cordis also applied this analysis in arguing that Drs. Anderson, Hanson and Helmus possessed such ordinary skill. (Id.) BSC consequently cited to the testimony of Dr. Hopfenberg in its opposition brief in arguing that the prior art would not have made the claimed invention obvious to one of ordinary skill. (D.I. 453 at 25-31) Given these circumstances, it was not inappropriate for Cordis, in its reply brief, to address the strength and credibility of Dr. Hopfenberg's testimony based on Cordis' earlier analysis of the level of ordinary skill in the art. See In re Fleming Co., 316 B.R. 809, 815 n.3 (D. Del. 2004) (denying a motion to strike portions of a reply where its arguments were "either in the original brief or in response to . . . arguments in opposition"). The court shall consider the arguments of Cordis in this area when considering Cordis' motion.

To the extent that Cordis made the argument in its reply brief that Dr. Hopfenberg's testimony was legally irrelevant, that particular contention was neither raised at trial nor offered in Cordis' opening brief and, therefore, the argument



violates Rule 7.1.3(c)(2). The court shall not consider the arguments in Cordis' reply brief which allege that Dr. Hopfenberg's testimony is legally irrelevant. BSC's motion to strike portions of Cordis' reply brief shall be granted in part and denied in part.

**B. Cordis' Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Infringement and Invalidity of the '536 Patent**

**1. Infringement**

A determination of infringement requires a two-step analysis. First, the court must construe the asserted claims so as to ascertain their meaning and scope. Second, the claims as construed are compared to the accused product. See KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1355 (Fed. Cir. 2000). Claim construction is a question of law while infringement is a question of fact. See id. To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995).

In arguing for a new trial on the issue of infringement of claim 8 of the '536 patent, Cordis asserts that BSC failed to prove infringement at trial with respect to three limitations of claim 8 of the '536 patent. The first such limitation is the

"substantially free of elutable material" limitation.<sup>5</sup>

Referencing the "implantable into the body of a patient" language of claim 1, Cordis contends that the accused Cypher stent cannot infringe the "substantially free of elutable material" limitation because undisputed evidence establishes that it is not suitable to be implanted in the body of a patient until it is sterilized and harmful toxins are removed. (D.I. 440 at 3-4) Cordis cites the testimony of its expert, Dr. Buller, and BSC's medical expert, Dr. Dawkins, to suggest that an unsterilized stent would not be implanted in a patient. (D.I. 440 at 4; citing D.I. 385 at 390:18-22, D.I. 390 at 1337:24-1339:6) Cordis argues that, by the time the Cypher stent is suitable for implantation in a patient, its topcoat contains a substantial portion of an elutable drug. (D.I. 440 at 4-6) Furthermore, Cordis maintains that BSC's focus on a single step in the stent manufacturing process is not sufficient to prove infringement of the "substantially free of elutable material" limitation because that step occurs before all toxic solvents have been removed, when "no responsible physician" would implant the device in the body of a patient. (D.I. 440 at 6-9) Finally, Cordis discounts the testimony of BSC's expert, Dr. Hopfenberg, because he is not a medical doctor. (D.I. 440 at 3)

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<sup>5</sup>The court construed "topcoat is substantially free of an elutable material" to mean "the topcoat is largely or approximately free of an elutable material." (D.I. 368 at 4)

In contrast to the arguments of Cordis, BSC cites evidence offered at trial which suggests that the topcoat of the Cypher stent is drug-free at an early point in the design process and has about 1 to 2 percent drug in the topcoat after manufacturing is completed. (D.I. 453 at 5; citing D.I. 386 at 620:22-621:12, 627:15-16, 652:14-15, D.I. 387 at 756:22-757:3) Furthermore, BSC cites the testimony of Dr. Hopfenberg where he applied the court's claim construction and concluded that the Cypher stent is substantially free of elutable material. (D.I. 453 at 5; citing D.I. 386 at 640:19-20, 652:10-23, D.I. 387 at 700:23-701:1) BSC notes that Dr. Hopfenberg testified that the '536 patent specifically contemplates that the elutable drug will move into the topcoat prior to implantation in a patient, even though the product is manufactured with a drug-free topcoat. (D.I. 453 at 6, citing D.I. 386 at 652:14-653:12) BSC argues that this evidence establishes that the Cypher stent infringes claim 8 of the '536 patent and shows that Cordis cannot avoid infringement by merely showing the presence of drug in the topcoat at one particular instance in the life of the product. (D.I. 453 at 6) BSC also provided evidence that the product of the '536 patent does not require sterilization in order to be considered an implantable medical device. (D.I. 387 at 844:20-845:18) BSC next points out that Dr. Hopfenberg was qualified to testify and delivered credible evidence due to his research in: (1) the

transport of materials through polymer systems; (2) drug delivery technology; and (3) the non-thrombogenic properties of biomedical materials. (D.I. 453 at 8-9, citing D.I. 386 at 608:17-615:9) Furthermore, BSC notes that Cordis did not object to the proffer of Dr. Hopfenberg as an expert and made no motion to strike his testimony. (D.I. 386 at 616:16-18) Based on the evidence adduced by the parties, the jury was entitled to give credence to the arguments of BSC in finding that the Cypher stent infringed the "substantially free of elutable material" limitation of the '536 patent.

The next limitation of claim 8 which Cordis asserts BSC failed to prove was infringed is the "elastomeric" limitation.<sup>6</sup> Cordis argues that, while BSC cited several documents which use the term "elastomeric," these documents are not probative as to infringement of the "elastomeric" limitation unless there is evidence to show that the term was used in those documents in a manner which was consistent with the claim construction of the court. (D.I. 440 at 10-15) In addition, Cordis suggests that BSC failed to offer any evidence on the second part of the court's construction and, thereby, did not demonstrate that the Cypher stent's polymers are capable of returning to their original, pre-expansion dimensions after being expanded. (D.I.

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<sup>6</sup>The court construed "elastomeric material" to mean "a material that is able to stretch or expand without breaking, and to return to its original dimensions." (D.I. 368 at 3)

440 at 15-16) Cordis notes that "the correct judicial claim construction is one that determines the meaning of [a] term as used by the inventor in the specification and file history - not as it may be used by other persons in extrinsic documents."

(D.I. 440 at 13, citing Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc)) Next, Cordis cites to the testimony of its expert, Dr. Storey, to suggest that the polymers on the Cypher stent are incapable of returning to their original dimensions after being expanded. (D.I. 440 at 15, citing D.I. 387 at 913:23-925:11)

Responding to Cordis' claims, BSC cites evidence that the Cypher stent has an undercoat comprising an elastomeric material and specifically contains a copolymer which was mentioned in the '536 patent as generally suitable for use as an elastomeric material in the undercoats of the invention. (D.I. 453 at 11) BSC points to numerous Cordis documents which characterized the Cypher coating as "elastomeric." (D.I. 453 at 12) Furthermore, BSC noted that Cordis' witness, Dr. Llanos, also considered the Cypher coating to be "elastomeric." (D.I. 453 at 12) BSC finally posits that Cordis did not present a single fact witness nor offer any deposition testimony from a fact witness to suggest that Cordis' documents were intended to convey a meaning for the term "elastomeric" which was inconsistent with the construction offered by the court. (D.I. 453 at 14) Given the evidence

offered by the parties, the jury was able to appropriately weigh such evidence and decide if it provided an adequate showing that the Cypher stent met the "elastomeric" limitation as construed by the court. In deciding that the stent met this limitation, the jury's verdict was supported by substantial evidence.

The last limitation of claim 8 which Cordis asserts BSC failed to prove was infringed is the "non-thrombogenic" limitation.<sup>7</sup> In support of this argument, Cordis cites evidence that the Cypher stent causes thrombosis to no lesser extent than bare metal stents. (D.I. 440 at 18, citing D.I. 385 at 399:14-20, D.I. 390 at 1348:7-1350:7, 1356:9-1357:14) Cordis further argues that Dr. Dawkins rendered his opinion as to "non-thrombogenicity" by relying on his own definition instead of the construction of the "non-thrombogenic" limitation offered by the court. (D.I. 440 at 20) Also, Cordis notes that Dr. Hopfenberg was unable to offer any expert opinion regarding what a medical doctor would consider "promoting thrombosis" under the court's claim construction. (D.I. 440 at 20, citing D.I. 387 at 791:11-15) Cordis maintains that "[t]he undisputed evidence from both sides' medical experts is that bare metal stents promote

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<sup>7</sup>The court construed "non-thrombogenic material which provides long term non-thrombogenicity to the device portion during and after release of the biologically active material" as meaning "a material that does not promote thrombosis for a period of time that extends both during and after release of the biologically active material." (D.I. 368 at 3-4)

thrombosis, and that the Cypher stent is no better than bare metal stents in this regard." (D.I. 440 at 22, citing D.I. 385 at 391:2-13, 393:24-394:3, 397:8-12, 399:14-20; D.I. 390 at 1267:21-1268:4)

As BSC correctly notes with respect to Cordis' comparison of the Cypher stent with bare metal stents, "[s]uch evidence has no bearing on the question of whether the Cypher topcoat polymer 'promotes' thrombosis." (D.I. 453 at 19) BSC cites testimony from Drs. Donahue, Hopfenberg and Dawkins that the Cypher stent is non-thrombogenic. (D.I. 453 at 17-19) BSC further notes that the testimony of Dr. Buller, on whom Cordis relies, is based on the incorrect belief that, for a drug-eluting stent to be considered "non-thrombogenic," it would have to "provide a significant reduction in thrombosis compared to bare metal stents." (D.I. 453 at 19-20, citing D.I. 390 at 1431:3-11) Given the considerable amount of evidence offered by both parties with respect to infringement of the "non-thrombogenic" limitation, the jury weighed the evidence and reached a conclusion supported by substantial evidence in finding that the Cypher stent infringes that limitation.

In the alternative to its motion for judgment as a matter of law of noninfringement of claim 8 of the '536 patent, Cordis urges the court to grant a new trial on the issue of the infringement of claim 8. Cordis alleges that BSC "undermined the

proper analysis" with respect to all three disputed limitations. (D.I. 440 at 22-23) Cordis also asserts that BSC successfully advocated the improper theory "that actual usage by persons in the field must be consistent with the court's claim construction because the claim construction reflects the meaning of those of ordinary skill." (D.I. 440 at 23-26) Cordis suggests that BSC's reliance on this theory and its related arguments tainted the trial "in ways that could not be remedied, resulting in a verdict that is clearly against the weight of the relevant evidence." (D.I. 440 at 26) In addition, Cordis argues that BSC's improper use of expert testimony provides further reason for a new trial on infringement. (D.I. 440 at 26-29) In particular, Cordis alleges that Dr. Hopfenberg improperly offered opinions on "elastomeric" that went beyond his expert report after BSC represented to the court that such opinions would not be offered. (D.I. 440 at 27-28) Finally, Cordis maintains that BSC improperly relied on Dr. Dawkins' own definition of "non-thrombogenic" when: (1) that definition was inconsistent with the court's claim construction of that term; and (2) BSC had already represented that Dr. Dawkins would not offer any testimony as to the construction of that term. (D.I. 440 at 28-29)

In response to Cordis' contentions in support of a new trial on the issue of infringement, BSC contends that the conduct of



its counsel at trial was appropriate and was not the subject of objection. (D.I. 453 at 21-25) BSC reasons that the arguments of which Cordis complains were "well within the bounds of appropriate advocacy." (D.I. 453 at 23) BSC correctly points out that no expert on either side of the case could directly address the court's claim construction in a pre-trial infringement or invalidity analysis because the court did not issue its claim construction ruling until shortly before trial, and neither side reassessed its experts' conclusions in new reports which would explicitly address the court's claim construction ruling. (D.I. 453 at 23, citing D.I. 368)

As previously discussed, Cordis first suggests that the jury's verdict was against the clear weight of the evidence. (D.I. 440 at 9, 16, 22, 26) Having already concluded that the jury's verdict with respect to infringement was supported by substantial evidence, the court does not find that the evidence supporting Cordis' case is so clear that to leave the jury's verdict undisturbed would result in a miscarriage of justice.

Similarly, the court finds that the conduct of BSC's attorneys does not rise to a level which would require a new trial. A motion for a new trial on the basis of attorney misconduct may only be granted if the movant demonstrates that such "conduct constitutes misconduct, and not merely aggressive advocacy, and that the misconduct is prejudicial in the sense of

affecting a substantial right in the context of the entire trial record." Lucent Techs., Inc. v. Newbridge Networks Corp., 168 F. Supp. 2d 181, 260-61 (D. Del. 2001). In evaluating that misconduct, the court must determine whether the conduct was so prejudicial that it was reasonably probable that the verdict was influenced by the conduct and that a miscarriage of justice would result if the verdict were left undisturbed. See Fineman v. Armstrong World Indus., 980 F.2d 171, 206-07 (3d Cir. 1992). Further, a party may not seek a new trial on the basis of objections not raised in the original trial. See Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1469 (Fed. Cir. 1997); Caisson Corp. v. Ingersoll-Rand Co., 622 F.2d 672, 681 (3d Cir. 1980); Finch v. Hercules Inc., 941 F. Supp. 1395, 1416 (D. Del. 1996). Consequently, the court will not consider, for purposes of this motion for a new trial, issues not properly preserved by Cordis through a contemporaneous objection at trial.

As mentioned above, Cordis makes numerous contentions with respect to how the improper arguments of BSC's counsel constituted misconduct. Cordis argues that these improper arguments prejudiced Cordis such that a new trial on infringement is warranted. As for Cordis' objections to the testimony of Dr. Hopfenberg, the court rejected the arguments which Cordis raised at trial on that issue and only asked that counsel for BSC provide an opportunity for objection if any further details which

were not included in Dr. Hopfenberg's report were offered as testimony. (D.I. 387 at 830:25-831:3) With respect to Cordis' objection to Dr. Dawkins testifying about whether the Cypher stent is non-thrombogenic, it appears that counsel for Cordis actually welcomed such testimony when stating, "I have no objection to him testifying as a doctor about thrombogenicity." (D.I. 385 at 332:21-24) Furthermore, Dr. Dawkins himself clarified the capacity in which he was testifying when he stated, "I understand the term, as a cardiologist, that non-thrombogenic means it doesn't promote or encourage thrombosis." (D.I. 385 at 368:14-16) Viewing the entire transcript as a whole, the conduct of the attorneys in the context of the case, and those objections properly preserved by Cordis' counsel, the court concludes that there was no prejudice to Cordis of the quality and quantity that would demand the jury's verdict to be set aside. Consequently, Cordis' motion for a new trial on the issue of infringement of claim 8 of the '536 patent will be denied.

## **2. Invalidity**

Aside from requesting judgment as a matter of law of noninfringement, Cordis urges the court to enter judgment as a matter of law of invalidity of claim 8 of the '536 patent. In the alternative to its motion for judgment as a matter of law of invalidity of claim 8 of the '536 patent, Cordis urges the court

to grant a new trial on the issue of the validity of claim 8.  
(D.I. 440 at 38-39)

A patent is presumed valid and the burden of proving invalidity, whether under § 112 or otherwise, rests with the challenger. See 35 U.S.C. § 282. In order to overcome this presumption, the party challenging validity bears the burden of proving by clear and convincing evidence that the invention fails to meet the requirements of patentability. See Hewlett-Packard Co. v. Bausch & Lomb, 909 F.2d 1464, 1467 (Fed. Cir. 1990). Clear and convincing evidence is evidence that "could place in the ultimate factfinder an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

To establish that a patent claim is obvious, clear and convincing evidence must exist to show that "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103 (2003). The question of obviousness, therefore, turns on four factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicators of non-obviousness, more commonly termed secondary considerations. See Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); B.F. Goodrich Co. v. Aircraft Braking

Sys. Corp., 72 F.3d 1577, 1582 (Fed. Cir. 1996). The existence of each limitation of a claim in the prior art does not, by itself, demonstrate obviousness. Instead, there must be a "reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success." Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356 (Fed. Cir. 1999). "Such a suggestion or motivation may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved." Id. at 1356.

To rebut a prima facie case of obviousness based on prior art, objective evidence of nonobviousness may be used. Tec Air, Inc. v. Denso Mfg. Mich, Inc., 192 F.3d 1353, 1360 (Fed. Cir. 1999). This objective evidence includes: (1) a long-felt and unmet need in the art for the invention; (2) failure of others to achieve the results of the invention; (3) commercial success of the invention; (4) copying of the invention by others in the field; (5) whether the invention was contrary to accepted wisdom of the prior art; (6) expression of disbelief or skepticism by those skilled in the art upon learning of the invention; (7) unexpected results; (8) praise for the invention by those in the field; and (9) independent invention by others. See Graham, 383

U.S. at 17-19. "The objective evidence of nonobviousness . . . should when present always be considered as an integral part of the analysis." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1393 (Fed. Cir. 1988) (quoting W.L. Gore & Assocs. Inc. v. Garlock, Inc., 721 F.2d 1540, 1555 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)).

In arguing that claim 8 of the '536 patent is invalid, Cordis contends that various prior art references would have made the claimed invention obvious to one of skill in the art. (D.I. 440 at 29-39) In particular, Cordis cites the following patents as such prior art: Myler '563, Dinh '227, Tuch '411, Fox '096, Wolff '208, and Domb '055. (D.I. 440 at 29-35) Cordis points to the testimony of Dr. Hanson to argue that "[a]ll six references disclose the use of coatings on stents, delivering a drug from a polymer reservoir and using a barrier membrane to control the rate of release." (D.I. 440 at 30-31, ex. 5; citing D.I. 390 at 1515:9-1522:5) Cordis also argues that the Domb '055 and Wolff '208 patents deserve particular attention because each alone discloses every limitation of the claimed invention.<sup>8</sup> (D.I. 440

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<sup>8</sup>Although Cordis argues that "there is nothing new" about the invention of claim 8 of the '536 patent and contends that each of the Wolff '208 and Domb '055 patents "standing alone, discloses every element of the claimed invention," it dropped its anticipation defense at trial to focus solely on the issue of obviousness. (D.I. 440 at 29, 31; D.I. 390 at 1449:2-7) Therefore, the post-trial invalidity arguments of Cordis will be treated as addressing only the issue of obviousness of claim 8 of the '536 patent.

at 31-35) Again, Cordis cites the testimony of Dr. Hanson as its primary support for this argument. (Id., citing D.I. 390 at 1522:15-1528:13, 1559:22-1564:1) Cordis argues that the Domb '055 patent teaches all of the limitations of claim 8; for example, it states that "[a] person of skill in the art reading Domb's disclosure unquestionably would have understood it to embrace metal stents." (D.I. 440 at 31-33; citing D.I. 390 at 1526:7-1527:1, D.I. 391 at 1562:10-13) Likewise, Cordis maintains that the Wolff '208 patent renders the claimed invention obvious, either alone or together with other prior art references. (D.I. 440 at 33-35) In particular, Cordis argues that the teachings of the Wolff '208 patent itself provide the necessary motivation to combine various embodiments described in that patent to create a stent which renders obvious claim 8 of the '536 patent. (Id.)

In refuting the arguments of Cordis with respect to the validity of claim 8 of the '536 patent, BSC cites various pieces of evidence offered at trial to support the nonobviousness of the claim. (D.I. 453 at 25-34) In particular, BSC notes that Dr. Hanson admitted to many deficiencies in the prior art such that claim 8 would not be rendered obvious by the prior art cited by Cordis. (D.I. 453 at 26) BSC also cites the testimony of Dr. Hopfenberg, who addressed each of the prior art references cited by Cordis and concluded that the claimed invention remained non-

obvious in light of them. (D.I. 453 at 26-27; citing D.I. 386 at 659:16-661:20, 668:7-689:11, 700:23-701:1) Furthermore, BSC argues that there was no motivation to combine any of the prior art references to arrive at the invention in claim 8. (D.I. 453 at 28; citing D.I. 386 at 667:23-668:6, 670:20-671:1, 672:1-8) With respect to the disclosure of the use of metal stents in the prior art, BSC cites evidence from Dr. Hopfenberg stating that: (1) the Domb '055 patent does not mention or suggest the use of metal; (2) no evidence shows a metallic esophageal stent (like that described in the Domb '055 patent) having a conformal coating with a base coat and drug-free topcoat as required under claim 8 of the '536 patent; and (3) absent was evidence of any motivation to combine the cited prior art references to arrive at the medical device of claim 8. (D.I. 453 at 29-30, citing D.I. 386 at 671:11-672:8) With respect to the Wolff patent, BSC cites the testimony of Dr. Hanson in asserting that the patent "does not teach a metallic stent having a two-layer coating." (D.I. 453 at 30, citing D.I. 391 at 1591:16-22) Furthermore, BSC argues that the failure of the assignee of the Wolff '208 patent to create a drug-eluting stent which encompassed all of the limitations of the claimed invention after more than a decade of work was evidence that a motivation to combine elements of the prior art was not present. (D.I. 453 at 30) Given the extensive evidence offered by BSC to suggest nonobviousness, the jury was



provided with substantial evidence to find that the Wolff '208 and Domb '055 patents, alone or in combination with other prior art references, do not render claim 8 of the '536 patent obvious.

Aside from particular prior art patents, Cordis contends that evidence of what persons of ordinary skill in the art were doing in 1995 through 1996 confirms the obviousness of the claimed invention. (D.I. 440 at 35-37) Cordis argues that Dr. Aron Anderson of Surmodics, who began designing the Cypher stent in 1994, was one of ordinary skill in the art and that his work "specifically discussed the development of a coated stent, recognizing that a variety of polymers could be used and that, in order to 'optimize [the] release kinetics' of the drug coated stent, one possibility was to 'use [a] barrier coating.'" (D.I. 440 at 36) Cordis asserts that the sophistication and work of Drs. Anderson, Hanson and Helmus, as scientists of ordinary skill prior to the filing date of the '536 patent, demonstrate that claim 8 is obvious. (D.I. 440 at 36-37)

In responding to Cordis' arguments with respect to the level of ordinary skill in the art, BSC argues that the failed work of Cordis scientists in the area of bioabsorbable polymers for coating materials shows that claim 8 of the '536 patent is non-obvious. (D.I. 453 at 32-33) BSC contends that Cordis' three years of work in that area resulted in the recognition that bioabsorbable polymers led to "severe chronic local

inflammation." (Id. at 33, citing D.I. 386 at 686:25-687:3) Furthermore, BSC argues that this realization "led to [Cordis'] abandonment of bioabsorbable polymers in favor of the biostable polymer combination that Helmus and Ding had invented years earlier" and offers further suggestion that the claimed invention was nonobvious. (D.I. 453 at 33) Based on the arguments advanced by both parties, the jury was entitled to give weight to BSC's argument in deciding that claim 8 of the '536 patent was nonobvious. Substantial evidence supported such a conclusion.

As its final argument in support of judgment as a matter of law of invalidity of claim 8 of the '536 patent, Cordis argues that the secondary considerations of nonobviousness which were offered by BSC did not rebut Cordis' clear and convincing proof of obviousness of claim 8. (D.I. 440 at 37-38) First, Cordis alleges that BSC failed to prove that the Cypher stent infringes claim 8 of the '536 patent. (Id. at 37) Second, Cordis contends that BSC failed to prove any nexus between the Cypher stent's success and the claimed invention. (Id.) Finally, Cordis argues that BSC failed to show that there was praise or long-felt need for the technology of the claimed invention. (Id. at 37-38) Instead, Cordis contends that the real breakthrough in developing a drug-eluting stent was the identification of the correct drug to use on a stent to fight restenosis rather than the formulation of a polymer coating to use on such a stent. (D.I. 440 at 38)

BSC addressed the arguments of Cordis with respect to secondary considerations by citing the testimony of Dr. Hopfenberg, who testified as to the presence of a nexus between the Cypher stent's commercial success and the claimed invention. (D.I. 453 at 34, citing D.I. 387 at 849:11-25) Dr. Hopfenberg also provided testimony as to the failure of Cordis to develop a drug-eluting stent, even after identifying an appropriate drug and stent, until it applied the coating combination found in claim 8 of the '536 patent. (Id.) Finally, BSC cited Dr. Hopfenberg's testimony that the praise and recognition for the Cypher stent are due to the features present in the claimed invention. (Id.) Given the evidence offered by the parties at trial, the jury was entitled to give credence to the arguments of either party. If the jury used BSC's evidence of secondary considerations to decide that claim 8 of the '536 patent was not rendered obvious in light of the prior art, the jury's verdict was supported by substantial evidence.

In the alternative to its motion for judgment as a matter of law of invalidity of claim 8 of the '536 patent, Cordis argues for a new trial on that issue. (D.I. 440 at 38-39) As its first argument in support of a new trial, Cordis maintains that, since BSC relied on the Cypher stent's success as a secondary consideration of nonobviousness, the validity and infringement verdicts were inter-connected. (D.I. 440 at 38) Pursuant to

this position, Cordis suggests that a decision granting judgment as a matter of law of no infringement would remove the Cypher stent's success as a secondary consideration of nonobviousness of the claimed invention. (Id.) Furthermore, Cordis argues that a decision for a new trial on infringement would leave open the question of whether the Cypher stent practices claim 8 of the '536 patent, thereby undermining the validity verdict and requiring a new trial on validity. (Id. at 38-39) As its second contention in support of a new trial on the issue of validity, Cordis maintains that a new trial is appropriate if judgment as a matter of law of invalidity is not granted because the nonobviousness verdict was against the weight of the evidence. (Id. at 39)

BSC responds to Cordis' motion for a new trial on the issue of validity by first asserting that "a finding of non-infringement of the '536 patent would not be inconsistent with the jury's finding of validity of the '536 patent." (D.I. 453 at 35) Second, BSC contends that the evidence of validity of claim 8 was substantial, even without consideration of the commercial success evidence. (Id. at 35-36) In light of the analysis above with respect to Cordis' motion for JMOL of invalidity of claim 8, the court notes that the jury's verdict of validity of claim 8 of the '536 patent was supported by substantial evidence. Even upon viewing the evidence outside of a light most favorable to BSC,

the court finds the evidence supporting the jury's verdict is substantial such that no miscarriage of justice would occur in upholding it. Thus, Cordis' motion for a new trial on the issue of validity shall be denied.

### 3. Prejudice

As a distinct argument for a new trial on the issues of infringement and validity, Cordis argues that "inflammatory and improper" arguments by BSC's counsel were delivered to the jury. (D.I. 440 at 39-40) Cordis alleges that prejudice due to BSC's counsel's "baseless and inflammatory accusation of copying" in his summation at the trial in the C.A. No. 03-027-SLR case (the "03-027 case"), which was tried with this case to the same jury, may have influenced the jury in this case. The court previously addressed this argument in its May 11, 2006 memorandum opinion in the 03-027 case and determined that it was unlikely that the arguments with respect to copying by BSC's counsel improperly influenced the jury verdict in that case. (C.A. No. 03-027-SLR, D.I. 416 at 56-60) In support of its motion for a new trial in this case, Cordis provides no arguments which undermine the reasoning applied by the court in rendering its May 11, 2006 memorandum opinion. In its response, BSC correctly notes that it had separate counsel, separate witnesses, and separate opening and closing arguments for the two cases, which served to prevent any prejudice which may have been present in one case from having

influenced the verdict in the other case. (D.I. 453 at 37) Moreover, BSC points out that the issues of infringement and invalidity in the two cases were distinct and did not overlap, providing further suggestion that arguments in one case would not influence the verdict in the other case. (Id.)

Cordis next argues that the prejudice which was present in the 03-027 case was compounded by BSC's counsel's similar comments in this case. In particular, Cordis alleges that prejudice resulted from the following arguments: (1) "They [Cordis] didn't do it until they learned of it [the '536 patent]. They learned of it, the teaching of it, which is in our patent."; (2) "They [Cordis] took the invention."; and (3) "they took it". (D.I. 440 at 39, citing D.I. 385 at 124:16-23, 156:8-12; D.I. 391 at 1647:17-20) In response to these allegations, BSC correctly argues that "Cordis makes no showing that the statements were in any way incorrect, much less the sort of misconduct which could give rise to a new trial." (D.I. 453 at 37-38) In fact, in its opening brief in support of its motion for a new trial, Cordis does not offer an explanation of how these comments by BSC's counsel were prejudicial. (D.I. 440) Additionally, Cordis does not address its allegation of prejudice with respect to these comments in its reply brief. (D.I. 461) At trial, Cordis did not offer objection to the comments, did not seek a curative instruction, and did not move for a mistrial. As noted above, a

party may not seek a new trial on the basis of objections not raised in the original trial. Furthermore, if Cordis failed to object and request a curative instruction after reasoning that a curative instruction would have been insufficient to cure the alleged prejudice, it should have moved for a mistrial. See Dougal v. Williams, 294 F. Supp. 1357, 1358 (E.D. Pa. 1968), aff'd, 405 F.2d 867 (3d Cir. 1969) (finding that it was "too late now for this complaint" regarding plaintiff's counsel's misconduct when there was "ample opportunity" for defense counsel to have moved for a mistrial). At trial, Cordis provided no indication that it believed prejudice was present.<sup>9</sup> As previously stated, the court will not consider, for purposes of Cordis' motion for a new trial, issues not appropriately preserved by Cordis through an objection at trial. Thus, Cordis' motion for a new trial on all issues, argued under the rationale that prejudice at trial unduly influenced the verdict, shall be denied.

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<sup>9</sup>Even if there were a risk of prejudice due to the statements by BSC's counsel in its closing argument, such risk of prejudice was minimized by the court. First, the court repeatedly instructed the jury that counsel's arguments are not evidence. (Civ. No. 03-027-SLR, D.I. 384 at 101:7-16, 105:21-106:1; Civ. No. 03-027-SLR, D.I. 392 at 1822:15-17) In addition, the court instructed the jurors as to the particular methods by which to evaluate the evidence and consider the questions before them. (Civ. No. 03-027-SLR, D.I. 392 at 1819:22-1853:3) In light of these instructions by the court and the manner in which the trial was conducted, it is unlikely that the statements of BSC's counsel improperly influenced the verdicts on infringement or validity.

**V. CONCLUSION**

For the reasons stated, Cordis' renewed motion for judgment as a matter of law or, in the alternative, a new trial on infringement and invalidity of the '536 patent (D.I. 440), is denied and BSC's motion to strike portions of Cordis' reply brief (D.I. 465) is granted in part and denied in part.



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC SCIMED, )  
INC. and BOSTON SCIENTIFIC )  
CORPORATION, )  
 )  
Plaintiffs, )  
 )  
v. ) Civ. No. 03-283-SLR  
 )  
CORDIS CORPORATION and )  
JOHNSON & JOHNSON, INC., )  
 )  
Defendants. )

O R D E R

At Wilmington this ~~15<sup>th</sup>~~ day of June, 2006, consistent with  
the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Cordis' renewed motion for judgment as a matter of law  
or, in the alternative, a new trial on infringement and  
invalidity of the '536 patent (D.I. 440), is denied.

2. BSC's motion to strike portions of Cordis' reply brief  
(D.I. 465) is granted in part and denied in part.

  
United States District Judge