IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	)	Civ. No. 03-027-SLR
BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION, Plaintiffs, v. CORDIS CORPORATION and JOHNSON AND JOHNSON, INC., Defendants.	)	Civ. No. 03-283-SLR

MEMORANDUM ORDER

At Wilmington this 24th day of September, 2007, having reviewed the various pending motions of Cordis Corporation ("Cordis") in the above captioned cases, and the papers filed in connection therewith;

IT IS ORDERED that Cordis's motion for judgment as a matter of law or, in the alternative, a new trial, on infringement of U.S. Patent No. 5,922,021 ("the '021 patent") (Civ. No. 03-027-SLR, D.I. 426) is denied, for the reasons that follow:

1. **Procedural background.** The above captioned litigation involves cross-claims of infringement by Cordis and Boston Scientific Corporation ("BSC"),[1] which parties count among the major players in the very lucrative medical device market related to interventional cardiology. More specifically, the patents at issue relate to stents, construed in this case as "tubular structure[s] left inside a vessel to hold the vessel open." Stent technology has advanced over the years (and the focus of the litigation has evolved) from various designs of bare metal stents to using those same designs as platforms for drug-eluting stents ("DES").

2. With respect to the instant litigation, the two cases were tried to separate juries and, in June 2005, the following verdicts were returned: (a) BSC's Express, Taxus Express, and Express Biliary stents (collectively, "the Express stents"), as well as the Liberte stents, literally infringe claim 23 of U. S. Patent No. 4,739,762 ("the '762 patent"); (b) BSC has induced literal infringement of claim 1 of the '762 patent with respect to those stents; (c) the Liberte stent literally infringes claim 2 of U.S. Patent No. 5,895,406 ("the '406 patent"); (d) claim 2 of the '406 patent is neither anticipated nor rendered obvious by the prior art; (e) Cordis's Cypher stent infringes claim 8 of U.S. Patent No. 6,120,536 ("the '536 patent"); (f) claim 8 of the '536 patent is not invalid for obviousness; (g) Cordis' Cypher, BX Velocity, BX Sonic and Genesis stents do not literally infringe claim 36 of the '021 patent; (h) the Cypher, BX Velocity, BX Sonic and Genesis stents infringe the "corners" limitation of claim 36 of the '021 patent under the

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[1]The parties to this litigation have undergone various corporate iterations. For ease of reference, however, the court has designated only "Cordis" and "BSC" as the primary litigants.

doctrine of equivalents; and (i) claim 36 of the '021 patent is not invalid for obviousness. (Civ. No. 03-027-SLR, D.I. 360, 381) The parties filed post-trial motions, which were resolved by memorandum opinion and order dated May 11, 2006. (Civ. No. 03-027-SLR, D.I. 416, 417) Cordis has since filed a motion for reconsideration,[2] the pending motion for judgment as a matter of law (its second such motion), and a motion for a new trial on the '536 patent based on newly discovered evidence concerning the incidence of late thrombosis (Civ. No. 03-283-SLR, D.I. 515).

3. Shortly before trial was conducted in the above captioned cases, the named inventor of the '021 patent, G. David Jang, M.D. ("Dr. Jang"), filed suit against BSC in the Central District of California. (D.I. 427 at ex. A) In his lawsuit, Dr. Jang charged, inter alia, that BSC was in violation of a certain Assignment Agreement whereby BSC had agreed to pay Dr. Jang up to $160 million based on revenues generated by products developed by BSC that incorporated Dr. Jang's coronary stent technology or patents, including the '021 patent. In order to determine whether BSC's stents were subject to the payment obligation (i.e., whether the BSC stents were "Contingent Payment Products" under the Assignment Agreement), the court had to determine whether the stents infringed the '021 patent. Consistent with the familiar two-step infringement analysis, the court construed the disputed claim limitations of the '021 patent. (D.I. 427 at ex. F)

4. **Analysis.** Cordis asserts at bar that this court should adopt the claim construction that BSC successfully advocated in the California case and should enter

[2](Civ. No. 03-027-SLR, D.I. 418, resolved by D.I. 429)

judgment of noninfringement based on that claim construction. The court agrees with Cordis in principle that courts are free to revise their interlocutory rulings on claim construction at any time prior to the entry of judgment and that, generally, a patent's claim limitations should be construed consistently from one party to another. Nevertheless, the court declines to overturn the jury verdict (a verdict that followed a voluminous motion practice) under the circumstances at bar. Significantly, Cordis never presented to this court for its consideration the specific claim construction disputes now identified by Cordis as being critical to its noninfringement case. (Compare, e.g., Civ. No. 03-027-SLR, D.I. 307, 368 with D.I. 427 and exs. C and F) Cordis is not only asking the court to nullify a multitude of proceedings based on post-trial stratagems[3] but, in essence, Cordis is asking the court to embrace a claim construction that is neither binding on the court nor necessarily persuasive.[4] The court declines to exercise its discretion in this manner.

IT IS FURTHER ORDERED that Cordis' motion for a new trial on the '536 patent based on newly discovered evidence concerning the incidence of late thrombosis (Civ. No. 03-283-SLR, D.I.. 515) is denied, for the reasons that follow:

1. **Factual background.** Unlike the '021 patent, which covers bare metal stents, the '536 patent is directed at a DES whose "topcoat" comprises "a biostable, non-thrombogenic material which provides long-term non-thrombogenicity to the device

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[3]The court acknowledges that Cordis moved to stay trial on the '021 patent just days before trial was to commence, which motion was denied by the court. (Civ. No. 03-027-SLR, D.I. 342, 351)

[4]According to Cordis, the court in California adopted the construction of the claim limitations at issue as advocated by BSC.

portion during and after release" of the drug. The above quoted limitation of claim 1 of the '536 patent[5] was construed by the court to mean "a material that does not promote thrombosis for a period of time that extends both during and after release of the biologically active material." (Civ. No. 03-283-SLR, D.I. 368) During the course of the trial, all parties conceded that bare metal stents were known to be thrombogenic, and that the thrombosis rates for Cordis's Cypher stent and bare metal stents were essentially the same. Based on this undisputed evidence, Cordis argued to the jury that the material in the Cypher's topcoat was not "non-thrombogenic" within the meaning of claim 8; BSC argued to the jury that the Cypher stent cannot be said to "promote" thrombosis because there are no additional thrombosis problems over bare metal stents.

2. More than a year after the jury reached its verdict in favor of BSC on this issue, the FDA announced the following:

> We are aware of recent data suggesting a small but significant increase in the rate of death and myocardial infarction (heart attack) possibly due to stent thrombosis (a blood clot in the stent) in patients treated with DES [drug-eluting stents]. The specific studies that have prompted recent media inquiries are the BASKET-LATE study (presented at the March 2006 American College of Cardiology Scientific Sessions in Atlanta, Ga.) and more recently, the Camenzind meta-analysis (presented at the September 2006 European Society of Cardiology Annual Meeting/World Congress of Cardiology Meeting in Barcelona, Spain). The small but significant increase in the rate of death and myocardial infarction observed in these studies was noted in patients followed 18 months to 3 years after stent implantation.
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> While the studies presented at the Atlanta and Barcelona meetings have raised important questions, the data we currently have do not

[5]Claim 8 of the '536 patent depends from claim 1.

> allow us to fully characterize the mechanism, risks, and incidence of DES thrombosis. A more formal evaluation of the data in these studies is necessary, and any conclusions are dependent upon a thorough peer review. FDA intends to more formally evaluate the studies presented in Atlanta and Barcelona.
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> At this time, FDA believes that coronary DES remain safe and effective when used in patients having clinical and coronary anatomic features similar to those treated in the pivotal trials conducted by the manufacturers for FDA approval. The approved indications are:
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> • The CYPHER Sirolimus-eluting Coronary Stent is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions of length ‹ 30 mm in native coronary arteries with reference vessel diameter of › 2.5 mm to ‹ 3.5mm.
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> • The TAXUS Express Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of de novo lesions ‹ 28 mm in length in native coronary arteries › 2.5mm to ‹ 3.75 mm in diameter.

(Civ. No. 03-283-SLR, D.I. 522 at ex. G) As far as the court knows, the Cypher and Taxus stents are still on the market.

3. **Analysis.** Cordis argues in its motion that BSC should either dismiss the case or the court should grant a new trial based on the "newly discovered" evidence summarized above which, according to Cordis, demonstrates conclusively that the Cypher topcoat is not a non-thrombogenic material (or, at least, is evidence that a jury should take into consideration in making its infringement determination). The problem, of course, with Cordis' argument is that the FDA has done no more than identify an additional, medically acceptable, risk associated with the use of DES (an increase in the rate of death and heart attack), has opined that this risk is only "**possibly due to stent thrombosis**," and has explained that it cannot "fully characterize the mechanism, risks,

or incidence of DES thrombosis." (Civ. No. 03-283-SLR, D.I. 522 at ex. G) (emphasis added) This "evidence" may well inflame a jury; the question is whether it would inform a jury.

4. The court concludes that the evidence identified by Cordis is too speculative to warrant either a dismissal or a new trial.[6]

IT IS FURTHER ORDERED that the Clerk of Court enter judgment consistent with the jury verdicts returned in these cases.

IT IS FURTHER ORDERED that the court will not consider any further motion practice, by any party, in connection with these cases until a final decision has been issued by the United States Court of Appeals for the Federal Circuit.

United States District Judge

[6]Even assuming that a causative relationship is established between the "material" at issue in claim 8 of the '536 patent and an increased risk of thrombosis, the court queries whether, in the field of interventional cardiology (or in any medical field), a drug that does not promote thrombosis in the vast majority of the patient population (and which is indicated for only this portion of the population) could be medically or legally characterized as thrombogenic, consistent with the court's claim construction.