

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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MEMORANDUM OPINION

Dated: June 3, 2005  
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 Cordis' Cypher stent infringes claims 6 and 8 of United States Patent No. 6,120,536 ("the '536 patent").

Pending before the court are the parties' motions for summary judgment. (D.I. 290, 293 and 301) On May 5, 2005, the court heard oral arguments on these motions.

## II. BACKGROUND

The '536 patent generally relates to a stent with a drug-eluting coating. The original application, Application Number 08/424,884 ("the '884 application"), was filed on April 19, 1995. This application was abandoned. On September 11, 1995, Application Number 08/526,273 ("the '273 application") was filed as a continuation-in-part of the '884 application. Later Application Number 08/663,518 ("the '518 application"), which led to the '536 patent, was filed as a continuation-in-part of the '273 application. There were more applications related to the '536 patent, including Application Number 08/730,542 ("the '542 application"), which was a continuation of the '884 application, and Application Number 08/663,490 ("the '490 application"), which was a continuation-in-part of the '273 application. The

specification of the '490 application is incorporated by reference into the '536 patent. ('536 patent, col. 1, ll. 12-17)

Claims 6<sup>1</sup> and 8<sup>2</sup> of the '536 patent depend from claim 1<sup>3</sup> and disclose drug-eluting balloon expandable stents. The court has construed the disputed limitations of these claims. (D.I. 368)

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

### III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party

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<sup>1</sup>Claim 6 states: "The device of claim 1 wherein said medical device is an expandable stent." ('536 patent, col. 13, ll. 37-38)

<sup>2</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>3</sup>Claim 1 reads:

An expandable stent for implanting in a body comprising a tubular metal body having open ends and an open lattice sidewall structure and a continuous conformal coating on the surface of said sidewall structure, said coating comprising a hydrophobic elastomeric material incorporating an amount of biologically active material therein for timed delivery therefrom, wherein said coating conforms to said sidewall structure in a manner that preserves said open lattice and wherein said coating has an outer surface having non-thrombogenic qualities.

is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving

party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

#### IV. DISCUSSION

##### A. Cordis' Motion To Bar BSC From Asserting Infringement Under The Doctrine Of Equivalents

Cordis asserts that BSC cannot argue infringement under the doctrine of equivalents due to prosecution history estoppel. According to Cordis, claim 1 of the '536 patent was narrowed to require an undercoat and a topcoat, that the topcoat be made of a biostable, long-term non-thrombogenic material and that the topcoat be substantially free from elutable material.

##### 1. Applicability of Prosecution History Estoppel

The doctrine of equivalents is limited by the doctrine of prosecution history estoppel. In Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002), the Supreme Court stated:

Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower

claim, and affirmatively chose the latter.

Id. at 734-735. In other words, the prosecution history of a patent, as the public record of the patent proceedings, serves the important function of identifying the boundaries of the patentee's property rights. Once a patentee has narrowed the scope of a patent claim as a condition of receiving a patent, the patentee may not recapture the subject matter surrendered. In order for prosecution history estoppel to apply, however, there must be a deliberate and express surrender of subject matter. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1580 (Fed. Cir. 1995).

As originally asserted, claim 1 of the '536 patent read as follows:

An expandable stent for implanting in a body comprising a tubular metal body having open ends and an open lattice sidewall structure and a continuous conformal coating on the surface of said sidewall structure, said coating comprising a hydrophobic elastomeric material incorporating an amount of biologically active material therein for timed delivery therefrom, wherein said coating conforms to said sidewall structure in a manner that preserves said open lattice and wherein said coating has an outer surface having non-thrombogenic qualities.

(D.I. 300, Ex. 1 at DFH 57) The original specification described the coating as consisting of many layers and "referred to or characterized as including an undercoat and topcoat . . . of different formulations with most or all of the active material being contained in the undercoat and a non-thrombogenic surface

is found in the topcoat." (D.I. 300, Ex. 1 at DFH 33) The examiner rejected claim 1, as being anticipated by U.S. Patent No. 5,578,075 ("the Dayton patent"). (Id., Ex. 6 at DFH 86) In response to this rejection, claim 1 was amended to read as follows:

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 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.

(Id., Ex. 9 at DFH 102)<sup>4</sup> To support the amendment, the patentees made clear that the claimed invention had a coating comprised of two separate coats and argued that the prior art did not have such a coating. (D.I. 300, Ex. 9 at DFH 106-10, Ex. 27 at DFH 188-90, Ex. 30) The examiner rejected the claim as anticipated or obvious four other times. The patentees responded by arguing that the prior art did not have a coating with two separate

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<sup>4</sup>This claim was amended twice more, but neither amendment is at issue here. It was amended to add the requirement that the device be "metallic." (D.I. 300, Ex. 21 at DFH 169) It was amended to require that "at least part of the metallic device portion is covered" with the bi-layered coating. (Id., Ex. 27 at DFH 186)

coats. Eventually the examiner agreed with the patentees and the claim was allowed. (Id., Ex. 30)

The court is not convinced that the patentees narrowed their claims when they amended claim one to more accurately describe a coating comprised of two separate coats. The amended claim merely better described what the patentees had been claiming all along. Therefore, Cordis' motion for summary judgment is denied.<sup>5</sup>

## 2. Applicability of Argument Based Estoppel

Cordis also argues that BSC should be estopped from arguing infringement by equivalents of the "elastomeric materials" limitation,<sup>6</sup> as the phrase "elastomeric" was addressed during the prosecution of the '542 application and the '490 application.<sup>7</sup> Arguments made during prosecution history, to obtain the allowance of claims, can give rise to estoppel. See, e.g.,

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<sup>5</sup>This conclusion does not mean that BSC can claim a stent with one coating infringes under the doctrine of equivalents, as "the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." Dolly Inc. v. Spaulding & Evenflo Co., 16 F.3d 394, 400 (Fed. Cir. 1994).

<sup>6</sup>Cordis also argues that BSC is estopped from asserting infringement of the "undercoat" and "topcoat" limitations due to the arguments made during prosecution of the '536 patent. As already stated by the court, it is not clear that the patentees disclaimed subject matter by their arguments in response to the examiner's rejections.

<sup>7</sup>Statements the patentees made in these applications can be relevant to considerations of the '536 patent. See Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990).

Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373, 1377 (Fed. Cir. 1999). In order for argument based estoppel to apply, however, a patentee must "evinced a clear and unmistakable surrender of subject matter." Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1458 (Fed. Cir. 1998). To determine whether there has been such surrender, a court must objectively determine "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998).

The court finds that the patentees' arguments during prosecution of the '542 and '490 applications were not an unequivocal surrender of subject matter.<sup>8</sup> The patentees distinguished the prior art because such art claimed a coating of crystalline, nonelastomeric material. (D.I. 304, Ex. 21 at 6-7; Ex. 22 at 13-14) In so doing, the patentees explained what their invention was, i.e., a stent with an elastomeric coating, as opposed to what it was not. (Id.) With their arguments, the patentees defined "elastomeric" as it was commonly used in the relevant art and it is not clear that, in doing so, they narrowed

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<sup>8</sup>This conclusion does not mean that BSC can claim nonelastomeric materials infringe under the doctrine of equivalents, as "the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." Dolly Inc. v. Spaulding & Evenflo Co., 16 F.3d 394, 400 (Fed. Cir. 1994).

the scope of their claims to distinguish the prior art. As such, there was no clear disavowal of subject matter.

**B. BSC's Motion For Summary Judgment That The Cypher Stent Infringes Claims 6 And 8 Of The '536 Patent**

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A court should employ a two-step analysis in making an infringement determination. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims to ascertain their meaning and scope. Id. Construction of the claims is a question of law subject to de novo review. Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998). The trier of fact must then compare the properly construed claims with the accused infringing product. Markman, 52 F.3d at 976. This second step is a question of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Literal infringement occurs where each limitation of at least one claim of the patent is found exactly in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987). The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

The court finds that there are material issues of fact for trial with respect to the coating of the Cypher stent. For example, although Cordis has represented the Cypher stent as having an elastomeric coating, it is not clear what Cordis meant by "elastomeric." Nor is it clear that the Cypher stent coating meets the "elastomeric material" limitation, as construed by the court. Cordis has presented evidence that the coating cracks when the stent is expanded, indicating that the coating cannot "stretch or expand without breaking." (D.I. 329, Ex. 31) As such, whether or not the Cypher stent literally infringes the '536 patent is an issue to be determined the jury.

**C. BSC's Motion For Summary Judgment That The '536 Patent Is Not Anticipated By The Prior Art**

Under 35 U.S.C. § 102(a), "a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the application for patent." A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987).

A single prior art reference may expressly anticipate a claim where the reference explicitly discloses each and every claim limitation. However, the prior art need not use identical

words as those recited in the claims to be expressly anticipating. See Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984).

A single prior art reference also may anticipate a claim where one of ordinary skill in the art would have understood each and every claim limitation to have been disclosed inherently in the reference. See Continental Can Co. USA Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. Id. That is, "the mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. The Federal Circuit also has observed that "inherency operates to anticipate entire inventions as well as single limitations within an invention." Schering Corp. v. Geneva Pharms. Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. Id. at 1377.

An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. See Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the

construed claims against the prior art to determine whether the prior art discloses the claimed invention. Id.

Even if the prior art discloses each and every limitation set forth in a claim, such disclosure will not suffice under 25 U.S.C. § 102 if it is not enabling. See In re Borst, 345 F.2d 851, 855 (1965). "Long ago our predecessor court recognized that a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if that disclosure fails to 'enable one of skill in the art to reduce the disclosed invention to practice.'" Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354 (Fed. Cir. 2003) (citations omitted). The patentee bears the burden to show that the prior art reference is not enabled and, therefore, disqualified as relevant prior art for an anticipation inquiry. Id. at 1355.

1. **U.S. Patent No. 5,019,096 ("the Fox patent")  
And U.S. Patent No. 5,512,055 ("the Domb  
patent")**

BSC argues that the Fox patent and the Domb patent do not individually anticipate the '536 patent because they do not disclose (1) an open lattice sidewall structure, as required by claim 8; or (2) an expandable metal stent that is coated, as required by claim 6.

With respect to the Fox patent, Cordis did not provide any evidence that it discloses a coating that would retain an open lattice sidewall structure. Therefore, BSC's motion is granted

as to claim 8. There is, however, evidence that it does disclose a coating for metal stents. The Fox patent discloses an infection resistant composition for coating medical devices. (D.I. 295, Ex. 2, col. 1, ll. 11-13) The patent could include metal stents because it includes "any surface in contact with patient," including metal surfaces and "arterial grafts." (Id., col. 3, ll. 6-9, 9-19) According to Dr. Hanson, an expert who testified at the preliminary injunction hearing, one of ordinary skill in the art in 1991 would have recognized "arterial grafts" as including metal stents. (03-27-SLR, D.I. 83 at 781-82) Therefore, BSC's motion is denied with respect to claim 6.

Cordis has presented evidence that the Domb patent disclosed coated metallic stents with open lattice sidewalls, as it cites Dr. Hanson's testimony at the preliminary injunction hearing stating that the '536 patent is anticipated by the Domb patent. (D.I. 83 at 740-42) In his testimony, Dr. Hanson walks through the limitations of the '536 patent and states that they are found in the Domb patent. (Id.) As such, BSC's motion is denied with respect to the Domb patent.

**2. United States Patent No. 5,474,563 ("the Myler patent")**

BSC argues that the Myler patent does not disclose (1) a top coat that is free of elutable material; (2) a biologically active coating; or (3) a coating that preserves the sidewall lattice structure. Cordis has presented Dr. Hanson's expert report as

evidence that these limitations are present in the Myler patent. According to Dr. Hanson, the Myler patent discloses a topcoat and, because it does not describe adding any elutable material to the topcoat, one of ordinary skill would inherently conclude that the topcoat is free of elutable material. (D.I. 329, Ex. 32 at 25; '536 patent, col. 4, ll. 36-39) The Myler patent may disclose a biologically active coating to one of ordinary skill in the art because it provides for a porous surface from which a drug can be released. ('536 patent, col. 4, ll. 53-56; D.I. 329, Ex. 32 at 24) The patent also discloses "other coatings . . . [that] may . . . inhibit thrombus formation . . . ." ('536 patent, col. 12, ll. 47-53) The fact that an embodiment in the Myler patent calls for painting a wire mesh stent with coating, may necessarily mean, to one of ordinary skill, that the coating facilitates an open lattice sidewall. ('563 patent, col. 13, ll. 5-8; D.I. 329, Ex. 32 at 25) Therefore, BSC's motion is denied with respect to the Myler patent.

**3. U.S. Patent No. 5,591,227 ("the Dinh patent")<sup>9</sup>**

BSC contends that the '227 patent does not anticipate the asserted claims because it does not disclose a biostable topcoat,

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<sup>9</sup>BSC disputes that the Dinh patent is prior art under § 102(e) and only characterizes it as such for the purposes of this motion. (D.I. 294 at 17 n.5)

as its topcoat includes fibrin.<sup>10</sup> Cordis argues that the Dinh patent refers to U.S. Patent No. 5,545,208 ("the Wolff patent"), which discloses a silicone topcoat and, as such, the Dinh patent discloses a biostable topcoat. Such an argument, however, is more akin to obviousness than anticipation, which requires disclosure within "the four corners" of the '227 patent. None of the cited references state that the fibrin topcoat can be replaced with those disclosed in the Wolff patent. Quite the contrary, two of the three refer to incorporation of some element of the Wolff patent into the fibrin topcoat and the third reference is merely background of the relevant art. Because Cordis has failed to carry its burden, BSC's motion is granted with respect to the Dinh patent.

**4. United States Patent No. 5,624,411 ("the Tuch patent")<sup>11</sup>**

BSC contends that the Tuch patent does not anticipate the '536 patent because it discloses a porous topcoat that would be thrombogenic. Cordis argues that pores of a minimum size would not cause thrombosis, as illustrated by Dr. Hanson's work on thrombosis. (D.I. 326 at 20) Because Cordis has not provided evidence that the Tuch patent individually discloses every

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<sup>10</sup>It is undisputed that fibrin is not a biostable compound.

<sup>11</sup>BSC disputes that the Tuch patent is prior art under § 102(e) and only characterizes it as prior art for the purposes of this motion. (D.I. 294 at 18 n.6)

limitation of the '536 patent within its four corners, BSC's motion is granted with respect to the Tuch patent.<sup>12</sup>

#### V. CONCLUSION

For the reasons stated, Cordis' motion for summary judgment precluding BSC from arguing infringement by equivalents is denied. BSC's motion for summary judgment that the Cypher stent infringes claims 6 and 8 of the '536 patent is denied. BSC's motion for summary judgment precluding Cordis from arguing anticipation of the '536 patent by certain prior art patents is granted in part and denied in part. An order consistent with this memorandum opinion shall issue.

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<sup>12</sup>BSC included U.S. Patent No. 5,545,208 ("the Wolff patent") and WO 91/12779 ("the Wolff application") in its motion. Cordis does not dispute that these references do not anticipate the '536 patent. (D.I. 326 at 18) Therefore, BSC's motion is granted as to these two references.

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CORDIS CORPORATION and )  
JOHNSON & JOHNSON, INC., )  
 )  
Defendants. )

O R D E R

At Wilmington this *3d* day of June, 2005, consistent with  
the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Cordis' motion for summary judgment precluding BSC from  
arguing infringement by equivalents (D.I. 301) is denied.

2. BSC's motion for summary judgment that the Cypher stent  
infringes claims 6 and 8 of the '536 patent (D.I. 290) is denied.

3. BSC's motion for summary judgment precluding Cordis  
from arguing anticipation of the '536 patent (D.I. 293) is  
granted as to:

a. The Fox patent anticipating claim 8 of the '536  
patent;

b. The Dinh patent anticipating either claim 6 or  
claim 8 of the '536 patent;

c. The Tuch patent anticipating either claim 6 or claim 8 of the '536 patent; and

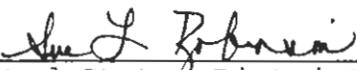
d. The Wolff prior art anticipating either claim 6 or claim 8 of the '536 patent.

4. BSC's motion for summary judgment precluding Cordis from arguing anticipation of the '536 patent (D.I. 293) is denied as to:

a. The Fox patent anticipating claim 6 of the '536 patent;

b. The Domb patent anticipating either claim 6 or claim 8 of the '536 patent; and

c. The Myler patent anticipating either claim 6 or claim 8 of the '536 patent.

  
United States District Judge