IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	)	Civil Action No. 97-550-SLR (consolidated)
MEDTRONIC AVE, INC., Plaintiff, v. CORDIS CORPORATION, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP, Defendants.	)	Civil Action No. 97-700-SLR
BOSTON SCIENTIFIC CORPORATION, Plaintiff, v. ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., Defendants.	)	Civil Action No. 98-19-SLR
CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	)	Civil Action No. 98-197-SLR

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OPINION

Dated: March 28, 2002
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiffs Expandable Grafts Partnership and Cordis Corporation, a division of Johnson & Johnson (collectively, "Cordis"), originally filed this patent infringement action on October 3, 1997 against defendants Medtronic AVE, Inc., Boston Scientific Corporation and Scimed Life Systems, Inc.[1] Cordis alleges that AVE infringed certain claims of United States Patent Nos. 4,739,762 (the "'762 patent") and 5,195,984 (the "'984 patent"). Cordis accuses BSC of infringing certain claims of the '762 patent and United States Patent Nos. 5,902,332 (the "'332 patent"), 5,643,312 (the "'312 patent"), and 5,879,370 (the "'370 patent"). The court held a seven-week bifurcated jury trial on the issues of infringement and invalidity, and a four-day bench trial on the issue of unenforceability. Currently before the court are the parties' motions for judgment as a matter of law and a new trial, and proposed findings of fact and conclusions of law regarding inequitable conduct.

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[1]Defendant Medtronic AVE, Inc. will be referred to as "AVE." Defendants Boston Scientific Corporation and Scimed Life Systems, Inc. will be referred to collectively as "BSC." Advanced Cardiovascular Systems, Inc. ("ACS") was originally a defendant, but entered into a stipulated order of dismissal with Cordis prior to trial. (D.I. 705)

II. BACKGROUND

A. The Technology

The dispute relates to balloon expandable stents. Balloon expandable stents and other types of stents are used to treat diseased blood vessels in the heart ("coronary arteries") and in other areas of the body ("peripheral arteries"). Coronary artery disease is caused by the buildup of fatty deposits on the inner lining of the coronary arteries. Known as atherosclerosis, this buildup narrows coronary arteries and may eventually block the flow of blood to the heart. Untreated coronary disease can have serious consequences, including angina, heart attack or even death. Similar narrowing in arteries away from the heart causes problems for people with peripheral artery disease.

Until about twenty-five years ago, the primary treatment for coronary lesions was medication or coronary artery bypass graft surgery. In approximately 1975, physicians began to use a non-surgical treatment called percutaneous transluminal coronary angioplasty, commonly known as "balloon angioplasty." During this procedure, a balloon attached to a wire catheter is snaked through a diseased artery until it reaches the site of blockage. A physician inflates the balloon, which compresses the fatty deposits against the vessel wall to open the artery and restore blood flow. The balloon and catheter are then removed from the body. Although balloon angioplasty represented a major

advancement in combating artery disease, blood vessels often closed again within several months of the procedure. This recurrence of blockage is called "restenosis."

A stent improves the success of balloon angioplasty by minimizing the occurrence of restenosis. A stent is a small device that holds open an artery just like scaffolding inside a tunnel keeps the tunnel from collapsing. At issue in this case are balloon expandable stents which are used in conjunction with angioplasty balloons. The stent is placed on a balloon and inserted into an artery via a catheter. Once the balloon is at the area of blockage, it is inflated, which causes the stent to expand and press against the vessel wall, thereby opening the artery. The balloon is then deflated and removed, leaving the expanded stent in the artery to keep the vessel open and allow blood to flow.

B. The Patents in Suit

1. The '762 Patent

The '762 patent, entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft," is a continuation-in-part of patent application serial no. 796,009 (the "'009 application"), which issued as United States Patent No. 4,733,665 (the "'665 patent"). Dr. Julio C. Palmaz is the named inventor of the '762 patent, and plaintiff Expandable Grafts Partnership ("EGP") is the listed

assignee. Dr. Palmaz filed the '009 application on November 7, 1985, and the '762 patent issued on April 26, 1988. A reexamination certificate (the "'762 reexamination certificate") issued on October 27, 1998 with amended and additional claims.

The '762 patent includes both apparatus and method claims. The apparatus claims are directed to an expandable tubular member that serves as vascular scaffolding. Figures 1A and 1B shown below depict the preferred embodiment of the '762 patent in its unexpanded state ("first diameter") and expanded state ("second diameter"), respectively.

Fig. 1A

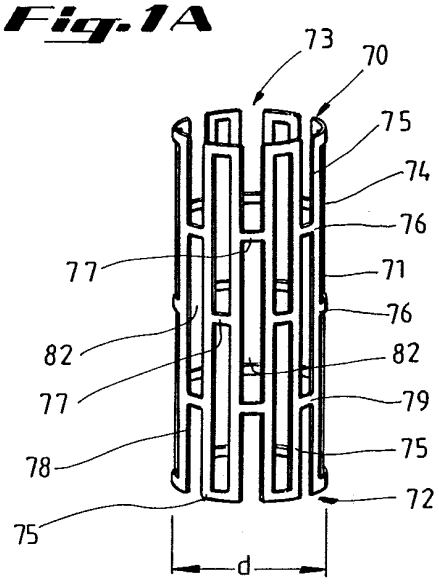
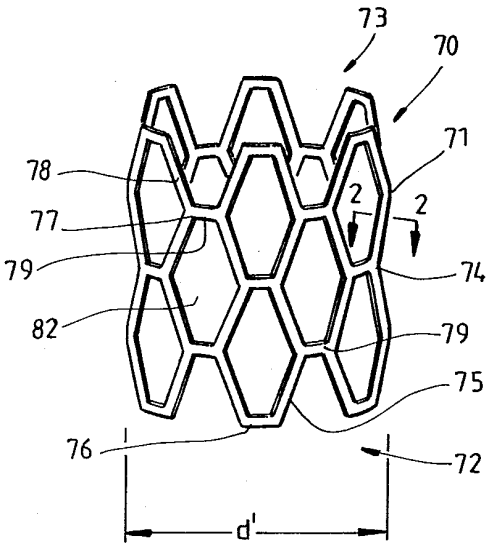
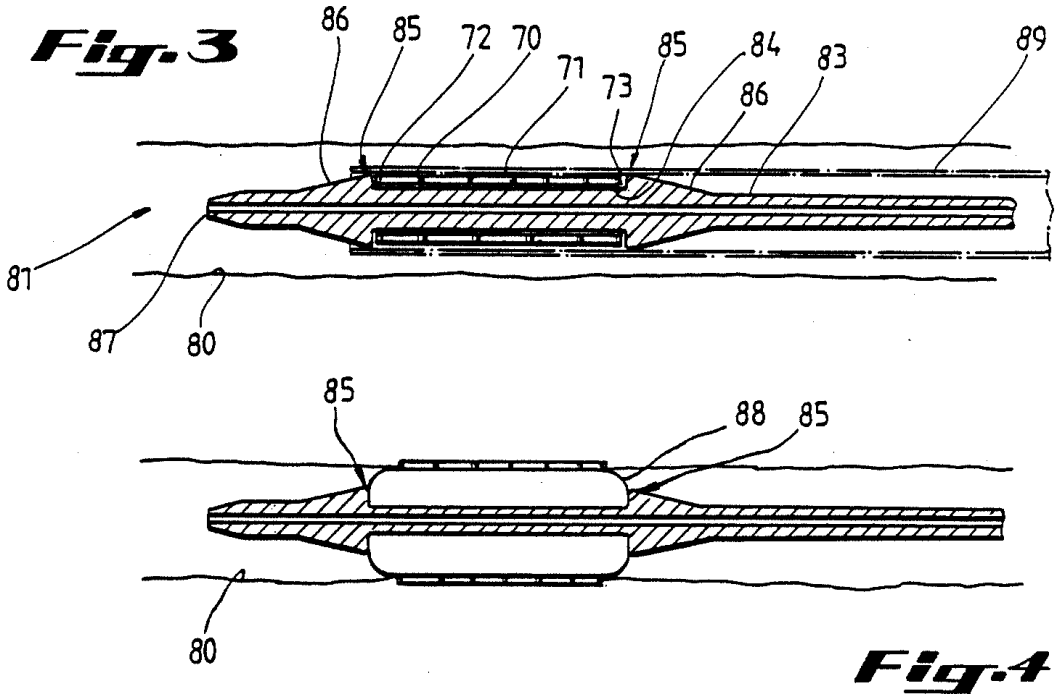


Fig. 1B



The method claims of the '762 patent describe the process of implanting the stent into a diseased vessel. As depicted in Figures 3 and 4 below, a stent is mounted upon a catheter and delivered in its first diameter to the diseased vessel. Next,

the stent is expanded and deformed radially into contact with the vessel. Finally, the balloon is deflated and removed along with the catheter, leaving the stent in the artery to support the vessel wall.



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;

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

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.

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, ln. 63 - col. 12, ln. 14; col. 12, lns. 56-59)

Claim 44, 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, lns. 22-44)

Claims 51 and 54, also added during reexamination, read:

51. In combination, a balloon expandable stent prosthesis for implementation in the passageway of a coronary artery having an area of stenosis and a catheter comprising:
an expandable stent prosthesis being a thin-walled tubular member having first and second ends and a wall having an outer 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;
a catheter having an expandable, inflatable balloon portion;
the tubular member having a first diameter which permits intraluminal delivery of the tubular member and the catheter into a lumen of a coronary artery having an area of stenosis and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; 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 controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the coronary artery in the area of stenosis.

> 54. The combination of claim 51, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

('762 reexamination certificate, col. 4, lns. 4-33, 41-44)

Prior to trial, the court construed disputed terms of the '762 patent as follows:

> (1) **"Graft"** and **"Prosthesis."** A graft and prosthesis must be functional, that is, once it is expanded and deformed it must be capable of serving to prevent a body passageway from collapsing.
>
> (2) **"Tubular member."** A discrete structure that has the form of a tube, that is, a hollow, elongated, usually cylindrical structure with two ends. "Elongate" is defined in the dictionary as "stretched out, lengthened; especially: having a form notably long in comparison to its width."
>
> (3) **"Thin-walled."** The wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters.
>
> (4) **"Wall surface."** The outer surface of the tubular member must be disposed in a common cylindrical plane.
>
> (5) **"Substantially uniform thickness."** The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. Variances

as little as .001 inches fall outside the scope of "substantially uniform."

(6) **"Plurality of slots."** More than one slot. A "slot" is a long and narrow opening or groove, an opening whose length is substantially greater than its width. The claim requires slots in the tubular members that run substantially parallel to the longitudinal axis.

(7) **"Slots formed therein."** Slots must be formed in the wall surface of a tubular member, as by the removal of material.

(8) **"Smooth surface."** The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

(D.I. 790, 1115, 1116)

2. The '984 Patent

The '984 patent, entitled "Expandable Intraluminal Graft," was filed on February 19, 1991 as a continuation of abandoned patent application serial number 253,115, filed on October 4, 1988. Dr. Richard A. Schatz is the named inventor, and EGP is the listed assignee. The '984 patent is directed to an improvement upon prior art stents, namely, connecting tubular members to "permit[] tissue of an elongated section of a body passageway to be supported by an elongated graft; and provide[] the necessary flexibility to negotiate the bends and curves in

tortuous body passageways, such as the vascular system." ('984 patent, col. 4, lns. 20-25)

Figures 7 and 8 depict the angularly offset connector members of the '984 patent and the resulting added flexibility in a body passageway.

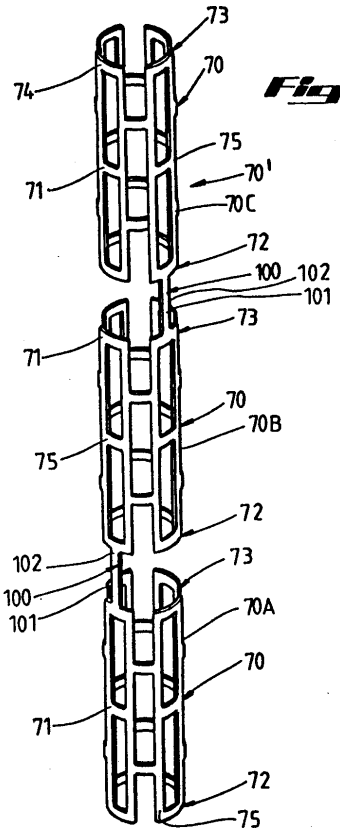


Fig-7

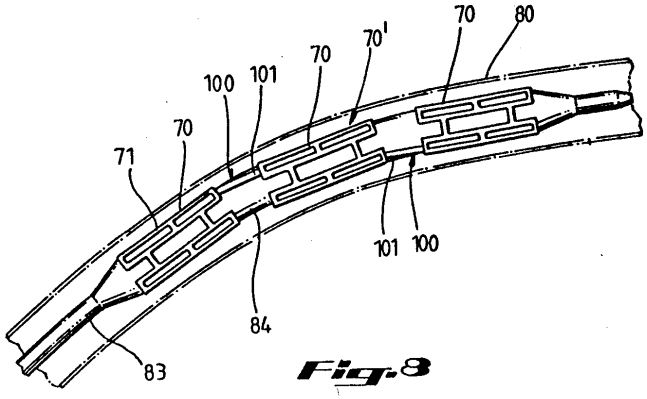


Fig-8

Claims 1 and 3 of the '984 patent read:

> 1. An expandable intraluminal vascular graft, comprising:
> a plurality of thin-walled tubular members, each 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 each tubular member;

only one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members, the connector member being disposed in a substantially parallel relationship with respect to the longitudinal axis of the tubular members and coplanar with each tubular member;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

3. The expandable intraluminal graft of claim 1, wherein a first connector member is disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member is disposed between the second end of the second tubular member and the first end of a third tubular member, the first and second connector members being angularly offset from one another and with respect to the longitudinal axes of the tubular members they interconnect.

('984 patent, col. 11, ln. 44 - col. 12, ln. 8; col. 12, lns. 13-22)

The court construed disputed terms of the '984 patent as follows:[3]

(1) **"Only one."** A single unit and no more.

(2) **"Connector member."** A discrete structure disposed or particularly arranged between adjacent tubular members in order to join them together.

(3) **"To flexibly connect adjacent tubular members."** To connect in such a way as to allow turning, bowing or twisting without breaking. The connector member must provide flexibility, whether or not the adjacent tubular members themselves are flexible.

(4) **"Substantially parallel."** The connector member must run in substantially the same direction as the longitudinal axis of the adjacent tubular members. This means that the slots and the connectors run in the same direction and are substantially aligned with one another.

(5) **"Coplanar."** The connector member must lie within the planes formed by the inner and outer wall surfaces of the adjacent tubular members.

(D.I. 790, 1115)

[3]Terms appearing in both the '762 and '984 patents are construed consistently.

3. The ‘332 Patent

The ‘332 patent, entitled “Expandable Intraluminal Graft,” was filed on November 24, 1992 as a continuation of patent application no. 07/657,296, which issued as the ‘984 patent. The specification of the ‘332 patent, therefore, is virtually identical to that of the ‘984 patent.

Claim 22 of the ‘332 patent reads:

> 22. A balloon expandable coronary stent for delivery to a coronary artery through an access artery, the stent comprising:
> at least two segments, each segment having a generally tubular shape and a first end and a second end;
> each segment having a plurality of openings that are disposed substantially parallel to the longitudinal axis of the segment, the openings forming a series of alternating open and closed portions in each of the first and second ends of the segment;
> the segments being arranged so that at least one closed portion of the second end of a first segment is in longitudinal alignment with a closed portion of the first end of a second segment;
> a connector extending between and connecting the aligned closed portion of the second end of the first segment to the aligned closed portion of the first end of the second segment, the connector being an elongate flexible member that extends between and is integrally formed with the aligned closed portions;
> whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is

delivered through a curved portion of the access or coronary arteries; and

the stent having a first diameter which permits intraluminal delivery of the stent through the access artery by percutaneous catheterization and a second, expanded and deformed diameter, the second diameter being attained upon the application from the interior of the stent of a radially, outwardly directed force by inflating a balloon, which second diameter is variable and dependent upon the amount of force applied to the stent, whereby the stent may be expanded and deformed beyond its elastic limit to expand the lumen of the coronary artery.

('332 patent, col. 13, ln. 13 - col. 14, ln. 13)

The court construed disputed terms of the '332 patent as follows:

(1) **"Segment."** A piece or separate fragment of something; one of the constituent parts into which a body is or may be divided.

(2) **"Generally tubular shape."** The phrase "segment having a generally tubular shape" is broader in scope than the phrase "tubular member" and may encompass segments that are not perfectly hollow, elongated or cylindrical in shape.

(3) **"Plurality of openings."** More than one opening, that is, more than one breach or aperture.

(4) **"Openings forming a series of alternating open and closed portions."** All openings have "open" and "closed" portions, the

closed portions comprising the material that gives form to or encloses the openings and serves to block or shut off entry or passage in some fashion. The claim requires that the openings in the segment alternate around the circumference so that each end of the segment consists of alternating open and closed portions. The court construes the phrase at issue to mean a combination of openings, some of which are "open," that is, without enclosing material at the end of the segment, thus permitting ingress and egress, and some of which are "closed," that is, having enclosing material at the end of the segment thus blocking or shutting off entry or passage.

(5) "**Connector.**" A discrete structure disposed or particularly arranged between adjacent tubular members in order to join them together. The language of the claim ("comprising . . . a connector") does not require that the claim be limited to a single connector.

(6) "**Whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of the access or coronary arteries.**" "Displaced" means to remove from the usual or proper place, to put out of place. An "angle" is a figure formed by two lines diverging from the same point or by two surfaces diverging from the same line. "Axis" is defined as a straight line with respect to which a body or figure, or system of points is either radially or bilaterally symmetrical. The

> phrase modifies the word "segment;" the phrase as written indicates that the entire segment (not a portion thereof) must be capable of angular displacement with respect to the longitudinal axis of the adjacent segment (not a portion thereof). In light of the specification, which speaks only in terms of a connector being disposed to flexibly connect rather than in terms of flexible segments, the court concludes that the limitation requires relatively rigid segments and relatively flexible connectors.

(D.I. 790, 1116)

4. The '312 and '370 Patents

The '312 patent, entitled "Stent Having a Multiplicity of Closed Circular Structures," was filed on February 25, 1994 by inventors Robert E. Fischell, David R. Fischell and Tim A. Fischell. The '370 patent, entitled "Stent Having a Multiplicity of Undulating Longitudinals," was filed on May 28, 1997 as a continuation of patent application serial no. 08/202,128, which issued as the '312 patent. Thus, the '312 and '370 patents have virtually identical specifications. The patents are directed to stents containing generally circular "rings" for radial strength upon expansion and "undulating longitudinals" for added flexibility. ('312 and '370 patents, col. 1, lns. 40-55)

Claim 21 of the '312 patent reads:

> 21. A predeployment stent structure adapted for placement in curved vessels of the coronary arteries, the stent structure being in the form of a thin-walled metal cylinder

> having a longitudinal axis, the stent including at least two undulating longitudinal structures each longitudinal structure having a multiplicity of straight sections and undulating sections with each straight section being joined continuously to at least one undulating section, the straight sections of all of the longitudinal structures being generally parallel to the longitudinal axis of the stent, the undulating sections of each longitudinal structure being of a generally curved shape so as to allow each undulating longitudinal structure to readily expand and contract in length when the stent is bent while passing through a curved coronary artery.

('312 patent, col. 7, lns. 4-17)

Claim 25 of the '370 patent is dependent upon claim 22. The claims read:

> 22. A pre-deployment balloon expandable stent structure adapted for percutaneous delivery to the curved coronary arteries, the stent structure being generally in the form of a thin-walled metal tube having a longitudinal axis, the stent structure having a multiplicity of closed perimeter cells, each cell having one or more undulating sections, each undulating section having a generally curved shape and having a first end point and a second end point wherein a line drawn from the first end point to the second end point is generally parallel to the stent's longitudinal axis.
>
> 25. The stent of claim 22 wherein the undulating section of each closed perimeter cell comprises a "U" shaped curve.

('370 patent, col. 6, lns. 17-26, 35-36)

Claim 26 of the '370 patent reads:

> 26. A balloon expandable coronary stent comprising:

> (a) a stent in the form of a thin-walled metal tube capable of being mounted on an expandable balloon for percutaneous delivery of the stent into a coronary artery, the stent having a plurality of zig-zag segments, the zig-zag segments capable of being expanded by the balloon; and
> (b) a plurality of longitudinally undulating sections of a generally curved shape positioned between and connection the zig-zag segments, wherein the plurality of longitudinally undulating sections can expand and contract in length while being passed through a curved coronary artery.

('370 patent, col. 6, lns. 37-49)

The court construed disputed terms of the '312 and '370 patents as follows:

> (1) **"Undulating."** Rising and falling in waves, thus having at least a crest and a trough.
>
> (2) **"Longitudinals"** and **"longitudinal structures."** Structures that extend or run lengthwise, in the direction of the stent's longitudinal axis. Although there is no requirement that the longitudinals or longitudinal structures extend the entire length of the stent, the structures have to extend long enough to be considered continuous across a number of points of support.
>
> (3) **"Closed perimeter cells."** A relatively small area on the perimeter of the stent that is bounded on all sides by continuous metal. The word "close" means to block or shut off entry or passage. The word "perimeter" means the boundary of a closed plane figure; outer limits.

(4) **"Zig-zag segments."** A portion of a stent that has one or more short sharp turns or angles.

(5) **"Stent"** or **"stent structure."** A device used to support, expand or hold open an artery or other body passageway.

(D.I. 1116; *D.I. 154[4])

C. The Accused Devices

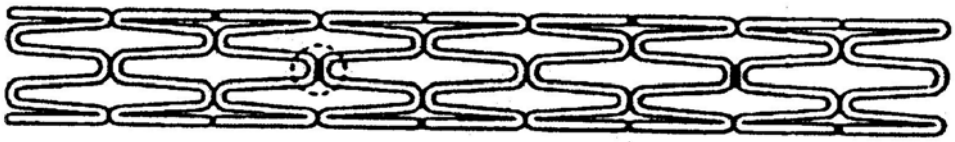
1. AVE's MicroStent II, GFX and GFX2 Stents

The stents manufactured by AVE at issue in this case include the MicroStent II, GFX, and GFX2 stents (the "AVE stents").[5] The AVE stents consist of multiple sinusoidal segments fused together to form a continuously connected device. Each sinusoidal segment is made from a torus, a circular-shaped object that has a circular cross-sectional shape, similar to a doughnut. AVE refers to these tori as "rings." After undergoing a heating process, the rings are bent from their normal configuration into a sinusoidal design characterized by a series of peaks and valleys called "crowns" interconnected by substantially straight portions called "struts." The segments are connected by fusing adjacent crowns together while the segments are positioned end to

[4]Docket item numbers designated with an asterisk refer to documents filed in Civil Action No. 98-197-SLR.

[5]Although Cordis alleged that AVE's MicroStent I also infringed the asserted patent claims, that question was not submitted to the jury because the court determined that Cordis had not presented sufficient evidence on the issue during trial. (D.I. 965 at 2202-03; D.I. 966 at 2275-86)

end in a helical arrangement. The crowns are fused to form a joint or weld using AVE's proprietary autogenous laser fusion process, which melts and fuses existing material from the two crowns so as to ultimately decrease the distance between them. Although it is still possible to identify the fused region using high magnification, there are no discrete sides, facets, faces, or other recognizable geometric features to the fused joints, which have a generally hourglass shape. There is only one weld between adjacent segments. The following is a drawing of an AVE stent with one of its welds circled:



The segments of the MicroStent II have four upper and lower crowns and are 3 mm in length. The segments of the GFX and GFX2 have six upper and lower crowns and are 2 mm in length. The AVE stents are constructed in a variety of sizes and lengths, created by connecting a number of individual 3 mm MicroStent II or 2 mm GFX segments together. They are no longer manufactured by AVE. (D.I. 296 at 3-9)

2. BSC's NIR Stent

The NIR stent is the only stent manufactured by BSC that is at issue in this litigation. It is manufactured from a flat sheet of metal upon which a design is etched. The sheet is then rolled into a cylindrical shape and the ends welded together, resulting in a stent composed of segments connected by U-shaped structures. (*D.I. 201 at 1924-27) A drawing of the NIR stent appears below.

D. The Trial

On November 6, 2000, the court commenced a seven-week jury trial in this case, with two separate juries (the "AVE jury" and the "BSC jury"), in four separate phases, per the parties' request.[6] In the first phase of the trial, the AVE jury determined whether the AVE stents infringed the asserted patent claims. In the second phase, the BSC jury determined whether BSC's NIR stent infringed the asserted patent claims. After reaching a verdict regarding BSC's liability, the BSC jury

[6]The court will refer to the portion of the trial against AVE as the "AVE trial" and the portion of the trial against BSC as the "BSC trial."

determined damages owed by BSC. Finally, the AVE jury returned after a three-week hiatus to determine damages owed by AVE.[7]

On November 21, 2000, the AVE jury returned a verdict finding that the AVE stents infringed claims 23, 51 and 54 of the '762 patent and claims 1 and 3 of the '984 patent under the doctrine of equivalents.[8] (D.I. 955) The AVE jury also found that the above claims were not invalid for failure to comply with the written description requirement. (Id.) On December 22, 2000, the AVE jury awarded Cordis $271,075,085 in damages, including $192,800,460 in lost profits, $77,274,625 based on a 25% reasonable royalty for domestic sales of stents, and a $1,000,000 payment for foreign sales of stents made in the United States. (D.I. 1013)

On December 11, 2000, the BSC jury returned the following verdict regarding the liability of BSC over its NIR stent:

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[7]The parties requested a "double bifurcation" of the trial to assist the lost profits damages analysis. To receive lost profits, a patentee must prove an absence of non-infringing alternatives. See Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) (citing Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978)). Thus, Cordis' ability to present a claim for lost profits in either case was contingent upon first receiving verdicts of infringement in both cases.

[8]Neither the jury charge nor the verdict form in the AVE trial distinguished between literal infringement and infringement under the doctrine of equivalents because the court previously granted AVE's motion for summary judgment of no literal infringement. The jury was given a general instruction on "infringement" which mirrored a doctrine of equivalents instruction.

(1) Claim 23 of the '762 patent: no literal infringement; infringement under the doctrine of equivalents.

(2) Claim 44 of the '762 patent: contributory infringement; invalid pursuant to 35 U.S.C. § 305.

(3) Claim 22 of the '332 patent: no literal infringement; no infringement under the doctrine of equivalents; invalid for obviousness; not invalid for failure to comply with the written description requirement.

(4) Claim 21 of the '312 patent: no literal infringement;[9] not invalid for obviousness; not invalid for failure to comply with the written description requirement.

(5) Claim 25 of the '370 patent: literal infringement, but no infringement by the reverse doctrine of equivalents; not invalid for failure to comply with the written description requirement.

(6) Claim 26 of the '370 patent: literal infringement, but no infringement by the reverse doctrine of equivalents; invalid for failure to comply with the written description requirement.

(*D.I. 182) On December 15, 2000, the BSC jury awarded Cordis $324,403,250 in damages, including $253,595,750 in lost profits and $70,807,500 based on a 20% reasonable royalty rate. (*D.I. 189)

[9]Cordis did not assert infringement under the doctrine of equivalents on this claim.

On February 7, 2001, the court commenced a four-day bench trial on the issue of unenforceability. The court's findings of fact and conclusions of law are rendered in the instant opinion.

III. STANDARDS OF REVIEW

A. Motion for Judgment as a Matter of Law

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. Ky. Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

B. Motion for a New Trial

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 (3d Cir. 1993); LifeScan Inc. v. Home Diagnostics, Inc., 103 F. Supp.2d 345, 350 (D. Del. 2000), aff'd per curiam, Nos. 00-1485, 00-1486, 2001 WL 345439 (Fed. Cir. Apr. 6, 2001) (citations omitted). 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 (D.N.J. 1997) (citations omitted). The court must proceed cautiously, mindful that it must not substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. 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, 926 F.2d at 1352; EEOC v. Del. Dep't of Health and Soc. Servs., 865 F.2d 1408, 1413 (3d Cir. 1989).

IV. CORDIS' STANDING TO SUE

In yet another challenge to Cordis' standing to sue, AVE and BSC argue that Ethicon NJ, a former exclusive licensee to the patents in suit, did not validly transfer its exclusive license to Technicare/Ethicon Ohio, a company with which it merged. This break in the chain of title, according to AVE and BSC, left Cordis with no right to sue on the patents. The court examined the corporate transactions that led to Cordis' license when it denied in part and granted in part ACS's motion to dismiss for

lack of standing.[10] (D.I. 162) The court declines to repeat this exercise, and maintains that Cordis was assigned an exclusive license to the patents at the time the complaint was filed.

V. INFRINGEMENT, INVALIDITY AND DAMAGES[11]

A. Infringement and Invalidity - AVE Trial

1. Infringement of Claims 23, 51 and 54 of the '762 Patent

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,

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[10]The court offered the following reasoning for its decision:

> The fact that the licensor may not have given its "express written consent" at the time of each corporate transformation is of no moment, where the parties' course of conduct over the years has been consistent with the licensor's knowledge and approval of the series of assignments.

(D.I. 162 at 4-5)

[11]Throughout their briefs, the parties make numerous arguments challenging the court's construction of various terms in the asserted claims. The court went through the claim construction exercise on multiple occasions during the course of these protracted proceedings and declines to readdress its conclusions on claim construction in this opinion.

"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). An accused product that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused product either literally or equivalently. See Sextant Avionique, S.A. v. Analog Devices, Inc., 172 F.3d 817, 826 (Fed. Cir. 1999). An element in an accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. KCJ Corp., 223 F.3d at 1359. A fact finder may also determine equivalence by assessing whether an element "does substantially the same thing in substantially the same way to get substantially the same result" as a claim limitation. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1260 (Fed. Cir. 1989).

Occasionally, "the issue of literal infringement may be resolved with the step of claim construction, for upon correct claim construction, it may be apparent whether the accused device is within the claims." Multiform Desiccants, Inc. v. Medzam, 133 F.3d 1473, 1476 (Fed. Cir. 1998). Similarly, the determination of infringement under the doctrine of equivalents may be limited as a matter of law. For example, a finding of infringement under the doctrine of equivalents is barred if a claim was amended

during prosecution to overcome the prior art. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 585 (Fed. Cir. 2000) (en banc), cert. granted, 69 U.S.L.W. 3673 (U.S. June 18, 2001) (No. 00-1543). The scope of equivalents may also be limited by statements in the specification or prosecution history that disclaim coverage of certain subject matter. See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1377 (Fed. Cir. 1999); Dawn Equip., 140 F.3d at 1016.

In the case at bar, the court granted AVE's motion for summary judgment of no literal infringement of claim 23 of the '762 patent by the AVE stents because they did not literally meet the "plurality of slots formed therein" limitation.[12] AVE now challenges the jury's finding that the AVE stents met that limitation by equivalence, arguing that the addition of the "formed therein" language to claim 13 of the '762 patent constitutes a narrowing amendment to the '009 application which bars Cordis from asserting the doctrine of equivalents on claim 23 under Festo.

In discussing the relationship between the doctrine of equivalents and prosecution history estoppel, the Federal Circuit

[12]The '762 reexamination certificate, which added claims 51 and 54, issued after AVE filed its motion for summary judgment of no literal infringement of claim 23. Because the limitation "plurality of slots formed therein" is also present in claims 51 and 54, the court holds that its finding of no literal infringement of claim 23 by the AVE stents is also applicable to claims 51 and 54.

in Festo ascribed to the doctrine of equivalents the purpose of "prevent[ing] an accused infringer from avoiding liability for infringement by changing only minor or insubstantial details of a claimed invention while retaining the invention's essential identity." Festo, 234 F.3d at 564. Prosecution history estoppel, on the other hand, is an equitable tool "that prevents the doctrine of equivalents from vitiating the notice function of claims." Id. More specifically, "'[p]rosecution history estoppel precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter that has been relinquished during the prosecution of its patent application.'" Id. (quoting Pharmacia & Upjohn Co., 170 F.3d at 1376-77). "The standard for determining whether particular subject matter was relinquished is an objective one that depends on what a competitor reasonably would conclude from the patent's prosecution history." Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995). In this regard, "[t]he prosecution history must be examined as a whole."[13] Id.

Original claim 19 of the '009 application, the precursor to claim 13 of the '762 patent, is a relatively broad claim, covering both the woven wire mesh and slotted tube embodiments of

[13]Because "[t]he application of prosecution history estoppel is a question of law," LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 867 F.2d 1572, 1576 (Fed. Cir. 1989), the issue was not presented to the jury but was preserved for post-trial review.

the "expandable intraluminal graft" first introduced by the '665 patent. The claim reads in relevant part:[14]

> [A] **tubular shaped member having** first and second ends and **a wall surface** disposed between the first and second ends, **the wall surface being formed by a plurality of intersecting elongate members**, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular member . . .

(PX 10 at 2353-54) (emphasis added)

As explained in greater detail in the court's claim construction analysis, claim 13 of the '762 patent is narrower in scope, describing only one of the embodiments covered by the '665 patent, that is, the slotted tube embodiment. Claim 13 requires

> 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** . . .

('762 patent, col. 11, lns. 64-68) (emphasis added) The court opined that, unlike the tubular member of the '665 patent whose wall surface is formed by "intersecting elongate members," the tubular member claimed by the '762 patent starts with a wall surface and the elongate members are formed by removing material from the wall surface (to wit, "slots [are] formed therein"). (D.I. 464 at 10-17)

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[14]Claims 13 and 18 of the '665 patent as it issued in March 1988 mirror this same language.

In light of this background, it is the court's conclusion that Cordis is not entitled to the protection of the doctrine of equivalents with respect to tubular members that do not have a pre-existing wall surface, such as the AVE stents. The patentee at bar chose to more narrowly define his invention in the '762 patent by emphasizing a specific feature of the balloon expandable intraluminal graft — a pre-existing wall surface that was required to have certain characteristics, i.e., "thin-walled," the wall surface having a "substantially uniform thickness," and "a plurality of slots formed therein." The notice function of patent claims would be ill served if this court were to allow Cordis, under the guise of equivalency, to embrace within the scope of the '762 patent stents lacking the very feature that distinguishes the '762 patent from the broader '665 patent. A competitor reviewing the development of Dr. Palmaz's slotted tube invention reasonably would conclude that a tubular member whose wall surface is formed by bending wire does not fall within the scope of claim 23 of the '762 patent. Therefore, the range of equivalents sought by Cordis is barred by the prosecution history of the '762 patent and the jury's verdict of infringement under the doctrine of equivalents is reversed.

2. Invalidity of Claims 23, 51 and 54 of the '762 Patent

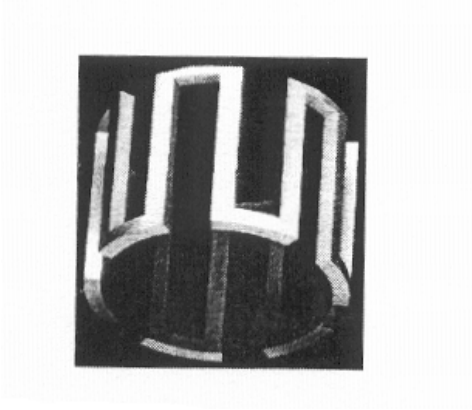
AVE challenges the jury's verdict that the asserted claims of the '762 patent are not invalid for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

Patent claims are presumed valid. See 35 U.S.C. § 282. See also Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989) ("The presumption of validity under 35 U.S.C. § 282 carries with it a presumption the examiner did his duty and knew what claims he was allowing."). To overcome this presumption, AVE was required to "provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention." Biacore v. Thermo Bioanalysis Corp., 79 F. Supp.2d 422, 467 (D. Del. 1999), aff'd per curiam, Nos. 01-1337, 01-1446, 2002 WL 418166 (Fed. Cir. Mar. 15, 2002).

AVE contends that Cordis' use of the "building block" theory during trial renders claims 23, 51 and 54 of the asserted claims of the '762 patent invalid for failure to comply with the written description requirement. The "building block," shown below, is essentially a severed portion of Figure 1A of the '762 patent, resembling a completely half-slotted stent.



AVE argues that the specification of the '762 patent fails to contemplate an all half-slotted stent and, therefore, the court should either find the asserted claims invalid as a matter of law, or clarify the definition of "plurality of slots" to require at least one complete slot.

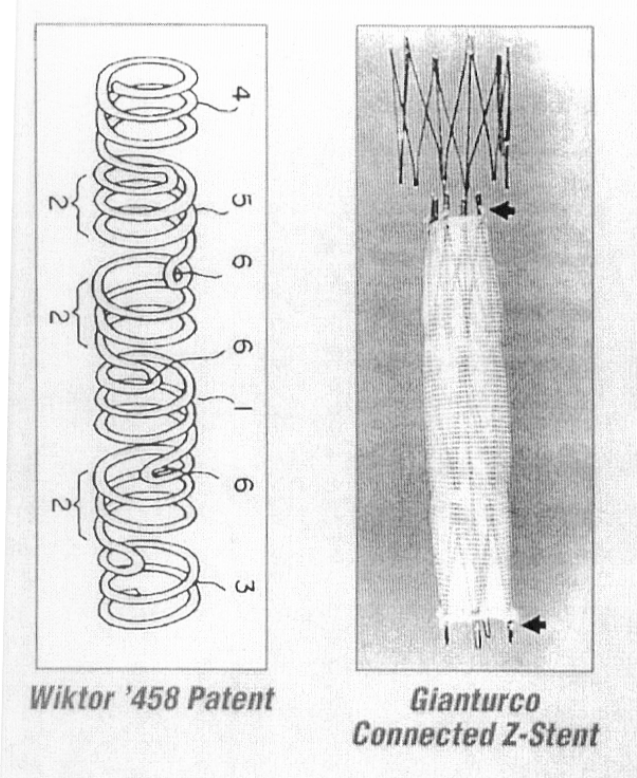
The court has declined over the course of these proceedings to limit the word "slot" to a long and narrow opening that is completely surrounded by material (i.e., a closed or complete slot), based on the ordinary meaning of the word (e.g., the "slots" of a comb) and the fact that each of Dr. Palmaz's tubular structures had to have open or half-slots in order to expand.

The tension between adequate disclosure of the scope of an invention and construing claims more broadly than the preferred embodiment has permeated the litigation at bar. The court declines to revisit the question. AVE's motion for judgment as a matter of law on this issue is denied.[15]

3. Infringement of Claims 1 and 3 of the '984 Patent

Prior to trial, the court granted AVE's motion for no literal infringement of claims 1 and 3 of the '984 patent because the AVE stents did not literally contain the "plurality of slots formed therein" limitation. (D.I. 462) AVE now challenges the jury's finding that its stents infringed claims 1 and 3 under the doctrine of equivalents because of arguments made by the patentee during prosecution of the '984 patent to distinguish two prior art references: United States Patent No. 4,969,458 ("Wiktor") and the Gianturco Connected Z-Stent disclosed in an article by Tetsuya Yoshioka, et al., entitled, "Self-Expanding Endovascular Graft: An Experimental Study in Dogs," published in the American Journal of Roentgenology in October 1988 ("Yoshioka"). (AVEX 438) The "bent wire" stents disclosed by Wiktor and Yoshioka are reproduced below.

[15]To the extent that AVE argues that claims 1 and 3 of the '984 patent are invalid for failing to satisfy the written description requirement, the court maintains that this defense was never a part of the case, and AVE is barred from raising it at this time. (D.I. 963 at 1365)



In arguing that "Wiktor is simply not responsive to the claimed structural limitations of [c]laims 1 and 4," the patentee explained that

> Wiktor does not disclose a plurality of "thin-walled tubular members, each 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 each tubular member." Wiktor discloses a single stent, or graft made up of coiled wire. **There is no wall surface having a plurality of slots**, nor slots disposed parallel to the longitudinal axis of each tubular member.

(PX 16, Tab 49 at 631) (emphasis added) A reasonable interpretation of this declaration is that the patentee surrendered bent wire stents, as AVE argues.

Such an interpretation is consistent with the prosecution history of the '984 patent, which is replete with references to the '665 and '762 patents, describing such prior art as disclosing

> expandable intraluminal grafts and methods and apparatus for implanting expandable intraluminal grafts which may be used in practicing the present invention. These three patents are commonly owned with the present application.

(PX 16, Tab 19 at 509; see also id., Tab 22 at 518) The above statement reflects the fact that the '665, '762 and '984 patents, among others, share essentially the same specification and the '984 patent claims the same basic structure (albeit in multiples) in the same language as does the '762 patent, to wit:

> [A] plurality of **thin-walled tubular members**, each **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 each tubular member.

('984 patent, claims 1 and 4, col. 11, lns. 46-52; col. 12, lns. 25-31) (emphasis added) Given the common history of the '762 and '984 patents, this court construed common claim limitations consistently. Having found that the patentee of the '762 patent

surrendered structures that have no pre-existing wall surface, it would be inequitable to find otherwise in connection with the '984 patent.

Therefore, Cordis is barred from asserting infringement of claims 1 and 3 of the '984 patent under the doctrine of equivalents. This conclusion is based upon the patentee's concession that Wiktor, a bent wire stent, does not disclose a "wall surface having a plurality of slots," as well as the common history of the '762 and '984 patents.

B. Infringement and Invalidity - BSC Trial

1. Infringement of Claim 23 of the '762 Patent

The jury determined that BSC's NIR stent infringes claim 23 of the '762 patent under the doctrine of equivalents. BSC contends that prosecution history estoppel narrows or bars the application of the doctrine of equivalents to the "substantially uniform thickness," "wall surface" and "smooth surface" limitations of claim 23, and that there was insufficient evidence to find that the NIR stent literally met any of those limitations. Because the jury was not given a detailed verdict form, the court must uphold the verdict only if it there was sufficient evidence to support a finding that the NIR stent meets one or more limitations by equivalence, and every other limitation literally. See, e.g., Comark, 156 F.3d at 1188. The court concludes that, although prosecution history estoppel bars

the application of the doctrine of equivalents to the "substantially uniform thickness" limitation, Cordis presented substantial evidence to support a finding that the NIR stent contains that limitation literally, and contains the "wall surface" and "smooth surface" limitations under the doctrine of equivalents. Thus, BSC's motion for judgment as a matter of law that claim 23 of the '762 patent is not infringed by the NIR stent is denied.[16]

a. "Substantially Uniform Thickness"

BSC contends that the patentee's efforts to distinguish United States Patent No. 3,657,744 ("Ersek") during reexamination of the '762 patent estops Cordis from asserting the doctrine of equivalents on the "substantially uniform thickness" limitation of claim 23. Ersek discloses a tubular structure that is manufactured by cutting openings in a flat sheet of metal,

[16]BSC also makes several arguments that Cordis is barred from asserting infringement of claim 23 under the doctrine of equivalents based on Festo and Intermatic, Inc. v. Lamson & Sessions Co., 273 F.3d 1355 (Fed. Cir. 2001). First, BSC argues that the addition of the terms "smooth surface" and "substantially uniform thickness" to claims 35 and 37 during reexamination bars the application of the doctrine of equivalents to claim 23, which also contains those limitations. Second, BSC claims that Cordis is estopped from asserting equivalence on the "smooth surface" limitation because of the cancellation of claim 13, from which claim 23 depends. Finally, BSC contends that Festo applies to argument-based estoppel as well as amendment-based estoppel. Because this court concludes that Cordis presented substantial evidence to support a finding that the NIR stent **literally** contains these limitations, and in light of the present review of Festo by the United States Supreme Court, this court declines to further address BSC's arguments.

pulling the sheet to expand the openings, and then rolling the sheet into a cylindrical shape and welding it together. Expanding the openings causes the struts of the resulting metal tube to be twisted, enabling the structure to become embedded in tissue upon surgical implantation. (BSCX 6228, col. 2, ln. 56 - col. 3, ln. 9) Figures 2 and 5 of Ersek are shown below.

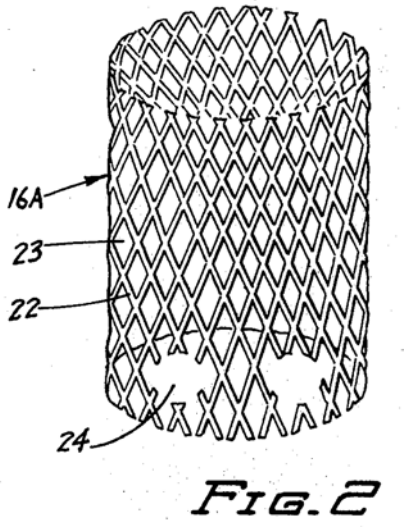


FIG. 2

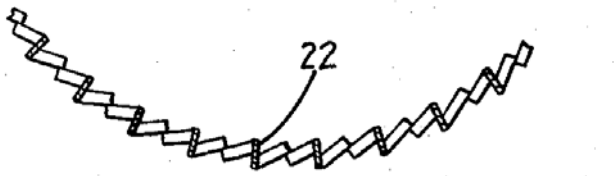


FIG. 5

During reexamination, the patentee stated the following to distinguish Ersek from the claims of the '762 patent:

> As shown therein and in Ersek Figure 5, in the first diameter configuration, the wall of sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.

(PX 13 at 3049) The patentee also cited the "Antonsson Affidavit," which stated that Ersek's wall thickness "ranged from a minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches." (PX 13 at 3050-51) The court integrated the patentee's arguments into its construction of the "substantially uniform thickness" limitation:

> The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. **Variances as little as .001 inches fall outside the scope of "substantially uniform."**

(D.I. 790, 1116) (emphasis added)

BSC contends that Cordis is estopped from claiming equivalence of any accused device that has a variance in wall thickness of 0.001 inches or more. Having incorporated the patentee's arguments distinguishing Ersek into its claim construction, the court is now confronted with the often puzzling task of determining where claim construction ends and prosecution history estoppel begins. Under the reasoning employed in Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 1106 (Fed. Cir. 2000), cert. denied, 532 U.S. 1008 (2001), however, the court concludes that the term "substantially uniform" is not entitled to a scope of equivalents. First, consistent with the court's construction that a wall surface with a "substantially uniform thickness" must not vary more that .001 inches, to characterize as equivalent what is by definition **not** of a

"substantially uniform thickness" would be to vitiate the limitation. Second, "it would defy logic to conclude that" a wall surface without a substantially uniform thickness "could be insubstantially different from a claim limitation requiring" a substantially uniform thickness, "and no reasonable juror could find otherwise." Id. Thus, as a matter of law, Cordis is estopped from claiming equivalence of any accused product whose wall surface varies in thickness by 0.001 inches or more.[17]

Nevertheless, the court finds that Cordis presented substantial evidence at trial to support a finding that the NIR stent literally contains the "substantially uniform thickness" limitation. Drs. Buller and Collins relied on engineering drawings of the NIR stent to show that the thickness of its struts varies by only .0004 inches, which is within the court's definition. (*D.I. 197 at 757-58; *D.I. 198 at 1202; PX 3776) They also relied on a weld grind elimination report to show that about 25% of the welds on the NIR stent do not vary in thickness by more than 0.001 inches. (*D.I. 197 at 758-61, 932-33, 938-40; *D.I. 198 at 1198-99, 1202-04; PX 3745) Because the jury was entitled to accept Cordis' theory of individual tubular members

[17]Cordis' contention that Ersek does not have a "substantially uniform thickness" because its tubular structure has areas that are several times the thickness of the starting material is misplaced. That argument was used to distinguish Ersek from the "thin-walled" limitation contained in certain claims of the '762 patent. (PX 13 at 3054-55)

serving as a basis for the infringement analysis, and each tubular member of the NIR stent contains one weld (*D.I. 198 at 1194), the jury reasonably concluded that the NIR stent literally contains the "substantially uniform thickness" limitation of claim 23.

b. "Smooth Surface"

BSC also argues that the patentee's efforts to distinguish Ersek during reexamination of the '762 patent estop Cordis from asserting the doctrine of equivalents on the "smooth surface" limitation. During reexamination, the patentee stated:

> A clear purpose of Dr. Palmaz's invention is to provide a low-profile, small diameter product that is **smooth enough that it can be intraluminally delivered** from a remote location to a desired location without the risk of damaging the body passageway.

(PX 13 at 3053) (emphasis added) Based on this argument, Cordis advocated a functional definition of "smooth surface" — that the surface be smooth enough for intraluminal delivery. The court determined, however, that the patent claims suggested a narrower structural definition. Claim 13 requires a "tubular member having a first diameter **which permits intraluminal delivery** of the tubular member into a body passageway having a lumen," whereas claim 23 requires that the "outside of the wall surface of the tubular member is a **smooth surface**, when the tubular member has the first diameter." Thus, the inclusion of "smooth

surface" in dependent claim 23 suggests that the term must mean more than simply "suitable for intraluminal delivery." The court adopted a dictionary definition of "smooth," also mentioned by the patentee in distinguishing Ersek from the '762 patent:

> The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

(D.I. 790, 1116; PX 13 at 003049-50) Because the court incorporated the patentee's arguments distinguishing Ersek into a structural definition of "smooth surface" and finds no reason in the prosecution history to preclude a finding of equivalence, prosecution history estoppel does not narrow the doctrine of equivalents on this limitation.

Furthermore, the court finds that there was substantial evidence presented at trial to support a verdict that the NIR stent contains the "smooth surface" limitation either literally or under the doctrine of equivalents. Dr. Buller testified that the NIR stent has a "smooth surface," and an article by Dr. Kobi Richter in the Handbook of Coronary Stents describes the NIR stent as having a "smooth surface." (*D.I. 197 at 766-68; *D.I. 200 at 1669; PX 275 at 134) Furthermore, the jury was given the opportunity to handle the NIR stent and determine if it was "without roughness, points, bumps or ridges, especially to the touch." (*D.I. 199 at 1533) In sum, Cordis presented

substantial evidence to support the jury's verdict and BSC's motion for judgment as a matter of law on this issue is denied.

c. "Wall Surface"

Finally, BSC contends that Cordis is estopped from asserting the doctrine of equivalents on the "wall surface" limitation of claim 23. The patentee distinguished Ersek as not having a "wall surface disposed between the first and second ends" because the wall of the stent was not "disposed in a common cylindrical plane:"

> As is evident from the specification of the '762 patent, with particular reference to Figure 1A, the connecting members and elongate members that collectively form the tubular member 71 have an outer surface that is disposed in a common cylindrical plane. No comparable wall surface is present in Ersek's fixation sleeve, and it would render Ersek inoperable for its intended purpose to modify sleeve 16 and eliminate the outwardly projecting edges, since the thus modified sleeve would eliminate the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway.

(PX 13 at 3054) Again, the court incorporated the patentee's prosecution arguments into its claim construction when it defined "wall surface" to require that the "outer surface of the tubular member must be disposed in a common cylindrical plane." The court finds no evidence in the prosecution history to preclude a finding of equivalence based on this definition, thus, Cordis is

not estopped from asserting the doctrine of equivalents on this limitation.

The court also finds that substantial evidence supports a finding that the NIR stent contains a "wall surface," either literally or under the doctrine of equivalents. Dr. Buller stated that the "tubular members of the NIR stent are disposed in a cylindrical shape . . . [i]t fulfills exactly that claim language," and that the welds lie in the same plane as the tubular members. (*D.I. 197 at 754-55) Dr. Collins also testified that the NIR stent's wall surface, including the welds, lies in a common cylindrical plane. (*D.I. 198 at 1201) In sum, the court finds that there is sufficient evidence in the record to support the jury's verdict.[18]

2. Contributory Infringement of Claim 44 of the '762 Patent

BSC argues that it is entitled to judgment as a matter of law that claim 44 of the '762 patent is not infringed or, in the alternative, to a new trial, for three reasons: (1) there is no predicate act of direct infringement by any one entity or related

[18]BSC's motion for a new trial to consider the reverse doctrine of equivalents for claims determined to be infringed under the doctrine of equivalents is denied. See Martin v. Barber, 755 F.2d 1564, 1567 n.1 (Fed. Cir. 1985) ("[The reverse doctrine of equivalents] becomes an issue only when the accused device falls within the literal words of a claim."). BSC's motion for a new trial to determine if the NIR stent infringes claim 23 under the doctrine of equivalents because the jury's verdict was against the weight of the evidence is also denied.

entities; (2) the NIR stent is suitable for substantial noninfringing use; and (3) Cordis failed to prove that BSC had the requisite knowledge for contributory infringement.

Pursuant to 35 U.S.C. § 271(c),

> [w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

There can be no contributory infringement in the absence of direct infringement. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341-42 (1961). Furthermore, "only proof of a defendant's knowledge, not intent, that his activity cause[s] infringement [is] necessary to establish contributory infringement." Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).

a. Predicate Act of Direct Infringement

To constitute a predicate act of direct infringement of a process claim, either a single entity must perform every step of the method or, if two or more entities perform different steps of the method, those entities must have some connection to each other. See, e.g., Faroudja Labs., Inc. v. Dwin Elecs., Inc., No. 97-20010, 1999 WL 111788, at *5 (N.D. Cal. Feb. 24, 1999) ("It is true that several district courts have found a party liable for

direct infringement of a process patent even where the various steps included in the patent are performed by distinct entities. However, these cases indicate that some connection between the different entities justified that finding.").[19]

BSC argues that, although physicians who implant NIR stents in coronary arteries may carry out some of the first, third, fourth and fifth steps of the method of claim 44 — utilizing, inserting, delivering and expanding the NIR stent, respectively — they do not carry out the second step of "disposing" the NIR stent on a balloon catheter. Rather, BSC performs this step by selling the NIR stent in the United States premounted on a catheter, and BSC has no relationship to physicians who perform the other steps.

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[19]During the jury charge conference, BSC argued that a higher standard is required to establish contributory infringement by related entities, one in which the entities must "work in concert," "work together jointly" or have an "agency" relationship. The court rejected these arguments and instead adopted the "some connection" standard used in the Faroudja case:

> Cordis must prove by a preponderance of the evidence each of the following to establish contributory infringement of claim 44, which covers a method of medical treatment:
> . . .
> 5. That every step of the method of medical treatment described in claim 44 is performed either by a single entity, or by different persons or entities who have **some connection** to each other.

(D.I. 1116) (emphasis added) BSC now presents no arguments that compel the court to change its prior decision.

The court finds that there was sufficient evidence presented at trial to support the finding of the jury that BSC has "some connection" to physicians who implant the NIR stent. For instance, Dr. Buller testified about the relationship between BSC and the medical community:

> There's a very close relationship. I think you heard evidence of the close relationship between Boston Scientific and its personnel and the doctors, and we, in all countries, in Europe as well, depend very much on industry for this relationship, for teaching us about new products, how to use them, when they're appropriate to be used and generally how the products perform and how they might benefit our patients.

(*D.I. 203 at 2549) He also testified that BSC supplies samples of the NIR stent to physicians, and recruits physicians to participate in clinical trials. (Id.)

BSC's chairman, Peter Nicholas, also testified about BSC's close relationship with physicians:

> Well, we have a network of thousands of people in the field. These are professional salespeople in the field all throughout the world. And they're talking to physicians every day. I think we talked to perhaps five, ten thousand physicians every single day with our organization. And we selected a handful, maybe 15 to 20 of those physicians throughout the world who are, in our view, really leaders in the world. And we asked them to tell us about the NIR stent.

(*D.I. 199 at 1457) Thus, BSC's motion for judgment as a matter of law or a new trial on this issue is denied.

b. NIR Stent as a Staple Article of Commerce Suitable for Substantial Noninfringing Use

BSC also challenges the jury's finding that the NIR stent is incapable of "substantial noninfringing uses." The court instructed the jury on this issue as follows:

> In determining whether the NIR stent is a "staple article of commerce," you should focus on the NIR stent actually supplied by Boston Scientific, and you should take into account the quality, quantity and efficiency of the suggested uses. That a product is known to have potential infringing uses is not sufficient to establish contributory infringement. You should also consider in this regard the uses for which the NIR stent has been approved by the FDA and the labeling and instructions of the NIR stent.

(D.I. 1116)

Although BSC presented evidence that the NIR stent is **suitable** for implantation in body passageways other than the coronary artery,[20] the court finds that the jury reasonably concluded that these uses are not "substantial." See Hoffmann-LaRoche, Inc. v. Promega Corp., No. C-93-1748-VRW, 1994 U.S. Dist. LEXIS 10174, at *29 (N.D. Cal. June 13, 1994) ("Whether a use is 'substantial' or not depends on how likely and often the use will occur. Thus, occasional aberrant use of a product does

[20]The instructions that accompany the NIR stent state that it may be used to treat lesions in saphenous vein grafts, and the NIR stent has been approved by the FDA for use in the biliary system. (PX 3796A; BSCX 9872; *D.I. 199 at 1464) Also, BSC's expert Dr. David Cumberland testified that the NIR stent is suitable for use in the renal arteries. (*D.I. 200 at 1602)

not make that use 'substantial.' Similarly, inefficient and uneconomical uses are less likely to be deemed 'substantial.'") (citations omitted). BSC promotes the NIR stent to physicians as a coronary stent, and FDA-approved labeling states that the NIR stent is used only for "improving coronary lumen diameter." (PX 276 at 281; PX 3796A) Dr. Buller, a member of BSC's advisory board when the NIR stent was launched, testified that he was not aware of any "substantial" use of the NIR stent outside the coronary arteries. (*D.I. 197 at 781) In sum, the court finds that, based on the evidence presented, the jury reasonably determined that any uses of the NIR stent outside the coronary arteries are not "substantial."

c. BSC's Knowledge

Finally, BSC argues that Cordis failed to show that BSC possesses the requisite knowledge for contributory infringement:

> That BSC sold or supplied the NIR stent with knowledge that the NIR stent was especially made for use in the manner claimed in claim 44 of the '762 patent.

(D.I. 1116) See Hewlett-Packard, 909 F.2d at 1469 n.4 (citing Aro Mfg., 377 U.S. at 488). The court finds that Cordis presented substantial evidence to support the jury's finding that BSC possessed knowledge that the NIR stent is "especially adapted for a particular use proscribed by a known patent." Snuba Int'l v. Dolphin World, Inc., No. 99-1357, 2000 WL 961363, at *7 (Fed. Cir. July 11, 2000). BSC is aware of how the NIR stent is used

and instructs physicians in that use. (PX 3796A) BSC's motion for judgment as a matter of law that its lacks the requisite knowledge to establish contributory infringement of claim 44 is denied.

3. Invalidity of Claim 44 of the '762 Patent

Cordis moves for judgment as a matter of law that claim 44 of the '762 patent is not invalid for failure to comply with 35 U.S.C. § 305. Section 305 provides, in pertinent part:

> In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title,[21] or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter.

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[21]Section 301 provides:

> Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential.

35 U.S.C. § 301.

35 U.S.C. § 305. Cordis argues that: (1) the question of invalidity under § 305 is one for the court and not the jury; and (2) claim 44 was added during reexamination for a proper purpose.

a. Question for the Court or the Jury

The Federal Circuit has characterized invalidity under § 305 as a question of law which it must review de novo. See In re Freeman, 30 F.3d 1459, 1464 (Fed. Cir. 1994) ("Whether amendments enlarge the scope of a claim is a matter of claim construction. Claim construction is a question of law which we review de novo.") (citing In re Donaldson Co., Inc., 16 F.3d 1189, 1192 (Fed. Cir. 1994)). During the trial, the court reserved decision on whether this issue is one for the court or jury, and allowed the jury to address the issue in the event that the court later determined that it was a jury question. (*D.I. 203 at 2493) Upon careful consideration, the court concludes that, pursuant to the language of the Federal Circuit in In re Freeman, invalidity under § 305 is a question for the court and not the jury. Although BSC argues that the specific issue at bar is not "whether amendments enlarge the scope of a claim," but rather, whether a claim was added for a proper purpose, the court finds no persuasive authority requiring a jury to decide such an issue, nor is such an issue an inappropriate question for the court. Contrary to BSC's position, the court may, and is often required to, address issues with similar factual underpinnings, such as

prosecution history estoppel. Thus, the court shall decide the issue of invalidity of claim 44 under § 305, using the jury's verdict as an advisory opinion.

b. Reasons for Addition of Claim 44 in Reexamination

According to § 305, a claim may be added or amended upon reexamination for only two reasons: (1) to distinguish the invention as claimed from the prior art; or (2) in response to a decision adverse to the patentability of a claim of a patent. See 35 U.S.C. § 305. See also In re Freeman, 30 F.3d at 1468 ("[T]he ability of a patentee to amend claims during reexamination must be seen in light of the fundamental purpose of reexamination — the determination of validity in light of a substantial new question of patentability. Thus, amendment of claims during reexamination is limited to amendment in light of prior art raising a substantial new question of patentability.") (citing In re Yamamoto, 740 F.2d 1569, 1572 (Fed. Cir. 1984)). Cordis argues that claim 44 was added to the '762 patent for both permissible reasons, whereas BSC contends that claim 44 was added solely to cover the stents of Cordis' competitors.

In October 1997, reexamination of the '762 patent was requested in view of three additional pieces of prior art: Ersek, U.S.S.R. Inventor's Certificate 660689 ("Kononov"), and United States Patent No. 4,787,899 ("Lazarus"). (PX 12 at 1407) In a subsequent office action, the examiner rejected claims 1-8

and 35-38 as unpatentable under 35 U.S.C. § 103(a) in light of the additional prior art. (PX 13, Tab 32) The patentee then submitted an Amendment on July 21, 1998 that included an amended claim 1 and several additional claims, including claim 44. In its remarks accompanying the Amendment, the patentee stated:

> Claims 1, 13, 24, 35 and 37 have been amended in accordance with the discussions with Examiner Thaler at the above-noted interviews, and in subsequent telephone discussions on July 13, 1998. **Added claims 44-59 are all narrower in scope than the original claims, and provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods.**

(PX 13 at 3045-46) (emphasis added)

The only other mention of claim 44 in the prosecution history appears in the Examiner's Reasons for Allowance dated August 25, 1998. Examiner Thaler remarked:

> Claim 44 is a new claim. This claim includes the step of expanding and deforming the stent prosthesis at an area of stenosis within the coronary artery. This claim is more limited than amended claim 1. It would not have been obvious to locate either the Lazarus or the Kononov device within the coronary artery at the area of stenosis for substantially the same reasons as those [applicable to claim 1].

(PX 14 at 3256-57)

The court finds that claim 44 was added solely to cover competitors' stents, and not for a permissible reason under § 305. The patentee clearly stated that claim 44 was added to

provide protection for "aspects of the disclosed invention which have been incorporated into competitive products and methods." Examiner Thaler's remarks about claim 44 pertain to the patentability of claim 44 itself, not how claim 44 enhances the patentability of claim 1. In fact, Examiner Thaler's prior objections to claim 1 were withdrawn not because of claim 44, but because of the insertion of the phrase, "at the location of an existing natural obstruction within the body passageway," into claim 1. (PX 14 at 3254-56) Claim 44 is simply a narrower version of claim 1, and there is no indication in the prosecution history that claim 44 was added to distinguish the invention as claimed from the prior art, or in response to the original rejection of claim 1 for obviousness. Although a patentee may add claims to cover a competitor's product, the addition of those claims must comply with the patent laws. See Kingsdown Med. Consultants Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988). Because the court finds that claim 44 was not added for a permissible reason under § 305, Cordis' motion for judgment as a matter of law on this issue is denied.

4. Invalidity of Claim 22 of the '332 Patent

BSC contends that it is entitled to judgment as a matter of law that claim 22 of the '332 patent is invalid for failure to comply with the written description requirement because the specification of the '332 patent fails to disclose multiple

connectors. The court finds that the jury reasonably concluded that BSC failed to demonstrate by clear and convincing evidence that claim 22 is invalid. The specification of the '332 patent states that "[t]he present invention includes . . . a single connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members," but never limits the invention to containing **only** single connector members. ('332 patent, col. 3, lns. 38-45) Moreover, because the '332 patent is a continuation of the '984 patent, the jury properly considered the specification and file history of the '984 patent, whose original claims were directed to a stent "**comprising** . . . a single connector member being disposed between adjacent tubular members." (PX 16 at 481-42) The use of the open-ended term "comprising" suggests that multiple connectors may also be present. Furthermore, the prosecution history of the '984 patent contains several references to multiple connectors. (PX 16 at 575-76; PX 17 at 2885) The jury's verdict is consistent with the weight of the evidence, thus, BSC's motion for judgment as a matter of law on this issue is denied.

5. Infringement of Claims 25 and 26 of the '370 Patent

BSC challenges the jury's finding that the NIR stent literally infringes claims 25 and 26 of the '370 patent. Specifically, BSC contends that Cordis inappropriately altered

the parties' and the court's understanding of the term "undulating" and, under the intended construction of the term, the evidence presented at trial does not support a conclusion that the NIR stent contains "undulating" sections.

During claim construction, the parties and the court agreed that the words "crest" and "trough" define arcing curves, not just points at the top or bottom of a curve.[22] With this understanding of the terms, the court defined "undulating" to mean "rising and falling in **waves**, thus having at least a crest and a trough." The use of the plural "waves" implies a change in direction, as suggested by Figure 8 of the '370 patent, shown below.

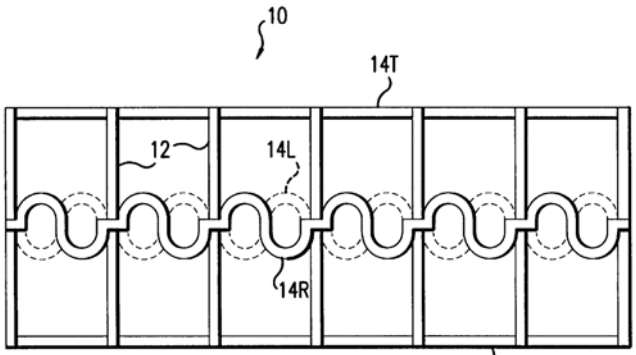

FIG.8

[22]The court added the "crest" and "trough" language to address a dispute between the parties about whether "undulating" required both a crest **and** a trough, as opposed to a crest **or** a trough.

The court did not include the "change in direction" language in the claim construction because neither party suggested it was necessary, as it was contemplated under BSC's definition which was embraced by the court.

At trial, Cordis presented no evidence to suggest that the NIR stent has two arcing curves or waves which can be identified as a crest and a trough. Instead, Cordis argued that the "U" shaped member of the NIR stent represents **one** full cycle of **a** sine wave, which includes one crest (the combined two top points of the "U") and one trough (the "U" curve itself). (*D.I. 203 at 2631-33) Cordis' attempt at satisfying the court's claim construction, albeit creative, is unsuccessful. "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." Southwall Techs., 54 F.3d at 1574. The court finds that Cordis failed to present sufficient evidence to prove that the NIR stent literally contains "undulating" sections as defined by the court. BSC's motion for judgment as a matter of law on this issue is granted. Because the court finds that the NIR stent does not literally infringe claims 25 and 26 of the '370 patent, Cordis' motion for judgment as a matter of law on the reverse doctrine of equivalents is denied as moot.

6. Invalidity of Claim 25 of the '370 Patent and Claim 21 of the '312 Patent

BSC moves for judgment as a matter of law that claim 25 of the '370 patent and claim 21 of the '312 patent are invalid for failure to comply with the written description requirement because the specifications disclose only "ring" stents whereas the claims refer broadly to a "stent" and "stent structure." See Tronzo v. Biomet, 156 F.3d 1154, 1158-59 (Fed. Cir. 1998) (holding that unless disclosure suggests to one skilled in the art that broader, more generic invention is necessarily part of disclosure, claims directed to broader invention are invalid for failure to comply with written description requirement). See also Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed. Cir. 1999). BSC also argues that the claims are invalid because they fail to claim "rings," which are an essential feature of the invention. See Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480 (Fed. Cir. 1998) (holding that if patent applicant has made clear that particular feature is essential to underlying invention, that feature may not be omitted from claims without violating written description requirement). See also Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 993 (Fed. Cir. 1999).

The court finds that the jury reasonably concluded that the '312 and '370 patent specifications disclose two separate and distinct attributes of a stent — circular rings for radial

strength and undulating structures for longitudinal flexibility. At trial, Dr. Tim Fischell stated that the inventors' goal was two-fold:

> . . . . our basic concepts at the time were to make a stent that would be very strong when expanded . . . . But also, to make a stent that would be very flexible. . . .

(*D.I. 196 at 526-27) Dr. Buller also described the Fischells' invention as follows:

> . . . . their invention was two different things. One component of their invention was trying to go to close to perfectly circular rings, to support the lumen . . . . And the other component of their invention was undulations within longitudinal structures, to actually bring about even better flexibility within the design of a stent.

(*D.I. 197 at 818-19) Furthermore, the specifications describe the benefits of undulating structures in general terms that are applicable to any kind of stent:

> A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

('312 patent, col. 3, lns. 45-49; '370 patent, col. 3, lns. 46-50)

Because claims 25 and 21 disclose "undulating" structures which are reasonably considered to be one of **two** separate features of the invention disclosed by the '312 and '370 patents, BSC's motion for judgment as a matter of law that the claims are

invalid for failure to comply with the written description requirement is denied.

C. Damages

Upon a finding of infringement, the patent laws permit an award of damages adequate to compensate the patentee for infringement, but in no event less than a reasonable royalty. See 35 U.S.C. § 284. To recover lost profits, "a patent owner must prove a causal relation between the infringement and its loss of profits." BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1218 (Fed. Cir. 1993). In other words, the burden rests on the patentee to show a reasonable probability that "but for" the infringing activity, the patentee would have made the infringer's sales. Water Tech. Corp. v. Calco Ltd., 850 F.2d 660, 671 (Fed. Cir. 1988). To prove entitlement to lost profits, the patentee must demonstrate, inter alia, an absence of non-infringing alternatives, and that it possessed the marketing capacity to make the lost sales. See Rite-Hite, 56 F.3d at 1545 (citing Panduit, 575 F.2d at 1156); Smithkline Diagnostics Inc. v. Helena Labs. Corp., 926 F.2d 1161, 1165 (Fed. Cir. 1991) (citing Panduit, 575 F.2d at 1156). For those infringing sales for which a patentee cannot establish an entitlement to lost profits, damages in the form of a "reasonable royalty" are required. A reasonable royalty is the amount that a person desiring to manufacture, use or sell a patented article, as a

business proposition, would be willing to pay as a royalty and yet be able to make, use or sell the patented article in the market at a reasonable profit. See Wang Labs. v. Toshiba Corp., 993 F.2d 858, 870 (Fed. Cir. 1993) (citation omitted). When an established royalty does not exist, a reasonable royalty may be determined based on "hypothetical negotiations between [a] willing licensor and [a] willing licensee" at the time that the infringement began. Id. (citation omitted). Although a "trier of fact must have some factual basis for a determination of a reasonable royalty," consideration of a hypothetical negotiation "necessarily involves an element of approximation and uncertainty." Unisplay, S.A. v. Am. Elec. Sign Co., 69 F.3d 512, 517 (Fed. Cir. 1995).

Because the court finds that Cordis is estopped from asserting equivalence of the "plurality of slots formed therein" limitation of claims 23, 51 and 54 of the '762 patent and claims 1 and 3 of the '984 patent, the parties' motions regarding the damages portion of the AVE trial are moot, and BSC's motion for a new damages trial is granted so that the AVE stents may be considered as non-infringing alternatives to the NIR stent.

VI. UNENFORCEABILITY

A. Findings of Fact, Pursuant to Fed. R. Civ. P. 52(a)

1. The '762 Patent

1. **Contention.** AVE and BSC contend that the '762 patent is unenforceable because the patentee committed inequitable conduct by presenting false and misleading arguments to distinguish Ersek during the first reexamination of the parent '665 patent and during the '762 reexamination.

2. **Facts of record.** In his 1983 monograph entitled "Expandable Vascular Endoprosthesis," Dr. Palmaz described the slotted tube configuration as follows:

> The tube could initially be a thin walled silver, tantalum or stainless steel continuous tube in which alternating fissures such as shown in Fig. 1 have been done. This process may require sophisticated techniques such as electronic or laser etching. **After expansion, the unfolded "bars" between fissures will twist and loss of length will result.** Although the expanded tube wall will be thicker than the wire mesh tube the unexpanded tube wall will be smoother and thinner therefore allowing an easier introduction and positioning before inflation.

(PX 1557 at 6) (emphasis added)

3. The '665 patent was filed in November 1985. Although Figures 2A and 2B appear to be smooth, none of the claims of the original '665 patent address this feature. (PX 1)

4. The '762 patent was filed in November 1986. Figures 1A and 1B show smooth first and second diameters, and original claim 23 expressly calls for a smooth first diameter. The second diameter is described in the specification as "relatively smooth." (PX 3, col. 7, lns. 41-45)

5. The early prototypes of the slotted tube invention were rigid and resulted in distortion and twisting upon expansion. (D.I. 1052 at 266-67; D.I. 1054 at 617) The distortion was minimized when an annealing process was applied to the devices. (D.I. 1054 at 652)

6. The '665 patent was submitted for reexamination in 1991, after Ersek was found. (PX 8, Tab 7; PX 12, Tab 6 at 1463) Claim 13 of the '665 patent was amended to include a "tubular shaped member having a second, expanded diameter and a substantially smooth outer wall surface." (PX 9, Tab 73 at 2184) The examiner initially rejected the amendment because,

> as the Palmaz graft (each embodiment) is expanded and the openings 82 are widened, the forces acting on the graft are similar to that described in Ersek in col. 2, lines 63-75 and col. 3, lines 1-6. The Palmaz elongated members 75, 76 would inherently twist so that the narrow edges of the Figs. 2A, 2B bars, for example, would face outwardly and thus preclude the outer surface from fairly being characterized as "smooth" or "substantially smooth."

(Id., Tab 68 at 2149)

7. In response, the patentee submitted the declaration of John S. Kula, dated March 11, 1993. In his declaration, Mr. Kula averred that, "[w]hen the graft/prosthesis of the Palmaz '665 Patent is expanded to **its maximum design specification diameter**, the outer wall surface of the graft/prosthesis remains substantially smooth." (Id., Tab 81 at 2252) (emphasis added) The examiner, in allowing amended claim 13 over Ersek, relied on the Kula declaration as evidence "that the elongated members 75, 76 of the embodiment of figs. 2A and 2B of the Palmaz '665 patent do not inherently twist when the graft is expanded." Therefore, the "outer surface of the graft shown in the Palmaz '665 patent is smooth." (Id., Tab 89 at 2282) The examiner also relied on his examination of PX 3986 and PX 3987, models of the Palmaz and Ersek stents, respectively.[23] (Id.)

8. Ersek also was reviewed during the course of the '762 reexamination, filed in October 1997. (PX 12) In comparing dependent claim 23 of the '762 patent to Ersek, the patentee declared:

> The Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is twice as thick in some areas as in others, and the thickness of the wall varies throughout. The fixation sleeve is

[23]The aspect ratio (the ratio of the width of the strut to the strut's thickness, in the cross-section) of the Palmaz peripheral stent (PX 3986) was 1.15, in contrast to the Ersek model's aspect ratio of 4.87 (PX 3987). (D.I. 1052 at 48-49)

> deliberately formed to provide a multitude of narrow projecting edges (Figure 5) that are intended to embed themselves into the tissue wall upon expansion of the sleeve. These sharp metal projecting and penetrating edges are a fundamental requirement for the successful operation of the fixation sleeve. Thus, the periphery of the Ersek sleeve is rough, sharp, and not smooth.

(PX 13, Tab 37 at 3079; see also id., Tab 36 at 3049-50; PX 12, Tab 4 at 1416, 1436)

9. The examiner ultimately allowed claim 23, finding that

> the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the bridge has a thickness which is twice as great as the strand. The outside of the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve (col. 3, lines 1-6).

(PX 14, Tab 58 at 3258)

10. According to the evidence of record, some degree of twisting is inherent in the design of the Palmaz and Palmaz-Schatz slotted tube stents upon the application of torsional force. The degree of twisting will depend on a number of factors, including the aspect ratio selected by the designer and the extent of expansion exercised by the cardiologist. (D.I. 1052 at 24-46, 68-69, 143-44, 214, 227-35, 280-85; D.I. 1053 at 358, 367-68; D.I. 1054 at 625-28, 659-60; PX 3989-A) With respect to the former factor, a large aspect ratio will show a greater degree of twisting for a given amount of expansion force. (D.I. 1052 at 48-49) With respect to the latter factor, the greater the expansion, the greater the tendency to twist. (Id. at 68-69) Cardiologists tend to overexpand the Palmaz and Palmaz-Schatz stents in order to take into account the recoil characteristics of such stents and to secure the stents in the vessels by embedding.[24] (D.I. 1052 at 44-45, 236-38; D.I. 1054 at 685-86) Therefore, even when these factors (aspect ratio, degree of expansion) are controlled, some degree of twisting can be detected in the Palmaz and Palmaz-Schatz stents, to wit: some struts of the stent will be twisted, some will not be, some will

[24]In contrast to the Ersek device, the edges of which must penetrate the tissue of the wall in order to function as designed (not to expand a lumen, but to replace a surgeon's sutures), the struts of the Palmaz and Palmaz-Schatz stents are ultimately "buried" on all three sides by the tissue of the lumen due to the pressure of expansion. (D.I. 1054 at 661, 744-47)

be twisted more than others. (D.I. 1052 at 39, 227-31) The twists, however, are "very, very small." (Id. at 27)

11. The record demonstrates that twisting is a desired feature in the Ersek fixation sleeve (the resulting "narrow projecting edges" are intended to embed themselves into the tissue wall upon expansion of the sleeve). In contrast, twisting is an undesired feature of the expanded Palmaz and Palmaz-Schatz stents, as twisting causes "microturbulence" and damage to the arterial wall which increase the risk of thrombus formation and of restenosis. (D.I. 1054 at 648-49, 690-91)

12. The clinical experience with the Palmaz and Palmaz-Schatz stents is not consistent with any significant degree of twisting, as they have performed well with low restenosis rates. (D.I. 1052 at 277-79; D.I. 1054 at 648-49, 690-91)

13. By the early 1990s, Dr. Palmaz did not believe that the struts of the Palmaz and Palmaz-Schatz stents "inherently twisted" but believed, instead, that the surface of said stents, as expanded, was "substantially smooth." (D.I. 1054 at 656-60)

2. The '984 and '332 Patents

14. **Contention.** AVE and BSC contend that, during the prosecution of the '417, '984 and '332 "connected stent" patents, the patentees concealed and misled the United States Patent and Trademark Office ("PTO") regarding material "connected Z stent" art.

15. **Facts of record.** Dr. Palmaz became aware of connected Z stents in the mid-1980s and followed the work thereafter. (D.I. 1053 at 565-67) Dr. Schatz began working with Dr. Palmaz in the summer of 1985. (D.I. 1054 at 699) Starting in 1985, Dr. Palmaz shared with Dr. Schatz and with their counsel, Ben D. Tobor, articles on stenting. (Id. at 662-63, 699) By 1988, Mr. Tobor knew of the existence of journals such as Radiology and knew where he could access information for patent prosecution searches. (D.I. 1053 at 600) By the late 1980s, stent research had progressed to the point where research papers were presented by the character of the stent, as opposed to all stent research being grouped together. (Id. at 567)

16. **The '417 patent.** The application for the '417 patent was filed in March 1988. (PX 15, Tab 7) On March 26, 1988, Dr. Palmaz acknowledged his duty to disclose material information of which he was aware to the patent examiner. (Id., Tab 9)

17. In response to an office action rejecting claims 1-24 (Id., Tab 11), Mr. Tobor argued in February 1989 that:

> Applicant would agree with the Examiner's reasoning and basis for rejection if independent Claims 1 and 17 did not include the method step of "disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other." This step, and claim limitation, does not read merely on "adding additional prosthesis" as contended by the Examiner, but requires some physical connection between discrete prostheses or intraluminal grafts, the physical connection

being "at least one connector member." Thus, the issue is not whether or not it would be obvious to use a plurality of prostheses or intraluminal grafts, but whether or not it would be obvious to practice a method, which not only uses a plurality of prostheses, or grafts, but also physically connects adjacent prostheses, or grafts to one another with a connector member.

To illustrate this issue, Applicant would call Examiner's attention to U.S. Patent No. 4,580,568, issued April 8, 1986, in the name of C. Gianturco, for a percutaneous endovascular stent method for insertion thereof. . . . With respect to the Gianturco '568 patent, this patent teaches the use of a plurality of prostheses or stents, as shown in FIGS. 7 and 8. Applicant would agree that this patent provides a teaching of the use of multiple stents although Applicant seriously questions its efficacy and operability when using multiple stents. However, this is not to say that Gianturco provides a teaching or suggestion of Applicant's methods wherein a connector member is disposed between adjacent prostheses, stents, or intraluminal grafts.

The extensive number of references cited against Applicant's prior patents were virtually all brought to the attention of the prior Examiner by Applicant, and virtually all of the cited references relate to stents, prostheses, or intraluminal grafts. To the best of Applicant's knowledge, and the knowledge of the undersigned counsel, other than the Gianturco '568 patent, none of the other cited references in the Palmaz '762 and '665 patents utilize a plurality of stents, grafts, or prostheses in the methods disclosed in those patents and publications. But for the Gianturco '568 patent, it would appear that the art teaches away from using more than one prosthesis. With the Gianturco '568 patent, Applicant submits that the most that can be said is that one patent teaches the use of a plurality of stents; however,

> the stents are not connected by a connector member, nor are the plurality of stents inserted into the body passageway at the same time as in Applicant's method.

(PX 15, Tab 15 at 81-83; see also id., Tab 33 at 152)

18. By February 1989, multiple journal articles had been published regarding connected Z stents. (See PX 3207; AVEX 364; AVEX 359; AVEX 438; AVEX 671; AVEX 1953) At least one such article (PX 3207) was cited as a reference in a January 1988 article for which Drs. Palmaz and Schatz were given credit for authorship. (PX 4049) Dr. Palmaz was aware of these publications. (D.I. 1053 at 587-99)

19. Sometime in 1989, Dr. Palmaz forwarded to Mr. Tobor a copy of Yoshioka (AVEX 438) as a "pertinent reference" regarding a "stent graft idea," not in connection with the '417 patent prosecution. At the time, Dr. Palmaz did not believe that connected Z stent art was relevant to the '417 patent: connected Z stents had a stabilizer bar between the stents to add rigidity (i.e., to keep them in a rigid position and in place after delivery), while the connector of the '417 patented invention added flexibility. (D.I. 1054 at 664-68)

20. In May 1991, Mr. Tobor brought Yoshioka to the attention of the '417 examiner. Mr. Tobor declared that he did not believe the article was prior art, but was bringing it to the examiner's attention "out of an abundance of caution." The article was described by Mr. Tobor as follows:

> The enclosed article to Yoshioka, et al., discloses an arterial endovascular graft constructed by wrapping an expandable nylon mesh around a framework of Gianturco self-expanding metallic stents. "Three or four stents were connected in tandem by metallic struts constructed from the same wire."

(PX 15, Tab 48) Dr. Palmaz does not recall reading this declaration, although he may have been aware of the "argument." (D.I. 1053 at 574-81)

21. The '417 patent issued on April 7, 1992. (PX 15, Tab 58)

22. **The '984 patent.** The application for the '984 patent was filed in October 1988. (PX 16, Tab 10) On September 30, 1988, Dr. Schatz acknowledged his duty to disclose material information of which he was aware to the patent examiner. (Id., Tab 11)

23. The '984 patent was assigned to EGP. (Id., Tab 8) Drs. Palmaz and Schatz were two of the three partners of EGP. Although Dr. Palmaz was consulted about background literature and prior art identified in the '984 patent, he believed that it was Dr. Schatz's responsibility to fulfill the duties of full disclosure in connection with the '984 patent. (D.I. 1053 at 562-63)

24. In response to an office action rejecting claims 1-6 (PX 16, Tab 16), Mr. Tobor argued in February 1990 that

> Gianturco, the only reference known to Applicant which teaches the use of a

> plurality of grafts, or stents, has **at most** a teaching of the use of a plurality of stents; however, the stents are not connected by a connector member, flexible or otherwise, nor is any connector member, such as claimed in the present application, disclosed, taught or suggested.

(Id., Tab 22 at 523) (emphasis in original)

25. In December 1990, Mr. Tobor brought Yoshioka to the attention of the '984 examiner, stating:

> It is not believed that the enclosed publication is prior art as against the present application in that the publication date of the publication is "October 1988," and the present application was filed October 4, 1988.
>
> This publication discloses an endovascular stent graft consisting of an expandable nylon cylinder supported by a framework of self-expanding stents. "Three or four stents were connected in tandem by metallic struts constructed from the same wire. The first stent was the lead stent, which acted as an anchor for the graft."

(Id., Tab 36)

26. Dr. Schatz testified that he has no independent recollection of knowing about connected Z stent references prior to July 1991. (D.I. 1054 at 706-17; PX 3996)

27. The claims of the '984 patent were allowed in August 1992. (PX 16, Tab 62)

28. **The '332 patent.** The application for the '332 patent was filed in November 1992 as a continuation of the '984 patent.

(PX 17, Tab 4) Dr. Schatz resubmitted his September 30, 1988 declaration acknowledging his duty of disclosure. (Id., Tab 5)

29. In March 1993, in response to an office action rejecting claims, Mr. Tobor argued that Yoshioka

> does not disclose the subject matter for which the Examiner relies upon this article. All Yoshioka et al. has to say about connecting stents is that they "were connected in tandem by metallic struts constructed from the same wire." The article does not say how many metallic struts were utilized, where they were connected, their angular disposition, whether or not they were flexible, or any other details of construction. . . .
>
> Assuming that Yoshioka et al. can be used as a reference, the rejection is still deficient for the following reasons. Neither Wiktor nor Yoshioka et al. discloses a plurality of "thin-walled tubular members, each 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 each tubular member" and "only one connector member being disposed between adjacent tubular members to flexibly connect the adjacent members." . . .
>
> In summary, with respect to the rejection based upon Wiktor and Yoshioka et al., assuming Yoshioka et al. is properly available as a reference, neither of these references discloses the particular claimed tubular members which are flexibly connected by only one connector member as claimed by Applicant.

(Id., Tab 11 at 2845-46)

30. In October 1994, in connection with Patent Interference No. 103,432, Mr. Tobor argued that the claims of United States Patent No. 5,104,404, filed in June 1991 (the "Wolff patent") were unpatentable over Yoshioka:

> Yoshioka discloses a plurality of tubular shaped stents formed of stainless-steel wire, wherein "three or four stents were connected in tandem by metallic struts constructed from the same wire" as shown in Fig. 1. As seen in Fig. 1 of Yoshioka, a single wire is disposed between the stents to "hinge" the stent segments together. Accordingly, Yoshioka clearly anticipates all of the claims of the Wolff '404 Patent which correspond to Count 1.

(BSCX 6759 at 2-3) The Wolff patent describes, e.g., a number of stents connected together by hinges (the hinges can be either straight or coiled wire) welded in place to provide articulation between the stent segments.

31. On March 21, 1996, Dr. Schatz submitted a declaration in connection with Patent Interference No. 103,432 regarding Yoshioka:

> I have been informed that this article was publicly available prior to October 1988.
>
> Based upon my review of and study of the Yoshioka article and based upon my extensive experience in the design, testing and use of various stents, including the stents of Schatz Exhibit No. 1 and the '667 application and those of Schatz Exhibit No. 3, it is my opinion that the Yoshioka article, Schatz Exhibit No. 11, teaches, discloses, and describes an articulated self-expanding separate stent comprising at least two stent segments, each stent segment having a

> generally tubular shape . . ., and a hinge means extending between and connecting adjoining stent segments, whereby the stent segments may flex and articulate about said hinge means to provide support for curved blood vessels.

(PX 106 at 8-9) At the time Dr. Schatz submitted this declaration, he "assumed" that the bar connecting the two Z stents was flexible. (D.I. 1054 at 717-19) Dr. Palmaz never agreed with the above description. (Id. at 684)

32. On December 2, 1998, Mr. Tobor presented new independent claims 26, 37 and 46 that were "specifically drafted to cover certain commercial competitive products[25] and to avoid the issues of patentability raised during" Interference No. 103,432. (PX 17, Tab 32 at 2933-34) In this submission, Mr. Tobor addressed the "prior art and other materials identified and discussed during Interference No. 103,432," including Yoshioka. (Id. at 2938-39) Specifically, Mr. Tobor distinguished the connected Z stent references as follows:

> As the Examiner is well aware, it is improper to combine references unless there is some teaching or suggestion in the prior art for the contemplated combination. . . .
>
> During the above mentioned interviews, Examiner Brittingham recognized the differences between balloon expandable stents, like those of the present application, and self-expanding stents, like

[25]Certain of claims 26-36 were intended to cover AVE's MicroStent II and GFX stents, while certain of claims 46-54 were intended to cover BSC's NIR stent. (PX 17, Tab 32 at 2940)

> those of the connected Gianturco Z-stent publications, and expressly acknowledged that it would be improper to combine references relating to self-expanding stents with references relating to balloon expandable stents, because of such differences.
>
> There is clearly no teaching or suggestion to combine either the self-expanding stents disclosed in the connected Gianturco Z-stent publications or the coiled wire stent disclosed in the Wiktor patent with the stents disclosed in the Palmaz patents in a manner that would create the structures defined in claims 26, 37 and 46. The sole basis for any such combination is impermissible hindsight gleaned from applicant's disclosure of his invention. At the time of the invention, there was no suggestion or teaching to interconnect a plurality of balloon expandable, plastically deformable segments as defined in the claims in a manner that would permit the segments to be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of an access or coronary artery.

(Id. at 2942-43)

33. The claims of the '332 patent were allowed on December 22, 1998. (PX 17, Tab 37)

3. The '312 and '370 Patents

34. **Contention.** BSC contends that, during the prosecution of the '312 patent, the patentees failed to disclose a reference they knew, or should have known, would have been material to the PTO's consideration of the patent application.

35. **Facts of record.** The application for the '312 patent was filed in February 1994 by Robert E. Fischell, David R.

Fischell, and Tim A. Fischell. (PX 5003, Tab 9) Dr. Robert Fischell began working on the invention of the '312 patent in 1993 and, at that time, began collecting articles and patents about stents. (D.I. 1054 at 825, 843-46) Initially, Dr. Fischell prosecuted the patent himself. (PX 5003, Tab 9) At the time the '312 application was filed, Dr. Fischell had personally prosecuted more than twenty patents and was fully aware of the duty of disclosure. (D.I. 1054 at 830-31)

36. Only claim 8 of the '312 patent as originally filed mentioned longitudinals having an undulating shape. (PX 5003, Tab 8 at 26) By March 1995, amended claims 24, 26 and 27 described longitudinals having "an undulating shape" or "an undulating structure." (Id., Tab 20 at 66-67) The undulating feature was considered an important way of distinguishing the prior art. (D.I. 1054 at 838; *D.I. 196 at 526-27; *D.I. 197 at 818-19)

37. On July 17, 1995, the attorney prosecuting the European counterpart to the '312 patent, Morton J. Rosenberg, forwarded to Dr. Fischell the "Search Report from the European Patent Office." Mr. Rosenberg noted that

> the only reference which is stated as being particularly relevant to Claim 1 is European Patent Application #579523 whose inventor is Jean-Claude Sgro. We have made a Patentee Search to determine whether we have any corresponding patent in the United States but have come up negatively. It may pay us to

> make a translation from the French to determine if this is relevant.

(BSCX 11021)

38. As was the case with the original '312 application, the only claim in the European application which mentioned undulating longitudinals was claim 8. (BSCX 11413)

39. In addition to the Sgro reference, among the references mentioned in the European search report and forwarded by Mr. Rosenberg to Dr. Fischell was United States Patent No. 4,856,516 (the "Hillstead patent"), which was noted as a "Y" reference relevant to claim 8. (BSCX 10003, 10004) A "Y" reference is a reference that is particularly relevant if combined with another document of the same category. (D.I. 1055 at 959-64)

40. The Hillstead patent is directed to a stent constructed as described in claim 1 of that patent:

> A stent for reinforcing a vessel within a subject comprising a cylindrical support dimensioned to fit within an interior of said vessel constructed from an elongated wire bent to define a series of relatively tightly spaced convolutions or bends, said wire also bent in the form of a plurality of loops spaced along an axial dimension of the stent and connected by a series of half hitch junctions where each of the plurality of loops includes a number of said regularly spaced convolutions around its circumference, said stent being radially expandable from a first outer diameter which fits within said vessel to a second increased diameter which contacts an inner wall surface of said vessel to reinforce said inner wall.

(PX 5313, Ex. D, col. 4, lns. 37-50; BSCX 10045) According to the specification, the "resultant structure has a high degree of flexibility." (PX 5313, col. 2, ln. 21) Reproduced below is Figure 2A, displayed on the cover page of the Hillstead patent.

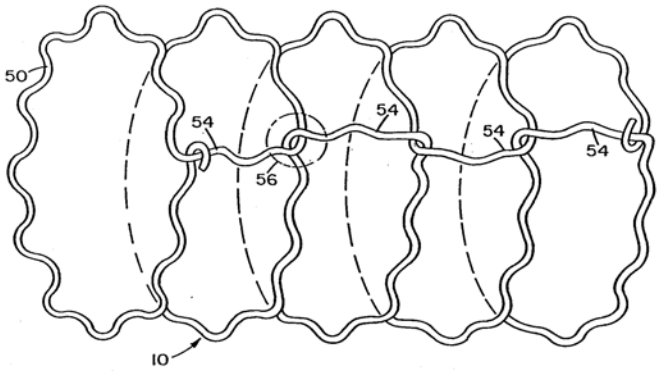

FIG. 2A

41. In December 1995, Dr. Fischell saw stents with undulating longitudinals at the Thorax Center Conference in Rotterdam. His exposure to such stents "heightened [his] perception of the value of claims on undulating longitudinal structures for stents because they enhance flexibility." (D.I. 1054 at 855-57)

42. Also in December 1995, the PTO informed Dr. Fischell that the file wrapper for the '312 patent application could not be located. (PX 5003, Tabs 22, 23) Dr. Fischell himself and through his newly hired attorney, Mr. Rosenberg (Id., Tab 25), submitted a duplicate file that had been maintained by Dr. Fischell. (Id., Tabs 21, 24) When the application submitted in

the duplicate file (Id., Tab 8 at 24) is compared with the original application (preserved by the PTO on microfilm), there is a difference of one sentence (emphasized below) contained in the latter and omitted from the former:

> It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-walled metal cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon. **Another method to form the pre-deployment stent is by etching the correct pattern onto a thin, flat metal plate, then forming a tube from that plate and then making a longitudinal weld to form a cylindrically shaped structure which is, in fact, the pre-deployment stent structure 20 shown in FIG. 9.**

(BSCX 12011 at 9) (emphasis added) As it happens, the NIR stent is made according to the method described in the emphasized language above.

43. In March 1996, the Fischells, through their company, IsoStent, Inc., entered into a collaboration agreement with Johnson & Johnson whereby Johnson & Johnson would fund IsoStent's stent development and would receive an option to buy IsoStent for more than $20 million. (D.I. 1054 at 854) By March 1996, the

Fischells had decided they wanted the claims of the '312 patent to cover all stents with undulating longitudinals, whether such stents had rings or not. (Id. at 857-58)

44. In June and July of 1996, the patentees filed a supplementary amendment, an information disclosure statement, and a list of patents and publications discussed in the information disclosure statement. (PX 5003, Tabs 29, 30 and 31) The supplementary amendment identified new claims 28 and 29 which featured undulating longitudinal structures. (Id., Tab 29 at 80) The references listed in the information disclosure statement were distinguished as not having undulating longitudinals. (Id., Tab 30 at 85-86) The Hillstead patent was not identified in any of these submissions. (Id., Tabs 30, 31)

45. An amendment was filed by Mr. Rosenberg in November 1996. (Id., Tab 36) Claims 1, 13, 15, 21, 22, and 23 were amended to add language requiring that the longitudinals of the stent have an "undulating shape" or an "undulating contour for enhancing longitudinal flexibility." (Id. at 99-102) The applicants distinguished the prior art, including the Sgro reference, on the ground that such art did "not provide for the undulating shape or contour of the 'longitudinals' of the subject Patent Application system." (Id. at 105-106)

46. The '312 patent issued on July 1, 1997. (PX 5003, Tab 1)

47. Through a series of transactions in 1998 and 1999, Cordis Corporation acquired certain assets of IsoStent and agreed to assume certain of IsoStent's obligations to the Fischells, including consulting agreements and royalty payments under, inter alia, the '312 patent. (BSCX 10953; D.I. 1054 at 830)

48. Dr. Fischell and Mr. Rosenberg testified that they did not look at the Hillstead patent until April 1998, despite both having copies of said reference in their respective files since at least July 1995. (D.I. 1054 at 849-50, 882-89, 914-16; D.I. 1055 at 955, 978-80, 995) The evidence indicates that neither took responsibility for conducting a prior art search directed to the added limitation of "undulating" longitudinals, despite their experience in the field and their focus on the limitation.

49. In May 1998, Dr. Fischell identified the Hillstead patent (along with some sixty other references) as relevant prior art in connection with the '370 patent. (D.I. 1054 at 889-90, 921-25; D.I. 1055 at 980; PX 5002, Tab 16 at 191)

B. Conclusions of Law, Pursuant to Fed. R. Civ. P. 52(a)

1. "Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). The duty to prosecute patent applications with candor, good faith, and honesty "rests on the inventor, on each attorney or agent who prepares or prosecutes an application and

on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application." Id. at 1178 n.6.

2. "The duty of candor extends throughout the patent's entire prosecution history. In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. 'Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it.' . . . Therefore, a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." Fox Indus., Inc. v. Structural Preservation Sys., Inc., 922 F.2d 801, 803-04 (Fed. Cir. 1991).

3. A charge of inequitable conduct includes within its scope "affirmative misrepresentation of a material fact, failure to disclose material information, or submissions of false material information, coupled with an intent to deceive." Molins PLC, 48 F.3d at 1178.

4. "A holding of inequitable conduct requires proof by clear and convincing evidence. This proof must include a threshold showing of both materiality and intent to mislead or

deceive the patent examiner." Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001) (citing Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 551 (Fed. Cir. 1990)).

5. "Information is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Molins PLC, 48 F.3d at 1179. A reference will not be considered material if it is not as relevant as that actually considered by the examiner or if it is merely cumulative of the information considered by the examiner. See id. "Information concealed from the PTO may be material even though it would not invalidate the patent. . . . As stated, the test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability." Li Second Family Ltd. P'ship, 231 F.3d 1373, 1383 (Fed. Cir. 2000), cert. denied, 533 U.S. 929 (2001).

6. "Intent" commonly means "a state of mind in which a person seeks to accomplish a given result through a course of action." Molins PLC, 48 F.3d at 1180 (citing Black's Law Dictionary at 810 (6th ed. 1990)). "Intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the

actor." Id. "For example, intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

7. "If the threshold requirements of materiality and intent are established, 'those fact findings are balanced to make the determination whether the scales tilt to a conclusion that inequitable conduct occurred.' . . . 'The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and visa versa.' . . . If, however, either materiality or intent is not found, then no further analysis need be performed and unenforceability must be denied.'" Monon Corp., 239 F.3d at 1261 (citations omitted).

8. "It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability." Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995). Disclosure of relevant prior art to the PTO during the course of another, subsequent patent prosecution "has no bearing on whether [the patentee] acted with deceptive intent during prosecution of the" application at issue. Li Second Family Ltd. P'ship, 231 F.3d at 1381.

9. "Because the adjudication of an inequitable conduct claim is an equitable determination, it is committed to the discretion of the trial court." Monon Corp., 239 F.3d at 1261.

10. **The '762 patent.** The court concludes that AVE and BSC have not carried their burden of proving by clear and convincing evidence that the patentee intended to deceive the PTO concerning a material fact. The "material fact" identified by AVE and BSC is that the struts of the Palmaz and Palmaz-Schatz stents "inherently twist." The patent examiner, however, started from that premise. The question before the court, therefore, is whether the submissions made by the patentee in response to the examiner's premise were materially false and meant to be so. The court finds neither to be the case. As evidenced by the record, whatever small degree of twisting that occurs upon expansion of the Palmaz and Palmaz-Schatz stents is meant to be minimized (as distinguished from the Ersek reference) and has been minimized by engineering and production solutions. The patentee believed at the time of the submissions, and continues to believe, that the outer surface of the Palmaz and Palmaz-Schatz stents is "substantially smooth" in the second diameter. Therefore, the threshold levels of materiality and intent have not been demonstrated by clear and convincing evidence. Even had AVE and BSC carried their burden of proof, it is the court's equitable

judgment that the patentee's conduct was not so culpable that the '762 patent should not be enforced.

11. **The '984 and '332 patents.** The court concludes that AVE and BSC have not carried their burden of proving by clear and convincing evidence that the patentee failed to adequately disclose material information — the connected Z stent art — to the PTO and intended to deceive the PTO in this regard. There is no question but that the connected Z stent art was before the PTO in all three related patents — the '417, the '984 and the '332 patents — before any of the patents issued. Although the patentee could have brought Yoshioka or a similar reference to the attention of the PTO earlier than he did, nevertheless, the PTO had the opportunity to consider the prior art before allowing any of the claims at issue. The fact that the patentee's arguments changed[26] over time does not demonstrate (in the court's view) an intent to deceive. Once again, even had the threshold levels of materiality and intent been demonstrated by clear and convincing evidence, in weighing materiality and intent, it is the court's equitable judgment that the patentee's conduct was not so culpable that the '984 and '332 patents should not be enforced.

[26]Initially, the focus was on whether any prior art disclosed connectors between a plurality of stents. Once such prior art references were found, the focus shifted to the type of connector (flexible or not) and the type of stent (balloon expandable or self-expanding).

12. **The ‘312 patent and ‘370 patents.** The court concludes that BSC has carried its burden to prove by clear and convincing evidence the threshold levels of materiality and intent with respect to nondisclosure of the Hillstead patent. By the time the ‘312 patent issued, the patentees considered the most significant invention disclosed in the ‘312 patent to be undulating longitudinals. The only prior art reference identified in the record that disclosed undulating longitudinals was the Hillstead patent. The patentees purposefully neglected their responsibility of candor to the PTO by “putting their heads in the sand” regarding prior art related to their newly added limitation. The court concludes that the threshold levels of materiality and intent have been demonstrated by virtue of the patentees’ increasing emphasis on undulating longitudinals during the course of the ‘312 patent prosecution and the fact that patentees knew, or should have known, that the Hillstead patent would be material to the PTO’s consideration of the ‘312 patent application. The court further concludes that the submission to the PTO of the Hillstead patent during the ‘370 patent prosecution has no bearing on whether the ‘312 patentees acted with deceptive intent during the ‘312 prosecution. The court finds that the ‘370 prosecution is tainted by the lack of candor exhibited during the ‘312 prosecution, since the Hillstead patent was submitted along with sixty other references and never

addressed by the patentees. In light of all the circumstances, the court concludes that the patentees' conduct was sufficiently culpable that the '312 and '370 patents should be held unenforceable.[27]

VII. CONCLUSION

For the reasons stated, AVE's motion for judgment as a matter of law is granted as to prosecution history estoppel on the "plurality of slots formed therein" limitation of claims 23, 51 and 54 of the '762 patent and claims 1 and 3 of the '984 patent. The parties' motions for a new AVE trial are denied as moot.

BSC's motions for judgment as a matter of law are granted as to prosecution history estoppel on the "substantially uniform thickness" limitation of claim 23 of the '762 patent and no literal infringement of claims 25 and 26 of the '370 patent, and denied as to all other issues. Cordis' motion for judgment as a matter of law against BSC is denied. BSC's motion for a new damages trial is granted.

The court finds that the '762, '984 and '332 patents are enforceable, and the '312 and '370 patents are unenforceable.

An appropriate order shall issue.

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[27]The court finds that BSC has failed to prove by clear and convincing evidence that the "missing sentence" in the '312 application was either material or intended to deceive the PTO.