

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIMED LIFE SYSTEMS, INC.,)
BOSTON SCIENTIFIC SCIMED, INC.,)
BOSTON SCIENTIFIC CORPORATION)
and MEDINOL, LTD.,)
)
Plaintiffs,)
)
v.) Civil Action No. 99-904-SLR
) (consolidated)
JOHNSON & JOHNSON, CORDIS)
CORPORATION and JOHNSON & JOHNSON)
INTERVENTIONAL SYSTEMS, INC.,)
)
Defendants.)

Josy W. Ingersoll, Esquire and Christian Douglas Wright, Esquire of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: George E. Badenoch, Esquire, Charles R. Brainard, Esquire, Walter E. Hanley, Jr., Esquire and Douglas E. Ringel, Esquire of Kenyon & Kenyon, New York, New York.

Steven J. Balick, Esquire and Steven T. Margolin, Esquire of Ashby & Geddes, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Gregory L. Diskant, Esquire, William F. Cavanaugh, Jr., Esquire, Michael J. Timmons, Esquire and Russell W. Faegenburg, Esquire of Patterson, Belknap, Webb & Tyler, LLP, New York, New York. Theodore B. Van Itallie, Jr., Esquire and Eric I. Harris, Esquire of Johnson & Johnson, New Brunswick, New Jersey.

MEMORANDUM OPINION

Dated: September 27, 2002
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiffs Scimed Life Systems, Inc., Boston Scientific Scimed, Inc., Boston Scientific Corporation and Medinol, Ltd. filed this patent infringement action on December 20, 1999 against defendants Johnson & Johnson, Cordis Corporation and Johnson & Johnson Interventional Systems, Inc. Plaintiffs allege that defendants infringed certain claims of United States Patent Nos. 5,733,303 (the "'303 patent"), 5,843,120 (the "'120 patent"), and 5,972,018 (the "'018 patent") (collectively, the "Medinol patents"). Defendants seek a declaratory judgment that the asserted claims of the Medinol patents are invalid and not infringed by their BX Velocity, Crown, Mini-Crown and Corinthian stents. The court held a two-week jury trial on the issues of infringement and invalidity. Currently before the court are plaintiffs' motion for judgment as a matter of law and motion for a new trial.

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 Medinol Patents

The Medinol patents, invented by Henry Israel and Gregory Pinchasik and assigned to Medinol, claim certain flexible expandable stents. The Medinol patents share the same drawings and essentially the same specification, and are described as continuations of a series of applications beginning with Application Serial No. 282,181 (the "'181 application"), filed on July 28, 1994, and continuations-in-part of Application Serial No. 213,272 (the "'272 application"), which was filed on March 17, 1994 and issued as United States Patent No. 5,449,373. The Medinol patents generally describe and illustrate stent designs that achieve the objectives of flexibility during delivery, compensation for foreshortening, continuous uniform scaffolding, and resistance to radial deformation and collapse upon expansion. Figure 8 of the Medinol patents is reproduced below. The stent displayed in Figure 8 is made up of a continuous network of

uniform closed cells 50, each of which has opposing horizontal loops 63 and 65 and flexible links 67 and 71.

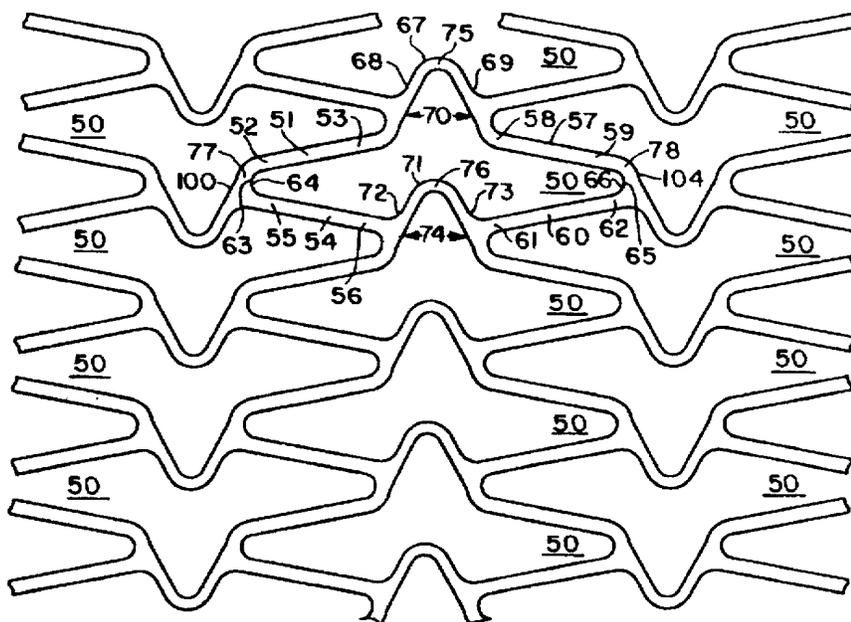


FIG. 8

1. The '303 Patent

The '303 patent issued on March 31, 1998 from Application Serial No. 457,354 (the "'354 application"), which was a continuation of the '181 application and a continuation-in-part of the '272 application. The claims of the '303 patent are directed to stents which have either: (1) flexible connected cells with a certain geometry or (2) meander patterns.

Claim 12 of the '303 patent is a claim which is dependent on claim 6. The claims read:

6. An expandable stent defining a longitudinal aperture, including:
a plurality of flexible connected cells, each of said flexible cells comprising:
- a) a first member having a longitudinal component having a first end and a second end;
 - b) a second member having a longitudinal component having a first end and a second end;
 - c) a third member having a longitudinal component having a first end and a second end;
 - d) a fourth member having a longitudinal component having a first end and a second end;
 - e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;
 - f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;
 - g) a first flexible compensating member or flexible link having a first end and a second end disposed between said first member and said third member, said first end of said first flexible compensating member or flexible link communicating with said second end of said first member and said second end of said first flexible compensating member or flexible link communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other.
 - h) a second flexible compensating member or flexible link having a first end and a second end disposed between said second member and said fourth member, said first end of said second flexible compensating member or flexible link

communicating with said second end of said second member and said second end of said second flexible compensating member or flexible link communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member or flexible links differentially extendable or compressible when said stent is bent in a curved direction away from the longitudinal axis of said aperture; and

- i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating member or flexible links disposed so that as said stent is expanded the distance between said first and said second flexible compensating member or flexible links increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the ends of said first and said second flexible compensating member or flexible links open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating member or flexible link and so as to increase said variable longitudinal distance between said first and said second ends of said second flexible compensating member or flexible link so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion.

12. The stent of claim 6, wherein said cells define a uniform cellular structure.

('303 patent, col. 7, lns. 1-65, col. 8, lns. 18-19)

The court construed disputed terms of the '303 patent as follows:

- (1) **"Stent."** A device, made of a body-compatible material, used to widen a blood vessel or other body opening (also called a "lumen"), and to maintain the resultant size of the blood vessel or lumen.
- (2) **"Cell."** An arrangement of structural elements that defines an enclosed space.
- (3) **"Member having a longitudinal component."** A "member" is a structural element that has its ends at different longitudinal positions with respect to the stent's longitudinal axis. A member's "longitudinal component" is the distance between the longitudinal positions of the first and second ends of the member.
- (4) **"Loop."** A structural element that turns back on itself.
- (5) **"First loop" and "second loop."** Horizontally-facing (or C-shaped) loops at the cell's two longitudinal ends.
- (6) **"Disposed between."** Positioned in the space that separates structural elements.
- (7) **"Disposed generally opposite."** The first and second loops, defined as horizontally-facing structural elements, are positioned across from each other and approximately aligned with each other along the longitudinal axis of the stent.

- (8) **"Flexible compensating member or flexible link."** A structural element that is flexible with respect to the stent's longitudinal axis and must be aligned along the longitudinal axis of the stent. A "flexible compensating member or flexible link" must connect adjacent cells, but the physical connection need not be made at points directly opposite each other.
- (9) **"Communicating with."** To have a common part, to be connected, join.
- (10) **"Said first and said second ends disposed a variable longitudinal distance from each other."** The flexible compensating member or flexible link is positioned so that, upon expansion of the stent, the distance between its two ends changes along the stent's longitudinal axis.
- (11) **"Disposed . . . so as to substantially lessen the foreshortening of said stent upon its expansion."** This limitation encompasses an increase in the distance between the longitudinal positions of the ends of the flexible compensating members or flexible links that is caused by expansion of the stent by a balloon or other mechanical means.
- (12) **"Uniform cellular structure."** The flexible connected cells of claim 6 have the same structure.

(D.I. 256)

2. The '120 Patent

The '120 patent issued on December 1, 1998 from Application Serial No. 881,594, a continuation of Application Serial No. 783,467 (the "'467 application"), which was a continuation of the '354 application. The claims of the '120 patent are all directed to stents with meander patterns.

Claim 13 of the '120 patent reads:

13. An expandable stent formed of an elongated cylindrical unitary tube suitable for insertion into a lumen or blood vessel in which it may be expanded, comprising: a plurality of first meanders extending in a first direction on the cylinder of the tube and a plurality of second meanders extending in a second direction, on the cylinder of the tube, wherein the first and second meanders are formed with loops and are interconnected such that at least one of the loops of each of the first meanders is disposed between each consecutive second meander to which the first meander is connected, and at least one of the loops of each of the second meanders is disposed between each consecutive first meander to which it is connected; the first and second meanders defining a plurality of enclosed spaces.

('120 patent, col. 7, lns. 13-26)

The court construed disputed terms of the '120 patent as follows:

"Meander." A periodic or repeating pattern of structural elements oriented about a center line. **"First meanders"** and **"second meanders"** identify and differentiate two different patterns.

(D.I. 256)

3. The '018 Patent

The '018 application issued on October 26, 1999 from Serial Application No. 026,999, which is a continuation of the '467 application. The claims of the '018 patent are directed to stents with meander patterns, cells or serpentine sections connected by flexible links. Claim 35 of the '018 patent reads:

35. A flexible, expandable stent, comprising:
a plurality of flexible cells provided with a plurality of first loops and a plurality of second loops, said first loops and said second loops disposed and adapted to cooperate so that upon the expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

('018 patent, col. 10, lns. 8-15)

Claim 47 of the '018 patent reads:

47. A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis including:
(a) a plurality of cells flexible around said longitudinal axis connected to one another about the circumference of said stent to form a band of flexible cells, each of said flexible cells having apices disposed apart and generally opposite to one another,
(b) each of said flexible cells having a plurality of flexible links disposed apart and generally opposite to one another,
(c) each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween, and

- (d) said flexible cells in said adjacent bands of flexible cells connected to one another.

('018 patent, col. 12, lns. 24-40)

Claim 60 of the '018 patent reads:

- 60. A stent having a longitudinal axis formed of a tube having a patterned shape, the patterned shape comprising:
 - a. first meander patterns having axes extending in a first direction;
 - b. second meander patterns having axes extending in a second direction, different than said first direction, wherein said second meander patterns intersect with said first meander patterns;
 - c. wherein said first meander patterns have loops;
 - d. wherein said first meander patterns are spaced apart to leave a portion of said second meander patterns between each pair of adjacent first meander patterns;
 - e. wherein each of said second meander patterns has at least one loop between at least one pair of adjacent first meander patterns; and
 - f. wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

('018 patent, col. 16, lns. 4-25)

The court construed disputed terms of the '018 patent as follows:

- (1) **"A plurality of first loops and a plurality of second loops."** Two sets of loops.

- (2) **"Disposed and adapted to cooperate so that upon expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.
- (3) **"Stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis."** The structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent.
- (4) **"Apices."** Points at the two longitudinal ends of a cell of a stent.
- (5) **"Plurality of flexible links."** Structural elements that serve to connect other structural elements but are themselves "disposed apart and generally opposite to one another."
- (6) **"Each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween."** The flexible links are loops.

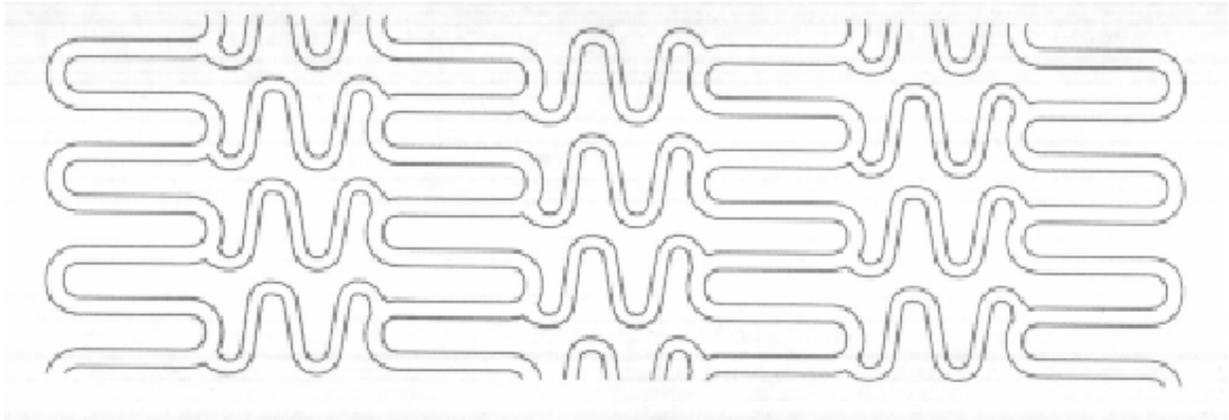
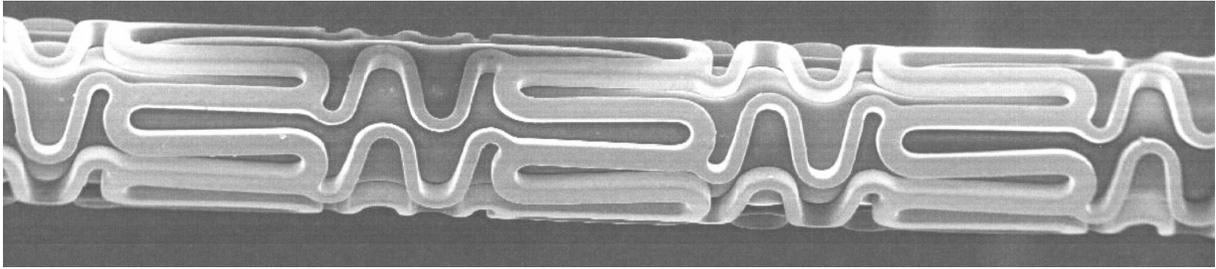
- (7) **"Wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The loops disposed on the first meander patterns and the loops disposed on the second meander patterns must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

(D.I. 256)

C. The Accused Devices

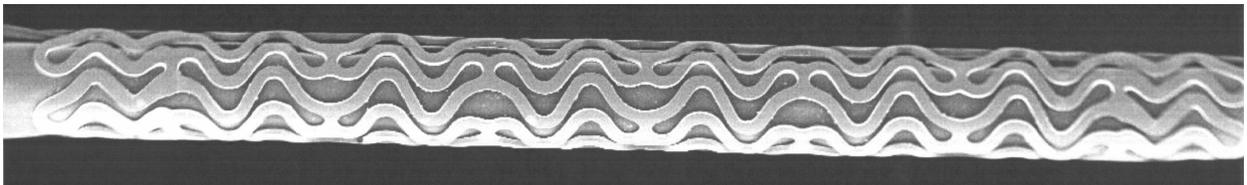
1. BX Velocity Stent

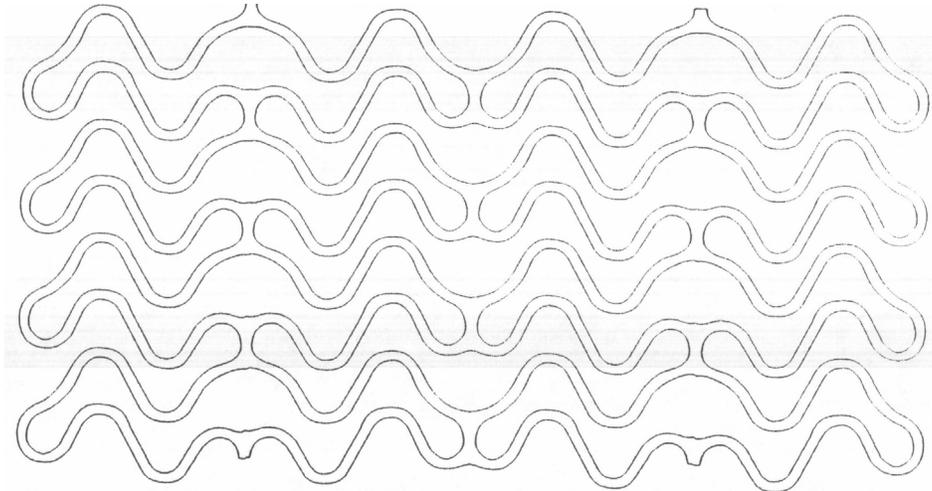
Defendants' BX Velocity stent is composed of closed flexible cells, each of which has opposing horizontal loops connected by flexible N-shaped regions. When the BX Velocity stent is expanded, the "N-regions" lengthen to compensate for the shortening of the stent. A photograph and schematic of the BX Velocity stent are shown below.



2. Crown and Mini-Crown Stents

Defendants' Crown and Mini-Crown stents are composed of a series of serpentine-ring structures which are fused together. A photograph and schematic of the Crown stent appear below.

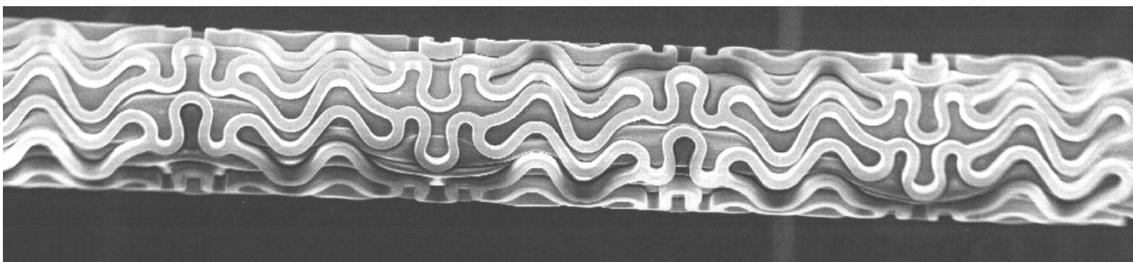


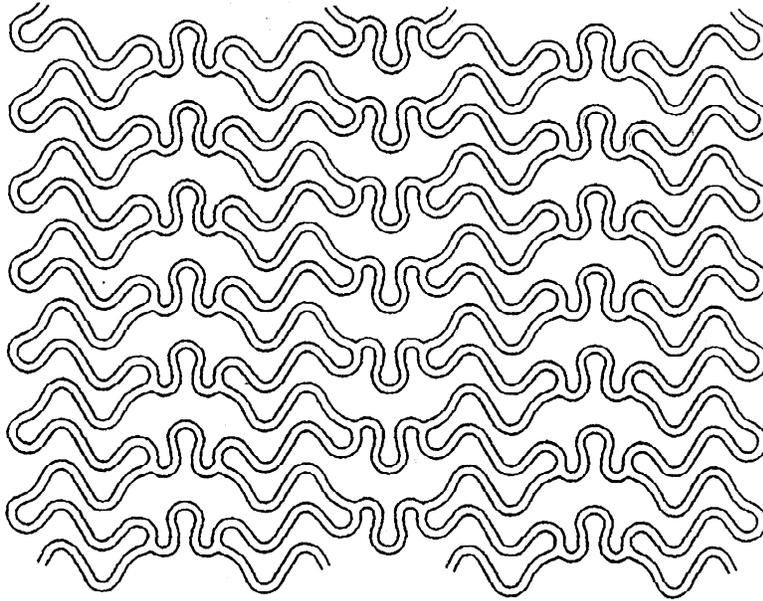


The Mini-Crown is based on the design of the Crown stent, but is scaled to treat coronary arteries with a smaller diameter. Thus, the Mini-Crown has fewer rows than the Crown and is cut from a smaller and thinner-walled tube.

3. Corinthian Stent

Defendants' Corinthian stent has a similar structure to the Crown stent, but is larger and is used in the biliary system and other peripheral arteries rather than in coronary vessels. A photograph and schematic of the Corinthian stent are reproduced below.





Defendants are not challenging the jury's verdict regarding infringement by the Corinthian stent.

D. The Jury Verdict

On September 7, 2001, after a two-week trial, a jury returned the following verdict regarding the parties' claims of infringement and invalidity:

(1) BX Velocity Stent

- (a) Claims 35, 47 and 60 of the '018 patent:
no literal infringement; no infringement under the doctrine of equivalents; did not address the reverse doctrine of equivalents

- (b) Claim 12 of the '303 patent: no infringement under the doctrine of equivalents¹
- (2) Crown and Mini-Crown Stents
 - (a) Claim 13 of the '120 patent: no literal infringement
- (3) Corinthian Stent
 - (a) Claim 13 of the '120 patent: literal infringement

The jury found all of the asserted claims invalid for both obviousness and failure to comply with the written description requirement except for claim 13 of the '120 patent, which the jury determined is valid. The jury also found that defendants' infringement was not willful, and awarded plaintiffs \$7,021,728 based on a 9% royalty rate for defendants' sale of the Corinthian stent in the United States, and \$1,279,556 based on a 7% royalty rate for defendants' foreign sales of the Corinthian stent manufactured in the United States. (D.I. 259)

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

¹The court previously found that the BX Velocity stent does not literally contain the "communicating with" limitation of claim 6 of the '303 patent. (D.I. 227) Thus, the BX Velocity stent cannot literally infringe claim 12, which depends from claim 6.

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 (1993); LifeScan Inc. v. Home Diagnostics, Inc., 103 F. Supp.2d 345, 350 (D. Del. 2000) (citations omitted). See also 9A Wright & Miller, Federal Practice and Procedure § 2531 (2d ed. 1994) ("On a motion for new trial the court may consider the credibility of witnesses and the weight of the evidence."). Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584-85 (D.N.J. 1997) (citations omitted). The court must proceed

cautiously, mindful that it should not simply substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. Rather, the court should grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand. See Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1352 (3d Cir. 1991); EEOC v. State of Del. Dep't of Health and Soc. Servs., 865 F.2d 1408, 1413 (3d Cir. 1989).

IV. DISCUSSION²

A. Infringement by the BX Velocity Stent

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

²Plaintiffs challenge the court’s construction of several limitations contained in the claims of the Medinol patents. The court went through the claim construction exercise prior to trial and declines to readdress its conclusions in this opinion.

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. Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquishes subject matter during the prosecution of the patent, either by amendment or argument. See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1376-77 (Fed. Cir. 1999); Dawn Equip., 140 F.3d at 1016.

1. "Flexible Compensating Member or Flexible Link"

Plaintiffs argue that defendants misinterpreted the court's claim construction and prejudiced the trial when they characterized the N-regions of the BX Velocity stent as "diagonal." Prior to trial, the court construed the limitation "flexible compensating member or flexible link" to require that the element "be aligned along the longitudinal axis of the stent." (D.I. 228) The court also denied plaintiffs' motion for summary judgment of literal infringement and, in doing so, limited the range of equivalents of "flexible compensating member or flexible link" to exclude connectors that join non-adjacent cells.³ (D.I. 227) At trial, defendants conceded that the BX Velocity stent's N-regions connected adjacent cells and, therefore, did not present the issue of prosecution history estoppel to the jury. Instead, defendants based their non-infringement argument solely on the court's claim construction – that the "flexible compensating member or flexible link" in claims 12 and 47 must be "aligned along the longitudinal axis of

³The court determined that plaintiffs surrendered all elements that connect non-adjacent cells when they distinguished United States Patent No. 5,102,417 during prosecution of the Medinol patents. (D.I. 227 at 7)

the stent.”⁴ At trial, defendants presented the following testimony by Dr. Nigel Buller, defendants’ medical expert:

Q. Now let’s take a look at the flexible link requirement. This requires a flexible compensating member or flexible link, and the Court has given the following definition of flexible link: A structural element that is flexible with respect to the stent’s longitudinal [axis] and must be aligned along the longitudinal [axis] of the stent. A flexible compensating member or flexible link must connect adjacent cells, but the physical connection need not be made at points directly opposite each other.

⁴The Federal Circuit has emphasized the difference between claim construction and prosecution history estoppel:

There is . . . a clear distinction between following the statements in the prosecution history in defining a claim term, and the doctrine of prosecution history estoppel, which limits expansion of the protection under the doctrine of equivalents when a claim has been distinguished over relevant prior art. Claim interpretation in view of the prosecution history is a preliminary step in determining literal infringement, while prosecution history estoppel applies as a limitation on the range of equivalents if, after the claims have been properly interpreted, no literal infringement has been found. The limit on the range of equivalents that may be accorded a claim due to prosecution history estoppel is simply irrelevant to the interpretation of those claims.

Southwall Techs., 54 F.3d at 1578. Although defendants’ application of the court’s claim construction was not anticipated by either the court or plaintiffs, defendants crafted their non-infringement case on a legally-permissible basis. Thus, the court shall deny plaintiffs’ motion for a new trial on the ground that defendants’ “diagonal” arguments misled and confused the jury, resulting in inconsistent verdicts.

Does the diagonal connector of the BX Velocity constitute a flexible link under this definition?

A. No.

Q. Why not?

A. Because, quite simply, because it is not aligned along the longitudinal [axis] of the stent. The BX Velocity's connector runs diagonally or spirally and, therefore, is clearly not aligned with the longitudinal [axis] of the stent.

Q. How many requirements do you understand that the Court's definition imposes on the definition of flexible link?

A. Two.

Q. Which are they?

A. The first sentence and the second sentence.

Q. Does BX Velocity meet the definition of the first sentence?

A. No.

Q. Is it aligned along the long - is its connector aligned along the longitudinal [axis] of the stent?

A. No. The connector is not aligned along the longitudinal [axis]. It runs diagonally or spirally.

(D.I. 271 at 1691-92) Thus, defendants presented sufficient evidence that the BX Velocity stent does not literally contain the "flexible compensating member or flexible link" limitation.

Dr. Buller also testified as to why the BX Velocity stent does not contain the "flexible compensating member or flexible link" limitation by equivalence:

Q. Now let's talk about the doctrine of equivalents. Do you have an opinion as to whether the flexibility connector or flexible link . . . of the BX Velocity, about whether or not it is substantially different from the structures disclosed in the patent and claim?

A. Yes. The spiral connectors of the BX Velocity are substantially different from the connectors shown in the patents.

Q. And why are they substantially different?

A. Because they are spirally oriented. They are diagonally or spirally oriented. By virtue of that they cause twisting, which was specifically excluded in the patents in the Cordis case.

Q. What is the function of the flexible link or loop of Figure 7 which we're showing model the claims of the patent?

A. The function of the loop in the NIR stent or in this patent figure is to bring about flexibility in the stent without there being any twisting. And this is a generally longitudinal connector. It connects along points of alignment along the stent. Its function is flexibility, but it musn't bring about any twisting as a result.

Q. Does the connecting of the BX Velocity serve the same function?

A. No. It does not serve the same function. It serves an entirely

different function by bringing about twisting and by virtue of this arrangement bringing about increased flexibility. It does it in an entirely different way. That is to say, that it brings about twisting of the stent as one of its features and it has an entirely different result.

Q. Do you have an opinion as to whether or not the flexible link or loop in the BX Velocity is a substantial change?

A. It is most certainly a substantial change. It is changing diagonal or helical connector, that has very many benefits as a result of this change to spiral orientation.

Q. Let me show you the design path again. Does this have any bearing in your analysis as to whether the diagonal connectors of the BX Velocity is a substantial change from the patents in suit?

A. Yes. In the patents in suit, there is a conventional generally longitudinal connector, which was conventional wisdom at the time. The design for the BX Velocity rejected this conventional wisdom and, instead, went towards a diagonal or spiral connector. It accepted the twisting and, indeed, found there were many features as a result of this and, indeed, the final design was for diagonal or spiral connectors that were all in alignment along the length of the stent.

(Id. at 1695-98)

The court concludes that defendants presented sufficient evidence for a reasonable jury to determine that the BX Velocity stent does not contain the "flexible compensating member or

flexible link" limitation of claims 12 and 47 either literally or by equivalence, regardless of whether its N-regions connect adjacent cells.

2. "Communicating With"

The court also finds that there was sufficient evidence in the record to support a reasonable jury's conclusion that the BX Velocity stent does not contain the "communicating with" limitation of claim 12 of the '303 patent by equivalence. Dr. Buller testified that the BX Velocity stent's connector

communicates not with the third member at all but, in fact, with what you could label as the fourth member of the cell above. So once again, it is clearly showing that the connector in the BX Velocity stent is diagonally or spirally orientated. It goes from the first member of this cell to what is, in effect, the fourth member of the cell above and doesn't connect at all with the third member of the cell in question.

(Id. at 1690-91) Dr. Buller further explained that the function of the BX Velocity stent is substantially different than the function of the "communicating with" limitation, namely, that the BX Velocity stent used twisting to gain increased flexibility, whereas there is no twisting intended by the "communicating with" limitation of claim 12. (Id. at 1696-97) Thus, the jury could have arrived at its conclusion that the BX Velocity stent does not infringe claim 12 of the '303 patent by finding either that it does not contain the "flexible compensating member or flexible link" limitation or the "communicating with" limitation.

3. Compensation for Foreshortening

The court finds that defendants also presented sufficient evidence for a reasonable jury to conclude that the BX Velocity stent does not compensate for foreshortening as required by claims 35 and 60 of the '018 patent, i.e., that the connecting loop of claim 35 and the meander pattern of claim 60 are not "generally horizontal or longitudinal." At trial, Dr. Buller testified that the connectors of the BX Velocity stent "run diagonally or spirally" and function differently by causing twisting of the stent. (Id. at 1695-97) Because the jury could have found that the BX Velocity stent does not compensate for foreshortening either literally or by equivalence, the court concludes that the jury reasonably determined that the BX Velocity stent does not infringe claims 35 and 60 of the '018 patent.

4. "Substantially Uniformly Flexible"

Finally, the court finds that the jury could reasonably have determined that the BX Velocity stent does not infringe claim 47 of the '018 patent because it does not contain the "substantially uniformly flexible" limitation of claim 47 either literally or by equivalence. At trial, Dr. Buller gave the following testimony regarding claim 47:

Q. Let me direct your attention to the substantially uniform requirement of Claim 47. Claim 47 also requires a stent which is substantially uniformly

flexible with respect to its longitudinal [axis]. And the Court has defined this to say that the structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal [axis] of the stent.

Does the BX Velocity infringe that claim element?

A. No.

Q. Why not?

A. Because in the BX Velocity, the flexibility is very dominantly in the zone of flexible connectors. So moving along the stent as a whole, one first of all meets a relatively inflexible zone, followed by a very flexible zone and the flexible links, inflexible, very flexible, inflexible, very flexible. So all along the wave of the stent, the flexibility is in discrete bounds and isn't uniform along the stent

Q. Does the BX Velocity infringe the substantially uniform stent requirement of Claim 47?

A. No.

(Id. at 1693-94)

Thus, the jury could have found that the BX Velocity stent does not infringe claim 47 of the '018 patent because it does not contain the "flexible compensating member or flexible link" limitation or the "substantially uniformly flexible" limitation.

B. Infringement by the Crown and Mini-Crown Stents

The court concludes that substantial evidence supports the jury's verdict that the Crown and Mini-Crown stents do not infringe claim 13 of the '120 patent. Dr. Buller described the Crown stent as having "first meanders" that run longitudinally along the length of stent and are simply connected at certain points. He testified that the Crown stent does not contain "second meanders" as required by claim 13, nor does it contain any "loops" between two sets of meanders, also required by the claim. (Id. at 1702-04) Although plaintiffs characterized the structure of the Crown stent differently, the jury was entitled to accept defendants' interpretation of the Crown and Mini-Crown stents. Thus, the court finds that the jury's verdict as to infringement by the Crown and Mini-Crown stents was supported by substantial evidence, and plaintiffs are not entitled to judgment as a matter of law on this issue.

C. Invalidity For Failure to Comply with the Written Description Requirement

Plaintiffs challenge the jury's verdict that the asserted claims of the '303 and '018 patents are 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, defendants were 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).

Defendants' evidence of invalidity of claims 12, 35, 47 and 60 for failure to comply with the written description requirement is essentially based on one exchange between defendants' counsel and Dr. Buller at trial:

Q. One final point, Dr. Buller. I want to just briefly address what is called the written description requirement. Do you have an opinion as to whether the specification – let me state the requirement.

The question I am going to ask you about is whether the specification of the patents in suit show that the inventor

actually possessed what he claimed at the time of the invention.

You understand that Medinol and Boston claim that the patents in suit include the diagonal connector of the BX Velocity. If that is so, do you have an opinion as to whether the specification of the patents in suit demonstrate that the inventor possessed such an invention?

- A. No. The inventor clearly didn't possess this invention. I think it is very clear from reading the patents that the inventor specifically excluded a diagonal or spiral connector, because of their very great concern about twisting. So not only did they not include this design within their patents, they very specifically excluded it and said, we are not interested in something that would cause twisting.

(D.I. 271 at 1724)

The court finds that defendants did not present clear and convincing evidence such that a reasonable jury could conclude that the claims are invalid for failure to comply with the written description requirement. The claims do not encompass a connector that connects non-adjacent cells (determined by the court during the prosecution history estoppel analysis), nor do they cover the "diagonal" connectors of the BX Velocity stent which function by twisting (determined by the jury during the infringement analysis). Defendants maintain that there is some "middle ground" where the claims are broader than the specification (which declares that the invention aims to avoid

twisting) but not broad enough to encompass the BX Velocity stent. The court finds that defendants have failed to present clear and convincing evidence of this "middle ground" at trial. Therefore, the court shall grant plaintiffs' motion for judgment as a matter of law as to the invalidity of claims 12, 35, 47 and 60 based on failure to comply with the written description requirement.

D. Invalidity for Obviousness

Plaintiffs move for judgment as a matter of law that the asserted claims of the '303 and '018 patents are not invalid for obviousness. To establish that a patent claim is obvious, it must be shown by clear and convincing evidence, that "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). The question of obviousness turns on four factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicators of non-obviousness, such as commercial success. See Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1582 (Fed. Cir. 1996).

The existence of each limitation of a claim in the prior art does not, by itself, demonstrate obviousness. Instead, there

must be a "reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success." Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1353 (Fed. Cir. 1999). "Such a suggestion or motivation may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved." Id. at 1356.

"The burden of showing, by clear and convincing evidence, the invalidity of patent claims is especially difficult when the prior art was before the PTO examiner during the prosecution of the application." Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1467 (Fed. Cir. 1990).

"Objective evidence of non-obviousness may be used to rebut a prima facie case of obviousness based on prior art references." Tec Air, Inc. v. Denso Mfg. Mich, Inc., 192 F.3d 1353, 1360 (Fed. Cir. 1999). In determining whether an invention is non-obvious, there are at least nine objective factors, i.e., "secondary considerations" that may be considered: (1) a long-felt and unmet need in the art for the invention; (2) failure of others to achieve the results of the invention; (3) commercial success of the invention; (4) copying of the invention by others in the field; (5) whether the invention was contrary to accepted wisdom

of the prior art; (6) expression of disbelief or skepticism by those skilled in the art upon learning of the invention; (7) unexpected results; (8) praise of the invention by those in the field; and (9) independent invention by others. See Graham, 383 U.S. at 17-19; Ruiz v. A.B. Chance Co., 234 F.3d 654, 667-68 (Fed. Cir. 2000).

The court finds that defendants presented substantial evidence to support a reasonable jury's conclusion that claims 12, 35, 47 and 60 would have been obvious to one of ordinary skill in the art in July 1994, the time the inventions described in those claims were made.

First, defendants presented numerous prior art references available in July 1994 that disclosed key features of the inventions in the asserted claims of the '303 and '018 patents, namely, the use of serpentine rings to provide radial strength upon expansion (DX 6, 7, 8, 9, 18, 1172; D.I. 268 at 924-31; D.I. 270 at 1536-40, 1547-54; D.I. 271 at 1909-12, 1915), the use of flexible connectors to provide flexibility to the stent upon insertion (DX 8, 13, 36; PX 22; D.I. 268 at 945, 955-57; D.I. 270 at 1557-62, 1567-77, 1582-84), the use of flexible cells and multiple connectors to improve scaffolding (DX 8, 13, 18; PX 22; D.I. 270 at 1577-79, 1617-19; D.I. 271 at 1712), and compensation for foreshortening. (D.I. 271 at 1712, 1921)

Defendants then compared the prior art to the limitations of the claims and demonstrated that there was a motivation among those of ordinary skill in the art to place flexible, looped connectors between pairs of individual serpentine rings to maintain radial strength yet enhance flexibility. (DX 8, 13, 18, 36; PX 22; D.I. 268 at 956-65; D.I. 270 at 1557-62, 1567-77, 1582-84; D.I. 271 at 1710-12) Defendants also presented evidence that it would have been obvious for a person of ordinary skill in the art to increase the number of connectors around a stent to improve scaffolding. (DX 8, 13; PX 22; D.I. 270 at 1578-79; D.I. 271 at 1712) Specifically, defendants offered testimony that the necessary result of a combination of serpentine rings with looped connectors was that the rings would shorten longitudinally and the looped connectors would open to compensate for foreshortening, the feature upon which plaintiffs rested their non-obviousness argument at trial. (D.I. 268 at 1001-06; D.I. 269 at 1498-1501; D.I. 271 at 1712, 1921)

In addition, defendants demonstrated the lack of secondary considerations of non-obviousness, including the absence of a long-felt need for a stent that compensates for foreshortening (D.I. 267 at 649-53; D.I. 269 at 1476-78, 1498-1500), the success of the flexible Multi-Link stent, which is based on a patent that constitutes prior art to the Medinol patents (D.I. 266 at 621; D.I. 270 at 1546-51; DX 18), and independent invention of the

stents encompassed by the asserted claims by others. (D.I. 271 at 1718-24; DX 12)

The record reflects substantial evidence that supports the jury's finding by clear and convincing evidence that the asserted claims of the '303 and '018 patents are invalid for obviousness over the prior art. Thus, the court shall deny plaintiffs' motion for judgment as a matter of law on this ground.⁵

V. CONCLUSION

For the reasons stated, plaintiffs' motion for judgment as a matter of law is granted in part and denied in part. Plaintiffs' motion for a new trial is denied. An appropriate order shall issue and judgment shall be entered accordingly.

⁵Plaintiffs' motion for a new trial based on an inconsistent jury verdict on obviousness is denied. Claim 13 of the '120 patent has an additional limitation, i.e., that the stent must have "at least one of the loops of each of the first meanders disposed between each consecutive second meander to which the first meander is connected" over claim 60 of the '018 patent. This supports the jury's verdict that claim 13 is not invalid for obviousness whereas claim 60 is invalid.