IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC, |))) | | |
|----------------------------------------------------------------------|-------------|----------|-----------|
| Plaintiffs, |)) | | |
| V . |)) | Civ. No. | 98-80-SLR |
| ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORP., |))) | | |
| Defendants. |)) | | |

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MEMORANDUM OPINION

Dated: January 5, 2005 Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Medtronic AVE ("Medtronic") filed suit against Advanced Cardiovascular Systems, Inc. ("ACS") on February 18, 1998, alleging patent infringement of U.S. Patent Nos. 5,292,331 and 5,674,278 (the "Boneau patents"), breach of contract, trade secret misappropriation, unfair competition, restoration of property wrongfully acquired, conversion, declaratory relief, and equitable claims. (See D.I. 1) Specifically, Medtronic alleges that ACS and Guidant infringe the Boneau patents by manufacturing, using, selling, offering for sale, and importing Multi-Link stents in the United States. (Id. at ¶2) Medtronic also contends that ACS wrongfully acquired and is misusing its stent technology to develop and to patent balloon expandable stents.¹ In this regard, Medtronic seeks a declaratory judgment that its stents do not infringe ACS's patents ("the Lau patents") relating to balloon expandable stents.

On March 30, 1998, ACS answered the complaint denying Medtronic's allegation and asserting a variety of affirmative defenses including the "first-to-file" rule, noninfringement, estoppel, invalidity, statute of limitations, laches, and federal preemption. (See D.I. 8) ACS amended its answer on June 15,

 $^{^{1}\}mathrm{ACS}$ holds the Lau patents, U.S. Patent Nos. 5,421,955, 5,514,154, and 5,603,721 relating to balloon expandable stents. (Id. at \P 3)

1998 to add an additional affirmative defense of inequitable conduct (D.I. 24 at $\P\P$ 113, 114) and to assert invalidity counterclaims as to the Boneau patents. (D.I. 24 at $\P\P$ 5, 6)

Due to its similarity to other actions involving the Boneau patents, namely Civil Action Nos. 98-80-SLR and 98-478-SLR, this case will be tried with both of these cases.

The patents in suit are the Boneau Patents, United States Patent Nos. 5,292,331 ("the '331 patent"), 5,674,278 ("the '278 patent"), 5,879,382 ("the '382 patent"), 6,344,053 ("the '053 patent"), and the Lau Patents, United States Patent Nos. 5,514,154 ("the '154 patent"), 5,603,721 ("the '721 patent"), 5,735,893 ("the '893 patent"), 6,056,776 ("the '776 patent"), 6,066,167 ("the '167 patent"), 6,066,168 ("the '168 patent"), 6,432,133 ("the '133 patent").

The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201(a). Pending before the court are the parties' motions for summary judgment with respect to infringement and validity. (D.I. 400, 402, 404, 406, 408, 410, 414, 426)

II. BACKGROUND

A. Patents In Suit

The Boneau patents share a common specification, that of the '331 patent, because they are all continuations of the '331 patent. The Lau patents, held by ACS, share a common

specification, that of the '154 patent.² Some of the Lau patents at issue have already been subjected to judicial review, e.g., the Southern District of Illinois has considered the '154, '721 and '893 patents. <u>See Advanced Cardiovascular Sys. Inc. v.</u> <u>Scimed Life Sys., Inc.</u>, No. IP98-1108-CH/G (S.D. Ind.). In addition, an infringement suit involving the '154 and '167 patents was arbitrated in 2002. In both instances certain claims or portions of claims were construed by either the court or the arbitration panel.

B. Medtronic Products

The Boneau patents, held by Medtronic, claim endovascular support devices that are generally used in the treatment of cardiovascular disease. The Boneau stents are balloon expandable stents, in that they are delivered to affected vessels via balloon catheters and, once in place, are expanded to support the vessel. (See, e.g., '331 patent, col. 3, 11. 19-67, col. 4, 11. 1-4) These stents are comprised of substantially straight segments that are connected at their ends to form peaks. (D.I. 541) A Boneau stent can be used alone or in multiples to treat an affected area.

²The '721 patent is a divisional of the '154 patent, the '893 patent is a divisional of the '721 patent, the '167 patent is a divisional of a non-asserted patent that is a divisional of the '893 patent, the '776 patent is a divisional of the '168 patent which is a divisional of the '893 patent. The '133 patent is a continuation of a non-asserted patent that is a divisional of the '776 patent.

Medtronic's S7 and Driver stents are also balloon expandable stents used to treat cardiovascular disease. They are comprised of multiple sinusoidal elements oriented out of phase; the tips of the adjacent rings are welded together to form a stent. (D.I. 436 at Ex. 2, Fig. 20.1; D.I. 411 at 4) The welding process does not require the addition of any metal material; the adjacent rings are simply melted together. (D.I. 411 at 5) The sinusoidal elements of both the S7 and Driver stents have a length less than their diameters. (D.I. 436 at Ex. 5 at 182-83, Ex. 7, Ex. 8 at AVEA851584)

C. ACS's Products

The Lau patents also claim endovascular support devices that are used in the treatment of cardiovascular disease. ACS's stents are balloon expandable devices that are formed from a metal tube. (D.I. 427 at 4) These stents are comprised of multiple circular elements that are connected together by connecting elements. Id.

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no

genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial." Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Literal Infringement

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

1. Infringement of the Boneau Patents By ACS

The court construed the contested terms of the Boneau patents in suit after considering oral arguments and the various motions on the issue of claim construction. The asserted claims are applied in the following analysis in light of the court's construction of the disputed terms. (D.I. 541)

ACS argues that none of its accused products³ infringe any of the Boneau patents, either literally or under the doctrine of equivalents. (D.I. 426) Medtronic argues for partial summary judgment that the accused ACS stents literally infringe claim 1 of the '382 patent and claim 27 of the '053 patent. (D.I. 414)

a. Literal Infringement of the '331 Patent

The court finds that the accused ACS stents do not literally infringe claim 1 of the '331 patent because none of them have substantially straight segments that extend from one end of the stent to the other.

b. Literal Infringement of the `278, `382 and `053 Patents

All of the asserted claims of the '278, '382 and '053 patents cite some form of a stent member as an element of the Boneau invention.⁴ Based on the written description of the

³Medtronic accuses the Multilink, Solo, Duet, Tristar, Tetra, Penta, Zeta, Vision, Pixel, Ultra, Omnilink, Megalink, and Herculink stents of infringement. (D.I. 269)

⁴Claim 1 of the `278 patent and claims 8 and 16 of the `053 patent refer to stent members as "circular members." Claim 1 of

Boneau patents, the court has construed all of these terms to mean "stent," or "a device implanted to maintain the patency of a vessel." (D.I. 541) ACS's accused stents are all formed from a series of short circular elements that are connected together by connecting elements. (D.I. 427 at 3-4) Medtronic argues that these circular elements are essentially stent members.

The circular elements of ACS's stents, however, are not used or marketed individually as stents. For support of its argument, Medtronic cites the deposition of Dr. Wagoner. Dr. Wagoner testified that "it would be speculation on his part really to say whether [a circular element] could or could not [maintain the patency of a vessel]." Medtronic also cited Dr. Vito's deposition testimony, in which Dr. Vito states there is no "engineering reason" why a "short stent" could not be used in small arteries. However, Dr. Vito refused to cite what was a "short stent." Medtronic has not provided evidence that these individual circular elements could be implanted in a vessel and maintain its patency. Therefore, the accused ACS stents do not literally infringe the Boneau patents because they do not have any stent members as construed by the court.

2. Infringement of the Lau Patents By Medtronic

the '382 patent refers to them as "stent members." Claim 1 of the '053 patent refers to them simply as "rings" and claim 27 of the '053 patent refers to them as "endovascular support members."

The court construed the contested terms of the Lau patents in suit after considering oral arguments and the various motions on the issue of claim construction. The asserted claims are applied in the following analysis in light of the court's construction of the disputed terms. (D.I. 542)

ACS argues that Medtronic's S7 and Driver stents literally infringe claim 1 of the '133 patent.⁵ (D.I. 401) Medtronic argues that none of its products infringe any of the Lau patents at issue because its stents do not have connecting elements. (D.I. 411)

a. A Longitudinally Flexible Stent

As construed by the court, this phrase requires that the stent be flexible along its longitudinal axis to facilitate delivery through tortuous body lumens. From the evidence of record, it is clear that the S7 and Driver stents are

wherein each of the cylindrical elements has a diameter and a length, the length of each cylindrical element being less than the diameter of the cylindrical element upon inflation of the expandable member; and

⁵Claim 1 of the **`**133 patent reads:

A longitudinally flexible stent, comprising:

 a plurality of interconnected cylindrical elements
 aligned along a stent longitudinal axis, each
 cylindrical element having a shape configured to
 enable the cylindrical element to expand with the
 inflation of the expandable member disposed
 disposed therein;

the cylindrical elements having a length less than 2.5mm.

longitudinally flexible; Medtronic has admitted as much. (See, e.g., D.I. 436 at Ex. 3, AVEA600220) Medtronic has not admitted, however, that its stents are flexible enough to be delivered through tortuous body lumens. ACS's experts, Dr. Segal and Dr. Kahn, reported that, in their experience, the accused Medtronic stents were flexible enough to allow delivery through tortuous body lumens. (D.I. 436 at Ex. 11, Ex. 12) Medtronic has not cited evidence to counter these expert opinions. Thus, the court concludes that, with respect to this limitation, Medtronic has not carried its burden of showing that there is a geniune issue for trial.

b. Interconnected

As construed by the court, "interconnected" means "connected." It is undisputed that the accused Medtronic stents have connected elements. (D.I. 411 at 4)

c. Cylindrical Elements

As construed by the court, cylindrical elements are radially expandable segments of a stent having a longitudinal length less than its diameter with a circumferential undulating pattern. The court further construes "undulating pattern" to mean "a wavelike pattern that includes any combination of U-shaped, W-shaped or Yshaped members." The evidence indicates that the accused Medtronic stents have cylindrical elements that expand radially outward. (D.I. 411 at 4-5) The cylindrical elements of the S7

stent are in fact shorter than their own diameters once expanded, as are the elements of the Driver stent. (D.I. 436 at Ex. 7, Ex. 9) Pictures of the accused products reveal that the cylindrical elements are made up of a combination of U-shaped and possibly Yshaped members. (Id. at Ex. 2, Ex. 8) Therefore, the accused products contain all the elements of this limitation.

d. The Remaining Limitations of Claim 1 of the `133 Patent

The accused Medtronic devices meet the remaining limitations. First, it is undisputed that the cylindrical elements are aligned along a longitudinal axis. (D.I. 411 at 4)⁶ Second, each of the cylindrical elements of the accused Medtronic stents have a shape that enables expansion upon inflation of a balloon catheter. If they did not, they would not be classified as balloon expandable stents. Third, as stated above, the cylindrical elements of the accused Medtronic devices are shorter than their own diameters once expanded. Fourth, the elements of both the S7 and Driver stents are approximately 1mm in length; therefore, they are shorter than 2.5mm. (D.I. 436 at Ex. 7, Ex. 9)

⁶Medtronic disputes whether the elements of the accused devices meet the cylindrical elements limitation. As stated above, however, the accused devices have cylindrical elements as construed by the court. Medtronic does not dispute the alignment of what the court has concluded are cylindrical elements of the accused devises.

e. Presence of "Connecting Elements" in Medtronic's stents

Medtronic argues that the welds of its stents are not connecting elements because they do not create any longitudinal space between the cylindrical elements. As construed by the court, "connecting elements," "connecting members," "interconnecting elements" and "struts for connecting" are "segments of a stent that extend between adjacent cylindrical elements, connecting them together." It is undisputed that the welds are used to connect cylindrical elements together and that welds are a part of the stent. ACS has presented evidence that the weld connections may take up space between the cylindrical elements. (D.I. 466, Ex. 3 at 132, 135-37, Ex. 6, Ex. 7, Ex. 8 at 276, 314) If a jury finds that the weld connections take up space between elements (i.e., space apart elements) they could reasonably conclude that the welds "extend between adjacent cylindrical elements." As such, a jury could find literal infringement by Medtronic. Therefore, Medtronic's motion for partial summary judgment that its stents do not have "connecting elements" is denied.

B. DOE Infringement of the Boneau Patents in Suit

ACS asserts that Medtronic cannot argue infringement under the doctrine of equivalents due to prosecution history estoppel.

The doctrine of equivalents is limited by the doctrine of prosecution history estoppel. In <u>Festo Corp. v. Shoketsu Kinzoku</u>

Koqvo Kabushiki Co., Ltd., 535 U.S. 722 (2002), the Supreme Court

stated:

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

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

Once a court has determined that prosecution history estoppel applies, it must determine the scope of the estoppel. See <u>id.</u> at 1580. This requires an objective examination into the

reason for, and nature of, the surrendered subject matter. <u>Id.</u>; <u>see also Augustine Med., Inc. v. Gaymar Indus., Inc.</u>, 181 F.3d 1291, 1299 (Fed. Cir. 1999). If one of ordinary skill in the art would consider the accused product to be surrendered subject matter, then the doctrine of equivalents cannot be used to claim infringement by the accused product; i.e., prosecution history estoppel necessarily applies. <u>Augustine Med.</u>, 181 F.3d at 1298. In addition, a "patentee may not assert coverage of a 'trivial' variation of the distinguished prior art feature as an equivalent." <u>Id.</u> at 1299 (quoting <u>Litton Sys., Inc. v.</u> <u>Honeywell, Inc.</u>, 140 F.3d 1449, 1454 (Fed. Cir. 1998)).

During the prosecution of the '331 patent,' Mr. Boneau argued that his stent was different from the Palmaz stent because his stent only had upper and lower peaks. (D.I. 240 at 101, 113, 138, 151, 226) These arguments were in response to the examiner's assertion that, due to the use of "comprising," the additional "Palmaz elements" could be added to the Boneau stent as claimed; therefore, Boneau's application encompassed prior art. (See, e.g., id. at 146) Mr. Boneau asserted that these additional "Palmaz elements" could not be added because then there would no longer be any "peaks," as required by his claims.

⁷For the purposes of prosecution history estoppel, the prosecution history of the '331 patent applies to all the patents in suit. <u>See Omega Eng'g, Inc. v. Raytek Corp.</u>, 334 F.3d 1314, 1333 (Fed. Cir. 2003).

(D.I. 240 at 101, 113, 151-52, 226) Therefore, it is clear that Mr. Boneau disclaimed the "Palmaz elements."

The Palmaz stent is made up of straight segments 78 that are connected at their ends 79 to form a circular band. (D.I. 240 at 214, fig. 2B) These circular bands are then connected to two straight segments 75 that attach adjacent circular bands. <u>Id.</u> The Boneau stent is made up of substantially straight segments 16 that are connected at their ends 14 and 12. ('331 patent, fig. 1) The Boneau stent does not have the straight segments that connect the circular bands; thus, these are elements that a Palmaz stent has that a Boneau stent does not have.

The court finds that one of ordinary skill in the art would have concluded that the additional "Palmaz elements" included connections between circular bands. Because Mr. Boneau did not indicate that it was only certain elements of the Palmaz stent that he was surrendering, one of ordinary skill would conclude that it was all of the additional elements. Also, Mr. Boneau consistently referred to the creation of "peaks" in connection with the surrender of the "Palmaz elements." (D.I. 240 at 113, 151-53, 226) One of ordinary skill would understand this to explicitly surrender any "Palmaz elements" that prevented the creation of "peaks," defined as either the very top or bottom. Therefore, estoppel applies to any connections that prevent the creation of peaks.

All of ACS's stents have connections at the top and bottom of the sinusoidal pattern that attach circular elements together. These connections create "non-peaks," or attachments between the substantially straight segments that are not peaks. Because this subject matter was surrendered by Mr. Boneau while distinguishing the Palmaz prior art, Medtronic cannot now use the doctrine of equivalents to argue that the accused ACS stents infringe the Boneau patents. In other words, Medtronic cannot argue that the EXPRESS stent is the equivalent of using multiple Boneau stents together.

C. Validity

1. Invalidity for Lack of Written Description

ACS argues that the Boneau stents are invalid for lack of written description because the claims cover "a single device comprising a plurality of stents connected together." (D.I. 403) The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, paragraph 1, which provides in relevant part:

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.

The Federal Circuit has explained that "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. . . . Tossing out the mere germ of an idea does not

constitute enabling disclosure." <u>Genentech, Inc. v. Novo Nordisk</u> <u>A/S</u>, 108 F.3d 1361, 1366 (Fed. Cir. 1997). To satisfy the enablement requirement, a specification must teach those skilled in the art how to make and to use the full scope of the claimed invention without undue experimentation. <u>Genentech</u>, 108 F.3d at 1365. The enablement requirement is a question of law based on underlying factual inquiries. <u>In re Wands</u>, 858 F.2d 731, 737 (Fed. Cir. 1988).

In this case, the asserted claims of the Boneau patents are enabled by the written description. As construed by the court, the claims cover the use of multiple unconnected Boneau stents. (D.I. 541) This concept is fully enabled by the written description, which specifically states that multiple Boneau stents can be used to treat a single lesion. ('331 patent, col. 6, 11. 26-41)

ACS further argues that the written description does not enable the use of stent members (i.e., "circular members," "stent members," "rings" and "endovascular support members"). The asserted Boneau claims call for the use of multiple stent members to treat a single affected area. The court construed these terms mean "stent." (D.I. 541) The written description does enable the use of multiple Boneau stents; therefore, as construed by the court the claims are enabled.

Invalidity of Claims 1 and 2 of the `331 Patent For Anticipation

ACS argues, based on its asserted claim construction, that claims 1 and 2 of the '331 patent are anticipated by U.S. Patent No. 4,580,568 ("the Gianturco '568 patent"). Under 35 U.S.C. § 102(b), "[a] person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States."8 The Federal Circuit has stated that "[t]here must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps, 927 F.2d at 1576. In determining whether a patented invention is explicitly anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995). The prosecution history and the prior art may be consulted if needed to impart clarity or to avoid ambiguity in ascertaining whether the invention is novel or was previously known in the art. Id. The prior art need not be ipsissimis verbis (i.e., use identical words as those recited in the claims) to be anticipating. Structural Rubber Prods. Co. v. Park Rubber <u>Co.</u>, 749 F.2d 707, 716 (Fed. Cir. 1984).

 $^{^{8}\}mbox{It}$ is undisputed that the Gianturco '568 patent is prior art under § 102(b).

A prior art reference also may anticipate without explicitly disclosing a feature of the claimed invention if that missing characteristic is inherently present in the single anticipating reference. Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. Id. That is, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. The Federal Circuit also has observed that "[i]nherency operates to anticipate entire inventions as well as single limitations within an invention." Schering Corp. V. Geneva Pharms. Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. Id. at 1377.

An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. <u>Key Pharms. v. Hercon Labs Corp.</u>, 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. <u>Id</u>. A finding of anticipation will invalidate the patent. <u>Applied Med. Res. Corp.</u> <u>v. U.S. Surgical Corp.</u>, 147 F.3d 1374, 1378 (Fed. Cir. 1998).

Claim 1 of the '331 patent reads:

A stent for implantation within a vessel within the human body comprising a plurality of N substantially straight segments of wire-like material, each segment having a first and second ends wherein the first end of the first segment is connected to the first end of a second segment, the second end of the second segment is connected to the second end of the third segment, the first end of the third segment is connected to the first end of the fourth segment, and so on until the second end of the Nth segment is connected to the second end of the first segment, with no segment overlapping any other segment and the plurality of segments being capable of being compressed onto a catheter for delivery to an affected area of a vessel and then forcibly expanded to maintain the affected area of a vessel at a diameter larger than if the support device were not implanted.

Claim 2 states, "[t]he stent of claim 1 wherein the value of N is between six and twenty." As construed by the court, claim 1 requires that a Boneau stent be capable of being compressed onto a balloon catheter. In other words, the stent must be able to be pressed together on a balloon catheter for delivery to an affected area. The Gianturco stent can be pressed onto a balloon catheter, assuming that the right diameter of balloon and stent are used, but before it can be delivered to an affected area it has to be held in place by a sheath. (D.I. 295 at 11-12) In its specification, the Gianturco '568 patent states, "[i]n order to practice the method of this invention, the stent is compressed <u>into</u> the first shape . . . and is placed within a tubular cartridge 15. The cartridge 15 is then inserted into the recess 16 in the adapter 17 of the sheath 20." (D.I. 260 at Ex. 4, col. 3, 11. 5-11) (emphasis added) The Boneau invention, however, can

be compressed onto a balloon catheter and delivered without any cartridge or sheath; it is not a self-expanding stent. ('331 patent, col. 5, ll. 36-67, col. 6, ll. 1-25)

There would have been a difference to one of ordinary skill in the art between a self-expanding and balloon expandable stent. There is nothing inherent in the properties of the Gianturco stent that would lead one of ordinary skill in the art to believe that such a stent could be used as anything other than a selfexpanding stent. Because the Gianturco '568 patent explicitly discloses a self-expanding stent with no reference to how it can be used as a balloon expandable stent,⁹ it does not anticipate either claim 1 or claim 2 of the '331 patent.¹⁰

3. Invalidity for Indefiniteness

A patent specification shall conclude with one or more claims that "particularly [point] out and distinctly [claim] subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P 2 (2003). "A determination of claim indefiniteness is a legal conclusion that is drawn from the Court's performance of its duty as the construer of patent

⁹ACS argues that another patent, the Wallsten '343 patent, and two academic articles, disclose how to use a self-expanding stent as a balloon expandable stent. However, in order to anticipate a patent, every element of the claimed invention must be present in a single prior art reference. Robert L. Harmon, Patents and the Federal Circuit § 3.2 (4th ed. 1998).

¹⁰Because claim 2 is dependant on claim 1, if claim 1 is not anticipated then claim 2 cannot be anticipated.

claims." <u>Personalized Media Communications, LLC v. Int'l Trade</u> <u>Comm'n</u>, 161 F.3d 696, 705 (Fed. Cir. 1998).

As construed by the court, "wire-like" means "a metal material capable of being bent to form peaks." The specification discusses turns and peaks formed by bending. ('331 patent, col. 4, 11. 49-51) The preferred embodiment specifically discusses bending to form the stent and the "optimum wire size." ('331 patent, col. 4, 11. 63-64, 67, col. 5, 11. 1) The prosecution history discusses metal material and bending to form a Boneau stent. (D.I. 240 at 124, 138) Thus, the court finds that "wirelike" has a discernable meaning that would be understood by one of ordinary skill in the art.

V. CONCLUSION

For the reasons stated, ACS's motion for summary judgment that its accused stents do not infringe the asserted claims of the Boneau patents in suit is granted. Medtronic's motion for partial summary judgment that ACS's accused stents literally infringe claim 1 of the '382 patent and claim 27 of the '053 patent is denied. ACS's motion for summary judgment that the Boneau patents in suit are invalid is denied.

Medtronic's motion for partial summary judgment that its accused stents do not infringe the asserted claims of the Lau patents in suit is denied. ACS's motion for summary judgment that Medtronic's S7 and Driver stents literally infringe claim 1

of the '133 patent is granted. An order consistent with this memorandum opinion shall issue.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| MEDTRONIC VASCULAR, INC. an | ld) |
|-----------------------------|----------------------|
| MEDTRONIC USA, INC, |) |
| |) |
| Plaintiffs, |) |
| |) |
| V. |) Civ. No. 98-80-SLR |
| |) |
| ADVANCED CARDIOVASCULAR |) |
| SYSTEMS, INC. and GUIDANT |) |
| SALES CORP., |) |
| |) |
| Defendants. |) |

ORDER

At Wilmington this 5th day of January, 2005, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

 Defendants' motion for summary judgment that plaintiff's S7 and Driver stents literally infringe Claim 1 of the '133 patent (D.I. 400) is granted.

2. Defendants motion for summary judgment of invalidity of the Boneau patents (D.I. 402) is denied.

3. Plaintiff's motion for partial summary judgment that its accused products do not infringe the asserted claims of the Lau patents in suit (D.I. 410) is denied.

4. Plaintiff's motion for partial summary judgment that defendant's accused stents literally infringe claim 1 of the `382 patent and claim 27 of the `053 patent (D.I. 414) is denied.

5. Defendants' motion for summary judgment that its accused stents to not infringe the asserted claims of the Boneau patents in suit (D.I. 426) is granted.

Sue L. Robinson United States District Judge