IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC VASCULAR, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 98-478-SLR
	)	
BOSTON SCIENTIFIC CORP.,	)	
BOSTON SCIENTIFIC SCIMED, INC. (formerly known as SCIMED LIFE SYSTEMS, INC.) and MEDINOL, LTD.,	)	
	)	
Defendants.	)	

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MEMORANDUM OPINION

Dated: January 5, 2005
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On August 13, 1998,[1] Arterial Vascular Engineering, Inc. ("Vascular") filed a complaint against Boston Scientific Corporation ("BSC") and Scimed Life Systems Inc. ("Scimed") alleging willful infringement of U.S. Patent Nos. 5,291,331 and 5,674,278 by the NIR model stents. (D.I. 1) On March 11, 1999, Vascular filed a first amended complaint against Scimed and BSC. (D.I. 17) On June 28, 2000, Medtronic AVE, Inc. ("Medtronic")[2] filed a second amended complaint to add Medinol, Ltd. ("Medinol") as a defendant in the infringement action. (D.I. 62) Medtronic also asserted a third Boneau patent, namely, U.S. Patent No. 5,879,382, and added claims for contributory infringement to the suit. (Id. at ¶ 12)

On July 13, 2000, Medinol answered the second amended complaint, denied all infringement allegations, and asserted numerous affirmative defenses. (D.I. 50) On February 20, 2004, Medtronic filed a third amended complaint that added a fourth Boneau patent to the infringment action, specifically, U.S. Patent No. 6,344,053. (D.I. 150)

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[1]On November 15, 2000, this case was stayed pending resolution of two different appeals to the Federal Circuit. The case was not reopened until March 20, 2003.

[2]Arterial Vascular Engineering, Inc. amended its complaint on March 11, 1999 to substitute Medtronic AVE as the plaintiff. (See D.I. 17)

The patents in suit are 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"). Together these patents are referred to as "the Boneau patents." Due to its similarity to other actions involving the Boneau patents, this case was joined with Civil Action Nos. 98-80-SLR and 04-34-SLR for trial.

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 infringment and validity. (D.I. 242, 244, 246, 248)

II. BACKGROUND

The '278, 382 and '053 patents are all continuations of the original Boneau patent, the '331 patent. These patents generally relate to endovascular support devises used in the treatment of cardiovascular disease and its effects. 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, ll. 19-67, col. 4, ll. 1-4)

The accused device, the NIR stent, is also a balloon expandable support device used in the treatment of cardiovascular disease. According to BSC, the NIR stent is a series of flexible cells, joined together to form a flexible stent. (D.I. 249 at 7-

8) These joined cells look like a series of connected circular elements, each with a circumferential sinusoidal pattern. Id. at 9. The circular elements are connected to each other by curved elements. Id. The stent pattern is etched from a single flat sheet of metal that is bent into a cylinder shape and welded together. Id. at 8.

Medtronic alleges the NIR stent infringes claim 1 of the '331 patent, claim 1 of the '278 patent, claim 1 of the '382 patent and claims 1, 8, 16, 24 and 27 of the '053 patent.

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. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

The court construed the contested terms of the Boneau patents 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. 337)

BSC argues that its NIR stent does not infringe any of the patents in suit, either literally or under the doctrine of equivalents. (D.I. 248) Medtronic argues for partial summary

judgment that the EXPRESS stent literally infringes claim 1 of the '382 patent and claim 27 of the '053 patent. (D.I. 244)

1. Literal Infringement of the '331 Patent

The court finds that BSC's NIR stent does not literally infringe claim 1 of the '331 patent because it does not have substantially straight segments that extend from one end of the stent to the other.

2. 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.[3] Based on the written description of the patents in suit, the court has construed all of these terms to mean "stent," or "a device implanted to maintain the patency of a vessel." (D.I. 337) The NIR stent is comprised of a series of circular elements that are connected together to form flexible cells. (See D.I. 249 at 8-9)

Medtronic argues that these circular elements are essentially stent members. These elements, however, are not used or marketed individually as stents. In support of its arguments, Medtronic states that BSC's experts' depositions show that one of

[3]Claim 1 of the '278 patent and claims 8 and 16 of the '053 patent refer to stent members as "circular members." Claim 1 of 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."

ordinary skill in the art would conclude that the macro and micro elements would have some functionality. (D.I. 274 at 12) The depositions transcripts, however, show that the experts either refuse to answer questions regarding functionality or did not form an expert opinion about the functionality of individual macro and micro elements. (D.I. 281, Exs. 41, 47) Merely pointing out that BSC's experts do not have opinions on the functionality of individual elements is not enough to carry Medtronic's burden of showing there is a genuine issue with respect to whether an individual element can maintain the patency of a vessel. Therefore, the NIR stent does not literally infringe the Boneau patents because it does not have stent members as construed by the court.

B. DOE Infringement of the Patents in Suit

BSC 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 Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002), the Supreme Court stated:

> Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the

> subject matter in question. The doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.

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

Once a court has determined that prosecution history estoppel applies, it must determine the scope of the estoppel. See id. at 1580. This requires an objective examination into the reason for and nature of the surrendered subject matter. Id.; see also Augustine Med., Inc. v. Gaymar Indus., Inc., 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. Augustine Med., 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." Id. at 1299 (quoting Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed. Cir. 1998)).

During the prosecution of the '331 patent,[4] 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. (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. Id.

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

The Boneau stent is made up of substantially straight segments 16 that are connected at their ends 14 and 12. (Id. at 2, 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.

BSC's NIR stent has several curved connections, A and B, that attach its circular elements together. (D.I. 249 at 9) These curved 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 NIR stent infringes the Boneau patents. In other words, Medtronic cannot argue that the NIR stent is the equivalent of using multiple Boneau stents together.

B. Validity

1. BSC's and Medinol's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement

BSC and Guidant argue that, if the Boneau claims cover "a single stent comprised of multiple rings," then the claims are invalid because the written description does not enable such a stent. (D.I. 243) 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." Genentech, Inc. v. Novo Nordisk A/S, 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. Genentech, 108 F.3d at 1365. The enablement requirement is a question of law based on underlying factual inquiries. Wands, 858 F.2d at 737.

The Boneau claims cover the use of multiple Boneau stents together, an idea that is enabled by the written description. (See '331 patent, col. 6, ll. 27-41) The claims do not cover connected Boneau stents because the claims require that the connections between substantially straight segments form peaks. (See *supra* Part IV.B) Therefore, as construed by the court, the Boneau patents are not invalid for lack of a written description.

2. BSC's and Medinol's Motion for Summary Judgment of Invalidity of the '331 Patent as Anticipated

BSC 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."[5] 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

[5]It is undisputed that the Gianturco '568 patent is prior art under § 102(b).

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 Co., 749 F.2d 707, 716 (Fed. Cir. 1984).

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. Key Pharms. v. Hercon Labs Corp., 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. Id. A finding of anticipation will invalidate the patent. Applied Med. Res. Corp. v. U.S. Surgical Corp., 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 into 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, ll. 5-11). 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 self-expanding 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,[6] it does not anticipate either claim 1 or claim 2 of the '331 patent.[7]

V. CONCLUSION

For the reasons stated, BSC's motion for summary judgment of noninfringement is granted. Medtronic's motion for partial summary judgment of infringement of claim 1 of the '382 patent and claim 27 of the '053 patent is denied. BSC's motion for summary judgment of invalidity is denied. An order consistent with the memorandum opinion shall issue.

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[6]BSC argues that another patent, the Wallsten '343 patent, discloses 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).

[7]Because claim 2 is dependant on claim 1, if claim 1 is not anticipated then claim 2 cannot be anticipated.