

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDTRONIC VASCULAR, INC.,)
)
 Plaintiff,)
)
 v.) Civ. No. 04-034-SLR
)
BOSTON SCIENTIFIC CORP.,)
and BOSTON SCIENTIFIC SCIMED,)
INC. (formerly known as)
SCIMED LIFE SYSTEMS, INC.,)
)
 Defendants.)

Karen Jacobs Loudon, Esquire, Philip Bangle, Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiffs Medtronic Vascular, Inc. And Medtronic USA, Inc. Of Counsel: Raphael V. Lupo, Esquire, Donna M. Tanguay, Esquire, Mark G. Davis, Esquire, James G. Rizzo, Esquire of McDermott Will & Emery, Washington D.C.

Frederick L. Cottrell, III, Esquire, Anne Shea Gaza, Esquire, Richards Layton & Finger, Wilmington, Delaware. Counsel for Defendants Advanced Cardiovascular Systems, Inc. and Guidant Sales Corp. Of Counsel: J. Michael Jakes, Esquire, Gerald F. Ivey, Esquire, Michael A. Morin, Esquire of Finnegan, Henderson, Farabow Garrett & Dunner, Washington, D.C.

Josy W. Ingersoll, Esquire of Young Conaway Stargatt & Taylor, Wilmington, Delaware. Counsel for Defendants Boston Scientific Corp. and Boston Scientific Scimed, Inc.. Of Counsel for Defendants Boston Scientific Corp., Scimed Life Systems, Inc., and Boston Scientific Scimed, Inc.: Albert Breneisen, Esquire of Kenyon and Kenyon, New York, New York, Douglas Ringel, Esquire of Kenyon and Kenyon, Washington, D.C., John M. Desmarais, Esquire, Peter J. Armenio, Esquire of Kirkland & Ellis, New York, New York.

Richard D. Kirk, Esquire of Morris James Hitchens & Williams, LLP, Wilmington, Delaware. Of Counsel for Defendant Medinol, Ltd.: Christopher A. Hughes, Esquire, Richard C. Komson, Esquire, Israel Blum, Esquire, Steven F. Meyer, Esquire, Dorothy R. Auth, Esquire of Morgan & Finnegan, New York, New York.

MEMORANDUM OPINION

Dated: January 5, 2005
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On January 15, 2004, plaintiff Medtronic Vascular, Inc. ("Medtronic") filed this suit against defendants Boston Scientific Corp., Scimed Life Systems, Inc., and Boston Scientific Scimed, Inc. (collectively "BSC"), alleging BSC's EXPRESS stent infringes certain of Medtronic's patents. Later, Medtronic amended its complaint to add an additional patent to the suit.

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"), and 6,344,053 ("the '053 patent"). Together these patents are referred to as "the Boneau patents."

On February 5, 2004, BSC answered the complaint and made counterclaims of invalidity and unenforceability. (D.I. 10) Due to its similarity to other actions involving the Boneau patents, namely Civil Action Nos. 98-80-SLR and 98-478-SLR, this case was put on an expedited discovery schedule so that all three cases could be tried at the same time.

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. 77, 81, 79) For the reasons stated these motions are granted in part and denied in part.

II. BACKGROUND

The '278, 382 and '053 patents are all continuations of the original Boneau patent, the '331 patent. Collectively these patents relate to endovascular support devices 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.

The accused device, the EXPRESS stent, is also a balloon expandable endovascular support device used in the treatment of cardiovascular disease. It is made up of smaller bands ("micro elements") and larger bands ("macro elements"). (D.I. 82 at 2) These elements have a circumferential sinusoidal pattern and are connected by straight elements. Id. The EXPRESS stent is laser cut from a stainless steel tube and given a chemical bath and electro-polish to remove any rough edges. Id. at 3-4.

Medtronic asserts that the EXPRESS 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

Diagnositics, 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. 155)

BSC argues that its EXPRESS stent does not infringe any of the patents in suit, either literally or under the doctrine of equivalents. (D.I. 82) 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. 80)

1. Literal Infringement of the '331 Patent

The court finds that BSC's EXPRESS 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.¹ Based on the written description of the

¹Claim 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

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." The EXPRESS stent is comprised of multiple macro and micro elements that are connected at various points.

Medtronic argues that these macro and micro 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 ordinary skill in the art would conclude that the macro and micro elements would have some functionality. (D.I. 100 at 11-12) 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. 105, Exs. 34, 41, 42) 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 EXPRESS stent does not literally infringe the Boneau patents because it does not have stent members as construed by the court.

the '053 patent refers to them as "endovascular support members."

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,² 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

²For 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).

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. 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 EXPRESS stent has several straight connections that attach its circular elements together. These straight 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 EXPRESS stent infringes the Boneau patents. In other words, Medtronic cannot argue that the EXPRESS stent is the equivalent of using multiple Boneau stents together.

C. BSC's Motion for Summary Judgment of Invalidity of Claims 1 and 2 of the '331 Patent

BSC argues that claims 1 and 2 of the '331 patent are anticipated by U.S. Patent No. 4,739,762 ("the '762 patent") based on Medtronic's claim construction.³ 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." The

³It is undisputed that the '762 patent is prior art under § 102(b).

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. However, the prior art need not be *ipsisssimis 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, among other things, that the stent have substantially straight segments that are connected only at their ends by peaks. Although the '762 patent discloses substantially straight segments, these segments are connected at more points than just their ends and only some

of the segments are connected at their ends to form peaks. These differences would be important to one of ordinary skill in the art because the different connections would change the way the stent expanded and functioned within a vessel. Nothing inherent in the '762 patent necessarily teaches a stent of substantially straight segments connected at their ends by peaks. Therefore, the court finds that claims 1 and 2 of the '331 patent are not anticipated by the '762 patent.⁴

V. CONCLUSION

For the reasons stated, BSC's motion for summary judgment of non-infringement is granted. (D.I. 81) 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. (D.I. 79) BSC's motion for partial summary judgment of invalidity of claims 1 and 2 of the '331 patent is denied. (D.I. 77) An order consistent with this opinion shall issue.

⁴Because claim 2 is dependant on claim 1, if the limitations of claim 1 are not anticipated, the limitations of claim 2 are not anticipated.