United States District Court,
S.D. Illinois.

MARCTEC, LLC,
Plaintiff/Counterclaim Defendant.
v.
JOHNSON & JOHNSON and Cordis Corporation,
Defendants/Counterclaim Plaintiffs.

No. 07-cv-825-DRH

March 31, 2009.

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FINDINGS OF FACT & CONCLUSIONS OF LAW ON CLAIMS CONSTRUCTION

HERNDON**, Chief Judge.**

On February 19, 2009, the Court conducted a claims construction hearing (a " Markman FN1 hearing") (Doc. 156), whereby the Parties presented their respective interpretations of patent claims from U.S. Patent Nos. 7,128,753 ("the '753 patent") and 7,217,290 ("the '290 patent") (collectively, the "patents-in-suit"). FN2 Plaintiff Marctec, LLC, has asserted the patents-in-suit against the Cypher drug-eluting stent. At the conclusion of the *Markman* hearing, the Court took the matter under advisement. The following is the Court's findings of fact and conclusions of law regarding claim construction of the patents-in-suit, made pursuant to FEDERAL RULE OF CIVIL PROCEDURE 52**.**

FN1. Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)**.**

FN2. These arguments were also addressed by the Parties in their Claims Construction briefings (*see* Docs. 67, 72, 91 & 92).

FINDINGS OF FACT

I. THE DISPUTED CLAIM TERMS OF THE '290 PATENT

1) MarcTec has asserted claims 1-8, 10 and 14 of the '290 patent. Claim 1 is an independent claim. Claims 2-8, 10 and 14 depend from claim 1 and thus incorporate all of its limitations.

2) **Claim 1** reads (the disputed claim language is indicated):

An implant for implantation in a human body comprising: ***a tubular member having a channel and mechanically expandable upon activation of a delivery mechanism from a contracted condition in which the tubular member has a first cross sectional size in a plane perpendicular to a longitudinal central axis of the tubular member to an expanded condition in which at least a portion of the tubular member has a second cross sectional size in a plane perpendicular to the longitudinal central axis of the tubular member, the second cross sectional size being larger than the first cross sectional size to thereby lock the tubular member against tissue in the human body;*** and ***a first component bonded to at least a portion of the tubular member*** and formed of ***a heat bondable material*** that includes ***a therapeutic agent*** selected from the group consisting of a ***tissue ingrowth promoter*** and an ***antibiotic, wherein the heat bondable material is non-flowable and non-adherent at room temperature and becomes flowable, tacky, and adherent upon the application of heat.***

3) **Claim 2** reads (the disputed claim language is indicated):

The implant of claim 1 wherein the heat bondable material is a ***thermoplastic*** material.

4) **Claim 3** reads (the disputed claim language is indicated):

The implant of claim 2 wherein the therapeutic agent is an ***antibiotic.***

5) **Claim 5** reads (the disputed claim language is indicated):

The implant of claim 4 wherein the therapeutic agent is an ***antibiotic.***

6) **Claim 10** reads (the disputed claim language is indicated):

The implant of claim 1 wherein the implant includes a ***laser cut surface.***

7) **Claim 14** reads (the disputed claim language is indicated):

The implant of claim 1 wherein the heat bondable material is a ***composite material.***

II. THE ASSERTED CLAIM TERMS OF THE '753 PATENT

8) MarcTec has asserted claims 1, 3 and 4 of the '753 patent. Claims 3 and 4 depend from claim 1 and thus incorporate all of its limitations.

9) **Claim 1** reads (the disputed claim language is indicated):

A surgical device for implantation in a body comprising: ***an implant, at least a portion of which is expandable;*** and ***a polymeric material bonded to the implant,*** wherein the polymeric material is a

thermoplastic, includes a therapeutic agent, is non-flowable and non-adherent at room temperature, and becomes flowable, tacky, and adherent upon the application of heat.

10) **Claim 3** reads (the disputed claim language is indicated):

The surgical device of claim 1 wherein the therapeutic agent is an ***antibiotic.***

III. THE SPECIFICATION

11) The '753 and '290 patents share the same specification.

A. Surgical Devices

12) The '753 patent is entitled "Surgical Devices Having a Polymeric Material With a Therapeutic Agent and Methods for Making Same," and the '290 patent is entitled "Surgical Devices Containing a Heat Bondable Material with a Therapeutic Agent." The titles of the patents-in-suit indicate that they relate to surgical devices.

13) The specification describes surgical devices having particular features. *See, e.g.,* D.I. 70, Ex. A ('753 patent) at 1:38-39 ("The present invention relates to surgical devices such as implants or suture fastenings."), Abstract ("Surgical devices such as implants or suture fastenings," where components of those devices are "bonded to each other by ... applying heat to the heat bondable material."), 1:63-64 ("The present invention includes an assembly for use in surgical applications in humans."), *see also* 2:19-21.

14) There is no description in the specification of any non-surgical devices, such as stents.

15) The specification discloses two embodiments-both are directed to surgery and surgical devices where the surgeon has direct access to the site of the operation to custom size or seal a surgical implant. The first embodiment concerns orthopedic implants (*e.g.* bone plates (Figs.1-2), hip prostheses (Fig.3), knee prostheses (Fig.4A-B) and other "surgical" devices (Figs.5-6)). The second embodiment concerns suture fasteners (Figs.7-11) that provide "surgical connections for holding adjoining tissues together ... by melting a fastener or anchor on the end of a suture, rather than by tying or by clipping the anchor on the end of the suture." D.I. 70, Ex. A ('753 patent) at 7:20-23.

B. Heat Bonding

16) The surgical devices that are described in the specification all have components that are bonded by the application of heat at the site of surgery.

17) There is no disclosure in the specification of any bonding other than through the direct application of heat.

18) The Abstract of the patents-in-suit describes heat bonding:

Surgical devices such as implants or suture fastenings are assembled from a plurality of discrete components, one of which components includes ***a heat bondable plastic material for bonding*** the components together. At least two components are bonded to each other ***by applying heat to the heat bondable plastic material*** of one component. D.I. 70, Ex. A ('753 patent) (emphasis added).

19) All seven paragraphs of the "Summary of the Invention" section concern heat bonding, with the first paragraph of the section defining "the present invention" in terms of bonding by the application of heat:

The present invention includes an assembly for use in surgical applications in humans. The assembly may include two components, at least one of which comprises a heat bondable material. The first and second components are bond to each other by the application of heat to the heat bondable material, to make the heat bondable material soften, become tacky, and bond to the other component. D.I. 70, Ex. A ('753 patent) at 1:63-2:2.

20) The specification defines the terms "bondable" or "bondable material" to refer to heat bonding: "any material, suitable for use in surgical applications, which can be softened and made flowable ***by the application of heat,*** and which when softened, will become tacky and bond to other materials and flow to fill available space." D.I. 70, Ex. A ('753 patent) at 3:52-57 (emphasis added); *see* id. at 3:59-65.

21) The specification goes on to describe how the benefits of the invention derive from the application of heat to heat bondable material:

[T]he present invention gives the surgeon the ability to immediately modify the shape and size of almost any existing surgical part including a prosthesis, in order to better fit the particular application for use in the body. This is accomplished by heat bonding a piece of bondable material onto the prosthesis, to make an assembly designed for the particular application. The piece can be custom shaped in the operating room ... by heating and bonding of a polymer or composite.

D.I. 70, Ex. A ('753 patent) at 5:61-6:3. In Figures 9-11, the sutures are put in place by "melting a fastener or anchor on the end of a suture," id. at 7:19-23, such that "[e]ither the anchor alone or the anchor and the suture are melted together to lock them into position," id. at 7:27-28. The specification teaches that "a melted anchor provides a stronger bond than the mechanical interlock of a suture knot." Id. at 7:34-35; *see* id. at 7:61-65, 8:7-11.

22) In numerous places, the invention is described as requiring the addition of heat directly to the heat bondable material to make it flow, become tacky and adhere. *See* D.I. 70, Ex. A ('753 patent) at 2:4-6 ("the application of heat ***to the heat bondable material ... causes*** the heat bondable material to soften and bond"); 2:7-11; 2:15-19; 3:54-57 ("can be softened and made flowable by the application of heat, and which, when softened, will become tacky and bond"); 4:46-48 ("the bondable material of the nut 16 ***is heated and softened to flow*** about the joint between the nut 16 and the bone plate 10, to bond the nut 16 to the bone plate 10"); 5:38-42 ("The connection 38 between the wedge 32 and the prosthesis 30 is secured ***by heating and softening the wedge 32 so that the material of the wedge 32 adheres or bonds to the prosthesis*** 30."); 5:50-53; 6:44-49; 6:53-58; 7:1-4.

23) The specification distinguishes and disfavors methods of bonding that do not involve heat. *See* D.I. 70, Ex. A ('753 patent) at 7:14-28 ("mechanical tying or crimping of sutures or K-wires, especially of polymers or biodegradables which are generally smooth, does not produce connections ***which are as strong as desirable,*** and suture connections sometimes may come untied as a result"); 7:34-37 ("[A] ***melted anchor provides a stronger bond*** than the mechanical interlock of a suture knot, because it will not unravel or come apart as a surgical knot may.").

24) The specification gives examples of heat sources to be used in practicing the invention: "any suitable heat generating apparatus can be used to heat and soften or spot weld the material, such as a hot air gun, a small welding or soldering gun, or a Bovie tip"; lasers may be used. D.I. 70, Ex. A ('753 patent) at 4:18-30; *see* id. at 6:36-38. Lasers are only mentioned in the specification in connection with heating and shaping the polymeric material used to cover the implant. Id. at Abstract; 4:18-26; 5:50-53; 6:21-23; 6:36-38; 6:45-52; and 6:53-64. There is no disclosure of lasers being used for any other purpose or on any other portions of the implant.

25) The specification does not discuss or disclose solution casting-the method by which the polymers on the Cypher stent are applied. The only bonding the specification teaches is heat bonding.

26) The specification provides a definition of composite materials: "Composite materials can include reinforced plastics, or polymers which are laminated or layered or reinforced with one or more other materials such as nylon, graphite fibers, Kevlar fibers, stainless steel fibers, etc." D.I. 70, Ex. A ('753 patent) at 3:65-4:2.

C. Therapeutic Agent

27) The term "therapeutic agent" does not appear in the specification.

28) The specification includes only one sentence relating to tissue ingrowth promoters, antibiotics and "other additives." That sentence states: "Items such as rods, bars, plates, or any type of construct useable in medical/surgical applications ... can also include tissue ingrowth promoters, antibiotics, or other additives as desired." D.I. 70, Ex. A ('753 patent) at 6:18-28.

D. The Patents-In-Suit Are Unrelated to Stents

29) The specification does not discuss or disclose stents, balloon angioplasty, or any of the attributes of stents or drug-eluting stents. Rather, it discloses only surgical devices such as hip and knee implants and suture anchors.

30) The claim terms "tubular member," "channel," and "delivery mechanism" are not found in the specification.

31) During prosecution of the patents-in-suit, the patent examiner rejected Dr. Bonutti's proposed claims as invalid over U.S. Pat. No. 5,102,417, which issued to Dr. Julio Palmaz (the "'417 patent" or "Palmaz patent"). D.I. 70, Ex. L at 3.

32) Dr. Palmaz, the inventor of the balloon-expandable stent, refers to this invention as an "expandable intraluminal vascular graft" or an "expandable prosthesis" in his early work, including the '417 patent. *See* D.I. 70, Ex. G ('417 patent) at 5:26-35, 6:44-54.

33) The '417 patent teaches a polymer/drug coating "placed upon the wall surfaces" of the stent. D.I. 70, Ex. G at 11:3-8, 11:26-34.

34) In the '417 patent, Dr. Palmaz makes a point of distinguishing his invention of the balloon-expandable stent from conventional surgery:

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel. D.I. 70, Ex. G ('417 patent) at 1:26-35.

35) To overcome this rejection, Dr. Bonutti represented to the Patent Office-and thus to the public-that his invention did not include stents, and, further, that his invention is directed to devices for use in surgical applications, in contrast to Palmaz's balloon-expandable stent, which is not a surgical device:

Palmaz discloses an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway (col.6., lns.21-23).... Applicants, on the other hand, disclose, *inter alia,* an assembly for use in surgical applications in humans.

D.I. 70, Ex. M at 5.

36) In short, Dr. Bonutti disclaimed stents during prosecution in order to obtain allowance.

37) In response to the same rejection over the Palmaz patent, Dr. Bonutti disclaimed devices in which a material is bonded to the device other than by the application of heat.

38) To further differentiate the Palmaz patent, Dr. Bonutti told the PTO that his method of applying polymer is different from the Palmaz method and that his method-unlike Dr. Palmaz's-bonds the polymer to the device by the application of heat. Dr. Bonutti argued that "[i]n contrast [to Palmaz], Applicants' implant includes a heat bondable material which is bonded to an implant by the application of heat." D.I. 70, Ex. M at 6. There is no heat used to bond the coating of the stent in the '417 patent. Dr. Bonutti relied on this difference to differentiate his invention from Palmaz, and, thus, to obtain allowance of his claims. Id.

39) To make clear that his invention requires bonding by the application of heat, Dr. Bonutti amended the claims of the patents-in-suit to require that the material bonded to the implant or tubular member "is non-flowable and non-adherent at room temperature and becomes flowable, tacky, and adherent upon the application of heat." D.I. 70, Ex. M at 2; D.I. 70, Ex. O at 2.

40) The amendments were made in direct response to the Examiner's rejection of the claims as anticipated by the disclosure of coating with drug "placed upon wall surfaces of tubular shaped members" in the prior art Palmaz patent. D.I. 70, Ex. M at 5-6.

41) Dr. Bonutti told the PTO that the purpose of his amendment was to "highlight" the distinction between his invention and the device disclosed in the Palmaz patent:

Palmaz teaches an implant including an absorbable polymer coating placed upon wall surfaces of tubular shaped members. In contrast, Applicant's implant includes a heat bondable material which is bonded to an implant by the application of heat.

To highlight this distinction, Applicants have amended independent claims 11 and 27 to include, *inter alia,* a polymeric material which is non-flowable and non-adherent at room temperature and becomes flowable,

tacky, and adherent upon the application of heat.

D.I. 70, Ex. M at 6.

42) This amendment made clear that Dr. Bonutti's invention required the application of heat to a heat bondable material to cause that material to transform from one state (non-flowable and non-adherent) to a different state (flowable, tacky and adherent).

43) The polymers disclosed by Palmaz in his '417 Patent ("polyglycoides, polylacoides and co-polymers thereof," D.I. 70, Ex. G ('417 patent) at 11:29-31) for bonding in the absence of heat are disclosed in the specification of the patents-in-suit as suitable materials for heat bonding. Id. at 11:56-12:34. The difference between the Palmaz patent and the patents-in-suit-as explained by Dr. Bonutti to the PTO-is that Palmaz does not teach bonding these polymers by the application of heat. In contrast, bonding by the application of heat is the only bonding taught in the patents-in-suit.

44) To obtain the benefit of a 1990 filing date, Dr. Bonutti tied his claims in the '753 and '290 patents back to his original 1990 patent application by pointing to the "bonded rivet" of Figures 11A-C. D.I. 70, Ex. N (April 27, 2005 Response to Office Action) at 7 ("[O]ne embodiment of the implant claimed in claim 17 is supported by FIGS. 11A-C and accompanying text, which was part of the [1990 Application]."); D.I. 70, Ex. O (August 22, 2005 Response to Office Action) at 5 (electing to seek coverage for the device of Figure 11 and stating that the claims at issue "read on" the elected device); D.I. 70, Ex. P (March 9, 2005 Response to Office Action) at 5 (same).

PROPOSED CONCLUSIONS OF LAW

I. LEGAL FRAMEWORK

1) "When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." O2 Micro, Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1361-62 (Fed.Cir.2008) **("In deciding that 'only if' needs no construction because the term has a 'well-understood definition,' the district court failed to resolve the parties' dispute because the parties disputed not the meaning of the words themselves, but the scope that should be encompassed by this claim language.")**

2) It is appropriate, and beneficial, for the court to be familiar with the accused device-here the Cypher stent, a non-surgical device containing a drug-eluting coating adhered by solution casting, not heat bonding-when construing claims. An understanding of the accused device helps provide a meaningful context for the claim construction analysis. Jang v. Boston Scientific Corp., 532 F.3d 1330, 1337 (Fed.Cir.2008)**;** ***see*** Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1326-27 (Fed.Cir.2006)**;** Serio-US Indus., Inc. v. Plastic Recovery Techs. Corp., 459 F.3d 1311, 1319 (Fed.Cir.2006)**.**

3) Proper construction of disputed claim terms requires examination of "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed.Cir.2005) **(en banc) (citations omitted).** The Court must "focus[ ] at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down." Id. at 1321.

4) The patent specification is "the single best guide to the meaning of a disputed claim term." Phillips, 415

F.3d at 1315 **(citing** Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)**).**

5) " 'The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.' " Phillips, 415 F.3d at 1316 **(quoting** Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998)**).**

6) Properly construed, the claims are limited to what Dr. Bonutti "actually invented." Phillips, 415 F.3d at 1316 **(quoting** Renishaw, 158 F.3d at 1250); ***see, e.g.,*** Nystrom v. TREX Co., 424 F.3d 1136, 1144-45 (Fed.Cir.2005) **("not entitled to a claim construction divorced from the context of the written description and prosecution history");** ***see also*** Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1318 (Fed.Cir.2006) **(same);** Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1383 (Fed.Cir.1999) **("Although Wang is correct that a claim is not invalid simply because it embraces subject matter that is not specifically illustrated, in order to be covered by the claims that subject matter must be sufficiently described as the applicant's invention to meet the requirements of s. 112.");** Schering Corp. v. Amgen, Inc., 222 F.3d 1347, 1354 (Fed.Cir.2000)**;** Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989)**.**

7) The prosecution history must also be examined in construing claim terms:

[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

Phillips, 415 F.3d at 1317 **(citations omitted).**

8) Where the inventor disclaimed certain interpretations of the claim language to get the PTO to approve his patent, those disclaimers limit how the patent's claims may be construed. Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 994 (Fed.Cir.2003) **("It is well established that 'the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.' " (citations omitted));** ***see*** Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1379 (Fed.Cir.2008)**;** Gillespie v. Dywidag Sys. Int'l USA, 501 F.3d 1285, 1291 (Fed.Cir.2007)**;** Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1314, 1316 (Fed.Cir.2007)**;** Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1384 (Fed.Cir.2005)**.**

II. MECHANICAL DEVICE CLAIM TERMS

A. "a surgical device" ('753 patent) and "an implant" ('290 patent)

9) The specification explicitly addresses only surgical devices. *See, e.g.,* D.I. 70, Ex. B ('290 patent) at Title; D.I. 70, Ex. A ('753 patent) at Title; id. at 1:38-39 ("The present invention relates to ***surgical devices*** such as ***implants*** or suture fastenings."); 1:63-64. "When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention." Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1308 (Fed.Cir.2007) **(citations omitted).**

10) In addition, the prosecution history reveals that Dr. Bonutti disclaimed stents in order to overcome a rejection over Dr. Palmaz's '417 patent by the Examiner:

Palmaz discloses an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway

(col.6, lns.21-23).... Applicants, on the other hand, disclose, *inter alia,* an assembly for use in surgical applications in humans.... An almost limitless number of surgical devices can be constructed in accordance with the present invention. D.I. 70, Ex. M at 5-6.

Dr. Palmaz used the terms "intraluminal vascular graft" and "expandable prosthesis" in the '417 patent to refer to his invention of the balloon-expandable stent. Having disclaimed stents in the prosecution history, Dr. Bonutti is not entitled to capture them through claim construction. Springs Window Fashions LP, 323 F.3d at 994 **(citations omitted) ("It is well established that 'the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.' "); *see*** Computer Docking Station Corp., 519 F.3d at 1379; Gillespie, 501 F.3d at 1291; Ormco Corp., 498 F.3d at 1314, 1316; Chimie, 402 F.3d at 1384**.**

11) MarcTec argues that the terms "surgical device" and "implant" cannot limit the scope of the claims because they are part of the preamble. This argument is flawed; terms in the preamble can, and often do, limit claims. "Whether to treat a preamble as a limitation is ... 'resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.' " In re Cruciferous Sprout Litig., 301 F.3d 1343, 1347 (Fed.Cir.2002) **(quoting** Corning Glass Works, 868 F.2d at 1257); Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1309 (Fed.Cir.2004)**.**

12) The term "surgical device" is "a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim itself." Poly-America, L.P., 383 F.3d at 1310 **(citation omitted).** Here, "the specification is replete with references to the invention as a [surgical device], including the title of the patent itself." ***Id.*** "Surgical device" is used in the first sentence of the Abstract and the first substantive sentence of the specification. This phrase "is used repeatedly to describe the preferred embodiments." ***Id.*** The specification does not disclose any non-surgical devices. "To read the claim in light of the specification indiscriminately to cover all types of [devices] would be divorced from reality." Corning, 868 F.2d at 1257**.**

13) Second, the preamble language is limiting because Dr. Bonutti relied on it to distinguish prior art. Cruciferous Sprout, 301 F.3d at 1347 **(preamble limiting where used to distinguish prior art).** When Dr. Bonutti's claim language was rejected because of Palmaz's invention of the balloon-expandable stent, Dr. Bonutti made it clear that his invention was limited for use in conventional surgery and did not cover non-surgical devices such as stents. D.I. 70, Ex. M at 5. Dr. Bonutti made this argument to distinguish Palmaz's stents from proposed claim 11 (now claim 1), directed to "a ***surgical device*** for implantation into a body," and proposed claim 27 (now claim 11), directed to "an ***implantable device*** for implantation in a human patient." *Id*. at 2-4. Dr. Bonutti's statements to the Patent Office show a "clear reliance by the patentee [on the "surgical device" and "implant" requirements] to persuade the Patent Office that the claimed invention is not anticipated by the prior art." Cruciferous Sprout, 301 F.3d at 1348**.** Where-as here-a patentee relies on the preamble to distinguish the prior art, the preamble is a claim limitation. Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1370 (Fed.Cir.2003) **(" '[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.' ") (citation omitted).**

14) With regard to "implant," Marctec also argues that excluding stents is inconsistent with dependent claims that are directed to a device "positionable in a vessel" or "conformable to a vessel." But many surgical implants are positionable in or conformable to a vessel without being stents. Examples include

vascular grafts, used to replace or connect vessels during conventional surgery, *see, e.g.,* D.I. 91, Ex. Z (U.S. Patent No. 4,300,244) at 1:10-14, as well as heart valves, which are surgically implanted and are positioned in or conform to a vessel, *see* D.I. 91, Ex. AA (U.S. Patent No. 4,689,046). *See also* D.I. 91, Ex. BB (U.S. Patent No. 4,483,339) (a vascular surgery roll for use in vessel to allow for easier suturing). Furthermore, similar claims were already in existence when Dr. Bonutti distinguished surgical devices, *see, e.g.,* D.I. 70, Ex. M at 4, and cannot be used to broaden claims that were limited to avoid the prior art.

15) Consistent with the claim language, the specification, and the prosecution history, the Court construes "a surgical device" from claim 1 of the '753 patent as meaning "a device for use in surgical applications, but not including an expandable intraluminal vascular graft or expandable prosthesis for a body passageway."

16) Consistent with the claim language, the specification, and the prosecution history, the Court construes "an implant" from claim 1 of the '290 patent as meaning "a device for use in surgical applications, but not including an expandable intraluminal vascular graft or expandable prosthesis for a body passageway."

B. an implant, at least a portion of which is expandable" ('753 patent) **and "at least a portion of the tubular member has a second cross sectional size ... larger than the first cross sectional size to thereby lock the tubular member against tissue in the human body"** ('290 patent)

17) The term "expandable" only appears in the specification with regard to the distal suture anchor of Figure 9 that "expands" to block removal of the suture. D.I. 70, Ex. A at Abstract; 2:27; 3:21-22; 8:44-9:2. This device has nothing to do with tubular members. The device of Figures 11A-C, which Dr. Bonutti pointed to as support for his claims (D.I. 70, Ex. N at 7; D.I. 70, Ex. O; D.I. 70, Ex. P), does not undergo expansion, but rather spreads. To the extent Figure 11 could be considered to expand at all, it necessarily must expand only in part. The body or sleeve of the rivet remains the same diameter so that the head has a greater diameter than the sleeve. That is how the rivet locks in place. This is no disclosure of a fully expandable device such as a stent. The claims are limited to what Dr. Bonutti "actually invented." Phillips, 415 F.3d at 1316 **(quoting** Renishaw, 158 F.3d at 1250).

18) Consistent with the claim language, the specification, and the prosecution history, the Court construes the language "an implant, at least a portion of which is expandable" from claim 1 of the '753 patent as meaning "a portion, but not all of the implant, is expandable."

19) Consistent with the claim language, the specification, and the prosecution history, the Court construes the language "a tubular member ... mechanically expandable ... from a contracted condition ... to an expanded condition in which at least a portion of the tubular member has a second cross sectional size ... larger than the first cross sectional size to thereby lock the tubular member against tissue in the human body" from claim 1 of the '290 patent as meaning "a portion, but not all, of the tubular member is expandable so that when expanded, its cross-sectional size is larger than its initial cross-sectional size. The expansion of only a portion of the tubular member enables it to be locked against tissue."

C. "a tubular member having a channel and mechanically expandable upon activation of a delivery mechanism" ('290 patent)

20) The claim terms "tubular member," "channel," and "mechanically expandable upon activation of a delivery mechanism" are never used in the specification. To the extent there is any support in the patent's written description for these terms, it is provided by Figures 11A-C, to which Dr. Bonutti pointed the Examiner. The sleeve of Figure 11 has a one-sided opening to hold the mandrel. The mandrel causes the

distal end of the sleeve to spread, locking behind the tissue. At best, sleeve 190 has an area for holding the mandrel which is closed at one end. It is the mandrel that causes the distal end of the sleeve, and only the distal end of the sleeve, to spread into the form of a rivet. There is no disclosure of any delivery mechanism. The claims are limited to what Dr. Bonutti "actually invented." Phillips, 415 F.3d at 1316 **(quoting** Renishaw, 158 F.3d at 1250).

21) Consistent with the claim language and the specification, the Court construes this phrase as meaning "the tubular member is a sleeve, closed at one end, having an area for holding a mandrel. The sleeve is mechanically expandable at only one end upon movement of the mandrel."

III. "HEAT BONDING" CLAIM TERMS

A. "a polymeric material bonded to the implant" ('753 patent) **and "a first component bonded to at least a portion of the tubular member" (**'290 patent)

22) Heat bonding is the only form of bonding taught by the patent. The specification defines "bondable material" as "any material, suitable for use in surgical applications, ***which can be softened and made flowable by the application of heat, and which, when softened, will become tacky and bond to other materials*** and will flow to fill available space." D.I. 70, Ex. A ('753 patent) at 3:52-57.

23) The specification describes the "present invention" as involving "heat bonding," putting the public on notice that Dr. Bonutti's invention covers heat bonding, not all bonding. Honeywell Int'l., Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed.Cir.2006) **("[T]he written description refers to the fuel filter as 'this invention' or 'the present invention'.... The public is entitled to take the patentee at his word and the word was that the invention is a fuel filter.");** Verizon Servs., 503 F.3d at 1308 **("When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention.").**

24) The specification distinguishes and disfavors methods of bonding that do not involve heat. *See* D.I. 70, Ex. A ('753 patent) at 7:14-28; 7:34-37. Such language indicates that the claims encompass heat bonding and nothing broader. Honeywell, 452 F.3d at 1320 **("[D]erogatory statements concerning one type of material are the equivalent of disavowal of that subject matter from the scope of the patent's claims.");** Scimed Life Sys., Inc. v. Advanced Cardiov. Sys., Inc. 242 F.3d 1337, 1341 (Fed.Cir.2001) **("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.").**

25) Confronted with prior art that taught bonding materials to a device using the same materials he had selected-the Palmaz '417 patent-Dr. Bonutti made arguments (D.I. 70, Ex. M at 6) and amendments to his claims (id. at 2; D.I. 70, Ex. O at 2.) to avoid that art. For claim construction purposes, these arguments and amendments are binding on Dr. Bonutti.

26) Dr. Bonutti disclaimed a device that has a polymer "placed upon" the implant by arguing that "[i]n contrast [to Dr. Palmaz' balloon-expandable stent], Applicants' implant includes a heat bondable material ***which is bonded to an implant by the application of heat.***" D.I. 70, Ex. M at 6. This argument limits his claims so as to exclude devices where a material is bonded to the device other than by the application of heat. Seachange Int'l, Inc. v. C-Cor, Inc., 413 F.3d 1361, 1372-73 (Fed.Cir.2005) **("Where an applicant**

argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language."); *see* Springs Window Fashions, 323 F.3d at 995 (**"A patentee may not state during prosecution that the claims do not cover a particular device and then change position...."); ** Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed.Cir.2003) (**"As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution.") (citation omitted); *see also*** Computer Docking, 519 F.3d at 1379; Gillespie, 501 F.3d at 1291; Chimie, 402 F.3d at 1384**.**

27) MarcTec argues that it is improper to limit a product claim to a particular process of manufacture (*i.e.* heat bonding). The Court does not agree. Dr. Bonutti's claims are limited to heat bonding because Dr. Bonutti relied on this aspect of his invention to distinguish Palmaz and obtain his patents. ***See*** Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1373-75 (Fed.Cir.2007) (**construing claims to a composite to be limited to composites prepared using a particular process because the specification made clear that this process was an essential part of the claimed invention and the particular process was used to distinguish prior art);** Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995) (**construing claim to sputter-deposited dielectric layer to be limited to a layer created by a particular process where the process was used to distinguish prior art).**

28) MarcTec also relies on the doctrine of claim differentiation to argue that it is improper to limit claim 1 of the '753 patent to heat bonding because such a construction would make claim 8 of the '753 patent ("The surgical device of claim 7 wherein the polymeric material is bonded to the implant by the application of heat") redundant. This argument is defeated by the specification and prosecution history.

29) "[T]he doctrine of claim differentiation cannot broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1384 (Fed.Cir.1999) (**quoting** Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed.Cir.1998))**;** Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed.Cir.2000) (**"[T]he written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation...."). ** First, as discussed, the specification discloses only heat bonding. Second, claim 8 is an original claim (filed originally as claim 18, which depended from original claim 11). D.I. 91, Ex. CC at 29. It was written before Dr. Bonutti's independent claims were rejected over Palmaz and before Dr. Bonutti obtained his patent by arguing that his invention was different than Palmaz because, unlike Palmaz, "[a]pplicants' implant includes a heat bondable material which is bonded to an implant by the application of heat." D.I. 70, Ex. M at 6. That argument limited the term "bonded" in the *independent* claims to "heat bonded"-claim 8 was not at issue.

30) Consistent with the claim language, the specification, and the prosecution history, the Court construes the phrase "a polymeric material bonded to the implant" from claim 1 of the '753 patent as meaning "a polymeric material is bonded to the implant by the application of heat."

31) Consistent with the claim language, the specification, and the prosecution history, the Court construes "a first component bonded to at least a portion of the tubular member" from claim 1 of the '290 patent as meaning "a material is bonded to the tubular member by the application of heat."

B. "heat bondable material" ('290 patent)

32) The term "heat bondable material" is construed, as the parties agree, as it is defined in the specification: "any material, suitable for use in surgical applications, which can be softened and made flowable by the application of heat, and which, when softened, will become tacky and bond to other materials and will flow to fill available space." D.I. 70, Ex. A ('753 patent) at 3:52-57.

C. "thermoplastic" ('753 and '290 patents)

33) The specification makes clear that a thermoplastic is a kind of heat bondable material. D.I. 70, Ex. A ('753 patent) at 3:52-61 ("Thus, the material may be thermoplastic."). Thermoplastic is construed in the same manner as "heat bondable material," i.e., "any material, suitable for use in surgical applications, which can be softened and made flowable by the application of heat, and which, when softened, will become tacky and bond to other materials and will flow to fill available space."

D. "the polymeric material ... is non-flowable and non-adherent at room temperature" ('753 patent) **and "the heat bondable material is non-flowable and non-adherent at room temperature"** ('290 patent)

34) The claim language "the polymeric material ... is non-flowable and non-adherent at room temperature" is more than a description of the heat bondable material in its isolated state. It requires the heat bondable material to be bonded by the application of heat.

35) The specification teaches that for the polymeric material to bond, it must be heated so as to flow and become adherent. Without heat, the material does not flow and will not adhere. D.I. 70, Ex. A ('753 patent) at 3:52-57; *see* id. at 3:59-65; 2:20-23. As Dr. Bonutti explained to the Patent Office-and thus to the public-this is an important limitation that distinguishes his invention from Palmaz's drug-eluting stent, where the polymeric material adheres merely by being "placed upon" the stent. D.I. 70, Ex. M at 5-6.

36) Consistent with the claim language, the specification, and the prosecution history, the Court construes the language "the polymeric material ... is non-flowable and non-adherent at room temperature" from claim 1 of the '753 patent as meaning "the polymeric material cannot flow at room temperature and cannot adhere to the implant if placed on the implant at room temperature."

37) Consistent with the claim language, the specification, and the prosecution history, the Court construes the phrase "the heat bondable material is non-flowable and non-adherent at room temperature" from claim 1 of the '290 patent as meaning "the heat bondable material cannot flow at room temperature and cannot adhere to the tubular member if placed on the tubular member at room temperature."

E. "the polymeric material ... becomes flowable, tacky and adherent upon the application of heat" ('753 patent) **and "the heat bondable material ... becomes flowable, tacky and adherent upon the application of heat"** ('290 patent)

38) The plain language of the claim language "the [polymeric/heat bondable] material ... becomes flowable, tacky and adherent upon the application of heat" requires that the material bonded to the implant be transformed by the addition of heat, from being non-flowable and non-adherent at room temperature to being flowable, tacky, and adherent. It takes heat to bond in the Bonutti invention and that heat must be sufficient to cause the material to be bonded to become flowable, tacky and adherent. This claim language is consistent with the specification that teaches that heat is required to bond.

39) This claim language was added to each patent during prosecution, (D.I. 70, Ex. M at 2; D.I. 70, Ex. O at 2), to avoid the prior art Palmaz patent, (id. at 5-6), and is construed consistent with this clear and unequivocal statement in the file history. Seachange, 413 F.3d at 1372-73; Springs Window, 323 F.3d at 995; Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed.Cir.2002).

40) Consistent with the claim language, the specification, and the prosecution history, the Court construes the phrase "the polymeric material ... becomes flowable, tacky and adherent upon the application of heat" from claim 1 of the '753 patent as meaning "the polymeric material is bonded to the implant by the application of heat sufficient to cause the polymeric material to become flowable, tacky and adherent."

41) Consistent with the claim language, the specification, and the prosecution history, the Court construes the phrase "the heat bondable material ... becomes flowable, tacky and adherent upon the application of heat" from claim 1 of the '290 patent as meaning "the heat bondable material is bonded to the tubular member by the application of heat sufficient to cause the heat bondable material to become flowable, tacky and adherent."

F. "laser cut surface" ('290 patent)

42) Lasers are only mentioned in the specification in connection with heating and shaping the polymeric material used to cover the implant. *See* D.I. 70, Ex. A ('753 patent) at Abstract; 4:18-26; 5:50-53; 6:21-23; 6:36-38; 6:45-52; 6:53-64. There is no disclosure of lasers being used for any other purpose or on any other portions of the implant. Laser cutting of metal stents was performed long before Dr. Bonutti filed his application. He did not invent it, he did not disclose it and cannot claim it. Dr. Bonutti's claims are limited to what he "actually invented." Phillips, 415 F.3d at 1316 (**quoting** Renishaw, 158 F.3d at 1250).

43) Consistent with the claim language and the specification, the Court construes this phrase as meaning "the surface of the implant includes a heat bondable material cut with heat from a laser."

G. "composite material" ('290 patent)

44) The specification defines this claim term: "Composite materials can include reinforced plastics, or polymers which are laminated or layered or reinforced with one or more other materials such as nylon, graphite fibers, Kevlar fibers, stainless steel fibers, etc." D.I. 70, Ex. A ('753 patent) 3 :65-4 :2.

45) Consistent with the claim language and the specification the Court construes this phrase as meaning "reinforced plastics, or polymers which are laminated or layered or reinforced with one or more other materials such as nylon, graphite fibers, Kevlar(R) fibers, stainless steel fibers, etc."

IV. THERAPEUTIC AGENT TERMS

A. "a therapeutic agent" ('753 patent)

46) The term "therapeutic agent" is not in the specification. The only support for this claim term is a single sentence explaining that the surgical devices of the invention "can also include tissue ingrowth promoters, antibiotics, or other additives as desired." D .I. 70, Ex. A ('753 patent) at 6:26-28. Consequently, the claim term "therapeutic agent" is limited to the only therapeutic agents taught in the specification-tissue ingrowth promoters and antibiotics. ***See The*** Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed.Cir.1997) (**a disclosure of only rat** insulin **cDNA did not support claims to the genus of vertebrate**

or mammalian insulin **cDNAs);** Amgen, Inc. v. Chugai Pharm. Co., Ltd ., 927 F.2d 1200, 1213-14 (Fed.Cir.1991) **(examples of preparing several EPO analog genes were insufficient to support claims to all EPO gene analogs);** In re Vaeck, 947 F.2d 488, 495-96 (Fed.Cir.1991) **(example of transformation of a single strain of cyanobacteria was insufficient to support claim to gene expression in all cyanobacteria).**

47) Consistent with the claim language, the specification, and the prosecution history, the Court construes "therapeutic agent" from the '753 patent as meaning "a tissue ingrowth promoter or antibiotic."

B. "antibiotic" ('**753 and** '290 patents)

48) The word antibiotic only appears once in the specification and is not further explained. D.I. 70, Ex. A ('753 patent) 6 :26-28. The antibiotic claim limitation was added during prosecution of the '753 patent, and the Examiner rejected claims because prior art taught using an antibiotic in a surgical implant to "minimize infection" of the implant and surrounding tissue or "to reduce the chance of infection." D.I. 70, Ex. Q at 3; D.I. 70, Ex. R at 3; D.I. 70, Ex. L at 4; D.I. 70, Ex. T at 3. The Examiner's understanding of "antibiotic" is consistent with the ordinary meaning of the term.

49) Consistent with the ordinary meaning of the claim language, the specification, and the prosecution history, the Court construes "antibiotic" as meaning "a therapeutic agent used to minimize or reduce infection."

C. "tissue ingrowth promoter" ('290 patent)

50) The term "tissue ingrowth promoter" only appears once in the specification and is not further explained. D.I. 70, Ex. A ('753 patent) 6 :26-28. Consistent with the plain meaning of the claim language and the specification, the Court construes this phrase as meaning "a therapeutic agent used to increase tissue growth."

IT IS SO ORDERED that the foregoing claim terms are construed as indicated herein.

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Marctec, LLC v. Johnson & Johnson

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