

United States District Court,
N.D. California.

EDWARDS LIFESCIENCES LLC, et al,
Plaintiffs.

v.
COOK INCORPORATED, and W.L. Gore and Associates,
Defendants.

No. C 03-03817 JSW

July 23, 2007.

David T. Pritikin, Hugh A. Abrams, Lisa Anne Schneider, Matthew Thomas Powers, Russell L. Johnson, Tracy A. Braun, Sidley Austin LLP, Stephanie Pauline Koh, Carrie W. Cotter, Sidley Austin Brown & Wood LLP, Ann M. Mace, Attorney at Law, Richard T. McCaulley, Jr., McAndrews Held & Malloy, Chicago, IL, Robert Burns Morrill, Sidley Austin LLP, Georgia Kloostra Vanzanten, Sidley Austin Brown & Wood LLP, San Francisco, CA, for Plaintiffs.

Gerard Haddad, Jennifer Bianrosa, Regina M. Lutz, Christopher K. Hu, David H. Pfeffer, John T. Gallagher, Morgan & Finnegan, L.L.P., New York, NY, Mark Jay Linderman, John Frederick Querio, Sonnenschein Nath & Rosenthal LLP, San Francisco, CA, David J. Johns, W.L. Gore & Associates, Inc., Flagstaff, AZ, John S. Campbell, W.L. Gore & Associates, Newark, DE, for Defendants.

CLAIM CONSTRUCTION ORDER

JEFFREY S. WHITE, United States District Judge.

INTRODUCTION

Plaintiffs Edwards Lifesciences LLC ("Edwards") and Endogad Research PTY Limited ("Endogad") (collectively "Plaintiffs") filed this suit alleging that Defendants, Cook Incorporated ("Cook") and W.L. Gore & Associates, Inc. ("Gore") (collectively "Defendants"), infringe U.S. Patent Nos. 6,582,458 ("the '458 Patent"), 6,613,073 ("the '073 Patent"), 6,685,736 ("the '736 Patent"), and 6,689,158 ("the '158 Patent") (collectively the "patents-in-suit").

Pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), on March 14, 2007, the Court held a claim construction hearing to construe disputed claim terms from the patents-in-suit. On June 28, 2007, the Court ordered supplemental briefing on whether preamble terms should be construed.

Having carefully considered the parties' papers, including their supplemental briefs, having heard the parties' arguments, and having considered the relevant legal authorities, the Court construes the disputed terms and

phrases as set forth in the remainder of this Order.

BACKGROUND

The patents-in-suit relate to devices for treating aneurysms, in particular abdominal aortic aneurysms, and occlusive disease without resort to "open" surgery. (*See* Declaration of Lisa A. Schneider in Support of Opening Claim Construction Brief ("Schneider Decl."), Exs. 2, 12, 20, 21.) In this case, the patents-in-suit each are continuations of U.S. Patent No. 5,782,904 ("the '904 Patent") and share a common specification. Further, each of the patents-in-suit claim devices, or articles of manufacture, rather than methods, systems or processes. For purposes of this Order, the Court sets forth the first claim of each of the patents-in-suit, which contain most, but not all, of the disputed terms or phrases.

Claim 1 of the '458 Patent recites:

A *prosthesis* comprising:

(i) a *bifurcated base structure* which defines a common flow lumen and a *pair of connector legs* which define divergent flow lumens from the common flow lumen;

and

(ii) a *graft which is adapted to be anchored within one of the flow lumens* of said *bifurcated base structure* to form a continuous extension of that lumen.

(Schneider Decl., Ex. 2, '458 Patent, col. 6, ll. 12-19 (disputed claim terms emphasized).)

Claim 1 of the '158 Patent recites:

A *prosthesis* comprising:

a *bifurcated base graft structure* which defines a common flow lumen and a *pair of connector legs* which define divergent flow lumens from the common flow lumen; and

a second *graft structure which is adapted to be anchored within one of the flow lumens* of said *bifurcated base graft structure* to form a continuous extension of that lumen; and

wherein at least of one of the *bifurcated base graft structure* and the second graft structure comprises a first end, a second end and a wire member having at least a portion adjacent to the first end, the wire member including a plurality of projecting apices, and wherein the first end includes *an edge which is scalloped between projecting apices of the wire member*.

(Schneider Decl., Ex. 12, '158 Patent, col. 6, ll. 14-29 (disputed claim terms emphasized).)

Claim 1 of the '073 Patent recites:

A *graft* for treatment of aneurysms or occlusive diseases comprising:

a primary *graft body*, said primary *graft body* having a primary graft flow lumen therethrough, said primary *graft body* having a first portion and a second portion; and

a supplemental *graft body*, said supplemental *graft body* having a secondary graft flow lumen therethrough, said supplemental *graft body* comprising a first end and a second end, *said first end of said supplemental graft body being dockable to said second end of said primary graft body while inside of a vessel to define a single flow lumen which transfers substantially all blood flow between said primary graft flow lumen and said secondary graft flow lumen.*

(Schneider Decl., Ex. 20, '073 Patent, col. 6, ll. 43-57 (disputed terms emphasized).)

Claim 1 of the '736 Patent recites:

A *graft* comprising:

a first *graft body*, said first *graft body* having a first *graft body* inlet end and a first *graft body* outlet end to define a flow passage therethrough; and

a second *graft body*, said second *graft body* having a second *graft body* inlet end and a second *graft body* outlet end to define a flow passage therethrough;

said second graft body inlet end being attachable in an overlapping relationship with said first graft body outlet end while inside of a vessel to define a continuous flow passage through said first graft body inlet end, said first graft body outlet end, said second graft body inlet end and said second graft body outlet end.

(Schneider Decl., Ex. 21, '736 Patent, col. 6, ll. 14-26 (disputed claim terms emphasized).)

ANALYSIS

A. Legal Standard.

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed.Cir.2004). The interpretation of the scope and meaning of disputed terms in patent claims is a question of law and exclusively within the province of a court to decide. *Markman*, 517 U.S. at 372. The inquiry into the meaning of the claim terms is "an objective one." *Innova/Pure Water*, 381 F.3d at 1116. As a result, when a court construes disputed terms, it "looks to those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." *Id.* In most cases, a court's analysis will focus on three sources: the claims, the specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). However, on occasion, it is appropriate to rely on extrinsic evidence regarding the relevant scientific principles, the meaning of technical terms, and the state of the art at the time the patent issued. *Id.* at 979-81.

The starting point of the claim construction analysis is an examination of the specific claim language. A court's "claim construction analysis must begin and remain centered on the claim language itself, for that is the language that the patentee has chosen to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." *Innova/Pure Water*, 381 F.3d at 1116 (internal quotations and

citations omitted). Indeed, in the absence of an express intent to impart a novel meaning to a term, an inventor's chosen language is given its ordinary meaning. *York Prods., Inc. v. Cent. Tractor Farm & Family Center*, 99 F.3d 1568, 1572 (Fed.Cir.1996). Thus, "[c]laim language generally carries the ordinary meaning of the words in their normal usage in the field of the invention." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1367 (Fed.Cir.2003); *see also Renishaw v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998) (recognizing that "the claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim"). A court's final construction, therefore, must accord with the words chosen by the patentee to mete out the boundaries of the claimed invention.

The claims, however, do not stand alone. Thus, the written description, the drawings, and, if included in the record, the prosecution history provide context and clarification regarding the intended meaning of the claim terms. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324-25 (Fed.Cir.2002). Rather, "they are part of 'a fully integrated written instrument.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed.Cir.2005) (en banc) (quoting *Markman*, 52 F.3d at 978). The specification "may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979. The specification also can indicate whether the patentee intended to limit the scope of a claim, despite the use of seemingly broad claim language. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed.Cir.2001) (when 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").

Intent to limit the claims can be demonstrated in a number of ways. For example, if the patentee "acted as his own lexicographer," and clearly and precisely "set forth a definition of the disputed claim term in either the specification or prosecution history," a court will defer to that definition. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002). In order to so limit the claims, "the patent applicant [must] set out the different meaning in the specification in a manner sufficient to give one of ordinary skill in the art notice of the change from ordinary meaning." *Innova/Pure Water*, 381 F.3d at 1117. In addition, a court will adopt an alternative meaning of a term "if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." *CCS Fitness*, 288 F.3d at 1367. Likewise, the specification may be used to resolve ambiguity "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone ." *Teleflex*, 299 F.3d at 1325.

However, limitations from the specification (such as from the preferred embodiment) may not be read into the claims, absent the inventor's express intention to the contrary. *Id.* at 1326; *see also CCS Fitness*, 288 F.3d at 1366 ("[A] patentee need not 'describe in the specification every conceivable and possible future embodiment of his invention.'") (quoting *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed.Cir.2001)). To protect against this result, a court's focus should remain on understanding how a person of ordinary skill in the art would understand the claim terms. *Phillips*, 415 F.3d at 1323.

If the analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language, a court then may turn to extrinsic evidence, such as expert declarations and testimony from the inventors. *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed.Cir.2003) ("When an analysis of *intrinsic* evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so

ascertained.") (emphasis in original). When considering extrinsic evidence, a court should take care not to use it to vary or contradict the claim terms. Rather, extrinsic evidence is relied upon more appropriately to assist in determining the meaning or scope of technical terms in the claims. *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1583-84 (Fed.Cir.1996).

Dictionaries also may play a role in the determination of the ordinary and customary meaning of a claim term. In *Phillips*, the Federal Circuit reiterated that "[d]ictionaries or comparable sources are often useful to assist in understanding the commonly understood meanings of words...." *Phillips*, 415 F.3d at 1322. The *Phillips* court, however, also admonished that district courts should be careful not to allow dictionary definitions to supplant the inventor's understanding of the claimed subject matter. "The main problem with elevating the dictionary to ... prominence is that it focuses the inquiry on the abstract meaning of the words rather than on the meaning of claim terms within in the context of the patent." *Id.* at 1321. Accordingly, dictionaries necessarily must play a role subordinate to the intrinsic evidence.

In addition, a court has the discretion to rely upon prior art, whether or not cited in the specification or the file history, but only when the meaning of the disputed terms cannot be ascertained from a careful reading of the public record. *Vitronics*, 90 F.3d at 1584. Referring to prior art may make it unnecessary to rely upon expert testimony, because prior art may be indicative of what those skilled in the art generally understood certain terms to mean. *Id.*

B. Claim Construction.

The parties dispute the meaning of twelve claim terms or phrases culled from each of the patents-in-suit. The parties' proposed constructions are set forth in an Appendix to this Order, and the key differences are summarized herein.

1. "Prosthesis" and "Graft" FN1

FN1. The term "prosthesis" is found in the preamble of independent claim 1 of the '458 Patent and in each of the dependent claims of that patent. The term "prosthesis" also is found in the preamble to independent claims 1, 15, 17 and 23 of the '158 Patent and in each of the dependent claims of that patent. The term "prosthesis" also is found in the bodies of dependent claim 22 and independent claim 23 of the '158 Patent.

The term "graft" is found in the preamble of independent claim 1 of the '073 Patent and is found in the preamble of independent claims 1, 20, 21 and 23 of the '736 Patent. It also is found in each of the dependent claims of those patents.

The parties ask the Court to construe the terms "prosthesis" and "graft," as those terms are used in the preambles to asserted claims. "Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Storage Technology Corp. v. Cisco Systems, Inc.*, 329 F.3d 823, 831 (Fed.Cir.2003) (citing *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed.Cir.2002)). A preamble "generally limits the claimed invention if it 'recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim.'" *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1305 (Fed.Cir.2005) (quoting *Catalina Mktg. Int'l*, 289 F.3d at 808); *see also* *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed.Cir.2003) ("When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention."); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1350 (Fed.Cir.1998) ("[A] preamble usually does not limit the scope of the claim unless the preamble provides antecedents for ensuring claim terms and limits the claim accordingly.").

If, however, the preamble merely "serves as a convenient label for the invention as a whole," and the body of the claim sets out the complete invention, a preamble term will not limit the scope of the claims. *Storage Technology*, 329 F.3d at 831; *Bristol-Meyers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1373-74 (Fed.Cir.2001) (citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999)).

In general, these terms are used only in the preambles to independent claims. (*See* '458 Patent, claim 1; '073 Patent, claim 1; '736 Patent, claims 1, 20, 22; and '158 Patent, claims 1, 15, and 17.) These terms also are used in dependent claims, prior to the introduction of additional limitations. (*See, e.g.*, '458 Patent, claim 2 ("The prosthesis as defined in claim 1, wherein said bifurcated base structure is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires.") The bodies of the independent claims, which use the terms solely in their preamble, set out a complete invention that is not dependent upon the preamble term for life, meaning or vitality. Further, because the bodies of these independent claims do not use the terms "prosthesis" or "graft," they do not "derive antecedent basis from the preamble." *See* *Eaton*, 323 F.3d at 1339.

Cook argues that because the terms "prosthesis" and "graft" are used in dependent claims, the terms in those claims must derive their antecedent basis from the independent claims. The Court does not find this argument persuasive, as it effectively negates the principle that a preamble term may serve merely as a label for the invention as a whole. Thus, the Court concludes that with respect to claim 1 of the '458 Patent, claim 1 of the '073 Patent, claims 1, 20 and 22 of the '736 Patent, and claims 1 and 15 of the '158 Patent, the terms "prosthesis" and "graft," are labels for the invention as a whole and need not be construed.

However, independent claim 21 of the '736 patent, and independent claim 23 and dependent claim 22 of the '158 Patent, which depends from independent claim 17 of that patent, use the terms "prosthesis" or "graft" in both the preamble and the body of the claims. In the *Catalina Mktg.* case, *supra*, the district court determined that a term used solely in a preamble of one claim and in the preamble and body of another claim should be construed as a limitation in both claims. The Federal Circuit reversed. With respect to the claim that used the term only in the preamble, the court held that the term was not a limitation because: "the applicant did not rely on this phrase to define its invention nor is the phrase essential to understand limitations or terms in the claim body[;]" the specification did show that the term provided additional structure for the invention described in the body of the claim; the inventors had not relied on the term to distinguish over prior art; and because if the disputed phrase was deleted from the preamble, it would not affect the fact that the claim body defined a structurally complete invention. *Catalina Mktg.*, 289 F.3d at 810. As to the claim where the term was used both in the preamble and the body, the Federal Circuit affirmed the district court's construction of the term as a limitation, because the term as used in the body derived antecedent basis from the preamble. *Id.* at 810-11. In this case, in those claims where the inventors chose to use the terms "prosthesis" and "graft," in the preamble and the bodies of claims, the Court concludes that the preamble does provide an antecedent basis for the terms as used in the body and, therefore, acts as a limitation for those terms.

Defendants assert that the Court should construe the terms "prosthesis" and "graft" to mean an intraluminal device. Plaintiffs argue that the terms should be construed more broadly and can encompass a device comprised in part of a traditional vascular graft. Gore also argues the Court should construe these terms as "multi-component" devices "used as a unit." FN2

FN2. The claim language demonstrates that the claimed "prosthesis" or "graft" is comprised of several components, *i.e.* a bifurcated base graft structure and a second graft structure, or a first graft body and a

second graft body. The Court, therefore, concludes it is not necessary to include "multi-component" in its construction of these terms.

The Court first looks to the language of the claims. Claim 21 of the '736 Patent refers to overlapping or attaching one portion of the "graft" to the second portion of the "graft," while it is inside of a vessel. ('736 Patent, col. 7, ll. 36-38.) As is discussed in more detail below, Claims 22 and 23 of the '158 Patent refer to the "prosthesis" being placed in a vessel. Thus, the language of these claims support Defendants' position that the terms should be construed to be limited to intraluminal devices.

The Court also considers the claim language in light of the specification of which it is a part. *See* Markman, 52 F.3d at 979. The specification shows that the inventors use the term "graft" as shorthand for "intraluminal graft." FN3 For example, in the "Field of the Invention" section, the inventors state that "[t]he present invention relates to an intraluminal graft for use in treatment of aneurysms or occlusive disease." ('458 Patent, col. 1, ll. 10-11.) In the section entitled "Background Art," the inventors state that "[i]t is known to use 'stents and intraluminal grafts of various designs for the treatment of aneurysms' (*Id.*, col. 1, ll. 15-16.) The inventors discuss the prior art intraluminal grafts and then state that "[s]uch *intraluminal grafts* are inserted through the femoral artery into the aorta in a catheter. Upon release of *the graft* from the catheter it expands to the size of the aorta[.] ... There are a number of problems associated with such known *grafts*." (*Id.*, col. 1, ll. 27-33 (emphasis added).) The inventors conclude by stating that "[t]he present invention is directed to an *alternative form of intraluminal graft* which provides an alternative to *known grafts*." (*Id.*, col 1., ll. 40-42 (emphasis added).) *See* Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed.Cir.2006) ("On at least four occasions the written description refers to the fuel filter as 'this invention' or 'the present invention.' ").

FN3. Because the patents-in-suit share a common specification, for ease of reference, the Court's citations to the specification in this Order are to the '458 Patent. The only time the term "prosthesis" appears in the specification is in the title of an article cited in the section of the specification describing the Background Art. (*See, e.g.*, '458 Patent, col. 1, ll. 22-24.) Defendants urge the Court to adopt their construction of the term "prosthesis," primarily based upon the language in the specification that refers to "the invention" as an "intraluminal graft." That is, Defendants essentially equate the term "prosthesis," as used in the preamble to claims of the '458 and '158 Patents, to the term "graft," as used in the preambles to claims of the '736 Patent and '073 Patent. Plaintiffs do not seem to seriously dispute this proposition and do not articulate a clear difference between the two terms, other than to argue that the term "graft" should include a requirement that it be formed in part of plastic or polymer.

Similarly, in the section entitled "Disclosure of the Invention," the inventors state that "[i]n another aspect the invention relates to a method for positioning an *intraluminal graft* as defined above ... causing an *intraluminal graft* as defined above to be carried through the catheter on an inflatable balloon until the *graft* extends into the vessel from the proximal end of the catheter" (*Id.*, col. 1, ll. 54-59 (emphasis added).) In addition, in the section entitled "Best Mode of Carrying Out the Invention," the inventors use the terms "intraluminal graft **10**" and "graft **10**" interchangeably. (*See, e.g.*, *id.* at col. 5, ll. 11, 17, 21, 26-27, 58-67, col. 6, ll. 1-10.) Finally, the specification is rife with references to the "intraluminal graft" or, the shorthand "graft", as "the invention" or "this invention." (*See, e.g.*, *id.*, col. 1, ll. 11-12, 40-41, 45-46, col. 3, ll. 33, 39-40, 45, col. 4, ll. 5-6, 20, 32, 55-56.)

Finally, each of the alternative embodiments described in the specification refer to devices that contain wires, which all parties agree are a feature of intraluminal grafts. None of the alternative embodiments, however, describe a traditional vascular graft. Nor do any of the figures disclose a traditional vascular graft. These facts further support Defendants' argument that the terms "prosthesis" and "graft" should be limited to intraluminal devices. (*See, e.g.*, '458 Patent, col. 3, ll. 26-32 & Figs. 1-7.)

Plaintiffs rely on declarations submitted during the prosecution history to support their position that the terms "prosthesis" and "graft" should not be so limited. (*See* Schneider Decl., Exs. 4-8.) These declarations describe a surgery that Dr. White performed, on October 6, 1993, in which he overlapped an intraluminal graft with a traditional vascular graft, using what Plaintiffs describe as the "Sydney Trombone Technique." With respect to the term "prosthesis," Plaintiffs also rely on the fact that a dictionary definition of the term "prosthesis," which comports with their proposed construction, is attached to the Declaration of Dr. Ian Gordon. (*See* Schneider Decl., Ex. 7.) However, a fair read of Dr. Gordon's declaration supports Defendants' position. In that declaration, Dr. Gordon did not refer back to the traditional vascular graft when he explained the meaning of the term "prosthesis." He referred back to the *endovascular* grafts. (Schneider Decl., Ex. 7 at 2 ("[E]ach *endovascular* graft is a prosthesis ...") (emphasis added).) Thus, although the language of the claims, read without reference to the specification, might be broad enough to encompass a non-intraluminal prosthesis or graft, when the Court reads the claims in light of the specification, it concludes that a person of ordinary skill in the art would understand that the inventors used the terms "prosthesis" and "graft" in these claims to claim intraluminal devices. *See* SciMed Life Sys., Inc., 242 F.3d at 1341.

The language of claim 21 of the '736 Patent, and the language of claims 22 and 23 of the '158 Patent also support Gore's position that the "prosthesis" or "graft" should be construed to require that the device is used in a unitary fashion. For example, dependent claim 22 of the '158 Patent teaches that "the prosthesis is adapted to be placed in a lumen of a first vessel that intersects with a second vessel...." ('158 Patent, col. 8, ll. 1-2.) Similarly, independent claim 23 reads as follows:

A prosthesis comprising:

a bifurcated base graft structure which defines a common flow lumen and a pair of connector legs which define divergent flow lumens from the common flow lumen; and

a second graft structure which is adapted to overlap and be attached to one of the flow lumens of said bifurcated base structure [*sic*] to form a continuous extension of that lumen;

wherein at least one of the bifurcated base graft structure and the second graft structure comprises a first end and a second end, and wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the wire structure apices extend across a lumen of a first vessel that opens into a second vessel *in which the prosthesis is being placed* without occluding the lumen of said first vessel.

(*Id.*, col. 8, ll. 17-36 (emphasis added).) Independent claim 21 of the ' 736 Patent contains language that is similar to the "wherein clause" of claim 23 of the '158 Patent. (*See* '736 Patent, col. 8, ll. 3-13 ("wherein *the graft is adapted to be placed in a lumen of a first vessel that intersects with a second vessel*; and wherein at least one of the said inlet end of said first graft body and said outlet end of said second graft body that is adjacent to a junction between the first vessel and the second vessel is reinforced with a wire member

which has a plurality of apices extending beyond at least a portion of said respective end adjacent to said junction, and said plurality of apices extend across said junction so that *the graft does not occlude the lumen of the second vessel*") (emphasis added).

The inventors specifically define the term vessel in the specification as "blood vessels or like ducts such as the bile duct and the ureter." (*See* '458 Patent, col. 1, ll. 18-20.) Thus, the claim language emphasized above, when combined with the inventors' explicit definition of vessel, supports a conclusion that the inventors intended that both portions of the "prosthesis" or "graft" described in these claims would be used in a unitary fashion. This claim language therefore undercuts Plaintiffs' argument that the "prosthesis" or "graft" claimed could be comprised, in part, of a device that already had been implanted in a patient.

Accordingly, the Court construes the terms "graft," as used in claim 21 of the '736 Patent, and the term "prosthesis," as used in claims 17, 22 and 23 of the '158 Patent, to mean: **"An intraluminal device that is used in unitary fashion to substitute, repair or replace a missing or defective part of a vessel."**

2. "Bifurcated Base Structure" and "Bifurcated Base Graft Structure" FN4

FN4. The term "bifurcated base structure" is found in independent claim 1 of the '458 Patent. The parties ask the Court to construe this term and the term "bifurcated base graft structure," found in independent claims 1, 15, 17 and 23 of the '158 Patent in the same manner.

The parties agree that the "bifurcated base [graft] structure" is divided at its downstream end. Cook argues that it must be "trouser" shaped. Plaintiffs and Gore argue it is either "Y-shaped" or "forked." FN5 The primary dispute between the parties is whether this term should be construed to mean that the "bifurcated base [graft] structure" is an intraluminal device that contains malleable wires.

FN5. Plaintiffs also propose a construction that includes a requirement that the "bifurcated base structure" permits the "connection of additional grafts." The Court concludes that this feature of the "bifurcated base [graft] structure" is addressed by the manner in which the Court construes the term "a pair of connector legs."

Plaintiffs support their position that the "bifurcated base [graft] structure" is not limited to intraluminal devices by reference to the declarations submitted during the prosecution history, which describe the October 6, 1993 surgical procedure. Plaintiffs argue that these declarations refer to an "aorto-iliac bypass graft," which previously had been implanted in the patient during open surgery. Plaintiffs equate that aorto-iliac bypass graft to the "bifurcated base [graft] structure" as used in the claims. Plaintiffs also argue that because claim 1 of the '158 Patent provides that "at least one" of the bifurcated base graft structure or the second graft structure has a wire member, the Court should not construe "bifurcated base [graft] structure" to require wires in all instances. Defendants, in contrast, argue that the specification does not support a construction of the term "bifurcated base [graft] structure" that could include a traditional surgical graft, *i.e.* a graft without wires. Defendants also argue that the specification demonstrates that the inventors disclaimed resilient wires.

Defendants' arguments do find support in the specification. For example, in the sections of the specification that describe a bifurcated device, the inventors state that when an aneurysm is located near a bifurcated

artery, "it is possible to place a graft according to the present invention which has a bifurcation at its downstream end, a so-called 'trouser-graft', *wholly within the primary artery*." ('458 Patent, col. 4 ll. 18-23 (emphasis added).) That section of the specification continues, "[i]n the case of an aneurysm in the aorta, for instance, that extended into each of the iliac arteries the primary graft of the 'trouser' type would be placed in the aorta *through one of the iliac arteries*." (*Id.*, col. 4, ll. 25-29 (emphasis added).) These references suggest that the device in question is placed intraluminally and is not a bifurcated device already implanted in a vessel.

Further support for Defendants' position is found in the section of the specification in which the inventors state that one leg of a trouser graft "will have a skirt which cannot be expanded by a balloon catheter." (*Id.*, col. 4, ll. 45-49.) This language again suggests that the "bifurcated base [graft] structure" of the claims would not encompass a traditional vascular graft. In addition, the prosecution history of the '158 Patent shows that when the inventors added the "bifurcated base graft structure" language to the claims, they referred to the portions of the specification, cited above, that describes a bifurcated device as support for that claim language. (*See* Prosecution History of '158 Patent, 37 CFR 1.111 Amendments dated Aug. 11, 2003 and October 30, 2003, Inventors Remarks and Support Chart.)

Plaintiffs also rely on the doctrine of claim differentiation to support their position that the "bifurcated base [graft] structure" could encompass a traditional vascular graft. Thus, by way of example, Plaintiffs argue that because dependent claim 2 of the '458 Patent recites a prosthesis "wherein said bifurcated base structure is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires," the Court should not construe the term as used in independent claim 1 of that patent to require wires. (*Compare* '458 Patent, col. 6, ll. 12-19, *with id.*, col. 6, ll. 20-23.)

In general, the doctrine of claim differentiation recognizes "that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1369 (Fed.Cir.2007) (quoting *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed.Cir.1999)). Thus, there is a presumption that "[t]o the extent the absence of such difference in meaning and scope would make a claim superfluous, ... the difference between claims is significant." *Id.* (quoting *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed.Cir.1987)). That presumption may be overcome, however, by the written description of the patent or its prosecution history. *Id.*

Defendants argue that claim 1 of the '458 Patent would not be rendered superfluous if the Court were to adopt their construction, because the dependent claims of that patent contain other limitations, such as "circumferentially reinforced at locations along its length." Indeed, dependent claim 11 of the '458 Patent provides that "said graft is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires." This language refers back to the "graft which is adapted to be anchored within one of the flow lumens," limitation of independent claim 1, which appears in the second portion of the body of the claim. Plaintiffs, however, argue that it is the second portion of the bodies of the asserted claims that incorporate the intraluminal limitation. Thus, under Plaintiffs' theory, the "circumferentially reinforced" language must be an additional limitation. Furthermore, when the Court views the term "bifurcated base [graft] structure" in light of the references in the specification that describe a bifurcated device, the Court does not find Plaintiffs' claim differentiation argument persuasive. (*See* '458 Patent, col. 4, ll. 18-23, 25-29, 45-49.)

Plaintiffs also propose a construction that would equate this term merely to a foundation. The term "base,"

however, implies that this portion of the device serves as a foundation. Therefore, the Court concludes that something additional is required to give meaning to the word structure. The Court concludes that the reinforcing wires give meaning to that word and, thus, agrees with Defendants that the term should be construed to include wires.

Finally, the Court concludes that the inventors disclaimed self-expanding wires in the specification. The inventors describe prior art intraluminal grafts as being comprised of "a sleeve in which is disposed a plurality of self expanding wire stents." ('458 Patent, col. 1, ll. 20-22.) They then state that "[t]here are a number of problems associated with such known grafts," including the "lack of precise control of the expansion of the graft in the lumen." The inventors then state that their invention is "directed to an alternative form of intraluminal grafts which provides an alternative to the known grafts." (*Id.*, col. 1, ll. 32-42.) Thereafter, the inventors describe the wires that form part of the invention as malleable or state that the device is expanded by use of balloons. (*See, e.g., id.*, col. 1, ll. 49, 60-63, col. 2, ll. 8-15, col. 3, ll. 8-10, col. 5, ll. 32-36, 58-60, 66-67, col. 6, ll. 5-7.) Thus, when the Court reads the claims in light of the specification, it concludes that a person of ordinary skill in the art would clearly understand that this invention requires malleable, rather than resilient, wires.

Accordingly, the Court construes the terms "bifurcated base structure" and "bifurcated base graft structure" to mean: **"An intraluminal graft that has one opening at its upstream end and two openings at its downstream end and which includes at least one malleable wire."**

3. "A Pair of Connector Legs" FN6

FN6. This term is found in independent claim 1 of the '458 Patent and is found in independent claims 1, 15, 17, and 23 of the '158 Patent.

The parties agree that the downstream end of the bifurcated base [graft] structure has two branches and that the term "a pair of connector legs" refers to those branches. The primary dispute is whether the word "pair" means identical.

The claim language is silent. The specification provides some guidance on the meaning of the term, because the inventors refer to "a graft according to the present invention which has a bifurcation at its downstream end, a so-called 'trouser graft.' " ('458 Patent, col. 4, ll. 20-22; *see also id.*, col. 4, ll. 45-49 ("This latter arrangement is particularly suitable in the case of 'trouser grafts' wherein one leg of the graft will have a skirt which cannot be expanded by a balloon catheter.")) Cook argues that the reference to "trouser grafts" demonstrates that the term "pair" must mean something of equal length, because trousers have legs that are the same length. Cook supports that definition by reference to a dictionary definition in which "pair" is defined as "two things equal." (*See Cook Ex. 14.*)

The word "pair" also means "two corresponding things designed for use together" or "something made up of two corresponding pieces (a-of trousers)." These definitions of the word, however, do not necessarily require a pair to be "equal" in all respects. *See Webster's Ninth New Collegiate Dictionary* at 847 (1987); *id.* at 293 (definition of corresponding: "having or participating in the same relationship (as kind, degree, position, correspondence, or function)). Thus, apart from the reference to "trouser grafts," neither the specification nor the prosecution history provide clear support for Defendants' proposed construction.

Gore also argues that the construction of the term should also include the requirement that each of the connector legs "has an opening for connecting to a graft adapted to be anchored within the branch." (Gore Br. at 14:21-23.) The Court agrees with Gore on this point. The word "connector" is an adjective for the verb "connect," which means "to become joined," or "to join or fasten together ... by something intervening" or "to place or establish in relationship." *See, e.g.*, Webster's Ninth New Collegiate Dictionary at 278. Support for incorporating a connection function in the construction of the term "a pair of connector legs," also is supported by the specification. The inventors state therein that supplemental grafts can be introduced to overlap or dock, *i.e.* connect to or with, the ends of a bifurcated device. ('458 Patent, col. 4, ll.18-32.)

Accordingly, the Court construes the term "a pair of connector legs" to mean: **"The two branches at the downstream end of the bifurcated base [graft] structure, each of which has an opening to which an additional graft may be connected."**

4. "Graft Body" FN7

FN7. This term is found in independent claim 1 of the '073 Patent and is found in independent claims 1, 20, 21 and 22 of the '736 Patent.

The primary dispute among the parties with respect to this term is whether the graft body contains malleable wires. The claim language again is silent. However, the specification supports Plaintiffs' position that the graft body does not include wires. Indeed, throughout the specification, when the inventors refer to the "graft" or "intraluminal graft," they distinguish between the material of which the graft body can be composed and the wires. (*See, e.g.*, '458 Patent, col. 3, ll. 8-25 ("If the graft body is of a woven material the wires may be interwoven with the graft body.").) The specification also contains a lengthy discussion of the graft body that distinguishes the graft body from the wires and suggests that the wires may be integrated with the graft body or attached to it by some other means. Again, this discussion supports a view that the graft body is separate and distinct from the wires. (*See id.*, col. 2, ll. 62-67, col. 3, ll. 1-25.) Finally, when they discuss the prior art, the inventors note that intraluminal grafts previously had been formed of a "sleeve, in which is disposed a plurality of self-expanding wire stents." (*Id.*, col. 1, ll. 20-22.) These references further reinforce the view that the "graft body," or sleeve, is separate from the wires or wire-stents.

Accordingly, the Court construes the term "graft body" to mean: **"an artificial device formed of plastic or fabric for use inside of a vessel."**

5. "Graft which is adapted to be anchored within one of the flow lumens" and "Graft structure which is adapted to be anchored within one of the flow lumens" FN8

FN8. The term "graft which is adapted to be anchored within one of the flow lumens" is found in independent claim 1 of the '458 Patent. The term "graft structure which is adapted to be anchored within one of the flow lumens" is found in independent claim 1 of the '158 Patent.

Because the parties requested that the Court construe the term "graft," as used in the preamble of the claims but not the bodies of claims, the Court inquired of the parties whether the crux of the dispute over this phrase, and other similar phrases, was with respect to the "adapted to be anchored within" language. Plaintiffs argued it was. Defendants argued it was not and argued that the Court must construe the entire

phrase. Defendants also argued that the phrase, as with their proposed construction of the term "graft," should be construed to be an intraluminal device. The Court concludes this phrase should be construed to require an intraluminal limitation. Although the word "graft" is followed by a "which" clause, that clause does not fully elaborate on the meaning of the word graft. As set forth above in Section B.1, the specification demonstrates how the inventors defined the word "graft."

Although the parties disagree on the intraluminal limitation, they do agree that this phrase should be construed in such a fashion as to make clear that the "graft" contains some structure that permits it to be attached to a flow lumen. Although the claim language is silent, the parties also agree that wires perform this function. (*See, e.g.*, Plaintiffs' Br. at 18:6-7 ("The parties seem to be in agreement that the structure that allows the anchoring to occur is the wires.") The parties again dispute, however, whether the wires must be malleable. The parties also dispute whether the wires must project beyond the end of the graft body.

For the reasons set forth above in Section B.2, the Court concludes that the wires must be malleable. Although the Court concludes that to serve their function, the wires in question must be located at or near the end of the graft or graft structure, the wire need not project beyond the end of the material forming the graft body. In the specification, the inventors state that the "projection of alternate crests or apices of the end wire or wires beyond at least part of the end or ends of the graft body is an important feature of this invention." (458 Patent, col. 2, ll. 6-8.) The inventors then elaborate on the importance of this feature as follows:

As the graft is expanded by a balloon, the expansion of the wires, and of the balloon, will be limited by the diameter of the tubular graft body except in the region of the alternate crests or apices of the end wire or wires. The balloon will be able to expand these crests slightly more than the remainder of the wire so that they bell outwardly away from the adjacent end of the graft body.... This belling out of the crests of the wires at one or both ends of the graft body into contact with the inside surface of the vessel wall and then being at least partly embedded in the wall will assist in resisting any tendency for the graft to move longitudinally within the vessel after insertion.

(*Id.*, col. 2, ll. 8-22.) Thus, the importance of the crests of wire is to permit the device to be expanded in such a fashion that it will engage with the vessel wall. With respect to how far the crests of wire might extend, the inventors state the crests of wire normally will extend beyond the end of the graft body. However, they also state that "[i]t would, ..., be possible to have flaps of graft material protruding up the outside of each crest even though intermediate the crests the end of the graft stops well short of the crests. *In this latter arrangement the crests are still free to bell outwardly as has been described above even though the crests do not extend absolutely beyond the end of the graft.*" (*Id.*, col. 2, ll. 29-35 (emphasis added).) It is clear from the specification that if the graft body covers the wire crests, that will not diminish the importance of the wire crests and will not preclude the wire crests from performing their function. As such, the Court concludes that the wires need not always extend beyond the end of the material forming the graft body.

Accordingly, the Court construes the term "graft [structure] which is adapted to be anchored within one of the flow lumens" to mean: "**An intraluminal graft that includes malleable wires located proximal to at least one end of the graft [structure], which enable the intraluminal graft to be secured or attached to one of the flow lumens of the bifurcated base [graft] structure in an overlapping relationship.**"

6. "Graft Structure Which is Adapted to Overlap and Be Attached to One of the Flow Lumens" FN9

FN9. This term is found in independent claims 15, 17 and 23 of the '158 Patent.

The parties' proposed constructions for this phrase are substantially similar to their proposed constructions for the previous phrase. The only differences are that Plaintiffs and Cook include a reference to the flow lumens in their proposed constructions, and Gore references a "second graft" in its proposed construction. Indeed, the parties seem to equate the phrases "adapted to be anchored within" and "adapted to overlap and be attached to," with one another. Once again the disputes center on whether the wires must be malleable and whether they must project beyond the ends of the graft.

The Court finds no significant difference between this phrase and the previous phrase and, accordingly, concludes they should be construed in the same manner. Accordingly, the Court construes the term "graft which is adapted to overlap and be attached to one of the flow lumens," to mean: **"An intraluminal graft that includes malleable wires located proximal to at least one end of the graft structure, which enable the intraluminal graft to be secured or attached to one of the flow lumens of the bifurcated base graft structure in an overlapping relationship."**

7. "Said First End of Said Supplemental Graft Body Being Dockable to Said Second Portion of Said Primary Graft Body While Inside of a Vessel" FN10

FN10. This term is found in independent claim 1 of the '073 Patent.

The parties' primary disputes over this phrase again are whether the phrase should be construed to require malleable wires and whether those wires must project beyond the end of the graft. Cook also argues that Plaintiffs' proposed construction, which includes a reference to a "fluid containing lumen," is contrary to the definition of vessel provided in the specification.

To place this phrase in context, claim 1 of the '073 Patent recites, in pertinent part:

a supplemental graft body, said supplemental graft body having a secondary graft flow lumen therethrough, said supplemental graft body comprising a first end and a second end, *said first end of said supplemental graft body being dockable to said second portion of said primary graft body while inside of a vessel* to define a single flow lumen which transfers substantially all flow between said primary graft flow lumen and said secondary graft flow lumen.

('073 Patent, col. 6, ll. 49-57.)

Thus, the claim language suggests that the "first end" of the "graft body" must have some additional structure that permits the first end to be coupled with or docked to the second portion of the primary graft body. Although Plaintiffs' proposed construction does not expressly refer to such a feature, they argued that the "adapted to be connected," and "being dockable" to language was intended to refer to the intraluminal aspect of the invention. (*See, e.g.*, Tr. at 40:15-41:4, 67:6-18.) Further, all parties concur that intraluminal grafts require some type of wires. Accordingly, the Court concludes that with respect to this phrase, the "first end" of the supplemental graft body must include some form of wire structure. For the reasons discussed above in Sections B.2 and B.5, the Court also concludes that the wires must be malleable but that they need not extend entirely beyond the end of the graft body.

Finally, the Court agrees with Cook and Gore that the construction of this term must include a reference to a vessel, rather than a general reference to a "fluid containing lumen," as Plaintiffs' propose. This is because the inventors clearly defined the term "vessel" in the specification to mean "blood vessels or like ducts such as the bile duct and the ureter (*which are all hereafter called 'vessels'*)." ('458 Patent, col. 1, ll. 18-20 (emphasis added).)

Accordingly, the Court construes the term "said first end of said supplemental graft body being dockable to said second portion of said primary graft body while inside of a vessel," to mean: **"The first end of the supplemental graft body includes a malleable wire structure that permits it to be intravascularly docked to or coupled with the second portion of the primary graft body."**

8. "Said Second Graft Body Inlet End Being Attachable in an Overlapping Relationship with Said First Graft Body Outlet End While Inside of a Vessel" FN11

FN11. This term is found in independent claim 1 of the '736 Patent. The parties ask the Court to construe this term and the term "said inlet end of said second graft body being attachable in an overlapping relationship with said outlet end of said first graft body while inside a vessel," found in independent claims 20, 21 and 22 of the '736 Patent in the same manner.

The Court finds the crux of the dispute is over the meaning of "being attachable in an overlapping relationship." Further, this phrase is substantially similar to the previous phrase, with the exception of the term "overlapping" and the use of the terms "inlet end" and "outlet end," rather than "first end" and "second end" or "first portion" and "second portion." Accordingly, for the reasons set forth in Section B.7, the Court construes the term "said second graft body inlet end being attachable in an overlapping relationship with said first graft body outlet end while inside of a vessel," to mean: **"The inlet end of the second graft body includes a malleable wire structure that permits it to be intravascularly docked to or coupled with the outlet end of the first graft body in an overlapping relationship."**

9. "To Define a Single Flow Lumen Which Transfers Substantially All Flow Between Said Primary Graft Flow Lumen" FN12

FN12. This term is found in independent claim 1 of the '073 Patent. The parties ask the Court to construe this term and the following terms in the same manner: (1) "to define a continuous flow passage through said first graft body inlet end, said first graft body outlet end, said second graft body inlet end, and said second graft body outlet end," found in independent claim 1 of the '736 Patent; (2) "to define a continuous flow passage between said inlet end and said outlet end of said first graft body and said inlet end and said outlet end of said second graft body," found in claims 20 and 22 of the '736 Patent; and (3) "to define a continuous flow passage through said first flow passage and said second flow passage," found in claim 21 of the '736 Patent.

Cook argues that this phrase must be construed to require only one flow lumen, *i.e.* that the phrase cannot encompass a bifurcated or "y-shaped" graft. It appears that Gore also suggests that the disputed phrase cannot encompass a bifurcated device, because its proposed construction focuses on the creation of a single flow lumen. (*See Gore Br. at 17.*)

The Court starts with the claim language. With respect to the '073 Patent, the claim language could be read to encompass a bifurcated device, if one assumes that branches or legs of a bifurcated device are the "second portion" of the primary graft body. This argument, however, is less convincing with respect to the claims of the '736 Patent, because those claims refer to a first graft body having an "inlet end" and an "outlet end," rather than outlet *ends*. Because the claim language is ambiguous, the Court looks to the specification. The specification discloses "trouser" or "bifurcated" grafts, which can be used when the device is to be placed in or near a bifurcated vessel. Thus, the specification provides support for Plaintiffs' assertion that the term "single flow lumen" need not be restricted to a lumen within a tubular graft.

Defendants find support for their argument in the prosecution history of the '073 Patent, and the inventors' efforts to distinguish over U.S. Patent 5,316,023 (Palmaz). Defendants cite to an Examiner Interview, which the inventors summarized and noted that the Examiner determined that "the claims could be amended to clearly distinguish over Palmaz based upon the fact that this application discloses forming a single lumen to carry substantially all blood flow in a vessel, whereas, what Palmaz '023 discloses is two adjacent lumens inside a stent or a stent graft, inside a vessel, and that the two adjacent lumens in the vessel split the flow of blood in the vessel between them." (*See* Edwards Ex. 28, '073 Response dated 11/28/01 at 53-54 (emphasis added).) The Court finds that this reference supports Plaintiffs' argument. The inventors' statement focuses on the fact that their device forms a *single* lumen in a vessel. They contrasted their invention to the invention taught by Palmaz, which formed *two* lumens inside a vessel. (*See also* id. at 52 ("Palma does not disclose connecting flow lumens of two graft bodies to define a single flow lumen which transfers substantially all flow between the engaged lumens.")) There is nothing in these statements that suggests the inventors intended to limit their invention to a device that could be used only in non-bifurcated vessels.

Accordingly, the Court construes the term "to define a single flow lumen which transfers substantially all flow between said primary graft flow lumen and said secondary graft flow lumen" to mean: **"When the primary graft body is connected to the secondary graft body a single, rather than a bilateral, lumen is formed and substantially all fluid flows from the primary graft body to the secondary graft body through that single flow lumen."**

10. "Circumferentially Reinforced at Locations Along Its Length by a Plurality of Separately Spaced Apart Wires" FN13

FN13. This term is found in dependent claims 2 and 11 of the '458 Patent and is found in dependent claims 2 and 8 of the '073 Patent. The parties ask the Court to construe this term and the term "circumferentially reinforced by a metal wire structure," found in independent claim 22 of the '736 Patent, in the same manner.

There is no dispute among the parties that this phrase should be construed to require more than one wire and that the wires are placed around the graft in a circular manner. It also is apparent that the parties agree that the wires are intended to strengthen or support the graft body, as the Court has defined that term. The parties again dispute whether the wires referenced in this phrase must be malleable. For the reasons set forth above in Section B.2, the Court concludes that the wires are malleable.

The parties also disagree about the meaning of "along its length" and "separately spaced apart." With respect to "along its length," Cook argues that it means "from end to end," *i.e.* that the wires extend the entire length of the device. Cook, however, finds support for its position from a reference in the specification where the inventors state that because "the wires are arrayed along the length of the graft the

complete position of the graft in the body can be continuously monitored" by X-ray. ('458 Patent, col. 3, ll. 42-45.) Plaintiffs and Gore, in contrast, propose constructions that do not ascribe any special meaning to this term.

The claim language states that the wires are placed at "locations along its length." ('458 Patent, col. 6, ll. 22-22.) The use of the word "locations" does not suggest that the wire must run the entire length of the device. In addition, the specification supports a conclusion that the wires do not need to run the entire length of the device. For example, in the Abstract, the inventors state that the invention may include a "plurality of wires spaced apart from each other and arranged to circumferentially reinforce said tubular graft body along a *substantial portion of its length*." ('458 Patent, Abstract (emphasis added).) The use of the term "substantial portion," rather than "along the entirety" or "along its entire length," supports Plaintiffs' position that the phrase should not be construed to mean the wires extend from "end to end." Further support for the Court's conclusion stems from the fact that, in certain preferred embodiments, the invention includes a skirt portion that has no reinforcing wires. Thus, in these embodiments, the wires would not extend the entire length of the invention. *See, e.g.,* *Primos, Inc. v. Hunters Specialties, Inc.*, 451 F.3d 841, 848 (Fed.Cir.2006) (court normally should not interpret a claim to exclude a preferred embodiment).

Finally, Cook also argues that the inventors, in a later patent application, distinguished over prior art that disclosed wires that were located only at the end of the graft. (Cook Br. at 19-20; Cook Ex. 15.) To the extent that statement is relevant to construction of the patents-in-suit, there is nothing in the inventors' response that suggests the wires must be placed along the entirety of the device. Rather, a plausible interpretation of the inventors' remarks is that they distinguished the prior art by stating that the prior art had wires only at each end of the device, whereas the device they were claiming had reinforcing wires at additional locations and not only at the ends. (*See* Cook Ex. 15 at 14.)

Gore argues "separate spaced apart" means that the wires cannot touch or overlap. Plaintiffs argue that in *most* instances the wires will not touch one another. Plaintiffs' proposed construction draws upon the language quoted above from the Abstract, which refers to where the wires are placed along the graft body. The claim language uses the word "apart," which suggests that the wires are separated from one another, *i.e.* they are not touching. The figures of the patents-in-suit also show that the wires do not touch or overlap with one another. ('458 Patent, figs. 2-3, 5-7.) Further, in the "Disclosure of the Invention" the inventors state:

It is preferred that the one wire has a greater amplitude than at least the next adjacent one or two wires. This allows the wires at the end of the graft to be positioned more closely together than would be the case if they were all of the same amplitude.... It is desirable to space the wires adjacent the end of the graft that will be placed "upstream" in the patient as close together as is possible as the neck of the aneurysm with which the graft is engaged can be quite short. Close spacing of the wires maximises the number of wires reinforcing that part of the graft in contact with the neck of the aneurysm. The spacing of the rest of the wires is desirably greater than those adjacent the one end of the graft as this avoids unnecessarily reducing the flexibility of the graft.

('458 Patent, col. 2, ll. 36-48; *see also* *id.*, col. 5, ll. 47-57 (describing spacing of wires in manner in which wires do not come into contact with one another).) Although this portion of the specification teaches that the wires may be spaced closely together, it does not teach that the wires can come into contact with one another. Further, the description of the purpose of spacing the wire also supports Gore's construction that the wires should not come into contact with one another.

Accordingly, the Court construes the phrase "circumferentially reinforced at locations along its length by a plurality of separately spaced apart wires" to mean: **"The graft body or bifurcated base structure is strengthened by at least two malleable wires that do not contact or touch one another and that are placed circumferentially along the length of the material forming the graft body or bifurcated base structure."**

11. "Edge Which is Scalloped Between Projecting Apices of the Wire"FN14

FN14. This term is found in independent claim 1 of the '158 Patent and is found in dependent claim 13 of the '736 Patent.

The parties agree that the term "scalloped" means that there are portions of material that have been cut out of the fabric or plastic. The primary dispute between Plaintiffs and Cook is whether the phrase must be limited such that the "scalloping" occurs only "between," *i.e.* in the space that separates, each wire apice, as depicted in figures 6-7 of the patents-in-suit, or whether the fabric may also contain scalloping underneath the wire apices.

The specification states that "[i]t is preferred" that the edge of the material is "scooped out or scalloped between each projecting crest." ('458 Patent, col. 2, ll. 56-58 (emphasis added).) If the Court looked only to the claim language, Cook's argument might have some force. However, because the specification makes clear that the scallops "between" the projecting crests are preferred but not required, the Court declines to construe this phrase to limit it to a preferred embodiment. *See, e.g.,* *Primos, Inc.*, 451 F.3d at 848 (court should not import limitations from preferred embodiments into claims).

Plaintiffs and Gore also disagree about whether the wires always extend beyond the edge of the material. For the reasons set forth above in Section B.5, the Court concludes that they do not.

Accordingly, the Court construes the term "edge which is scalloped between projecting apices of the wire member/structure" to mean: **"The edge of the material may be scooped out or removed between or underneath each projecting crest of the wire."**

CONCLUSION

Based on the analysis set forth above, the Court adopts the foregoing constructions of the disputed terms and phrases. The parties are ordered to submit a further joint case management report pursuant to Patent Standing Order para. 13 by no later than August 20, 2007.

IT IS SO ORDERED.

APPENDIX

1. Prosthesis

Plaintiff's Proposed Construction:

"An artificial device to repair or replace a missing or defective part of the body."

Cook's Proposed Construction:

"An intraluminal device that substitutes for a missing or defective part of the body."

Gore's Proposed Construction:

"A multi-component device used as a unit to treat medical conditions such as aneurysms or occlusive diseases endoluminally, that is, from the inside of a body vessel."

* * *

2. Graft

Plaintiffs' Proposed Construction:

"An artificial (or man-made) device, formed of polymer (plastic) or fabric material, that is attached to or inserted into another vessel or graft."

Cook's Proposed Construction:

"An intraluminal device that substitutes for all or part of a vessel."

Gore's Proposed Construction:

"A multi-component device used as a unit to treat medical conditions such as aneurysms or occlusive diseases endoluminally, that is from inside of a body vessel."

* * *

3. Bifurcated Base [Graft] Structure

Plaintiffs' Proposed Construction:

"A Y-shaped graft that forms a structure (or foundation) for connection of additional grafts."

Cook's Proposed Construction:

"A trouser-shaped intraluminal graft composed of a material integrated with at least one malleable wire that does not expand by virtue of its own resilience."

Gore's Proposed Construction:

"A forked or divided fabric liner for the inside of a body vessel with one tubular opening at one end and two tubular openings at the other end, attached to a malleable wire structure."

* * *

4. A Pair of Connector Legs

Plaintiffs' Proposed Construction:

"The two branches of the Y-shaped base."

Cook's Proposed Construction:

"Two legs of the same size."

Gore's Proposed Construction:

"Two substantially identical branches shaped like trousers on the bifurcated base structure, each of which has an opening for connecting to a graft adapted to be anchored within the graft."

* * *

5. Graft Body

Plaintiffs' Proposed Construction:

"An artificial (or man-made) device, formed of polymer (plastic) or fabric material, that is attached to or inserted into another vessel or graft body."

Cook's Proposed Construction:

"An intraluminal graft composed of a material integrated with at least one malleable wire that does not expand by virtue of its own resilience."

Gore's Proposed Construction:

"A tubular fabric liner for the inside of a body vessel attached to a malleable wire structure with an inlet end and an outlet end forming a single flow cavity or channel."

* * *

6. Graft [structure] which is adapted to be anchored within one of the flow lumens

Plaintiffs' Proposed Construction:

"A graft having additional structure that allows the graft to be mechanically attached (not sewn) to the base structure by insertion and expansion into the base structure in an overlapping position. The graft structure sufficiently secures the graft to the base so that it is not transported away from the base structure (i.e., remains secured to the base structure) under conditions of fluid (blood) flow."

Cook's Proposed Construction:

"An intraluminal graft composed of a material integrated with at least one malleable wire that does not expand by virtue of its own resilience and that projects beyond the end of the wire so that the wire can be

expanded into contact with the bifurcated base [graft] structure."

Gore's Proposed Construction:

"The malleable wire structure of the tubular endoluminal graft gives it the ability to attach to or connect to the inside of the connector legs or the inside of the common flow lumen of the bifurcated base structure inside a body vessel."

* * *

7. Graft [structure] which is adapted to be overlap and be attached to one of the flow lumens

Plaintiffs' Proposed Construction:

"A graft having additional structure that allows the graft to be mechanically attached (not sewn) to one of the flow lumens of the base structure by insertion and expansion into the base structure in an overlapping position. The graft structure sufficiently secures the graft to the base so that it is not transported away from the base structure (i.e., remains secured to the base structure) under conditions of fluid (blood) flow."

Cook's Proposed Construction:

"An intraluminal graft composed of a material integrated with at least one malleable wire that does not expand by virtue of its own resilience and that projects beyond the end of the wire so that the wire can be expanded into attachment to one of the flow lumens of the bifurcated base [graft] structure."

Gore's Proposed Construction:

"The malleable wire structure of the tubular endoluminal second graft structure gives it the ability to attach to or connect *it* to the inside of the connector legs or the inside of the common flow lumen of the bifurcated base structure inside a body vessel."

* * *

8. Said first end of said supplemental graft body being dockable to said second portion of said primary graft body while inside of a vessel

Plaintiffs' Proposed Construction:

"One end of a second graft portion can be maneuvered to be coupled with one end of a first graft portion while in a fluid-containing lumen (i.e., endovascularly)."

Cook's Proposed Construction:

"At least one malleable wire (that does not expand by virtue of its own resilience) in the supplemental graft body projects beyond the end of the material so that the wire can be expanded into attachment with the primary graft body while both graft bodies are entirely inside of a vessel."

Gore's Proposed Construction:

"The malleable wire structure of the supplemental graft body gives it the ability to dock or connect to the inside of the primary graft body while inside of a body vessel."

* * *

9. *Said second graft body inlet end being attachable in an overlapping relationship with said first graft body outlet end while inside of a vessel*

Said inlet end of said second graft body being attachable in an overlapping relationship with said outlet end of said first graft body while inside of a vessel

Plaintiffs' Proposed Construction:

"The inlet end of a second graft body can be maneuvered to be coupled with the outlet end of a first graft body while in a fluid containing lumen (i.e., endovascularly)."

Cook's Proposed Construction:

"At least one malleable wire in the second graft body projects beyond the end of the material so that the wire can be expanded into attachment with the first graft body outlet end while both graft bodies are entirely inside of a vessel."

Gore's Proposed Construction:

"The malleable wire structure of the second graft body gives it the ability to attach itself to the inside of the first graft body when it is extended into and is partially covered by the first graft body while inside of a body vessel to form a single, continuous flow passage."

* * *

10. *To define a single flow lumen which transfers substantially all flow between said primary graft flow lumen and said secondary graft flow lumen*

To define a continuous flow passage through said first graft body inlet end, said second graft body inlet end, and said second graft body outlet end

To define a continuous flow passage between said inlet end and said outlet end of said first graft body and said outlet end of said second graft body

To define a continuous flow passage through said first flow passage and said second flow passage

Plaintiffs' Proposed Construction:

One end of one structure can be coupled with one end of another structure to form a single fluid flow cavity for transfer of essentially all of the flowing fluid between the two structures-substantially all flow means more of the flow within a blood vessel than would be carried by each of the two parallel tubes of Palmaz.

Cook's Proposed Construction:

After they are docked, the primary and supplemental graft bodies together have only one flow lumen therethrough so that substantially all the flow that enters the upstream end of the primary graft body exists the downstream end of the supplemental graft body.

Gore's Proposed Construction:

When joined, the graft bodies form a single cavity or channel which transfers substantially all fluid between the single cavity or channel in the primary graft body to the single cavity or channel in the supplemental graft body.

* * *

11. *Circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires*

Circumferentially reinforced by a metal wire structure

Plaintiffs' Proposed Construction:

The graft material is augmented or strengthened along its length at its circumferential perimeter (i.e. radially) by at least two wires that are separated (not contacting or touching along a substantial portion of their lengths).

Cook's Proposed Construction:

The material is strengthened around its circumference from end to end by at least two distinct integrated malleable wires that do not expand by virtue of their own resilience.

Gore's Proposed Construction:

The [bifurcated base graft structure or graft or primary graft body or supplemental graft body] is reinforced at discrete locations along its length by two or more distinct and malleable wires which individually encircle the graft, but which are not attached to and do not overlap one another.

* * *

12. *Edge which is scalloped between projecting apices of the wire [member/structure]*

Plaintiffs' Proposed Construction:

At least part of one edge of the graft material is scooped out or removed between extending wire forms.

Cook's Proposed Construction:

The edge of the material is scooped out between (and not underneath) each projecting crest of the wire so that there are the same number of scoops as there are projecting crests.

Gore's Proposed Construction:

The structure has a wire member near the end with more than one apex or tip that extends beyond the end of the fabric liner with the edge of the fabric liner cut away between the wire apices or tips that extend beyond the edge of the fabric liner.

N.D.Cal.,2007.

Edwards Lifesciences LLC v. Cook Inc.

Produced by Sans Paper, LLC.