IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W.L. GORE & ASSOCIATES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 11-515-LPS-CJB
	)	
C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

In this action filed by Plaintiff W.L. Gore & Associates, Inc. ("Gore" or "Plaintiff") against Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard" or "Defendants"), Gore alleges infringement of U.S. Patent Nos. 5,735,892 (the "'892 Patent") and 5,700,285 (the "'285 Patent") (the "Asserted Patents" or the "patents-in-suit").[1] Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions as set forth below.

I. BACKGROUND

A. The Parties

Gore is a Delaware corporation with its principal place of business in Newark, Delaware. (D.I. 64 at ¶ 2) It is the owner of the patents-in-suit. (*Id.* at ¶¶ 14-15)

Defendant C.R. Bard, Inc. is a New Jersey corporation with its principal place of business in Murray Hill, New Jersey. (D.I. 189 at ¶ 3) Defendant Bard Peripheral Vascular, Inc. is an

[1] Gore also originally asserted infringement of U.S. Patent No. 8,221,487 (the "'487 Patent"), but is no longer asserting that patent. (D.I. 191 at 1-2)

Arizona corporation with its principal place of business in Tempe, Arizona, and a wholly owned subsidiary of Defendant C.R. Bard, Inc. (*Id.* at ¶¶ 4-5) Defendant Bard Peripheral Vascular, Inc. makes and sells the FLUENCY ® Plus Tracheobronchial Stent Graft ("Fluency") and the FLAIR ® Endovascular Stent Graft ("Flair"). (*Id.* at ¶¶ 16-17)

B. The Asserted Patents

Gore asserts two related patents against Bard that share a common specification. Both of the Asserted Patents are entitled "Intraluminal Stent Graft." (D.I. 96, ex. A & V) The '892 Patent issued on April 7, 1998 from U.S. Appl. No. 109,214, which was filed on August 18, 1993. ('892 Patent) The '285 Patent is a divisional of the '892 Patent and was issued on December 23, 1997. ('285 Patent) The Asserted Patents are two among a family of 14 patents claiming priority to the original application for the '892 Patent. (D.I. 99 at 5)

The Asserted Patents relate to intraluminal graft devices. The patents explain that conventional vascular grafts—typically, flexible tubes of woven or knitted polyethylene terephthalate or of porous polytetrafluoroethylene ("PTFE")—had long been used to repair damaged and diseased blood vessels and veins. ('892 Patent, col. 1:9-13) Implantation of these devices typically required invasive surgery that exposed much of the vessel to be repaired and caused major trauma to the patient. (*Id.*, col. 1:9-20) As an alternative, some physicians had begun to use intraluminal devices that combined conventional vascular grafts with stents. (*Id.*, col. 1:22-24) These devices were placed inside the damaged portion of the vessel using a less invasive "catheter type of delivery system." (*Id.*, col. 1:24-26, 37-38) However, the "relatively thick, bulky wall[s]" of these devices limited their use, making them difficult to "be contracted into a small cross-sectional area for insertion into a blood vessel." (*Id.*, col. 2:10-15) The

present inventions were designed to overcome the limitations of the prior art, claiming thin-walled stent-graft devices "useful as an inner lining for blood vessels or other body conduits[,]" and methods of making such devices. (*Id.*, col. 1:5-6)

C. Procedural History

On June 10, 2011, Gore commenced this action. (D.I. 1) Gore alleges that Bard's Fluency and Flair products infringe claims 32, 33, and 40 of the '892 Patent, as well as claim 15 (which incorporates the elements of claims 12 and 13) of the '285 Patent. (D.I. 191 at 1) On November 29, 2011, this case was referred to the Court by Chief Judge Leonard P. Stark to hear and resolve all pretrial matters, up to and including the resolution of case dispositive motions. (D.I. 20)

The parties filed simultaneous opening claim construction briefs on May 10, 2013, and simultaneous responsive briefs on June 7, 2013. (D.I. 99, 101, 111, 115) The Court held a *Markman* hearing on July 16, 2013. (D.I. 130, hereinafter "Tr.")

II. STANDARD OF REVIEW

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). The proper construction of claim terms is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The Court should generally give claim terms their "'ordinary and customary meaning[,]'" which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent

application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent, but rather should endeavor to reflect their "meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321.

To that end, the Court should look first and foremost to the language of the claims, because "[i]t 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." *Id.* at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable" in discerning the meaning of particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* Moreover, "[d]ifferences among claims can also be a useful guide," as when "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which "may reveal a special definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess." *Id.* at 1316. In that case, "the inventor's lexicography governs." *Id.* Even if the specification does not contain a special definition of the term-at-issue, it "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (internal quotation marks and citation omitted).

That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). In addition to the specification, a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention[.]" *Phillips*, 415 F.3d at 1317 (citations omitted).

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises[,]" can also "shed useful light on the relevant art." *Id.* (internal quotation marks and citations omitted). Dictionaries (especially technical dictionaries) may be useful in this process because they typically provide "the accepted meanings of terms used in various fields of science and technology[.]" *Id.* at 1318. However, the United States Court of Appeals for the Federal Circuit has cautioned that "heavy reliance on [a] dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Id.* at 1321. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotation marks and citations omitted); *accord Markman*, 52 F.3d at 981.

In utilizing these resources during claim construction, courts should keep in mind that "[t]he 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." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

The parties set out six disputed terms or sets of terms for the Court's review.[2] The Court takes up the disputes in the order in which they were argued.

A. Disputed Terms

1. Terms Relating to the Claimed Stent Structure

Asserted claims 32 and 40 of the '892 Patent and claim 12 of the '285 Patent (incorporated into asserted claim 15) claim a stent structure that is the subject of the parties' competing claim construction proposals. The use of the disputed terms in claim 32 of the '892 Patent ("claim 32") is representative:

> 32. A tubular intraluminal graft comprising:
>
> a) a *tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent*;
>
> b) a first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent; and
>
> c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent;
>
> wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm thick exclusive of the stent.

('892 Patent, col. 11:25-39 (emphasis added))

Bard offers proposed constructions for the following terms relating to the claimed stent

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[2] The parties had originally presented eight terms or sets of terms to be construed by the Court. However, the parties' dispute regarding a term that appeared in the '487 Patent ("adjacent") is now moot because Gore is no longer asserting that patent. (D.I. 191 at 2) Additionally, the parties agreed at the *Markman* hearing that, for claim construction purposes, there is no current dispute regarding terms that appear in both Asserted Patents ("less than about 0.10 mm thick"/"about the collapsed diameter"). (Tr. at 150-55)

structure: (1) "tubular, diametrically adjustable stent"/"diametrically adjustable stent"; (2) "wall"; and (3) "multiplicity of openings." (D.I. 101 at 6-9) For its part, Gore asserts that no construction is necessary for any of these terms, as "[w]hen read as a whole, the meaning of this phrase is clear both on its face and in the context of the specification." (D.I. 99 at 11; *see also* D.I. 111 at 2) Alternatively, Gore proposes that for each of the disputed terms relating to the claimed stent structure, the Court adopt the constructions entered by the United States District Court for the Eastern District of Virginia in *W.L. Gore & Assocs., Inc. v. Medtronic, Inc.*, 834 F. Supp. 2d 465 (E.D. Va. 2011), *aff'd*, 530 F. App'x 939 (Fed. Cir. 2013), a case in which Gore asserted related U.S. Patent No. 5,810,870 (the "'870 Patent") against Medtronic. (Tr. at 38-39, 79-81)

The Court will examine each of these terms separately, as, by and large, that is how they are addressed in the briefing. However, the Court agrees with Gore that the terms are related, as they each touch on the characteristics of the stent at issue that is described in the respective claims. (Tr. at 26-27, 39) That inter-relationship will be important in the Court's treatment of each of the terms below.

a. "tubular, diametrically adjustable stent"/"diametrically adjustable stent"

Bard proposes that these terms be construed to mean "structure designed for insertion in a lumen that is adjustable to contact the surface of the lumen." (D.I. 101 at 6; D.I. 115 at 4) Gore contends that no construction is necessary, or alternatively, that the definition for "stent" set out by the *Medtronic* Court be adopted: "[e]longated members [connected in such a way as to create a multiplicity of openings, and] forming a substantially cylindrical [] structure."

Medtronic, 834 F. Supp. 2d at 473; *Medtronic*, 874 F. Supp. 2d 526, 563 n.16 (E.D. Va. 2012).[3] Bard asserts that its proposed construction is "broader" than Gore's view of the claimed stent, and in line with the patent's description of "all different types of stents[.]" (Tr. at 51-53, 63-64) The Court will address the appropriate construction by focusing on the two strands of argument that Bard puts forward in support of its proposal.

First, the Court addresses Bard's assertion that "[t]he patent is very clear that it covers all types of stents" and therefore the claimed stent should itself be defined very broadly as a "structure[.]" (Tr. at 64) In doing so, the Court looks first to the language of the claims, for it is well-settled that "[i]t is the claims that define the metes and bounds of the patentee's invention." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). Focusing on the claim language is particularly crucial here, in order to honor the Federal Circuit's instruction that "[p]roper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation." *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999); *see also Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1347 (Fed. Cir. 2008) (warning against "interpret[ing] claim terms in a vacuum, devoid of the context of the claim as a whole").

As Gore points out, an examination of claim 32 (and the other relevant claims) as a whole

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[3] The *Medtronic* Court included in its definition for "stent" that the structure be "rigid[,]" *Medtronic*, 834 F. Supp. 2d at 473, but here Gore proposes that "rigid" be excluded from the construction for "stent," (Tr. at 38-39, 81). It is also important to note that the *Medtronic* Court initially construed "stent" to mean "[e]longated members forming a substantially cylindrical and rigid structure," but later clarified in its bench trial opinion that the elongated members of the stent must be "connected in such a way as to create [a multiplicity of] openings." *Medtronic*, 874 F. Supp. 2d at 563 n.16. Gore asserts that if the Court takes the route of adopting the *Medtronic* Court's constructions, this clarification should be included. (Tr. at 80-81)

reveals "important information about the structure that's claimed" therein. (Tr. at 25-26; *see also* Tr. at 33 (Gore's counsel explaining that "for the claims at issue here, we have . . . specific requirements [for the claimed stent]")) These claims require a particular stent structure, one in which the stent at issue must be tubular and diametrically adjustable (and, for that matter, must have "an exterior surface, a luminal surface and a wall, and [] a multiplicity of openings through the wall[.]"). ('892 Patent, col. 11:26-39; Tr. at 41 (Gore's counsel explaining that the claims disclose a "specific [stent] structure" as opposed to a "generic structure"); *id.* at 78) Thus, Bard's proposal, which largely (if not exclusively) relies upon the generic term "structure" to define the physicality of the stents at issue, does not do justice to the claims' requirements.

The patent's specification does not alter the Court's view. Bard supports its broad definition of "stent" as being consistent with the specification, which it contends "doesn't require any particular stent." (Tr. at 59; *see also id.* at 51-53, 63-64) However, it is undisputed here that there is a large family of related patents, including patents not in suit, that each share the same specification. (*Id.* at 7, 46-47) For purposes of this claim construction dispute, it is sufficient to say that in light of the specific requirements for the stent structure recited in the claims at issue, the specification's general references to other patents—patents that in turn disclose many different stents—does not automatically render all characteristics of all such stents necessarily encompassed by the scope of the instant set of claim terms. (*Id.* at 33 (noting that the specification's "reference to a different stent . . . could fall within [the scope of other] claims [of other patents not in suit]"); *see also* D.I. 111 at 6 (asserting that a stent structure with helical spring disclosed in U.S. Patent No. 5,197,978 ("Hess") patent may fall within the scope of other

non-asserted claims))[4] Bard's counsel questioned why Gore was "carving out particular stents within the meaning of stent" as "[t]here is no basis to do that in the patent specification[,]" (Tr. at 63), but it is the "*claims* of a patent [that] define the invention[,]" and the claims here clearly impose additional limitations on the stent that is to be used in the claimed device. *Phillips*, 415 F.3d at 1312 (emphasis added, internal quotation marks and citation omitted). Any construction put forward should take that fact into account.

Second, the Court addresses the fact that Bard's proposed construction contains functional requirements—specifically, that the stent be "designed for insertion in a lumen" and "adjustable to contact the surface of the lumen." In support, Bard explains that "the term[s] stent and diametrically adjustable stent [are] technical term[s] [] not used and understood by every-day jurors"; it asserts that these functional references will help the jury to better understand the terms. (Tr. at 53-54; *see also* D.I. 115 at 5)

The Federal Circuit has explained that "[a]n invention claimed in purely structural terms generally resists functional limitation." *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1371 (Fed. Cir. 2001). It has also noted, however, that "it is 'entirely proper to consider the functions of an invention in seeking to determine the meaning of particular claim language.'" *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1375-76 (Fed. Cir. 2009) (citation omitted) (affirming district court's construction of "spike[,]" which included functional language of "'for piercing the seal[,]'" because, *inter alia*, the entire specification "never suggests that the spike can be anything other than pointed"). "A description of what a component does may add

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[4] The Court takes no view here as to whether any piece of prior art anticipates or helps render obvious the claimed inventions. (*See* Tr. at 55, 64-65)

clarity and understanding to the meaning and scope of the claim[,]" and "[t]he criterion is whether the explanation aids the court and the jury in understanding the term as it is used in the claimed invention." *Funai Elec. Co., Ltd. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010).

With these principles in mind, the Court finds that the functional language that Bard proposes here should be rejected. The Court agrees with Gore that the first portion of Bard's proposal ("designed for insertion in a lumen") is unnecessary. The preamble of the claims recites that the stent is an element of a device intended to be inserted into the lumen, and the parties do not dispute that fact. (Tr. at 26, 41, 57) And the second portion of Bard's proposed construction ("adjustable to contact the surface of the lumen") improperly reads certain requirements out of the claims. For example, the proposal does not clearly account for the "tubular" shape of the claimed stent. Moreover, the proposal is contrary to the claims' allowance that the stent can be "diametrically adjustable" without requiring a specific degree. That is, Bard's proposal improperly adds a requirement for a specific amount of adjustability—"to contact the surface of the lumen"—when "[n]either the claims nor the specification discuss contact with a lumen as a requirement for a stent." (D.I. 111 at 4)[5]

For all of the foregoing reasons, the Court declines to adopt Bard's proposed

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[5] To support this language, Bard cites to a passage of the specification that describes an "*intraluminal graft*" that is "collapsed and inserted into a body conduit" and that can then "expand its diameter appropriately to conform to the inner surface of the living vessel." (D.I. 101 at 6 (citing '892 Patent, col. 1:43-48 (emphasis added))) However, this portion of the specification describes the intraluminal graft device as a whole—which *contains* the claimed stent—and not necessarily the stent itself. (*See, e.g.*, D.I. 111 at 4 (noting that the claims of the patents-in-suit "require an exterior covering that could prevent contact between the stent and the lumen"))

construction. Moreover, the Court finds that the phrases "tubular, diametrically adjustable" and "diametrically adjustable"—phrases whose plain meaning are not really disputed by the parties—need not be further construed. (*See, e.g.*, Tr. at 26, 57-58) However, as to "stent," there is a dispute as to its scope and meaning (one that also relates at least to the dispute below regarding the term "multiplicity of openings"). Therefore, the Court agrees with Bard that a construction for "stent" is necessary and would be helpful to a fact finder. *See, e.g.*, *02 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008) ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on the term's 'ordinary' meaning does not resolve the parties' dispute."); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, C.A. No. 08-309-LPS, 2012 WL 938926, at *6 (D. Del. Mar. 13, 2012) (construing a claim term when doing so was appropriate to assist the jury in understanding the meaning of the patent claims it will be asked to consider).

In so doing, the Court is aided by the *Medtronic* Court's construction of identical claim terms in a related patent, which the Court treats as "persuasive authority[.]" *Biovail Labs. Int'l SRL v. Intelgenx Corp.*, Civ. No. 09-605-LPS, 2010 WL 5625746, at *5 (D. Del. Dec. 27, 2010); *see also Clear with Computers, LLC v. AGCO Corp.*, CASE NO. 6:12-CV-622, 6:13-CV-161, 2014 WL 2700376, at *2 (E.D. Tex. June 13, 2014) (stating that the court "gives reasoned deference to prior claim construction rulings involving common terms in related patents"). In the *Medtronic* litigation, both Gore and Medtronic proposed constructions for the term "stent," with Gore's proposed definition focusing strictly on the structure of the stent and Medtronic's proposal including functional language. *Medtronic*, 834 F. Supp. 2d at 471. As noted above,

after a careful examination of both proposals, the *Medtronic* Court arrived at its own construction: "[e]longated members [connected in such a way as to create a multiplicity of openings, and] forming a substantially cylindrical and rigid structure." *Id.* at 473; *Medtronic*, 874 F. Supp. 2d at 563 n.16.[6]

The Court largely agrees with the *Medtronic* Court's construction. That construction focuses exclusively on the claimed structure of the stent, does not import unwarranted functional limitations into the construction, and recognizes that the "stent" at issue has particular features further called out later in the claims. However, the Court agrees with Gore that inclusion of the limiter "rigid" is unnecessary here; neither party argues that it would be appropriate to include that limitation.

Therefore, the Court finds that the terms "tubular, diametrically adjustable" and "diametrically adjustable" should be afforded their plain and ordinary meaning, and recommends that "stent" be construed to mean "elongated members connected in such a way as to create a multiplicity of openings, and forming a substantially cylindrical structure."

b. "wall"

In its briefing, Bard proposes that this term be construed to mean "projected surface defined by the luminal and exterior surfaces of the stent." (D.I. 101 at 7; D.I. 115 at 6) Gore argues that no construction is necessary and the term should be given its plain and ordinary meaning. (D.I. 99 at 11; *see also* D.I. 111 at 2) Alternatively, Gore proposes that the Court

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[6] In doing so, the *Medtronic* Court, *inter alia*, refused to "import a functional limitation into its construction of the term" where "the claim language, the specification, and the prosecution history make no mention of one particular function for the 'stent' used in the intraluminal stent graft[.]" *Medtronic*, 834 F. Supp. 2d at 472.

adopt the *Medtronic* Court's construction for "wall," (Tr. at 38-39, 79-81), which is "[a] substantially cylindrical plane defined by the structure of the stent." *Medtronic*, 834 F. Supp. 2d at 474. During the *Markman* hearing, Bard represented that it would be agreeable to adoption of the *Medtronic* Court's definition for the term. (Tr. at 67-70; *see also id.* at 67 (Bard's counsel noting that this term is "sort of a stepping stone to get to [the other stent-related] limitations"))

In light of both parties' agreement that the *Medtronic* Court's construction for "wall" is appropriate, the Court recommends that the *Medtronic* Court's construction for the term be adopted.

c. "multiplicity of openings"

Bard proposes that this term be construed to mean "two or more open spaces or gaps." (D.I. 101 at 9; D.I. 115 at 8) Gore agrees that "multiplicity" may be defined to mean "two or more[,]" (D.I. 99 at 16), and argues that no construction is necessary for "opening" and that the term should therefore be given its plain and ordinary meaning, (D.I. 99 at 11; *see also* D.I. 111 at 2). Gore notes that its position gibes with the *Medtronic* Court's approach to the term in question. *Medtronic*, 834 F. Supp. 2d at 475. In the end, the crux of the parties' dispute regarding this term (and really, as to all of the stent-related terms) is set out here—whether the claimed "multiplicity of openings" encompass a stent with unbounded openings, in addition to bounded openings. (D.I. 101 at 9; D.I. 111 at 7; D.I. 115 at 9; Tr. at 31, 70-71, 80-81)

Looking first to the claim language itself, it is clear that the claims require selection of a stent with a "multiplicity of openings *through the wall* of the stent." (*See, e.g.*, '892 Patent, col. 11:26-29 (emphasis added))[7] The *Medtronic* Court called out this relationship between the

[7] As even Bard acknowledges, the term "openings" "relates to the wall." (Tr. at 72)

"openings" and the stent's structure when it noted that the "stent can only have a multiplicity of openings *through* the wall if the elongated members [of the stent] are *connected* in such a way as to create these openings." 874 F. Supp. 2d at 563 n.16 (emphasis in original). If the stent has a "multiplicity of openings" *through* the wall, then this suggests that the "openings" in question are bounded on all sides by the structure of the stent. That is, as the *Medtronic* Court observed, that the openings are created by the spaces between the stent's physical connections.

The specification provides some additional insight into the relationship between the claimed openings and the stent wall and structure. For example, the "Summary of Invention" section explains how two coverings may be affixed via thermal adhesion, noting that this may be done "[w]here first and second tubular coverings of expanded PTFE film are affixed to each other *through the multiplicity of openings in the stent wall*[.]" ('892 Patent, col. 3:1-4 (emphasis added)) Additionally, Example 1 refers to a wire stent (depicted by Figure 1), described as "a tubular shape of interlocking hexagons." (*Id.*, col. 4:49-54) Later in the explanation of Example 1, the specification refers to "openings" in the stent, and describes the "openings" as being "between the adjacent wires of the stent." (*Id.*, col. 5:45-50, 63-65) Likewise, Example 3 also indicates that the stent depicted by Figure 7 has "openings[.]" (*Id.*, col. 7:26-28) And like Figure 1, Figure 7 depicts traditional wire stents, such that it is plain that the open hexagons depicted in those stents qualify as the type of claimed "openings" through the wall of the stent at issue here. Taken together, this evidence from the specification suggest that the "multiplicity of openings" at issue are "through" or "in" the wall of the stent—that is, they are bounded openings.

The patents' claims and specification never utilize the terms "spaces" or "gaps." Bard gleaned its proposed construction for "multiplicity of openings" (one allowing for unbounded

openings, in addition to bounded openings) from the specification's general reference to the Hess patent as disclosing various suitable stents. (D.I. 101 at 9 (asserting that the "patents disclose stents having both bounded openings (as shown in Figure 1) and unbounded openings (as shown in the prior art Hess helical spring)")) However, as was previously discussed above (in relation to the term "stent"), the Court does not view the scope of the claimed stents at issue here as needing to be broad enough to encompass: (1) all characteristics of any stent (2) referenced in any patent (3) that itself is anywhere referenced in the specification of the patents-in-suit. Such a reading—that, for example, because the specification cites to the Hess patent as disclosing various diametrically adjustable stents, ('892 Patent, col. 2:37-53, 3:44-53), this means that all stents described in the Hess patent necessarily have a wall with a "multiplicity of openings" through the wall—stretches these references too far.[8]

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[8] The specification references the Hess patent twice as disclosing "[v]arious suitable" diametrically adjustable stents. ('892 Patent, col. 2:37-53, 3:44-53) Among the stents disclosed in Hess are traditional wire stents similar to that depicted in Figure 1 of the '892 Patent as well as a stent made up of a helical spring. (D.I. 96, ex. T, Fig. 1-4, 6A) During prosecution of a European patent application for a patent sharing the same specification as the Asserted Patents, Gore represented to the European Patent Office that "the present claims require a stent having a multiplicity of openings through the walls. A helical spring clearly does not have (or suggest) a multiplicity of discrete openings." (*Id.*, Ex. S at BARD-11-515-00057824 (emphasis in original)) Thus, at least in Gore's view as reflected in this document, a stent with a helical spring structure does not satisfy the claim requirement at issue.

Likewise, the "Background of the Invention" section of the specification makes general reference to the prior art U.S. Patent No. 5,123,917 ("Lee") as describing grafts that include diametrically-expandable stents. ('892 Patent, col. 1:66-2:2) According to Bard's interpretation, the claimed stent structure at issue would encompass stents referenced in Lee—indeed, it would encompass all stents. (Tr. at 63-65) However, as Gore points out, during prosecution of the '487 Patent, a patent in the same family as the Asserted Patents, the requirement for a "multiplicity of openings" was originally not included in claim 1. (D.I. 96, ex. Y at WLG-11-515_00453734, WLG-11-515_00453774) After claim 1 (and others) were rejected as being anticipated in view of Lee, Gore amended claim 1 to add a requirement that the wall of the stent have "a multiplicity of openings" through the wall, and emphasized that "[n]one of the rings in Lee have a

In view of the surrounding claim language and the specification, as well as the other evidence of record, the Court finds that the plain meaning of "openings" in these claims—i.e., "openings" that are "through the wall of the stent"—comports with bounded openings in the stent wall.[9] Because the Court finds that this is the plain and ordinary meaning of the term as used in the claims, the Court recommends that the term "openings" not be further construed (and that "multiplicity" be construed as "two or more" as agreed upon by the parties).

2. "covering"

Bard proposes that the term be construed to mean "film that covers a stent." (D.I. 101 at 11; D.I. 115 at 10) Gore argues that no construction is necessary as the term "has a well understood plain and ordinary meaning[.]" (D.I. 99 at 16; *see also* D.I. 111 at 9-10) The dispute between the parties boils down to whether the definition of this term is limited to a particular type of covering—a film—or whether it can include coverings that are not films. (*See* D.I. 115 at

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multiplicity of openings." (*Id.* at WLG-11-515_00453825-26) So again, at least in Gore's view as expressed in this document, the stents disclosed in Lee do not satisfy this limitation.

[9] Bard points to the *Medtronic* litigation as support for its argument that "openings" in the context of the patent encompasses both bounded and unbounded openings, but the Court is not persuaded. Specifically, Bard argues that in the *Medtronic* litigation, "Gore made clear that [a series of unbounded rings] contained a 'multiplicity of openings' even though the zigzag-shaped rings [at issue in the *Medtronic* litigation] are *not* interconnected by any structure other than the graft material." (D.I. 115 at 9-10 (emphasis in original)) The relevant accused stent at issue in *Medtronic* was made up of zigzag single springs and a double spring connecting bar that traversed the length of the device. *Medtronic*, 874 F. Supp. 2d at 559. In its bench trial opinion, the *Medtronic* Court points out that "Gore questioned [the defendant's expert's opinion] that the springs were not connected to the double spring" by showing him a document that explained that the stent "is composed of a series of serpentine springs stacked in a tubular configuration and *connected* by a full length connecting bar [and] [t]hese structures form the frame of the stent." *Id.* at 560 (internal quotation marks and citation omitted) (emphasis in original). The *Medtronic* Court further notes that Gore "pressed [the defense expert] to acknowledge that the individual springs were in fact 'sutured to the connecting bar.'" *Id.* (citation omitted). Thus, Bard's argument is in conflict with certain portions of the bench trial opinion.

11, 13; Tr. at 89)

The term appears in, *inter alia*, claims 32, 33 and 43 of the '892 Patent, and in claims 12, 13 and asserted claim 15 of the '285 Patent. Claim 32 of the '892 Patent is again reproduced below, followed by claim 33 of the '892 Patent ("claim 33"):

> 32. A tubular intraluminal graft comprising:
>
> > a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
> >
> > b) a first tubular *covering* of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent; and
> >
> > c) a second tubular *covering* of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent;
>
> wherein the combined thickness of the first and second tubular *coverings* is less than about 0.10 mm thick exclusive of the stent.
>
> 33. A tubular intraluminal graft according to claim 32 wherein the first tubular *covering* of porous expanded polytetrafluoroethylene is affixed to the second tubular *covering* of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.

('892 Patent, col. 11:25-44 (emphasis added))

Bard argues that "[t]he claims themselves equate the term 'covering' to a film, or sheet[,]" (D.I. 101 at 11; *see also* D.I. 115 at 10; Tr. at 111, 113), but the Court finds that the claim language is the strongest evidence that, while there is a relationship between the terms "covering" and "film," they do not carry an identical meaning. In doing so, the Court focuses on the language of claim 32. Bard's argument would have more force if the last portion of that

claim read "wherein the combined thickness of the first and second tubular [*films*] is less than about 0.10 mm thick"—since the preceding body of the claim describe a first and second tubular *covering*. ('892 Patent, col. 11:37-39) But the claim does not read as such, and although it sets forth other requirements for the claimed "coverings," none of that language requires that the covering be a "film." (*Id.* at col. 11:31-35)

Bard points to dependent claim 33's reciting of "the second tubular covering of porous [ePTFE] *film*" in support of its contention that the claims equate a "covering" to a "film." (D.I. 101 at 11 (certain emphasis omitted)) However, here, Bard's suggestion runs afoul of the presumption that when different words are used in claims, they are generally presumed to carry different meanings. *See, e.g.*, *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008); *Novartis Pharms. Corp. v. Actavis, Inc.*, Civil Action No. 12-366-RGA-CJB, 2013 WL 6142747, at *5 (D. Del. Nov. 21, 2013) (citing cases); *see also Phillips*, 415 F.3d at 1324-25. The portion of claim 33 that Bard highlights does not compel the conclusion that the terms "covering" and "film" are used interchangeably—instead, it suggests that "film" describes the *type* of covering required by the claim—a "covering *of porous* [ePTFE] *film*." ('892 Patent, col. 11:42-43 (emphasis added)) Indeed, if Bard were correct that "covering" and "film" meant the same thing, then this phrase in claim 33 would read as "the second tubular *film* that covers a stent of porous [ePTFE] *film*."[10] Adopting Bard's proposal, then, would render portions of claim 33 redundant, which is disfavored. *See Novartis Pharms. Corp.*, 2013 WL 6142747, at *4

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[10] That "film" and "covering" do not carry the same meaning in the context of the patent is further supported by several references in the specification to a "film covering[.]" ('892 Patent, col. 6:7, 6:58-59, 6:66, 7:34; *see also id.* at 7:49-51 (describing a "film-covered stent")) Juxtaposing Bard's proposal as to the meaning of "covering" onto these references would cause them to read "film film that covers a stent." (D.I. 111 at 11)

(declining to adopt portion of the defendants' construction of "diseases" where the proposal "would render other portions of the claim redundant and inject confusion, rather than clarity, into the understanding of this term's meaning") (citing cases); *AVM Techs., LLC v. Intel Corp.*, Civil Action No. 10-610-RGA, 2012 WL 1134484, at *6 (D. Del. Mar. 30, 2012) (same, as to term "a delay").[11] It would also contradict the familiar notion that "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *see also Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

The Court's conclusion is strengthened by examining other claims in the patents-in-suit. As Gore notes, it is clear that the patentee knew how to (and did, at times) include claim language specifying that the "covering" at issue must be a "film." "Covering" is used in 12 of the 48 claims of the '892 Patent with a subsequent reference to the type of covering as being a "film." ('892 Patent, col. 8:44-12:56; Tr. at 95) But there are other claims of the '892 Patent in which there is reference to a tubular "covering[,]" with no further reference to a "film." (*See, e.g.*, '892 Patent, col. 9:60-10:7) And there are no references to a "film" covering at all in any of the claims of the '285 Patent. ('285 Patent, col. 8:44-10:30) Yet Bard's proposed construction would import a "film" limitation into all such references to "covering," even where the claims

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[11] As Gore notes, (D.I. 99 at 16), Bard's proposal raises redundancy concerns in claim 32 as well. If one replaces "covering" with Bard's proposal, claim 32 would read, in part, "a first [] film *that covers a stent* of porous [ePTFE] affixed to *the exterior surface of the . . . stent*." The functional language of Bard's proposal ("covers a stent") is already captured by the express language of the claim, as it explicitly "describe[s] what the coverings cover—either the 'luminal surface' of the stent [] or both the 'luminal' and 'exterior surface' of the stent []." (*Id.* (internal citations omitted))

themselves do not. (Tr. at 95) This would be inappropriate, and contrary to the precedent cited above. *See Life Techs. Corp. v. Illumina, Inc.*, Civil Action No. 09-706-RK, 2010 WL 5343177, at *8-9 (D. Del. Dec. 15, 2010) (declining to construe "thin layer" to include a specific range of thickness where several claims reciting the term already defined a specific range that the thin layer falls within, and other claims did not recite a specific numerical range, and therefore "[t]he proposed construction would have us incorporating redundant language where a numerical range is specified . . . and importing limitations into claims containing no such limitation").

Bard also relies heavily on the specification in arguing that "covering" means only one thing in the asserted patents—a film that covers a stent. Bard first points to the statement summarizing the "present invention" as the "most telling[]" evidence supporting its argument, (D.I. 101 at 11):

> *The present invention* is a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and further having a tubular *covering of porous expanded PTFE film* affixed to the stent, said covering being less than about 0.10 mm thick.

('892 Patent, col. 2:24-29 (emphasis added)) It is true that a patentee's consistent reference to a certain limitation as being part of "the present invention" can indicate that the scope of the entire invention is so limited, particularly where no other intrinsic evidence suggests otherwise. *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136 (Fed. Cir. 2011) (internal quotation marks omitted). On the other hand, the Federal Circuit has been careful to note that "use of the phrase 'present invention' . . . is not always so limiting, such as where the references to a certain limitation as being the 'invention' are not uniform, or where other portions of the

intrinsic evidence do not support applying the limitation to the entire patent." *Id.*; *see also Intellectual Ventures I LLC v. Check Point Software Techs. Ltd.*, Civil Action No. 10-1067-LPS, 2012 WL 6200337, at *7 n.4 (D. Del. Dec. 12, 2012) (same).

With regard to this description of the "present invention[,]" Gore's arguments during the *Markman* hearing were compelling. As Gore noted, this description includes all of the different elements of the entire invention. (Tr. at 103) However, as was noted above, many of the claims included in the family of patents sharing this specification do not contain each and every one of these elements. (*Id.* at 104-05)[12] By way of just one additional example, claim 18 of the '892 Patent does not require a "film," nor that the coverings at issue there be less than about 0.10 mm thick. ('892 Patent, col. 10:11-27) Moreover, at the *Markman* hearing, Gore noted that Bard's own position as to the force of the "present invention" language cuts against Bard's argument here. That is, although the "present invention" is described as including "covering of [] *expanded PTFE* film," ('892 Patent, col. 2:24-28 (emphasis added)), Bard asserted in its briefing that its "proposal does not limit the type of covering material to ePTFE[,]" (D.I. 115 at 13). Thus, as Gore pointed out, Bard appears to be selectively picking and choosing as to which features identified in the "present invention" description *must* make up the claimed invention (and which need not). (*See* Tr. at 107)

Looking to other portions of the specification, it is true that the specification frequently describes coverings as ePTFE "film[,]" (*see, e.g.*, '892 Patent, col. 2:30, 2:54-64, 3:1-6, 3:13-30, 3:54-4:30), and it undisputed that all four listed embodiments use an ePTFE film as the

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[12] Gore asserts that in total, 68 claims in the '892 Patent, the '285 Patent and the '487 Patent do not include all of the limitations cited in the "present invention" paragraph of the specification. (Gore's Markman Hearing Presentation)

"covering," (D.I. 99 at 17; D.I. 101 at 11; '892 Patent, col. 4:49-8:43). Yet the specification does not exclusively and uniformly convey that a "covering" must always be of the film type. For example, the Abstract refers to a "tubular covering" more broadly, or at least does not specifically recite "film" as the type of covering called for by the invention. Rather, it describes "[a] tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular *covering of porous [ePTFE] which is less than 0.10 mm thick.*" ('892 Patent at Abstract (emphasis added)) This terminology mirrors the language of claim 32, which does not include the "film" limitation (and not claim 33, which does).

And as for the embodiments described in the patent, they alone are not dispositive, as the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323; *see also Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1347 (Fed. Cir. 2009) (finding that specification's repeated discussion of a "key embedded in the preestablished data" and inclusion of this feature in the only detailed embodiments of the patent was "not enough . . . to limit the patentee's clear, broader claims"); *Mondis Tech., Ltd. v. Hon Hai Precision Indus. Co. Ltds.*, Nos. 2:07-CV-565-TJW-CE, 2:08-CV-478-TJW-CE, 2011 WL 245507, at *9 (E.D. Tex. Jan. 24, 2011) (declining to construe "display unit" and "display apparatus" as meaning "a CRT display" even though every embodiment in the patent is implemented on a CRT display). Indeed, the specification expressly states that the disclosed examples "are not intended to limit the scope of the invention to only the constructions described by these examples." ('892 Patent, col. 4:42-45); *see Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1331 (Fed. Cir. 2012) (citing to similar statement as further evidence that

embodiments did not limit a claim term).

For all of these reasons, the wording of the specification fails to convince the Court that "covering" is limited to mean a "film that covers a stent."[13]

Lastly, the Court turns to the extrinsic evidence highlighted by Bard in support of its proposal. Here, Bard first points to representations made by the applicants during prosecution of "related European application" 714,269, which shares an identical specification with the asserted patents. (D.I. 101 at 13; Tr. at 119) During this European prosecution, the applicants stated that

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[13] Bard also argues that the specification's criticism of prior art extruded tubes equates to the patent's exclusion of "other types of ePTFE coverings that are not films, such as extruded tubes." (D.I. 101 at 12; *see also* D.I. 115 at 10) The portion of the specification to which Bard refers is found in the "Background of the Invention" section and explains that "[t]he difficulty with the use of either the [prior art] GORE-TEX Vascular Graft or the Impra graft . . . is that the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the ability of the tube to be contracted into a small cross-sectional area for insertion into a blood vessel." ('892 Patent, col. 2:10-15) However, the Court does not equate this statement—directed to the thickness of two specific products, and not at tubes or extruded tubes generally—with a clear exclusion "from the scope of the *claimed* invention coverings whose predicate material was made in any particular way, such as by extrusion." (D.I. 111 at 14 (emphasis in original)); *see Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1180-81 (Fed. Cir. 2006) (general statements in specification distinguishing the invention over prior art do not, without more, amount to "a disavowal of coverage by the inventor of features in the prior art"); *see also Thorner*, 669 F.3d at 1366 (noting that "even where a particular structure makes it particularly difficult to obtain certain benefits of the claimed invention, this does not rise to the level of disavowal of the structure") (internal quotation marks and citation omitted).

Bard also contends that "[d]uring prosecution of the patents, Gore . . . distinguished extruded tubes from the scope of the invention[.]" (D.I. 101 at 12-13; *see also* D.I. 115 at 10) But as Gore points out, (D.I. 111 at 14), the two cited passages from the prosecution history of the '892 Patent do not mention tubes or extruded tubes at all. (D.I. 101 at 13 (citing D.I. 96, ex. B at BARD-11-515-00058905; *id.* at BARD-11-515-00059002)) The Federal Circuit has instructed that the prosecution history "cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter." *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002). While the passages do refer to coverings of film, they are "not directed towards overcoming any specific rejection by the Patent Office[.]" (D.I. 111 at 14)

a "fundamental aspect of the present claimed invention" was that "it teaches a method of making a truly diametrically adjustable intraluminal graft by providing a stent form with a covering of expanded *PTFE film* which is specifically thin enough to accommodate the diameter change" and expressly confirmed that the claimed "covering" did not include an extruded tube. (D.I. 101 at 13 (citing D.I. 96, ex. S at BARD-11-515-00057822 (emphasis added); *id.* at BARD-11-515-00058013)) This argument has initial appeal. However, Federal Circuit "precedent cautions against indiscriminate reliance on the prosecution of corresponding foreign applications in the claim construction analysis." *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011). And here, the statements at issue are in reference to different claims that required a seam in the claimed coverings, a limitation that is absent from the claims at issue. (D.I. 111 at 15 (citing D.I. 96, ex. S at BARD-11-515-00057940))[14] Thus, in the absence of better articulation from Bard relating the context of these statements to the particular claims and claim terms at issue here, the impact of the statements is tempered. *See, e.g.*, *ParkerVision, Inc. v. Qualcomm*

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[14] *See also* (D.I. 96, ex. S at BARD-11-515-0057787-88 (applicant stating that "PTFE coverings of the prior art take the form of extruded seamless tubes. It is difficult however to extrude tubes with walls thin enough to conform to the requirements of the present invention. Further, it is difficult to manufacture extruded tubes with walls of uniform thinness. In the present case, the desired thinness is achieved by wrapping a PTFE film around the stent to provide an overlapping seam"); *id.* at BARD-11-515-00057805 (applicant explaining that "the seamed construction of the present invention allows a stent covering of the desired thinness to be achieved" and thus "the seam has a technical effect and cannot be regarded as a 'simple constructional detail without any particular effect'"); *id.* at BARD-11-515-00057813, BARD-11-515-00057825 (Examiner stating that certain passage in specification "referring to a tubular covering apparently without a seam is not covered by Claim 1" and applicant responding that the passage in question "clearly specifies that the tubular coverings described and referred to therein may be made from a film [] and therefore incorporate the seam as described" (emphasis in original)); *id.* at BARD-11-515-00057824 (applicant discussing another piece of prior art that "does not teach or suggest the use of a thin sheet of expanded PTFE film (resulting in seams) to achieve practical diametrical adjustability"))

Inc., No. 3:11-cv-719-J-37TEM, 2013 WL 633077, at *7 (M.D. Fla. Feb. 20, 2013) (finding that "import and relevance of [statements made during prosecution of foreign counterpart application] murky at best" where the statements were made in relation to a different limitation that those at issue in claim construction, and the court was "not . . . presented with the context in which these statements were made, that is, the claims that the limitation modified, the requirements of foreign laws to which the applications are responding, and the examination practices of the foreign office"); *St. Jude Med., Inc. v. Access Closure, Inc.*, No. 4:08-cv-04101-HFB, 2010 WL 2868507, at *33 (W.D. Ark. July 19, 2010) (citations to foreign prosecution unpersuasive where "directed at different claims, with different limitations").

Bard also relies on testimony from the inventors, asserting that they developed the invention with ePTFE films, and that they did not know how to make extruded tubes of the claimed dimensions. (D.I. 101 at 14) The Federal Circuit has explained that "the inventor's subjective intent as to claim scope, when unexpressed in the patent documents" has no effect on claim construction. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). Here, the specification never states that the claimed "covering" excludes extruded tubes, other types of tubes, or all other coverings, except for film. Indeed, as Gore notes, (D.I. 111 at 15 n.4), if inventor testimony should be given weight, the Court would have to also note that one of the inventors testified that the "covering" disclosed in claim 32 "doesn't specify . . . any . . . shape" and "[c]ould be a tube." (D.I. 112, ex. 26 at 52; *see also id.* at 52-54)

For the above reasons, the Court declines to adopt Bard's proposed construction. The Court has thus clearly resolved the disputed issue between the parties (i.e., that the meaning of "covering" is not restricted to a particular *type* of "covering"—a "film" covering). In light of

that, because there is not a dispute about what a "covering" *covers* (here, a stent), and because "covering" thus otherwise has a readily understandable plain and ordinary meaning that is clear and unambiguous in the context of the patent, the Court finds that the term should be afforded that plain and ordinary meaning.[15] *See Warner Chilcott Co., LLC v. Zydus Pharms. (USA) Inc.*, C.A. No. 11-1105-RGA, 2013 WL 1729383, at *2-3 (D. Del. Apr. 22, 2013) (finding no reason to read a particular "boundary limitation" into the disputed claim terms "inner coating layer" and "outer coating layer" and adopting the plain and ordinary meaning of those terms); *see also* (D.I. 101 at 12 (noting that the dispute at issue here is simply over whether the meaning of "covering" excludes "*types*" of "coverings that are not films" and not about what a "covering" is more

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[15] Importantly, the Court's conclusion with respect to "covering" is also in line with the rationale of the decision of the *Medtronic* Court, which declined to construe "covering" to mean "film of ePTFE material" and found that the term should be afforded its plain and ordinary meaning. *Medtronic*, 834 F. Supp. 2d at 475, 479. While the dispute there was technically a different one, focusing on whether "covering" should be limited to "ePTFE material[,]" *id.* at 475, the *Medtronic* Court employed the "same kind of logic" in its analysis as that the Court employs here, (Tr. at 87-88; *see also id.* at 99). This is because the specification, including its "Summary of Invention" section, consistently describes a "covering" as being made of ePTFE. (*See, e.g.*, '892 Patent, col. 2:27-28) As a result, the *Medtronic* Court faced similar arguments to those Bard pursues here, including that "the Abstract of the Invention, the Summary of Invention . . . and every embodiment disclosed refers to a covering made with ePTFE material[.]" *Medtronic*, 834 F. Supp. 2d at 476. Although acknowledging this fact, the *Medtronic* Court ultimately found that the term "covering" was not limited to a covering "of ePTFE," in part because to so find would "render [a certain dependent claim of the patent-in-suit that specifically limited the 'covering' to a 'covering . . . of porous expanded PTFE'] superfluous." *Id.* at 477-79. That is the same strain of argument that Gore raises here as to why the coverings at issue should not be limited to those comprised of a "film."

During the instant *Markman* hearing, Bard's counsel stated that the *Medtronic* Court "just assumes that [the ePTFE is] film, and [that Court] talks about ePTFE material, ePTFE sheet." (Tr. at 121; *see also id.* at 111-12, 122 (asserting that *Medtronic* Court uses "covering" and "film" interchangeably)) However, the *Medtronic* Court's analysis regarding the "covering" term never refers to the term "sheet[,]" and only uses the term "film" in presenting the defendant's proposed construction. *Medtronic*, 834 F. Supp. 2d at 475-79. Therefore, the Court cannot agree with Bard that the *Medtronic* Court clearly "just assume[d]" that a "covering" was a "film."

generally) (emphasis added); Tr. at 84-85).

3. "affixed"/"affixing" and "the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent"

In their briefing, the parties presented multiple disputes that in some way relate to the terms "affixed" or "affixing."

The parties first briefed a dispute regarding the terms "affixed" and "affixing," standing alone. Those terms are found in relevant claims 32, 33 and 43 of the '892 Patent and in claim 12 of the '285 Patent. Bard proposed that "affixed"/"affixing" should be construed to mean "secured"/"securing," while Gore contended that the terms should be given their plain and ordinary meaning. (D.I. 99 at 18-19; D.I. 101 at 14-16; D.I. 111 at 16-17; D.I. 115 at 15-16)

During the *Markman* hearing, it became clear that the parties were not really in disagreement about the meaning of these terms. In its briefing, Gore had focused on *the method by which* a covering could be "affixed" pursuant to the claims, believing that Bard's construction was meant to exclude some of the specification's disclosed means of "affixing" coverings (via adhesive, thermal adhesion, or suture). Bard confirmed, however, that this was not the case. (Tr. at 126-27, 129, 133-36; *see also* D.I. 115 at 16) Bard's proposal, in turn, was motivated by a desire to ensure that Gore would not suggest that "affixing" meant "merely placing on"—and that instead, "affixing" connotes a "secure connection." (D.I. 101 at 15) Gore, as it turned out, was not suggesting otherwise. (Tr. at 126-27) Thus, as there is not a dispute as to the meaning of these terms standing alone, no construction of the terms is necessary.

There is, however, a live dispute with respect to the meaning of another phrase containing

the word "affixed." This involves the following term in claim 33: "the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent[.]" ('892 Patent, col. 11:41-44) Again, for ease of reference, the Court reproduces claim 33 (and independent claim 32, upon which it relies) here:

> 32. A tubular intraluminal graft comprising:
>
> a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
>
> b) a first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent; and
>
> c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent;
>
> wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm thick exclusive of the stent.
>
> 33. A tubular intraluminal graft according to claim 32 wherein *the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.*

('892 Patent, col. 11:25-44 (emphasis added))

In its briefing, Bard proposes that this term at issue be construed to mean "the first and second coverings are secured to each other through openings through the wall of the stent in addition to being secured to the exterior and luminal surfaces of the stent," while Gore argues that the term should be afforded its plain and ordinary meaning. (D.I. 101 at 16-17; D.I. 111 at

17-18; D.I. 115 at 16-17) During the *Markman* hearing, the parties further clarified the crux of their dispute. That is, Gore argues that the method of affixing disclosed in claim 33 (i.e., two coverings affixed together "through openings through the wall of the stent") is a specific way of accomplishing the type of affixing of the coverings to the surface of the stent that is described in claim 32. (Tr. at 126 (Gore's counsel arguing that the method of affixing described in claim 33 is a "subcategor[y] of the primary affixing that's talked about in [independent claim 32]")) Bard disagrees, asserting that "where the real fight comes in . . . is the argument that when the first tubular covering is affixed to the second tubular covering [as set out in claim 33], that means it's affixed to the exterior surface of the stent[,]" which it believes is "not the case [since the affixation described in claim 33 is not] a way of affixing [the covering] to the stent." (*Id.* at 133-34; *see also id.* at 140, 142)

The Court agrees with Gore's position. As Gore asserts, (*id.* at 124, 136-37), the following key paragraph of the '892 Patent's specification guides the Court to that conclusion:

> *Stent coverings may be affixed to a stent surface by variations on this method.* For example, ... *The inner **83** and outer **85** portions of the tubular sleeve **81** may be thermally adhered to each other through the openings in the stent wall*, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends **87** of the tube together.

('892 Patent, col. 7:51-61 (emphasis added)) The specification thus plainly sets out three "variations" of how coverings may be affixed *to a stent surface*: (1) coverings may be thermally adhered to each other through stent wall openings; (2) the coverings may be adhered to the stent surfaces by an adhesive; or (3) the open ends of the coverings may be sutured together. That these three methods are all ways in which coverings may be affixed to a stent surface is

highlighted not only by the fact that they are grouped together in the same paragraph with such a clear topic sentence, but that they are presented as alternatives to one another, separated by the conjunction "or."

The claims of the '892 Patent reinforce Gore's position. Independent claim 32 describes a stent with, *inter alia*, two coverings affixed to the exterior and luminal surfaces of the stent, but does not include any limitations specifying *how* that particular type of affixation to the stent must occur. ('892 Patent, col. 11:26-39) Various dependent claims of the patent disclose examples of the how—the three methods of affixation to a stent surface set out in the specification and described in the previous paragraph. For example, dependent claim 36 describes affixing with adhesive (*id.*, col. 11:52-54), dependent claim 17 describes affixing with sutures (*id.*, col. 10:10-11), and (most relevant here) dependent claim 33 describes affixing through openings through the wall of the stent, (*id.*, col. 11:40-44). And since claim 33 depends from claim 32, it must of course contain all the limitations of claim 32. *Pi-Net Int'l Inc. v. JPMorgan Chase & Co.*, — F. Supp. 2d — , 2014 WL 1997150, at *10 (D. Del. May 14, 2014) (noting that a claim dependent on an independent claim contains all the limitations of the independent claim) (citation omitted); *Creo Prods., Inc. v. Presstek, Inc.*, No. C.A. 99-525-GMS, 2001 WL 637397, at *6 n.12 (D. Del. May 11, 2001) (same). Thus, the coverings described in claim 33 must be "affixed to a stent surface," and it is clear that claim 33 describes a "variation[]" or way in which this occurs. ('892 Patent, col. 7:51-52; Tr. at 126, 137, 139, 143) As Gore explains, it follows that "once the two coverings are affixed to one another, they are also affixed to the relevant surfaces of the stent." (D.I. 111 at 18; Tr. at 125; *see also id* at 139 (Gore's counsel explaining that one of the ways you can affix coverings to the stent surface "is by affixing the two coverings to each other through the

openings and capturing the stent in-between them"))

For these reasons, the Court finds that the claim language and specification corroborate the notion that dependent claim 33 describes a way in which stent coverings may be affixed to a stent surface, and provide little support for Bard's proposed construction. With the Court having resolved that dispute, and because claim 33 is otherwise clear as to the method of affixing disclosed therein, the Court finds that the term "the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent" should be afforded its plain and ordinary meaning.

4. "collapsed diameter"/"enlarged diameter"

These terms—"collapsed diameter" and "enlarged diameter"—appear in independent claim 12 (incorporated into asserted claim 15) of the '285 Patent, as shown below:

> 12. A method of making a tubular intraluminal graft comprising:
>
> a) selecting at least one a tubular diametrically adjustable stent having an exterior surface, a luminal surface and a wall and having a multiplicity of openings through the wall, said tubular diametrically adjustable stent having a *collapsed diameter* and an *enlarged diameter* wherein said *enlarged diameter* is at least 1.5 times the *collapsed diameter*, wherein said tubular diametrically adjustable stent has been adjusted to the *enlarged diameter*;
>
> b) affixing a tubular covering to the luminal surface of the tubular, diametrically adjustable stent;
>
> c) collapsing the tubular, diametrically adjustable stent to about the *collapsed diameter*; and
>
> wherein said intraluminal graft is adapted for implantation in a body conduit.

('285 Patent, col. 9:27-10:11 (emphasis added)) Bard proposes that the term "collapsed diameter" be construed to mean "minimum diameter of the stent as designed" and that the term "enlarged diameter" be construed to mean "maximum diameter of the stent as designed." (D.I. 101 at 9; D.I. 115 at 13) Gore argues that these terms need no construction because their plain and ordinary meanings are clear in the context of the claim. (D.I. 99 at 19-20)

Bard asserts that the claim language supports its proposal, (D.I. 101 at 9-10), but the Court cannot agree. According to Bard, the "claim . . . recites discrete design parameters of the stent; it is not referring to the many actual, in-use diameters for which a stent may be used." (*Id.* at 10) Bard then asserts that "the *only* two discrete diameters that could qualify as the claimed 'collapsed' and 'enlarged' diameters must be the minimum and maximum diameters as designed." (D.I. 115 at 14 (emphasis in original); *see also* D.I. 101 at 10 ("the enlarged and collapsed diameters are specific, measurable endpoint parameters, *i.e.*, the minimum and maximum diameters of the stent as designed")) It is true that claim 12 recites a "method of making a tubular intraluminal graft" that includes selecting a stent with an identifiable "collapsed diameter" and an identifiable "enlarged diameter"—the latter being at least 1.5 times the former. ('285 Patent, col. 9:27-10:3) However, nothing in the claim language clearly compels the conclusion that these diameters are the minimum and maximum diameters of the stent. On the face of the claim, for example, the stent can transition to an enlarged diameter that is 1.5 times the collapsed diameter, or to a measurement that is greater than that.

Indeed, as Gore points out, the surrounding language of the claim implies not that the collapsed and enlarged diameters must refer to the minimum and maximum diameters, respectively, but instead that the terms refer to "one or more collapsed diameters and one or more

expanded diameters." (D.I. 111 at 8); *see also ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (explaining that "the context of the surrounding words of the claim . . . must be considered in determining the ordinary and customary meaning of those terms") (citing cases). When the terms first appear in the claim, they are modified by the articles "a" and "an[.]" ('285 Patent, col. 10:1) Federal Circuit law instructs that "[a]s a general rule, the words 'a' or 'an' in a patent claim carry the meaning of 'one or more.' [] The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit 'a' or 'an' to 'one.'" *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012) (internal quotation marks and citations omitted). The claim's later reference to "the" enlarged or collapsed diameter does not alter the force of this rule; instead, those references to "the" diameter at issue are simply viewed as reinvoking the previously-referenced non-singular meaning. *SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360 (Fed. Cir. 2012) (explaining that "the later use of 'the' and 'said' to refer back to an earlier claim term does not limit that claim term to the singular"). "An exception to the general rule that 'a' or 'an' means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008). But here, as noted above, the claim language does not provide the basis for such a departure.

Neither does the specification; if anything, it supports Gore's reading. The specification does not equate the collapsed diameter or enlarged diameter with the minimum or maximum diameter of the stent as designed; indeed, as Gore points out, "the words 'minimum' and 'maximum' do not appear anywhere in the specification." (D.I. 111 at 9; *see also* Tr. at 159)

Rather, the specification simply discusses stent devices that expand from collapsed diameters to expanded diameters—they get larger, without necessarily transitioning from minimum diameter to maximum diameter. (*See, e.g.*, '285 Patent, col. 1:46-53 ("the intraluminal graft . . . may be collapsed and inserted into a body conduit at a smaller diameter location . . . . and then expand its diameter appropriately to conform to the inner surface of the living vessel"); *id.* at 3:45-47 (Figure 1 referring to "stent [being] shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter" without referencing a "maximum" diameter))

Example 3, as Gore explains, further tends to illustrate that "multiple expanded and collapsed diameters are acceptable within the meaning of the claims." (D.I. 111 at 9; *see also* Tr. at 157-159) The portion of the specification describing this example first references a stent that "was adjusted from its collapsed outside diameter of 3.4 mm to an enlarged outside diameter of 8.0 mm[.]" ('285 Patent, col. 7:8-9) The device is then described as having "collapsed back to an outside diameter of 4.5 mm"—clearly a larger measurement than the first collapsed outside diameter referenced—before being enlarged again "to a diameter of 8 mm[.]" (*Id.* at col. 7:41-50)

Bard's proposed construction primarily flows from its desire to "eliminate[] any ambiguity[,]" (D.I. 115 at 14), and to establish "two reference points to understand the 1.5 limitation[,]" (Tr. at 165). But claim language gleans its meaning from the context of the patent, and the patent itself simply does not clearly support Bard's chosen reference points—a point that Bard's counsel seemed to acknowledge during the *Markman* hearing. (*See* Tr. at 167 (explaining that "[t]he only support for the reference points are the maximum as manufactured, it's a

manufacturing claim")) Bard argued that without reference points "you end up in a situation where you don't know whether it's enlarged or collapsed, it could potentially be both." (*Id.*) But all the claim itself requires in terms of collapsed diameter and enlarged diameter is the selection of a stent that must be able to expand to a point at which the enlarged diameter is at least 1.5 times the collapsed diameter, and for the stent to then be collapsed back down to the collapsed diameter once a covering has been affixed. ('285 Patent, col. 9:27-10:11)

At this stage, the Court sees no reason to depart from the claim language used, or to read limitations into the terms that are not present in the claim or specification of the '285 Patent.[16] Thus, the Court finds that the terms should be afforded their plain and ordinary meanings.

B. Conclusion

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "tubular, diametrically adjustable" and "diametrically adjustable" should be afforded their plain and ordinary meaning, and "stent" should be construed to mean "elongated members connected in such a way as to create a multiplicity of openings, and forming a substantially cylindrical structure"

2. "wall" should be construed to mean "a substantially cylindrical plane defined by the structure of the stent"

3. "multiplicity" should be construed to mean "two or more" and "openings" should be afforded its plain and ordinary meaning

4. "covering" should be afforded its plain and ordinary meaning

5. "the first tubular covering is affixed to the second tubular covering . . . through

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[16] The Court's decision here is without prejudice to Bard's ability to challenge the validity of the claim as indefinite at the summary judgment stage if it believes there is a basis to do so. (Tr. at 167-68); *see also Spectrum Pharms., Inc. v. InnoPharma, Inc.*, Civil Action No. 12-260-RGA-CJB, 2014 WL 3365684, at *9 (D. Del. July 3, 2014) (citing cases).

openings through the wall of the stent" should be afforded its plain and ordinary meaning

6. "collapsed diameter"/"enlarged diameter" should be afforded their plain and ordinary meaning

IV. CONCLUSION

The Court recommends that the District Court adopt the constructions set out in Section III.B above, for the reasons discussed in Section III.A above.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: August 8, 2014

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE