EXHIBIT A

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 United States 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 are Bard's Motion for Summary Judgment of Invalidity (D.I. 235), Bard's Motion for Summary Judgment of Non-infringement as to the Thickness Limitation (D.I. 244), and Bard's *Daubert* Motion to Exclude Certain Testimony from Gore's Expert Dr. Robert C. Gorman (D.I. 253). The Court recommends that the Motion for Summary Judgment of Invalidity be DENIED, the Motion for Summary Judgment of Non-infringement be GRANTED-IN-PART, and the *Daubert* Motion be DENIED.

I. BACKGROUND

A. Factual Background

1. The Asserted Patents

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

The asserted patents, both of which are entitled "Intraluminal Stent Graft[,]" share a common specification and relate to thin-wall intraluminal graft devices. (D.I. 96, ex. A & V)[2] The patents explain that implantation of conventional vascular grafts usually required invasive surgery that caused major trauma to the patient. ('892 Patent, col. 1:9-20) As an alternative, some physicians had begun to use intraluminal devices that combined conventional vascular grafts with stents which were placed inside the damaged portion of the vessel using a less invasive "catheter type of delivery system." (*Id.*, col. 1:22-26, 37-38) However, the "relatively thick, bulky wall[s]" of prior art devices made 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 claim 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)

2. The Accused Products

Gore alleges that two of Bard's stent-graft products, the FLUENCY® Plus Tracheobronchial Stent Graft ("Fluency Plus") and the FLAIR® Endovascular Stent Graft ("Flair"), infringe claims 32, 33, and 40 of the '892 Patent and claim 15 (which incorporates the elements of claims 12 and 13) of the '285 Patent. (D.I. 64 at ¶¶ 16-17, 19, 23; D.I. 191 at 1; *see also* D.I. 291 at 1)

The accused Fluency Plus and Flair devices are manufactured in a multi-step process occurring in Tempe, Arizona and in Germany. (D.I. 248 at 4; D.I. 259, Declaration of Dr. Nigel Buller ("Buller Decl."), ex. B at ¶ 80) The metal stents are manufactured in Germany and then

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[2] The asserted patents are found in a number of places in the record, including as Exhibits A and V to D.I. 96. Further citation will simply be to the "'892 Patent" or the "'285 Patent."

shipped to Arizona. (Buller Decl., ex. B at ¶ 80) Once there, Bard encapsulates the stents with extruded tubes of expanded polytetrafluoroethylene ("ePTFE"), (*id.*), which is a porous form of Teflon and a soft, compressible material, (*id.*, ex. A at ¶¶ 54, 75-76; D.I. 260, Declaration of Robert Calcote ("Calcote Decl."), ex. A at ¶ 55). The encapsulated stents are then shipped back to Germany where they are mounted on delivery systems. (Buller Decl., ex. B at ¶ 80)

During the encapsulation process, Bard loads a tubular ePTFE covering over the stent and a second tubular ePTFE covering inside the outer tube/stent structure. (D.I. 248 at 4; D.I. 291 at 4; Buller Decl., ex. B at ¶¶ 83-87; D.I. 303, Declaration of Enrique Criado, M.D. ("Criado Decl."), ex. A at 42-43) Bard regularly measures the thickness of the ePTFE tubes used to make the devices with an optical microscope, and records these measurements, prior to the next step in the process. (D.I. 245 at 5; Buller Decl., ex. B at ¶¶ 96, 155 & ex. 2A) The stent structure is then placed on a cylindrical rod called a mandrel, and the loaded mandrel is tightly wrapped with PTFE (Teflon) tape. (D.I. 248 at 4-5; Buller Decl., ex. B at ¶¶ 83-88; Criado Decl., ex. A at 42-43) The wrapping process causes the ePTFE coverings to become compressed. (D.I. 307, ex. 2 at 486-87) Next, the wrapped, loaded mandrel device is heated in an oven for several minutes, a step known as the "sintering" procedure. (D.I. 248 at 5; D.I. 291 at 4-5; Buller Decl., ex. B at ¶ 89; Criado Decl., ex. A at 45) This heating process causes the inner and outer ePTFE coverings to bond together through the stent strut openings, a process known as "lamination." (D.I. 248 at 5; D.I. 291 at 4-5; Buller Decl., ex. B at ¶ 89; Criado Decl., ex. A at 45) The Teflon tape is then removed from the device. (Buller Decl., ex. B at ¶ 47)

B. Procedural History

On June 10, 2011, Gore commenced this action. (D.I. 1) On January 10, 2014, Bard

timely answered Gore's Second Amended Complaint, and asserted counterclaims against Gore. (D.I. 189) 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) Fact discovery closed on December 20, 2013, and expert discovery closed on June 30, 2014. (D.I. 291 at 1) After a hearing, (D.I. 130), the Court issued a Report and Recommendation on claim construction on August 8, 2014, (D.I. 221). Objections to that Report and Recommendation are currently pending. (D.I. 222, 263)

Briefing on the instant motions was completed on November 12, 2014, and the Court held oral argument on the motions on January 30, 2015. (D.I. 360 (hereinafter, "Tr."))[3] A 10-day trial is set to begin on December 7, 2015. (D.I. 362)

II. STANDARD OF REVIEW

A. Summary Judgment

A grant of summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). If the moving party meets this burden, the nonmovant must then "come forward with specific facts showing that there is a *genuine issue for trial*." *Id.* at 587 (emphasis in original) (internal quotation marks omitted). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of

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[3] The parties filed a large number of additional motions for summary judgment and *Daubert* motions seeking to exclude certain expert testimony, some of which remain pending before the Court. (D.I. 226, 229, 231, 238, 241, 250, 256)

proof, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586-87; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks and citation omitted). The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are "material," and a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials"; or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce

admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

B. *Daubert* Motion

Federal Rule of Evidence 702 governs the admissibility of qualified expert testimony, providing that an expert witness may testify if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. Rule 702's requirements have been examined in detail by the Supreme Court of the United States in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and have been said to embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *see also B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010).

In terms of expert qualifications, an inquiry under Rule 702 must address whether the expert witness has "'specialized knowledge regarding the area of testimony.'" *Elcock*, 233 F.3d at 741 (quoting *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998)). The basis of this specialized knowledge may be "practical experience as well as academic training and credentials." *Id.* (internal quotation marks and citations omitted). At a minimum, however, "a proffered expert witness . . . must possess skill or knowledge greater than the average layman." *Id.* (internal quotation marks and citations omitted). The United States Court of Appeals for the Third Circuit has tended to apply this standard liberally. *Id.*; *see also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

With regard to the second requirement of reliability, Rule 702 mandates that the relevant expert testimony "must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590; *see also Schneider*, 320 F.3d at 404. The information provided by experts should be "ground[ed] in the methods and procedures of science" and be "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590; *see also Schneider*, 320 F.3d at 404.[4] In examining this requirement, a court's focus must be on "principles and methodology" rather than on the conclusions generated by the expert. *Daubert*, 509 U.S. at 595; *see also Daddio v. Nemours Found.*, 399 F. App'x 711, 713 (3d Cir. 2010).

The third requirement of expert testimony, the "fit" requirement, "goes primarily to relevance" as the testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue" and have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591-92; *see also Schneider*, 320 F.3d at 404. The standard for fit, however, is not a high one; it is met "when there is a clear 'fit' connecting the issue in the case with the expert's opinion that will aid the jury in determining an issue in the case." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009) (citations omitted).

Overall, "Rule 702 embodies a 'liberal policy of admissibility.'" *B. Braun Melsungen AG*, 749 F. Supp. 2d at 222 (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008)). Nonetheless, the burden is placed on the party offering expert testimony to show that it

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[4] The Supreme Court later held in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), that the obligations imposed by *Daubert* extended to not only scientific expert testimony but rather to all expert testimony. *Kumho Tire Co.*, 526 U.S. at 147.

meets each of the standards for admissibility. *Id.* (citing *Daubert*, 509 U.S. at 592 n.10).[5]

III. DISCUSSION

Bard has filed a motion for summary judgment of invalidity, asserting that two limitations found in the asserted claims are indefinite. Additionally, it filed a motion for summary judgment of non-infringement, claiming that its accused products do not infringe the asserted claims because they do not meet the thickness limitation of those claims. Finally, Bard filed a *Daubert* Motion to exclude certain testimony of Gore's technical expert, Dr. Gorman, relating to infringement of the thickness limitation. The Court will consider each of the motions in turn.

A. Invalidity

1. Standard Regarding the Definiteness Requirement

A patent claim must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112.[6] If it does not, the claim is

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[5] Although Bard requested oral argument on its pending motions, (which the Court held), (D.I. 343), neither party sought an evidentiary hearing as to the *Daubert* motion or suggested that the factual record was insufficiently developed such that a hearing of that type was required. The Third Circuit has held that a trial court need not conduct an evidentiary hearing on a *Daubert* challenge if the record is sufficient to allow the Court to make a determination on the issues in dispute. *See, e.g.*, *Oddi v. Ford Motor Co.*, 234 F.3d 136, 151-55 (3d Cir. 2000); *Maldonado v. Walmart Store No. 2141*, Civil Action No. 08-3458, 2011 WL 1790840, at *13 n.10 (E.D. Pa. May 10, 2011). Here, Dr. Gorman's expert reports were provided to the Court, and they addressed the basis of Dr. Gorman's conclusions. The parties also ably addressed issues relating to Dr. Gorman's report in their briefing, in the slides they put forward at oral argument, and during oral argument itself. Under such circumstances, the Court has determined that the record before it is sufficient to allow for a decision on the admissibility of Dr. Gorman's testimony under *Daubert*. *See, e.g.*, *Furlan v. Schindler Elevator Corp.*, 516 F. App'x 201, 205-06 (3d Cir. 2013); *Oddi*, 234 F.3d at 151-55; *Maldonado*, 2011 WL 1790840, at *13 n.10.

[6] The Court here quotes from the version of 35 U.S.C. § 112 in effect prior to passage of the Leahy-Smith America Invents Act ("AIA"); this prior version of Section 112 applies to all patents with an effective filing date of on or before September 16, 2012, including the asserted patents in this action. *See Eidos Display, LLC v. AU Optronics Corp.*, 779 F.3d

indefinite and therefore invalid. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2125 (2014). In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), the Supreme Court set out the test to be applied in the indefiniteness inquiry: "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124.

The primary purpose of the definiteness requirement is to ensure that patent claims are written in such a way that they give notice to the public of what is claimed, thus enabling interested members of the public (e.g., competitors of the patent owner) to determine whether they infringe. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002). Indefiniteness is to be evaluated from the perspective of someone skilled in the relevant art at the time the patent was filed. *Nautilus*, 134 S. Ct. at 2128 (citing cases).

Indefiniteness is a question of law for the court. *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1332 (Fed. Cir. 2014); *Pi-Net Int'l Inc. v. JPMorgan Chase & Co.*, 42 F. Supp. 3d 579, 586 (D. Del. 2014). The United States Court of Appeals for the Federal Circuit has stated that "[a]ny fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed.

1360, 1364 n.2 (Fed. Cir. 2015).

Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).[7]

2. Analysis

Bard moves for summary judgment of invalidity on the grounds that two limitations are indefinite: (1) the "thickness" limitation, appearing in all asserted claims; and (2) the "diameter" requirements, found in claim 15 of the '285 Patent. (D.I. 236 at 1)

a. Thickness Limitation

The asserted claims of the '892 Patent require the combined thickness of the first and second ePTFE coverings to be "less than about 0.10 mm thick" exclusive of the stent. ('892 Patent, col. 11:37-39) The asserted method claim of the '285 Patent requires the single luminal covering to be "less than about 0.10 mm thick." ('285 Patent, cols. 9:27-10:13)

During claim construction, Bard proposed that "about" be construed to mean "approximately." (D.I. 101 at 18; D.I. 115 at 18-19) Meanwhile, Gore proposed that the thickness limitation be construed to specify a particular method for measuring thickness—the use of a snap gauge. (D.I. 99 at 10-11 (proposing that "[l]ess than about 0.10 mm thick" means "[l]ess than about 0.10 mm thick as measured by snap gauge"); *see also* D.I. 111 at 18-20

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[7] In *Nautilus*, the Supreme Court left open the question of whether factual findings subsidiary to the ultimate issue of indefiniteness should, in fact, trigger the application of a "clear and convincing evidence" standard, noting that it would "leave th[is] question[] for another day." *Nautilus*, 134 S. Ct. at 2130 n.10. Other courts have noted the uncertainty regarding the applicability of this standard post-*Nautilus*. *See, e.g.*, *In re MyKey Tech. Inc. Patent Litig.*, No. MDL 13-02461 GAF (PLAx), 2014 WL 2740733, at *6 & n.1 (C.D. Cal. June 17, 2014); *Cal. Inst. of Tech. v. Hughes Commc'ns Inc.*, 35 F. Supp. 3d 1176, 1182 n.4 (C.D. Cal. 2014). Absent further indication from the Supreme Court on this point, the Court will apply the clear and convincing evidence standard in the manner suggested by existing Federal Circuit precedent as set out above. *In re MyKey Tech.*, 2014 WL 2740733, at *6 n.1; *Cal. Inst. of Tech.*, 35 F. Supp. 3d at 1182 n.4.

(same)) The parties did not otherwise offer constructions for the "less than about 0.10 mm thick" term. At the *Markman* hearing, the parties agreed that, for claim construction purposes, there was no dispute regarding the term that required resolution by the Court. (D.I. 221 at 6 n.2) Nonetheless, Bard reserved its right to later raise the issue of indefiniteness regarding the term. (D.I. 130 at 153-54)

In the instant motion, Bard argues that "less than about 0.10 mm thick" is indefinite for two reasons. First, it contends that the term fails the *Nautilus* test for definiteness because it is "inherently ambiguous" and prevents the skilled artisan from knowing "whether a covering thickness is in or out of the scope of the claims." (D.I. 236 at 7-9 (emphasis omitted)) Second, Bard asserts that the term fails to "reasonably convey when, where, and how to measure graft thickness." (*Id.* at 9-14 (emphasis omitted)) The Court addresses these arguments in turn.

(1) Bard's arguments regarding ambiguity and the patents' use of "inconsistent modifiers"

Bard contends that the language of the claim term is "ambiguous" and creates a "fuzzy zone of uncertainty" that precludes one skilled in the art from assessing "where the exact boundary lies between what is claimed and what is not." (*Id.* at 1, 6) To make its case, Bard highlights the presence in the limitation of "two potentially inconsistent modifiers[,]": "less than" and "about." (*Id.* at 7; D.I. 336 at 1)

Bard's first "ambiguity"-related argument is that use of "less than" and "about" together leaves the skilled artisan to wonder, for instance, whether "a thickness of 0.11 mm [is] 'less than about 0.10 mm.'" (D.I. 336 at 1; *see also* Tr. at 187 ("I just . . . can't conceive of what less than about a particular number means.")) The Court is not convinced that the skilled artisan would suffer from such confusion.

The Supreme Court in *Nautilus* explained that "[t]he definiteness requirement . . . mandates clarity, while recognizing that absolute precision is unattainable." *Nautilus*, 134 S. Ct. at 2129. To that end, nothing in the patent suggests that a thickness of 0.11 mm would fall within the scope of the claims; instead, the specification points to "0.10 mm" as the relevant upper boundary. Indeed, in the "Abstract" section of the patent, the patentee describes the invention as a "graft . . . having a tubular covering of porous expanded polytetrafluoroethylene *which is less than 0.10 mm thick.*" ('892 Patent at Abstract (emphasis added)) The specification then discusses multiple exemplary embodiments with coverings ranging in thickness from "about 0.01 mm" to "about 0.08 mm"—all well below 0.10 mm. ('892 Patent, cols. 6:55-59, 7:23-25; *see also* D.I. 299 at 11)[8]

Moreover, here, all of the experts appear to agree that thicknesses measuring 0.10 mm or greater would not be "less than about 0.10 mm thick." *See Nautilus*, 134 S. Ct. at 2128 ("patents are . . . addressed . . . to those skilled in the relevant art") (internal quotation marks and citation omitted); *see also Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002) ("Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field."). Bard's expert Dr. Nigel Buller opined that "if [the term 'less than about 0.10 mm thick'] *means what I think it should*, [it means] less than point 1." (D.I. 307, ex. 1 at 192 (emphasis added); *see also id.* at 190 (Dr. Buller stating "I

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[8] At oral argument, Bard's counsel acknowledged the same: that "all of the measurements that are provided in the patent . . . are well below that .10 number. They're .01 or .08 or well below it." (Tr. at 175)

believe for [the term] to be definite and therefore understandable to a person of skill in the art, it must be less than point 1 . . . .")) Another Bard expert, Mr. Robert Calcote, likewise pinpoints 0.10 mm as the relevant limiter. (*Id.*, ex. 3 at 86 ("I'm here to opine on whether or not the measurements I made were greater or less than point 1."))[9] Gore's experts voiced this conclusion as well. (*Id.*, ex. 13 at 256-57 (Dr. Criado testifying that "the majority . . . of the measurements have to be under .1, so the .1 is a very definite . . . limitation" and "the claim . . . intends [] to, in my opinion, [] keep the thickness under about .1, so the majority of the measurements of the thickness are going to be under .1"); *id.*, ex. 14 at 109 (Dr. Gorman testifying that to test the accused products, he set his micrometer opening at 0.097 mm "[b]ecause it was less than the 0.1"))

Bard takes issue with this view as effectively "writ[ing] 'about' out of the claim[] [limitation]." (Tr. at 175; *see also id.* at 182; D.I. 336 at 5) But as Gore notes, here "about" would still have real meaning, as it is used to reflect that the thickness of a covering "may not be perfectly uniform across a device[.]" (D.I. 299 at 11-12)

The specification comports with this explanation. This is evidenced in part by the fact that nearly every time the specification recites the thickness of a covering in discussion of the

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[9] Bard nevertheless contends in its briefing that its experts "recogniz[e] the imprecision in the claim language." (D.I. 336 at 6) In support of this statement, Bard cites primarily to Dr. Buller's expert reports. (*Id.* (citing Buller Decl., ex. A at ¶¶ 403-04; *id.*, ex. C at ¶¶ 229-35)) But most of the cited portions of those reports do not focus on the issue discussed here—whether the use of the term "less than about" might, for example, be read by a person of skill in the art to create significant uncertainty because it could encompass measurements *at or greater* than 0.10 mm thick. Instead, for the most part, these portions of Dr. Buller's reports focus on other arguments as to why the term is indefinite—e.g., that the term does not sufficiently instruct the skilled artisan as to when, where, or how to measure covering thickness. Those additional arguments are further addressed Section III.A.2.a.(2) below.

four examples, the thickness measurement is modified by the word "about." (*See, e.g.*, '892 Patent, col. 5:25-27 ("[t]he . . . [ePTFE] film used to construct this example was of *about 0.01 mm thickness*") (emphasis added); *id.*, col. 6:38-40 ("[t]his film was of . . . *about 0.08 mm thickness*") (emphasis added); *id.*, col. 7:23-24 ("[t]he wall thickness of the film covering was *about 0.01 mm*") (emphasis added)) It is also particularly evidenced by Example 2 in the patents. There, a film measuring "about 0.08 mm thickness" is wrapped around a mandrel, overlapping enough to form a 2 mm wide seam (a seam that comprises less than 5% of the surface area of the stent), and then a stent is fitted over the film-covered mandrel. ('892 Patent, col. 6:39-59; *see also* D.I. 299 at 12 & n.3 (citing Declaration of Robert C. Gorman, M.D. ("Gorman Decl."), ex. C at 17)) Since the seam is created by a double layer of the original film, that would result in a greater thickness along the seam (as appears to be demonstrated in the example found in Figure 5 of the patent). (*See* D.I. 299 at 12 (citing '892 Patent, FIG. 5)) And yet the specification describes the thickness of the resulting ePTFE film covering as "about 0.08 mm"—notwithstanding that the measurement at the point of the seam would be thicker than the dimension of a single layer of ePTFE (and thus, would presumably be thicker than 0.08 mm). ('892 Patent, col. 6:58-59; *see also* D.I. 299 at 12)

In addition, the experts on both sides provided testimony supporting this explanation. Gore's experts, for example, concluded that the person of skill in the art would understand the term "about" to reflect variability in covering thickness—i.e., that *some portions* of a covering on a covered stent-graft device may be greater than 0.1 mm thick. Dr. Gorman explains that while the limitation requires the "overall thickness of the claimed coverings to be less than about 0.1 mm thick," he does not understand the claims to require that "no individual location on the

covering can be greater than 0.1 mm thick" —"[f]or example, the term 'about,' as used in the claims themselves, takes into account some level of manufacturing variability." (Gorman Decl., ex. C at 17) Similarly, Dr. Criado opines that "the term 'about' is used in the [] limitation to accommodate any minor variations that may exist in the thickness of the covering." (Criado Decl., ex. B at 206-07)[10] And the testimony of Bard's experts also confirmed that ePTFE coverings do not exhibit a uniform thickness.[11]

Bard's second "ambiguity"-related argument is that the claims are indefinite because they "fail to identify how much of the 'covering[s]' may be greater than 0.10 mm and still fall within the claims[.]" (D.I. 336 at 1; *see also* Tr. at 177-78, 181) But the experts did not seem to have any real trouble with the patent's lack of explicit guidance in this regard. Rather, they all expressed agreement that the skilled artisan would look to the average, or overall, thickness of

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[10] Bard argues (with no citation to supporting expert testimony or case law) that "[m]anufacturing variability or tolerance may make sense in the context of a finished device with uniform thickness [but] [i]t has no meaning in the context of a covering that is designed and understood by a skilled artisan to be necessarily non-uniform in thickness." (D.I. 336 at 6) Yet regardless of whether the finished device is or is not designed or intended to be non-uniform in thickness, in the Court's view, the term "about" is meant to capture the reality that there will in fact be some resulting non-uniformity. (*See, e.g.*, Gorman Decl., ex. C at 17; Criado Decl., ex. B at 206-07) As Bard explains, "the thickness limitation does not refer to some particular point on the 'covering'—according to the claim, it refers to the *entire* covering[,]" (D.I. 336 at 5 (emphasis in original))—and in this context, the Court is not convinced that the limitation's inclusion of "about" is fatal. Instead, the evidence suggests that the skilled artisan would understand it to reflect the fact that not every single portion of the covering will measure less than 0.10 mm.

[11] (*See, e.g.*, D.I. 307, ex. 3 at 154 (Mr. Calcote explaining that as to the accused Flair product, "it's natural to have some variability whereby individual measurements may be lower [than 0.1 mm]"); *id.*, ex. 2 at 503 (Dr. Buller stating that Mr. Calcote "made several measurements on each device" because "there is variation in thickness" of the coverings); *see also id.* at 502 (Dr. Buller acknowledging that the accused devices had a distribution of thicknesses because "[i]n any real world on any real manufactured thing, there's going to be distribution, yes, of course"))

the covering(s) in determining whether the limitation is met. Mr. Calcote testified that "what matters here is that the average wall thickness of the tube is above point one." (D.I. 307, ex. 3 at 154; *see also id.* at 150, 152; Calcote Decl., ex. A at ¶ 87 (summarizing his measurement results by explaining that "[m]any of the individual thickness measurements were substantially greater than 0.10 mm . . . and the averages of the individual measurements—the proper number one of skill in the art would use when evaluating the thickness of the ePTFE of the tubes—were all over 0.10 mm")) Dr. Buller explained that Mr. Calcote took individual measurements of the accused devices, some of which were thicker than others, and "generalizing to the covering[,]" stated there was no evidence that Bard produced coverings that are less than 0.10 mm thick. (D.I. 307, ex. 2 at 503) For their part, Gore's experts seem to agree that a person of skill in the art would look to the average thickness of the covering at issue.[12]

In rebutting Bard's arguments regarding asserted ambiguity, Gore makes a number of additional points that have helped convince the Court that its position here is correct. For example, in support of the idea that "less than about" would not create significant uncertainty for one of skill in the art, Gore's expert notes that the term is used in a number of patents in the field—including certain of Bard's own patents. (D.I. 299 at 2, 14-15 (citing Criado Decl., ex. B at 203-04)) For example, Bard's U.S. Patent No. 6,436,135 claims, *inter alia*, an ePTFE graft

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[12] (*See* Criado Decl., ex. C at 21 (opining that "what matters for purposes of this claim is the overall thickness of the covering, not the maximal thickness from one discrete area of the covering"); *see also* D.I. 237, ex. 4 at 293 (Dr. Criado noting that "[Mr.] Calcote himself . . . admits that . . . the importance is to have an average, you know, pretty much the average of the . . . thickness"); D.I. 307, ex. 13 at 256 (Dr. Criado explaining that the person of skill in the art would understand the limitation at issue to mean that "the devices on average and by the most are going to be thinner [than 0.10 mm]"); Gorman Decl., ex. C at 17 (explaining that the patents "require the overall thickness of the claimed coverings to be less than about 0.1 mm thick"))

with "a wall thickness *greater than about* 0.2 millimeters and *less than about* 0.8 millimeters." (D.I. 307, ex. 48, col. 12:18-22 (emphasis added); *see also* D.I. 299 at 2, 14-15) The Court agrees that it is fair to consider this as further evidence that language such as "less than about" would be understood by the skilled artisan in this field.[13]

Gore also notes that many courts (including the Federal Circuit) have ruled that a patent's use of a term of approximation does not necessarily render its claims invalid for indefiniteness. (D.I. 299 at 7-10)[14] Bard counters by citing to the Federal Circuit's decision in *Amgen, Inc. v.*

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[13] *See, e.g., Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, Civil No. 1:CV-09-1685, 2011 WL 2632352, *1 (M.D. Pa. July 5, 2011) (vacating a prior order that found claim terms with language "at least about" and "less than about" to be indefinite and explaining that the plaintiff's citation to defendants' patents which used this language "is relevant insofar as it shows that the claim terms are commonly used by those skilled in the art, and thus goes against [the defendants'] invalidity arguments"); *Paradox Sec. Sys. Ltd. v. ADT Sec. Servs., Inc.*, 710 F. Supp. 2d 590, 599 (E.D. Tex. 2008) (finding that the term at issue was "not as incongruous as defendants suggest[,]" despite the lack of guidance in the specification and prosecution history as to the term's meaning, where "[p]laintiffs point to one of the defendant's use of the same term in one [of] its recent patent applications"); *cf. Hay & Forage Indus. v. New Holland N. Am., Inc.*, 25 F. Supp. 2d 1180, 1186 (D. Kan. 1998) (finding that the term "at least approximately equidistant" was not indefinite where, *inter alia*, "every prior art patent cited on the face of the [asserted patent] uses terms in its claims that are very similar to, and in some cases even identical to, the 'at least approximately' language").

[14] Indeed, at least prior to *Nautilus*, courts regularly found that the use of "about" in a limitation can be reflective of minor variations, and did not necessarily render claims indefinite. *See, e.g., Accentra, Inc. v. Staples, Inc.*, 500 F. App'x 922, 930 (Fed. Cir. 2013) (holding that a defendant failed to prove by clear and convincing evidence that a limitation was indefinite, despite the fact that the relevant distance could be measured in several different ways, as "[a]ny minor differences can be accounted for in the claims' use of the word 'about'—a term that, when considered in context, is not ordinarily regarded as giving rise to fatal indefiniteness"); *ACCO Brands v. PC Guardian Anti-Theft Prods., Inc.*, 592 F. Supp. 2d 1208, 1222 (N.D. Cal. 2008) (rejecting defendant's argument that "about 3mm x 7mm" was indefinite where the patentee's expert testified that the dimension 3mm x 7mm indicated a "high level of precision" and that the skilled artisan would understand "about" as referring to "some allowance for manufacturing variances") (internal quotation marks and citations omitted); *see also Verve, LLC*, 311 F.3d at 1120 (explaining that expressions like "substantially" and "about" may be used in patents "when warranted by the nature of the invention, in order to accommodate the minor variations that may

Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991), (D.I. 236 at 7; D.I. 336 at 3-4), but that citation is inapposite. In *Amgen*, the Federal Circuit affirmed the district court's finding that claims 4 and 6 of the asserted patent were invalid because their specific activity limitation of "at least about 160,000" was indefinite. *Amgen*, 927 F.2d at 1217-18. The limitation at issue related to the potency or activity of the human hormone erythropoietin ("EPO") as measured by bioassays, which "'provide an imprecise form of measurement with a range of error[.]'" *Id.* at 1217 (citation omitted). The prosecution history reflected that the "at least about 160,000" claim language was added after the patent examiner rejected a broader claim covering specific activity of "at least 120,000" based on close prior art disclosing a product with a potency of 128,620. *Id.* at 1217-18 (internal quotation marks omitted). The district court found that the "'term 'about' 160,000 gives no hint as to which mean value between . . . 128,620 and . . . 160,000 constitutes infringement'" and that the term was thus indefinite. *Id.* at 1218 (internal quotation marks and citation omitted). Further emphasizing the indefiniteness of the limitation at issue was the fact that "nothing in the specification, prosecution history, or prior art provide[d] any indication as to what range of specific activity is covered by the term 'about,' and by the fact that no expert testified as to a definite meaning for the term in the context of the prior art"; indeed, even the patentee's own employee could not define the term's meaning. *Id.*

The facts here paint a much different picture. *Cf. id.* (noting that use of the term "'about'" "may be acceptable in appropriate fact situations"). Unlike in *Amgen*, here the intrinsic evidence suggests that the term "less than about 0.10 mm thick" places a boundary line at 0.10 mm, with thicknesses measuring under that line falling within the scope of the claim. *Cf. Young*

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be appropriate to secure the invention").

v. Lumenis, Inc., 492 F.3d 1336, 1347 (Fed. Cir. 2007) ("Unlike the situation in *Amgen*, here the intrinsic evidence does provide guidance on the meaning of the [allegedly ambiguous claim term.]"). And, again contrary to *Amgen*, here there is expert testimony from both sides confirming that a person of skill in the art would understand the meaning of the "less than about" limitation. *Cf. ACCO Brands v. PC Guardian Anti-Theft Prods., Inc.*, 592 F. Supp. 2d 1208, 1222 (N.D. Cal. 2008) (distinguishing *Amgen* on the basis that there, "no expert testified as to a definite meaning for the term in the context of the prior art").

In sum, when the Court considers the claim language, specification and extrinsic evidence, Bard has not shown by clear and convincing evidence that the use of "less than" and "about" creates sufficient ambiguity or a "fuzzy zone of uncertainty" such that the claims at issue are indefinite.

(2) Bard's "when, where, and how" arguments

Bard also asserts that the claims are indefinite because the patents do not "reasonably convey when, where, and how to measure graft thickness." (D.I. 236 at 9-14 (emphasis omitted); *see also* D.I. 336 at 7-9; Tr. at 180-81, 185) The Court is not convinced that these are issues of indefiniteness.

As to the question of timing—*when* must the thickness of the claimed coverings meet the thickness limitation for purposes of infringement—both parties agreed during oral argument that this is an issue of claim construction (i.e., that the parties here are having a dispute about what the claim language requires). (Tr. at 42-43, 190-91) The Court agrees as well, and will take up this issue below in considering the Motion for Summary Judgment of Non-infringement.

As to the issue of *where* (on the stent-graft) to measure graft thickness, Bard's counsel

stated at oral argument that "the where is not even disputed" because both parties' experts agreed that the appropriate place to look to is "in between the stents." (Tr. at 51-52; *see also id.* at 39 (Bard's counsel explaining "there's one place to measure [thickness] and that is not at the stents, but between the coverings. That's undisputed."); Gorman Decl., ex. A at 12 (explaining that samples were prepared for testing by "cut[ting] away a portion of the ePTFE covering that covered an opening through the stent wall")) There is no ambiguity for skilled artisans with respect to the issue of where to assess graft thickness.

That leaves the issue of *how* to measure. The patent clearly describes one method of measuring ePTFE covering thickness: the use of a snap gauge. ('892 Patent, col. 4:33-41) And Bard acknowledges that as to "measuring" thickness of the covering(s) "[i]f you went through the steps exactly as the patent tells you, you went through it and did it reliably [the use of a snap gauge] would be [an acceptable] way of doing it[.]" (Tr. at 182-83) Moreover, Bard has also acknowledged that the method described in the patent is not the only way in which thickness can be measured—rather, "one of skill in the art at the time of the invention would have known that there were numerous ways of measuring thickness." (D.I. 115 at 19; *see also* Tr. at 40-41 ("We certainly agree there's different techniques to do that measurement."); Calcote Decl., ex. A at App. D at 15 (Mr. Calcote's report listing, in an appendix, numerous methods for measuring wall thickness))

Bard's indefiniteness argument relating to measurement techniques really flows from its disagreement with the *particular methodology* that Gore's expert Dr. Gorman used to measure the accused products. Bard appears to argue that if Dr. Gorman's measurement approach is permissible, then the claims are indefinite because Gore utilized "non-standard and undisclosed

methods of measurement that no competitor could fairly be expected to employ in assessing its products in light of the thickness limitation." (D.I. 236 at 11-14; *see also* D.I. 336 at 8-9)

The Court is not persuaded that indefiniteness is the proper lens through which to address this dispute. Indeed, at oral argument, in response to a question from the Court, Bard's counsel agreed that "questions about how [to appropriately measure covering thickness] get filtered through *Daubert*, we see what's acceptable, and then we look at whether we have genuine issues of material fact." (Tr. at 43-44) The Court agrees.[15] The dispute here regarding how to measure really sounds in the language of *Daubert* (and not of indefiniteness). It is a largely a fight over whether the particular testing process that Dr. Gorman used is sufficiently reliable and whether it is relevant to the issues in the case (and not a fight about whether the claims fail to inform, with reasonable certainty, a skilled artisan as to the proper scope of the invention).[16] *See 3M*

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[15] During claim construction, at a time when Bard was arguing that methodologies for measuring thickness other than use of a snap gauge (such as the use of a calibrated optical microscope or a scanning electron microscope as suggested by its expert, Mr. Calcote) were appropriate, Bard seemed to concede that any disagreements among the experts about which testing method to use were for the ultimate fact finder to resolve. (D.I. 115 at 20 (arguing that "a dispute . . . over the appropriate testing method for the thickness of the coverings on the accused products" raises "a factual question to be resolved by the fact finder in the application portion of the infringement inquiry, not a legal question over the scope of the claims") (internal quotation marks and citation omitted))

[16] The Federal Circuit has made it clear that a patent is not indefinite merely because it fails to specify which method of measurement should be used, or because different methods may produce different results. *Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1366-67 (Fed. Cir. 2014); *see also Purdue Pharm. Prods., L.P. v. Actavis Elizabeth, LLC*, Civil Action Nos. 12-5311 (JLL), 13-5003, 2014 WL 2624787, at *5 (D.N.J. June 11, 2014). In circumstances where there are several possible acceptable methods that can be used to measure whether a claim limitation is met, and where those methods could produce different results, the key questions for indefiniteness purposes are: (1) whether the competing method in question produces a result that is generally accurate and (2) whether there is clear and convincing evidence that the method of measurement is in fact outcome-determinative in the infringement analysis. *Takeda Pharm.*, 743 F.3d at 1367 & n.4; *cf. Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341

Innovative Props. Co. v. GDC, Inc., Civil No. 13-1287 (DWF/JJK), 2015 WL 2381046, at *4, *20 & n.12 (D. Minn. May 19, 2015) (noting that disputes over testing methods did not support a finding of indefiniteness, but instead were more properly raised in the context of infringement and *Daubert* motions). Bard has, in fact, filed a *Daubert* motion on that score. (D.I. 253; D.I. 254) The Court will address that dispute below in resolving the *Daubert* motion.

For the reasons set out above, Bard has not demonstrated, by clear and convincing evidence, that its cited "when, where and how" issues relating to measurement render the claims indefinite.

b. Diameter Requirements

Bard's other indefiniteness arguments implicate the "diameter" requirements, and relate to asserted claim 15 of the '285 Patent. Independent claim 12 of the patent, which is incorporated into claim 15, recites:

> 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

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F.3d 1332, 1340 (Fed. Cir. 2003) (affirming that the claims at issue were indefinite where the specification did not discuss which sample preparation method should be used to produce a polyester yarn product, and the particular method chosen was "critical to discerning whether [an infringing yarn] has been produced by the claimed process"). Here, there is no dispute that there are a number of ways to accurately measure covering thickness. And as to Dr. Gorman's methodology for measurement, Bard has not proven by clear and convincing evidence that this method produces an inaccurate result, or that the method is necessarily outcome determinative (as opposed to, for example, this amounting to a situation where the parties' experts are using acceptable methodologies that could have produced similar results, and where the differing results actually produced are a product of the experts' use of those methodologies to measure different portions of the areas between the stents, or of their differing decisions as to the number of measurements to take). (*See, e.g.*, D.I. 301 at 17-18 (Gore asserting that Mr. Calcote "made sure to test only the 'maximal' thickness of [the] coverings") (citing Gorman Decl., ex. C at 15-16))

> 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, cols. 9:27-10:11 (emphasis added)) As to the relevance of a stent graft's diameter, the patent specification explains that:

> If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at a smaller diameter location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel.

(*Id.*, col. 1:47-53) The specification gives examples of these types of stents. (*See, e.g.*, *id.*, cols. 4:51-54, 7:6-8) These include Figure 1, which is described as a "side view of a typical diametrically adjustable stent. The stent is shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter." (*Id.*, col. 3:46-49) The specification further describes applying ePTFE coverings to a stent with an enlarged diameter, then collapsing the device, and then expanding the device again to an enlarged diameter. (*See, e.g.*, *id.*, col. 7:7-15, 27-28, 42-51) For instance, Example 3 refers to a stent that "was adjusted from its collapsed outside diameter of 3.4 mm to an enlarged outside diameter of 8.0 mm" and which is then "collapsed back to an outside diameter of 4.5 mm." (*Id.*, col. 7:8-42)

During claim construction, Bard sought to construe "collapsed diameter" as "minimum diameter of the stent as designed" and "enlarged diameter" as "maximum diameter of the stent as designed." (D.I. 101 at 9-10; D.I. 115 at 13-15) The Court did not find sufficient support for Bard's proposals in the claim language and specification, and therefore recommended that the terms be afforded their plain and ordinary meaning. (D.I. 221 at 32-36) In so doing, it noted that all that the claim requires as to these terms "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." (*Id.* at 36)

At oral argument, Bard asserted that the "collapsed diameter" and "enlarged diameter" terms are indefinite for two reasons. It claimed that the patent fails to inform the person of skill in the art: (1) *when* to determine whether the enlarged diameter is at least 1.5 times the collapsed diameter ("[t]he enlarged diameter might actually be extra enlarged during the manufacturing process time, but is that the enlarged diameter of the stent or is it the enlarged diameter as it's being put in vivo in the body or is it the enlarged diameter before the covering's applied") and (2) "*what* is that diameter at that time." (Tr. at 183-84 (emphasis added))

Bard's "when" argument was raised for the first time at oral argument—Bard had not raised it in its briefing. (D.I. 236 at 14-15; D.I. 336 at 9-10) Even were this argument not waived, it is worth noting that during claim construction, Bard appeared to have a clear understanding of the relevant time period in which the presence of an "enlarged diameter" and "collapsed diameter" are assessed. As Bard then explained, the claim is a method of manufacture

claim.[17] Thus, the determination at issue would be made at the time in the manufacturing process at which the stent is "select[ed.]" Accordingly, the Court finds Bard's new "when" argument unpersuasive.

As for Bard's "what" argument, Bard contends that particular numbers, or objective reference points, are required for the diameters in question in order to allow the public "to evaluate infringement . . . and the objective boundaries of the claim." (Tr. at 185; *see also* D.I. 236 at 15) Without such fixed reference points, it argues, the person of skill in the art would not know "whether any particular diameter [that fell] somewhere in between the minimum and maximum diameter [amounted to] the enlarged diameter, the collapsed diameter, or potentially both. [] One of skill may consider a device partially collapsed, partially enlarged, or both." (D.I. 236 at 15 (internal citations omitted); *see also* D.I. 130 at 166) The Court does not agree that, in this regard, the claim fails to inform the skilled artisan with reasonable certainty about the scope of the invention.

For one thing, in support of its argument, Bard cites almost exclusively to certain paragraphs from Dr. Buller's expert reports on invalidity—and yet these paragraphs contain little of substance to support Bard's position. (D.I. 236 at 15 (citing Buller Decl., ex. A at ¶ 406; *id.*,

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[17] (*See, e.g.*, D.I. 115 at 14 (explaining that claim 12 recited a "'method of making a tubular intraluminal graft' that includes the selection of a stent with a particular, identifiable 'collapsed diameter,' and a particular, identifiable 'enlarged diameter'"); *see also* D.I. 130 at 164-69 (Bard's counsel noting that "[t]his, again, is in the context of making [the stent], collapsing the stent to its original collapsed diameter, and then enlarging it" and the "claim language is talking about making a stent graft; you are going to select a stent. And it's going to have an enlarged diameter and it's going to have a collapsed diameter, but importantly there is going to be a relationship between those two in connection with the selection process."))

ex. C at ¶¶ 253-55))[18] For example, the first cited paragraph is paragraph 406 from Dr. Buller's opening report, which states (in relevant part):

> However, I understand that Gore appears to interpret the terms "enlarged diameter" and "collapsed diameter" to encompass the infinitely many diameters between the maximum and minimum diameters of the stent graft. Under such an interpretation the terms "enlarged diameter" and "collapsed diameter" are not defined, and as a result one of ordinary skill in the art would not have been able to distinguish what is claimed from what is not.

(*Id.*, ex. A at ¶ 406) But Dr. Buller does not elaborate any further, rendering this part of his opinion not much of a step up from a bare conclusion. Next, as to cited paragraphs 253-55 from Dr. Buller's reply report, of the points made there, only one is set out in more than a cursory fashion:

> Specifically, for purposes of infringement, Dr. Criado and Dr. Gorman [i.e., Gore's experts] contend that a stent is adjusted to an "enlarged diameter" when it is made smaller. *E.g.*, Rebuttal Rep. ¶¶ 213-14. But if making a stent smaller satisfies the requirement of adjusting to an enlarged diameter, then one of ordinary skill in the art would not be able to determine if an infringement occurred.

(*Id.*, ex. C at ¶¶ 253-55) But Dr. Buller's citation for the proposition that Gore's experts believe that a stent is adjusted to an enlarged diameter "when it is made smaller" ("*E.g.*, Rebuttal Rep. ¶¶ 213-14") is to *his own* rebuttal report regarding non-infringement—not to any portion of a Gore expert's report. And even in those portions of his own rebuttal report, Dr. Buller does not cite to any argument made by Gore's experts. Instead, he cites to his personal observations of Bard's manufacturing processes, from which he concluded that "[a]t no time is the stent adjusted to an

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[18] The Court notes that one portion of these citations was to paragraph 406 in Exhibit A1, a version of Dr. Buller's opening expert report. The version of that exhibit provided to the Court appears to be missing a page or pages, including the page on which the majority of paragraph 406 is set out. (Buller Decl., ex. A1 at 158, 162)

enlarged diameter" and that it is "in fact manipulated to a smaller diameter" prior to the ePTFE covering being put on it. (*Id.*, ex. B at ¶¶ 213-14) Thus, it does not necessarily follow that *Gore's experts* believe a stent is adjusted to an enlarged diameter when it is made smaller—alternatively, they could (and it appears they do) simply disagree with how Dr. Buller interprets this particular step in Bard's manufacturing process and how it relates to the infringement analysis. (*See, e.g.*, Criado Decl., ex. A at 222; *id.*, ex. C at 62-64)[19]

Additionally, the testimony of Gore's experts Dr. Criado and Dr. Gorman persuasively demonstrates why a person of skill in the art would, with reasonable certainty, understand the scope of the claim terms at issue. (Criado Decl., ex. B at 210; Gorman Decl., ex. B at 27-28) Here, Dr. Criado and Dr. Gorman point to the specific relationship between the two diameters disclosed in the claim ("at least 1.5 times"), explaining that it prevents the claims from encompassing (as Dr. Buller had asserted) "infinitely many diameters." (Criado Decl., ex. B at 208; Gorman Decl., ex. B at 25) Dr. Criado and Dr. Gorman explain that the claim language simply allows for multiple collapsed and enlarged diameters to fall within the limitation at issue, so long as the difference between the enlarged diameter is at least 1.5 times the collapsed diameter. (Criado Decl., ex. B at 210 ("Further, it is my opinion that the '285 Patent claims and

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[19] Bard also argues that if "enlarged diameter" and "collapsed diameter" "mean, as Gore proposed, any of the various ranges of diameters through which the stent passes, then one of skill in the art would be unable to determine whether a particular stent has been 'adjusted to *the* enlarged diameter,' or collapsed to 'about *the* collapsed diameter'" as the claims require. (D.I. 236 at 15 (emphasis in original)) Yet at claim construction, the Court made clear its view that claim 12's use of the word "the" in requiring that the stent be "adjusted to the enlarged diameter" or collapsed to "about the collapsed diameter" was not a reference to a singular diameter. (D.I. 221 at 34) Instead (in light of earlier wording in the claim) it was meant to "reinvok[e] the previously-referenced non-singular meaning." (*Id.*) Therefore, Bard's argument in this regard is not persuasive.

specification clarify that the main importance of the 'collapsed diameter' and 'enlarged diameter' is the 1.5-times difference between the two."); Gorman Decl., ex. B at 27-28 (same))[20] Moreover, as Gore's experts note, the meaning of this claim language was clear enough that they and Dr. Buller were "each able to opine on whether certain devices or references had a 'collapsed diameter' and an 'enlarged diameter' for the purposes of infringement and validity." (Gorman Decl., ex. B at 27 (citations omitted); *see also* Criado Decl., ex. B at 209-10 (citations omitted)); *cf. Soitec, S.A. v. Silicon Genesis Corp.*, 81 F. App'x 734, 738 (Fed. Cir. 2003) (rejecting the defendant's argument that the claims were indefinite where, *inter alia*, "[o]bjective evidence also suggests that [the defendant's] own experts were able to understand the bounds of the claims"); *Procter & Gamble Co. v. Team Techs., Inc.*, 46 F. Supp. 3d 764, 769 (S.D. Ohio 2014) (finding the ability of both parties' experts to understand the meaning of the disputed claim term "provides probative evidence that the scope of the claim was reasonably certain to be understood by persons of skill in the art at the time the patent applications were filed").[21]

In view of the light shed by the intrinsic evidence on the meaning of the claim terms, the

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[20] *Cf. Storm Prods., Inc. v. Ebonite Int'l, Inc.*, 638 F. Supp. 2d 1307, 1312-13 (D. Utah 2009) (holding that terms "'large number of bowlers'" and "'relatively small number of balls'" are indefinite where, *inter alia*, the evidence failed to "definitively tie[] a 'large number of bowlers' to any anchor, such as a numeric threshold . . . . there is nothing in the patent or the supporting evidence to provide a baseline over which any number would be understood to be 'large'").

[21] Additionally, although it does not bind the Court, it is worth noting that in another litigation involving Plaintiff and a related patent (the "*Medtronic* litigation"), where the related patent contained the same claim language at issue here, the parties were able to determine whether the accused product "'had a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter' and that the [accused] device 'had been diametrically adjusted to the enlarged diameter.'" *W.L. Gore & Assoc., Inc. v. Medtronic, Inc.*, 874 F. Supp. 2d 526, 564 n.19 (E.D. Va. 2012) (citations omitted).

lack of detailed expert testimony fleshing out Bard's position, and the substance of Gore's experts' opinions on the issue, the Court recommends denial of the summary judgment motion on indefiniteness grounds as it relates to the "diameter" requirements.

B. Infringement

1. Standard

The patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning and scope of the patent claims asserted to be infringed. *Id.* Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing device. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between the claimed invention and the accused product are insubstantial. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24, 40 (1997); *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014). The patent owner has the burden of proving infringement, and must do so by a preponderance of the evidence.

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

When an accused infringer moves for summary judgment of non-infringement, such relief is only appropriate if, viewing the facts in the light most favorable to the patentee, no reasonable jury could find that every limitation recited in the properly construed claim is found in the accused device, either literally or under the doctrine of equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001) ("[S]ummary judgment is proper only if no reasonable jury could return a verdict for the nonmoving party.") (internal quotation marks and citation omitted). Because the patentee bears the burden of proof on infringement, the accused infringer moving for summary judgment is not required to put forward evidence of non-infringement. *Exigent Tech., Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1307-09 (Fed. Cir. 2006). Rather, "nothing more is required than the filing of a summary judgment motion stating that the patentee ha[s] no evidence of infringement and pointing to the specific ways in which [the] accused [products] d[o] not meet the claim limitations." *Id.* at 1309. The burden of production then shifts to the patentee to "identify genuine issues that preclude summary judgment." *Novatek, Inc. v. Sollami Co.*, 559 F. App'x 1011, 1022 (Fed. Cir. 2014) (internal quotation marks and citation omitted).

2. Analysis

Bard moves for summary judgment on the grounds that its accused Flair and Fluency Plus products do not infringe any of the asserted claims because they do not meet the thickness limitation of those claims. (D.I. 244, 245, 340) In resolving this motion, the Court will first take

up an issue of claim construction regarding the thickness limitation in the claims. The Court then considers whether summary judgment is warranted for each asserted patent.

a. When Must the "Less Than About 0.10 mm Thick" Limitation be Satisfied?

The parties' arguments regarding infringement here hinge on a key question: *when* must the thickness of the claimed coverings satisfy the "less than about 0.10 mm thick" limitation for there to be infringement? This "when" issue was not raised prior to the Court's earlier *Markman* hearing, and so it remains unresolved. Nevertheless, the Court retains discretion to address claim construction during consideration of a summary judgment motion, *see Va. Innovation Scis., Inc. v. Samsung Elecs. Co., Ltd.*, 983 F. Supp. 2d 713, 727 (E.D. Va. 2014); *Stern v. SeQual Techs., Inc.*, 840 F. Supp. 2d 1260, 1266 (W.D. Wash. 2012), and both parties agree that the Court should decide this "when" issue in that fashion in resolving the motion, (*see* Tr. at 43-44, 74, 95, 190-91). Accordingly, the Court will consider the issue below.[22]

(1) '285 Patent

The relevant term "wherein said tubular covering is less than about 0.10 mm thick" is found in claim 13 of the '285 Patent, which incorporates claim 12, as shown below:

> 12. A method of making a tubular intraluminal graft comprising:
>
> a) selecting at least one a tubular diametrically adjustable stent . . . .
>
> b) affixing a tubular covering to the luminal surface of the tubular, diametrically adjustable stent;

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[22] In doing so, the Court turns for guidance to precedent from the Supreme Court and the Federal Circuit regarding claim construction, previously set out in the Court's August 8, 2014 Report and Recommendation. (D.I. 221 at 3-5)

> 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.
>
> 13. A method according to claim 12 *wherein said tubular covering is less than about 0.10 mm thick.*

('285 Patent, cols. 9:27-10:13 (emphasis added))

Bard contends that these claims require affixing a tubular covering that is less than about 0.10 mm thick to the stent surface—in other words, that the thickness that matters here is the thickness of the covering *before* it has been affixed to the stent. (*See, e.g.*, D.I. 245 at 3-4 (explaining that "the relevant covering thickness is before the stent graft is manufactured")) For its part, Gore argues that the relevant thickness as to the '285 Patent (and indeed, for both asserted patents) is the thickness of the covering *after* it has been affixed to the stent. (D.I. 301 at 7-9) Here, the Court agrees with Bard.

First and foremost, the claim language itself best supports Bard's position. Claim 13 is a method claim that describes a method of making a stent graft. As set out in claim 12, the steps of making the device include selecting a stent, affixing a tubular covering to the luminal surface of that stent, and collapsing the stent down. ('285 Patent, cols. 9:27-10:9) Claim 13's added requirement—"wherein *said* tubular covering is less than about 0.10 mm thick"—clearly refers back to the "tubular covering" that is described in claim 12—the one that is to be affixed to the luminal surface of the stent. (*See* D.I. 340 at 3) Thus, according to the plain language of the claims, the thickness of the covering at issue is the thickness prior to affixation.

In arguing to the contrary, Gore too cites to the claims' language. First, it asserts that "[b]y definition, a 'covering' already covers the stent." (Gore's Motions Hearing Presentation at

Section 1, Slides 10-11; *see also* Tr. at 74-75, 80; D.I. 294 at 19 ("before affixation, the ePTFE is not even a covering")) Furthermore, Gore points to the stent limitation's inclusion of the word "selecting"; it argues that while this word indicates a focus on the pre-manufacturing nature of the stent component, the fact that the subsequent "covering" limitation does not also use the word "selecting" indicates that the patentee was not focused there on pre-manufacturing aspects of the covering. (Tr. at 78-79, 81-82) Finally, Gore argues that the claim structure confirms that the relevant thickness is post-affixation, in that the "wherein" clause at the end of claim 12 refers to the final stent graft product, and the thickness limitation in claim 13 is likewise recited in a "wherein" clause. (*Id.* at 78-80; Gore's Motions Hearing Presentation at Section 1, Slides 17-22)

The Court does not find Gore's arguments persuasive. Claim 12 refers only once to a "covering" and in that sole reference, the "covering" is an item that clearly exists and is utilized at a pre-affixation stage (i.e., "affixing a tubular covering"). This language would not make sense if "covering" could only refer to a covering that was already secured to the stent—one cannot be "affixing" a covering that is already affixed. (*See* Tr. at 97-98)[23] And although claim 13 uses the word "wherein," the next words it uses are "*said* covering"—words that have to be referring only to the type of "covering" that is previously referenced in claim 12. As noted above, the only type of covering referred to there is one existing at the pre-affixation stage.[24]

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[23] Gore also suggests that because the method includes reference to time periods after affixation (e.g., the step in which the stent is collapsed back down), this is further evidence that the relevant thickness is the post-affixation thickness. (D.I. 301 at 7) But the relevant inquiry as to claim 12 is focused on the step involving "affixing a . . . covering," not on any step that follows.

[24] The Court addresses an additional Gore argument to the contrary—that "[c]laim construction must be consistent across patent families"—below in looking to the '892 Patent. (Gore's Motions Hearing Presentation at Section 1, Slides 23-26)

The specification does not contradict Bard's reading of the limitation. Importantly, the specification uses "covering" to refer to both the ePTFE component that gets affixed to the stent, and to the component that has already been affixed to the stent. (*See, e.g.*, '285 Patent, col. 2:58-60 ("The tubular *covering* of porous expanded PTFE film *may be affixed* to either the exterior surface or the luminal surface of the stent." (emphasis added)); *id.*, col. 4:51-54 ("A Nitinol wire stent . . . was provided with both a luminal covering and an exterior covering of expanded PTFE film.")) And the specification discloses thickness measurements of the covering both prior to use in the affixing step, and after the covering has been affixed to the stent. For instance, Example 2, which describes a device with a luminal covering only, provides measurements of the covering material both pre-affixation and post-affixation. (*Id.*, col. 6:43-44, 62-63)

As for the extrinsic evidence, Gore suggests that Bard's experts conceded that for both patents, the covering thickness limitation must be satisfied after affixation. (D.I. 301 at 8-9) Yet this argument reads too much into the experts' statements. As for Mr. Calcote, Gore claims that his expert report confirms that post-affixation thickness is what is relevant—in light of Mr. Calcote's statement that "'to one of skill in the art, the appropriate time to measure the thickness of both ePTFE layers on the stent graft is after the stent is encapsulated[.]'" (*Id.* at 8 (quoting Calcote Decl., ex. A at ¶ 105)) While this quotation is certainly relevant to the '892 Patent, it clearly was not intended to refer to claim 15 of the '285 Patent, which only claims a single-layer ePTFE covering. (D.I. 340 at 6) With regard to Dr. Buller, his expert report clearly states that the plain language of claim 15 "requires measuring the thickness of the ePTFE covering that is used to perform the affixing step—i.e., the pre-fabrication material." (Buller Decl., ex. B at ¶ 154) The portion of Dr. Buller's deposition testimony that Gore cites in support of a contrary

conclusion, (D.I. 301 at 9 (citing D.I. 307, ex. 2 at 507-08)), does not clearly demonstrate an about-face.

For all of these reasons, the Court finds that the answer to the "when" question for the '285 Patent is "pre-affixation." That is, that the relevant portion of claims 12 and 13 (incorporated into asserted claim 15) require affixing a tubular covering that is less than 0.10 mm thick prior to the covering's affixation to the stent. *Cf. W.L. Gore & Assoc., Inc. v. Medtronic, Inc.*, 874 F. Supp. 2d 526, 561 (E.D. Va. 2012) (concluding, as to a related patent, that in assessing a "method of making an intraluminal graft, the Court must consider the accused manufacturing process itself and not the final fully formed product alone").

(2) '892 Patent

In contrast to the asserted method claim of the '285 Patent, asserted claim 32 of the '892 Patent is an apparatus claim that covers:

> 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)) There is no serious dispute that claim 32 refers to the thickness of the coverings after they have been affixed to the stent. (*See* Tr. at 34 (Bard's

counsel acknowledging that "[t]he argument is much better for claim 32 as an apparatus claim that it's referring to something later and not pre-manufacture"); *id.* at 37 (explaining that the '892 Patent "does describe . . . after affixing thickness[]"))[25]

Gore had argued that, assuming this was so, then the thickness limitation found in *both* asserted patents must refer exclusively to post-affixation thickness. It pointed in support to Federal Circuit case law indicating that when patents "'derive from the same parent application and share many common terms, [the court] must interpret the claims consistently across all asserted patents.'" (Gore's Motions Hearing Presentation at Section 1, Slide 26 (quoting *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005)); *see also Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) (explaining that the Court "presume[s], unless otherwise compelled, that the same claim term in . . . related patents carries the same construed meaning"). And it then contended that "nothing about claim 15 indicates that the thickness limitation has a different meaning than in the '892 [P]atent." (D.I. 301 at 7; *see also* Tr. at 84-85)

But this is not correct. For one thing, the thickness limitation in the '285 Patent references a different "kind" of covering from that in the '892 Patent. In the relevant claims of the '285 Patent, as noted above, the thickness limitation consistently refers to a single tubular covering that then gets affixed to the luminal surface of the stent. ('285 Patent, cols. 9:11-22,

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[25] Bard did make an attempt to argue that "[c]laim 32 [of the '892 Patent] likewise should be properly understood to refer to thickness of the pre-manufacture covering," but this position was tied to a concern that the claim would otherwise be indefinite. (D.I. 245 at 4 & n.2; *see also* D.I. 236 at 13; D.I. 340 at 6 (contending that "the pre-manufacture thickness is the only time that provides any reasonable certainty as to the scope of the claims because the covering then has a relatively uniform thickness"); Tr. at 34-35) As explained above, the Court finds that "less than about 0.10 mm thick" is not indefinite.

9:27-10:17) Meanwhile, in the '892 Patent, the thickness limitation refers to two pieces of material—to either the "combined" thickness of two coverings that have been affixed to the stent surface, ('892 Patent, cols. 8:45-64, 9:42-55, 11:25-39, 12:26-36), or to the thickness of a tubular covering that has been folded over the stent edge and affixed to both surfaces of the stent, (*id.*, cols. 9:60-10:7).[26] Therefore, because the thickness limitation in the two patents refers to different "types" of coverings, and because the specification discusses measurements of the covering(s) at two different stages of the manufacturing process, the presumption that the same claim term in the same related patents carries the same meaning falls away. *Cf. Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1031 (Fed. Cir. 2002) (noting that where the same claim term was used in two different contexts in two different claims, the term "should not necessarily be interpreted to have the same meaning in both [claims]"). Therefore, the Court is not compelled to answer the "when" question in the same way for both patents.

Turning back to the '892 Patent itself, a dispute remains about exactly "when," post-affixation, the "combined thickness" of the "coverings" described in claim 32 must meet the claim limitation. Bard argues that the limitation refers to covering thickness after the coverings are affixed to the stent, but before "collapsing the device into and deploying it from a delivery system." (D.I. 245 at 9-10; *see also* Tr. at 37-38 (Bard's counsel explaining that the patent never "describe[s] the thickness measurement for a product that's compressed into a delivery system. . .

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[26] Another difference between the limitations appearing in the asserted claims is worth noting. In the '892 Patent, claim 32 specifies that the coverings must satisfy the thickness requirement "exclusive of the stent." ('892 Patent, col. 11:37-39) In contrast, claim 13 of the '285 Patent does not specify that the measurement is "exclusive of the stent"—a difference that further suggests that the thickness measurement in claim 13 refers to pre-affixation thickness. ('285 Patent, cols. 9-10)

. [and] no thickness measurements at all with respect to in vivo, what it's going to be like inside the body. That's not what the patent is concerned about.")) For its part, Gore argues that the thickness of the coverings may be measured at any point post-affixation. (Tr. at 93, 191-92 (Gore's counsel asserting that "there's nothing in the patent to suggest that there's a special moment post-affixation that you measure [the thickness limitation] by"))

Here again, the Court agrees with Bard. The specification discloses thickness measurements for the coverings after they have been affixed to the stent surface. ('892 Patent, cols. 5:65-6:8, 6:58-67, 7:23-51) However, *all* of these measurements are taken prior to the stent being subsequently collapsed. (*Id.*, cols. 5:65-6:8, 6:58-67, 7:23-51) They are also all taken prior to the stent being expanded with a balloon. (*Id.*, col. 7:23-25, 7:47-51) Bard, summarizing what the patent does and does not disclose, aptly notes that the patent references "[n]o thickness measurement disclosed for product compressed into delivery system[;] [n]o thickness measurement after heating and removal from delivery system[;] [n]o thickness measurement after dilation with a balloon[; and] [n]o thickness measurement under 'in vivo' conditions." (Bard's Summary Judgment and Daubert Hearing Presentation at Section 1, Slide 19) This is significant. By uniformly referring to thickness at a specific stage in the product's life cycle (and not at others), the specification indicates that there is a particular period after the coverings are "affixed" that the claims are referring to when they refer to covering thickness: post-affixation, but before the stent grafts have been collapsed onto delivery systems. Thus, the patent does not support the notion that the thickness of the claimed coverings can satisfy the "less than about 0.10 mm thick" limitation at any time post-affixation.

With the "when" issue answered and the scope of the thickness limitation properly

defined, the Court now turns to whether summary judgment of non-infringement is proper.

b. '285 Patent

Bard argues that it is entitled to summary judgment of non-infringement with respect to the '285 Patent because "[t]he only evidence is that Bard manufactures its Flair and Fluency Plus products with ePTFE that is greater than 0.10 mm thick." (D.I. 245 at 3) Specifically, Bard explains that it regularly measures thickness of the ePTFE used to manufacture the accused products, and that thousands of quality control documents recording these measurements show that those thicknesses are greater than 0.10 mm. (*Id.* at 5, 11 (citing Buller Decl., ex. B at ex. 2A ([redacted]); ex. 2C ([redacted])) Additionally, Bard's expert Mr. Calcote used a snap gauge to measure the thickness of the inner ePTFE tubes used in the encapsulation process for the accused products. (*Id.* at 5, 11 (citing Calcote Decl., ex. A at ¶¶ 91-100 & Appx. H (average Flair thickness is between 0.185 mm and 0.250 mm and average Fluency Plus thickness is between 0.117 mm and 0.154 mm)) According to Bard, "Gore does not challenge [this] evidence, and presents no evidence of its own on the thickness of the ePTFE that Bard uses to manufacture the accused products to satisfy its burden of proof." (*Id.* at 3)

To the extent that Gore does challenge this assertion, it points to very little. Its main argument in response is to assert summary judgment is improper "because none of Bard's evidence—including its own pre-manufacturing specifications and Calcote's component part testing []—relates to the thickness of Bard's ePTFE components *at the point of affixing*." (D.I. 301 at 19-20 (emphasis added)) During manufacture of the accused products, before the encapsulated stent-graft device is heated up to cause the coverings to adhere together through the

stent wall openings, the device is wrapped with Teflon tape, resulting in compression of the coverings. (D.I. 307, ex. 64 at BARD-11-515-00008884-88; Buller Decl., ex. B at ¶ 47 (noting that the Teflon tape is used to "wrap and compress the ePTFE material"); *see also* D.I. 301 at 20; Tr. at 152-53) Bard's measurements (i.e., the measurements relied upon by Mr. Calcote and Dr. Buller) are of the starting components prior to the application of this compression procedure. (D.I. 301 at 20 (citing D.I. 307, ex. 2 at 490-91); *see also* Tr. at 87 (Gore's counsel noting that "there was no measurement by [Mr.] Calcote at the point up to the last moment before affixation")) Indeed, Dr. Buller testified that he was not aware of any measurements taken post-compression but pre-affixation, and that he was not even sure how such measurements *could* be taken:

> [B]ecause once it's wrapped up, [the covering] is inside. It's sort of mummified . . . . It's there in the wrapping, and I've never seen any measurements or attempted measurements in that state, because if you unwrapped it, it could spring back, and therefore, you would have to think very carefully about how you could measure it.

(D.I. 307, ex. 2 at 491) Since the compression tape is removed after the lamination, according to Gore, "if anything, Bard's coverings would be thinner at the point of affixing than in the commercial devices." (D.I. 301 at 20 (citing D.I. 307, ex. 2 at 491)) In other words, Gore argues that summary judgment is not warranted with respect to the '285 Patent because (1) it has produced post-affixation evidence of covering thickness indicating that the coverings are less than 0.10 mm thick at that stage, and since (2) Bard's compression process only has the effect of reducing covering thickness, then (3) Gore's post-affixation evidence indicates that the coverings must be less than 0.10 mm just prior to affixation. (*Id.* at 19-20)

The Court concludes that Gore has failed to meet its burden with regard to the thickness

limitation in the '285 Patent. As noted above, Bard has put forward significant evidence of pre-affixation graft material thickness indicating non-infringement of the '285 Patent.[27] And though Gore argues that the compression step "drastically reduc[es] [the coverings'] thickness," (D.I. 301 at 20), the evidence to which it cites describes the wrapping step, but does not include any discussion of a resulting reduction in covering *thickness*, drastic or otherwise, (*id.* (citing D.I. 307, ex. 64 at BARD-11-515-00008884; Buller Decl., ex. B at ¶ 47)). The lack of factual support for Gore's position also seemed apparent during oral argument, where Gore could not even clearly assert that this compression step results in a thinning of the covering. (Tr. at 86-87 (Gore's counsel describing the Bard process and asserting that "the [compressive] wrap itself would be something that in our view would *quite likely make it more narrow* than it is in the final product post affixation") (emphasis added)) Nor has Gore pointed to any expert testimony in support of its theory in this regard; what it has put forward amounts simply to attorney argument.[28]

In the end, after Bard asserted that summary judgment was warranted as to the '285 Patent, it was Gore's burden to point to evidence of record that would identify genuine issues that preclude summary judgment. However, in the absence of a clear articulation in the record (from

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[27] To the extent Gore suggests that Bard's evidence of pre-affixation covering thickness is irrelevant because the covering must satisfy the thickness limitation only right "*at the point of affixing*" (i.e., post-compression but pre-affixation), (*see* D.I. 301 at 19-20 (emphasis added)), Gore has not pointed to any evidence demonstrating that this specific pre-affixation time period is the only one that matters for infringement purposes.

[28] It is also worth noting that as to Bard's measurements, which were taken both pre- and post-affixation, there were noticeable differences in those measurements, with pre-affixation results almost uniformly thicker than post-affixation results. (*See* Calcote Decl., ex. A at Apps. F & H)

an expert witness or otherwise) as to how Gore's post-affixation evidence sheds light on or relates to the accused coverings' pre-affixation thickness, Gore's argument that its post-affixation evidence is "powerful evidence" of pre-affixation thickness amounts to mere speculation. Accordingly, and in light of the significant pre-affixation evidence that Bard put forward demonstrating non-infringement, the Court recommends that Bard's motion for summary judgment of non-infringement with respect to the '285 Patent be granted.

c. '892 Patent

Bard next argues that Gore has no competent admissible evidence relating to post-affixation thickness prior to the devices being collapsed and deployed, and therefore summary judgment of non-infringement as to the thickness limitation is proper. (D.I. 245 at 11-13; D.I. 340 at 8-10) For the reasons discussed below, the Court disagrees.

(1) Bard's Composite Testing

In responding to Bard's motion, Gore first highlights test data regarding Bard's "composite" test devices. (D.I. 301 at 11-13) Gore's expert Dr. Criado analyzed the evidence with respect to these composites, finding that it further confirmed his opinion that the accused devices satisfy the thickness limitation. (Criado Decl., ex. A at 113-115, 153-55) Dr. Gorman also referenced the composite measurements in opining that the accused products meet the thickness limitation. (Gorman Decl., ex. A at 25)

Bard created these composites during the mid-2000s, and, according to Bard's Rule 30(b)(6) witness, Scott Randall, the composites each consisted of "two layers of the PTFE that we've used to make [the accused products] . . . processed the same way as we would the device but minus the stent." (D.I. 307, ex. 4 at 102; *see also id.* at 296) Bard measured the wall

thickness of the composites pursuant to its standard manufacturing procedures, and was considering the thickness as a manufacturing control parameter for its commercial products. (*Id.* at 102-03; *id.*, ex. 19 at 160-61; *id.*, ex. 70 at BARD-11-515-00071973) A Bard spreadsheet "summariz[ing] the available data . . . for composite and stent graft thickness variation" includes 6,821 composite wall thickness measurements for Fluency and Fluency Plus, all of which are less than 0.10 mm thick. (*Id.*, ex. 71 at BARD-11-515-00069744, BARD11-515-00069746-877, BARD-11-515-00070021) With respect to Flair, former Bard employee Michelle Bushmire reported that "[t]he composite thicknesses for 6 and 9 mm range between [redacted]." (*Id.*, ex. 49 at BARD-11-515-00070178) In response to a request from another Bard employee for the specification for the covering thicknesses of Flair, Ms. Bushmire explained Bard did not have such thickness specifications. (*Id.*, ex. 73 at BARD-11-515-00554752, BARD-11-515-00554758) Instead, she forwarded composite thickness data, and she described these measurements as "the closest thing we have to the different nominal thicknesses and variation to be expected in covering thickness on Flair and Flair Optimized." (*Id.* at BARD-11-515-00554752; Criado Decl., ex. A at 153)

In Bard's view, because these composites are not the accused products, "evidence of their wall thickness is not imputable to the accused devices." (D.I. 245 at 12; *see also* D.I. 340 at 8) During oral argument, Bard repeatedly asserted that the evidence relating to the composites could not create a genuine issue of material fact because the composites are "not intended to be representative of the product." (Tr. at 45-49) Bard points out that Ms. Bushmire testified that the composites were used for the limited purpose of testing bond strength between the ePTFE coverings, and that the lack of a stent in the composites "'causes some differences in

measurements between the composite and the stent graft[.]'" (D.I. 245 at 12 (quoting D.I. 246, ex. 7 at 181-83))

"A patentee may prove direct infringement . . . by either direct or circumstantial evidence." *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006); *see also Masimo Corp. v. Philips Elec. N. Am. Corp.*, — F. Supp. 3d — , Civil Action No. 09-80-LPS-MPT, Civil Action No. 11-742-LPS-MPT, 2014 WL 6468872, at *11 (D. Del. Mar. 31, 2014). Bard is wrong that the composite testing evidence is "wholly irrelevant" to ePTFE thickness of the accused products. (D.I. 245 at 12) If years before this litigation commenced, Bard itself was using this composite data as the "closest thing" it had to "the different nominal thicknesses and variation to be expected in covering thickness" as to certain accused products, (D.I. 307, ex. 73 at 11-515-00554752), it would not be out of line for Gore to ask a jury to consider this data in determining whether the accused products infringe. Any differences between this data and Bard's proffered evidence of non-infringement can be a subject of Bard's cross-examination of Gore's expert. But this evidence may be at least be used, along with other evidence, to raise a genuine issue of material fact.

Bard relies on two inapposite cases to support its contrary position that this evidence is irrelevant. (D.I. 245 at 13) In *Alcon Research Ltd. v. Barr Labs, Inc.*, 745 F.3d 1180 (Fed. Cir. 2014), the Federal Circuit affirmed a district court's finding that a plaintiff's study results had no bearing on whether the defendant's accused product infringed, because "[t]he formulations tested in [the plaintiff's] stability study were meaningfully different from [the accused product.]" *Alcon Research Ltd.*, 745 F.3d at 1187. In that case, even the plaintiff "itself admitted that [these differences could] have a substantial impact on [the relevant properties of the accused product;]"

this admission prompted the *Alcon* Court to find that the study "provided no basis from which to draw any reliable inferences regarding" whether the accused product met a limitation. *Id.* Here, in contrast, the measurement data at issue does not come from tests run by Gore; instead it is Bard-generated data relating to the accused products at issue. (D.I. 301 at 13) And on this record, the Court cannot conclude that Bard's composite testing data is so meaningfully different from the accused products that it cannot even be considered as circumstantial evidence of infringement. (*See* Tr. at 91 (Gore's counsel referring to Ms. Bushmire's e-mail as evidence that Bard was "very much using [the composite testing] to approximate as closely as possible the nominal thickness and variation on their coverings"))

In *L & W, Inc. v. Shertech, Inc.*, 471 F.3d 1311, 1316 (Fed. Cir. 2006), the patentee's infringement expert tested one of the 16 accused products and asserted that this product was "'typical'" of all products. Yet the expert provided no indiction of which features of the tested product he regarded as "'typical[.]'" *Id.* Moreover, his expert report gave no hint as to what kind of examination he conducted on the remaining accused products, and its wording even suggested that the expert had not personally examined all of the other accused products. *Id.* Faced with this deficient record, the Federal Circuit explained that the patentee "cannot simply 'assume' that all of [the accused infringer's] products are like the one [its expert] tested." *Id.* at 1318. The evidence here does not suffer from the same deficiencies. Here there is evidence indicating that the composites are comparable to the coverings of the accused products (and evidence that Bard itself was suggesting the same in the mid-2000s).

(2) Bard's Training Manuals

As further evidence that Bard's coverings meet the thickness limitation, Gore points to a

document in a 2007 Bard training manual, in which Bard describes the covering wall thickness "'[i]n [the] open diamond area'" of Fluency Plus as "'0.07 mm[.]'" (D.I. 301 at 9-10; *see also* Tr. at 90; D.I. 307, ex. 16 at BARD-11-515-00464689, BARD-11-515-00464698; *id.*, ex. 46 at 66) Dr. Criado referenced this document in reaching his opinion that Fluency Plus satisfies the thickness limitation. (Criado Decl., ex. A at 109-10)

During oral argument, Bard's counsel acknowledged that this portion of the 2007 training manual was "probably [Bard's] toughest one [to argue against], because that's actually pointing at the right place [to measure for wall thickness, in Bard's view]." (Tr. at 55) Nevertheless, Bard asserts that this document "by itself isn't enough, doesn't cut it." (*Id.* at 56) But this single document is not the *only* piece of evidence to which Gore can reasonably point in support of infringement of the patent. (*See, e.g.*, D.I. 301 at 9-18) And, in conjunction with the other evidence discussed herein, it certainly helps to create a genuine issue of material fact as to whether the relevant covering thickness was less than 0.10 mm.[29]

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[29] The three cases that Bard cites, (D.I. 340 at 9), to argue against the import of this document are not persuasive, for various reasons. In *Aqua-Aerobic Sys., Inc. v. Aerators Inc.*, 211 F.3d 1241 (Fed. Cir. 2000), the Federal Circuit affirmed summary judgment of non-infringement where the plaintiff relied "solely on [the accused infringer's] advertising statement[.]" *Aqua-Aerobic Sys.*, 211 F.3d at 1245. Here, Gore relies on additional evidence. Moreover, this 2007 document is not directed merely to advertisement of Bard's products, but was instead part of an internal training manual that Bard's own employees were to use. (D.I. 307, ex. 16 at BARD-11-515-00464689, BARD-11-515-00464698)

In *Scantibodies Lab., Inc. v. Immutopics, Inc.*, 374 F. App'x 968, 970-71 (Fed. Cir. 2010), the Federal Circuit held that the district court correctly construed a term; in doing so, the Federal Circuit gave the inventor's "self-serving" testimony as to a contrary meaning little weight. There, the inventor had pointed to, *inter alia*, statements in "marketing materials" in support of the patentee's rejected claim construction. *Scantibodies Lab.*, 374 F. App'x at 970-71. Yet it is not clear that the type of "marketing materials" at issue there amounted to the same type of document as the training manual at issue here. And the cited portion of the opinion in *Scantibodies* related to a decision regarding claim construction, involving an analysis different

(3) Dr. Criado's Subtraction Analysis

To "[c]onfirm[]" that the thickness of the coverings exclusive of the stent satisfies the thickness limitation, Dr. Criado compared the (1) thickness of the accused devices as a whole to (2) the thickness of the stent alone. (Criado Decl., ex. A at 111-13, 150-51; D.I. 301 at 13-14) Dr. Criado explained that "[l]ogically, one may subtract the thickness of the stent from the total wall thickness of the stent graft (including the stent strut) to arrive at the thickness of the coverings exclusive [of] the stent." (Criado Decl., ex. A at 111) To that end, he subtracted the total wall thickness of the Fluency Plus stent ([redacted]) from the wall thickness of the stent graft as a whole ([redacted]) to arrive at a covering thickness of [redacted] (*Id.* at 111-13) Bard's Rule 30(b)(6) witness, Mr. Randall, testified that such analysis would provide the thickness of the exterior covering and the luminal covering of ePTFE on the Fluency Plus product at that location. (D.I. 307, ex. 4 at 317) For the Flair device, Dr. Criado subtracted the wall thickness of the Flair stent ([redacted]) from the maximum measured Flair stent graft thickness ([redacted]) to yield a covering thickness of [redacted] (Criado Decl., ex. A at 150-52)

Bard argues that this subtraction analysis is irrelevant because Claim 32 of the '892 Patent

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from that used in deciding whether summary judgment should be granted.

Lastly, in *CCC Grp., Inc. v. Martin Eng'g. Co.*, Civil Action No. 05-cv-00086-RPM-MJW, 2008 WL 4277764 (D. Colo. Sept. 17, 2008), the patentee, in attempting to prove infringement, noted that the defendant's product advertising materials remained the same from the time period in which defendant had a license to the patent-in-suit, through to a time period in which it did not. *CCC Grp., Inc.*, 2008 WL 4277764, at *9. The *CCC Grp., Inc.* Court found that "[c]omparisons of generic drawings from [defendant's] marketing materials for the periods during and after the license period do not satisfy the plaintiff's burden." *Id.* Here, the Court cannot similarly conclude that the import of the instant training document, which Bard itself describes as the toughest piece of evidence it must confront here, is as weak as the "generic" evidence referred to in *CCC Grp., Inc.* Nor is it the only piece of evidence on which Gore relies as to infringement of this patent.

requires the combined covering thickness to be "less than about 0.10 mm thick" in the recited "openings" through the wall of the stent, while Dr. Criado's analysis depends on measurements taken over the area of a stent-graft where the covering overlaps the stent strut. (D.I. 245 at 13) But Dr. Criado is simply asserting that "[i]t is my opinion that the resulting [wall thickness figures] *relates to* the [relevant] combined thickness of the coverings exclusive of the stent[.]" (Criado Decl., ex. A at 113, 152 (emphasis added)) The Court cannot say that this evidence is wholly irrelevant to the disputed issue at hand.

(4) Specification Statements

As further evidence, Gore points to Bard's "[s]pecification [s]tatements" which purportedly demonstrate that "Bard targeted ePTFE coverings less than about 0.10 mm thick when developing the accused products." (D.I. 301 at 15) These Bard documents do not purport to give specific thickness measurements. Instead, they reflect Bard's intent that the coverings of its to-be-developed accused devices "should be very thin (i.e. 0.1 mm)" or "[a]s thin as possible" or "ultra thin." (D.I. 301 at 15 (citing D.I. 307, ex. 76; *id.*, ex. 66 at BARD-11-515-00001304; *id.*, ex. 67 at BARD-11-515-00001463; *id.*, ex. 4 at 262-63))

Bard's complaint with regard to these statements is that "[i]nfringement is shown by comparison of the claims to the accused products" and therefore not by documents that "discuss[] in general the purported benefits of 'thin' coverings." (D.I. 340 at 9) But again, Gore is not claiming that these documents alone create a genuine issue of material fact. It argues only that Bard statements about its *plans* for the covering thickness of the ultimate accused products amounts to circumstantial evidence shedding light on what the covering thickness of those actual products ended up to be. (D.I. 301 at 15; Tr. at 89) Standing alone, such evidence could not

support denial of summary judgment. But the Court agrees that it can amount to relevant information a fact finder may consider.

(5) Gore's Litigation Testing

In addition to the documents above, Dr. Criado relies on Dr. Gorman's testing of the accused products to support his opinion that Bard's coverings satisfy the thickness limitation. (Criado Decl., ex. C at 17) For the reasons discussed in Section III.C, Dr. Gorman's test results further help to create a genuine issue of material fact.

(6) Conclusion

As set out above, Gore puts forward multi-faceted evidence to oppose summary judgment regarding the asserted claims of the '892 Patent. This includes: (1) evidence of covering thickness below 0.10 mm as to coverings that were *actually affixed* to Bard's accused products; (2) evidence of covering thickness below 0.10 mm as to coverings *meant to approximate those affixed* to the accused products; and (3) evidence suggesting that Bard's *intent was to have coverings affixed* to the accused products that were at or about 0.10 mm thick. Admittedly, not all of this evidence relates to measurements of the accused products that were actually taken post-affixation, but before the stent grafts have been collapsed onto delivery systems (i.e., the point in time to which the asserted claims' thickness limitation relates). But Bard has presented no case law suggesting that Gore's evidence could not be *circumstantially relevant* to the point in time called out in the claim limitation. Moreover, Gore notes that Bard's own evidence indicates that covering thickness does not change significantly from the point when coverings are affixed to the stent graft to the point after the graft is compressed down into the final product. (D.I. 301 at 17 & n.6; Criado Decl., ex. C at 52 & n.182; Calcote Decl., ex. A at App. H) And Gore's

experts have sufficiently explained the relevance of Gore's post-affixation evidence to the nature of the infringement question at issue regarding the '892 Patent. (Criado Decl., ex. C at 52; D.I. 307, ex. 14 at 289-90)

Taken together, Gore's evidence may or may not be enough to demonstrate liability. But it is certainly of a quantum sufficient to withstand Bard's motion. Therefore, the Court recommends that Bard's motion for summary judgment of non-infringement as to the '892 Patent be denied.

C. Bard's *Daubert* Motion

The last motion relevant to this Report and Recommendation is Bard's *Daubert* motion seeking to exclude some of Dr. Gorman's testimony. Dr. Gorman is a cardiovascular surgeon with experience in cardiovascular device design and engineering; Gore hired him to serve as an expert in this action and to offer opinions regarding, *inter alia*, infringement. (Gorman Decl., ex. A at ¶¶ 1, 3, 15 (hereinafter, "Gorman Report")) On February 27, 2014, Dr. Gorman issued an expert report in which he purported to measure the thickness of the ePTFE covering material used in the accused products. (Gorman Report) To arrive at the measurements, Dr. Gorman utilized a micrometer to perform two tests (the "Clearance Test" and the "Free-Movement Test") on samples of the ePTFE coverings from the accused products. (*Id.* at 12-19) Based on the test results, Dr. Gorman concluded that the accused products satisfy the thickness requirements of the asserted claims. (*Id.* at 21-26) After further describing Dr. Gorman's thickness testing methods and results, the Court will address Bard's arguments.

1. Dr. Gorman's Thickness Testing Methods

In his testing of the accused products, Dr. Gorman used nine commercially-packaged

samples of the devices, produced by Bard, that had been collapsed and mounted onto delivery systems. (Gorman Report at 9, 21; D.I. 255, ex. 1 at 282) After removing the devices from the packaging, Dr. Gorman submerged the products into a water bath set to 37°C (approximately body temperature) for several minutes, in order to simulate *in vivo* conditions. (Gorman Report at 10; *see also* D.I. 255, ex. 1 at 78-79) Next, Dr. Gorman deployed the devices from their delivery systems and dilated them using a 10 mm diameter balloon. He then measured the diameter of each device to ensure that they had not been expanded beyond their stated nominal diameters. (Gorman Report at 11-12)

Dr. Gorman subsequently performed the Clearance Test and Free-Movement Test on the devices. (*Id.* at 12-17) Both tests utilized a micrometer, which is a tool that measures the distance between two metal structures called the anvil and spindle. (*Id.* at 13-14) A micrometer can be used to take a thickness measurement by manually adjusting the spindle until it comes into contact with the material. (D.I. 119, ex. 5 at ¶¶ 20, 21, 24) Alternatively, the micrometer can be used as a "Go/No-Go gauge," where the anvil and spindle are fixed at a set distance and material is then passed through the gap. (Gorman Report at 13-14) For his tests, Dr. Gorman set up the micrometer as a Go/No-Go gauge with the anvil and spindle adjusted to create a gap of 0.097 mm between the two. (*Id.*) Two of Gore's attorneys observed Dr. Gorman's testing and took photographs during the process, at least some of which are included in Dr. Gorman's expert report. (*Id.* at 8; D.I. 255, ex. 1 at 75-76)

a. Clearance Test

To conduct the Clearance Test, Dr. Gorman excised three portions of the ePTFE covering from each device, cutting away diamond-shaped samples of the combined luminal and exterior

coverings from openings in the stent wall. (Gorman Report at 12; *see also* D.I. 255, ex. 1 at 99-100) He excised one "sample near one end of the stent graft [], a sample near the opposite end of the stent graft [], and a sample from a middle portion of the stent graft." (Gorman Report at 12) These samples were approximately 3 mm in diameter. (D.I. 255, ex. 1 at 100) Holding the samples with forceps, Dr. Gorman then attempted to pass the material through the micrometer's 0.097 mm gap. (Gorman Report at 14) Dr. Gorman relied on his sense of sight (aided by 2X and 3X magnifying surgical loupes) and his tactile sensitivity to determine whether each sample passed through the gap. (*Id.* at 9, 13-14, 18; *see also id.*, ex. C at 6) For each sample that he observed pass through cleanly, he recorded a "Pass." (Gorman Report at 14, 22, 24) Dr. Gorman subsequently discarded the diamond-shaped samples that he had tested, but kept the nine devices from which the samples came. (D.I. 255, ex. 1 at 282-83)

b. Free-Movement Test

For the Free-Movement Test, Dr. Gorman cut each device along its length so that it was no longer tubular in shape. (Gorman Report at 15) He then inserted an edge portion consisting only of ePTFE covering material into the 0.097 mm gap of the micrometer. (*Id.*) Holding the sample with his hands and using magnifying surgical loupes, Dr. Gorman next observed whether the edge portion "could move freely" within the gap. (*Id.*) Then, he adjusted the micrometer's spindle to open the gap, and inserted a middle portion of these samples consisting only of ePTFE covering material between the spindle and anvil, and adjusted the gap back down to 0.097 mm. (*Id.*) Holding the sample with his hands and using magnifying surgical loupes, he "observed whether the middle portion could move freely within the 0.097 mm gap." (*Id.*) Finally, with the aid of his loupes, he "visually inspected the surfaces of the stent graft" for signs of contact

between the covering and the spindle. (*Id.* at 16) He recorded a "Pass" if he felt the sample was able to "freely move" within the gap. (*Id.*)

c. Test Results

Dr. Gorman reported a "Pass" for each of the 27 total samples from the nine devices that he tested. (*Id.* at 21-24) For the Clearance Test, he observed that every sample was able to pass through the gap "with clearance"—at all times he saw space on both sides of the sample. (*Id.* at 21, 23; D.I. 255, ex. 1 at 111-12) And for the Free-Movement Test, he likewise observed that every sample could "freely move" within the gap. (Gorman Report at 21, 23) He testified that he did his best to "look on both sides [of the sample], and there was no tactile sensation of touching." (D.I. 255, ex. 1 at 127-28) He also testified that for all the samples, his post-test visual inspection showed "no evidence that the testing had altered the covering." (*Id.* at 132) His testing methodologies did not include taking precise thickness measurements of the samples. (Gorman Decl., ex. C at 5)

2. Analysis

Bard challenges the reliability and fit of Dr. Gorman's test results. (D.I. 254, 338) The Court will address these arguments in turn.

a. Reliability

The Third Circuit has set out eight non-exclusive factors for courts to consider in assessing reliability:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the

> qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994). "The District Court has broad discretion in determining the admissibility of evidence, and 'considerable leeway' in determining the reliability of particular expert testimony under *Daubert*." *Simmons v. Ford Motor Co.*, 132 F. App'x 950, 952 (3d Cir. 2005) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152-53 (1999)).

On the one hand, a few of these factors redound in Bard's favor. Bard accurately asserts that Dr. Gorman's methodology is neither generally accepted nor peer reviewed. (D.I. 254 at 15-17) Dr. Gorman testified that he was not aware of whether anyone else has ever used a Go/No-Go gauge test to measure the thickness of ePTFE. (D.I. 255, ex. 1 at 115) The Court can also see how the "known or potential rate of error" factor is a concern here, given that Dr. Gorman is not aware that the test has previously ever been used for ePTFE measurement and due to the compressible nature of ePTFE material, (D.I. 254 at 14)—although Dr. Gorman did utilize certain checks against error, such as his use of magnification and his inspection of the samples post-testing to rule out alternative explanations for the "Pass" results, (Gorman Decl., ex. C at 6-11; D.I. 294 at 14).

On the other hand, certain other factors tend to support the reliability of Dr. Gorman's methodology. With respect to "the relationship of the technique" to reliable methods, Dr. Gorman's methodology utilized a micrometer to analyze the thickness of Bard's ePTFE coverings. Bard's own expert has opined that a micrometer is a "tool[] that would have been [a] known option [] to measure thickness in [the relevant period]" and a "suitable" option in that

regard. (D.I. 115, ex. 5 at ¶¶ 16, 20) Bard's main objection here appears to be Dr. Gorman's reliance on his sense of sight and his tactile senses in utilizing the Go/No-Go methodology. (D.I. 254 at 12-13) However, other testing methods that Mr. Calcote identified as "suitable" rely on these same senses, (*see, e.g.*, D.I. 115, ex. 5 at ¶ 21 (Mr. Calcote explaining that with the microscope, "thickness of the material can be measured visually at a magnification using a calibrated scale or special software"))—including the use of a micrometer to measure material, (*see id.* at ¶ 24 (such use requires one to manually adjust the spindle until it is in contact with the material)). While it is true that Dr. Gorman did not use the micrometer to obtain a precise measurement of the samples, Bard has not persuaded the Court that the difference between using a micrometer as a Go/No-Go gauge and using its anvil and spindle to generate a precise measurement are so different, that the latter method would be an acceptable way to analyze covering thickness, while the former method should be discarded entirely as unreliable. In the end, Dr. Gorman utilized his senses of sight and touch in a way that appears focused on assessing the key issue (whether the coverings are less than 0.10 mm thick), and used a tool identified by Mr. Calcote as suitable, all while attempting to avoid imparting pressure on the coverings (a concern identified by Mr. Calcote with respect to ePTFE testing). (*See* Gorman Report at 18 (citing D.I. 115, ex. 5 at ¶ 22); *see also* D.I. 294 at 13-14)

Additionally, the Court is not convinced that Dr. Gorman's methodology lacks a testable hypothesis. (D.I. 254 at 12) Dr. Gorman testified that someone with similar experience in surgical training or working with small structures could perform the same tests he could, (D.I.

307, ex. 14 at 130, 139-40, 147-48), and the Court is not persuaded otherwise.[30] While it is less than ideal that Dr. Gorman did not keep the diamond-shaped samples that he used to conduct the Clearance Test, thus preventing reproduction of the testing on those specific samples, (D.I. 255, ex. 1 at 282), one with similar qualifications to Dr. Gorman could perform that test on other accused products (or on other portions of the nine devices from which Dr. Gorman's discarded samples came). Bard's argument that Dr. Gorman's testing is not reproducible "because he did not describe in any level of detail where the excised portions of ePTFE material came from on the sample stent grafts" is unavailing, (D.I. 254 at 13), given that Dr. Gorman's report provides a detailed description of exactly what he did, as well as pictures to corroborate certain steps, (*see* Gorman Report; *see also* D.I. 294 at 17-18 (citations omitted)).

Finally, as for the "non-judicial uses to which the method has been put," while Bard is correct that Dr. Gorman has utilized his methodology to test ePTFE thickness solely for purposes of this litigation, (D.I. 254 at 15; *see also* D.I. 237, ex. 3 at 42-43), this method was identical to the tests Dr. Gorman uses in his independent work designing and developing medical devices, (Gorman Report at 9, 17; *id.*, ex. C at 5, 11; D.I. 307, ex. 14 at 71-73, 115-18, 284-85). Dr. Gorman testified that the main material he measures in his independent work, pericardium, is similar to ePTFE, as it too is compressible. (D.I. 307, ex. 14 at 141)[31]

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[30] Mr. Calcote testified in his deposition that he unsuccessfully attempted to duplicate Dr. Gorman's methodology, but provided no detail as to why it was unreproducible and provided no supplemental expert report describing that attempt. (D.I. 338, ex. 7 at 57)

[31] Bard further argues that Dr. Gorman is not qualified to identify a methodology to test the covering thicknesses of the accused products because he "is not an expert in ePTFE or in measuring ePTFE." (D.I. 254 at 4; *see also id.* at 15-16) It is true that Dr. Gorman testified that prior to his work in this case, he had not measured the thickness of ePTFE, and acknowledged that he was "not an expert on . . . ePTFE." (D.I. 255, ex. 1 at 63, 218) However, Dr. Gorman

Ultimately, the Court finds that Dr. Gorman's methodology passes muster under *Daubert*'s "reliability" prong. "[T]he standard for determining reliability 'is not that high.'" *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) (citation omitted); *see also Paoli*, 35 F.3d at 744 (noting that "[t]he evidentiary requirement of reliability is lower than the merits standard of correctness"). To some degree, the Court can understand how Bard is left to wonder "why [Gore] provided no actual measurements . . . and why [Gore] elected not to use [other] techniques that the industry (including Gore) has tested and accepted as a reliable means of measurement." (D.I. 338 at 8) Those concerns, however, seem more appropriately addressed via cross-examination. The Court cannot conclude that they require the exclusion of this portion of Dr. Gorman's testimony. *Cf. Schneider*, 320 F.3d at 405-06 (finding an expert's testimony to be reliable, even though his opinion had not obtained general acceptance or been subject to peer review, where other factors demonstrated the reliability of the expert's methodology); *Newport Corp. v. Lighthouse Photonics Inc.*, No. SACV12-0719-DOC (JPRx), 2014 WL 1370749, at *2-3 (C.D. Cal. Apr. 8, 2014) (rejecting the argument that an expert's deviation from standard methodologies rendered his testimony inadmissible as "[f]ailure to perfectly adhere to methodologies promulgated by a standard-setting organization is not, by itself, grounds for precluding expert testimony" and instead such "concerns speak to weight, not admissibility").

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explained that he did have experience with the material, testifying that he has handled ePTFE (1) in his design work, having experimented with it as a covering in prototypes for a family of stent graft devices, and (2) extensively in his work as a surgeon. (*Id.*, ex. 1 at 79; D.I. 307, ex. 14 at 59-62; *see also* D.I. 294 at 11) In light of Dr. Gorman's past experience with ePTFE and with testing the thickness of similar material in his design work, the Court cannot find that Dr. Gorman's qualifications should negatively impact the calculus as to reliability. Any criticisms regarding Dr. Gorman's lack of experience with ePTFE may be brought out via cross-examination.

b. Fit

Whether expert testimony meets the fit requirement depends on whether there is a connection between the scientific research or test results to be presented and the disputed factual issues in a particular case. *Paoli*, 35 F.3d at 742-43. The standard is also "not that high"; it is satisfied when there is a clear "fit" connecting the issue with the expert's opinion that will aid the jury in determining that issue. *Id.* at 745; *see also Meadows*, 306 F. App'x at 790.

The relevant disputed factual issue here is whether the coverings in Bard's accused devices satisfy the "less than about 0.10 mm thick" limitation. As discussed above, as to the remaining patent at issue, claim 32 of the '892 Patent requires the coverings to be less than about 0.10 mm thick after they have been affixed to the stent, but before they have undergone subsequent steps such as being collapsed onto a delivery system. Dr. Gorman did not test Bard's accused products at these times. Instead, Dr. Gorman tested the ePTFE coverings of Bard's commercial devices after heating them in water baths set to "approximately body temperature," deploying the products from their delivery systems, and dilating them with balloons. (Gorman Report at 10-12; *see also* D.I. 254 at 19)[32] Bard asserts that Dr. Gorman's test results are irrelevant and do not "fit" because he tested the products at the wrong stages. (D.I. 254 at 18-20; *see also* D.I. 338 at 8) In doing so, Bard raises some valid concerns.

For example, Bard is correct that Dr. Gorman tested the products at a different point in their life cycle than that called for by the patents. (D.I. 254 at 19) To that end, Dr. Gorman

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[32] According to Gore's counsel, Bard "never provided [Gore with] pre-manufacturing materials. . . . [the devices provided] were all after they had been . . . mounted on a stent. . . . that's what they gave us for testing[.]" (Tr. at 93; *see also* Gorman Decl., ex. C at 13 ("I note that I did not have access to any unmounted Flair or Fluency Plus devices for use in my testing."); D.I. 307, ex. 14 at 175)

testified that his goal was to measure the thickness as it would be inside the human body, and accordingly he deployed the devices consistent with Bard's instruction for use in order to "approximate in vivo." (D.I. 246, ex. 1 at 78-79; D.I. 340, ex. 9 at 166) And Dr. Gorman expressed disagreement with Mr. Calcote's testing of unmounted devices (i.e., products that had not yet been loaded into delivery systems), asserting that such devices are "*different* than the commercially available device [that Dr. Gorman tested]; and, therefore, they would . . . not be as consistent with the *in vivo* state of the device." (D.I. 307, ex. 14 at 174 (emphasis added))

In addition to pointing out this testimony of Dr. Gorman, Bard also argues that Dr. Gorman's further processing of the products "unquestionably may alter thickness" of the ePTFE material. (D.I. 254 at 19; *see also* D.I. 338 at 10) Here, Bard points to some evidence suggesting that balloon expansion can thin ePTFE graft material. (Criado Decl., ex. A at 26; D.I. 237, ex. 7 at 144 (Mr. Calcote opining that "the balloon that Dr. Gorman used potentially could change the measurement"))

Despite all of this, the Court ultimately concludes that Dr. Gorman's test results pass the "fit" test. The thrust of Bard's argument is that the devices tested by Dr. Gorman were subjected to "additional steps (collapse into the delivery system and expansion by balloon)" that impacted the coverings' thickness. (D.I. 338 at 9) Yet Bard does not convincingly show that these steps altered covering thickness in a material way.

First, as to the "collapsing" step, Bard's argument is contradicted by the fact that its own expert, Mr. Calcote, measured the covering thickness of several Flair devices at two different points in the product's life cycle: (1) before the devices had been collapsed down and placed onto catheters (i.e., unmounted devices); and (2) after the products had been collapsed down and

placed onto catheters (i.e., commercial devices). (Calcote Decl., ex. A at ¶ 119; *see also* Tr. at 95; D.I. 294 at 20)[33] Mr. Calcote explained that he took measurements on the commercial devices "*to further confirm* the measurements [he] performed on the unmounted samples." (Calcote Decl., ex. A at ¶ 119 (emphasis added)) To prepare these commercial devices for testing, Mr. Calcote testified that he had to deploy the devices, which entailed removing them from their packages and placing them into "heated water. . . . because they were designed to be deployed in . . . essentially simulated body conditions." (D.I. 307, ex. 3 at 143-44) He then used a snap gauge and a scanning electron microscope to measure diamond shaped samples that he excised from the devices, which measurements "*reinforce[d] [his] conclusion that Bard's Flair stent grafts have ePTFE between the stents that is greater than 0.10 mm thick.*" (Calcote Decl., ex. A at ¶¶ 120-32 (emphasis added)) It is difficult for the Court to accept Bard's argument that measurements on collapsed accused devices are irrelevant to determining whether the '892 Patent claims' thickness limitation has been met, when Bard's own expert performed these measurements in order to further support his own non-infringement conclusions.

Second, as for the "expansion by balloon" step, Bard has not pointed to persuasive evidence that this changes the thickness of the devices to such an extent that the results must be excluded as irrelevant. While it is true that there is evidence of record that the use of a balloon to expand a stent graft device could result in thinner coverings, (*see* Criado Decl., ex. A at 26; D.I. 237, ex. 7 at 144-45), Dr. Gorman explained that he performed this step with the intent to return the devices to their pre-collapsed configuration, (Gorman Decl., ex. C at 14), and that he

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[33] Mr. Calcote tested only one unmounted Fluency Plus device, and did not test any commercial Fluency Plus devices. (D.I. 307, ex. 3 at 142, 147)

subsequently took diameter measurements to ensure that "[n]one of the sample stent grafts [he] prepared had been expanded beyond their stated nominal diameters," (Gorman Report at 12). From this testimony, it seems that Dr. Gorman was trying to convert the devices back to the way they were at the relevant stage for measurement called for by the '892 Patent claims; whether he fully succeeded is a topic that can be tested at trial.

In the end, although Dr. Gorman tested the commercial devices that he had access to, rather than unmounted devices, the Court is not convinced that this makes enough of a difference as to the thickness analysis so as to render his testing wholly irrelevant to whether the '892 Patent is infringed. As the standard for fit is not a high one, and Rule 702 "embodies a liberal policy of admissibility," *Withrow v. Spears*, Civil Action No. 12-06-LPS-CJB, 2013 WL 4510305, at *5 (D. Del. Aug. 22, 2013) (internal quotation marks and citation omitted), the Court finds that Dr. Gorman's testing is sufficiently connected to the issue, and amounts to circumstantial evidence as to covering thickness. Bard's complaints about Dr. Gorman's additional processing of the devices go to the weight of his testimony rather than to its admissibility. *Cf. Quirin v. Lorillard Tobacco Co.*, Case No. 13 C 2633, 2014 WL 904072, at *3 (N.D. Ill. Mar. 7, 2014) (concluding that any differences between test conditions and the event at issue were not enough to render a study irrelevant and could be brought out on cross-examination).

IV. CONCLUSION

For the reasons set out above, the Court recommends that Bard's Motion for Summary Judgment of Invalidity be DENIED, Bard's Motion for Summary Judgment of Non-infringement be GRANTED as to the '285 Patent and DENIED with respect to the '892 Patent, and that Bard's *Daubert* Motion be DENIED.

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 Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987).

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.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **June 26, 2015** for review by the Court, along with a detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: June 17, 2015

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE