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 No. 5,735,892 (the "asserted patent" or the "patent-in-suit").[1] Presently before the Court is Gore's Motion for Summary Judgment of No Anticipation (the "Motion"). (D.I. 226) The Court recommends that the Motion be GRANTED-IN-PART.

I. BACKGROUND

A. The '892 Patent

The '892 patent, entitled "Intralurninal Stent Graft[,]" was issued on April 7, 1998. (D.I. 96, ex. A)[2] The patent is directed to thin-wall intralurninal graft devices. The patent explains

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Gore originally asserted infringement of U.S. Patent No. 8,221,487 (the "'487 patent"), but is no longer asserting that patent. (D.I. 191 at 1-2) And until recently, Gore was also asserting infringement of U.S. Patent No. 5,700,285 (the "'285 patent"). The '285 patent is no longer at issue following the District Court's adoption of the Court's recommendation to grant summary judgment of non-infringement of that patent. (D.I. 405 at 10-11; D.I. 423)

[2] The asserted patent is found in a number of places in the record, including as Exhibit A to D.I. 96. Further citation will simply be to the "'892 patent."

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 invention claims 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)

B. Procedural History

On June 10, 2011, Gore commenced this action. (D.1. 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 bear and resolve all pretrial matters, up to and including the resolution of case dispositive motions. (DJ. 20) After a hearing, (D.I. 130), the Court issued a Report and Recommendation on claim construction on August 8, 2014, (D.I. 221). Chief Judge Stark overruled objections to that Report and Recommendation on September 28, 2015. (D.1. 405)

Briefing on the instant Motion was completed on November 12, 2014, (D.I. 333), and the Court held oral argument on the Motion (and various other summary judgment and *Daubert* motions filed in the case) on January 30, 2015, (D.I. 360 (hereinafter, "Tr.")). A 10-day trial is set to begin on December 7, 2015. (D.1. 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 oflaw." 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.l0 (1986). Ifthe moving party meets this burden, the nonmovant must then "come forward with specific facts showing that there is a *genuine issuefor trial." Id.* at 587 (emphasis in original) (internal quotation marks and citation omitted). Ifthe nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *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;*see also Podobnik* v. *US. 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. Invalidity

A patent granted by the United States Patent and Trademark Office ("PTO") is presumed to be valid. 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245-46 (2011). The rationale underlying this presumption of validity is that "the PTO, in its expertise, has approved the claim[.]" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). The burden of proving invalidity rests with the patent challenger at all times, who must establish a patent's invalidity by clear and convincing evidence in order to prevail. *Microsoft Corp.*, 131 S. Ct. at 2245-49. Clear and convincing evidence places within the mind of the fact finder "an abiding conviction that the truth of [the] factual contentions are highly probable." *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

C. Anticipation

A claim is anticipated under 35 U.S.C. § 102(a) or (b) if:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . .

35 U.S.C. § 102.[3] A patent claim is anticipated if each and every limitation is found, either expressly or inherently, in a single prior art reference. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. *2009); Moba, B.V* v. *Diamond Automation, Inc.*, 325 F.3d 1306, 1321-22 (Fed. Cir. 2003). This test mirrors, to some extent, the test for infringement, and "it is axiomatic that that which would literally infringe iflater anticipates if earlier." *Bristol-Myers Squibb Co.* v. *Ben Venue Labs.. Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001). In order to anticipate, however, a reference must enable one of skill in the art to make and use the invention without undue experimentation, *In re Gleave*, 560 F.3d at 1334 (citing impax *labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008)), and must also "show all of the limitations of the claims arranged or combined in the same way as recited in the claims,"*Net Money!N, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed. Cir. 2008).

"While anticipation is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact." *Encyclopaedia Britannica, Inc. v. Alpine*

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[3] The Court will rely upon the version of 35 U.S.C. § 102 in effect prior to passage of the Leahy-Smith America Invents Act; this prior version of Section 102 applies to all patents with an effective filing date of on or before March 16, 2013, including the asserted patent. *See Solvay SA. v. Honeywell Int '/ Inc.*, 742 F.3d 998, 1000 n.1 (Fed. Cir. 2014).

Elecs. of Am., Inc., 609 F.3d 1345, 1349 (Fed. Cir. 2010) (citation omitted). "[A] moving party seeking to have a patent held not invalid at summary judgment must show that the non-moving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001).

III. DISCUSSION

Bard asserts anticipation of the '892 patent by various references that disclose the stent-graft work of three physicians: Dr. Peter Lee ("Lee"), Dr. Christian Vallbracht ("Vallbracht") and Dr. Julio Palmaz ("Palmaz"). (D.I. 234, ex. 6 at 211-12; DJ. 309 at 4) With this Motion, Gore moves for summary judgment of no anticipation, contending that each allegedly anticipatory reference is missing at least one claim limitation from the asserted claims. (DJ. 227, 333) The Court will consider the parties' arguments with respect to the references of Lee, Vallbracht and Palmaz in turn.[4]

A. Lee

Each asserted claim of the '892 patent (claims 32, 33 and 40) requires "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" (the "stent structure limitations"). ('892 patent, cols. 11:25-44, 12:19-21) Gore argues that the Lee references do not anticipate the asserted claims as a matter of law because they are missing the stent structure limitations. The

[4] While Gore suggests that some of Bard's references may not qualify as prior art, for purposes of its Motion, Gore assumed that all of the references were prior art. (DJ. 227 at 9 n.7) In the absence of any argument from Gore that such references do not qualify as prior art, the Court assumes herein that they do.

Court prefaces its discussion on the merits of the parties' arguments with brief background regarding (1) the stent structure limitations in the '892 patent; and (2) the Lee prior art.

1. The stent structure limitations in the '892 patent

During claim construction regarding the '892 patent, the Court construed some of the terms that are a part of the stent structure limitations of the asserted claims. Specifically, the Court construed the term "stent" to require "elongated members connected in such a way as to create a multiplicity of openings, and forming a substantially cylindrical structure." (D.I. 221 at 13) Further, the Court construed "wall" to mean a "substantially cylindrical plane defined by the structure of the stent." (*Id.* at 14) As for the "multiplicity of openings" requirement, the Court rejected Bard's proposal for a definition that would encompass a stent with unbounded openings in addition to bounded openings. (*Id.* at 14-17) Looking to the language of the claims, the Court explained, "[i]f the stent has a 'multiplicity of openings' *through* the wall, then this suggests that the 'openings' in question are bounded on all sides by the structure of the stent. . . . [t]hat is, [], that the openings are created by the spaces between the stent's physical connections." (*Id.* at 15 (emphasis in original)) Bard objected to the Report and Recommendation's "implicit interpretation excluding stents with unbounded openings[,]" (D.I. 222 at 3), but the District Court overruled the objection and adopted the Report and Recommendation in its entirety, (D.1. 405 at 4-5).

The '892 patent depicts longitudinally connected tubular stents, shown in Figures 1 and 7 below, which the patentee describes as "typical diametrically adjustable stent[s]." ('892 patent, col. 3:43-44)

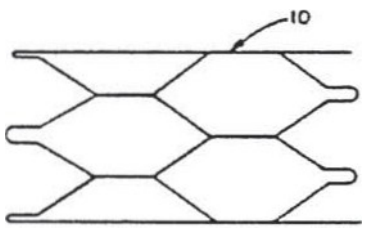

FIG. 1

Thus, these stents clearly fall within the claims. The inquiry here is whether the different stent device structure disclosed in Lee, which contains a series of rings, also discloses the stent structure limitations of the asserted claims of the '892 patent.

2. Lee **patent**

Bard's main anticipation argument with respect to Lee relates to U.S. Patent No. 5,123,917 (the "Lee patent"), (D.I. 259 (Declaration of Dr. Nigel Buller, hereinafter "Buller Deel."), ex. A at inf 170-91), which was submitted to the PTO and considered before the claims of the asserted patent were allowed, (D.I. 234, ex. 6 at 229-30). The Lee patent claims an "expandable intraluminal vascular graft" that "includes a flexible cylindrical inner tube having a outer periphery and a plurality of separate scaffold member[s] mounted on the outer periphery of the inner tube." *(Id.*, ex. 12, Abstract)[5] These "ring-like" scaffold members "provide circumferential rigidity to the graft" while allowing it "to be flexible along its longitudinal axis." *(Id.*, Abstract & cols. 2:34-40, 54-63, 3:23-24, 46-50) The patent discloses two embodiments of the invention, with the scaffold members shaded gray in the figures below:

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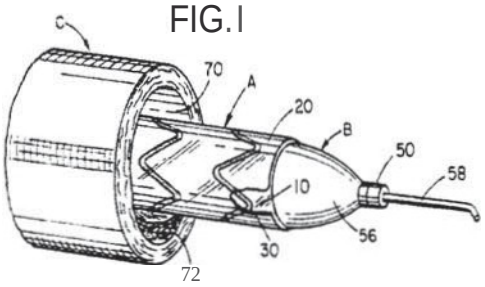
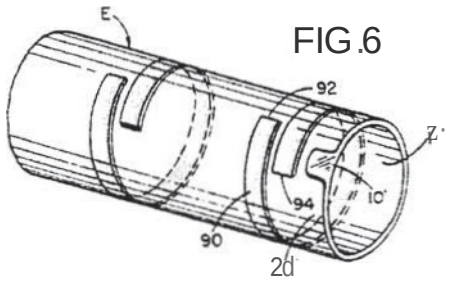
[5] The Lee patent is found here in the record; further citations will simply be to the "Lee patent."





3. Arguments regarding the Lee patent and anticipation

Gore argues that the Lee references are not anticipatory because the "unconnected rings of Lee" do not satisfy the stent structure limitations of the asserted claims. (D.I. 227 at 2, 11-15; D.I. 333 at 3-6) Bard argues to the contrary, pointing for support particularly to the following in the Lee patent: (1) a preferred embodiment illustrated by Figure 1; and (2) claim 17. (Buller Deel., ex. A at ml 170-91; Tr. at 251-52)

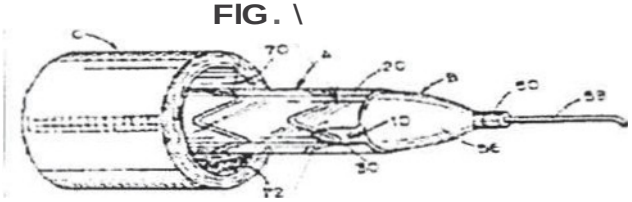
a. Preferred embodiment

Bard first contends that the preferred embodiment illustrated by Figure 1 of the Lee patent, reproduced above, expressly discloses the claimed stent structure. (DJ. 309 at 12-13; Tr. at 251-52) It is Wldisputed that the zig-zag shaped individual rings foWld in this embodiment are separate and spaced apart. (D.1. 227 at 2; D.I. 309 at 12-13) According to Gore, such a device cannot anticipate the asserted claims because the series of rings are not "connected in such a way as to create a multiplicity of openings" required by the stent structure limitations and the Court's construction thereof. (DJ. 227 at 2, 11-12; *see also* D.I. 221 at 13) In response, Bard points to the covering of the Lee device as the key to its anticipation argument, explaining that the material "connect[s]" the rings together, with the resulting "arrangement of scaffold members forrn[ing] a

wall spanning the length of the series and creat[ing] a multiplicity of openings through the wall between individual members as shown [below]." (D.I. 309 at 12; *see also id.* Tr. at 251-52)

stent

FIG. \



openings

In other words, while Gore "suggests that the connection between the elongated members of the stent must be direct and cannot be made [via] the graft material[,]" Bard interprets the construed stent structure limitations as having no such requirement. (D.I. 309 at 13) Bard asserts that there is "nothing . . . that says that the rings can't be connected through the [] covering . . . . [with] bounded areas [formed] through those rings[.]" {Tr. at 251-52; *see also id.* at 256)

Bard's argument simply overlooks key portions of the claim language and the Court's construction thereof. As described above, the features of the claimed stent structure limitations require: (1) a "wall" that is a "substantially cylindrical plane *defined by the structure of the stent"* and (2) a "stent" that involves "elongated members connected in such a way as to create a multiplicity of openings" that in turn are *"bounded* openings" that go *"through the [stent} wall[.]"* (D.I. 221 at 17, 36 (internal quotation marks omitted) (emphasis added)) The spaced-apart rings depicted in Figure 1 of Lee, containing only a covering spanning the whole of these ring elements, thus lack a wall that is *defined by the structure of the stent.* (Tr. at 242-43) Instead, to the extent any wall could be said to exist in the Lee patent's preferred embodiment,

that wall would be a cylindrical plane that is defined by the structure of the *covering-a* covering that encloses the series of spaced-apart, otherwise unconnected rings. Put another way, the stent structure described in the asserted claims has a "wall" irrespective of the coverings that get affixed to the device, ('892 patent, col. 11:26-36), while the material placed over the otherwise unconnected rings in Lee is what creates any wall that exists in the Lee device.[6] With the preferred embodiment in Lee lacking the "wall" required by the asserted claims, it then follows that this embodiment also lacks the requisite "multiplicity of openings" that are through that stent wall-that is, it lacks bounded openings that are located "between the stent's physical connections." (D.I. 221 at 15) The separate zig-zag shaped rings in the Lee preferred embodiment do not have any physical stent-related connection to each other. Thus, for this additional reason, their arrangement could not satisfy the stent structure limitations of the asserted claims.

The conclusion that the Lee preferred embodiment fails to disclose the stent structure limitations is underscored by Bard's own characterization of the Lee device during a European Opposition proceeding involving one of Bard's patents. (D.I. 227 at 14-15; D.l. 333 at 2) Bard's

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[6] Bard's invalidity expert, Dr. Nigel Buller, states in conclusory fashion that the skilled artisan "would have understood that the collection of zig-zag ring-like scaffold members" disclosed in the Lee patent's preferred embodiment "together comprises a stent with a wall and openings in the wall[.]" (Buller Deel, ex. A at 176) He does not offer any explanation as to how it is that a series of separate, spaced-apart rings could amount to the requisite "wall." *(See id.; see also id.*, ex. C at 50; D.I. 310, ex. 6 at 164-65) It is true that at the time Dr. Buller offered his expert reports, the Court had not yet issued its claim construction for "wall." Yet Gore's claim construction briefing, which was available at the time Dr. Buller filed his expert reports, made clear Gore's view that a "wall" encompassed something distinct that was defined by the structure of the stent-not something "more akin to a space" (as had been suggested by Bard's claim construction briefing). *(See. e.g.*, D.I. 99 at 14-15) And yet Dr. Buller's expert reports did not directly address this dispute.

then-pending claims covered a "tubular radially expandable support member (] having a *plurality of openings* passing *through walls of the support member."* (D.I. 234, ex. 30 at WLG-11-515-00455503 (emphasis added)) In distinguishing the Lee device from its invention, (D.I. 309 at 14-15 n.8), Bard argued as follows:

> [The Lee device] lacks a stent wall .... (Lee) is not concerned with radial compliance but with longitudinal flexibility (column 2, line 15). The stent graft is to be a bendy one. This is why it prescribes a plurality of *separate* stiffening rings (column 3, line 5) and these stiffening rings have to be *spaced* (column 3, line 47). It would not be obvious to replace the plurality of spaced individual stiffening rings of (Lee) with the apertured waJl required in the present claims because that would conflict with the objective of longitudinal flexibility.

(D.I. 234, ex. 31 at WLG-l 1-515_00455411 (emphasis in original)) It is quite clear from this passage that Bard itself at one point did not consider the Lee device to have the requisite "wall" that is defined by the structure of the stent.[7]

The Court's conclusion is also bolstered by a piece of evidence that Gore pointed out during the claim construction process. (D.l. 221 at 16 n.8; DJ. 227 at 12) During prosecution of the related '487 Patent (a patent that, as previously noted, was originally asserted in this case), the patent application contained claims that did not require a "multiplicity of openings." (D.I. 96,

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A Court may consider an accused infringer's own statements regarding a prior art reference when assessing the state of the evidence on the question of anticipation. *Cf Haberman v. Gerber Prods. Co.,* 236 F. App'x 592, 598 (Fed. Cir. 2007). While such statements do not necessarily bind the accused infringer, *see id.* at 598 n.5, they can be a helpful part of the evidentiary mix for a court considering the question of anticipation. Bard, citing in support to *In re McDaniel,* 293 F.3d 1379, 1387 (Fed. Cir. 2002), characterizes these statements about the Lee device as being made "in an unrelated patent prosecution of an unrelated Bard patent application" and asserts that they are "are at most evidence for the jury to consider." (D.I. 309 at 14 n.8) But such statements are surely also evidence that the Court can consider in deciding the instant summary judgment motion, and nothing in *In re McDaniel* is to the contrary.

exs. Y-1 at WLG-l 1-515_00453734 & Y-2 at WLG-1l-5l5_00453774) The PTO initially rejected the patent's claims as being anticipated by Lee, and only allowed them after the claims were amended to add the "multiplicity of openings" requirement. In an intervening responsive office action to the PTO, Gore successfully distinguished Lee on precisely this basis, explaining that "[n]one of the rings in Lee have a multiplicity of openings" through the wall of the stent. *(Id.,* ex. Y-5 at WLG-l l-515_00453825-26)

The Court finds that, in view of the undisputed material facts, the preferred embodiment represented by Figure I in the Lee patent does not disclose the stent structure limitations. Therefore, it cannot anticipate the asserted claims.

b. Claim 17

Bard also points to claim 17 of the Lee patent as disclosing the stent structure limitations. The crux of the dispute is whether this claim discloses a "stent" with members connected by a connecting structure, and which in tum form the required "multiplicity of openings." Claim 17 of the Lee patent reads as follows:

> 17. An endothelial liner for a vein or an artery of a body, comprising:
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> an inner membrane comprising a cylindrical tube of a pliable continuous radially expandable material having a luminal side with minimal thrombogenic potential;
>
> an outer membrane enclosing said inner membrane, said outer membrane comprising a cylindrical tube of a pliable continuous radially expandable material having a vascular side with minimal tissue reaction potential; and,
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> *a plurality of stiffening elements disposed between said inner and outer tubes to provide the liner with circumferential stiffness, said elements being spaced from each other disposed along a length to allow the liner to be flexible along its longitudinal axis* wherein

> said inner and outer membranes and said stiffening elements are expandable from a first respective diameter, at which they are introduced into a vein or artery of the body, to a second respective diameter at which they are operatively secured in the vein or artery of the body.

(Lee patent, col. 10:17-38 (emphasis added))

Bard argues that claim 17 "expressly and inherently discloses to a skilled artisan a stent structure having interconnecting members." (D.I. 309 at 13-14 (citing Buller Deel., ex. A at ii 176)) This argument has a couple of components. Bard sets the stage by asserting that "(p]rior art references must be read from the perspective of one of ordinary skill in the art-not attorneys-and 'in combination with [the experts'] own knowledge of the particular art.'" *(Id.* at 15 (quoting *Jn re Graves,* 69 F.3d 1147, 1152 (Fed. Cir. 1995));*see also* Bard's Motions Hearing Presentation, "Anticipation" Section, Slide 58) Next, Bard argues that the Lee patent includes claims directed to devices with both separate rings and non-separate rings; to do so, it juxtaposes the language in claim 17 (asserted to describe rings that are *not* separate) with that in claims 1 and 8, *(see* D.l. 309 at 13-14 (quoting Buller Deel., ex. A at iJ 176 & ex. C at ii44)), reproduced below:

> 1. An expandable intraluminal vascular graft, comprising ... a plurality of *separate*, expandable, ring scaffold members which are mounted on said outer periphery along a length of said inner tube in spaced relation to each other, said scaffold members providing circumferential rigidity to the graft; and ....
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> 8. An expandable intraluminal vascular graft comprising ...
>
> a plurality of *separate* stiffening rings each being secured to one of said conduit inner surface and outer surface, said stiffening rings being spaced from each other along the length of said conduit from said first end to said second end providing circumferential stiffness to said conduit, said stiffening rings being spaced from each other to allow the graft to be flexible along its longitudinal axis ....

(Lee patent, cols. 7:66-8:8, 8:48-61 (emphasis added)) From there, Bard asserts that stents formed from a series of individual members (including stents having rings connected via an interconnecting member), were known in the art and were used to enhance flexibility of the devices. (D.I. 309 at 13 (citing Buller Deel, ex. A at 176)) And then, citing exclusively to Dr. Buller's expert opinion, Bard contends that "one of skill in the art would know that the 'spaced apart but not separate' rings disclosed in claim 17 refer to a well-known stent structure" (i.e., one with a support structure that interconnects the series of rings to one another). *(Id.* at 14 (quoting Buller Deel., ex. A at 176))

As an initial matter, it is clear (and really not strongly disputed) that Claim 17 does not *expressly* disclose a stent structure with an interconnecting member connecting the spaced-apart stiffening elements. There is no mention in the claim of such a stent component, or otherwise of a requirement that the rings be connected in some way. (D.I. 333 at 4; Tr. at 244)[8] Therefore, claim 17 does not expressly anticipate the stent structure limitations of the asserted claims.

Nor does claim 17 inherently disclose such a structure. To establish anticipation by inherent disclosure, the evidence must make it clear that the reference discloses prior art that

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[8] The Court notes that in another patent that Dr. Buller and Bard point to as disclosing "[c]onnected [r]ings," U.S. Patent No. 5,514,154 (the "Lau patent"), (Bard's Motions Hearing Presentation, "Anticipation" Section, Slide 62; Buller Deel., ex. A at ml 51, 176; *id.*, ex. C at ml 44-45), the Abstract describes the invention as a stent consisting of "a plurality of radially expandable cylindrical elements generally aligned on a common axis *and interconnected by one or more interconnective elements[,]"* (Lau patent, Abstract (emphasis added)). Each independent claim expressly discloses, in addition to the ring elements, "a plurality of [] connecting elements for interconnecting said cylindrical elements." *(Id.*, cols. 8:43-44, 9:28-29, 10:30-31) Likewise, the device invented by Palmaz and Schatz that Bard and Dr. Buller highlight as having "(c]onnected [r]ings" explicitly discloses "a single connector member disposed substantially parallel to the longitudinal axis of the tubular members." (Bard's Motions Hearing Presentation, "Anticipation" Section, Slide 64; United States Patent No. 5,195,984 at Abstract; *see also id.* at cols. 11:53-55, 12:32-34)

must *necessarily* include the unstated limitation. *See, e.g., Therasense, Inc.* v. *Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010); *Transclean Corp.* v. *Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). "Inherency [] may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Therasense, Inc.*, 593 F.3d at 1332 (internal quotation marks and citation omitted) (emphasis in original). Bard's evidence fails to create a sufficient question of fact as to inherent anticipation.

At the outset, an organizing principle of Bard's inherent anticipation argument regarding claim 17 is legally flawed. (D.I. 333 at 5) Bard seems to suggest that the skilled artisan would have read claim 17 and, *in combination with* the artisan's own knowledge of the prior art (i.e., knowledge drawn from sources outside of the Lee patent itself), would then have determined that the rings described in claim 17 of the Lee patent could be connected with an interconnecting member. (D.I. 309 at 13-15; *see also* Tr. at 254 (Bard's counsel addressing Dr. Buller's opinion regarding claim 17 and explaining that "the express[] things that Dr. Buller points to is in the claims where one claim it talks about having separate rings and another one it doesn't and then his understanding from one skilled in the art in that field at the time based on the other evidence that's out there, that it was well known that you could have other types of connected rings. For example, Lau.")) Bard cites to a single case two decades old in support of its "anticipation by combination" proposition: *In re Graves*, 69 F.3d 1147 (Fed. Cir. 1995). (D.I. 309 at 15; Bard's Motions Hearing Presentation, "Anticipation" Section, Slide 58) However, in a later case in which the infringer's anticipation argument similarly relied on this statement from *In re Graves*, the Federal Circuit clarified that "anticipation requires that each limitation of a claim *must be*

found in a single reference. . . .Although we have permitted the use of additional references *to confirm the contents of* the allegedly anticipating reference . . . we have made clear that anticipation does not permit an additional reference to supply a missing claim limitation." *Teleflex, Inc.* v. *Ficosa N. Am. Corp.*, 299 F.3d 1313, 1335 (Fed. Cir. 2002) (emphasis added).[9] Thus, contrary to the way Bard frames it, "the dispositive question regarding anticipation [is] whether one skilled in the art would reasonably understand or infer *from a prior art reference"* that every claim element is disclosed in that reference. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1055 (Fed. Cir. 2010) (certain brackets and citation omitted) (emphasis added).

Moreover, Bard's characterization of the supposed inherent disclosure conflicts with the law of inherency in that Bard seems to acknowledge that use of a device with a connecting bar is really only one possible choice that claim 17 might be suggesting. (D.I. 309 at 13 ("One of ordinary skill in the art would have understood that [claim 17] disclose[s] a series of rings *that may be* a single structure with interconnecting members.") (quoting Buller Deel., ex. A at ii 176 (emphasis added)); *see also id.* at 2 (stating that the "Lee Patent discloses a second embodiment *that allows* a series of rings to be connected to each other by a support structure, in addition to the graft material") (emphasis added); Buller Deel., ex. C at ii46 (explaining that Dr. Lee described his invention in terms of certain functional characteristics and that "[b]oth separate and connected rings *can* achieve these ends") (emphasis added)) In other words, Bard does not

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[9] *See also Callaway Golf Co.* v. *Acushnet Co.*, 778 F. Supp. 2d 487, 501 (D. Del. 2011) ("For purposes of anticipation, the knowledge of persons of skill in the art may not be used to supplement the disclosure of a reference[.]"); *Rockwell Int'l Corp.* v. *SDL, Inc.*, 103 F. Supp. 2d 1202, 1206-07 & n.2 (N.D. Cal. 2000) (recognizing that this excerpt from *In re Graves* appears to conflict with the Federal Circuit case law on inherent anticipation, which dictates that "the common knowledge of a skilled artisan cannot be used to add an inherent element into a patent claim for the purpose of a[n] [] anticipation analysis").

appear to be arguing that claim 17 absolutely requires a device with an interconnecting member; instead, it seems to contend only that the claim does not foreclose the use of such a device. This is simply not enough to win the day for inherent anticipation. *Cf Transclean Corp.*, 290 F.3d at 1373 (affirming the district court's conclusion that the asserted claims were not invalid as being anticipated where the prior art reference at issue allowed for the possibility that the missing claim limitation could occur under some circumstances, but where it was also possible for that not to be the case); *MIA-COM Tech. Solutions Holdings, Inc. v. Laird Techs., Inc.*, C.A. No. 14-181-LPS, 2014 WL 2727198, at *4 (D. Del. June 13, 2014) (finding that the defendant failed to raise a substantial question of inherent anticipation in resolving a preliminary injunction motion, where the defendant's best prior art reference suggested only "(a] possibility (among others)" that the missing limitation was a part of the product at issue).

Turning to the Lee patent itself, there is nothing in that document that makes clear (or even suggests) that the device claimed in claim 17 must include a structure connecting the stiffening rings. Instead, the claim emphasizes that the spaced apart stiffening elements allow the device "to be flexible along its longitudinal axis[,]" (Lee patent, col. l0:32-33), a characteristic that, if anything, would seem to be inhibited a bit by the inclusion of such an interconnecting member.

Further, an examination of the beginning of the Lee patent's specification, where the patentee describes the prior art, provides some helpful context for what is invented. The patent begins by identifying a few problems with prior art devices. For one, the patent describes how certain grafts-such as those made of coiled stainless steel springs, helically wound coil springs, and expandable stainless steel stents formed from wire configured into a "zig zag"

pattern-exerted "constant outwardly radiating pressure [] on the interior surface of the body passageway [that] can cause erosion" thereof. *(Id.,* cols. 1:55-60, 2:4-7) It also explains how devices "comprised of a thin walled tubular member having a plurality of slots formed therein" have "inadequate longitudinal flexibility to enable the stent to be delivered into a serpentine body passage[.]" *(Id.,* col. 2:8-17) Lee was seeking a device that overcame these issues.

Lee's solution was a device having circumferential rigidity and longitudinal flexibility, made up of spaced-apart rings that are not interconnected.[10] For instance, the Abstract describes the invention as "[a]n expandable intraluminal vascular graft [that] includes a flexible cylindrical inner tube having a[n] outer periphery and a *plurality of separate scaffold member[sj ."* *(Id.,* Abstract (emphasis added)) Thereafter, the specification describes the "present invention" as a graft made up of coverings and "a plurality of separate expandable ring-like scaffold members which are secured to the inner tube outer periphery in spaced relation to each other. The scaffold members provide circumferential rigidity to the graft. . . . [t]he stiffening rings are spaced from each other to allow the graft to be flexible along its longitudinal axis." *(Id.,* 2:35-40, 61-63) Lee's invention was a device with a "maximum amount of manueverability [,]" with the spaced-apart rings allowing for "maximal longitudinal flexibility[,]" making the device "sufficiently pliable so that it can be folded during insertion into a vascular lumen[.]" *(Id.* at 5:44-52)

Bard's expert Dr. Buller does flatly contend that "[o]ne of skill in the art would have

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[10] This is also consistent with Dr. Lee's own testimony. When asked during his deposition if, aside from the figures depicted in the patent, he had any significantly different designs in mind that he did not include in the patent, he responded "I did not consider a different design." (D.l. 234, ex. 15 at 72-73) In other words, Dr. Lee was not considering a device containing rings connected with an interconnecting member at the time of the invention of his stent graft.

understood that [claim 17 discloses] a series of rings that may be a single structure with interconnecting members." (D.I. 259, ex. A at 176) But he never articulates *why or how* the skilled artisan would come to this understanding as a result of something found in the Lee reference itself. Dr. Buller's bare conclusion, then, cannot be enough for Bard to withstand summary judgment.

Ultimately, Bard bas not pointed to any evidence suggesting that a connecting member is necessarily present in claim 17. Instead, its analysis appears to rest on the kind of possibi lity-that the claim's failure to include the term "separate" means that a skilled artisan *could* have thought to use the device with a connecting member-that is not enough to create an issue of fact with respect to inherency.[11]

B. Vallbracht

The asserted claims of the '892 patent also require a first tubular covering and a second tubular covering "wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm thick exclusive of the stent" (the "thickness limitation"). ('892 patent, col. 11:31-39) Gore claims that the Vallbracht references are missing the thickness limitation of the asserted claims. (D.I. 227 at 17)

Bard's contrary arguments regarding anticipation rely on a few different references that can be grouped into two categories: (1) those that do not disclose a specific numerical thickness; and (2) those that disclose a thickness of exactly 0.10 mm. The Court will address both

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[11] Bard's arguments with respect to the "Other Lee Work" and "Lee Invention," (D.I. 309 at 15-16 & n.9), fail for the same reasons. There is no evidence that these references disclose an interconnecting member. And, as explained above, the presence of spaced-apart, separate rings in Lee does not anticipate the stent structure limitations of the asserted claims. (D.I. 333 at 5-6)

categories in turn.

1. Vallbracht Patent and Presentation

Bard asserts anticipation of claims 32 and 33 based on German Patent No. 3,918,736 (the "Vallbracht patent"), (Buller Decl., ex. A at 215), which was submitted to the PTO and considered before the asserted claims were allowed, (D.I. 234, ex. 6 at 303-04). The Vallbracht patent claims an intraluminal graft including a stent with at least one covering of «very thin" polyetrafluoroethylene ("PTFE") attached to the surface(s). *(Id.,* exs. 22 & 23 ("[A] very thin film, peeled from a block of PTF, is inserted from the inside into the stent . . . . Optionally, a further film may be placed from outside around the stent in order to achieve complete inclusion of the metal."))[12] The Vallbracht patent does not disclose any specific numerical thickness for these coverings. *(See generally id.; see also id.,* ex. 24 at 31; *id.,* ex. 6 at 308) In addition to the Vallbracht patent, Bard relies on notes prepared by Dr. Vallbracht regarding a presentation he gave at a 1991 conference of the Radiological Society of North America ("RSNA") (the "Vallbracht Presentation"). (Buller Decl., ex. A at iM[213, 247) The Vallbracht Presentation discloses a stent "closed" with a "thin layer" of PTFE. (D.l. 234, ex. 28 at BARD-11-515-00111202)[13]

Gore argues that these two Vallbracht references do not anticipate because they fail to "disclose any thicknesses range at all, let alone specific thicknesses within Gore's claimed

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[12] The Vallbracht patent and its translation into English are located here in the record. Further citations will simply be to the "Vallbracht patent."

[13] The Vallbracht Presentation is found here in the record. Further citations will simply be to the "Vallbracht Presentation."

range." (D.I. 333 at 8; *see also* D.I. 227 at 17)[14] Citing to Dr. Buller's contrary opinion, Bard counters that the skilled artisan would understand the citation to "thin" or "very thin" coverings in the Vallbracht patent and Vallbracht Presentation, respectively, to disclose an anticipatory range of thickness. (D.I. 309 at 8)

In making their arguments, the parties both cite to case law regarding how courts should approach the question of anticipation as to patents and prior art references that claim a range. (D.I. 309 at 9; D.I. 333 at 7-8) These cases explain that when "a patent claims a range . . . that range is anticipated by a prior art reference if the reference discloses a point within the range." *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015). However, if the prior art reference discloses its own range, then the prior art is only anticipatory if it describes the claimed range with sufficient specificity such that a reasonable fact finder could conclude that there is no reasonable difference in how the invention operates over the ranges. *Id.*[15] Additionally, when the prior art does disclose a range, rather than a point, and that range overlaps with the claimed range, the disclosure may be sufficient to anticipate if the claimed range is not "critical" to the invention. *Id.* at 871; *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

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[14] Gore does not point the Court to any case law dictating a *per se* rule that prior art *must* expressly identify a specific numerical range of measurement in order to anticipate an invention that includes such a range of measurement.

[15] *Cf In re Haase*, 542 F. App'x 962, 965 (Fed. Cir. 2013) ("But if the prior art itself also discloses only a range of values, and the new claim recites an overlapping but different range, we have said that the prior-art reference must 'describe [] the claimed range with sufficient specificity to anticipate th[e] limitation' of the claim-a broad prior-art disclosure that encompasses a narrower claimed range is sometimes not enough for anticipation.") (citation omitted).

In this case, the thickness limitation in the '892 patent clearly claims a range relating to covering thickness (i.e., "less than about 0.10 mm thick"). But Bard asserts that Gore does not tout this claimed range of thickness as being critical to the invention. It notes, for example, testimony from one of the '892 patent's inventors, in which the inventor seems to suggest that the thickness limitation was simply added for the purpose of avoiding prior art. (D.I. 309 at 8-9 (citing D.I. 237, ex. 2 at 124; *ClearValue*, 668 F.3d at 1344-45)) Bard also points out that the '892 patent does not specifically describe the importance of its particular thickness limitation. *(See generally* '892 patent)

Gore does not help shed much light on the "criticality" issue. It responds only by stating that "Bard itself admits that the thickness limitations *are* critical[,]" and simply cites in support to two sentences found in Bard's summary judgment briefs. (D.I. 333 at 8 (citing D.I. 236 at 1; D.I. 302 at 12) (emphasis in original)) Nevertheless, other record evidence cited to or referenced within the briefing here surely creates at least a genuine issue of fact as to whether the thickness limitation is critical to the patent. *(See. e.g.*, D.I. 310, ex. 14 at WLG-11-515_00882752 (a 1992 letter to Gore from a university researcher who shows interest in an intraluminal tube graft and notes that "[i)n order to create the most collapsible device the 'skin' needs to be thin, we are thinking around 0.1 if that is possible") *(cited in* D.I. 309 at 18); *id.*, ex. 1 at 254-55 (Gore's infringement expert, Dr. Robert Gorman, in response to a question regarding whether there is evidence that the patent's inventors found the thickness limitation to be critical, cites to evidence that clinicians in the field were telling the inventors just that) *(cited in* D.I. 309 at 9); D.I. 306, ex. 12 at 21 (Gore's infringement expert, Dr. Enrique Criado, citing evidence that the inventors incorporated coverings of "'less than .1 mm wall thickness"' in their invention because it

"'defines the sweet spot' between strength and thinness") *(cited in* D.I. 302 at 12, in tum *cited in* D.I. 333 at 8)); *cf Ineos*, 783 F.3d at 869 (noting that patentee "failed to raise a genuine question of fact about whether the range claimed is critical to the operability of the invention").

On the other hand, the Court concludes that Bard has itself demonstrated that there is a sufficient question of fact regarding the nature of the alignment of the respective ranges at issue, so as to preclude summary judgment of no anticipation regarding the Vallbracht patent and Vallbracht Presentation. Although Gore argues that the *Ineos/ClearValue* line of case law set out above is inapplicable here because those cases address "prior art that explicitly disclosed a numeric range encompassing the claimed range[,]"(D.I. 333 at 8), Bard's point is that the skilled artisan would have understood the "very thin film" or "thin layer" references in the respective pieces of prior art to *"necessarily disclose[}"* a thickness range that anticipates the claimed thickness range of "less than about 0.10 mm thick(,]" (D.I. 309 at 9 (emphasis added) (citing Buller Deel., ex. A at 228)). In explaining that "thin" is a relative term, Dr. Buller set out why the "very thin" disclosure in the Vallbracht patent would be understood by the skilled artisan to be relative to two known thicknesses. *(Id.* at 10 (citing D.I. 310, ex. 6 at 201)) First, he points out that the background of the Vallbracht patent references "thin" tubes of PTFE that had been successfully used for bypass, while also describing the "very thin film" that makes up the invention. (Buller Deel., ex. A at 228 (citing Vallbracht patent at WLG-l l-515_00934448)) According to Dr. Buller, the skilled artisan "would have been aware that the common PTFE bypass tubes used at the time of the Vallbracht [] patent could be as thin as 0.4 mm" and therefore "would have understood the disclosure of a 'very thin film' . . . to require material significantly thinner than 0.4 mm." *(Id.)* More critically, Dr. Buller also explained that the

skilled artisan would have understood the term "very thin" in the context of stent coverings to be measured relative to the thickness of a Palmaz-Schatz stent (which measured 0.076 mm)--the best-known stent in the field during the relevant time period. (DJ. 333 at 9-11; Buller Deel., ex. C at ii94; DJ. 310, ex. 6 at 196-97) Thus, he opines, the artisan would have understood the Vallbracht patent's reference to include materials measuring "less than about 0.1O mm thick."[16]

There is also extrinsic evidence in the record that can support Bard's position. (D.I. 309 at 18-19) The Federal Circuit has explained that a "gap in the reference may be filled with recourse to extrinsic evidence" if "[s]uch evidence [] make[s] clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA, Inc.* v. *Monsanto Co.,* 948 F.2d 1264, 1268 (Fed. Cir. 1991). Extrinsic evidence may be considered to explain, but not to expand on, the meaning of an anticipatory reference. *In re Baxter Travenol Labs.,* 952 F.2d 388, 390 (Fed. Cir. 1991). Bard's extrinsic evidence includes the following:

- Gore documents from 1990 and 1991 that show that Gore was contacted by Dr. Jan Carlos Parodi who wanted a "very thin walled" stent graft of 0.10 mm, (DJ. 310, ex. 11 at WLG-1 1-515_00881848);
- A February 1991 letter from another researcher who contacted Gore wanting ePTFE to cover a stent with "an extremely thin-walled tube so as to add minimal bulk" to the device, with the material be sought to test measuring 0.004 mm thick, *(id.,* ex. 12 at WLG-l 1-515_00882047-

[16] Although Gore characterizes the Palmaz-Schatz stent as "a commercial stent not referenced by Vallbracht[,]" (D.I. 333 at 8), for purposes of inherent anticipation, the Court notes that the Vallbracht patent does cite to Palmaz's work in describing intravascular stents then in use, *(see* Vallbracht patent at 2). The Court cannot definitively conclude that Dr. Buller is wrongly pulling a reference to the Palmaz-Schatz stent's dimensions from a source other than what is inherently disclosed in the Vallbracht patent itself.

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- Evidence that in that same month, Dr. Vallbracht communicated to Gore about his new idea to "close" a metal stent with "a thin layer of PTFE" which was 0.10 mm, *(id.,* ex. 13 at BARD-11-515-0011 J 199);

- A February 1992 letter to Gore from researchers requesting "thin" ePTFE material to use as a stent covering "around 0.1 mm if that is possible[,]" *(id.,* ex. 14 at WLG-11-515_00882752).

To be sure, some of this evidence makes reference to coverings that are exactly 0.10 mm thick, not to coverings "less than about 0.10 mm thick." *(See* D.I. 369 at 15-16, 18-19) But drawing all reasonable inferences in Bard's favor, and taking this evidence together with the other evidence discussed above, the Court concludes that a reasonable fact finder could find for Bard. That is, the fact finder could conclude that by clear and convincing evidence, Bard has demonstrated that a person of ordinary skill in the art would understand these two Vallbracht references' use of "very thin" and "thin" to anticipate the claimed range.[17]

2. Vallbracbt Abstracts and Other Vallbracbt Work

Bard also asserts anticipation of claims 32 and 33 of the '892 patent based on a Vallbracht

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[17] Gore makes much of the fact that Vallbracht had not used coverings less than 0.10 mm thick and that therefore the Vallbracht patent and Vallbracht Presentation cannot anticipate the thickness limitation. **(D.I.** 227 at 18, 20) For one, it is notable that, in support of the proposition that it is "undisputed that Vallbracht never made a device with both an exterior and luminal covering with a combined thickness less than 0.1 mm[,]" Gore cites only to deposition testimony of Or. Buller (and not to that of Vallbracht) in which Dr. Buller testifies merely that he is not aware of Vallbracht making such a device in the relevant time period. (D.l. 227 at 9-10 & 18 (citing D.I. 234, ex. 6 at 316-18); *see also* D.I. 309 at 11) Moreover, it is well-settled that "(a]nticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." *Schering Corp. v. Geneva Pharms., Inc.,* 339 F.3d 1373, 1380 (Fed. Cir. 2003); *see also Kennameta l, Inc. v. Ingersoll Cutting Tool Co.,* 780 F.3d 1376, 1383 (Fed. Cir. 2015) (explaining that "actual performance" is not required for anticipation) (citation omitted).

1991 RSNA Abstract and a Vallbracht 1990 German Abstract ("Vallbracht Abstracts"). (Buller Deel., ex. A at W 232-60) These documents relate to an intraluminal graft including a stent covered "by a 0.1-mm thin [] PTFE film." (D.I. 234, ex. 26 at WL-11-515-00668957 ; *see also id.* ex. 27 at WL-l1-515_00934473)[18] Bard also relies on a prototype, tests, and communications with others, including Gore, relating to Vallbracht's work ("Other Vallbracht Work"), which provide a specific numerical thickness of 0.10 mm. (Buller Deel., ex. A at W 261-76)

Dr. Buller opined that these references "anticipate only under Gore's apparent construction of the term 'less than about 0.10 mm thick.'" (D.I. 309 at 8 n.4 (citing Buller Deel., ex.A at iM! 244, 275; D.I. 310, ex. 6 at 189-90)) In other words, Bard's assertion that these references (disclosing covering thickness of exactly 0.10 mm) are anticipatory was based on its view of Gore's infringement position-that Gore was asserting that coverings having thicknesses of 0.10 mm or greater could meet the thickness limitation. (Tr. at 257-59) However, as Gore explains, "Gore does not have a construction, apparent or otherwise, under which coverings 0.10 mm thick or thicker satisfy the asserted claims. [Rather], all experts agree that coverings must have an overall *(i.e.,* average) thickness less than 0.1 mm to either infringe or anticipate." (D.I. 333 at 7) And, inde:ed, the Court has found that this is the meaning of "less than about 0.10 mm thick" in the patent. (D.I. 369 at 15-16, 18-19)

These Vallbracht Abstracts and Other Vallbracht Work disclose a covering thickness of 0.10 mm, which is greater than the thickness limitation in the asserted claims. *(See* DJ. 234, ex. 6 at 192 (Dr. Buller testifying during his deposition that if the thickness limitation "requires it to

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[18] The Vallbracht Abstracts are found here in the record; further citations will simply be to the "Vallbracht Abstracts."

be less than 0.1, something that isn't less than 0.1 doesn't satisfy it")) Therefore, these references do not anticipate the thickness limitation as a matter oflaw. *See Net MoneyIN, Inc.*, 545 F.3d at 1371 ("[D]ifferences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation.").[19]

C. Palmaz

Bard asserts that claims 32 and 33 are anticipated by U.S. Patent No. 5,316,023 (the "Palmaz patent"). (D.1. 309 at 5; Buller Deel., ex. A at iMJ 280-93) The European counterpart to the Palmaz patent, which contains the same disclosures, was submitted to the PTO and considered before the asserted claims were allowed. (D.I. 234, ex. 6 at 335-36) The Palmaz patent discloses grafts that are supported along at least a portion of their length by one or more stents, which are referred to as "expandable and deformable tubular members." *(See, e.g.*, D.I. 234, ex. 10 at Abstract)[20] The Palmaz patent explains that "[t]he plurality of tubular members **201** are then embedded within a layer **202** of a deformable and expandable plastic material[.]" *(Id.*, col. 10:22-24) The patent teaches that these grafts may be made from a variety of materials, including ePTFE and other materials such as Teflon® or porous polyurethane. *(Id.*, cols. 9:3-42, 10:25-32) It is undisputed that the Palmaz patent itself says nothing specific about the thickness

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[19] Bard also asserts anticipation based on Vallbracht's prior conception under the former 35 U.S.C. § 102(g) (the "Vallbracht Invention"). (Buller Deel., ex. A at ii277) In their briefing, the parties do not make specific arguments with regard to this reference. Bard simply notes that Gore's Motion regarding the Vallbracht Invention fails for the same reasons as described for the other Vallbracht references. (D.l. 309 at 11 n.6) To the extent the Vallbracht Invention discloses a specific numerical covering thickness of 0.10 mm, it does not anticipate as a matter oflaw.

[20] The Palmaz patent is located here in the record; further citations will simply be to the "Palmaz patent."

of its grafts (in that it never provides a numerical measurement of covering thickness, for example). *(See generally id.;* D.I. 227 at 8; D.l. 309 at 16-17)

Bard's anticipation argument as to the Palmaz patent therefore relies on a different patent on which Palmaz is the inventor: U.S. Patent No. 4,776,337 (the "'337 patent"). (D.l. 309 at 16; Buller Deel., ex. A at **1j** 292) The Palmaz patent cites to the '337 patent in teaching how to make a stent component (referred to as a "tubular member"), and incorporates the '337 patent by reference. (Palmaz patent, col. 8:54-63)[21] The '337 patent, in tum, covers an "expandable intraluminal vascular graft . . . . [that] may be a wire mesh tube, having a biologically inert coating thereon." (D.1. 234, ex. 21 at Abstract)[22] The '337 patent specification also contains a paragraph that describes coating stents. *(Id.,* col. 9:24-46) The patentee provides a couple of examples of a suitable biologically inert coating, such as porous polyurethane, Teflon, or other conventional biologically inert plastic materials (though he does not specifically call out ePTFE as one such material). *(Id.,* col. 9:29-32) The '337 patent also notes that such a "coating . . . should be thin" but does not identify any specific coating thickness. *(Id.,* col. 9:32)

In its Motion, Gore's primary argument is that because the Palmaz patent "does not disclose any particular thickness for its covering, [it] therefore cannot anticipate" the thickness

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[21] Specifically, the Palmaz patent explains: "It has been found that one type of tubular member **166,** which is particularly useful as securing means **165** are the expandable intraluminal grafts disclosed in U.S. Pat. No. 4,733,665, issued Mar. 29, 1988; U.S. Pat. No. 4,739,762, issued Apr. 26, 1988; and U.S. Pat. No. 4,776,337, issued Oct. 11, 1988, all of the foregoing patents being in the name of Julio C. Palmaz . . . . Each of these patents is incorporated herein by reference." (Palmaz patent, col. 8:54-63)

[22] The '337 patent is located here in the record; further citations will simply be to the "'337 patent."

limitation. (D.I. 227 at 2; *see also id.* at 15-17)[23] The Court thus turns to the evidence presented on that question.

In this regard, admittedly, the section of Dr. Buller's initial expert report that relates to the Palmaz patent is not robust. He merely states that "(o]ne of ordinary skill in the art would have understood that embedding a stent in a material would yield a device with thin coverings." (Buller Deel., ex. A at ii292) His rebuttal opinion is not much more full; he adds only that "it was well-known that ePTFE coverings could be thin, including as thin as 0.10 mm." *(Id.*, ex. C at ii99) However, Dr. Buller expanded on his opinion during his deposition. There he explained

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[23] Gore also (very briefly) argues that Bard's anticipation argument with respect to the Palmaz patent should fail because "the '337 patent is only incorporated by reference for its teachings on stents (i.e., 'tubular members') . . . not for its teachings on coverings." (D.I. 227 at 16 n.10) Whether and to what extent a piece of prior art incorporates by reference another document is a question of law. *Helicos Biosciences Corp. v. Illumina, Inc.*, 888 F. Supp. 2d 519, 533 (D. Del. 2012). The Federal Circuit has explained that "[t)o incorporate matter by reference, a host document must contain language clearly identifying the subject matter which is incorporated and where it is to be found; a mere *reference* to another . . .patent . . . is not an *incorporation* of anything therein." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (internal quotation marks and citation omitted) (emphasis in original). Here, the Court is not persuaded by Gore's argument. The Palmaz patent describes the grafts disclosed in the '337 patent as being "one type" of stent that can be used, and the '337 patent, in turn, clearly discusses stent devices that should contain "thin" coatings. (Palmaz patent, col: 8:47-62) The Court's decision is also affected here by the fact that Gore does not set out its "incorporation by reference" argument in any detail-the argument comes only in a single sentence of one Gore footnote. In light of all of this, the Court concludes that the Palmaz patent's reference to the '337 patent is a sufficiently clear reference to the '337 patent's discussion of covering thickness, so as to incorporate that material by reference into the Palmaz patent itself.

Additionally, in the same footnote, Gore also argues that the "thin" reference in the '337 patent is not made with reference to ePTFE coverings specifically, and so Dr. Buller's attempt to link this reference to the ePTFE material referenced in the Palmaz patent is suspect. (D.I. 227 at 16 n.10) However, while the '337 patent lists two particular materials that could be used as coatings, it does not limit itself to these materials, stating that "other conventional biologically inert plastic materials" could also be utilized. ('337 patent, col. 9:31-32) For this reason, Gore's argument is not persuasive.

that (as he did regarding the Vallbracht patent and Vallbracht Presentation discussed above): (1) the term "thin" is relative; (2) the skilled artisan would have understood the reference to a "thin" coating to be in comparison to the other structure making up the device (the stent); and (3) the artisan would "want something that's thinner than the stent." (D.1. 310, ex. 6 at 195-96; *see also* DJ. 309 at 17) The Palmaz patent uses the Palmaz-Schatz stent, asserted to be the best-known stent at the time, (Buller Deel., ex. A at iM! 46-48; D.I. 310, ex. 6 at 196), which had stent struts measuring 0.076 mm, (D.1. 310, ex. 6 at 196-97; *id.*, ex. 10 at BAR.D-11-515-00671242); *see also In re Baxter Travenol Labs.*, 952 F.2d at 390. Accordingly, Dr. Buller opined that "you would want to put a covering on which was certainly less than point 1 because even point ▌ would be thicker than the stent itself. . . . most people wanted to cover stents with things that were thinner than the stent with the hope that you wouldn't add too much [] extra bulk to the stent." (D.I. 310, ex. 6 at 197)

Here, while Gore might disagree with Dr. Buller's opinion, (*see* D.I. 333 at 10), the Court finds that opinion to be sufficiently grounded in the factual record and supported by a logical process of reasoning. The extrinsic evidence described above with respect to the Vallbracht reference can also support Bard's position. (D.I. 309 at 18) Thus, the Court finds that a genuine issue of material fact exists as to whether the Palmaz patent discloses the thickness limitation, such that a reasonable jury could agree with Bard's anticipation argument.

IV. CONCLUSION

For the reasons set out above, the Court recommends that Gore's Motion for Summary Judgment of No Anticipation be GRANTED-IN-PART. More specifically, the Court recommends that Gore's Motion be GRANTED with respect to the Lee references and to the

Vallbracht references that specifically disclose a thickness of 0.10 mm. The Court recommends that the Motion be DENIED with respect to the Vallbracht patent, the Vallbracht Presentation and the Palmaz patent.

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. Objections to this Report and Recommendation, if any, are due by **November 16, 2015.** Responses are due by **November** 23, **2015.** 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 Stancling 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 **November 16, 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: November 9, 2015

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE