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 Invalidity Based on Non-Enablement or Insufficient Written Description ("the Motion"). (D.I. 229) The Court recommends that the Motion be GRANTED.

I. BACKGROUND

A. Factual Background

The '892 patent, entitled "Intraluminal Stent Graft[,]" was issued on April 7, 1998, with the application having been filed on August 18, 1993. (D.I. 96, ex. A)[2] The patent is directed to

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[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) It was additionally asserting infringement of U.S. Patent No. 5,700,285 (the "'285 patent"), but that 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."

thin-wall intraluminal graft devices. The patent explains 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)

One prior art patent taught that the covering material of these devices shall be made of materials such as GORE-TEX® Vascular Graft or Impra® Graft, which are extruded and longitudinally expanded polytetrafluoroethylene ("ePTFE") tubes. (*Id.*, col. 2:2-8) The '892 patent's specification identified the "difficulty" with the use of these two particular tubular products—their "relatively thick, bulky wall[s]" made them difficult to "be contracted into a small cross-sectional area for insertion into a blood vessel." (*Id.*, col. 2:10-15) The wall thickness of these products was "limited by the difficulty of manufacturing an extruded, longitudinally expanded tube having a thin wall of uniform thickness." (*Id.*, col. 2:17-20)

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) Gore asserts three product claims of the '892 patent—independent claim 32 and dependent claims 33 and 40. (D.I. 191 at 1) Claim 32 is representative:

> **32.** A tubular intraluminal graft comprising:
>
> a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
>
> b) *a first tubular covering of porous [ePTFE]* affixed to the exterior surface of the tubular, diametrically adjustable stent;

and

c) *a second tubular covering of porous [ePTFE]* 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))

At the time of the invention, it was known by the person of skill in the art that ePTFE coverings could be made from films or extruded tubes. (D.I. 302 at 5; D.I. 260, Declaration of Robert Calcote (hereinafter, "First Calcote Decl."), ex. A at ¶ 145) Films of ePTFE are extruded as flat PTFE and then stretched or expanded to form the node and fibril structure of ePTFE. (First Calcote Decl., ex. A at ¶ 146) Expansion of these films can occur in one direction, creating a uniaxial node and fibril structure, or in many directions, creating a multiaxial structure. (*Id.*) This manufacturing process can result in very thin dimensions, and it has been known in the art since the 1970s that ePTFE films can be wrapped to form tubular structures. (*Id.*) As to extruded tubes of ePTFE, they are first extruded as PTFE tubes using an extrusion technique that utilizes an extrusion mandrel and extrusion die, which is similar to a funnel. (*Id.* at ¶ 147) PTFE material is forced through the tubular opening created by the die and mandrel, forming the extruded tube. (*Id.*) These tubes are then stretched or expanded to form a node and fibril structure. (*Id.*) Because these tubes are usually expanded in one direction, they have a uniaxial node and fibril orientation. (*Id.*) Following the extrusion and expansion process, an extruded tube of ePTFE can be longitudinally slit to create a flat sheet. (D.I. 234, ex. 4 at 220-21)

During claim construction, Bard asserted that the term "covering" should be construed to mean "film that covers a stent," thus limiting the term to coverings made from ePTFE films and

excluding from the scope of the claims coverings made from, *inter alia*, extruded tubes; Gore, for its part, argued that no construction was necessary. (D.I. 221 at 17) The Court ultimately rejected Bard's proposal, finding that the meaning of "covering" in the '892 patent is not restricted to ePTFE film coverings. (*Id.* at 17-28) Bard objected to this decision, and the District Court overruled Bard's objection. (D.I. 405 at 5-6)

B. Procedural History

On June 10, 2011, Gore commenced this action. (D.I. 1) On November 29, 2011, this case was referred to the Court by Chief Judge Leonard P. Stark to hear and resolve all pretrial matters, up to and including the resolution of case dispositive motions. (D.I. 20) Briefing on the Motion was completed on November 12, 2014, (D.I. 334), and the Court held oral argument on the Motion (and various other *Daubert* and summary judgment motions filed by the parties) on January 30, 2015, (D.I. 360 (hereinafter, "Tr.")). A 10-day trial is set to begin on December 7, 2015. (D.I. 362)

II. LEGAL STANDARDS

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 (internal quotation marks and citation omitted) (emphasis in original). 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 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. 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. Invalidity

A patent granted by the United States Patent and Trademark Office (the "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)).

III. DISCUSSION

Gore argues that Bard has failed to create an issue of fact as to whether Bard can prove, by clear and convincing evidence, that any of the asserted claims are invalid due to lack of enablement and/or lack of written description. The Court will consider Gore's arguments as to enablement and lack of written description in turn.

A. Enablement

1. Legal Standard

The statutory basis for the enablement requirement is set forth in 35 U.S.C. § 112, ¶ 1:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .[3]

To meet the enablement requirement, a patent specification must enable one skilled in the art to practice the full scope of the claimed invention without undue experimentation. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (citation omitted). "The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (internal quotation marks and citation omitted). The enablement requirement is a question of law based on underlying factual inquiries, and is determined as of the filing date of the patent application. *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009) (citation omitted). An enablement analysis is considered from the vantage point of the person of skill in the art. *See Sitrick*, 516 F.3d at 1000.

A patent claim is presumed enabled. *Pharm. Resources, Inc. v. Roxane Labs., Inc.*, 253 F. App'x 26, 28 (Fed. Cir. 2007). "The party alleging invalidity for lack of enablement bears the burden of proving by clear and convincing evidence that the specification of a challenged patent fails to teach one of ordinary skill in the art how to make the invention." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1318 (Fed. Cir. 2007).

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[3] The Court herein will cite to the version of Section 112 that was in force prior to the passage of the Leahy-Smith America Invents Act, as the application resulting in the asserted patent was filed prior to the passage of that Act. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1369 n.5 (Fed. Cir. 2014); *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1336 n.9 (Fed. Cir. 2013).

2. Analysis

The crux of the parties' dispute with respect to enablement is whether the '892 patent enables the full scope of the claimed "tubular covering" of ePTFE. It is undisputed that the asserted claims do not mention a specific method of making the claimed coverings, (*see* D.I. 234, ex. 3 at 451), and it is also not contested that the patent enables claims that encompass coverings made from ePTFE film, (D.I. 230 at 1-2 (citing D.I. 234, ex. 3 at 442); *id.* at 3-4, 12-13 (citations omitted); D.I. 302 at 1; Tr. at 271).[4] Gore argues this disclosure is sufficient because "[t]he law is unequivocal" that it need only enable and describe one method of making the claimed invention in these circumstances. (D.I. 334 at 1 (citing *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005)) In other words, according to Gore, because the asserted claims do not claim a covering component that is made by a particular process, but instead "specify a 'tubular covering' made by *any method* so long as the claimed physical specifications are satisfied[,]" the enablement requirement is satisfied here. (D.I. 230 at 7 (emphasis added))

For its part, Bard argues that because the covering limitation is not limited to those made from films, the '892 patent fails to enable the skilled artisan to practice the full scope of the claimed invention because it does not teach the use of coverings made from extruded tubes. (D.I. 302 at 8) Bard counters Gore's claim that the patent need enable only one *method* of making the claimed covering by asserting that extruded tubes and films were not merely two "ways of making a covering" but also resulted in two distinctly different "end [covering] products[.]" (Tr. at 286-87; *see also* D.I. 302 at 3) Therefore, Bard argues, the '892 patent's enablement of only

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[4] As Gore notes, the specification of the asserted patent discusses "at length the manufacture of tubular coverings using a film extrusion process." (D.I. 230 at 11-12 (citing '892 patent, cols. 2:30-35, 3:57-4:21, 4:54-5:67, 7:6-8:26))

coverings made from films is insufficient under the law. (D.I. 302 at 13-14)

The Court agrees with Gore. For the reasons set out below, the Court finds that Bard has not presented sufficient evidence to allow a reasonable fact-finder to find that the '892 patent did not enable the claimed coverings.

As an initial matter, as Gore accurately points out, the expert opinions on this issue presented by Bard's invalidity experts, Mr. Robert Calcote and Dr. Nigel Buller, "were not based on structural or operational differences in final coverings, but differences in the *process* of making coverings[.]" (D.I. 334 at 1 (emphasis in original)) For instance, Mr. Calcote explained that "[t]here can be extruded films or extruded tubes of ePTFE, each of which is made from a different manufacturing process." (D.I. 304, Declaration of Robert Calcote (hereinafter, "Second Calcote Decl."), ex. A at ¶ 15; *see also id.* at ¶ 17) Dr. Buller's opinion is also focused on whether the '892 patent enables a process of constructing the claimed covering from an extruded tube. (*See, e.g.*, D.I. 259, Declaration of Dr. Nigel Buller (hereinafter, "Buller Decl."), ex. A at ¶¶ 410-11; *see also id.*, ex. C at ¶ 239 (explaining that the asserted patent fails to "teach one of ordinary skill in the art how to make and use the claimed inventions with an extruded tube"))

As Bard must have recognized when it shifted its enablement argument to an assertion that coverings made from films and those made from extruded tubes result in "distinctly different products," (*see* D.I. 334 at 1, 5; Tr. at 274), the law does not require enablement of unclaimed alternative methods when a claim is directed to a physical structure and makes no reference to limits on the method of making that structure. In such circumstances, the "enablement requirement is met if the description enables any mode of making and using the invention." *Invitrogen*, 429 F.3d at 1071 (citation omitted); *see also, e.g.*, *Amgen Inc. v. Hoechst Marion*

Roussel, Inc., 314 F.3d 1313, 1335 (Fed. Cir. 2003); *Astrazeneca LP v. Breath Ltd.*, Civil Action No. 08-1512 (RMB/AMD), 2014 WL 2526909, at *6 (D.N.J. June 4, 2014) ("For product claims, such as those asserted here by virtue of the now-governing broad claim construction, the enablement requirement is satisfied if the specification provides a *single* way to make the claimed product.") (emphasis in original).[5]

The United States Court of Appeals for the Federal Circuit's decision in *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052 (Fed. Cir. 2005), illustrates this well-settled principle. In *Invitrogen*, the claims covered a compound—an enzyme containing a genetic mutation—without regard to the method used to create the genetic mutation. 429 F.3d at 1070. At the time that the patent application was filed in 1988, those skilled in the art knew several techniques for altering genetic sequences, including deletion mutation and point mutation. *Id.* The patent's specification clearly described how to arrive at the claimed compound by deletion mutation, but the parties disputed whether it also taught how to implement the claimed invention by point mutation. *Id.* The defendant accordingly argued that the claims-in-suit did not satisfy the enablement requirement. *Id.* The Federal Circuit rejected this argument, explaining that while the defendant's "validity argument might have had force had [the patentee] limited its claims to [the claimed compound] by reference to point mutation, [the defendant] overlooks *that the claims are not limited by the method of achieving the mutation.*" *Id.* at 1071 (emphasis added). Accordingly, because the specification disclosed one method of making the compound (by

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[5] Gore suggests that Bard's experts' focus on the process differences between constructing a covering with film and with extruded tubes arose from their failure to consider this black letter statement of the law—that a patent's product claims are sufficiently enabled if the patent's description enables any one mode of making and using the invention. (Tr. at 272) And it is true that Mr. Calcote's and Dr. Buller's expert reports do not mention this principle. (*See* Second Calcote Decl., ex. A at ¶ 23; Buller Decl., ex. A at ¶¶ 131-33)

deletion mutation), the Court held that the patent satisfied the enablement requirement. *Id.*[6] As for the overarching reasoning behind the *Invitrogen* Court's holding, the Federal Circuit explained:

> Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.

Id.; *cf. Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1292 (D. Del. 1987) ("A patent applicant is not required . . . to predict every possible variation, improvement or

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[6] A host of cases following *Invitrogen* have reiterated the rationale expressed in that case. *See, e.g., Advanced Fiber Techs. (AFT) Trust v. J & L Fiber Servs, Inc.*, No. 1:07-cv-1191 (LEK/DEP), 2015 WL 1472015, at *17 (N.D.N.Y. Mar. 31, 2015) (rejecting the defendant's argument that a patent directed to a screen cylinder (used in the pulp and paper industry) containing a screening medium engaged to a backing plate was not enabled, explaining that while the defendant was correct that there are many methods of connecting a screening medium and backing plate, the full scope of the claim was not all theoretical methods of connecting the two components, and therefore only a single method "engaging" a screening medium to a backing plate need be enabled); *Medicines Co. v. Mylan Inc.*, No. 11-cv-1285, 2013 WL 6633085, at *22 (N.D. Ill. Dec. 16, 2013) (rejecting the defendant's claim that if the patent encompassed a drug product generated using two different mixing methods, the patent was invalid for failure to enable the full scope of the claims, because the asserted patent was a "product patent[,]" and its "invention . . . is a bivalirudin drug product having the characteristics described in the patent, not a bivalirudin drug product made using a specific process"); *Balivi Chem. Corp. v. JMC Ventilation Refrigeration, LLC*, No. 1:07-CV-353, 2010 WL 2652280, at *11-12 (D. Idaho June 29, 2010) (rejecting the defendant's enablement defense where the alleged omissions from the patent's teachings were simply different ways to make and use the patented apparatus, and the patent disclosed at least one method for making and using it); *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 648 F. Supp. 2d 1294, 1342-43 (M.D. Fla. 2009) ("The full scope of the product claimed by these five asserted claims is a contact lens, without regard to the process by which it is made. As a result, the process by which the claimed contact lens product is made—with or without a surface treatment process—is immaterial and 'legally irrelevant' . . . and cannot be relied on as a basis to render these five claims invalid for lack of enablement.") (internal citation omitted).

commercial embodiment of his invention."), *aff'd, U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989).

In light of this, in order for Bard to withstand Gore's Motion, it must put forward sufficient evidence demonstrating not that a requisite covering made from a film and one made from a tube represent two different ways of making an ePTFE covering, but instead that they represent two "distinctly different" end covering products (such that both types of end products must be enabled). *See Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007) (explaining that where the scope of the claim included both mechanical and electronic side impact sensors, which were "distinctly different" apparatuses, the specification failed to satisfy the enablement requirement because it only disclosed mechanical sensors). Bard can demonstrate that such coverings are indeed two distinctly different products by pointing out differences in the "structure and operation" of embodiments made by these different processes. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1289 (Fed. Cir. 2012); *see also LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (same); *cf. Soitec, S.A. v. Silicon Genesis Corp.*, 81 F. App'x 734, 738 (Fed. Cir. 2003) ("When a patentee chooses to claim 'A or B,' [] the specification must fully enable 'B' as well as 'A' when the differences between 'A' and 'B' substantially affect the practice of the invention."); *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 648 F. Supp. 2d 1294, 1340 (M.D. Fla. 2009) (same); *see also* (Tr. at 274-75; *id.* at 295-96 (Gore's counsel noting that "the issue [the Court will] need to decide is [whether] there [is] evidence of a structural or operational difference between coverings made by [a] tube extrusion process or by a film extrusion process")).

But Bard has failed to do so. Although Bard asserts that it "[has] evidence"

demonstrating that the "end products that are made [via the use of a tube and a film] are different[,]" (Tr. at 286-87, 290), the evidence to which it points either does not back up this claim or is legally irrelevant to the enablement inquiry. Specifically, in support of its assertion that "[b]ecause film coverings and extruded tubes are made in different ways, the resulting products have different properties[,]" (D.I. 302 at 5-6), Bard points to the following two categories of evidence:

- In 1993, coverings made from film could be made to thicknesses below 0.10 mm, while coverings made from extruded tubes at these dimensions were not made available in 1993 due to the difficulty in achieving uniform wall thickness, (*see id.* at 6 (citing First Calcote Decl., ex. A at ¶¶ 146-47; Second Calcote Decl., ex. A at ¶¶ 14-19; D.I. 306, exs. 3, 4)); and

- "[A]s of 1993, it is undisputed that extruded tubes and films were known and sold as distinctly different types of products with different characteristics[,]" (*id.* at 12 (citing First Calcote Decl., ex. A at ¶¶ 145-47; D.I. 306, exs. 5, 7); *see also id.* at 6 (citing D.I. 306, exs. 5, 7)).[7]

The Court will primarily focus on the latter category of evidence here. The fact that extruded tubes and films were sold as different products (with different prices) simply does not say anything about the structure and operation of tubular coverings made from those respective processes. (*See* D.I. 334 at 5 ("[T]he prices of flat sheets and tubes are irrelevant to the structure

[7] Later in its briefing, Bard also seemed to suggest that certain comments in the Court's Report and Recommendation regarding claim construction, in which the Court referred to a covering made from film as being one "type" of covering, also demonstrates that the end results are two "'distinctly different'" products. (D.I. 302 at 11-12 (citing D.I. 221 at 19, 23)) However, as Gore points out, (D.I. 334 at 6), the issue of enablement was not before the Court during the claim construction process. Therefore, these comments were not intended to (and did not) amount to a finding that claimed coverings made from film and coverings made from extruded tubes have a distinctly different structure and operation.

and operation of tubular stent coverings made from those predicate materials, and thus irrelevant to proving 'distinctly different' embodiments.")) And while Mr. Calcote states in the cited paragraphs 145-47 of his expert report that extruded tubes and films are materials with "different characteristics," the only difference cited that could even arguably go to a characteristic of the *end product* relates to thickness—that "extruded ePTFE tubes are also more difficult to fabricate at thinner dimensions because it is harder to produce a uniform wall thickness using this technique." (First Calcote Decl., ex. A at ¶ 147)[8] But even that cited difference has not been shown to bear on the relevant inquiry—an examination of the structure and operation of the end claimed covering.

For one thing, if what Mr. Calcote means to convey here is that the typical fabrication process at the time relating to extruded tubes would have *produced a covering that was thicker than 0.10 mm*, that would be irrelevant to the claimed product. As Gore points out, the argument

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[8] During oral argument, Bard's counsel also stated that coverings made from films and coverings made from extruded tubes differ in structure and operation because the former would contain a seam, while the latter would not. (Tr. at 290-91; Bard's "Summary Judgment and *Daubert* Hearing" Presentation at Section 8, Slide 24) This argument does not appear in Bard's answering brief. Even were this argument not waived, *see Montrose Med. Grp. Participating Savings Plan v. Bulger*, 243 F.3d 773, 783 (3d Cir. 2001); *Hoffmann-La Roche Inc. v. Apotex Inc.*, Civil Action No. 07-4417 (SRC)(MAS), 2013 WL 323335, at *1 (D.N.J. Jan. 25, 2013), the assertion would need to be supported by an explanation in the record of how the presence of a seam results in a distinctly different product from one that did not include a seam. But all Bard provided in the way of further explanation was attorney argument to the effect that "[i]f you have a seam, the thickness is going to be different at the seam [which is] a difference that matters with respect to what's being claimed here." (Tr. at 291) And, as is further explained below, the claims call for coverings that are less than 0.10 mm thick, so the comparison must be to embodiments that meet this thickness limitation in the first place. (*See* D.I. 334 at 6) Bard provided no record evidence regarding such a comparison. Ultimately, Bard has not sufficiently demonstrated an issue of fact as to whether the presence of the seam in the requisite covering made from film is anything other than "merely an artifact of the process"; that is, it has not provided facts to counter Gore's assertion that "there is no material difference based on the presence of absence of a seam, the coverings do the same thing." (Tr. at 297)

that coverings made from extruded tubes "would have been thicker than 0.1 mm . . . does not relate to a comparison of 'embodiments' at all—only tubular coverings less than about 0.1 mm thick are embodiments of the asserted claims." (D.I. 334 at 6) In other words, the tubular covering disclosed in the claim must meet a specific thickness limitation, whether they are made from film or extruded tubes. And so Bard must provide evidence of a difference in structure and operation between: (1) a covering made from extruded tube material that meets the thickness limitation, and (2) a covering made from film material that also meets that thickness limitation. This portion of Mr. Calcote's report does not speak to that issue.

Alternatively, this portion of Mr. Calcote's report could be (and indeed, appears to be) meant to convey how difficult it was in 1993 *to make* extruded tubes of the kind that would meet the thickness limitation of the asserted patent.[9] But this too does not go to an argument about the structure and operation of the relevant end product. *See Abbott Biotechnology Ltd. v. Centocor Ortho Biotech, Inc.*, 35 F. Supp. 3d 163, 180-81 (D. Mass. Apr. 16, 2014) ("Whether the [claimed] antibody is created by recombinant or non-recombinant means does not change the ultimate structure and function of the antibody."). Instead, it is an argument about the manufacturing process used in generating the end product, (*see, e.g.*, First Calcote Decl., ex. A at ¶ 147), and thus is really about assessing whether, at the relevant time, achieving a covering from an extruded tube that met the claimed thickness limitation would have required "undue experimentation[,]" (D.I. 334 at 5-6; s*ee also, e.g.*, D.I. 302 at 2 (Bard asserting that "a patentee cannot argue that its claims cover every embodiment, including embodiments that a person of

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[9] This topic is also what Bard's first set of evidence referenced above—that suggesting that in 1993 it was either difficult or impossible to make coverings from extruded tubes that met the thickness limitations—relates to. (*See* D.I. 302 at 6 (citing First Calcote Decl., ex. A at ¶¶ 146-47; Second Calcote Decl., ex. A at ¶¶ 14-19; D.I. 306, exs. 3, 4))

skill in the art could not practice without undue experimentation, or practice at all given technology at the time of filing, and still contend that broad claim is enabled"); *id.* at 15-17; Tr. at 276-77). Yet this "undue experimentation" inquiry is distinct from an inquiry into whether ePTFE film and extruded tube coverings with a thickness of less than 0.10 mm have differences in their "structure and operation." And where a product claim does not limit a component part to the method of making (as here), it is irrelevant whether an alternative method requires undue experimentation—since (as discussed above) only one method of making the invention need be enabled. *Cf. John Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (agreeing with the patentee that the defendant's argument that no one ever succeeded in making embodiments using two methods disclosed in the patent specification as alternatives was "legally irrelevant[,]" in light of the uncontested fact that at least one mode of making and using the invention was enabled); *see also Invitrogen*, 429 F.3d at 1070 n.15 & 1071 (finding that the patentee's teaching of one method of making the claimed invention (deletion mutation) was sufficient, where the claims were not limited by the method of achieving the mutation, and rejecting the defendant's argument that the claims were invalid for lack of enablement where they did not exclude another method (point mutation), even though that method was not disclosed in the patent and the record could not "support a contention that the disclosure, coupled with the knowledge of those skilled in the art [] in January 1987, enabled a point mutation").

In circumstances like these—where a material difference has not been demonstrated in an end product made by two different methods[10]—the method of constructing the claimed covering

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[10] In contrast to Bard's lack of evidence demonstrating a difference in end product coverings made from ePTFE films and extruded tubes, Gore cites to evidence indicating that such coverings (1) perform the same functions of directing blood flow and preventing tissue ingrowth in a stent graft, (D.I. 334 at 7 (citing D.I. 303, ex. A at 96; D.I. 335, ex. 2 at 525, 527));

using extruded tubes simply amounts to an improved mode of achieving the claimed invention that need not be enabled by the patent. *See Invitrogen*, 429 F.3d at 1071. As the Federal Circuit has explained, "where the method is immaterial to the claim, the enablement requirement simply does not require the specification to describe technological developments concerning the method by which a patented composition is made that may arise after the patent application is filed." *Amgen*, 314 F.3d at 1335 (citations omitted). Accordingly, the Court finds that Bard has failed to present evidence sufficient to raise a genuine issue of fact regarding whether Gore failed to satisfy the enablement requirement.

B. Written Description

1. Legal Standard

A patent must also contain a written description of the invention. 35 U.S.C. § 112, ¶ 1. For the written description requirement to be satisfied, the patentee must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002). The test for possession "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Compliance with the written description requirement is a question of fact, and summary judgment is proper only if no reasonable fact-finder could return a verdict for the non-moving party on the issue. *ScriptPro, LLC v. Innovation Assocs., Inc.*, 762 F.3d 1355, 1359 (Fed. Cir. 2014).

The Federal Circuit has explained that the written description requirement and the

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and (2) may be affixed in the same ways, including by thermal adhesion, (D.I. 337 at 8 (citing '892 patent, col. 7:52-61; D.I. 307, ex. 2 at 460)).

enablement requirement are distinct, but they "often rise and fall together[.]" *Ariad Pharm., Inc.*, 598 F.3d at 1352. "That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa." *LizardTech, Inc.*, 424 F.3d at 1345.

2. Analysis

Bard argues that the '892 patent fails to satisfy the written description requirement because it does not convey that the inventors had possession of any embodiment of the invention that used extruded tubes to achieve the claimed device. For the same reasons that Bard's arguments failed with respect to enablement, however, they fail with respect to the written description requirement. (*See* D.I. 230 at 20; D.I. 302 at 4, 17; D.I. 334 at 8; Tr. at 269) As explained above, it is undisputed that the inventors possessed the claimed invention, including coverings less than about 0.10 mm thick, and described embodiments of this invention in the specification. (D.I. 302 at 1, 8; D.I. 334 at 8) When a claim is directed to a product, as it is here, the written description requirement does not demand that all methods of making the product be described in the specification; instead, one way of making the product is sufficient. *See Amgen*, 314 F.3d at 1331-32 ("The written description inquiry . . . focuses on a comparison between the specification and the invention *referenced by the terms of the claim*—not comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made.") (citation omitted) (emphasis added); *see also Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 873 (Fed. Cir. 2010) (explaining that apparatus claims need not recite every method of making the claimed apparatus and finding that the claim at issue "which covers a blue noise mask that is calculated in

any way, has written description support even if it does not recite the exact method steps described in the specification or any other methods for making a blue noise mask"); *Regents of Univ. of Cal. v. Dako N. Am., Inc.*, No. C 05-03955 MHP, 2009 WL 1083446, at *10 (N.D. Cal. Apr. 22, 2009) (rejecting the defendant's written description argument and noting that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention") (citation omitted).[11]

IV. CONCLUSION

For the reasons set out above, the Court recommends that Gore's Motion be GRANTED.

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 23, 2015**. Responses are due by **November 30, 2015**. Alternatively, to the extent the parties jointly agree to complete briefing on objections and responses on a date prior to the **November 25, 2015** pre-trial conference, they should alert the Court to the agreed-upon schedule and submit their filings in accordance with that schedule. In that case, it may be possible for the District Court to resolve the objections at the pre-trial conference. If the parties do not jointly agree to such an alternative briefing schedule, the deadlines set forth above will

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[11] Gore additionally moves for summary judgment that the "less than about 0.10 mm thick" limitation is enabled and adequately described. (D.I. 230 at 14, 19) Bard asserts that the '892 patent lacks sufficient disclosures regarding how to reduce ePTFE thickness during manufacture of a stent graft because the skilled artisan would not understand where or how to measure the specified thickness or at what point during the lifespan of the device to measure it, nor would the artisan understand how to account for variation in thickness across a device or material. (D.I. 302 at 4, 20; Buller Decl., ex. A at ¶ 412) Its arguments in this regard, however, are the same as those that the Court already considered and rejected when considering Bard's Motion for Summary Judgment of Invalidity. (*See* D.I. 369 at 10-22) Therefore, the Court recommends that Gore also be granted summary judgment with respect to this version of Bard's enablement and written description defenses.

control. 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 **November 23, 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 16, 2015

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE