IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W.L. GORE & ASSOCIATES, INC.,	:	
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Plaintiff,	:	
	:	
v.	:	C.A. No. 11-515-LPS
	:	
C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.,	:	
	:	
Defendants.	:	

MEMORANDUM ORDER

WHEREAS, on November 17, 2015, Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. ("Defendants" or "Bard") filed a Motion to Strike the Supplemental Expert Report of Dr. Enrique Criado on Comparable Technologies ("Motion to Strike") (D.I. 442), arguing in their opening brief (D.I. 443) that Dr. Criado's supplemental expert report "went outside the 'limited' and 'focused' scope that Judge Burke authorized in his October 23, 2015 Memorandum Order [D.I. 411]" and additionally challenging the supplemental expert report under Rule 702 as unreliable and not fitting this case (D.I. 443 at 1);

WHEREAS, on November 24, 2015, Plaintiff W.L. Gore & Associates, Inc. ("Plaintiff" or "Gore") filed an answering brief in opposition to the Motion to Strike (D.I. 475), arguing that "Criado's supplemental report is not untimely, contains no new opinions, provides a reliable opinion on the technical comparability of the Goldfarb patent [U.S. Patent No. 5,735,892 ("'892 patent")], and works no prejudice on Bard" (*id.* at 1);

WHEREAS, the Court has considered the Motion to Strike in light of the Court's prior ruling (D.I. 474), Federal Rule of Civil Procedure 702, and all of the pertinent filings;

WHEREAS, Judge Burke issued a 9-page Report and Recommendation ("Willful Infringement Report") (D.I. 436), dated November 16, 2015, recommending that Defendants' Motion for Summary Judgment of No Willful Infringement ("Willful Infringement Motion") (D.I. 241) be denied, stating that "[t]his is one of those circumstances where it seems most prudent and appropriate to wait until the record is more fully developed at trial before coming to a conclusion as to the objective reasonableness of Bard's defenses" (D.I. 436 at 7) (internal quotation marks omitted);

WHEREAS, on November 23, 2015, Defendants objected to the Willful Infringement Report ("Defendants' Willful Infringement Objections") (D.I. 464), arguing that "Bard has actual products, microscopic photographs, and snap gauge measurements that show it does not infringe the asserted claims" and that "[t]he reasonableness of Bard's prior art invalidity defenses is illustrated by the recent report and recommendation denying-in-part Gore's motion for summary judgment of no anticipation" (*id.* at 1);

WHEREAS, on November 30, 2015, Plaintiff responded to Defendants' Willful Infringement Objections (D.I. 483), arguing that "the reasonableness of Bard's defenses is best decided after a presentation of the facts at trial, exactly as Judge Burke held" (*id.* at 2);

WHEREAS, Judge Burke issued a 20-page Report and Recommendation ("Section 112 Report") (D.I. 435), dated November 16, 2015, recommending that Plaintiff's Motion for Summary Judgment of No Invalidity Based on Non-Enablement or Insufficient Written Description ("Section 112 Motion") (D.I. 229) be granted;

WHEREAS, on November 23, 2015, Defendants objected to the Section 112 Report ("Defendants' Section 112 Objections") (D.I. 463), and specifically objected to (1) the Section

112 Report's conclusion that a reasonable jury could not find that the "tubular covering" limitation is not enabled (*id.* at 5-8), (2) the Section 112 Report's conclusion that a reasonable jury could not find that the tubular covering limitation does not comply with the written description requirement (*id.* at 8-9), and (3) the Section 112 Report's determination that there were no genuinely disputed factual issues regarding whether the "less than about 0.10 mm" limitation complies with both the enablement and written description requirements (*id.* at 9-10);

WHEREAS, on November 30, 2015, Plaintiff responded to Defendants' Section 112 Objections (D.I. 482), arguing that "Bard's objections to Judge Burke's [Section 112 Report] either articulate new and unsupported arguments that have no merit or reiterate the same arguments Judge Burke fully analyzed and rejected as being insufficient to create a material issue of fact" (*id.* at 1);

WHEREAS, the Court has considered the Section 112 Motion and the Willful Infringement Motion *de novo*,[1] *see Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 379 (D. Del. 2014); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3), and has further reviewed all of the pertinent filings;

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Defendants' Motion to Strike (D.I. 442) is GRANTED IN PART and DENIED IN PART.[2] Specifically, the motion is granted with respect to the following portions of Dr. Criado's

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[1]In doing so, the Court has applied the familiar legal standards of Federal Rule of Civil Procedure 56, which include drawing all reasonable inferences in favor of the non-moving party.

[2]In evaluating the Motion to Strike, the Court has considered several legal standards. Under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993), the Supreme Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to

Supplemental Expert Report on Comparable Technologies (D.I. 443-1) ("Supplemental Report"), and the Court hereby STRIKES these portions: (1) Dr. Criado's incorporation by reference of his previous expert reports (*see id.* at 1); (2) the "additional materials reviewed" by Dr. Criado and "attached as Exhibit B" to his Supplemental Report, and all references to such materials; (3) the phrase "and of similar importance to Bard's accused peripheral stent graft products" in the last sentence on page 2; (4) all of page 4 of the Supplemental Report below the chart; and (5) all of page 5. The motion is denied with respect to all portions not listed above.

2. In a Memorandum Order (D.I. 411) ("Stamm *Daubert* Order") addressing Defendants' *Daubert* motion to exclude opinions of Plaintiff's damages expert, Laura B. Stamm, Judge Burke permitted Plaintiff's technical expert, Dr. Enrique Criado, "one opportunity to offer

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the task at hand." Rule 702 requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Civ. P. 702(a). Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Civ. P. 702(b)-(d).

Also implicated are Federal Rule of Civil Procedure 26(a)(2)(B)(i), which requires that an expert's report contain "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as Rule 26(a)(2)(c), providing that "a party must make these [expert] disclosures at the time and in the sequence that the court orders." In determining whether a failure to disclose is harmless courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "Pennypack factors"). *See Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir.1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904–905 (3d Cir.1977)).

Additionaly, pursuant to Rule 37(c)(1), the Court has the power to exclude evidence as a sanction for a party's failure to comply with its obligations under the rules, including the specific deadlines and obligations imposed by a scheduling order – and, here, including Plaintiff's failure to keep Dr. Criado's Supplemental Report within the confines set out in Judge Burke's order.

a brief supplemental expert report ***limited to the issue of the technological comparability*** of the Goldfarb patent and [the '892 patent]." (*Id.* at 15) (emphasis added) This Court determined that Judge Burke did not abuse his discretion in providing Dr. Criado this opportunity, and the Court adopted the Stamm *Daubert* Order in all respects. (D.I. 474 at 3-4) Inherent in the Court's adoption of the Stamm *Daubert* Order is the Court's agreement with Judge Burke that, in order for Ms. Stamm's challenged opinions to "pass muster under *Daubert*," there must be a showing – disclosed in one or more of Dr. Criado's expert reports – that the claimed technologies in the Goldfarb and '892 patents are comparable.[3] (*See* D.I. 411 at 11)

3. Defendants argue that Dr. Criado's Supplemental Report went beyond the "limited" and "focused" scope that Judge Burke authorized in his Stamm *Daubert* Order. With respect to the stricken portions of the Supplemental Report listed above, the Court agrees. First, the Supplemental Report improperly incorporated by reference all of Dr. Criado's past expert reports. Dr. Criado was required to limit his Supplemental Report to articulating the precise opinions on technological comparability of the Goldfarb and '892 patents that he purportedly disclosed to Ms. Stamm ***before*** expert reports were served. (*See* D.I. 411 at 15-16) Dr. Criado's wholesale incorporation by reference of every opinion he has ever given in this case into his Supplemental Report does come within this limited scope.

4. Second, Dr. Criado improperly considered "additional materials" attached as Exhibit B to his report. Dr. Criado was not permitted to rely on these additional materials, which

[3]The record indicates that Ms. Stamm had one or more conversations with Dr. Criado regarding the technical comparability of the Goldfarb and '892 patents. (*See* D.I. 411 at 4) Defendants argued, and Judge Burke and this Court agreed, that Dr. Criado had not disclosed opinions regarding technical comparability of the Goldfarb and '892 patents in any of his expert reports.

include the opinions of another expert, Dr. Leonard. Dr. Criado was permitted simply to "set out in writing the very opinion that Ms. Stamm has been relying on all along." (*Id.*) Dr. Leonard's opinions did not exist before Dr. Criado's conversations with Ms. Stamm. (*See* D.I. 443 at 6)

5. Finally, Dr. Criado was not permitted to opine on the "comparable importance" of the Goldfarb and '892 patents by referring to (1) alleged incorporation of technology covered by the Goldfarb and/or '892 patents into various products, (2) alleged difficulty of designing around the '892 patent, or (3) licensing issues involving the Goldfarb patent. (*See generally* D.I. 443-1 at 4-5) These categories of Dr. Criado's opinions fall outside of the limited scope articulated by Judge Burke in the Stamm *Daubert* Order, because they are unrelated to a comparison of the ***technologies*** of the Goldfarb and '892 patents.

6. Regarding the portion of the Supplemental Report that the Court has not stricken, the Court determines that Defendants' arguments under Rule 702 go to the weight rather than the admissibility of Dr. Criado's opinions. Defendants argue that Dr. Criado's Supplemental Report is unreliable and does not fit this case because "he did not compare the ***claimed*** invention in Goldfarb to the ***claimed*** invention of the '892 patent." (D.I. 443 at 1) The Court disagrees. Dr. Criado explicitly discusses the claims of the Goldfarb patent in his Supplemental Report (*see* D.I. 443-1 at 3), and the admissibility of the surviving portions of his Supplemental Report does not turn on inclusion of a claim-by-claim comparison of the two patents. The surviving portions of Dr. Criado's Supplemental Report meet Rule 702's requirements for reliability and fit, because they will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Civ. P. 702(a).

7. Defendants' Willful Infringement Objections (D.I. 464) are SUSTAINED. The

Willful Infringement Report (D.I. 436) is REJECTED. Defendants' Motion for Summary Judgment of No Willful Infringement (D.I. 241) is GRANTED.

8. The Willful Infringement Report states that Defendants' invalidity and non-infringement positions "are rather fact-specific" and that the "District Court will be in the best position" to decide whether the objective prong of the willfulness inquiry is met, under *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007), "after having seen any relevant evidence presented at trial." (D.I. 436 at 6) The objective prong of the willfulness inquiry "is not met when the infringer, whatever its state of mind at the time of its infringement, presents in the litigation a defense, including an invalidity defense, that is objectively reasonable." *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 2015 WL 4639309, at *12 (Fed. Cir. Aug. 4, 2015). Here, Defendants have asserted objectively reasonable non-infringement and invalidity defenses.

9. In order to meet the objective prong under *Seagate*, Plaintiff must show "by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* at 1371. If the objective prong cannot be shown, then the Court should not put the issue of willfulness – including the second "subjective" prong – before a jury. *See Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1236 (Fed. Cir. 2011) ("Since *Seagate*, [the Federal Circuit] has required patentees to prove the objective prong of the willful infringement inquiry by clear and convincing evidence ***as a predicate to the jury's consideration of the subjective prong***. . . . Should the court determine that the infringer's reliance on a defense was not objectively reckless, ***it cannot send the question of willfulness to the jury***, since proving the objective prong is a predicate to consideration of the subjective prong.") (emphasis added).

10. Defendants' non-infringement arguments with respect to the "affixed" limitations ("exterior" and "luminal") are objectively reasonable. Regarding the "affixed" limitations, Defendants cite expert opinions analyzing scanning electron microscope photographs showing "large gaps between the ePTFE layers and the outer and luminal stent surfaces." (*See* D.I. 464 at 5) (citing D.I. 260-1 ¶ 139, App. I, J) Although Plaintiff disputes this evidence (*see* D.I. 483 at 5-7), the Court determines that Defendants' non-infringement arguments are supported by enough evidence to be objectively reasonable, even if they were generated during litigation. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1382 (Fed. Cir. 2014) (holding District Court properly considered defense developed during litigation in determining no willful infringement); *see also Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, 2015 WL 1883937, at *2 (D. Del. Apr. 23, 2015) (concluding first prong of *Seagate* could not be satisfied in light of credible, reasonable non-infringement theories).

11. At least some of Defendants' invalidity arguments are also objectively reasonable. In *Carnegie Mellon*, the Court reasoned that "there was enough uncertainty about what [a prior art reference] discloses and what CMU's claims require that we cannot say that the [invalidity] defenses were objectively unreasonable." *Id.* at *14. In this case, there was enough uncertainty about whether certain prior art references anticipated claims 32 and 33 of the '892 patent that Judge Burke recommended denial of summary judgment of no anticipation as to the references. (*See, e.g.*, D.I. 428 at 28-31) (discussing "Palmaz" reference and holding that expert opinion regarding Palmaz was "sufficiently grounded in the factual record and supported by a logical process of reasoning") The Court adopted the recommended denial of summary judgment as well as Judge Burke's reasoning with respect to the prior art references that survived the motion.

(*See* D.I. 474 at 4-6) Defendants' objectively reasonable invalidity defenses are an independent reason why Plaintiff's willfulness allegations with respect to claims 32 and 33 of the '892 patent must fail.

12. Defendants' Section 112 Objections (D.I. 463) are OVERRULED. Judge Burke's Section 112 Report (D.I. 435) is ADOPTED in all respects. Plaintiff's Motion for Summary Judgment of No Invalidity Based on Non-Enablement or Insufficient Written Description (D.I. 229) is GRANTED.

13. The Court agrees with the Section 112 Report's determination that "the method of constructing the claimed covering using extruded tubes simply amounts to an improved mode of achieving the claimed invention that need not be enabled by the patent." (D.I. 435 at 16-17) (citing *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005)) "Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise." *Invitrogen*, 429 F.3d at 1071. As such, the Court disagrees with Defendants' objection regarding lack of enablement of the "tubular covering" limitation. For similar reasons, the Court also disagrees with Defendants' objection regarding the tubular covering limitation's alleged failure to comply with the written description requirement. "[T]he 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." (D.I. 435 at 18) (citing case law supporting this proposition) Finally, the Court agrees with the Section 112 Report's statement, in footnote 11 (*id.* at 19), that the Court has "already considered and rejected" Bard's arguments regarding enablement and adequate description of the "less than about 0.10 mm thick" limitation. Therefore, the Court overrules Defendants' objection with

respect to this limitation and determines, as a matter of law, that the "less than about 0.10 mm thick" limitation is enabled and adequately described in the patent's specification in compliance with the requirements of § 112.

14. Given the detailed reasoning provided in the Section 112 Report, and given that Defendants have not raised any arguments that are not adequately addressed therein, the Court finds it unnecessary to address Defendants' Section 112 Objections any further.

15. Further, having reviewed the parties' letter of November 30, 2015 (D.I. 484), IT IS ORDERED that the asserted claims have already been found not to be invalid as indefinite and Bard will not be permitted to present evidence or argument relating to indefiniteness at the jury trial. In connection with summary judgment, the Court has already concluded that the asserted claims are not indefinite. (*See* D.I. 405 at 6-8) The Court does not agree with Bard that there is a factual dispute related to whether "the method of measurement is outcome determinative" and that this dispute must be resolved before indefiniteness can be decided. (D.I. 484 at 4) Instead, as a matter of law (i.e., as a matter of claim construction and based solely on intrinsic evidence as well as Bard's admissions), the claims are not indefinite in light of the specification of the '892 patent, which (as Bard admits) discloses at least one method for measuring thickness. (*See* D.I. 405 at 8 ("[T]he specifications of the patents-in-suit provide guidance as to how to perform the measurement at issue here."); D.I. 484 at 3 ("Bard's expert, for example, measured the thickness using a snap gauge during manufacturing and before the stent graft is collapsed into the delivery system – precisely as the patent describes."))

Bard's arguments regarding the alleged "outcome determinative" nature of the dueling experts' methodologies for measuring thickness raise issues of infringement that may be heard

and decided by the jury. An accused product may infringe at one point in time and, after manipulation of some kind, cease to infringe at another point in time. *See In re Electro-Mech. Indus.*, 359 F. App'x 160, 164 (Fed. Cir. 2009) (holding certain products infringed ***before*** "gaps" in products were "filled" but not ***after***). In this case, the "0.10 mm" limitation may be met by the accused products at certain times post-affixation but not at others. While Bard may present evidence and make arguments to this effect in the context of infringement, it may not do so in relation to indefiniteness, as the Court has resolved indefiniteness in this case.

16. In light of the Court's narrowing of the issues for trial, and having considered the parties' request for 13 hours per side, IT IS HEREBY ORDERED that the parties' trial presentations shall not exceed twelve (12) hours per side. The Court finds that the remaining issues that are the subject of the upcoming jury trial may be fairly and adequately presented in this amount of time.

Specifically, trial will be held at some or all of the following times, subject to the parties' time limits: (i) Monday, Dec. 7: 8:30 a.m. to 4:00 p.m. (no evidence will be presented this first day); (ii) Tuesday, Dec. 8 through Friday, Dec. 11: 8:30 a.m. to 5:00 p.m.; and (iii) Monday, Dec. 14: 8:30 a.m. to 5:00 p.m.

17. Finally, the parties shall SUBMIT Revised Preliminary Jury Instructions to the Court on or before Friday, December 4, taking into account the issues resolved in this Order.

December 2, 2015
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE