

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

W.L. GORE & ASSOCIATES, INC.,

Plaintiff,

v.

C.A. No. 11-515-LPS

C.R. BARD, INC., and BARD
PERIPHERAL VASCULAR, INC.,

Defendants.

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 37-page Report and Recommendation (the “Claim Construction Report”) (D.I. 221), dated August 8, 2014, recommending that the Court adopt certain claim constructions for disputed terms in U.S. Patent Nos. 5,735,892 (the “892 Patent”) and 5,700,285 (the “285 Patent”) (the “patents-in-suit”);

WHEREAS, on August 25, 2014, Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. (“Defendants”) objected to the Claim Construction Report (“Claim Construction Objections”) (D.I. 222), and specifically objected to the Claim Construction Report’s constructions of the terms “stent,” “openings,” “covering,” and “enlarged/collapsed diameter” as “inconsistent with the intrinsic evidence” (*id.* at 2);¹

WHEREAS, on September 15, 2014, Plaintiff W.L. Gore & Associates, Inc. (“Plaintiff”) responded to the Claim Construction Objections (D.I. 263), arguing that the Claim Construction Report was “a model of claim construction, carefully analyzing every aspect of the intrinsic

¹Defendants also “conditionally objected” to the Claim Construction Report’s construction of “affixing,” but later withdrew their objections with respect to this term. (*See* D.I. 367)

evidence to arrive at recommended constructions that comport with the claim language, specification, and prosecution history, as well as the prior constructions of another federal court” (*id.* at 1);

WHEREAS, the Court has considered the parties’ claim construction disputes addressed by the Claim Construction Report *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3);

WHEREAS, Judge Burke issued a 62-page Report and Recommendation (the “Motions Report”) (D.I. 369), dated June 17, 2015, recommending that (1) Defendants’ Motion for Summary Judgment of Invalidity (D.I. 235) be denied, (2) Defendants’ Motion for Summary Judgment of Non-Infringement as to the Thickness Limitation (D.I. 244) be granted in part and denied in part, and (3) Defendants’ *Daubert* Motion to Exclude Certain Testimony from Gore’s Expert Dr. Robert C. Gorman (D.I. 253) be denied;

WHEREAS, on July 8, 2015, Defendants objected to the Motions Report (“Defendants’ Motions Objections”) (D.I. 374), and specifically objected to (1) the Motions Report’s recommendation to deny Defendants’ motion for summary judgment of indefiniteness, arguing that the asserted claims failed to define “how” to measure the thickness of the covering(s), and (2) the Motions Report’s recommendation to deny Defendants’ motion to exclude testimony of Dr. Gorman, arguing that Dr. Gorman’s method of measuring the covering(s)’ thicknesses was unreliable and did not “fit” the facts of the case (*see id.* at 1-3, 5-6, 7);

WHEREAS, on July 27, 2015, Plaintiff responded to Defendants’ Motions Objections (D.I. 382), arguing that (1) the Motions Report correctly denied Defendants’ motion for summary

judgment of indefiniteness of the asserted claims, because the “0.1 mm” limitation was sufficiently definite to give notice to persons of ordinary skill in the art as to what was claimed and how to measure the thickness of the covering(s) under § 112, and (2) the Motions Report correctly denied Defendants’ motion to exclude the challenged testimony of Dr. Gorman, because Dr. Gorman’s measurement method was reliable and fit the facts of the case (*see id.* at 1-2, 10);

WHEREAS, on July 8, 2015, Plaintiff objected to the Motions Report (“Plaintiff’s Motions Objections”) (D.I. 373), and specifically sought to “correct a few specific aspects of the [Motions Report]’s claim construction determinations involving the timing of the measurements of the thickness limitations in the asserted claims,” and further objected to the Motions Report’s “recommendation to grant summary judgment of non-infringement as to the ’285 patent, a recommendation that was premised on one of the claim constructions to which Gore hereby objects” (*id.* at 1);

WHEREAS, on July 27, 2015, Defendants responded to Plaintiff’s Motions Objections (D.I. 381), arguing that the Motions Report “correctly construed the ‘thickness’ limitations of the two Gore patents-in-suit consistently with the claim language and patent specification” and that “the [Motions Report] properly granted summary judgment of non-infringement of the ’285 patent” (*id.* at 1-2);

WHEREAS, the Court has considered the two summary judgment motions addressed in the Motions Report (D.I. 235, 244) *de novo*, *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;

WHEREAS, the Court has considered the *Daubert* motion addressed in the Motions Report (D.I. 253) using a “clearly erroneous and contrary to law” standard of review, *see Masimo*, 62 F. Supp. 3d at 388; 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a),² and has further reviewed all of the pertinent filings;

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Defendants’ Claim Construction Objections (D.I. 222) are OVERRULED. Judge Burke’s Claim Construction Report (D.I. 221) is ADOPTED in all respects.

2. Defendants “object[] to the [Claim Construction Report]’s implicit interpretation excluding stents with unbounded openings.” (D.I. 222 at 3) The Claim Construction Report correctly rejected proposed constructions that would capture stents with unbounded openings, by carefully interpreting the claim language, explaining: “If the stent has a ‘multiplicity of openings’ ***through the wall***, then this suggests that the ‘openings’ in question are bounded on all sides by the structure of the stent.” (D.I. 221 at 15) (emphasis added) The Court agrees with this

²A *Daubert* motion to exclude testimony presents a non-dispositive matter, and objections to a Magistrate Judge’s recommendation on a non-dispositive motion are subject to a “clearly erroneous and contrary to law” standard of review. Under a “clearly erroneous” standard, the reviewing court will only set aside factual findings when it is “left with the definite and firm conviction that a mistake has been committed.” *Green v. Fornario*, 486 F.3d 100, 104 (3d Cir. 2007) (internal quotation marks omitted). Accordingly, it is “the responsibility of an appellate court to accept the ultimate factual determination of the fact-finder unless that determination either (1) is completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bears no rational relationship to the supportive evidentiary data.” *Giles v. Kearney*, 571 F.3d 318, 322 (3d Cir. 2009) (internal quotation marks omitted). A Magistrate Judge’s order is contrary to law “when the magistrate judge has misinterpreted or misapplied the applicable law.” *Doe v. Hartford Life & Accident Ins., Co.*, 237 F.R.D. 545, 548 (D.N.J. 2006); *see also Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, 629 F. Supp. 2d 416, 424 (D.N.J. 2009) (stating “a magistrate judge’s decision typically is entitled to deference” but “a magistrate judge’s legal conclusions on a non-dispositive motion will be reviewed *de novo*”) (internal quotation marks omitted).

analysis. Defendants' proposed constructions cannot be correct in light of the claim language and other intrinsic evidence analyzed in the Claim Construction Report. Defendants' argument that the claimed invention is required to cover certain stent embodiments disclosed in the specification (*see* D.I. 222 at 3-5) is unavailing. *See AllVoice Computing PLC v. Nuance Commc 'ns, Inc.*, 504 F.3d 1236, 1248 (Fed. Cir. 2007) (“[E]very claim need not contain every feature taught in the specification.”); *Nazomi Commc 'ns, Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005) (holding that claim may “embrac[e] different subject matter than is illustrated in the specific embodiments in the specification”).

3. Defendants argue that the “collapsed/enlarged diameter” terms refer only to minimum/maximum diameters, respectively. (D.I. 222 at 8) As the Claim Construction Report determined, however, “nothing in the claim language clearly compels the conclusion that these diameters are the minimum or maximum diameters of the stent;” rather, “the stent can transition to an enlarged diameter that is 1.5 times the collapsed diameter, or to a measurement that is greater than that.” (D.I. 221 at 33) Defendants' proposed constructions for these terms attempt to read in limitations from the specification. (*See* D.I. 222 at 8-9) This is improper where, as here, there is “no clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

4. Defendants object to the Claim Construction Report's construction of “covering” and argue that this term should be limited to a “film.” (*See* D.I. 222 at 9-10) The Court agrees with Plaintiff that all of Defendants' arguments with respect to this term were properly addressed and rejected in the Claim Construction Report. (*See* D.I. 263 at 8-10) Defendants' proposed

construction contradicts the claim language, improperly attempts to read in a limitation from the specification, and is not buttressed by the specification's characterization of the "present invention." In addition, the Claim Construction Report properly rejected Defendants' extrinsic evidence of statements made during prosecution of a foreign patent application. (See D.I. 221 at 25-26) (citing authority against reliance on foreign prosecution evidence for claim construction)

5. Given the detailed reasoning provided in the Claim Construction Report, and given that the parties have not raised any arguments that are not adequately addressed therein, the Court finds it unnecessary to address Defendants' Claim Construction Objections (D.I. 222) any further.

6. Defendants' Motions Objections (D.I. 374) are OVERRULED. Judge Burke's Motions Report (D.I. 369) is ADOPTED with respect to (1) Defendants' Motion for Summary Judgment of Invalidity (D.I. 235) and (2) Defendants' *Daubert* Motion to Exclude Certain Testimony from Gore's Expert Dr. Robert C. Gorman (D.I. 235). Accordingly, Defendants' Motion for Summary Judgment of Invalidity (D.I. 235) is DENIED and Defendants' *Daubert* Motion directed at Dr. Gorman (D.I. 253) is DENIED.

7. Regarding Defendants' Motion for Summary Judgment of Invalidity (D.I. 235), the Court concludes that the Motions Report properly applied the Supreme Court's standard for indefiniteness articulated in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2125 (2014). Specifically, the Court finds that Defendants have failed to produce clear and convincing evidence that the asserted claims are indefinite in light of the existence of multiple methods of measuring thickness of the covering(s). Defendants' arguments with respect to *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1367 n.4 (Fed. Cir. 2014), *cert. denied*, 135 S.

Ct. 711 (2014), are inapposite, because the choice of expert methods in the instant case is not necessarily “outcome-determinative.” *Takeda* stands for the proposition that when – as here – “no extensive manipulation of the samples is required prior to measurement” and – also as here – the party arguing indefiniteness has not presented clear and convincing evidence that the method of measurement is in fact outcome-determinative, there is no indefiniteness. The Court agrees with Plaintiff that “both parties dispute whether the other’s expert correctly *applied* their chosen methods” rather than disputing whether the methods “necessarily and systematically lead to different results.” (See D.I. 382 at 8-9) (emphasis in original)

8. Defendants’ citation to *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1337 (Fed. Cir. 2015), is also unavailing. Defendants argue that “the Federal Circuit found claims indefinite [in *Teva*] under circumstances similar to that presented here: there were three possible methods of measuring a claim limitation, and each ended up with significantly different results.” (D.I. 374 at 7) In *Teva*, however, the indefiniteness issue was more fundamental than merely having three potential *methods* for measuring a single measurement. Instead, there were “three different *measures* of molecular weight,” i.e., there were three different types of measurements, whereas only one type of measurement is at issue here: the thickness of the covering(s). See *Teva*, 789 F.3d at 1344 (“To summarize, it is undisputed that ‘molecular weight’ or average molecular weight can be ascertained by any of three possible measures: M_p , M_n , and M_w . The claims do not indicate which measure to use.”). Therefore, *Teva* is not sufficiently analogous to the instant case to compel adoption of Defendants’ position.

9. Defendants submitted a Notice of Supplemental Authority in support of their motion for summary judgment of indefiniteness, notifying the Court of the Federal Circuit’s

recent decision in *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 2015 WL 5060947, at *1 (Fed. Cir. Aug. 28, 2015). The Court asked the parties to submit letter briefs regarding the relevance, or lack thereof, of *Dow* to the instant case (*see* D.I. 390), and the parties did so (*see* D.I. 391, 392, 394, 395). Having reviewed *Dow* and the parties' letters, the Court agrees with Plaintiff that *Dow* is inapposite for at least the reasons discussed in Plaintiff's letter of September 10, 2015. (D.I. 392) Specifically, the instant case does not involve an abstract and undefined claim limitation, as in *Dow*. To the contrary, a thickness of 0.1 mm is clear, as the Motions Report articulated. (*See generally* D.I. 369 at 10-29) In addition, Defendants have not shown any method-driven differences in the results in this case, in contrast to *Dow*, and the specifications of the patents-in-suit provide guidance as to how to perform the measurement at issue here. (*See* D.I. 392 at 2-3)

10. Regarding Defendants' *Daubert* Motion to Exclude Certain Testimony from Gore's Expert Dr. Robert C. Gorman (D.I. 253), the Court finds that Defendants' arguments go to the weight, rather than the admissibility, of Dr. Gorman's testimony. The Court agrees with the Motions Report's legal reasoning regarding this motion and does not find any of the factual findings relevant to this motion to be clearly erroneous. (*See generally* D.I. 369 at 50-61) In particular, the Court views as significant the fact that Dr. Gorman used a micrometer to perform his thickness measurements, a device which *Defendants' own expert* admitted was a "suitable" option for "measur[ing] thickness." (*See* D.I. 369 at 54)

11. Plaintiff's Motions Objections (D.I. 373) are SUSTAINED IN PART and OVERRULED IN PART. Judge Burke's Motions Report (D.I. 369) is ADOPTED IN PART and REJECTED IN PART with respect to Defendants' Motion for Summary Judgment of Non-

Infringement as to the Thickness Limitation (D.I. 244). Specifically, Judge Burke's Motions Report is adopted in all respects EXCEPT with regard to the conclusion that the "thickness limitation" of the '892 patent is restricted to the time period after affixing but before collapsing.³ Accordingly, Defendants' Motion for Summary Judgment with respect to non-infringement (D.I. 244) is GRANTED IN PART and DENIED IN PART.

12. Plaintiff argues that the Motions Report incorrectly construed the thickness limitation in the '892 patent to require measurement after affixation but before collapsing. (D.I. 373 at 3-5) First, Plaintiff argues that this requirement contradicts Federal Circuit precedent which holds that apparatus claims are infringed "any time" that "all of the claim limitations are present in an accused structure." (*See id.* at 4) (citing *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1558 (Fed. Cir. 1995))⁴ Second, Plaintiff argues that the Motions Report reads in limitations from the specification without any analysis of the relevant claim language, and despite the fact that there is no "express definition or disavowal" of claim scope. (D.I. 373 at 4-5) (citing *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)) The Court agrees with Plaintiff's arguments, as the Court finds no indication in the claim language that such a temporal restriction should be read into the claim and finds no clear

³The primary portion of the Motions Report that contains Judge Burke's analysis on this point is found at pages 37-38 (starting with the paragraph beginning with "Turning back . . ." on page 37 and ending at the second-to-last line on page 38). To the extent this conclusion is reflected in other sections of the Motions Report, however, it is rejected in such other sections as well.

⁴Defendants contend that Plaintiff "failed to raise this argument in its briefing [before Magistrate Judge Burke], and accordingly has waived it." (D.I. 381 at 7) The Court disagrees because the parties did not address this issue at all in their motion briefing. (*See generally* D.I. 248, 291, 341) Instead, Judge Burke independently raised this issue as part of his claim construction.

disavowal of claim scope or definition that would require limitations to be read into the claims from the specification.

13. Plaintiff's remaining objections challenge (1) the Motions Report's construction of the thickness limitation in claim 15 of the '285 patent as being directed to a time before affixation and (2) Judge Burke's judgement of non-infringement, based, in part, on this construction. These objections are overruled.

14. Plaintiff challenges the Motions Report's construction of the thickness limitation in claim 15 of the '285 patent, arguing that the limitation does not require measurement prior to affixation. The construction set forth in the Motions Report is correctly tethered to the claim language and intrinsic evidence of the '285 patent. Specifically, the Court agrees with the following analysis of claim 15:

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

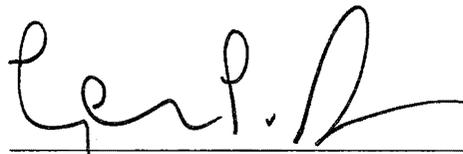
In light of the above analysis, Plaintiff's objection to this construction is overruled.

15. Plaintiff argues that, “even if the Court adopts the [Motions Report]'s pre-affixation construction for the '285 patent, Bard's summary judgment motion should still be denied.” (D.I. 373 at 9) The Court disagrees. Plaintiff's cited evidence is not enough to create a genuine issue of material fact in light of the entire record as discussed in the Motions Report. (See D.I. 369 at 39-42) Therefore, Plaintiff's objection to Judge Burke's recommendation to

grant summary judgment of non-infringement of the '285 patent is overruled.

IT IS FURTHER ORDERED that because this Memorandum Order is filed under seal, the parties shall meet and confer and shall, no later than October 1, 2015, submit a proposed redacted version. Thereafter, the Court will issue a public version of this Memorandum Order.

September 28, 2015
Wilmington, Delaware

A handwritten signature in black ink, appearing to read "L.P. Stark", written over a horizontal line.

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE