

**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.)	

MEMORANDUM ORDER

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 now alleges infringement of United States Patent Nos. 5,735,892 (the “892 Patent”) and 5,700,285 (the “285 Patent”) (the “asserted patents” or the “patents-in-suit”). Presently before the Court is Plaintiff’s *Daubert* motion (“Motion”) to exclude certain opinions and testimony of Defendants’ damages expert, Dr. Gregory Leonard. (D.I. 231)¹ For the following reasons, the Court DENIES the Motion.

I. BACKGROUND

A. Factual Background

In this case, Gore alleges that two of Bard’s stent-graft products, the FLUENCY® Plus Tracheobronchial Stent Graft (“Fluency Plus”) and the FLAIR® Endovascular Stent Graft (“Flair”), infringe certain claims of the patents-in-suit. Stent-grafts like these accused products

¹ Under the circumstances here, the resolution of this *Daubert* Motion is properly treated as non-dispositive, and is resolved by the Court pursuant to 28 U.S.C. § 636(b)(1)(A) and D. Del. LR 72.1(a)(2). See, e.g., *Withrow v. Spears*, 967 F. Supp. 2d 982, 987 n.1 (D. Del. 2013) (citing cases).

are used in at least two broad areas: for performing arteriovenous access (“AV access”) and in the treatment of peripheral vascular diseases. (D.I. 234, ex. 33 (“Leonard Rep.”) at ¶¶ 13, 19)² In addition to Bard, the suppliers of stent-grafts used in these applications in the United States are Gore (with its Viabahn® stent-graft), Atrium Medical (with its iCast® stent-graft) and Boston Scientific (with its Wallgraft® stent-graft). (*Id.* at ¶ 19)

On February 28, 2014, Gore’s damages expert, Laura Stamm, provided an expert report (“Stamm Opening Report”) that, *inter alia*, attempted to quantify the amount of lost profits damages that Gore was entitled to as a result of Bard’s alleged infringement. (D.I. 233, ex. A (“Stamm Opening Rep.”)) In doing so, she subdivided the market for stent-grafts into two segments: the AV access segment and an “All Other” segment (capturing stent-grafts used in all other procedures). (*Id.* at ¶¶ 102, 110) As to the AV access segment, Ms. Stamm concluded that Bard’s accused products and Gore’s Viabahn product competed for nearly all stent-graft sales—such that in the absence of the accused products, customers would have purchased Gore’s Viabahn product in the vast majority of cases (and the Wallgraft product in the few remaining cases). (*Id.* at ¶ 109) In the “All Other” segment, Ms. Stamm determined that, were Bard’s Fluency Plus product not to have been on the market, the Viabahn, iCast and Wallgraft products would all have competed for those sales. (*Id.* at ¶ 114) She suggested that a reasonable method to estimate how those sales would have been apportioned across these products was to rely on market share data as to those products. (*Id.*) As part of her analysis, Ms. Stamm concluded that,

² AV access refers to one of the methods of gaining vascular access (and associated procedures) for patients with end-stage renal disease whose kidneys do not function adequately. (Leonard Rep. at ¶ 15) Peripheral vascular disease is a reference to disorders outside of the brain and heart that affect the blood vessels. (*Id.* at ¶ 14)

were Bard's accused products not available to a physician who otherwise would have used them to treat a patient, the physician would not have used other non-stent-graft treatment options, such as angioplasty, bare metal stents, and surgical revision (collectively, "alternative treatments"). (*Id.* at ¶ 95; D.I. 298, ex. 2 at 117; *see also* Leonard Rep. at ¶ 62) In total, she placed Gore's lost profit damages for the relevant periods (as to Bard's United States-based sales alone) at just over \$171.8 million. (Stamm Opening Rep. at ¶ 159)

On March 28, 2014, Dr. Leonard authored an expert report responsive to the Stamm Opening Report. (Leonard Rep.) In it, he disagreed with Ms. Stamm's premise that the accused products in fact competed with Gore's Viabahn product. Instead, citing to certain evidence of record, Dr. Leonard asserted that in the absence of the accused products, many physicians would have turned to one of the alternative treatments—not to Gore's product. (*Id.* at ¶¶ 34-35, 63-64, 69)

In his report, Dr. Leonard wrote that Ms. Stamm's "assumption that the accused Bard sales would go to the other stent graft products in proportion to their shares of the stent graft segment, with none of the sales going to alternative treatments, is tantamount to assuming a particular economic model of demand called a logit model, with the further assumption that there are no treatment options beyond stent grafts." (*Id.* at ¶ 72) Dr. Leonard went on to write that he had "conducted a further test of Ms. Stamm's assumption" by generalizing her "assumed logit demand model to include the possibility that a doctor might choose an alternative form of treatment[.]" (*Id.*) Then he "calibrate[d] the generalized model to the economic facts of the case, namely the shares and profit margins of the suppliers." (*Id.*) Ultimately, he determined that the "calibrated parameters of the generalized model" were a "better fit to the actual market data"

than were Ms. Stamm's calculations. (*Id.* at ¶¶ 72, 78) After thus having "generalized the model that Ms. Stamm [was] already using[,]" Dr. Leonard concluded that, were lost profits even attainable in the case (and he does not agree that they are) and were both of Bard's accused products unavailable, Gore would have captured just 4.6% of Bard's United States accused product sales in the AV Access market and just 15.2% of such sales in the "All Other" segment; in total, he placed lost profits damages related to Bard's United States sales at just under \$15 million. (*Id.* at ¶ 78 & ex. 2a)³

In his report, Dr. Leonard does not further describe what a "logit model" (also known as a "nested logit model") is, or how he performed the "generaliz[ations]" or "calibrat[ions]" of Ms. Stamm's model that are described in his report. In her Reply Expert Report, however, Ms. Stamm explained what a nested logit model is:

In a nested logit model, products are grouped into 'nests' based on the way in which consumers are perceived to choose among the products. Products that are thought to be close substitutes are typically grouped together in a nest. Once a consumer chooses a particular nest over the alternatives, he or she then chooses which product within the nest to purchase.

(D.I. 233, ex. B ("Stamm Reply Rep.") at ¶ 48; *see also* D.I. 297 at 3 (Bard noting that a "nested logit analysis is a statistical econometrics model that determines probabilities of consumer choice among alternatives"))

When Dr. Leonard was later deposed, he explained that in preparing his expert report, he ran three different versions of nested logit models, grouping three categories of alternative

³ Dr. Leonard also used the same model to determine the amount of Bard sales that Gore would have captured assuming only one of Flair or Fluency Plus were unavailable during the applicable damages period. (Leonard Rep. at ¶¶ 80-84 & exs. 4-5) These calculations resulted in significantly lower estimates of lost profits damages. (*Id.*)

products (Bard stent grafts, Gore stent grafts and alternative treatments) in various ways. (D.I. 234, ex. 32 (“Leonard Dep.”) at 205) Each version produced different results for the AV access and “All Other” segments. Dr. Leonard selected the 4.6% figure for the AV access market from the results of the second equation, and selected the 15.2% figure for the “All Other” segment from the results of the first equation; he did not use the other results from those equations, deeming them to be “nonsensical results” or not a good “fit” to the data. (Leonard Dep. at 204-07; D.I. 232 at 6) He did not utilize any results from his third equation, also deeming those results “just not a good fit to the data[.]” (Leonard Dep. at 205).

In discovery, in order to demonstrate the “specifics of what [Dr. Leonard] did” in utilizing these equations, Bard produced to Gore certain “backup materials” that Dr. Leonard used. (Leonard Dep. at 140-45) Among these were “STATA computer subroutines, resource files and directory structure necessary for duplicating the statistical analyses contained in Dr. Leonard’s report.” (D.I. 234, ex. 37; *see also* D.I. 232 at 7)

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. 332) A 10-day trial is set to begin on December 7, 2015. (D.I. 362)

II. DISCUSSION

With its Motion, Gore asks that Dr. Leonard be precluded from offering testimony quantifying Gore’s lost profits, as the basis for such testimony would be drawn from Dr.

Leonard's challenged nested logit calculations. (D.I. 232 at 17) Gore makes two arguments in support of its request: (1) Bard violated Federal Rule of Civil Procedure 26 by failing to timely disclose "crucial details" of Dr. Leonard's nested logic analysis, such that his testimony should be excluded pursuant to Federal Rule of Civil Procedure 37, (*id.* at 10-13); and (2) Dr. Leonard's analysis is insufficiently reliable and does not "fit" the facts of the case, such that it should be excluded under Federal Rule of Evidence 702, (*id.* at 13-17). The Court will take up these issues in turn.

A. Rule 26

1. Legal Standard

The Federal Rules of Civil Procedure require a testifying expert to prepare and sign a written report containing, *inter alia*, "a complete statement of all opinions the witness will express and the basis and reasons for them . . . at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(B)(i) & (a)(2)(D). "If a party fails to provide information or identify a witness [in the manner required by the Court under Rule 26], the party is not allowed to use that information or witness . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).⁴ If an expert report is stricken, that action effectively precludes the expert from testifying as to the subject matter and opinions contained in the report. *See, e.g., Kenexa Brassring, Inc. v. Taleo Corp.*, 751 F. Supp. 2d 735, 759 (D. Del. 2010); *Inline*

⁴ District courts in the Third Circuit have determined that the non-moving party, i.e., the party that failed to make the required disclosure, bears the "burden of proving substantial justification for its conduct or that the failure to produce was harmless." *Vaskas v. Kenworth Truch Co.*, Civil Action No. 3:10-CV-1024, 2013 WL 1207963, at *3 (M.D. Pa. Mar. 25, 2013) (quoting *Tolerico v. Home Depot*, 205 F.R.D. 169, 175 (M.D. Pa. 2002)); *see also M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, Civil Action No. 97-1568-(JAG), 2007 WL 979854, at *12 n.12 (D.N.J. Mar. 30, 2007).

Connection Corp. v. AOL Time Warner Inc., 472 F. Supp. 2d 604, 615 (D. Del. 2007).

Although the Federal Rules clearly contemplate the exclusion of untimely or improper expert disclosures (and the concomitant exclusion of expert testimony), the Third Circuit has cautioned that because “[t]he exclusion of critical evidence is an extreme sanction,” it should not be imposed where an untimely or improper expert disclosure amounts to only a “slight deviation from pre-trial notice requirements” or occasions only “slight prejudice” to the movant. *In re Paoli R.R. Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks and citations omitted). Instead, the remedy of exclusion should be reserved for circumstances amounting to “willful deception or flagrant disregard of a court order by the proponent of the evidence.” *Id.* at 792 (internal quotation marks and citations omitted); *see also Bridgestone Sports Co., Ltd. v. Acushnet Co.*, No. CIVA 05-132 JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (noting that while the decision to exclude expert testimony is context-specific, “evidence should be excluded sparingly and only in circumstances involving litigation conduct that is clearly unprofessional or inappropriate, and in circumstances creating prejudice to the party against whom the evidence is offered”). Although district courts tend to err on the side of admitting expert testimony in such cases, this Court has noted that such testimony may be excluded in order to protect against the “flouting of discovery deadlines,” so as to maintain “fidelity to the constraints of Scheduling Orders and deadlines[, which] is critical to the Court’s case management responsibilities.” *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 463 (D. Del. 2005) (internal quotation marks and citation omitted), *rev’d on other grounds*, 543 F.3d 1306 (Fed. Cir. 2008).

In considering whether to exclude an untimely or otherwise improper expert disclosure,

the Third Circuit has directed district courts to weigh certain factors: (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply with the court's order; (5) the explanation for the failure to disclose; and (6) the importance of the testimony sought to be excluded. *See Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904–05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985); *see also Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997). Although these factors are sometimes articulated in slightly different ways, they are generally referred to as “the Pennypack factors.” *See, e.g., Paoli*, 35 F.3d at 792.

2. Analysis

As noted above, Gore asserts that Bard violated Rule 26 by failing to timely disclose key details regarding Dr. Leonard's nested logic analysis. (D.I. 232 at 10) As such, it argues that his testimony should be excluded pursuant to Rule 37. (*Id.* at 10-13)

As an initial matter, the Court has sympathy for Bard's assertion that “Gore's [Rule 26] argument comes too late and is waived.” (D.I. 297 at 15) Dr. Leonard's expert report was submitted on March 28, 2014. On April 2, 2014, Gore asked for documentation regarding statistical models on which, *inter alia*, Dr. Leonard's nested logit analysis was based; Bard provided that information on April 7, 2014. (D.I. 234, ex. 37) And yet—despite assertedly having qualms about the lack of completeness of Dr. Leonard's disclosures—Gore apparently did not seek additional documentation from Bard, either prior to or after Dr. Leonard's June 24, 2014 deposition. (Leonard Dep.) It did not seek such materials via motion practice, nor did it file a

Rule 26 motion during this time frame. Expert discovery closed on June 30, 2014, but Gore did not further press the issue then. Instead, it waited three more months to bring its request for exclusion under Rule 26, embedding that request in its *Daubert* Motion, which was filed on September 11, 2014. (D.I. 232) That September 11 deadline was reserved in the applicable scheduling order only for the filing of “motions for summary judgment and objections to expert testimony pursuant to *Daubert*[.]” (D.I. 225) A Rule 26 motion is neither of those.

Some courts have found that when a party delays the filing of a Rule 26 motion in this manner, it has waived its right to object to the sufficiency of an expert report. *See, e.g., White Elec. Servs., Inc. v. Franke Food Serv. Sys., Inc.*, No. 09-CV-504-CVE-PJC, 2010 WL 3368541, at *3 (N.D. Okla. Aug. 24, 2010) (finding that by waiting to file a Rule 26 motion until more than five months after the receipt of allegedly deficient expert materials, and doing so after the discovery cutoff period had passed, a party had waived any objection to the completeness of such materials); *Richman v. Sheahan*, 415 F. Supp. 2d 929, 940 (N.D. Ill. Feb. 23, 2006) (finding a four-month delay in challenging an expert report’s contents pursuant to Rule 26 to amount to waiver). The Court is unsure that the concept of waiver (i.e., the intentional relinquishment of a known right or privilege) is apt here. But even if waiver is not the right lens through which to view the issue, and even if Gore’s motion is not untimely pursuant to the Scheduling Order, at a minimum, Gore’s delay in raising the Rule 26 issue “seriously undermines” its contention that there was a lack of disclosure here that has caused it prejudice. *Emerson Elec. Co. v. Suzhou Cleve Elec. Appliance Co., Ltd.*, No. 4:13-CV-01043 SPM, 2015 WL 2176964, at *4 (E.D. Miss. May 8, 2015); *see also White*, 2010 WL 3368541, at *3 (noting that such delay was “strong evidence that [the moving party] felt the information provided was sufficient”). Had a lack of

disclosure truly hampered Gore's discovery efforts, or its ability to understand the nature of Dr. Leonard's anticipated trial testimony, surely Gore would have raised its voice earlier.

Turning to the merits of Gore's Rule 26 motion, the Court is unpersuaded that, as to his nested logit analysis, Dr. Leonard failed to provide "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" Fed. R. Civ. P. 26(a)(2)(B)(i). The Committee Note regarding this portion of the Rule explains that the Rule's requirements are intended to allow "opposing parties [] a reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses." *Walsh v. Chez*, 583 F.3d 990, 993 (7th Cir. 2009) (quoting Fed. R. Civ. P. 26, 1993 Comm. Note, para. (2)).

To be sure, Dr. Leonard's report itself said very little about the particular inputs and outputs he used in his nested logit analysis, or about exactly how he made his nested logit calculations. And, as Gore notes, what the report does say about the "generaliz[ations]" or "calibrat[ions]" involved in this analysis lacks specificity. (D.I. 232 at 12)

But Rule 26(a)(2) does not require that an expert's report contain or be accompanied in the first instance by all of the working notes that underlie its conclusions; nor does the Rule suggest that a report is necessarily incomplete unless it contains all information an opposing expert would need to precisely replicate the methods used therein. *See Gillespie v. Sears, Roebuck & Co.*, 386 F.3d 21, 35 (1st Cir. 2004); *Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1121-22 (D. Col. 2006); *In re Xerox Corp. Sec. Litig.*, 746 F. Supp. 2d 402, 414 (D. Conn. 2010). And in any event, just days after Dr. Leonard's expert report was filed, Bard *did* disclose the spreadsheets, exhibits, appendices and computer data reflective of how Dr. Leonard made his nested logit calculations. (D.I. 234, ex. 37; *see also* D.I. 297 at 12)

Gore complains that these submissions were nevertheless insufficient because the data it received setting out Dr. Leonard's calculations was contained in "programming code" and was not "written in English[.]" (D.I. 232 at 11; *see also* D.I. 332 at 5-6) But the Court is unaware of a *per se* rule that data contained in computer code cannot be used to help a party meet its obligations under Rule 26. And the record is clear that this data *was* understandable—and ultimately sufficient to give Gore's attorneys "a reasonable opportunity to prepare" for Dr. Leonard's deposition, for cross-examination at trial, and to arrange for competing expert testimony. As Bard notes, (D.I. 297 at 12-13), this is best demonstrated by Ms. Stamm's Reply Expert Report. In that report—filed roughly two months prior to Dr. Leonard's deposition— Ms. Stamm cogently explains, in significant detail: (1) the various inputs that Dr. Leonard used in his calculations; (2) information that Dr. Leonard did not include in those calculations; (3) various "problems" (such as an alleged "mistake" in an equation, or an allegedly false assumption Dr. Leonard made as to the pricing of stent-grafts) that she identified in Dr. Leonard's models; and (4) why certain portions of those models produced "nonsensical" or "implausible" results from her perspective, or why they conflict with the evidence of record. (Stamm Reply Rep. at ¶¶ 49-54) Ms. Stamm even explained how, after reviewing Dr. Leonard's data, she was able to "replicate[]" Dr. Leonard's models and make "correct[ions]" to the perceived flaws. (*Id.* at ¶ 51; *see also* D.I. 298, ex. 2 at 234)⁵; *see also* *Cook.*, 580 F. Supp. 2d at 1122 (finding that the fact that the challenged expert's report was sufficient to allow the moving party's expert to prepare a "lengthy rebuttal report analyzing and critiquing [the non-movant's expert's] methodology"

⁵ Indeed, it is a credit to Ms. Stamm that, of the entire record before the Court as to this Motion, she provides by far the most clear explanation of what a nested logit model is, how she and Dr. Leonard utilized such a model, and what results those models produced.

militated in favor of denial of the movant's Rule 26 motion).

Lastly, even if Bard's combined disclosures regarding Dr. Leonard's testimony were violative of Rule 26, Gore wholly fails to address the *Pennypack* factors. Thus, it never explains why those factors would suggest that outright exclusion of Dr. Leonard's testimony is the right result here. One of those factors, for example, asks whether there was the opportunity for Gore to cure any such prejudice. *Pennypack*, 559 F.2d at 904. And here, Gore did have the opportunity to fully depose Dr. Leonard about, *inter alia*, his nested logit analysis.⁶ Other of the *Pennypack* factors—such as those focusing on whether allowing the testimony would disrupt the order and efficiency of trial (it does not appear that it would), or whether there is evidence of bad faith or willfulness on Bard's part (it does not appear that there is), or whether the testimony at issue is important (it surely is to Bard's ability to combat Gore's lost profits arguments)—all militate against striking the testimony. In the end, Gore's failure to build a credible case that the *Pennypack* factors favor striking Dr. Leonard's testimony would doom its Rule 26 motion, even were the motion otherwise well taken (which it is not).

B. Rule 702

⁶ It is clear from the briefing that the instant Motion was prompted in part by the fact that, during this deposition, Dr. Leonard's answers were at times elliptical, and occasionally (particularly when speaking about his counterpart, Ms. Stamm) strikingly rude. (*See, e.g.*, Leonard Dep. at 135 (Dr. Leonard stating to Gore's attorney: "Let me just point out something to you here. You are wasting your time because the real difficulty here is that your witness or expert or whatever you want to call her does not have the slightest clue about what's going on here"); *id.* at 179 (Dr. Leonard referring to Ms. Stamm and stating "[s]he has no idea what she is doing at all in this area.")). But the deposition did also produce substantive answers regarding how Dr. Leonard's nested logit model worked, and how he used that model in his damages calculations. (D.I. 297 at 14 (citations omitted)). To the extent that Dr. Leonard's deposition testimony at times lacked clarity or was off-putting, were such testimony replicated at trial, the Court agrees that this could affect Bard's ability to effectively make its damages case. But these are not reasons to strike the testimony pursuant to Rules 26 and 37.

1. Legal Standard

Rule 702 governs the admissibility of qualified expert testimony, providing that an expert witness may testify if: “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702. Rule 702’s requirements have been examined in detail by the Supreme Court of the United States in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and have been said to embody “three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *see also B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010).⁷ As to this Motion, the parties dispute only the reliability and “fit” of the expert testimony at issue.

With regard to the requirement of reliability, Rule 702 mandates that the relevant expert testimony “must be supported by appropriate validation—*i.e.*, ‘good grounds,’ based on what is known.” *Daubert*, 509 U.S. at 590; *see also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). The information provided by experts should be “ground[ed] in the methods and procedures of science” and be “more than subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 590; *see also Schneider*, 320 F.3d at 404.⁸ In examining this

⁷ In applying Rule 702 to a patent action, the Court will look to the law of the regional circuit. *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1371 (Fed. Cir. 2015).

⁸ The Supreme Court later held in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), that the obligations imposed by *Daubert* extended to not only scientific expert

requirement, a court's focus must be on "principles and methodology" rather than on the conclusions generated by the expert. *Daubert*, 509 U.S. at 595; *see also Daddio v. Nemours Found.*, 399 F. App'x 711, 713 (3d Cir. 2010).

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

Overall, "Rule 702 embodies a 'liberal policy of admissibility.'" *B. Braun Melsungen AG*, 749 F. Supp. 2d at 222 (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008)). Nonetheless, the burden is placed on the party offering expert testimony to show that it meets each of the standards for admissibility. *Id.* (citing *Daubert*, 509 U.S. at 592 n.10).⁹

testimony but rather to all expert testimony. *Kumho Tire Co.*, 526 U.S. at 147.

⁹ Although Bard requested oral argument on its pending motions, (which the Court held), (D.I. 343), neither party sought an evidentiary hearing as to this *Daubert* Motion or suggested that the factual record was insufficiently developed such that a hearing of that type was required. The Third Circuit has held that a trial court need not conduct an evidentiary hearing on a *Daubert* challenge if the record is sufficient to allow the Court to make a determination on the issues in dispute. *See, e.g., Oddi v. Ford Motor Co.*, 234 F.3d 136, 151-55 (3d Cir. 2000); *Maldonado v. Walmart Store No. 2141*, Civil Action No. 08-3458, 2011 WL 1790840, at *13 n.10 (E.D. Pa. May 10, 2011). Here, Dr. Leonard's expert report was provided to the Court, as was his deposition testimony regarding that report. The parties also ably addressed issues relating to Dr. Leonard's report in their briefing. In light of this, the Court has determined that the record before it is sufficient to allow for a decision on the admissibility of Dr. Leonard's

2. Analysis

The Court will first address Gore's argument as to Rule 702's reliability requirement. Here, the Third Circuit has listed a multitude of factors deemed important in assessing the reliability of an expert opinion, including: "(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put." *Paoli*, 35 F.3d at 742 n.8.

Gore did not specifically address any of these factors in its briefing. Instead, it admits that its Rule 702 reliability argument is really a re-packaged version of its Rule 26 disclosure argument. (D.I. 232 at 15 (arguing that Dr. Leonard's nested logit testimony is insufficiently reliable under Rule 702 "for all of the same reasons" as to why the testimony should be excluded under Rule 26 and Rule 37)). Put differently, Gore argues that because Dr. Leonard did not disclose enough information for it to determine how his "nested logit model works" or "how he applied his nested logit equations" to the facts here, then permitting his testimony would be akin to allowing such testimony to "spring from a 'black box[,] [which] is not permitted [by Rule 702]." (D.I. 332 at 3 (quoting *GPNE Corp. v. Apple, Inc.*, No.: 12-CV-02885-LHK, 2014 WL 1494247, at *4 (N.D. Cal. Apr. 16, 2014))

testimony under *Daubert*. See, e.g., *Furlan v. Schindler Elevator Corp.*, 516 F. App'x 201, 205-06 (3d Cir. 2013); *Oddi*, 234 F.3d at 151-55; *Maldonado*, 2011 WL 1790840, at *13 n.10.

This argument fails for some of the same reasons that Gore's Rule 26 argument was unsuccessful. Dr. Leonard's nested logit data and calculations were sufficiently clear, after all, to enable Gore and its expert Ms. Stamm to: (1) analyze those calculations in detail; (2) understand the inputs that were used (relating to market share, profit margin, and the share of alternative treatment options) and those that were allegedly not used (such as product attributes, treatment prices, and margin information for alternative treatments); (3) point out perceived flaws in the models; and (4) reconstruct Dr. Leonard's calculations. (Stamm Reply Rep. at ¶¶ 49-50) That kind of clarity does not gibe with Gore's "black box" argument.

Moreover, Bard does address some of the factors that the Third Circuit has taken into account in the reliability analysis. For example, Bard articulates how nested logit models have been used as a generally accepted method of quantifying consumer demand among differentiated products. (D.I. 297 at 8-9 & n.5-13 (citing D.I. 298, exs. 3-10)) Indeed, Bard points out that Ms. Stamm used just such a model (a "modified" version of Dr. Leonard's model) in this case, in order to demonstrate why her own calculations as to lost profits were correct. (*See* D.I. 298, ex. 2 at 230-36; Stamm Reply Rep. at ¶ 51; *see also* D.I. 298, ex. 2 at 234-35 (Ms. Stamm testifying that "I constructed a nest[ed] logit model that takes into account price"))

Ultimately, to the extent that Gore quarrels with certain factual assumptions embedded in Dr. Leonard's model (such as whether the record indicates that alternative treatment options had similar advantages to the use of the patented stent-graft technology at issue in this case), (*see* Stamm Reply Rep. at ¶ 45), those disputes go to the weight that the expert's testimony should be given. They do not persuade the Court, on this record, that the method used by Dr. Leonard is inherently unreliable.

Nor do Gore's arguments as to "fit" fare any better. As previously noted, *see supra* n.6, Dr. Leonard's articulation of how he conducted his nested logit analysis could certainly have been more user-friendly and accessible. But the Court cannot say that the subject matter of that testimony would fail to assist the trier of fact in assessing the issue of lost profits damages, nor that it lacks a valid connection to such an inquiry. Indeed, after reading Dr. Leonard's deposition testimony and Ms. Stamm's Reply Expert Report, the Court concludes that (with the help of experts) a fact finder *could* understand: (1) what a nested logit model is; (2) exactly how the two experts disagree over whether different variations of such a model are better suited to the facts of this case; and (3) what impact that disagreement has on the experts' ultimate calculations regarding damages. The Court concludes that were Bard unable to promote this understanding at trial through Dr. Leonard's testimony, it would be more a failure of communication and less a failure of "fit." The "standard for this factor is not high[.]" and for the reasons set out above, Bard has met it. *Meadows*, 306 F. App'x at 790.¹⁰

III. CONCLUSION

In the end, the Court agrees with Bard that "[a]ny challenge of Dr. Leonard's analysis should go to weight, not admissibility." (D.I. 297 at 20) For the reasons set out above, the Court hereby ORDERS that the Motion be DENIED.

¹⁰ Gore also argues that Dr. Leonard's nested logit calculations do not sufficiently "fit" the facts of the case because they utterly fail to take into account two factors that should be included in such an analysis: product features and price. (D.I. 332 at 3-4) But a closer read of Dr. Leonard's deposition testimony suggests not that he felt that these two factors should be *ignored*, but that they were sufficiently taken into account through his consideration of the market share of the products at issue. (Leonard Dep. at 119, 133-37, 194-96) A dispute over whether the inputs Dr. Leonard has used sufficiently take these factors into consideration is one that should be pressed through cross-examination.

Because this Memorandum Order 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 Memorandum Order. Any such redacted version shall be submitted no later than **October 2, 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 Memorandum Order.

Dated: September 25, 2015



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE