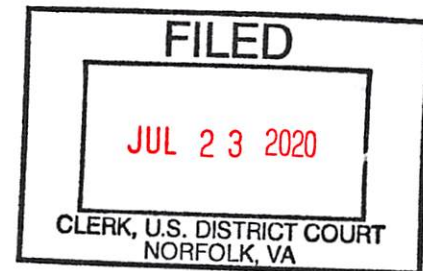


IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division



TRANS-RADIAL SOLUTIONS, LLC,

Plaintiff,

v.

CIVIL ACTION NO. 2:18-cv-656

BURLINGTON MEDICAL, LLC, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Before the Court are Trans-Radial Solutions, LLC's ("Plaintiff") Objections to Magistrate Judge Douglas E. Miller's Order regarding the testimony of Kenneth P. Gall ("Dr. Gall") and Jennifer Vanderhart ("Dr. Vanderhart"). ECF No. 208.

I. FACTUAL AND PROCEDURAL HISTORY

Dr. Gaul is a physicist with more than 30 years of experience relating to radiation protection products. Dr. Vanderhart is an economist with over 20 years of experience in her field. Relevant to the instant matter, Plaintiff offers the testimony of Dr. Gall for the following purposes: (1) to establish the efficacy of two of Plaintiff's products (the Rad-Guard and the Cardio-Trap); (2) for an opinion on Defendants' alleged patent infringement on those two products; and (3) to demonstrate the market share that was lost because of Defendants' alleged patent infringement. Relatedly, Plaintiff offers the testimony of Dr. Vanderhart to calculate the financial losses that resulted from Defendants' alleged patent infringement.

Defendants Burlington Medical, LLC, Fox Three Partners, LLC, and Phillips Safety Products, Inc. challenged the testimony of Dr. Gall and Dr. Vanderhart by filing Motions to Strike on January 31, 2020. ECF Nos. 102, 103. On May 12, 2020, Magistrate Judge Miller

conducted a hearing on the Motions to Strike. ECF No. 175. During the hearing, Magistrate Judge Miller made some rulings on the record. *Id.*; ECF No. 190. On May 20, 2020, Magistrate Judge Miller issued an order memorializing his rulings from the May 12 hearing. ECF No. 200. On June 3, 2020, Plaintiff filed its objections to Magistrate Judge Miller's order. ECF No. 208. Defendants filed their opposition to Plaintiff's objections on June 17, 2020. ECF No. 214. Plaintiff replied on June 23, 2020. ECF No. 215. This matter is ripe for decision.

II. LEGAL STANDARDS

A. Review of Non-dispositive Pretrial Orders

A district judge may modify or set aside any portion of a magistrate judge's decision only if it is "clearly erroneous or contrary to law." FED. R. CIV. P. 72(a); *see* 28 U.S.C. § 636(b)(1)(A). An order is clearly erroneous when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed. *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948).

B. Expert Testimony

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise 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.

Under Rule 702, courts are required to act as "gatekeepers" to ensure that expert testimony is relevant and reliable. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) *citing* *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993). In fulfilling this

gatekeeping function, district courts “must conduct a preliminary assessment” to determine whether the methodology underlying the expert witness’ testimony is valid. *Id.* District courts have considerable leeway in evaluating an expert reliability, but must focus on the expert’s underlying methodology, not the expert’s conclusion itself. *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017). Further, questions regarding the factual underpinnings of an expert witness’ opinion affect the weight and credibility of the assessment, not its admissibility. *Id. citing Structural Polymer Grp. v. Zoltek Corp.*, 543 F.3d 987, 997 (8th Cir. 2008).

In support of the objectives outlined in *Daubert*, most expert witnesses are required to provide a report containing the following information:

- (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
- (ii) the facts or data considered by the witness in forming them;
- (iii) any exhibits that will be used to summarize or support them;
- (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years;
- (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and
- (vi) a statement of the compensation to be paid for the study and testimony in the case.

FED. R. CIV. P. 26(a)(2)(b).

III. DISCUSSION

Magistrate Judge Miller’s Order on Defendants’ Motions to Strike found that Dr. Vanderhart’s opinions on damages calculations are inseparable from Dr. Gall’s opinions on market share that was lost because of Defendants’ alleged patent infringement. *See* ECF No. 200 at 2 (“the sole basis for Dr. Vanderhart’s opinions on lost...future sales is Dr. Gall’s excluded projections of those sales”). Plaintiff challenges Magistrate Judge Miller’s exclusion of Dr. Gall’s opinions on market share, but implicitly acknowledge that Dr. Vanderhart’s opinions on future lost sales and lost investment value cannot be separated from Dr. Gall’s opinions on

market share. *See* ECF No. 208 at 13 (“Because the Magistrate Judge’s ruling with respect to Dr. Gall’s market opinions is clearly erroneous and contrary to law, the Magistrate Judge’s ruling with respect to Dr. Vanderhart’s opinions is likewise clearly erroneous and contrary to law”). Independent of Magistrate Judge Miller’s ruling on Dr. Gall’s market opinions, Plaintiff challenges his ruling on the evidence supporting Dr. Vanderhart’s damages calculation with respect to the Cardio-Trap.

A. Dr. Gall’s Opinions on Future Sales of the Rad-Guard Were Properly Excluded

In his expert report, Dr. Gall identifies approximately 2,000 cardiac catheterization labs (“cath labs”) in the United States as the primary market for the Rad-Guard. He opines that 100% of cath labs in the United States will purchase an average of 5 Rad-Guards within 10 years based on generalized hospital purchasing practices, his opinions on the utility of the product, increasing concern about radiation exposure, and the advantages that patent protection would provide.

Dr. Gall’s credentials as a physicist and his experience as a health professional in the field of radiotherapy are beyond dispute, which explains why his testimony on the technical merits of the Rad-Guard and the Cardio-Trap will be permitted. *See* ECF No. 200 at 2 (“[Dr. Gall’s] education, skills, training, and experience in radiation therapy sufficiently inform his evaluation of the accused product and the claims at issue”). However, Plaintiff may not use Dr. Gall’s scientific expertise to bootstrap his opinions on the products at issue into his conclusion on future sales of the Rad-Guard, which support Dr. Vanderhart’s opinions.

“When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable facts contradict or otherwise render the opinion unreasonable, it cannot support a jury’s verdict.” *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993). While expert testimony may be a useful guide to interpreting market facts,

it is not a substitute for the facts of the market itself. *Id.* Further, “expert opinion evidence has little probative value in comparison with the economic factors” that may dictate a particular conclusion. *Id. citing Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 594, n. 19 (1986). As a result of the Supreme Court’s jurisprudence, expert opinions on market penetration must be informed by a survey of the relevant market or some other reliable method of analyzing that market. *See myServiceForce, Inc. v. Am. Home Shield*, 2014 WL 1317554, at *3–*5 (E.D. Pa. Apr. 2, 2014) (discussing the efficacy of an expert’s market penetration assumptions based on contractors’ responses to regulatory pressures); *SCO Group, Inc. v. Novell, Inc.*, 2010 WL 11614865, at *2–*3 (D. Utah Mar. 2, 2010) (discussing an expert’s reliance on a survey of businesses in an identified market for intellectual property licenses); *see also Craig v. Xlear, Inc.*, 2019 WL 1119429, at *11–*12 (D. Utah Mar. 11, 2019) (disallowing expert testimony relying on self-serving assumptions from interested parties in the case).

Dr. Gall’s opinions on market penetration are based only on his “three decades in the very system in which the Rad-Guard would be sold, on all sides of the product market.” ECF No. 208 at 12. Specifically, Dr. Gall opines that the “Rad-Guard could reasonably capture close to 100% of its Total Addressable Primary Market within a timeframe of 10 years” based on a “standard market penetration curve.” ECF No. 209-2 at 23, 26. However, Dr. Gall’s expert report does not contain a survey of cath labs gauging actual demand for the Rad-Guard. *Id.* at 23–27. His report does not contain any methodology for his “estimate that each cath lab would purchase 5 Rad-Guard shield units on average.” *Id.* at 23. He does not consider any preexisting solutions or unprotected alternatives to the Rad-Guard that may decrease radiation exposure in cath labs or the secondary markets he purports to analyze. His report does not even provide a basis to conclude that a standard market penetration curve is the most likely scenario for the cath

lab market's reaction to the Rad-Guard. In fact, Dr. Gall's opinions on lost future sales of the Rad-Guard are based exclusively on his opinions that every cath lab in the United States would have recognized their need for five Rad-Guards and purchased them from Plaintiff within the next decade, but for Defendants' alleged infringement. His opinion on the effect of Defendants' alleged interference with the market are similarly devoid of any facts, data, or specialized methodology. *Id.* at 26–28. In total, Dr. Gall's speculation on behalf of the entire cath lab market is not based on any sort of specialized methodology, facts, or data gathered from the relevant market. As a practical matter, Dr. Gall uses his opinion as a physicist on the merits of the Rad-Guard as a scientific matter as the only support for his opinions on lost future sales. Unfortunately for Plaintiff, Dr. Gall's market opinions are baseless in the eyes of Rule 702, absent some examination of the relevant market beyond Dr. Gall's speculation. As a result, Dr. Gall's credibility as a physicist would serve only to confuse the jury on the issue of lost future sales and cannot be permitted.

In requesting reconsideration of the magistrate judge's order, Plaintiff claims that the issue with Dr. Gall's unsupported speculation amounts to a question on the factual underpinnings of his opinion on expected market performance. ECF No. 208 at 7–9 (discussing *Bressler*, 855 F.3d at 195). Plaintiff also claims that the magistrate judge failed to explain how Dr. Gall's opinion on market penetration is unreliable. *Id.* at 10. These contentions are without merit because Dr. Gall does not offer any facts, data, or specialized methodology to support his opinions on the Rad-Guard's expected market performance or market penetration. Plaintiff may not rely on Dr. Gall's resume, however impressive it may be, as license to offer his opinion on behalf of the entire cath lab market without any facts or data from that market in support of his opinion. The Court's exclusion of Dr. Gall's future sales testimony does not amount to an issue

with his underlying factual assumptions, his credentials as physicist, his personal experience as a hospital procurement specialist, or his ultimate conclusions. Instead, the Court recognizes—as the magistrate judge also found—that Rule 702 and *Daubert* do not allow Dr. Gall to use his resume to offer unsupported opinions on behalf of an entire market without a reliable method of evaluating that market.

For the foregoing reasons, Magistrate Judge Miller’s exclusion of Dr. Vanderhart’s opinions on the Rad-Guard based on Dr. Gall’s market penetration and expected performance opinions were also properly excluded. Dr. Vanderhart shall not be permitted to opine on lost Rad-Guard profits derived from future sales, lost future sales, or present value calculations based solely on Dr. Gall’s opinions on the cath lab market.

B. Dr. Vanderhart’s Opinion on Lost Sales of the Cardio-Trap

In its Objection to the Magistrate Judge’s ruling on Dr. Vanderhart’s testimony, Plaintiff takes issue with the following paragraph:

if the trial court finds based on other testimony and evidence that Burlington had some ongoing duty to actively market and sell the Cardio-Trap (a contested point) and other evidence supports a quantity of lost future sales, Dr. Vanderhart’s credentials and research support her precise calculations of per unit revenue and profit figures attributable to that loss. However, her selective citation to opinions of sales representatives is insufficient—standing alone—to support any continuing obligation by Burlington to market the product, or the precise number of units she claims could have been sold.

However, the order goes on to rule that “the limits of Dr. Vanderhart’s testimony with regard to lost sales of the Cardio-Trap is deferred to the trial judge based on the evidence admitted regarding a duty to market and projections of future sales.” ECF No. 200 at 3.

Plaintiff correctly points out “that it must show Burlington’s obligation to market the Cardio-Trap” and that it is not required to “prove future damages with precision” with regard to lost sales of the Cardio-Trap product. *Id.* at 14–15. Further, nothing in the magistrate judge’s

order conflicts with the foregoing points or sets a “higher standard...from an evidentiary standpoint or damages standpoint” regarding the Plaintiff’s allegations on lost sales of the Cardio-Trap. *Id.* at 15. Therefore, nothing about the magistrate judge’s order is clearly erroneous or contrary to law. Further, the Court declines to offer additional guidance on Plaintiff’s burden of establishing liability or damages related to the Cardio-Trap.


IV. CONCLUSION

For the reasons set forth above, Plaintiff’s Objections to Magistrate Judge Douglas E. Miller’s Order on the Testimony of Dr. Gall and Dr. Vanderhart are **OVERRULED** and **DENIED**.

The Court **DIRECTS** the Clerk to provide a copy of this Order to the parties.

IT IS SO ORDERED.

Norfolk, Virginia
July 23, 2020



Raymond A. Jackson
United States District Judge