

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
NORTHERN DIVISION**

XODUS MEDICAL, INC.,)
 ALESSIO PIGAZZI, and GLENN KEILAR,)
)
 Plaintiffs,)
)
 v.)
)
 PRIME MEDICAL, LLC., and)
 SYMMETRY SURGICAL INC.)
)
 Defendants.)

No. 3:18-cv-413-JPM

XODUS MEDICAL, INC.,)
 ALESSIO PIGAZZI, and GLENN KEILAR,)
)
 Plaintiffs,)
)
 v.)
)
 PRIME MEDICAL, LLC., and)
 SYMMETRY SURGICAL INC.)
)
 Defendants.)

No. 3:18-cv-414-JPM

XODUS MEDICAL, INC.,)
 ALESSIO PIGAZZI, and GLENN KEILAR,)
)
 Plaintiffs,)
)
 v.)
)
 G&T INDUSTRIES, INC.)
)
 Defendant.)

No. 3:18-cv-415-JPM

**ORDER DENYING PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF
JOHN M. REYNOLDS**

Before the Court is Plaintiffs Xodus Medical, Inc. (“Xodus”), Alessio Pigazzi, and Glenn Keilar’s Motion to Exclude Expert Testimony of John M. Reynolds, filed on October 15, 2021. (ECF No. 242.) Plaintiffs also filed a Memorandum in Support. (ECF No. 243.) Defendants filed a Response in Opposition on November 12, 2021. (ECF No. 277.) Plaintiffs filed a Reply on November 19, 2021. (ECF No. 294.) For the reasons discussed below, Plaintiffs’ Motion is **DENIED**.

I. BACKGROUND

This is a patent infringement case for technology “related to patient slippage within the [] context of the Trendelenburg position for surgery—when using a viscoelastic foam.” (Claim Construction Order, ECF No. 138 at PageID 2894.) The asserted patents are U.S. Patent No. 8,511,314 (the “’314 Patent”), U.S. Patent No. 8,464,720 (the “’720 Patent”), and U.S. Patent No. 9,161,876 (the “’876 Patent”). (*Id.*) John M. Reynolds (“Dr. Reynolds”) is Defendants’ invalidity expert. (ECF No. 277 at PageID 7574.) Plaintiffs contend that Dr. Reynolds “is not a person of ordinary skill in the art due to the fact that he does not have the requisite experience in performing operations that position patients in the Trendelenburg position.” (ECF No. 243 at PageID 5361–62.) Plaintiffs also seek to exclude his testimony on anticipation because “he has failed to provide an element-by-element analysis.” (*Id.* at PageID 5362.) Defendants contend that “[a]t best, Plaintiffs’ Motion goes to the weight of the evidence, not its admissibility.” (ECF No. 277 at PageID 7574.)

II. LEGAL STANDARD

“[A] proposed expert’s opinion is admissible, at the discretion of the trial court,” if (1) the witness is qualified by “knowledge, skill, experience, training, or education”; (2) the witness’s testimony is relevant, meaning that it “will assist the trier of fact to understand the evidence or to

determine a fact in issue”; and (3) the witness’s testimony is reliable. In re Scrap Metal Antitrust Litig., 527 F.3d 517, 528–29 (6th Cir. 2008) (quoting Fed. R. Evid. 702). In evaluating the reliability of expert opinion testimony, a trial court must consider whether the testimony is based on “sufficient facts or data” and is the “product of reliable principles and methods,” as well as whether the expert “has applied the principles and methods reliably to the facts of the case.” See Fed. R. Evid. 702. “Such factors as testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique’s operation, and general acceptance in the relevant scientific community should be considered in this review.” United States v. Langan, 263 F.3d 613, 621 (6th Cir. 2001) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593–94 (1993)).

“The party offering the expert’s testimony has the obligation to prove the expert’s qualifications by a preponderance of the evidence.” Burgett v. Troy-Bilt LLC, 579 F. App’x 372, 376 (6th Cir. 2014). That being said, “the rejection of expert testimony is the exception rather than the rule.” Fed. R. Evid. 702 advisory committee’s note, 2000 amend. “The task for the district court in deciding whether an expert’s opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation.” In re Scrap Metal Antitrust Litig., 527 F.3d at 529–30. “[M]ere weaknesses in the factual basis of an expert witness opinion bear on the weight of the evidence rather than on its admissibility.” McLean v. 988011 Ontario, Ltd., 224 F.3d 797, 801 (6th Cir. 2000) (quoting United States v. L.E. Cooke Co., 991 F.2d 336, 342 (6th Cir. 1993) (internal quotation marks and alternations omitted)).

III. ANALYSIS

Plaintiffs assert that “Dr. Reynolds is not one of skill in the art of the Asserted Claims or the Patents-in-Suit,” and therefore, “[i]t would be ‘contradictory to Rule 702’ to allow Dr. Reynolds to testify to invalidity of the Asserted Claims, where the Asserted Claims and Patents-in-Suit are directly drawn to methods and apparatuses for use with the Trendelenburg position [because] Dr. Reynolds has no experience using the Trendelenburg position in practice.” (ECF No. 243 at PageID 5369.) (citing Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008).) In the alternative, Plaintiffs seek to exclude Dr. Reynolds’s opinion on anticipation “because he failed to provide an element-by-element analysis of the Asserted Claims.” (Id. at PageID 5369.)

A. Dr. Reynolds Qualifies as a Person of Skill in the Art.

Plaintiffs contend that Dr. Reynolds “has admitted that he has never performed gynecological or colorectal surgeries in his practice,” and that those are the types of surgeries where “the Trendelenburg position or related inclined position of a patient may be more advantageous.” (Id.) As a result, Plaintiffs contend that “Dr. Reynolds can hardly be held to be qualified as one of skill in the pertinent art, and thus cannot be permitted to testify.” (Id. at PageID 5370.) (citing Sundance, Inc., 550 F.3d at 1363.) In support of their contention, Plaintiffs point to multiple points in Dr. Reynolds’s deposition that they assert show his lack of experience regarding those types of surgeries. (See id. at PageID 5370–75.) (citing Reynolds Dep., ECF No. 243-2.)

In response, Defendants contend that “Plaintiffs’ Motion dismisses this Court’s definition of a person of ordinary skill in the art, ignores Dr. Reynolds’ qualifications and attempts to challenge him as not having the requisite experience in ‘performing operations that position patients in the Trendelenburg position.’” (ECF No. 277 at PageID 7576.) Defendants assert that

“Dr. Reynolds regularly uses the Trendelenburg position and cushioning pads during [his surgeries].” (Id. at PageID 7577.) Defendants point to deposition testimony that they contend shows Dr. Reynolds has the relevant expertise. (See id. at PageID 7577–79.) (citing Reynolds Dep., ECF Nos. 277-2, 277-3.) Defendants further contend that Plaintiffs’ “argument seeks to improperly import a temporal limitation into both the claim language and the Court’s definition of a person of ordinary skill in the art, but such argument is unsupported by the controlling case law.” (Id. at PageID 7579–80.) Defendants contend that “[a]t most, this argument goes to the weight of Dr. Reynolds’ testimony, not its admissibility.” (Id. at PageID 7582.)

In reply, Plaintiffs contend that “Prime overstates the relevant experience of John Reynolds, M.D.” (ECF No. 294 at PageID 9000.) They assert that Defendants’ arguments “do[] not grapple with the additional requirements imposed on an opinion expert seeking to be qualified as a PHOSITA.” (Id. at PageID 9001.) Plaintiffs reiterate that “[t]he circumstances of this case require, therefore, that a PHOSITA have specific surgical experience that Dr. Reynolds lacks.” (Id. at PageID 9003.) Plaintiffs also contend that Defendants’ argument about inserting a temporal limitation misses the point:

[T]he relevant question is whether the surgical team’s passing the patient through the Trendelenburg position to the beach chair position, prior to the actual performance of the surgery, provides Dr. Reynolds with a specific and substantial background in performing surgeries in the Trendelenburg position such that he can reliably opine about the requirements, performance, and risks of such surgeries.

(Id. at PageID 9005.)

This Court’s Claim Construction Order does not give an exact description of a person having ordinary skill in the art (“PHOSITA”) for the patents at issue, but it does provide some guidance: “Certainly, the PHOSITA should have experience and knowledge of the function of foam (particularly memory foam), as well as knowledge of surgical and medical settings using the

positions described.” (ECF No. 138 at PageID 2894.) “It follows that a PHOSITA may have training or experience with the foam materials that are used in surgery and would appreciate the significant aspects of foam materials used in Trendelenburg surgical kits.” (Id.) Thus, Dr. Reynolds’s qualifications as a PHOSITA will be assessed under this understanding.

In Sundance, Inc., the Federal Circuit held it was “an abuse of discretion” for the district court to allow a patent attorney, Mr. Bliss, “to testify as an expert on the issues of noninfringement or invalidity.” 550 F.3d at 1362. The Federal Circuit found that “Mr. Bliss has no experience whatsoever in ‘the field of tarps or covers.’ Nor does DeMonte purport that Mr. Bliss’s experience with engines and the like is sufficiently related to covers.” Id. As a result, the Federal Circuit held that “Mr. Bliss is not ‘qualified as an expert by knowledge, skill, experience, training, or education’ in the pertinent art; we therefore fail to see how he could ‘assist the trier of fact to understand the evidence or to determine a fact in issue.’” Id. (citing Fed. R. Evid. 702).

Similarly, in Sport Dimension, Inc. v. Coleman Co., Inc., the Federal Circuit upheld the district court’s exclusion of expert testimony from “an industrial design consultant with four decades of industry experience, because he had ‘no experience whatsoever in the field of [personal flotation devices].” 820 F.3d 1316, 1323 (Fed. Cir. 2016) (brackets in original). In addition to the consultant’s lack of experience in the relevant field, his proposed alternative design “was based on his ‘imagination.’” Id.

Here, there is sufficient evidence that Dr. Reynolds has at least some experience with using foam materials in a surgical setting and in using foam materials to hold patients in place while in the Trendelenburg position. (See ECF No. 277-2 at PageID 7593–96.) As a result, Dr. Reynolds’s experience and qualifications are distinguishable from those of the experts at issue in Sundance, Inc. and Sport Dimension, Inc. because in both of those cases, the expert had “no experience

whatsoever” in the relevant field. See Sundance, Inc., 550 F.3d at 1362; Sport Dimension, Inc., 820 F.3d at 1323. While a surgeon who regularly performs gynecological or colorectal procedures would likely be more knowledgeable about the patents-in-suit, the requirement is not that a party choose the most qualified expert. See Burgett, 579 F. App’x at 378 (“The question before the district court was not whether Nogan was the best qualified expert Plaintiffs could have called upon. . . . The district court only had to decide if Nogan met Rule 702’s basic qualifications requirement.”). Here, Dr. Reynolds’s qualifications meet the standards from this Court’s Claim Construction Order of a PHOSITA for the patents in suit, and any perceived deficiencies in his experience as a surgeon using foam materials are a matter for cross examination rather than exclusion. For this reason, Plaintiff’s Motion is **DENIED** regarding Dr. Reynolds’s qualifications and expertise.

B. Dr. Reynolds Will Not Testify Regarding Anticipation.

In the alternative, Plaintiffs request exclusion of “any opinion as to anticipation” from Dr. Reynolds. (ECF No. 243 at PageID 5376.) Plaintiffs contend that “[d]uring his deposition, Dr. Reynolds claimed that VanSteenburg and Landvik anticipate some of the Asserted Claims. But his report failed to do the same, and failed to provide the required element-by-element analysis.” (Id. at PageID 5377.) In their Response, Defendants state that they “will not proffer testimony from Dr. Reynolds at trial or otherwise on the issue of invalidity by anticipation.” (ECF No. 277 at PageID 7577 n.1.) Because Defendants concede that Dr. Reynolds will not offer an opinion or testimony regarding anticipation, Plaintiffs’ Motion is **DENIED AS MOOT** regarding Dr. Reynolds’s anticipation opinion.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Expert Testimony of John M. Reynolds is **DENIED**.

IT IS SO ORDERED, this 17th day of December, 2021.

/s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE