IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC., Plaintiff, v. EXELA PHARMA SCIENCES, LLC, Defendant.	Civil Action No. 22-1233-GBW

Kelly E. Farnan, Christine D. Haynes, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE; Imron T. Aly, Kevin Nelson, Matthew T. Wilkerson, Julie A. Vernon, ARENTFOX SCHIFF LLP, Chicago, IL; Ahmed M.T. Riaz, Max Heckendorn, ARENTFOX SCHIFF LLP, New York, NY.

Counsel for Plaintiff

Robert M. Oakes, Douglas E. McCann, Gregory R. Booker, FISH & RICHARDSON P.C., Wilmington, DE; Deanna J. Reichel, Sarah E. Jack, Madison Murhammer Colon, FISH & RICHARDSON P.C., Minneapolis, MN; Corrin N. Drakulich, Christina D. Brown-Marshall, Dexter S. Whitley, Charles N. Reese, FISH & RICHARDSON P.C., Atlanta, GA; Caroline G. Koonce, FISH & RICHARDSON P.C., Washington, DC; Satish Chintapalli, CHINTAPALLI LAW FIRM PLLC, Cary, NC.

Counsel for Defendant

MEMORANDUM OPINION

July 16, 2025
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court are Plaintiff's *Daubert* Motion to Exclude the Expert Testimony of Dr. Patricia Powell ("Motion" or "Plaintiff's Motion" or "Plaintiff's *Daubert* Motion") (D.I. 199), which has been fully briefed (D.I. 200; D.I. 227; D.I. 256), and Plaintiff's Request for Oral Argument (D.I. 263) on Plaintiff's *Daubert* Motion.[1] For the following reasons, the Court grants in part and denies in part Plaintiff's *Daubert* Motion (D.I.199) and denies-as-moot Plaintiff's Request for Oral Argument (D.I. 263).

I. BACKGROUND

This action concerns U.S. Patent Nos. 11,464,752 ("the '752 patent"), 11,426,369 ("the '369 patent"), and 11,571,398 ("the '398 patent") (together, the "Asserted Patents"). *See* D.I. 200 at 1. The Asserted Patents generally relate to 5 mg/mL ephedrine sulfate products. "The parties served opening expert reports on November 13, 2024, rebuttal reports on December 20, 2024, and reply reports on January 17, 2025." *See* D.I. 200 at 1. On February 28, 2025, Nexus filed the present Motion.

II. LEGAL STANDARD

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the U.S. Supreme Court held 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 the task at hand." 509 U.S. 579, 597 (1993). Rule 702 provides:

> 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 the proponent

[1] The Plaintiff is Nexus Pharmaceuticals, Inc. ("Nexus" or "Plaintiff"). The Defendant is Exela Pharma Sciences, LLC ("Exela" or "Defendant").

> demonstrates to the court that it is more likely than not that: (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's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. As the Third Circuit has explained:

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have . . . [held] that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony . . . must be relevant for the purposes of the case and must assist the trier of fact.

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (cleaned up); *Kuhar v. Petzl Co.*, No. 19-cv-3900, 2022 WL 1101580, at *7 (3d Cir. Apr. 13, 2022) (acknowledging the same trilogy).

Rule 702 "has a liberal policy of admissibility," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted); *see also United States v. Scripps*, 599 F. App'x 443, 447 (3d Cir. 2015) (same), as "the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court," *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (quoting *Daubert*, 509 U.S. at 596).

III. DISCUSSION

In its Motion, Nexus contends that the Could should exclude some of the testimony of Exela's expert, Dr. Powell, because (A) "Dr. Powell is not a POSA,[2] has no relevant experience, and offers contradictory opinions that are not helpful to the jury" and (B) "Dr. Powell fail[s] to apply any legal standard to her invalidity opinions and applies the incorrect legal standard for contributory infringement." D.I. 200 at 7, 9. The Court addresses each argument below.

A. The Court Grants Nexus' Request to Exclude Dr. Powell's Testimony on Certain Claim Limitations and Denies Nexus' Request to Exclude Certain Portions of Dr. Powell's Testimony Because She is Not a POSA and for Other Asserted Reasons.

Nexus contends that the Court should exclude Dr. Powell's testimony, under Federal Rules of Evidence 402, 403, and 702, on the basis of (1) Dr. Powell's admission that she is not a POSA, (2) Dr. Powell's purported lack of relevant experience, and (3) Dr. Powell's purported issuance of contradictory, unhelpful opinions. D.I. 210 at 7-9. Nexus appears, in its Motion and opening brief, to request that the Court categorically exclude the entirety of Dr. Powell's testimony on these bases. *See, e.g.*, D.I. 199 (titling its motion "Motion to Exclude the Expert Testimony of Dr. Patricia Powell"); D.I. 200 at 7 (requesting, in light of Dr. Powell's admission that she is not a POSA, to "exclude Dr. Powell from offering testimony in this matter"). In its reply brief in further support of its Motion, however, Nexus clarifies that Nexus' Motion "is based on those areas where POSA knowledge is required, including the components of the obviousness and anticipation analyses, or where Dr. Powell addressed the invalidity and infringement inquiries without using the acceptable standards." D.I. 256 at 5.[3]

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[2] "POSA" is a personal of ordinary skill in the art.

[3] The Court briefly corrects a misstatement of the law. Nexus contends that the "Federal Circuit" in *Kyocera Senco Industrial Tools Inc. v. International Trade Commission* "made clear the logical requirement that an expert witness in a patent case must be able to offer testimony from the

As to "those areas where POSA knowledge is required, including the component of the obviousness and anticipation analyses," Nexus appears to have identified two categories of testimony from Dr. Powell that are purportedly from the perspective of a POSA. These two categories regard Dr. Powell's testimony on the claim limitations "removing, from sealed packaging, a syringe containing a sterilized ready-to-use ephedrine composition" and "injecting the sterilized ephedrine composition from the syringe into the subject without diluting the sterilized ephedrine composition." D.I. 200 at 8-9.

In response, Exela concedes that "to narrow issues for the Court, Dr. Powell will not testify to those opinions at trial." D.I. 227 at 10 n.3; *see id.* at 10 n.2. Given that Exela concedes that Dr. Powell will not testify to those opinions at trial, the Court grants Nexus' *Daubert* Motion to exclude Dr. Powell's testimony on the claim limitations "removing, from sealed packaging, a syringe containing a sterilized ready-to-use ephedrine composition" and "injecting the sterilized ephedrine composition from the syringe into the subject without diluting the sterilized ephedrine composition."

The Court does not exclude any other testimony from Dr. Powell on the basis that Dr. Powell is not a POSA for three reasons. *First*, Exela fails to identify any other instances in which Dr. Powell purportedly opined through the lens of a POSA. *See Live Face on Web, LLC v. Rockford Map Gallery, LLC*, No. CV 17-539, 2020 WL 13718835, at *1 n.1 (D. Del. Dec. 11,

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perspective of a POSA." D.I. 200 at 7 (citing 22 F.4th 1369, 1376-77 (Fed. Cir. 2022)). However, in that case, the Federal Circuit explained that to "offer expert testimony *from the perspective of a skilled artisan* in a patent case . . . a witness must at least have ordinary skill in the art." *Kyocera*, 22 F.4th 1369, 1376-77 (emphasis added). On that basis, the Federal Circuit held that the administrative law judge in the court below "abused his discretion by admitting [the expert's] testimony on any issue that is analyzed *through the lens of an ordinarily skilled artisan.*" *Id.* at 1377 (emphasis added). In other words, non-POSAs can offer testimony, assuming the testimony satisfies the other gatekeeping safeguards, as long as expert's testimony is not from the perspective of a POSA.

2020) ("Judges are not like pigs, hunting for truffles buried in briefs."). *Second*, the parties seem to agree that Dr. Powell's testimony on, for example, the uses of the ephedrine sulfate products will be helpful. *See, e.g.*, D.I. 256 at 6 ("Dr. Powell may still testify about the description of ephedrine sulfate products, uses, and alternatives that Exela believes customers would use if Exela's products were unavailable."); D.I. 227 at 4-5 (setting forth Dr. Powell's experience, including that she "is an anesthesiologist with over 25 years of experience practicing medicine"). *Third*, considering testimony from non-POSAs in patent cases, where that testimony is not offered from the perspective of a POSA and is within the expert's realm of expertise, is consistent with the practice of this Court. *See, e.g.*, *Hospira, Inc. v. Amneal Pharms., LLC*, 285 F. Supp. 3d 776, 811 (D. Del. 2018) (considering, notwithstanding a credibility challenge, testimony from an expert, where the expert "acknowledged that as a biostatistician, he was not a POSA in the field of drug development," because the expert "did not offer opinions based on matters within the expertise of a POSA" and the expert's "testimony remained squarely within his realm of expertise"); *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 404 F. Supp. 2d 575, 579-80 (D. Del. 2005) ("In *Endress,* the court relied on the plaintiff's expert witness in coming to its claim construction, and the defendants challenged that reliance, claiming that the expert was not a person of ordinary skill in the relevant art. The court rejected the defendants' challenge. Likewise, here Dr. Rinard had an adequate understanding of trading, and, more to the point, an exceptional grasp of the requisite programming issues related to trading. He was thus able to render a helpful opinion to the factfinder." (citations omitted)).

Thus, the Court declines to exclude other testimony from Dr. Powell, on the basis that she is not a POSA, under Federal Rules of Evidence 402, 403, and 702, and because "the Third Circuit has cautioned that pretrial Rule 403 exclusions should rarely be granted and excluding evidence

as being more prejudicial than probative at the pretrial stage is an extreme measure that is rarely necessary, because no harm is done by admitting it at that stage." *See Koninklijke Philips N.V. v. Zoll Lifecor Corp.*, No. 2:12-cv-1369, 2017 U.S. Dist. LEXIS 116337, at *92 (W.D. Pa. May 12, 2017) (cleaned up).

With respect to those instances where Dr. Powell purportedly "addressed the invalidity and infringement inquiries without using the acceptable standards," the Court addresses such instances below.

B. The Court Denies Nexus' Request to Exclude Certain Testimony from Dr. Powell on Invalidity and Grants Nexus' Request to Exclude Dr. Powell's Contributory Infringement Opinions.

Nexus contends that the Court should exclude portions of Dr. Powell's testimony on the purported bases that Dr. Powell does not apply any legal standard in her invalidity opinion and applies the incorrect legal standard in her contributory infringement opinion.

"Expert testimony must be relevant 'to the task at hand.'" *Exela Pharma Scis., LLC v. Eton Pharms., Inc.*, No. 20-CV-365 (MN), 2022 WL 806524, at *3 (D. Del. Feb. 8, 2022) (citing *Daubert*, 509 U.S. at 591). "An expert's opinion that crucially depends on an incorrect legal theory is not likely to be relevant to the Court's fact-finding." *Id.* "Consequently, courts routinely preclude those portions of an expert's report that are premised on a misunderstanding of the law." *Id.* (collecting cases).

The Court will not exclude the subject testimony from Dr. Powell on the purported basis that Dr. Powell did not apply a legal standard in her invalidity opinion for four reasons. *First*, Dr. Powell acknowledged in the beginning of her Opening Report the following:

> I understand that Dr. Myers opines that the claims of the '398 patent are invalid because they would have been anticipated by the prior art and obvious to a person of ordinary skill in the art. As I explain below, the treatment steps contained in the '398 patent were the well-known, standard way of administering compounded ephedrine sulfate syringes prior to May 2019. I personally practiced the treatment

> steps described in the '398 patent, and administered the pre-diluted compositions described in all three patents, when administering compounded ephedrine sulfate syringes prior to 2019, as did virtually all practitioners using compounded ephedrine sulfate syringe products.

D.I. 202-1, Ex. A ¶ 78. Dr. Powell's acknowledgement of the law at issue, in concert with her opinion on whether professionals in the industry practiced the asserted claims, confirms that her testimony will assist the factfinder because it is "relevant to the task at hand." *See Exela Pharma*, 2022 WL 806524, at *3 (cleaned up).

Second, Nexus fails to cite any invalidity testimony from Dr. Powell that is inconsistent with the law on invalidity. *Third*, while Nexus contends in its opening brief that Dr. Powell's reports "entirely omit a description of legal standards" (D.I. 200 at 10), Nexus clarifies in its reply in further support of its Motion that it is not arguing that "an expert must list the relevant legal standards in reports[.]" (D.I. 256 at 1).

Fourth, that Dr. Powell may have briefly conflated the standards for invalidity and infringement during direct examination at her deposition (*see, e.g.*, D.I. 202-1, Ex. D at 89:14-92:5) does not divest the utility of Dr. Powell's opinions on invalidity because, as discussed above, Nexus fails to identify any testimony that is actually inconsistent with the law on invalidity, and Dr. Powell's opinions remain "relevant to the task at hand." *See Exela Pharma*, 2022 WL 806524, at *3 (cleaned up). Moreover, Dr. Powell is not offering testimony on the legal standards for infringement and invalidity; rather, Dr. Powell is (as discussed above) opining, for example, on whether professionals in the industry practiced the asserted claims. Thus, Nexus fails to demonstrate that Dr. Powell proffers actual invalidity testimony that "crucially depends on an incorrect legal theory." *See Exela Pharma*, 2022 WL 806524, at *3. For these reasons, the Court denies the request to exclude testimony from Dr. Powell on invalidity on grounds that Dr. Powell does not apply the correct legal standard in her invalidity analysis.

With respect to Dr. Powell's contributory infringement opinions, Exela advises that it has voluntarily withdrawn "these paragraphs of Dr. Powell's report." D.I. 227 at 13. Nexus therefore does not, in its reply brief in further support of its Motion, "address Exela's [other] arguments related to Dr. Powell's . . . contributory infringement analysis." D.I. 256 at 6. Given that Exela advises that it is withdrawing the paragraphs of Dr. Powell's report related to Dr. Powell's contributory infringement opinions, the Court grants Nexus' *Daubert* Motion to exclude Dr. Powell's contributory infringement opinions.

IV. CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Plaintiff's *Daubert* Motion to Exclude the Expert Testimony of Dr. Patricia Powell (D.I. 199). Specifically, given the concessions to withdraw by Defendant, the Court grants Plaintiff's *Daubert* Motion with respect to (1) excluding and precluding Dr. Powell's testimony on the claim limitations "removing from sealed packaging, a syringe containing a sterilized ready-to-use ephedrine composition" and "injecting the sterilized ephedrine composition from the syringe into the subject without diluting the sterilized ephedrine composition"; and (2) excluding the paragraphs of Dr. Powell's report related to Dr. Powell's contributory infringement opinions and precluding at trial any expert testimony by Dr. Powell on contributory infringement. The Court denies Plaintiff's *Daubert* Motion to exclude Dr. Powell's testimony on invalidity to the extent the testimony is not offered from the perspective of a POSA, is within the expert's realm of expertise, and is not inconsistent with the law. Since the Court was able to resolve Plaintiff's *Daubert* Motion without oral argument, the Court denies-as-moot Plaintiff's Request for Oral Argument (D.I. 263) as it pertains to Plaintiff's *Daubert* Motion.