IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (sacubitril/valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, GERBERA THERAPEUTICS, INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	Civil Action No. 22-cv-1395-RGA

MEMORANDUM ORDER

The parties dispute whether Defendants' ANDA products will infringe Plaintiff's patent. In connection with that dispute, Plaintiff Novartis has moved to exclude the testimony of three experts at trial: Dr. Richard McCreery on behalf of Defendants Noratech and MSN[1], Dr. Clare Strachan on behalf of Noratech, and Dr. Jonathan Steed on behalf of MSN. (D.I. 1555).[2] Defendants have moved to exclude the testimony of one of Novartis's experts, Dr. Aeri Park. (D.I. 1559). I have reviewed the parties' briefing, which was completed on October 25, 2024. (D.I. 1557, 1571, 1590, 1592, 1606, 1609). Trial is scheduled to begin on December 9, 2024. (D.I. 1098).

[1] By "Noratech," I refer to Gerbera and Nanjing Noratech. By "MSN," I refer to the three MSN parties.
[2] The docket item citations refer to the 20-md-2930 docket.

I. BACKGROUND

This case involves Noratech's and MSN's ANDAs for sacubitril/valsartan products. (D.I. 1571 at 1). Novartis alleges the products infringe its U.S. Patent No. 11,096,918 (the "'918 patent") (*Id.*). Central to the patent and this case is the claimed amorphous trisodium valsartan-sacubitril ("amorphous TVS"), including what its spectroscopy scans look like and whether Defendants' ANDA products contain it. (D.I. 1557 at 1; D.I. 1571 at 1–2). Novartis has offered the testimony of Dr. Park on the creation and Raman spectroscopy scans of a "glassy solid" made by Triclinic Laboratories, purportedly according to a method recited in the '918 patent. (D.I. 1571 at 1–2). Dr. Park will testify that the Raman scans show the glassy solid is the claimed amorphous TVS complex. (*Id.*). Defendants seek to exclude this testimony, arguing that Dr. Park is unqualified (*id.* at 13–16) and will offer testimony based on the use of unreliable scientific methods (*id.* at 16–20).

Defendants have offered the testimony of Dr. McCreery to counter Dr. Park's testimony. (D.I. 1557 at 3). Novartis challenges six opinions from Dr. McCreery, five of which are about Dr. Park's process and opinions and one of which is about amorphous TVS formation more generally. (*Id.*). Novartis argues Dr. McCreery is unqualified and will provide unreliable testimony. (*Id.* at 10–11). Noratech has offered the testimony of Dr. Strachan to counter the testimony of Novartis's expert Dr. Adam Matzger. (*Id.* at 5). Novartis challenges this testimony primarily on reliability grounds. (*Id.* at 6–7). MSN has offered the testimony of Dr. Steed to counter Dr. Matzger's testimony. (*Id.* at 8). Novartis challenges this testimony primarily on reliability grounds. (*Id.*).

II. LEGAL STANDARD

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> 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 demonstrates to the court that it is more likely than not: (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. 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 interpreted this requirement liberally, holding 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 fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."
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> By means of a so-called "*Daubert* hearing," the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) [of the Federal Rules of Evidence] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404–05 (3d Cir. 2003) (footnote and internal citations omitted).[3]

III. DISCUSSION

While I acknowledge the "gate-keeper" function of a federal trial judge, it is not so important that it be done pretrial when the trial is a bench trial. *See In re Salem*, 465 F.3d 767, 777 (7th Cir. 2006); *United States v. Brown*, 415 F.3d 1257, 1269–70 (11th Cir. 2005); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, 2018 WL 2422003, *2 (D. Del. May 29, 2018); *Sanofi v. Glenmark Pharms. Inc.*, 2016 WL 10957311, *1 (D. Del. May 12, 2016). I still must evaluate the admissibility of expert testimony in a bench trial, but there is more flexibility in how I do it. *See UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 836 (3d Cir. 2020). Here, live testimony and cross-examination are much more likely to result in a correct decision from me about whether an expert is giving appropriate scientific testimony. Thus, while I am denying the motions for now, the parties may make (and, indeed, in order to preserve the issue, must make) objections at appropriate times. Failure to make a timely appropriate objection will result in the objection being waived. I will consider only evidence actually adduced at trial (whether through cross-examination or testimony from other witnesses) in ruling on any renewed motion.

A few comments on the motions:

Much of what the parties argue in their briefs boils down to factual disputes and the merits of the case, not reliability of testimony. For example, Defendants' argument that Dr.

[3] The Court of Appeals wrote under an earlier version of Rule 702. Subsequent amendments affect the substance of the rule, but I do not think they alter the applicability of the quoted discussion.

Park's testimony is unreliable is based on their own expert's testimony.[4] (*See* D.I. 1571 at 18). And Novartis argues Defendants' experts are unreliable based in part on its own expert's testimony and excerpts from publications. (*See* D.I. 1557 at 12, 16 & n.5). Both sides point to supposed issues with each expert's processes and evaluations. (*See id.* at 13; D.I. 1571 at 16). Each expert's credibility, processes, and bases for their opinions can be explored on cross-examination. Which expert should be deemed credible and "right" is best determined at trial. The parties also argue about the relevance of testimony concerning an internal Novartis document which may or may not contain information about amorphous TVS. (*See* D.I. 1557 at 14). This seems to boil down to the issue of whether the internal document is indeed referring to amorphous TVS, as opposed to some other compound. That is a factual dispute that the parties can explore at trial. My determination on that issue, if it is indeed explored at trial, is best rendered based on examination and cross-examination, not *Daubert* briefs.

I find the arguments about Dr. Park's and Dr. McCreery's qualifications unconvincing. Indeed, I think Novartis has shown that Dr. Park is qualified to testify as an expert in analytical chemistry, including the use and interpretation of Raman spectroscopy.[5] I think Defendants have shown that Dr. McCreery is a retired chemistry professor with a Ph.D. and extensive experience

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[4] Generally speaking, Defendants' criticisms of Dr. Park's experimental work and the conclusions that she draws from it are that the work was badly performed and that the conclusions do not follow. I think these arguments are essentially that she does not have "good grounds" for her opinions. At this point, I think Novartis has shown that she has good grounds for her opinions.

[5] I note that it is only nine months since I last heard Dr. Park testify. There, in a related case that did not involve the defendants in this case, I admitted her expert testimony without objection. (D.I. 1324 at 553:20–555:9). Novartis notes that I found at least some of the testimony credible (D.I. 1590 at 2, citing D.I. 1326 at 897:20–24), but I do not rely upon that for this ruling. Further, a finding of credibility (or lack of credibility) in one trial does not carry over to a second trial with different parties.

in Raman spectroscopy.[6] Both experts have "specialized knowledge" in their "area of testimony," which is "greater than the average layman" and renders their testimony admissible over a "qualifications" objection. *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (internal citation and quotation marks omitted).

Defendants argue Dr. Park in unqualified to testify at least in part because she is merely "very familiar" with Raman spectroscopy and would not call herself an "expert" in a deposition. (D.I. 1571 at 13). Defendants also point to Dr. Park's CV, which contains various scientific and leadership skills but lacks "professional honors" or leadership of a professional association or journal. (*Id.* at 14–15). That, to Defendants, renders Dr. Park unqualified. (*Id.*). On the other side, Novartis argues Dr. McCreery is unqualified because, though he has experience in Raman spectroscopy, including analysis of pharmaceutical compounds, "he has not studied any supramolecular complexes." (D.I. 1592 at 2; D.I. 1557 at 4). That, plus Mr. McCreery no longer having access to a laboratory, his own Raman spectrometer, or the Raman spectrometer used by Dr. Park, renders him unqualified according to Novartis. (D.I. 1557 at 4). I find neither argument convincing. Neither party has pointed to sufficient facts to show that either expert lacks the necessary qualifications required by the "liberal standard" of the Federal Rules that

[6] Novartis says that Dr. McCreery is not a POSA because he does not have "two or more years of experience with solid forms of pharmaceutical compounds." (D.I. 1557 at 4). Defendants do not directly respond to this statement. I had some initial concern about this in view of appellate cases requiring that expert "testimony on any issue that is analyzed through the lens of an ordinarily skilled artisan" must come from a person having such qualifications. *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1377–78 (Fed. Cir. 2022); *see Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1340–41 (Fed. Cir. 2024). It seems likely to me that Dr. McCreery has such experience based on his many years of performing Raman spectroscopy, but, in order to be sure, I request that Defendants send me a one-page letter addressing this issue within three business days of the issuance of this Memorandum Order. I also note that Dr. McCreery does not appear to be offering an opinion on non-infringement, which would require him to be a POSA. (D.I. 1558-1, Ex. 5, ¶ 92, at 128 of 305). Instead, his opinions mostly critique Dr. Park's work and conclusions.

tends to allow experts to testify. *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (internal citation and quotation marks omitted).

Finally, in a footnote at the end of their opening brief, Defendants argue Dr. Park should be excluded from testifying because Novartis falsely claimed it did not have possession of Triclinic's glassy solid when requested by Defendants on October 6, 2023. (D.I. 1571 at 20 n.3). Arguments in footnotes are forfeited. *Higgins v. Bayada Home Health Care Inc.*, 62 F.4th 755, 763 (3d Cir. 2023). It does not matter that Novartis responded and Defendants addressed the issue more fully in their reply brief. (D.I. 1590 at 19–20; D.I. 1608 at 8–9). Arguments first made in reply briefs are forfeited. *In re Niaspan Antitrust Litig.*, 67 F.4th 118, 135 (3d Cir. 2023).

Defendants argue that Dr. Park said, at a September 4, 2024 deposition, that Novartis's counsel was aware the glassy solid was in Triclinic's storage in October 2023 and could have produced it. (D.I. 1571 at 20 n.3; D.I. 1608 at 9 n.6). Novartis argues that, at the time it was requested, the glassy solid was protected work product. (D.I. 1590 at 20). Defendants cite only one authority, Federal Rule of Civil Procedure 37(c)(1), in their reply brief. (D.I. 1608 at 9). A *Daubert* motion is not the time or the place to bring up a discovery dispute. Considering the discretion I have under Rule 37, the present motion being a *Daubert* motion, and that Defendants have forfeited this argument, I do not exclude Dr. Park's testimony on the basis of failure to produce the glassy solid.

IV. CONCLUSION

The *Daubert* Motions (D.I. 1555, 1559) are **DENIED** without prejudice to any specific objections at trial.

Entered this 5th day of November, 2024.

United States District Judge