

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., *et al.*,

Plaintiffs,

v.

DEXCEL PHARMA TECHNOLOGIES
LIMITED, *et al.*,

Defendants.

Civil Action No. 23-879-GBW-CJB

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MEMORANDUM OPINION

March 10, 2026
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court is the motion of Defendants Cipla Limited (“Cipla”) and Hikma Pharmaceuticals USA Inc. (“Hikma”) (collectively, the “Moving Defendants”) to exclude proposed testimony of Dr. Adam Matzger, Ph.D. (“Dr. Matzger”) (the “Moving Defendants’ Motion”). (D.I. 271). Plaintiffs Pfizer Inc., FoldRx Pharmaceuticals, LLC, PF PRISM IMB B.V., Wyeth LLC and The Scripps Research Institute (collectively, “Plaintiffs”) oppose. (D.I. 281). For the reasons set forth below, the Moving Defendants’ Motion is DENIED.

I. BACKGROUND

A. Procedural History

On July 15, 2022, Plaintiffs initiated this action by filing a Complaint against Defendant Dexcel Pharma Technologies Limited (“Dexcel”), alleging infringement of U.S. Patent Nos. 7,214,695 (“the ’695 patent”), 7,214,696 (“the ’696 patent”), and 9,770,441 (“the ’441 patent”) (collectively, the “Asserted Patents”). (D.I. 1 ¶ 1). In the Dexcel Complaint, Plaintiffs alleged that Dexcel’s Abbreviated New Drug Application (“ANDA”) No. 218365 (“Dexcel’s ANDA”) contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), and that Dexcel’s ANDA product, which is a generic version of tafamidis, is infringing certain claims of the Asserted Patents. (D.I. 1 ¶¶ 2, 30, 61, & 93).

On November 27, 2023, Magistrate Judge Christopher Burke, to whom this action is referred for pre-trial matters (*see* D.I. 14), consolidated the *Dexcel* action with related actions brought against Defendants Cipla, Aurobindo Pharma Limited (“Aurobindo”), and Zenara Pharma Private Limited (“Zenara”). (D.I. 22 ¶ 1).

On October 11, 2024, Plaintiffs, along with Zenara and Hikma, stipulated that Zenara had transferred all interest in its ANDA No. 218205, through which it sought to market a generic version of tafamidis, to Hikma. (D.I. 105 ¶ 3). Therefore, Hikma was substituted for Zenara as a Defendant in this action. (*Id.* ¶ 19).

On January 15, 2026, Defendants Hikma and Cipla moved to exclude the proposed testimony of Plaintiffs' expert Dr. Adam Matzger, Ph.D ("Dr. Matzger"). (D.I. 271 at 1). The Moving Defendants' Motion has been fully briefed (D.I. 272; D.I. 281; D.I. 287).

B. The '441 Patent

The Moving Defendants' Motion challenges portions of Dr. Matzger's proposed testimony concerning infringement of the '441 Patent. (*See* D.I. 272 at 1-2). Claim 1 is the only independent claim asserted in the '441 Patent and it recites:

1. A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
 - a solid state NMR spectrum comprising ^{13}C chemical shifts (ppm) at 120.8 ± 0.2 and 127.7 ± 0.2 ,
 - a powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6 ± 0.2 , and
 - a Raman spectrum comprising a Raman shift peak (cm^{-1}) at 1292 ± 2 .

('441 Patent at Claim 1).

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 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. 19-3900, 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); *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 also Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (quoting *Daubert*, 509 U.S. at 596).

Rule 702 applies to expert testimony offered in a bench trial. *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832-33 (3d Cir. 2020). However, in a bench trial, there is greater flexibility as to how and when a trial judge may exercise his or her gate-keeping function. *Id.*; *see also In Re Novartis Pharms. Corp. v. MSN Pharms. Inc.*, No. 20-md-2930-RGA, 2024 WL 4723274, at *2 (D. Del. Nov. 8, 2024) (collecting cases).

III. DISCUSSION

The Moving Defendants attempt to exclude Dr. Matzger’s proposed testimony regarding two topics: (1) infringement opinions that rely on curve fitting and (2) infringement opinions that rely on unvalidated Raman Mapping. (D.I. 272 at 9-20). The Court will address each in turn.

A. The Court Does Not Exclude Dr. Matzger’s Infringement Opinions that Rely on Curve Fitting

The Moving Defendants first attempt to exclude the portions of Dr. Matzger’s infringement opinions that rely on a “curve fitting” analysis. (D.I. 272 at 9-18). According to the Moving Defendants, the curve-fitting used by Dr. Matzger involves little more than artificially selecting a “peak position[] in a Raman spectrum in a region where no peaks have been detected by peak-picking software.” (*Id.* at 10). In the Moving Defendants’ view, because “Dr. Matzger’s curve-fitted spectra are arbitrary theoretical models that are influenced by user choices,” they cannot be relied upon to show the existence of a peak in a Raman spectrum without validation. (*Id.* at 11). In attempting to show the lack of reliability by the curve-fitting methodology used by Dr. Matzger, the Moving Defendants contend that Hikma’s expert, Dr. Jonathan Steed, produced an alternative, non-infringing spectrum using the data and methods outlined by Dr. Matzger (but with a different

postulated peak) and obtained a result with a lower χ^2 value (which, according to Dr. Matzger, shows greater fidelity)¹. (*Id.* at 11-12).

Additionally, the Moving Defendants assert that Dr. Matzger does not attempt to validate the “underlying assumptions of his curve fitting method,” as well as the “resulting theoretical spectra to determine if any such spectra are accurate,” despite multiple ways Dr. Matzger could have done so. (D.I. 272 at 15). Instead, according to the Moving Defendants, Dr. Matzger impermissibly relies solely on his “visual inspection” of the underlying spectra produced and a decreasing χ^2 value to justify its accuracy. (*Id.* at 14-15).

Lastly, the Moving Defendants claim that Dr. Matzger’s “curve-fitting” technique is not accepted in the scientific community. (D.I. 272 at 15-16). Although the Moving Defendants acknowledge that curve fitting is used in scientific literature, they claim that such uses concern a different purpose: quantification of *known* peaks in a Raman spectrum. (*Id.* at 16). The Moving Defendants contend that all references cited by Dr. Matzger in support of his “curve-fitting” methodology use the curve-fitting technique to quantify known peaks, not fit the spectrum around an unknown peak, and in fact warn how “curve fitting can result in theoretical peaks that do not exist in the experimental data.” (*Id.* at 17). Moreover, the Moving Defendants assert that Dr. Matzger has never used curve-fitting for such a purpose outside the litigation context. (*Id.*).

Plaintiffs disagree. Plaintiffs assert that, although automatic peak-picking can be useful in some circumstances, it does not work where peaks overlap, as a large peak can obscure the positions of adjacent, smaller peaks. (D.I. 281 at 12). This phenomenon is known as peak convolution, which Plaintiffs contend is extensively described in scientific literature. (*Id.* at 12-

¹ A chi-squared value (χ^2) measures “the similarity between a projected and actual spectra.” (D.I. 272, Ex. 6 ¶¶ 189, 192).

13). Furthermore, Plaintiffs assert that Dr. Matzger did not arbitrarily pick an infringing peak, as the Moving Defendants suggest, but instead identified a region where a large peak could be obscuring a smaller peak. (*Id.*). After the region containing an obscured peak was identified by Dr. Matzger through a visual inspection, an algorithm found the best fit around the region that Dr. Matzger identified. (*Id.* at 13).

The Court declines to exclude the proposed testimony of Dr. Matzger that relies on curve fitting. In Dr. Matzger's opening report, he explained that he analyzed the samples of drug products provided by the Moving Defendants using Raman Spectroscopy. (D.I. 272, Ex. 3 ¶ 213; D.I. 282, Ex. 3 ¶ 174). Dr. Matzger first used "a software program called WiRE," which "automatically identified the Raman shift peaks in the individual [Raman] spectra." (D.I. 272, Ex. 3 ¶ 214; D.I. 282, Ex. 3 ¶ 175). However, Dr. Matzger explained that "[a]utomatic peak picking using a simple peak picking algorithm can be less accurate where multiple peaks are overlapping," because "[o]verlapping peaks can cause the true peak position to appear shifted, especially when the peak being identified is smaller than its neighbors." (D.I. 272, Ex. 3 ¶ 215). In light of the weaknesses of automatic peak-picking software, Dr. Matzger determined that there was likely a peak between the ranges of 1274 cm^{-1} and 1351 cm^{-1} , but that the precise location of the peak was "not immediately discernible through visual inspection . . . because the area contains multiple overlapping peaks from a mixture of forms contributing to the signal." (D.I. 272, Ex. 6 ¶ 142).

In order to appropriately fit the spectra, Dr. Matzger took the following steps: (1) he first "truncated the spectral window to include the peak of interest and any adjacent peaks that could influence the intensity of the peak of interest," (2) he "then removed the baseline using a second-order polynomial leaving the Raman shift peaks;" (3) he next "indicated all potential peak positions based on a visual inspection, *i.e.*, [he] approximately marked what appeared to be the

true position of overlapping peaks,” (4) he ran a fitting procedure built in the WiRE program, “which consists of moving and resizing each modelled peak and minimizing the difference between the theoretical and experimental spectra,” and, finally, (5) he “inspected the fit by comparing the theoretical and experimental spectra and determined the fit was good for each experimental spectrum in the region of the 1292 cm^{-1} peak.” (D.I. 272, Ex. 3 ¶ 215). Dr. Matzger explained that this is the procedure outlined for performing deconvolution in WiRE by Renishaw, the manufacturer of his Raman instrument. (D.I. 272, Ex. 6 ¶¶ 187-189).

Here, the Court was provided more than Dr. Matzger’s “qualifications, [his] conclusions and [his] assurances of reliability.” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (“*Daubert II*”). Instead, Dr. Matzger identified a region where he believed a peak exists (but the precise peak location was unclear due to interference from neighboring peaks), and performed deconvolution according to a method outlined by the manufacturer of his Raman instrument and accepted in scientific literature. (See D.I. 272, Ex 3 ¶¶ 174-76, 213-215; D.I. 272, Ex. 6 ¶¶ 187-89). The Moving Defendants’ arguments to the contrary are unpersuasive.

First, the Moving Defendants assert that curve-fitting is not reliable because of the arbitrary nature in which Dr. Matzger selected the initial postulated peak position at 1292 cm^{-1} . (See D.I. 272 at 10). However, the Moving Defendants fail to appreciate that Dr. Matzger explained *why* he chose to position a Raman peak at 1292 cm^{-1} : a visual inspection that resulted in identifying overlapping peaks. (D.I. 272, Ex. 3 ¶¶ 215, 220). The Court finds Dr. Matzger’s explanation to be sufficient. See *Breidor v. Sears, Roebuck & Co.*, 722 F.2d 1134, 1138-39 (3d Cir. 1983) (“Where there is a logical basis for an expert’s opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge.”). Moreover, “[t]he test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether

the opinion is supported by the best methodology or unassailable research,” but “whether the expert’s testimony is supported by ‘good grounds.’” *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 81 (3d Cir. 2017) (quoting *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000)). The Moving Defendants will have an opportunity to challenge Dr. Matzger’s foundation during cross examination.

Second, the Moving Defendants’ reliance on their experts’ curve-fitting methods is misplaced. (See D.I. 272 at 11-14). Although the Court recognizes that the Moving Defendants were not offering an alternative curve-fitting calculation to substantively challenge the way in which Dr. Matzger conducted his curve-fitting analysis, and were instead using their experts to show the arbitrary nature of curve-fitting, “disagreement[s] with the calculation methodology and the underlying assumptions” Dr. Matzger made go “to the weight given to his testimony, rather than admissibility.” *Leonard v. Stemtech Int’l Inc.*, 834 F.3d 376, 391 (3d Cir. 2016) (citing *Breidor*, 722 F.2d at 1138-39).

Third, the Moving Defendants’ assertions that Dr. Matzger should have independently validated his curve-fitted spectra likewise does not affect the admissibility of his testimony. Although the Moving Defendants attempt to frame validation of curve-fitting spectra as part of a proper methodology for curve-fitting, the Court believes such validation “is a question of the strength of Dr. [Matzger’s] conclusions, not his methodology, and, therefore, is properly the subject of cross-examination, not a *Daubert* exclusion.” *ARM Ltd. v. Qualcomm Inc.*, C.A. No. 22-1146 (MN), 2024 WL 5504800, at *3 (D. Del. Dec. 10, 2024) (citing *AVM Techs., LLC v. Intel Corp.*, No. 15-33 (RGA), 2017 WL 1536453, at *2 (D. Del. Apr. 27, 2017)); *see also Oddi v. Ford Motor Co.*, 234 F.3d 136, 145-46 (3d Cir. 2000) (“The test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather,

the test is whether the particular opinion is based on valid reasoning and reliable methodology. The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.” (cleaned up)).

Fourth, assuming, without deciding, that the cited scientific literature does not endorse curve-fitting for the identification of a peak not thought to be present, the Court is nonetheless unpersuaded that Dr. Matzger’s curve-fitting methodology is unreliable due to a lack of acceptance in the scientific community. Although “general acceptance” is undoubtedly relevant under *Daubert*, “[a] ‘reliability assessment does not require . . . explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.’” *Daubert*, 509 U.S. at 594 (quoting *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985)). The Court does recognize that “scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Daubert*, 509 U.S. at 591. However, Dr. Matzger’s testimony concerns identifying peaks in Raman spectra, which, in the Court’s view, is sufficiently related to the scientific literature cited in his expert reports. Moreover, the Moving Defendants fail to point to literature that teaches that curve-fitting is *not* suitable for the purpose Dr. Matzger employs it. (*See generally* D.I. 272 at 16-18 (differentiating Dr. Matzger’s references but failing to cite any references that discourage using curve-fitting for unknown peak identification)). The *Daubert* standard is not high, and Plaintiffs have shown that Dr. Matzger’s methods have more than a bare relevance to their already accepted use in the scientific community. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) (“Once again, we emphasize that the standard is not that high.”). Therefore, any weaknesses the Moving Defendants perceive in the way Dr. Matzger employed curve-fitting can be adequately addressed during cross examination and through the use of competing experts.

Fifth, the Moving Defendants' final argument regarding Dr. Matzger's failure to use the curve-fitting for peak identification in the past is unpersuasive. As explained in detail above, Plaintiffs have adequately shown that Dr. Matzger's proposed testimony is sufficiently reliable to be introduced at trial, and that the problems identified with Dr. Matzger's foundations, methodology, and conclusions can be adequately addressed through competing experts and cross-examination. In support of their contention that Dr. Matzger's testimony is "biased" and should not be admitted because he does not use curve-fitting in his research for the purposes he used curve-fitting in this litigation, the Moving Defendants cite to *Schering Corp. v. Apotex Inc.*, C.A. No. 09-6373 (PGS), 2012 WL 2263292 (D.N.J. June 15, 2012), *aff'd sub nom. Merck Sharp & Dohme Corp. v. Apotex Inc.*, 517 F. App'x 939 (Fed. Cir. 2013). In *Schering*, a district court credited the testimony of an opposing expert that disagreed with the methods Dr. Matzger used. (D.I. 272 at 18 (citing *Schering*, 2012 WL 2263292, at *5)). However, the cited *Schering* opinion was issued *after* trial. *See Schering*, 2012 WL 2263292, at *1. Moreover, Dr. Matzger's unpersuasive testimony in *Schering* was the subject of a *Daubert* motion, which the *Schering* court denied. (Transcript of Trial at 27:8-29:7, *Schering Corp. v. Apotex Inc.*, C.A. No. 09-6373 (PGS) (D.N.J. July 6, 2012), (ECF No. 468) ("I rule that based on the Federal Rules of Evidence especially Section 700, dealing with the testimony of experts, that Dr. Matzger may testify with regard to the conversion.")). Given the posture of *Schering*, which the Moving Defendants cite with approval, the Court is further persuaded that cross-examination and opposing expert testimony are adequate to address any deficiencies with Dr. Matzger's proposed testimony in this case.

In sum, Plaintiffs have shown that the testimony relying on curve-fitting that Dr. Matzger intends to offer is sufficiently reliable for the purpose of admissibility.

B. The Court Does Not Exclude Dr. Matzger's Infringement Opinions that Rely on Raman Mapping

The Moving Defendants next attempt to exclude testimony from Dr. Matzger that relies on Raman mapping, because he “admits that he did not use any reference standards.” (D.I. 272 at 18). This failure, according to the Moving Defendants, causes “his conclusions about infringement [to be] unreliable,” as there would be no way to know whether the alleged “peak” required by the claims “is due to tafamidis,” or due to an excipient/degradant in the Moving Defendants’ drug products. (*Id.* at 18-19). Additionally, the Moving Defendants claim that Dr. Matzger’s testimony is unreliable as he did not offer sufficient proof of instrument calibration on the day he tested the Hikma and Cipla samples. (*Id.* at 20).

In response, Plaintiffs contend that “Dr. Matzger offered cogent explanations for why the peaks he identified are attributable to tafamidis and not excipients or degradants.” (D.I. 281 at 18). Additionally, Plaintiffs assert that Dr. Matzger did testify that his Raman instrument was calibrated. (*Id.* at 19).

The Court agrees with Plaintiffs. As explained above, weaknesses in Dr. Matzger’s conclusions, rather than the unreliability of his chosen methodology, are not sufficient to warrant the exclusion of his proposed testimony. *Oddi*, 234 F.3d at 146. However, “[a] court ‘must examine the expert’s conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used.’” *Id.* (quoting *Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 153 (3d Cir. 1999)). In the present case, the Court concludes that Dr. Matzger’s conclusions could have reliably flowed from his methodology. Dr. Matzger provided cogent explanations as to why his methods supported his conclusion that the infringing peaks were caused by tafamidis, rather than an excipient or degradant. (*See* D.I. 282, Ex. 3 ¶ 185 (“Consistent with my opinion above, I performed a Raman map of samples of Cipla’s *tafamidis API*, and found

spectra having all the peaks recited in claims 1 and 8” (emphasis added)); D.I. 282, Ex. 7 ¶ 218 (“the crystalline API was readily distinguishable from the surrounding excipients (which were in liquid form)”). The Moving Defendants’ assertions to the contrary are therefore better categorized as performing an “analysis of [Dr. Matzger’s] conclusions themselves,” rather than alleging “too great a gap between the data and the opinion proffered.” *Oddi*, 234 F.3d at 146 (cleaned up). The Moving Defendants may question Dr. Matzger as to his conclusions during cross-examination.

Additionally, Dr. Matzger has repeatedly stated that he calibrated his Raman instrument “before each day’s collection.” (D.I. 282, Ex. 3 ¶ 174; D.I. 282, Ex. 6 ¶ 213). The Moving Defendants’ assertion that Dr. Matzger’s testimony relying on Raman mapping should be excluded because he failed to provide proof or data (other than his testimony) regarding his calibration is therefore unpersuasive. If the Moving Defendants believe that Dr. Matzger’s calibrations of his Raman instrument were insufficient, they are free to cross-examine him on this point.

IV. CONCLUSION

For all of the foregoing reasons, the Court denies the Moving Defendants’ Motion (D.I. 271) and will enter an Order consistent with this Memorandum Opinion.

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DEXCEL PHARMA TECHNOLOGIES
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ORDER

At Wilmington this 10th day of March 2026, **IT IS HEREBY ORDERED** that the Motion of Defendants Cipla Limited and Hikma Pharmaceuticals USA Inc. to Exclude the Proposed Testimony of Dr. Adam Matzger, Ph.D. (D.I. 271) is **DENIED**.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE