IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HARMONY BIOSCIENCES, LLC, BIOPROJECT SOCIÉTÉ CIVILE DE RECHERCHE and BIOPROJECT PHARMA SAS,	)	
Plaintiffs,	)	Civil Action No. 23-1286-JLH-SRF
v.	)	
LUPIN LIMITED, *et al.*,	)	
Defendants.	)	

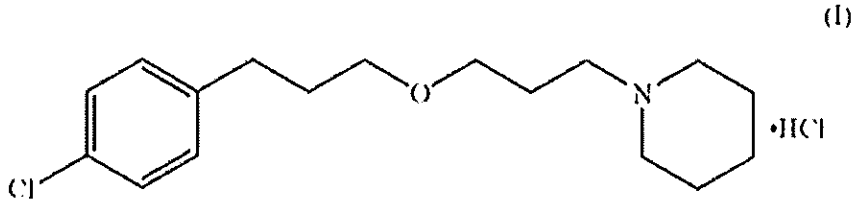
MEMORANDUM ORDER

At Wilmington this **27th** day of **October, 2025**, the court having considered the parties' discovery dispute letter submissions and associated filings (D.I. 355; D.I. 356; D.I. 357; D.I. 361), IT IS ORDERED that the motion to strike the expert report of Stephan Parent and any reliance thereon in the reply expert reports of Dr. Allan S. Myerson,[1] as raised in the emergency motion for teleconference to resolve discovery dispute filed by defendants AET Pharma US, Inc. ("AET"), Novitium Pharma LLC ("Novitium"), and Hikma Pharmaceuticals USA Inc. ("Hikma;" collectively, "Movants"), (D.I. 348), is GRANTED for the following reasons:

1. Background. Plaintiffs filed this Hatch-Waxman case in November of 2023 against multiple defendants, alleging that those defendants submitted Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiffs' Wakix® drug for the treatment of narcolepsy prior to the

[1] Movants move to strike portions of three reply expert reports by Dr. Myerson regarding infringement of the '197 patent by AET, Hikma, and Novitium, respectively. (D.I. 355, Exs. C, D, E; Proposed Order)

expiration of certain patents covering Wakix®. (D.I. 1) The active pharmaceutical ingredient ("API") in Wakix® is pitolisant hydrochloride. (*Id.* at ¶ 4) The asserted patent at issue in this dispute, U.S. Patent No. 8,207,197 ("the '197 patent"), covers a specific crystalline form of pitolisant hydrochloride. (*Id.*, Ex. B) Independent claim 1 of the '197 patent defines the crystalline form of pitolisant hydrochloride as "having an X-ray diffractogram that comprises characteristic peaks" as follows:

> 1. Crystalline 1-[3-[3-(4-chlorophenyl)propoxy]propyl]-piperidine monohydrochloride of formula (I)
>
> 
>
>
> optionally comprising water up to 6%, and having an X-ray diffractogram that comprises characteristic peaks (2θ) at 11.2° , 19.9° ,20.7° and 34.1° ±0.2°

('197 patent, col. 22:12-28)

2. Movants represent that AET's ANDA product samples were provided to at least one of Plaintiffs' experts, Dr. Fabia Gozzo, by March of 2025. (D.I. 355 at 1) According to Movants, Dr. Gozzo had experience with performing synchroton X-ray diffraction ("s-XRD") testing. (*Id.*) Although Movants cite no exhibits or other evidence confirming Dr. Gozzo's receipt of AET's ANDA product samples, the court assumes the truth of the representation because Plaintiffs do not refute it or otherwise mention Dr. Gozzo in their responsive submission. (D.I. 361)

3. Under the scheduling order, Plaintiffs were required to serve opening expert reports on infringement by July 1, 2025. (D.I. 34 at ¶ 9(f)(i); D.I. 310) On that date, Plaintiffs served opening infringement reports by Dr. Allan S. Myerson and Dr. Robert Wenslow. (D.I. 330) Dr. Wenslow's opening expert report described the solid-state nuclear magnetic resonance ("ssNMR") testing he performed on Movants' ANDA products to demonstrate that the accused ANDA products exhibited the characteristic peaks of the claimed crystalline pitolisant hydrochloride. (D.I. 361, Ex. 1) Dr. Myerson relied on Dr. Wenslow's ssNMR findings to support his conclusion that Movants' ANDA products infringe. (*Id.*, Ex. 2 at ¶¶ 65-67, 85; Ex. 3 at ¶¶ 102-04, 124; Ex. 4 at ¶¶ 79-81, 100) There appears to be no dispute that Dr. Gozzo's opening infringement report served on non-moving defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (together, "MSN") included s-XRD testing on MSN's ANDA product to show that the X-ray diffractogram limitation in the '197 patent was met. (*Id.* at 1; D.I. 355 at 1 n.3)

4. Movants represent that, before they served their rebuttal reports on non-infringement, Plaintiffs disclosed Stephan D. Parent as an expert in s-XRD testing. (D.I. 355 at 1) Although Movants cite no evidence of record to support the timing of Parent's disclosure, Plaintiffs do not challenge Movants' representation. Plaintiffs did not seek leave to supplement their opening infringement reports after disclosing Parent. (*Id.* at 2)

5. Movants served their rebuttal reports on non-infringement on August 28, 2025. (D.I. 331) Each of these rebuttal reports challenged Dr. Wenslow's use of ssNMR testing to identify the presence of crystalline pitolisant hydrochloride with the claimed XRD peaks. (D.I. 361, Ex. 5 at ¶¶ 15, 80, 89; Ex. 6 at ¶¶ 47, 49; Ex. 7 at ¶¶ 56-61, 109, 116-17; Ex. 8 at ¶¶ 87-89, 131-39, 141, 144, 170-74)

6. On September 29, 2025, Parent performed synchroton X-ray powder diffraction ("s-XRPD") testing "on one of the ANDA Products previously tested using ssNMR." (D.I. 361 at 1; D.I. 355, Ex. A at ¶ 61) Parent disclosed the results of his s-XRPD testing on a sample from AET's ANDA product in an expert report served on October 9, 2025, the deadline for service of reply expert reports. (D.I. 331; D.I. 347; D.I. 355, Ex. A at 1) The excerpts of Parent's expert report included in this record do not mention Dr. Wenslow's ssNMR testing or any rebuttal reports served by Movants. (D.I. 355, Ex. A) Dr. Myerson's reply expert reports rely on the data from both Dr. Wenslow's ssNMR testing and Parent's s-XRPD testing. (D.I. 361, Exs. 10-12)

7. Movants objected to Parent's report and Dr. Myerson's reliance on that report, and Plaintiffs offered to stipulate to Movants' service of sur-reply reports. (D.I. 361 at 2) Movants declined. (*Id.*) Expert depositions are underway, with expert discovery set to close on November 25, 2025. (D.I. 331) The pretrial conference is scheduled for January 21, 2026, and a four-day bench trial is set to begin on February 17, 2026. (D.I. 34)

8. Analysis. Movants contend that Parent's report should be stricken as untimely under the scheduling order pursuant to Federal Rules of Civil Procedure 26(a)(2)(D) and 16(f)(1)(C). (D.I. 355 at 2-3) Rule 26(a)(2)(D) requires a party to disclose expert testimony "at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(D). According to Movants, Parent's report is an untimely opening expert report, and the court should therefore invoke its discretion to sanction Plaintiffs by striking Parent's report for "fail[ure] to obey a scheduling or other pretrial order." Fed. R. Civ. P. 16(f)(1)(C).

9. The court agrees. Paragraph 9(f)(i) of the scheduling order required the party with the initial burden of proof on the subject matter to serve an opening expert report on or before

July 1, 2025. (D.I. 34 at ¶ 9(f)(i); D.I. 310) There is no dispute that Plaintiffs bear the initial burden of proof on infringement. *See Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1125 (Fed. Cir. 2018). To meet that burden, Plaintiffs served the opening expert report of Dr. Wenslow, which relied on ssNMR testing purporting to show the "characteristic peaks" claimed in the '197 patent. Plaintiffs did not serve an opening expert report by Parent or any other expert that relied on XRD testing to show infringement of the '197 patent by Movants' ANDA products.

10. Plaintiffs first disclosed s-XRPD testing data regarding Movants' ANDA products in Parent's "reply" expert report served on October 9, 2025. (D.I. 355, Ex. A) Parent's reply report is untimely "because the expert report process as to that subject matter w[as] never . . . properly set in motion in the first place[,]" and it precludes "a direct response from any opposing expert" on his s-XRPD methodology. *Bausch & Lomb Inc. v. SBH Holdings LLC*, 20-1463-GBW-CJB, D.I. 141 (D. Del. July 1, 2024) (D.I. 356, Ex. K), *adopted*, 2024 WL 4315054, at *5 (D. Del. Sept. 27, 2024); *Oracle Am., Inc. v. Google Inc.*, 2011 WL 5572835, at *3 (N.D. Cal. Nov. 15, 2011) (striking the reply report of a new expert who did not serve an opening expert report and "crept out of the woodwork" only for the purpose of serving a reply report). Movants aptly state that, "[i]f Plaintiffs intended on carrying their burden of proof against any Defendant via s-XRD testing, whether in addition to or instead of ssNMR testing, then they were required to include that theory and supporting evidence in their opening expert reports, not three months later." (D.I. 355 at 2) Parent's report cannot be viewed as anything other than an out-of-time attempt to introduce an additional expert opinion on infringement based upon testing under another technique that could have been utilized alongside of, or in place of, the original ssNMR testing methodology.

11. Plaintiffs have not demonstrated good cause for failing to comply with the expert report deadlines because their exclusive reliance on ssNMR testing data in their opening infringement reports was a strategic choice. (D.I. 356, Ex. K) The use of XRD testing to demonstrate a claimed "X-ray diffractogram that comprises characteristic peaks" is facially apparent from the claim language of the '197 patent. ('197 patent, col. 22:25-27) Accordingly, Plaintiffs' opening expert report on MSN's ANDA product relied on XRD testing to show infringement, and Plaintiffs disclosed Parent as an expert in XRD testing before the service of any rebuttal reports challenging Dr. Wenslow's use of ssNMR testing. Moreover, Dr. Wenslow's deposition testimony confirms that, "[a]s an analytical chemist, I would measure the X-ray diffractogram, I would obtain an X-ray diffractogram and determine the presence of peaks and the 2-theta values associated with those peaks" to determine whether the claimed crystalline material exhibits the recited peaks. (D.I. 355, Ex. B at 67:2-18)

12. According to Plaintiffs, Parent's report is proper because it "directly contradicts [and] rebuts" Movants' rebuttal reports challenging Dr. Wenslow's ssNMR methodology. (D.I. 361 at 2-3) In support, Plaintiffs reference portions of Movants' rebuttal reports stating that:

- "ssNMR testing is not a surrogate for XRD testing," (D.I. 361, Ex. 5 at ¶ 15);
- "ssNMR is not an appropriate test to identify specific solid-state forms of pitolisant hydrochloride, especially in formulated products," (*id.*, Ex. 6 at ¶ 49);
- "ssNMR as employed by Dr. Wenslow can[not] identify specific solid-state forms of pitolisant hydrochloride," (*id.*, Ex. 6 at ¶ 47);
- "SSNMR testing cannot alone be taken as proof of the existence of polymorphism," and "overlapping SSNMR peaks do not prove that two APIs have the same crystalline form or the same XRPD diffraction peaks," (*id.*, Ex. 7 at ¶ 116);

- "the SSNMR testing that Dr. Wenslow conducted is insufficient to show the presence of crystalline pitolisant hydrochloride with the claimed characteristic peaks," (*id.*, Ex. 7 at ¶ 109)
- "the C-ssNMR testing performed on Novitium's ANDA products cannot prove that the products contain the claimed crystalline form," (*id.*, Ex. 8 at ¶ 133); and
- "ssNMR results generally cannot be converted to, or used to predict, the XRPD peaks that a tested sample would have," (*id.*, Ex. 8 at ¶ 89).

But the attached excerpts of Parent's report do not mention Movants' rebuttal reports, nor do they directly acknowledge Dr. Wenslow's report or ssNMR testing more generally by comparing the results of his s-XRPD testing with the ssNMR test results. Instead, Parent's report purportedly "detected the claimed crystalline form in AET's ANDA Products—which were already [purportedly] found to contain the claimed crystalline form by Dr. Wenslow." (D.I. 361 at 2) Parent's report is thus being used to supplement or buttress Dr. Wenslow's ssNMR data with another testing methodology, instead of being used to "directly contradict or rebut the opposing party's expert." *See Wang v. Injective Labs Inc.*, C.A. No. 22-943-WCB, D.I. 149 at 2, (D. Del. Mar. 11, 2025) (D.I. 356, Ex. M at 2). Simply stated, Parent's report reads like an opening expert report because it acknowledges that "XRPD has been a well-known method for analyzing solid pharmaceutical materials for decades[,]" then discusses the data from his s-XRPD testing and opines on the results. (D.I. 355, Ex. A at ¶ 21)

13. Plaintiffs contend that Dr. Myerson used Parent's s-XRPD testing data to properly rebut Movants' criticisms of Dr. Wenslow's methodology. (D.I. 361 at 2) The tables of contents for unchallenged portions of Dr. Myerson's reply reports indicate that he discussed why Dr. Wenslow's ssNMR testing was a reliable method for detecting crystallinity and distinguishing

among crystalline forms. (*Id.*, Ex. 10 at i) But the challenged portions of Dr. Myerson's reply reports do not directly address the issue posed in rebuttal that "a person of ordinary skill would not consider ssNMR testing to be a surrogate for the XRD testing specified in the claims" and that "ssNMR testing does not provide an XRD diffractogram or otherwise identify any characteristic XRD peaks." (D.I. 355, Ex. C at ¶ 64) Instead, Dr. Myerson indirectly addresses these criticisms by describing the results of Parent's s-XRPD testing, a different methodology yielding testing data that allegedly supports the results of Dr. Wenslow's ssNMR testing:

> Mr. Parent's testing refutes the criticisms leveled by Defendants' experts and further substantiates the reliability of the method Dr. Wenslow used to conduct is C-ssNMR filtering experiments on the AET, Novitium, and Hikma ANDA Products. It demonstrates that Dr. Wenslow's C-ssNMR filtering experiment accurately identified crystalline pitolisant hydrochloride in AET's ANDA Products. It further demonstrates that the crystalline pitolisant hydrochloride in the AET, Novitium, and Hikma ANDA Products identified by Dr. Wenslow's C-ssNMR experiments is the claimed form with the characteristic XRPD peaks.

(D.I. 361, Ex. 10 at ¶ 67) Rather than directly contradicting the positions taken in Movants' rebuttal reports, Dr. Myerson's analysis of Parent's data reads as additional support for Dr. Wenslow's affirmative case on infringement, which could have been made in opening expert reports based on the claim language Plaintiffs are asserting against Movants.

14. The case authority cited by Plaintiffs does not support a different outcome. For example, in *Helios Software, LLC v. SpectorSoft Corp.*, the plaintiffs moved to exclude certain opinions of the defendant's invalidity expert because his experimental testing analysis appeared for the first time in his reply report. C.A. No. 12-81-LPS, 2014 WL 4796111, at *3 (D. Del. Sept. 18, 2014). After the plaintiffs' rebuttal report criticized the lack of testing data in the defendant's opening report, the defendant's expert explained in his reply report that he did not believe testing was necessary to support the points made in his opening report. *Id.* The court permitted the reply report, noting that the subsequent testing was "precisely the type of evidence

[that is] intended solely to contradict or rebut evidence on the subject matter identified by another party that Rule 26(a)(2)(D)(ii) permits in rebuttal." *Id.* Here, in contrast, Plaintiffs provided ssNMR testing data at the outset in Dr. Wenslow's opening report and now attempt to supplement that data with Parent's s-XRPD testing. There is no evidence that either Parent or Dr. Wenslow believed s-XRPD testing to be superfluous in an infringement analysis of a patent claim reciting a chemical compound "having an X-ray diffractogram that comprises characteristic peaks[.]" ('197 patent, col. 22:25-27)

15. The *Pennypack* factors also weigh in favor of striking Parent's report and the portions of Dr. Myerson's reply reports that rely on Parent's analysis. *See Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977)). Although the "exclusion of critical evidence is an extreme sanction" and "the *Pennypack* factors may be very forgiving, they are not a sieve." *Natera, Inc. v. CareDx, Inc.*, C.A. No. 20-38-CFC-CJB, D.I. 392 (D. Del. Oct. 6, 2023) (internal citations and quotation marks omitted) (D.I. 356, Ex. O). "[I]n sophisticated, complex litigation involving parties represented by competent counsel, courts have been less indulgent in applying the *Pennypack* factors and more willing to exclude evidence without a strict showing that each of the *Pennypack* factors has been satisfied." *TQ Delta, LLC v. 2Wire, Inc.*, C.A. No. 13-1835-RGA, 2021 WL 3525234, at *2 (D. Del. Aug. 11, 2021) (quoting *Bridgestone Sports Co. v. Acushnet Co.*, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (internal quotation marks omitted)).

16. Movants have shown that they are prejudiced by the untimely Parent report because AET has no opportunity to retain its own s-XRD expert and generate its own s-XRD studies on its ANDA products in response. (D.I. 355 at 3) "It is undoubtedly surprising and prejudicial

when a party springs a new theory in the middle of expert discovery without any prior hint that it might do so." (D.I. 356, Ex. O) Citing Parent's own report, Movants explain that access to specialized facilities capable of performing s-XRD testing is limited, and testing likely could not be completed in a timely fashion. (*Id.*; Ex. A at ¶¶ 31-33, 62) Plaintiffs respond that Hikma has access to an expert who can perform s-XRPD testing, and AET and Novitium have not adequately demonstrated the need for more time to perform the testing. (D.I. 361 at 4) The court is not persuaded that Movants can perform s-XRPD testing, retain experts, and issue sur-reply reports in a time frame that would not disrupt the January 21, 2026 pretrial conference date, especially in the midst of expert depositions. The prejudice, cure, and disruption of trial factors therefore weigh in favor of Movants.

17. The fourth factor, which considers bad faith or willfulness, is neutral. Although Plaintiffs' conduct does not rise to the level of bad faith or willfulness, Plaintiffs have not plausibly explained why they initially chose to forego XRD testing on Movants' ANDA products to establish infringement of a claim reciting a chemical compound "having an X-ray diffractogram that comprises characteristic peaks[.]" (D.I. 356, Ex. O) ("The Court cannot countenance a world where, for no good reason at all, parties simply wait until the middle of expert discovery to disclose new theories.").

18. The final *Pennypack* factor regarding the importance of the information withheld also weighs in favor of Movants. As previously described, Plaintiffs made a strategic choice not to include XRD testing in their opening infringement reports. Plaintiffs' decision to reserve this information for Parent's reply report suggests that Plaintiffs do not view it as critical to their infringement case. (D.I. 356, Ex. O)

19. Conclusion. For the foregoing reasons, IT IS ORDERED that Movants' motion to strike the expert report of Stephan Parent regarding s-XRPD testing and any reliance thereon in the reply expert reports of Dr. Myerson is GRANTED and the following are STRICKEN:

a. Parent's expert report;

b. Paragraphs 64 to 67 of Dr. Myerson's reply expert report regarding infringement of the '197 patent by AET;

c. Paragraphs 7, 63, 66 to 67, and 74 of Dr. Myerson's reply expert report regarding infringement of the '197 patent by Hikma; and

d. Paragraphs 7, 32, 47, and 50 to 51 of Dr. Myerson's reply expert report regarding infringement of the '197 patent by Novitium.

(D.I. 357) IT IS FURTHER ORDERED that the discovery dispute teleconference set for October 28, 2025 at 2:00 p.m. is CANCELLED.

20. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties shall jointly submit a proposed redacted version by no later than **November 3, 2025**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court

determines the motion lacks a meritorious basis, the documents will be unsealed within fourteen (14) days of the date the Memorandum Order issued.

21. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to four (4) pages each.

22. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge