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.	)	[redacted]
LUPIN LIMITED, *et al.*,	)	
Defendants.	)	

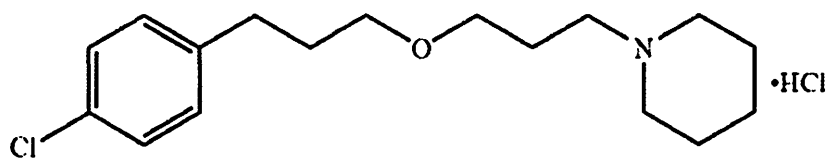
MEMORANDUM ORDER

At Wilmington this **13th** day of **January, 2026**, the court having considered the parties' discovery dispute letter submissions and associated filings (D.I. 488; D.I. 497) and the parties' arguments during the discovery dispute hearing on January 12, 2026, IT IS ORDERED that Plaintiffs' motion to strike paragraphs 101 to 115, 122 to 125, and Exhibits 6 to 11B and 13 of the November 24, 2025 sur-rebuttal expert report of Dr. Robert Dinnebier, which was raised in the pending motions for teleconference to resolve discovery dispute, (D.I. 497), is GRANTED-IN-PART for the reasons set forth below:

1. **Background.** Plaintiffs Harmony Biosciences, LLC, Harmony Biosciences Management, Inc., Bioprojet Société Civile de Recherche, and Bioprojet Pharma SAS (collectively, "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 expiration of

certain patents covering Wakix®. (D.I. 1) The active pharmaceutical ingredient ("API") in Wakix® is pitolisant hydrochloride. (*Id.* at ¶ 4)

2. Plaintiffs allege infringement of two patents. United States 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)**
>
> (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) United States Patent No. 8,486,947 ("the '947 patent") is directed to a method for treating excessive daytime sleepiness. (D.I. 1, Ex. A)

3. On November 4, 2025, the court issued a Memorandum Order denying defendant MSN's motion to strike portions of the reply expert report of Dr. Fabia Gozzo. (D.I. 396) In her opening expert report, Dr. Gozzo described the synchroton X-ray powder diffraction ("s-XRPD") testing she performed on samples of MSN's ANDA product to illustrate the characteristic peaks claimed in the '197 patent. (*Id.* at 6-7) Dr. Gozzo then used TOPAS® software to analyze her original s-XRPD data to generate peak lists with better visibility in her reply report. (*Id.* at 7)

4. Instead of striking Dr. Gozzo's TOPAS® analysis, the court granted leave for MSN to submit a sur-reply report addressing Dr. Gozzo's peak list analysis and use of the TOPAS® software because MSN's rebuttal expert, Dr. Jennifer Swift, did not have expertise in the use of TOPAS®. (*Id.* at 10) Therefore, the court ordered the parties to "submit to the court a joint proposed form of order setting forth a deadline for MSN to serve a sur-reply report addressing Dr. Gozzo's peak list analysis and use of the TOPAS® software." (*Id.* at 10-11)

5. On November 7, 2025, the parties proposed a schedule for the court-ordered sur-reply briefing. (D.I. 402) The proposal provided that MSN would serve a sur-reply report to Dr. Gozzo's reply report on November 24, 2025, limited in scope to specific portions of Dr. Gozzo's reply report. (*Id.*) MSN retained Dr. Robert Dinnebier, to provide a sur-reply report. Plaintiffs now claim that the sur-reply report of Dr. Robert Dinnebier exceeds the scope permitted by the court's November 4, 2025 Memorandum Order and the parties' stipulated sur-reply briefing schedule. (D.I. 488) In the unchallenged portion of Dr. Dinnebier's report, he disputes the accuracy of Dr. Gozzo's TOPAS® peak list analysis because she disabled the "Lorentz correction," a critical setting for determining whether a peak is present. (D.I. 497, Ex. E at ¶ 98)

6. Expert discovery closed on November 25, 2025. (D.I. 331) MSN deposed Dr. Gozzo on December 3 and 4, 2025, and Plaintiffs deposed Dr. Dinnebier on December 17, 2025. (D.I. 402; D.I. 488 at 1) 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)

7. Analysis. This ruling addresses whether the challenged portions of Dr. Dinnebier's sur-reply report are consistent with the parameters set forth in the court's November 4, 2025 Memorandum Order and the parties' stipulated schedule for MSN's sur-reply briefing. (D.I. 396; D.I. 402) Plaintiffs present three issues: (1) whether paragraphs 101 to 107 and Exhibits 6,

7, and 8 of Dr. Dinnebier's sur-reply report contain improper analysis regarding the validity of the '197 patent; (2) whether Dr. Dinnebier's relative intensity analysis at paragraphs 108 to 115 and Exhibits 9, 10, 11A, and 11B is responsive to the opinions in Dr. Gozzo's reply report; and (3) whether Dr. Dinnebier's analysis of U.S. Patent No. 11,623,920 ("the '920 patent") at paragraphs 122 to 125 and Exhibit 13 falls within the scope of a response to Dr. Gozzo's peak list analysis or use of the TOPAS® software. (D.I. 488) The court addresses each of these issues in turn.

8. ***Plaintiffs' motion to strike Dr. Dinnebier's alleged invalidity opinions is GRANTED.*** According to Plaintiffs, paragraphs 101 to 107 and Exhibits 6, 7, and 8 of Dr. Dinnebier's sur-reply report contain analysis regarding the validity of the '197 patent that falls outside the permitted scope ordered by the court. (D.I. 488 at 1-2) MSN responds that these portions of Dr. Dinnebier's report are proper because they "address the use of TOPAS to model the figures in the asserted '197 Patent for purposes of assessing relative intensities of the claimed peaks—not to analyze or opine on the legal question of claim validity." (D.I. 497 at 2) MSN argues that the challenged paragraphs provide necessary context for Dr. Dinnebier's opinion by demonstrating the flaws in Dr. Gozzo's peak intensity analysis resulting from her disablement of a key setting (the "Lorentz correction") in the TOPAS® software. (1/12/2026 Tr.)

9. Plaintiffs' motion to strike paragraphs 101 to 107 and Exhibits 6, 7, and 8 of Dr. Dinnebier's sur-reply report is GRANTED. Instead of confining his comments to criticism of Dr. Gozzo's peak list analysis and methodology, Dr. Dinnebier segues into a critique of the '197 patent itself, questioning the validity of the patent based on what is disclosed in Figure 1 of the '197 patent. (D.I. 497, Ex. E at ¶¶ 101-07) During his deposition, Dr. Dinnebier expressed his "personal belief" that the '197 patent is invalid because it "contains a single crystal structure

which doesn't match the powder pattern which is in the patent." (D.I. 488, Ex. 4 at 21:22-22:19) This statement, which Dr. Dinnebier associates with his personal opinion on invalidity, is reflected in paragraphs 103 and 104 of his sur-reply report:

> Upon digitizing the powder pattern in Figure 1 of the '197 Patent and comparing it to a calculated pattern generated from the atomic coordinates disclosed in Table 3 of the '197 Patent, I observed substantial discrepancies. . . .
>
> I observed multiple intensity and positional deviations throughout the pattern. Such discrepancies raise questions regarding the accuracy and reliability of the powder pattern presented in the '197 Patent. . . . In my opinion, the powder scan shown in Figure 1 of the '197 Patent is not of sufficient quality to reliably support the detailed structural claims made. Thus, based on my analysis, I do not consider the reported structural model in the '197 Patent to be correct. The unit cell content and molecular arrangement are inconsistent with the powder data, and the model does not accurately reproduce the diffraction pattern.

(*Id.*, Ex. 2 at ¶¶ 103-04)

10. MSN focuses on the report's assessment of the relative intensities of the claimed peaks without resolving the fact that those statements were made in the context of Dr. Dinnebier's opinion regarding the "accuracy and reliability of the powder pattern presented in the '197 Patent." (D.I. 497 at 2; D.I. 488, Ex. 2 at ¶ 104) In other words, the challenged portions of Dr. Dinnebier's report focus on alleged internal discrepancies within the '197 patent without addressing Dr. Gozzo's alleged detection of the [redacted] peak in MSN's ANDA. A comparison of Dr. Dinnebier and Dr. Gozzo's reports does not support MSN's position that Dr. Dinnebier's opinion is responsive:

Dr. Gozzo's Reply Report (D.I. 488, Ex. 1 at ¶ 29)	**Dr. Dinnebier's Sur-Reply Report (D.I. 488, Ex. 2 at ¶ 105)**
The peak at [redacted] is intrinsically weak (see Figure 4 of my Opening Report) and further complicated by overlapping excipient peaks. For this reason, its direct visibility is limited. However, as can be seen by the peak lists, a [redacted] peak was in fact detected in MSN's ANDA Product. See Exhibit 11 (peak lists for	Furthermore, the reflection reported as a peak at 34.1° 2θ in the '197 Patent is particularly problematic from a crystallographic perspective. (See Gozzo Reply ¶ 29.) According to the simulated pattern derived from the '197 Patent's own atomic coordinates, the region around 34.1° 2θ

Batch Nos. [redacted] Our analysis was not designed to determine how the detected intensity in this region is partitioned between the HARMONY API and the excipients in view of the above-mentioned intrinsic weakness of the peak and its overlap with excipient signals. One certainly cannot conclude that the HARMONY API does not contribute to this intensity. The presence of the HARMONY API is firmly established by the [redacted], so there is no compelling reason to invest further effort into this particular weak and overlapping peak. Although we have not attempted to partition the [redacted] peak between the excipients and the crystalline HARMONY API, it was detected in MSN's ANDA Products. To state that the peak is "absent," Swift Report ¶ 205, is therefore incorrect.	contains at least four distinct Bragg reflections lying in close proximity. In a correctly measured, randomly oriented powder pattern, these reflections would appear as a cluster of partially resolved peaks, each corresponding to a unique set of Miller indices. However, the '197 Patent lists a single "peak" at 34.1° without identifying which of the four underlying reflections it is intended to represent. If preferred-orientation effects are present, it becomes impossible to determine which of the overlapping reflections is being amplified or suppressed. Under such circumstances, the reported "34.1° peak" has no well-defined crystallographic meaning with respect to the structure disclosed in the '197 Patent.

As MSN explained at the hearing, Dr. Dinnebier directly critiques Dr. Gozzo's TOPAS® peak list analysis in paragraph 98 of his report, describing how the Lorentz correction was disabled and the impact it had on her analysis. (D.I. 497, Ex. E at ¶ 98) However, the context necessary to understand Dr. Dinnebier's critique is adequately preserved in the unchallenged portions of his report.

11. MSN offered to stipulate that "Dr. Dinnebier will not offer any invalidity opinion at trial and [MSN] will not rely on Dr. Dinnebier in support of its invalidity briefing." (D.I. 497 at 2) Exhibit D to MSN's responsive letter shows that Plaintiffs rejected this offer because "MSN cannot control how the other Defendants or the Court will use this testimony once it is in the record, so the prejudice to Plaintiffs would remain even if we were to stipulate as you have described." (*Id.*, Ex. D at 1) In their opening letter, Plaintiffs reiterated their concern that "other Defendants could still use Dr. Dinnebier's analysis to support their invalidity arguments." (D.I.

488 at 2 n.1) MSN does not address Plaintiffs' concern that other Defendants could still use Dr. Dinnebar's analysis in support of their invalidity arguments. MSN's proposed stipulation would not fully resolve the parties' dispute and is therefore not a viable form of relief.

12. ***Plaintiffs' motion to strike Dr. Dinnebier's relative intensity analysis is DENIED without prejudice.*** Plaintiffs next move to strike paragraphs 108 to 115 and Exhibits 9, 10, 11A, and 11B of Dr. Dinnebier's report. (D.I. 488 at 2) At the hearing on January 12, 2026, Plaintiffs confined their arguments to the scope of the court's November 4, 2025 Memorandum Order and did not focus on the timing of Dr. Dinnebier's argument under the *Pennypack* factors. (1/12/2026 Tr.) Nonetheless, Plaintiffs claim that they are prejudiced because they have no opportunity to respond to Dr. Dinnebier's opinions in an expert report. (*Id.*)

13. Plaintiffs object to Dr. Dinnebier's reliance on the diffractograms included in Dr. Gozzo's opening report while acknowledging that those diffractograms constituted "***the exact same data***" Dr. Gozzo used to generate the peak lists included in her reply report. (D.I. 372 at 2) (emphasis in original). MSN explains that "Dr. Gozzo's TOPAS® peak list analysis is fundamentally based on the data in her opening report diffractograms." (D.I. 497 at 3) Dr. Gozzo's use of the TOPAS® software to analyze the peaks in the diffractograms was not disclosed until her reply report, and MSN's rebuttal expert had no access to or expertise in TOPAS®. (1/12/2026 Tr.) The challenged portions of Dr. Dinnebier's report adequately tie his discussion of the diffractogram data to his analysis using the TOPAS® software and his critique of Dr. Gozzo's TOPAS® analysis. (D.I. 497, Ex. E at ¶¶ 98, 108-15) Plaintiffs have not shown that Dr. Dinnebier was obligated to view Dr. Gozzo's reply report in a vacuum and remove any reference to data included in her opening report.

14. Plaintiffs further contend that Dr. Dinnebier's own relative intensity analysis goes beyond the scope of Dr. Gozzo's generation of peak lists using TOPAS®. (D.I. 488 at 2) Dr. Dinnebier is critical of Dr. Gozzo's conclusions about the presence of the claimed peaks and their relative intensities, as well as her use of TOPAS® with a disabled setting that calls into question the accuracy of her peak intensity analysis. (D.I. 497, Ex. E at ¶ 98) To demonstrate the flaws in her analysis, Dr. Dinnebier conducts his own relative peak intensity analysis and opines on his findings. (*Id.*, Ex. E at ¶¶ 108-15) This is responsive to the TOPAS® peak list analysis disclosed in Dr. Gozzo's reply report, distinguishing this case from *Withrow v. Spears*. *See Withrow v. Spears*, 967 F. Supp. 2d 982, 1002-03 (D. Del. 2013) (finding reply expert report was not proper where it addressed the content of the rebuttal report only "at the highest level of abstraction" without "referenc[ing] or critiqu[ing] the content of *what was discussed*" in the rebuttal report). A comparison of relevant excerpts from Dr. Gozzo's reply report and Dr. Dinnebier's sur-reply report demonstrates the foregoing:

Dr. Gozzo's Reply Report	**Dr. Dinnebier's Sur-Reply Report**
[A]s can be seen by the peak lists, a [redacted] peak was in fact detected in MSN's ANDA Product. . . . The presence of the HARMONY API is firmly established by the [redacted], so there is no compelling reason to invest further effort into this particular weak and overlapping peak. Although we have not attempted to partition the [redacted] peak between the excipients and the crystalline HARMONY API, it was detected in MSN's ANDA Products. (D.I. 488, Ex. 1 at ¶ 29)	Next, I performed a normalized comparison of Harmony's API, generated using the diffraction data provided by Dr. Gozzo. . . . Normalization allows for direct evaluation of the relative intensities of the reflections independent of absolute scaling. . . . The normalized comparison therefore provides an additional verification that the experimentally observed peak-height ratios can be meaningfully assessed. In addition, the normalization comparison further supports the conclusion that, if the patented crystal structure were present in MSN's ANDA Product samples, the relative intensity of the 19.9° reflection would appear with at least approximately 80% of the intensity of the 11.2° reflection[.] (D.I. 488, Ex. 2 at ¶ 108)
Using the TOPAS software, I prepared peak lists corresponding to the diffractograms for	I prepared overlays of all of Dr. Gozzo's scans together. (See figures below, also

testing on capillaries taken from [certain] batches to compare to Dr. Swift's peak identification. Dr. Swift's criteria for the existence of a peak suggests that there is no peak at [redacted] for [certain] Batch Nos. . . . However, the peak lists generated with the TOPAS software show that each of these tablets demonstrated a peak at [redacted] . . . Indeed, the [redacted] peak at [redacted] is visible in the diffractograms for these samples if we plot the diffraction pattern with the appropriate zoomed-in XY-axes scales. (D.I. 488, Ex. 1 at ¶¶ 46-47)	attached as Exhibits 11A ([redacted]) and 11B ([redacted].) Upon visual inspection of the overlays, a peak at [redacted] is visible across the samples. However, there is no visible peak at [redacted] and certainly not with an intensity comparable or at least 80% that of any peak at [redacted]. . . . This peak intensity analysis contradicts Dr. Gozzo's TOPAS peak list analysis (by which Dr. Gozzo concluded that a peak at [redacted] is present in MSN's ANDA Product samples) by confirming that no diffraction peak is present at [redacted] (D.I. 488, Ex. 2 at ¶ 112)
[F]or batches FGCB161 and FGCB162 the peak at [redacted] is stronger in the intact tablet patterns than the capillary whereas for FGCB164, the peak is more visible in the pattern of the capillary. This further demonstrates that peak detection is totally uncorrelated with whether the samples were ground. (D.I. 488, Ex. 1 at ¶ 47 n.1)	Dr. Gozzo appears to be arguing that there are discrepancies in intensity for so-called peaks in MSN's ANDA Product samples. Dr. Myerson similarly attempts to explain the mismatch between the relative intensities in the MSN samples and those predicted by the '197 Patent by citing "preferred orientation, counting statistics, and interference from other components." (Myerson Reply ¶ 31.) However, issues with preferred orientation, counting statistics, and interference from the other components in the drug product fail to explain why the relative intensities of the so-called peaks in MSN's ANDA Product samples would be so different from what the '197 Patent predicts. (D.I. 488, Ex. 2 at ¶ 115)

15. ***Plaintiffs' motion to strike Dr. Dinnebier's analysis of the '920 patent is DENIED without prejudice.*** Plaintiffs move to strike paragraphs 122 to 125 and Exhibit 13 of Dr. Dinnebier's report, which are directed to indexing the diffractogram provided in the '920 patent, because these portions of the report are not related to Dr. Gozzo's peak list analysis or her use of the TOPAS® software. (D.I. 488 at 3) Plaintiffs explain that Dr. Jennifer Swift first addressed the '920 patent in her rebuttal report, and Dr. Gozzo responded to that analysis in her reply report. (*Id.*) As a result, Plaintiffs allege that further indexing of the diffractogram provided in

the '920 patent by Dr. Dinnebier falls outside the scope of a permissible sur-reply under the court's November 4, 2025 Memorandum Order. (*Id.*) In response, MSN contends that the challenged portions of Dr. Dinnebier's report pertaining to the '920 patent are proper because they directly contradict Dr. Gozzo's conclusion that "the presence of the HARMONY API is firmly established by [redacted]." (D.I. 497 at 3) (quoting D.I. 488, Ex. 1 at ¶ 29).

16. Dr. Dinnebier's opinion is within the scope of the court's November 4, 2025 Memorandum Order permitting a sur-reply report on "Dr. Gozzo's peak list analysis and use of the TOPAS® software." (D.I. 396 at 10-11) At the time of the parties' letter briefing on MSN's motion to strike portions of Dr. Gozzo's reply report, MSN did not know that Dr. Gozzo performed her analysis of the '920 patent using the TOPAS® software. (1/12/2026 Tr.) Dr. Dinnebier's own TOPAS® analysis of the '920 patent allegedly demonstrates the error in Dr. Gozzo's finding that the peaks cannot be attributed to anything other than the Harmony API. (D.I. 497, Ex. E at ¶ 122) The challenged portions of Dr. Dinnebier's report are tailored to Dr. Gozzo's peak list analysis and are therefore properly within the scope of the court's November 4, 2025 Memorandum Order as demonstrated in the comparison below:

Dr. Gozzo's Reply Report	**Dr. Dinnebier's Sur-Reply Report**
[A]s can be seen by the peak lists, a [redacted] peak was in fact detected in MSN's ANDA Product. . . . The presence of the HARMONY API is firmly established by the [redacted] so there is no compelling reason to invest further effort into this particular weak and overlapping peak. Although we have not attempted to partition the [redacted] peak between the excipients and the crystalline HARMONY API, it was detected in MSN's ANDA Products. (D.I. 488, Ex. 1 at ¶ 29)	Dr. Gozzo asserts that "the presence of the HARMONY API is firmly established by the [redacted][.]" (Gozzo Reply ¶ 29.) However, the peak lists generated by Dr. Gozzo and shown in the Gozzo Reply Report Exhibit 11 [redacted] In fact, all four of the peaks in claim 1 of the '197 Patent (11.2°, 19.9°, 20.7°, 34.1°) are also found in crystalline

	pitolisant hydrochloride sesquihydrate within ±0.2° 2θ. [redacted] (D.I. 488, Ex. 2 at ¶ 122) [redacted] I used the procedure described above to digitize the powder diffraction data reproduced in Figure 5 of the '920 Patent and performed indexing followed by whole pattern refinement according to the Pawley method. . . . [T]he diffraction pattern disclosed in the '920 Patent is most consistent with a pure pitolisant hydrochloride sesquihydrate phase and does not indicate the presence of any additional crystalline form of pitolisant hydrochloride. In other words, it is unlikely that pitolisant hydrochloride sesquihydrate reported in U.S. Patent No. 11,623,920 is actually a mixture of various crystalline forms of pitolisant. (*Id.*, Ex. 2 at ¶ 123)

17. The court permitted MSN to file a sur-reply report so it could address Dr. Gozzo's peak list analysis and use of the TOPAS® software. (D.I. 396 at 10-11) A hypertechnical comparison of the expert opinions and a narrow construction of the scope of the court's November 4, 2025 Memorandum Order would run the risk of fragmenting Dr. Dinnebier's expert opinion and diminishing its utility. Matters regarding the weight and admissibility of this evidence are reserved for the trial judge.

18. Conclusion. For the foregoing reasons, Plaintiffs' motion to strike portions of Dr. Dinnebier's sur-reply report is GRANTED-IN-PART as follows:

a. Plaintiffs' motion to strike paragraphs 101 to 107 and Exhibits 6, 7, and 8 of Dr. Dinnebier's sur-reply report is GRANTED.

b. Plaintiffs' motion to strike paragraphs 108 to 115, paragraphs 122 to 125, and Exhibits 9, 10, 11A, 11B, and 13 of Dr. Dinnebier's sur-reply report is DENIED without prejudice.

19. 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 **January 20, 2026**, 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.

20. 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.

21. 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