

Problem Clarification Questions – 2024 HLMCC

1. The record states that Riley is a citizen of “Wohio”, but does not mention “Wohio” anywhere else in the problem. In fact, the problem seems to indicate that she is a citizen of Transylvania in later discussions. Is Riley a citizen of the State of Wohio or the State of Transylvania? What role does Wohio play in the problem?

Riley is a citizen of Wohio. She is bringing this case in Transylvania because its products liability statute is more protective to litigants like her than the one in Wohio. The original draft of the problem included information about diversity jurisdiction having been met under 28 U.S.C. § 1332. That information was removed for the sake of keeping the competition problem simplified. A footnote has been added to the problem clarifying that diversity jurisdiction is not at issue in this case.

2. The record does not specify how the action was brought. Are we to assume that the initial filing was in the district court? Can the problem drafters provide any indication as to where the action was first filed and why this was the case?

This case was initially filed in the United States District Court for the Southern District of Transylvania. The plaintiff believed that bringing an action in federal court would work better for her case for various reasons (e.g., a significant backlog of cases in Transylvania’s state courts). We have updated the problem to include specific language regarding this point.

3. I would like to ask about the fact that Riley Ortega is a Wohio Citizen (R. at 3) but is filing a cause of action under a Transylvania statute. Are we to assume that jurisdiction is proper in this problem?

Yes. Per the answer to Question #1, we have updated the problem to include specific language stating that diversity jurisdiction has been met in this case and is not at issue.

4. In the full paragraph on page 4 of the record, there's a sentence that begins "Sleepternity allegedly made the modification to reduce manufacturing costs..." Should "Sleepternity" be "Mednology" in this sentence?

Yes. “Sleepternity” should be “Mednology” in that sentence. The updated problem has corrected this error.

5. On page 24 of the record, the end of the district court's order, should the order contain a certification for immediate appeal under 28 U.S.C. 1292(b) or Federal Rule of Civil Procedure 54(b)? Since the district court's order denies Mednology's motion to dismiss Riley's state-law claims, the order appears to not be a final appealable order subject to immediate appeal. The Seventeenth Circuit would therefore have lacked jurisdiction over the appeal, rendering its decision void. The Supreme Court's order granting certiorari on the two specific questions suggests that appellate jurisdiction is not meant to be a focus of the parties' arguments. If the district court had certified the order for immediate appeal under 28 U.S.C. 1292(b) or Federal Rule of Civil Procedure 54(b), there shouldn't be any issue with appellate jurisdiction.

That is correct. The original draft of the problem contained the following sentence at the end of the district court's opinion:

“This Judgment Entry is certified and entered by the Court pursuant to Rule 54(b) of the Federal Rules of Civil Procedure.”

This sentence was footnoted, and the corresponding footnote stated:

“The Rule 54(b) certification and a written explanation for this certification are not provided in this competition problem packet, since they are not needed for resolving the principal issues that will be litigated during the Health Law Moot Court Competition.”

We have updated the problem to reintroduce this language.

6. Is Ms. Ortega a Medicare recipient or is that fact omitted intentionally?

The status of whether Ms. Ortega is a Medicare/Medicaid recipient has been omitted intentionally.

7. Did Sleepternity get FDA premarket approval or market approval?

- “Sleepternity was recently approved for marketing as a Class III medical device by the FDA on December 30, 2022.” R. at 3-4.
- “Mednology fraudulently obtained from the FDA pre-marketing approval for Sleepternity.” R. at 19.
- “that CMS’s decision to pay or reimburse for the use of Sleepternity was based on the FDA approving the medical device for marketing and distribution,” R. at 36.

Mednology obtained pre-marketing approval from the FDA for its Sleepternity device. We have updated the problem to clarify this point and make it explicit in the record.

8. Did the relator continue using Sleepternity? What parts of Sleepternity did she continue to use? Do the parts of Sleepternity the relator continued to use contain PE-PUR foam?

- “she discontinued her use of Sleepternity . . . [a]lthough she continues to use the Sleepternity headband to treat her insomnia.” R. at 5. (she stopped using it but also continued using part of it?)
- “Additionally, the device comes with noise-cancelling sleep headphones that can be attached to the mask.” R. at 3. (no headband is described. Did the relator discontinue using the mask but continue using the headphones?)
- “Mednology modified the sound-dampening foam contained in the Sleepternity machine.” R. at 4. (what parts of Sleepternity contain the sound-dampening foam?)

The relator continued to use part of the Sleepternity machine, specifically the noise-cancelling headphones. She discontinued using the mask. Therefore, the

Record on Page 5 should have stated “headphones” rather than “headband.” We have updated the problem to correct this error.

Finally, the part of Sleepternity that the relator continued to use, which is the headphones, did not contain any PE-PUR foam. We have updated the problem to make this point explicit in the record.

We have become aware of a recent ruling out of the Middle District of Florida in *United States ex. rel. Zafirvo v. Florida Medical Associates*, 8:19-cv-1236-KKM-SPF (M.D. Fla.). The District Court held that qui tam enforcement of the FCA is unconstitutional. The Board has discussed this case and believes that it too heavily favors one side of the competition. Therefore, for the purposes of this competition, you are to assume that this case does not exist in any way.

All of the corrections above have been incorporated into the competition problem. The corrections appear in the updated problem in red ink. Any removed items have been struck through. Please take note that, due to the corrections being added in, some of the page numbers may have changed for citations to the record. This will not affect your brief score in any way. An updated copy of the problem has been uploaded to the competition’s website. As a courtesy, we have also emailed each competitor a copy of this document and the updated problem. The judges for the competition will be sent a copy of the problem clarification and updated problem, and they will be instructed to carefully review both prior to judging competition rounds.

Thank you for your patience. We look forward to seeing you all in November!

Sincerely,

The Moot Court Board