

Filed: February 4, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN INSTITUTIONAL LLC and PFIZER INC.,

Petitioners

v.

NOVO NORDISK A/S,

Patent Owner

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Case No. IPR2020-00324<sup>1</sup>

U.S. Patent No. 8,114,833

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**PETITIONER'S OBJECTIONS TO PATENT OWNER'S  
SUR-REPLY EVIDENCE**

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<sup>1</sup> IPR2020-01252 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Institutional LLC (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Novo Nordisk A/S (“Patent Owner”) with the Patent Owner Sur-Reply in the above-captioned *inter partes* review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five (5) business days of the Patent Owner Sur-Reply filed by Patent Owner on January 29, 2021, Paper Nos. 44 (Confidential) and 45 (Redacted). Petitioner’s objections provide notice to Patent Owner that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’833 patent” means U.S. Patent No. 8,114,833. All objections under FRE 801-803 (hearsay) apply to the extent that Patent Owner relies on the exhibit identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are from Patent Owner’s exhibit list and are used for identification purposes only. The use of an exhibit description does not indicate that Petitioner agrees with that description or characterization of the document.

Petitioner objects to paragraphs in the Patent Owner Sur-Reply that rely on

exhibits objected to in this Petitioner's Objections to Sur-Reply Evidence.

<b>Exhibit</b>	<b>Patent Owner's Description</b>	<b>Objection</b>
2095	Witte, R. & Witte, J. Chapter 11: More about Hypothesis Testing. 11 STATISTICS, 195-220 (2017)	A, B, C, E, G, J, K, L
2096	Deposition Transcript of Laird Forrest, Ph.D., dated January 21, 2021 (Confidential – Protective Order Material)	J, Z
2097	Redacted Version of Deposition Transcript of Laird Forrest, Ph.D., dated January 21, 2021	J, Z

**Objection Key:**

- A: FRE 801/802/803 (hearsay)
- B: FRE 901/902 (lacking authentication)
- C: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '833 patent or the prior art status is not clear
- D: FRE 402 (relevance) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods
- E: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '833 patent or the prior art status is not clear
- F: FRE 403 (confusing, waste of time) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods
- G: FRE 106 (completeness) the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document
- H: FRE 1001-1003 (best evidence)
- I: FRE 403, 901 (improper compilation)
- J: FRE 403 (cumulative)
- K: FRE 402 (relevance) the document is not relevant to any issue in the IPR proceeding
- L: FRE 403 (confusing, waste of time) the document is not relevant to any issue in the IPR proceeding
- M: FRE 702/703 to the extent that Patent Owner submits an Expert Declaration that improperly or unreasonably relies on the exhibit
- N: FRE 1006 (improper summary)

- O: 37 C.F.R. § 42.65 (fails to provide underlying facts or data on which opinion is based)
- P: Expert testimony fails to identify with particularity the underlying facts or data on which the opinion is based, violating 37 C.F.R. § 42.65(a)
- Q: FRE 701, 702 (improper expert testimony) improper expert testimony by a lay witness
- R: FRE 702 (improper expert testimony) expert testimony that relies on the document is not based on sufficient facts or data and/or is not the product of reliable principles and methods
- S: FRE 703 (bases of expert opinion) expert testimony that relies on the document is unreliable because the document is not of a type reasonably relied upon by experts in the field
- T: FRE 702/703 to the extent that the expert declarant relies on an exhibit objected to under grounds R and S, the testimony is (i) not based on sufficient facts or data and/or is not the product of reliable principles and methods and/or is (ii) is unreliable because the exhibit is not of a type reasonably relied upon by experts in the field
- U: FRE 602 (lack of personal knowledge)
- V: FRE 403 (confusing, waste of time, unfair prejudice) the document is in a different forum and its use would unfairly prejudice Petitioner, waste time and confuse the issues
- W: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding because the disclosure and/or purported date of the document is not sufficient to antedate Exhibit 1005 as a prior art reference.
- X: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the disclosure and/or purported date of the document is not sufficient to antedate Exhibit 1005 as a prior art reference.
- Y: 37 C.F.R. § 42.63(b) (failing to file an affidavit) the translation filed with the underlying document is not filed with an affidavit in accordance with 37 C.F.R. § 42.63(b)
- Z: 37 C.F.R. § 42.53(f)(5) as the deposition transcript is unsigned and (i) the

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