

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00050
U.S. Patent 8,377,903

**PATENT OWNER'S OBJECTIONS TO EVIDENCE FILED AND SERVED
WITH PETITIONER'S REPLY PURSUANT TO 37 C.F.R. § 42.64**

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply

Pursuant to 37 C.F.R. § 42.64, Patent Owner submits the following objections to evidence filed and served with Petitioner's Reply ("Reply").

Patent Owner's objections apply equally to Petitioner's reliance on these exhibits in any subsequently filed documents. These objections are timely, having been filed within five business days of service of evidence to which the objection is directed (June 20, 2024).

Exhibit 1047 (Rebuttal Declaration of Benjamin M Greenberg, M.D.)

Patent Owner objects to Exhibit 1047 as misleading, incomplete, lacking relevance, and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106 and 401-403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 2-4, 6-7, 9, 11-12, 14, 17, 19, 22, and 33 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited;
- ¶ 34 as misleading, incomplete, and irrelevant because it lacks support for the contentions for which it is cited and improperly characterizes the

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply teachings of the '903 patent;

- ¶¶ 5, 8, 10, 13, 15-16, 18, 20-21, 23-32, and 34-39 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of Bodor and Rice;
- ¶¶ 4-5, 9, 11-14, 16, 18-21, 25, 29-31, 33-34, 38-39 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Lublin;
- ¶¶ 2, 7, 34 and 39 as irrelevant because these paragraphs refer to U.S. Patent No. 7,713,947, which is not at issue in this *inter partes* review. Further, any probative value of these paragraphs is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, needlessly presenting cumulative evidence.

Patent Owner further objects to ¶¶ 2-39 as not being based on sufficient facts or data, the product of reliable principles and methods, and/or not reflecting a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702-703.

Patent Owner further objects to ¶¶ 1-4, 6-9, 11-12 and 31-33 because

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply these paragraphs are not directly cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401-402.

Patent Owner further objects to ¶¶ 9, 18, 21-22, 28, which cite to exhibits that are not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Exhibit 1039

Patent Owner objects to Exhibit 1039 under Fed. R. Evid. 401-403 as lacking relevance and because its probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, and/or wasting time.

Patent Owner objects to Exhibit 1039 as inadmissible hearsay, to the extent it is being offered to prove the truth of the matter asserted.

Patent Owner further objects to Exhibit 1039 under Fed. R. Evid. 901 because the document lacks authentication.

Patent Owner further objects to any paragraph of Exhibit 1047 to the extent it relies on Exhibit 1039 for at least the reasons identified here.

Exhibits 1041, 1042, 1045

Patent Owner objects to Exhibit 1041 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the April 18, 2024 Deposition of Dr. Nicholas Bodor because the transcript does not include any forthcoming errata sheet, which must in fairness be considered at the same time as the exhibit.

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply
Patent Owner objects to Exhibit 1042 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the June 14, 2024 Deposition of Dr. Fred Lublin because the transcript does not include any forthcoming errata sheet, which must in fairness be considered at the same time as the exhibit.

Patent Owner objects to Exhibit 1045 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the June 7, 2024 Deposition of Dr. Alain Munafò because the transcript does not include any forthcoming errata sheet, which must in fairness be considered at the same time as the exhibit.

Patent Owner further objects to Exhibits 1041, 1042, 1045 for the same reasons as the objections stated in those transcripts.

Patent Owner further objects to any paragraph of Exhibits 1047 to the extent it relies on Exhibits 1041, 1042, 1045, for at least the reasons identified here.

Respectfully submitted,

Date: June 27, 2024

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