

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00481
U.S. Patent No. 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 (April 5, 2024).

Exhibit 1084 (Second Declaration of Aaron E. Miller, M.D.).

Patent Owner objects to Exhibit 1084 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:

- ¶¶ 10, 18, 27-35, 62, 93, and 124-125 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of the '903 patent;
- ¶¶ 7, 9, 12-14, 16, 21-35, 49-50, 53-55, 59, 61-64, 66-67, 69, 72-74, 76, 78, 80-83, 86, 89-91, 97, 99-102, 104-119, 121-130, and 132-133 as misleading,

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incomplete, and irrelevant because they lack support for the contentions for which they are cited;

- ¶¶ 8, 10-11, 15, 17-19, 51-52, 56-58, 60, 65, 68, 70-71, 75, 77, 79, 84-85, 87-88, 92-96, 98, 103, 120, and 131 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 Stelmasiak;
- ¶¶ 7-15, 17-19, 22-26, 29-31, 50-55, 57-58, 60, 62-97, 102, 104-115, 117, 119-127, and 129-133 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;
- ¶¶ 8, 15, 17, 58, 60, 63-65, 91, and 94 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. Meibohm;
- ¶¶ 8 and 58 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. Bodor; and
- ¶¶ 16, 18, and 91-93 as irrelevant because these paragraphs refer to art not relied upon in the Grounds at issue in this inter partes review. Further, any probative value of these paragraphs is substantially outweighed by the

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danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence.

Patent Owner further objects to ¶¶ 7-19, 21-35, and 49-133 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 ¶¶ 9, 21, and 49, because these paragraphs are not directly cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401-402. Petitioner includes two citations in the Reply to all paragraphs in Exhibit 1084. *See* Reply, 18 (citing “EX1084, ¶¶1-133” for the assertion that “Merck’s remaining arguments also fail”), 23 (citing “EX1084, ¶¶1-133” for the assertion that “Merck’s other arguments” should be rejected). This does not moot Patent Owner’s objection to ¶¶ 9, 21, and 49 because Petitioner’s wholesale citation to every paragraph in Dr. Miller’s second declaration amounts to improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3); *see also Instrumentation Lab. Co. v. HemoSonics LLC*, IPR2017-00855, Paper 55 at 22-23 (P.T.A.B. Feb. 13, 2019) (declining to consider paragraphs of declaration “merely because they are cited in the Petition”).

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Patent Owner further objects to ¶ 23, n.1, which cites to an exhibit that is not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Patent Owner further objects to paragraphs that cite to Exhibit 1080 for the same reasons Patent Owner objects to Exhibit 1080 as discussed below.

Exhibit 1080 (Declaration of Rodolfo Pinal, Ph.D.).

Patent Owner objects to Exhibit 1080 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:

- ¶¶ 14-15, 20, 22, 27-44, 46-49, 51-52, 55, 59, 62-63, 66-68, 70, 74-75, 78-79, 82-83 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited;
- ¶¶ 16-19, 45, 50, 53-54, 56-58, 60-61, 64-65, 69, 71-73, 76-77, and 80-81 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 Stelmasiak;

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- ¶¶ 17-18, 67-69, and 78 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;
- ¶¶ 15, 17-18, 32-34, 41, 43, 67-69, 72-73, and 78 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. Meibohm;
- ¶¶ 15-16, 31, 34, 38, 41-42, 54, 60, and 63 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. Bodor;
- ¶¶ 45, 54, and 62 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. Munafo;
- ¶¶ 38, 41, and 63 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. Dandiker; and
- ¶¶ 19, 79, and 82 as irrelevant because these paragraphs refer to art not relied upon in the Grounds at issue in this inter partes review. Further, any probative value of these paragraphs is substantially outweighed by the

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danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence.

Patent Owner further objects to ¶¶ 14-20, 22, and 27-83 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 ¶¶ 14 and 19-20 because these paragraphs are not directly cited in the Petition and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401-402. Petitioner includes two citations in the Reply to all paragraphs in Exhibit 1080. *See* Reply, 23 (citing “EX1080, ¶¶1-83” for the assertion that “Merck’s other arguments” should be rejected). This does not moot Patent Owner’s objection to ¶¶ 14 and 19-20 because Petitioner’s wholesale citation to every paragraph in Dr. Pinal’s declaration amounts to improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3); *see also Instrumentation Lab. Co. v. HemoSonics LLC*, IPR2017-00855, Paper 55 at 22-23 (P.T.A.B. Feb. 13, 2019) (declining to consider paragraphs of declaration “merely because they are cited in the Petition”).

Patent Owner further objects to ¶¶ 4, 31, 33, 44, 46, 61, 77, and 81, which cite to exhibits that are not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

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Patent Owner further objects to paragraphs that cite Exhibit 1084 for the same reasons Patent Owner objects to Exhibit 1084 as discussed above.

Exhibits 1068, 1070-1071, 1073, 1075, 1079, and 1081-1083.

Patent Owner objects to Exhibits 1068, 1070-1071, 1073, 1075, 1079, and 1081-1083 under Fed. R. Evid. 401-403 as lacking relevance and because their 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 further objects to these exhibits under Fed. R. Evid. 401-402 because the exhibits are not cited in the Reply.

Exhibits 1055-1056, 1064-1079, and 1081-1083.

Patent Owner objects to Exhibits 1055-1056, 1064-1079, and 1081-1083 under Fed. R. Evid. 401-403 as lacking relevance and because their 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 Exhibits 1064-1074, 1076-1079, and 1081-1083 as inadmissible hearsay, to the extent they are being offered to prove the truth of the matter asserted.

Patent Owner further objects to Exhibits 1064-1074, 1076-1079, and 1082-1083 under Fed. R. Evid. 901 because the documents lack authentication.

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Patent Owner further objects to any paragraph of Exhibits 1080 and 1084 to the extent they rely on Exhibits 1064-1074, 1076-1079, and 1081-1083, for at least the reasons identified here.

Exhibits 1059-1063.

Patent Owner objects to Exhibit 1059 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the February 15, 2024 Deposition of Dr. Nicholas Bodor because the transcript does not include the accompanying errata sheet, as served by Planet Depos on March 13, 2024. The submitted errata sheet must in fairness be considered at the same time as the exhibit.

Patent Owner objects to Exhibit 1060 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the February 16, 2024 Deposition of Dr. Yogesh Dandiker because the transcript does not include the accompanying errata sheet, as served by Planet Depos on March 20, 2024. The submitted errata sheet must in fairness be considered at the same time as the exhibit.

Patent Owner objects to Exhibit 1061 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the March 5, 2024 Deposition of Dr. Fred Lublin because the transcript does not include the accompanying errata sheet, as served by Planet Depos on April 1, 2024. The submitted errata sheet must in fairness be considered at the same time as the exhibit.

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Patent Owner objects to Exhibit 1062 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the March 6, 2024 Deposition of Dr. Bernd Meibohm because the transcript does not include the accompanying errata sheet, as served by Planet Depos on April 4, 2024. The submitted errata sheet must in fairness be considered at the same time as the exhibit.

Patent Owner objects to Exhibit 1063 under Fed. R. Evid. 106 as an incomplete and/or inaccurate transcript of the March 27, 2024 Deposition of Dr. Alain Munafo because the transcript does not include the accompanying errata sheet, as served by Planet Depos on April 5, 2024. The submitted errata sheet must in fairness be considered at the same time as the exhibit.

Patent Owner further objects to Exhibits 1059-1063 for the same reasons as the objections stated in those transcripts.

Patent Owner further objects to any paragraph of Exhibits 1080 and 1084 to the extent they rely on Exhibits 1059-1063, for at least the reasons identified here.

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Respectfully submitted,

Date: April 12, 2024

By: /Emily R. Whelan/

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CERTIFICATE OF SERVICE

I hereby certify that, on April 12, 2024, I caused a true and correct copy of the following document:

- Patent Owner's Objections to Evidence Pursuant to 37 C.F.R. § 42.64 to be served via e-mail, as consented to by Petitioner, on the following attorneys of record:

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