UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARINUS PHARMACEUTICALS, INC.,
Petitioner,

v.

OVID THERAPEUTICS INC.,
Patent Owner.

PGR2023-00020
Patent No. 11,395,817 B2

PATENT OWNER'S OBJECTIONS TO PETITIONER'S REPLY EVIDENCE

The Federal Rules of Evidence ("FRE") generally apply to proceedings before the Board. 37 C.F.R. § 42.62(a). Pursuant to 37 C.F.R. § 42.64(b)(1) and the FRE, Patent Owner Ovid Therapeutics Inc. ("Ovid" or "Patent Owner") submits the following objections to certain exhibits submitted by Petitioner Marinus Pharmaceuticals, Inc. ("Marinus" or "Petitioner") with its Reply to Patent Owner Response filed on March 7, 2024. These objections apply equally to Petitioner's reliance on these exhibits in any subsequently filed documents. These objections are timely filed and served within five business days of service of the challenged evidence.

Exhibit 1033

Ovid objects to Exhibit 1033 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1033 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1034

Ovid objects to Exhibit 1034 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this

exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1034 as lacking authenticity (*see* FRE 901) because it appears to be a printout of a website. Petitioner offers no explanation of whether Exhibit 1034 is the Table of Contents to "Neurology Issue 86 (16 Supplement), dated April 5, 2016," apart from merely stating that it is. *See* Pet. Reply, ix (Petitioner's List of Exhibits); Ex. 1033, ¶ 10.

Ovid also objects to Exhibit 1034 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1035

Ovid objects to Exhibit 1035 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1035 as lacking authenticity (*see* FRE 901) because it appears to be a printout of a website. Petitioner offers no explanation of whether Exhibit 1035 is the Abstract to "Saporito et al., Gana[x]olone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat

Lithium-Pilocarpine Model of Status Epilepticus (I11.003)" or the Abstract to the "Data Blitz" presentation apart from merely stating that it is. *See* Pet. Reply, ix (Petitioner's List of Exhibits); Ex. 1033, ¶ 11.

Ovid also objects to Exhibit 1035 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1041

Ovid objects to Exhibit 1041 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1041 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Until Petitioner offers Dr. Rogawski for cross-examination as part of routine discovery under 37 C.F.R. § 42.51(b)(1)(ii), Exhibit 1035 is inadmissible hearsay under FRE 802.

Ovid also objects to Exhibit 1041 as improper reply evidence under the PTAB Consolidated Trial Practice Guide dated November 2019.

Exhibit 1043

Ovid objects to Exhibit 1043 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1043 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1045

Ovid objects to Exhibit 1045 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time, at least because it is not prior art.

Ovid also objects to Exhibit 1045 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1046

Ovid objects to Exhibit 1046 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it.

This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time, at least because this exhibit is not prior art.

Ovid also objects to Exhibit 1046 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1048

Ovid objects to Exhibit 1048 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time, at least because this exhibit is not prior art.

Ovid also objects to Exhibit 1048 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1050

Ovid objects to Exhibit 1050 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1050 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1051

Ovid objects to Exhibit 1051 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time, at least because it is not prior art.

Ovid also objects to Exhibit 1051 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1052

Ovid objects to Exhibit 1052 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1052 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1053

Ovid objects to Exhibit 1053 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it.

This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1053 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1054

Ovid objects to Exhibit 1054 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1054 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1055

Ovid objects to Exhibit 1055 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid also objects to Exhibit 1055 as lacking authenticity (*see* FRE 901). Exhibit 1055 provides no information on its face as to its source. Petitioner offers no

explanation of whether Exhibit 1055 is supplemental information to "Vaitkevicius et al., "Intravenous Ganaxolone for the Treatment of Refractory Status Epilepticus: Results from an Open-Label, Dose-Finding Phase 2 Trial," *Epilepsia* 63:2381-91 (2022)" apart from merely stating that it is. *See* Pet. Reply, x (Petitioner's List of Exhibits).

Ovid further objects to Exhibit 1055 under FRE 1002, which requires production of the original of a document to prove its contents. Petitioner offers no explanation of whether Exhibit 1055 is supplemental information to "Vaitkevicius et al., "Intravenous Ganaxolone for the Treatment of Refractory Status Epilepticus: Results from an Open-Label, Dose-Finding Phase 2 Trial," *Epilepsia* 63:2381-91 (2022)" apart from merely stating that it is. *See* Pet. Reply, x (Petitioner's List of Exhibits).

Ovid also objects to Exhibit 1055 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1056

Ovid objects to Exhibit 1056 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time, at least because this exhibit is not prior art.

Ovid also objects to Exhibit 1056 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1057

Ovid objects to Exhibit 1057 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time, at least because this exhibit is not prior art.

Ovid also objects to Exhibit 1057 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1058

Ovid objects to Exhibit 1058 under FRE 401-403 as lacking relevance to the grounds on which the Board has instituted a post-grant review. In particular, this exhibit does not make any fact more or less probable than it would be without it. This exhibit is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Ovid further objects to Exhibit 1058 under FRE 702(a) for failure to demonstrate that Dr. Baughman's scientific or technical knowledge will help the trier of fact to understand the evidence or to determine a fact in issue. Ovid also objects to Ex. 1058 under FRE 702(b), (c), and (d) for failure to demonstrate that Dr.

Baughman's testimony is based on sufficient facts or data, is the product of reliable principles and methods, and that her opinions reflect a reliable application of the principles and methods to the facts of the case.

Ovid also objects to Exhibit 1058 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Ovid also objects to Exhibit 1058 as inadmissible hearsay (*see* FRE 801 and 802), that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Until Petitioner offers Dr. Baughman for cross-examination as part of routine discovery under 37 C.F.R. § 42.51(b)(1)(ii), Exhibit 1035 is inadmissible hearsay under FRE 802.

Ovid also objects to Exhibit 1058 under 37 C.F.R. § 42.65(a) for failing to disclose the underlying facts or data on which the opinion is based. In particular, Petitioner and Dr. Baughman fail to disclose the "pharmacokinetic information related to ganaxolone that Marinus submitted to FDA" that Dr. Baughman received and reviewed in providing her opinions. Ex. 1058, ¶ 14. Ovid also objects to this exhibit use of "WinNonlin modeling" under 37 C.F.R. § 42.65(b) for failing to explain why the test or data is being used, how the test was performed and the data was generated, how the data is used to determine a value, and how the test is regarded in the relevant art.

Ovid also objects to Exhibit 1058 as improper reply evidence under the PTAB Consolidated Trial Practice Guide dated November 2019.

Respectfully submitted,

Date: March 14, 2024

By: /Anthony C. Tridico/
Anthony C. Tridico Reg. No. 45,958
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.

Counsel for Patent Owner
Ovid Therapeutics Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Objections to Petitioner's Reply Evidence** was served electronically via email on March 14, 2024, in its entirety on the following:

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Petitioner has consented to electronic service by email.

Date: March 14, 2024

By: /William Esper/
William Esper
Case Manager and PTAB Coordinator
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP