

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARINUS PHARMACEUTICALS, INC.,
Petitioner

v.

OVID THERAPEUTICS, INC.,
Patent Owner

Case PGR2023-00020
Patent 11,395,817

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
MOTION TO EXCLUDE**

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PETITIONER'S LIST OF EXHIBITS

Exhibit Number	Exhibit Description
1001	U.S. Patent No. 11,395,817 to Ovid Therapeutics, Inc. “the ’817” or “the ’817 patent”
1002	Excerpts from the File History of the ’817 Patent
1003	Declaration and Curriculum Vitae of Dr. Michael A. Rogawski (“the Rogawski Declaration” or “First Rogawski Declaration”)
1004	Reddy and Kuruba, “Experimental Models of Status Epilepticus and Neuronal Injury for Evaluation of Therapeutic Interventions,” <i>Int. J. Mol. Sci.</i> 14:18284-318 (2013) (“Reddy” or “Reddy & Kuruba”)
1005	Seinfeld et al., “Status Epilepticus,” in Additional Perspectives on Epilepsy: The Biology of a Spectrum Disorder (Cold Spring Harbor Laboratory Press, 2016, ed. Gregory L. Holmes and Jeffrey L Noebels) (“Seinfeld”)
1006	Imtiyaz et al., “The Evolution of the Pilocarpine Animal Model of Status Epilepticus,” <i>Heliyon</i> 6:e04557 (2020) (“Imtiyaz”)
1007	Turski, et al., “Review: Cholinergic Mechanisms and Epileptogenesis. The Seizures Induced by Pilocarpine: A Novel Experimental Model of Intractable Epilepsy,” <i>Synapse</i> 3:154-71 (1989) (“Turski”)
1008	Kokate et al., “Neuroactive Steroids Protect Against Pilocarpine- and Kainic Acid-induced Limbic Seizures and Status Epilepticus in Mice,” <i>Neuropharmacology</i> , 35(8):1049-56 (1996) (“Kokate”)
1009	WIPO Publication No. WO 2016/127170 (“Zhang”)
1010	WIPO Publication No. WO 2007/062266 (“Shaw”)

1011	Press Release: “Marinus Pharmaceuticals Receives FDA Orphan Drug Designation for Ganaxolone IV to Treat Status Epilepticus,” Published April 15, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus-Pharmaceuticals-Receives-FDA-Orphan-Drug-Designation-for-Ganaxolone-IV-to-Treat-Status-Epilepticus/default.aspx (“April 15, 2016, Press Release” or “Marinus’s Orphan Drug Press Release”)
1012	American Academy of Neurology (“AAN”) 2016 Annual Meeting Scientific Abstract Listing and Meeting Information, AAN 2016 Annual Meeting, Vancouver, BC, Canada, April 15-21, 2016, Available at: https://issuu.com/americanacademyofneurology/docs/16am_abstractlistingdigi_v1424 (“AAN Meeting Brochure”)
1013	Saporito et al., “Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus,” Poster, presented April 17, 2016, at the 2016 AAN Annual Meeting (“Saporito P1” or “Saporito Poster 1” or “2016 AAN Poster 1” or “2016 AAN Saporito Poster 1”)
1014	Saporito et al., “Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus,” Poster, presented April 19 and April 20, 2016, at the 2016 AAN Annual Meeting (“Saporito P2” or “Saporito Poster 2” or “2016 AAN Poster 2” or “2016 AAN Saporito Poster 2”)
1015	Declaration of Michael Saporito
1016	Saporito, “Ganaxolone Administered IV Blocks Experimental Status Epilepticus,” “Data Blitz” Presentation, April 20, 2016, at the 2016 AAN Annual Meeting (“Saporito Data Blitz Slides”)
1017	Wylie et al., Status Epilepticus. [Updated 2022 May 15]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430686/ (“Wylie”)

1018	Trinka et al., “A definition and classification of status epilepticus—Report of the ILAE Task Force on Classification of Status Epilepticus.” <i>Epilepsia</i> , 56(10):1515-1523 (2015) (“Trinka”)
1019	2016 AAN Annual Report
1020	Tsai et al., “Phase I Study to Determine the Pharmacokinetics, Pharmacodynamics, and Safety of IV Ganaxolone in Healthy Adults,” Abstract of Poster Presented at the 6 th London-Innsbruck Colloquium on Status Epilepticus and Acute Seizures April 6-8, 2017, Salzburg, Austria (“Tsai”)
1021	Drug Development and Review Definitions, August 20, 2015, Available at: https://www.fda.gov/drugs/investigational-new-drug-ind-application/drug-development-and-review-definitions
1022	Press Release: “Marinus Pharmaceuticals Doses First Subject in Phase I Clinical Trial for Ganaxolone IV,” Published on June 22, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus-Pharmaceuticals-Doses-First-Subject-in-Phase-1-Clinical-Trial-for-Ganaxolone-IV/default.aspx (“June 22, 2016, Press Release” or “Marinus’s Phase I Press Release”)
1023	U.S. Patent No. 10,799,485
1024	U.S. Patent No. 10,603,308
1025	U.S. Patent No. 10,363,246
1026	Excerpts from the File History of US Patent No. 10,603,308
1027	Excerpts from the File History of US Patent No. 10,799,485
1028	Carter et al., “Characterization of the Anticonvulsant Properties of Ganaxolone (CCD 1042: 3 α -Hydroxy-3 β -methyl-5 α -pregnan-20-one), a Selective, High-Affinity, Steroid Modulator of the γ -Aminobutyric Acid _A Receptor,” <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 280(3):1284-95 (1997)

1029	Saporito et al., Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus, <i>Neurobiology</i> , 86 (16 supplement), Abstract, published April 4, 2016 (“Saporito A2”)
1030	Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus, <i>Neurology</i> 86 (16 Supplement), Abstract, published April 4, 2016 (“Saporito A1”)
1031	Chez, “Ganaxolone Therapy Improves Interictal EEG and Seizure Control in Lennox Gastaut Syndrome in Patients with PCDH19 and CDKL5,” <i>Annals of Neurol.</i> 80 (suppl 20), S326 published October 26, 2016.
1032	Declaration of Deanna Reichel in Support of Motion for pro hac vice Admission
1033	Supplemental Declaration of Michael Saporito
1034	Table of Contents, <i>Neurology</i> Issue 86 (16 Supplement), dated April 5, 2016; available at https://n.neurology.org/content/86/16_Supplement
1035	Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus (I11.003), <i>Neurology</i> 86 (16 Supplement), Abstract, published April 5, 2016, available at https://n.neurology.org/content/86/16_Supplement/I11.003
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1041	Supplemental Declaration of Dr. Michael A. Rogawski (“Second Rogawski Declaration”)
1042	Transcript of Deposition of Dr. Raman Sankar, February 9, 2024 (“Sankar Deposition Transcript”)

1043	Beale and Ostrander, “Sizing up Dogs,” <i>Current Biology</i> 22(9):R315-6 (2012) (“Beale”)
1044	Intentionally Left Blank
1045	Clinicaltrials.gov record for NCT03350035
1046	Marinus PCT/US2020/044843 (WO 2021/026124))
1047	Excerpts from the File History of the ’817 Patent
1048	Ovid’s 2022 Annual Report
1049	Intentionally Left Blank
1050	Patterson, “Status Epilepticus and Cluster Seizures,” <i>Vet Clin Small Anim</i> 44:1103-1112 (2014) (“Patterson”)
1051	Charlambous et al., “ACVIM Consensus Statement on the Management of Status Epilepticus and Cluster Seizures in Dogs and Cats,” <i>J Vet Intern Med</i> 2023:1-22 (2023). DOI: 10.1111/jvbm.16928 (“Charlambous”)
1052	Rosetti and Lowenstein, “Management of Refractory Status Epilepticus in Adults,” <i>Lancet. Neurol.</i> 10(10):922-30 (2011) (“Rosetti”)
1053	Shorvon and Ferlisi, “The Treatment of Super-Refractory Status Epilepticus: a Critical Review of Available Therapies and a Clinical Treatment Protocol,” <i>Brain</i> 134:2802-18 (2011) (“Shorvon”)
1054	Nohria and Giller, “Ganaxolone,” <i>Neurotherapeutics</i> 4:102-105 (2007) (“Nohria”)
1055	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,” <i>Epilepsia</i> 63:2381-91 (2022) (“ <i>Epilepsia</i> Supplemental Information” or “ <i>Epielpsia</i> SI”)
1056	Publication of Marinus’s U.S. Patent Application Serial No. 17/729,427 (US20220265680)
1057	Publication of Marinus’s U.S. Patent Application Serial No. 17/186,569 (US20210186987)
1058	Declaration of Sharon Baughman, Ph.D.
1059	RESERVED

1060	Supplemental Declaration of Sharon Baughman, Ph.D.
1061	Gasior, et al., “Intravenous Ganaxolone: Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability in Healthy Adults,” Clinical Pharmacology in Drug Development 2042
1062	September 15, 2023, Supplemental Evidence Served
1063	March 22, 2024, Supplemental Evidence Served

I. INTRODUCTION

Patent Owner Ovid’s Motion to Exclude (Paper 34, the “Motion”) is defective and should be denied. Each of Petitioner Marinus’s Exhibits 1013, 1014, 1015, 1033, 1058, and 1060 is admissible under the Federal Rules of Evidence (“FRE” or the “Rules”), and Ovid fails to prove otherwise.

II. EXHIBITS 1013 and 1014—Saporito Posters

The “Saporito Posters” or “Posters” Saporito P1 (Ex. 1013) and Saporito P2 (Ex. 1014) are 35 U.S.C. § 102(a) prior art. Petition at 5–7. They are highly probative evidence of the unpatentability of the Challenged Claims.

A. FRE 401, 402, and 403

In its Motion, Ovid pivots from objecting (generically) to the posters as “lacking relevance” and instead raises an attack on the *sufficiency* of the evidence showing that the Saporito Posters are prior art. Motion at 1–4. A challenge on sufficiency, however, is not properly raised in a motion to exclude. *Chi. Mercantile Exch., Inc. v. 5th Mkt., Inc.*, CBM2014-00114, Paper 35, 52 (PTAB Aug. 18, 2015) (“[A] motion to exclude is not the proper vehicle to challenge the sufficiency of the evidence used to demonstrate that [a reference] qualifies as a prior art printed publication.”); *see also* 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) (“A motion to exclude . . . may not be used to challenge the sufficiency of the evidence to prove a particular fact.”). In any case, Petitioner has provided

more than sufficient evidence to demonstrate that the Posters qualify as § 102(a)(1) art. Petition at 5–7; Reply at 15–16; Exhibits 1015, 1033, 1034, 1035.

Moreover, the Board—a non-jury tribunal with administrative expertise—is well positioned to determine and assign the appropriate weight without any danger of being unfairly prejudiced, confused, or misled. *See, e.g., Google LLC, v. IPA Technologies Inc.*, IPR2019-00730, Paper 72, 30 (PTAB Sept. 16, 2020). And considering this highly probative evidence is not a waste of the Board’s time.

B. FRE 901 / FRE 1002

To authenticate an item of evidence under FRE 901, “the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is,” such as “testimony of a witness with knowledge.” FRE 901(b)(1). Along with the Saporito Posters, Petitioner submitted the declaration of Dr. Michael Saporito (Ex. 1015). In his declaration, Dr. Saporito provided testimony about the creation and publication of the Saporito Posters, based on his personal knowledge. Ex. 1015. This is precisely the type of evidence that Rule 901 itself states is sufficient to authenticate.

Initially, Ovid objected that “Petitioner offer[ed] no explanation of whether [Exhibit 1013 | Exhibit 1014] is the same poster that was presented at the April 2016 AAN meeting apart from merely stating that it is.” That, however, was not

true. Dr. Saporito had already testified that the Saporito Posters were the posters that he presented at the meeting. Ex. 1015 at 7–8, 12–13.

In response to Ovid’s objections, Petitioner timely served Patent Owner with Supplemental Evidence (Ex. 1033—Dr. Saporito’s Supplemental Declaration). Ex. 1062. Dr. Saporito *reiterated* that the Posters were the same documents that he presented at the meeting. Ex. 1033 at 3–4, 6–7. He also explained that the “[t]he full-page version of [the Posters are] small version[s] of the large poster[s] that [were] displayed at the meeting,” and that “[t]he four partial pages that appear after that full-page version simply split the full-page version up and were added for this proceeding to make the data easier to read.” Ex. 1033 at 5, 8. Prior to filing their Motion, Patent Owner also deposed Dr. Saporito on the contents of both of his declarations (Ex. 1015 and Ex. 1033). Ex. 2016 at 8–9.

Despite all of this, the Motion *again* asserts that “Petitioner provides no explanation of whether Exhibits 1013 and 1014 are the same posters that were presented at the April 2016 AAN meeting apart from merely stating that they are.” Motion at 4. But, as Ovid acknowledges, Dr. Saporito, *based on his own personal knowledge as the presenter*, confirmed that they were the posters presented. Ex. 1015 at 7–15; Ex. 1033 at 3–8; Ex. 2016 at 48:4–52:15, 70:17–73:8.

Ovid further attempts to exclude the Saporito Posters under FRE 1002 “for failure to produce the original document.” Paper 11, 7, 9; Motion at 4. But Ovid

admits that the Saporito Posters were saved electronically in Dr. Saporito's files, where they were labeled as "final." Motion at 4. Dr. Saporito explained that he labels as final "the final version of the poster that's to be presented." Ex. 2016 at 49:3–6. Dr. Saporito testified that Exhibits 1013 and 1014 are accurate reflections of the Posters as presented at the meeting (Ex. 1033 at 5, 8), which is all that is required for their admissibility. FRE 1001, 1002, 1003.

Ovid misrepresents Dr. Saporito's deposition testimony as an "admission that there may be changes made to the final PDF version after it is sent for printing" (citing Ex. 2016 at 45:16–52:12). The statement was made in the context of Dr. Saporito explaining how, during the preparation of posters for conferences *in general*, there are sometimes corrections made before printing, "[u]sually a typo, spelling," but that "[i]n this particular case" (speaking of Exhibit 1013) "there [were] no changes." to the "final PDF version." Ex. 2016 at 48:4–52:15; *see also* Ex. 2016 at 70:17–73:8 (indicating no changes to Exhibit 1014). Furthermore, when those change are made "in other cases" (but not this one), as Dr. Saporito explained, those would be "sent back to [him] for review" as part of the finalization process. Ex. 2016 at 51:24–52:14.

C. FRE 801/802

Here, Ovid again pivots and improperly raises an attack on the *sufficiency* of the evidence demonstrating that the Saporito Posters are prior art, not their

admissibility under FRE 801/802. Motion at 5. Ovid argues that “the asserted date is inadmissible hearsay for the proposition that Exhibits 1013 and 1014 were published or publicly accessible as of those dates.” But Ovid acknowledges that the Saporito Posters contain no statement of an “asserted date” at all, so there can be no hearsay issue there. *See* Ex. 2016 at 48:8–15, 71:16–18. The date the posters were presented appears in other exhibits that Ovid has not moved to strike (Ex. 2012), and Dr. Saporito, *based on his own personal knowledge as the presenter*, confirmed that they were the posters presented at the 2016 AAN meeting (Ex. 1033 at 3–4, 6–7).

Ovid also states only that “to the extent that Petitioner attempts to rely on Exhibits 1013 and 1014 for the truth of any statements contained therein, those statements are inadmissible hearsay.” Motion at 5. However, the Posters are not hearsay because the Posters are offered as evidence of what the Posters say, not the truth of what the Posters say. *Creston Elecs., Inc. v. Intuitive Building Controls, Inc.*, IPR2015-01460, Paper 14, 15–16 (PTAB Jan. 14, 2016).

II. EXHIBITS 1015 and 1033—Saporito Declarations

Ovid’s motion to exclude the Saporito Declarations (Exhibits 1015 and 1033) is simply an attempt to keep the Board from considering highly relevant evidence as to the status of the Saporito Posters as prior art. Exhibit 1015 was submitted along with the Petition. Ovid objected to Exhibit 1015 under FRE 401–

403, 602, and 801/802. Paper 11 at 10. Exhibit 1033 was timely served as supplemental evidence in response to Patent Owner's objections to evidence (Ex. 1062) and filed with Petitioner's Reply (Paper 25). Ovid objected to Exhibit 1033 under FRE 401–403 and 801/802, but not under FRE 602. Paper 26 at 1.

A. FRE 401, 402, and 403

In the Motion, Ovid makes an (untimely) objection that “[b]ecause Petitioner offers no admissible evidence on which Dr. Saporito could base his opinions [(referencing the Saporito Posters)], they should be excluded under FRE 401, 402, and 403.” Motion at 6. However, Dr. Saporito is not offering opinions; as discussed above, he is offering facts based on his own personal knowledge. Again, the Board is well positioned to assign the appropriate weight to the evidence.

B. FRE 602

In support of its motion to exclude, Ovid cherry picks snippets of deposition testimony to allege that the Saporito Declarations “lack sufficient support to find that Dr. Michael Saporito has personal knowledge of the subject matter to which he is testifying.” Motion at 7. But FRE 602 requires only that “evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter,” which “may consist of the witness’s own testimony.” Here, Ovid does not dispute that Dr. Saporito presented the Posters at the 2016 AAN Meeting, as he testified. Their cherry-picked snippets from his deposition relate to

recollection of very specific details seven years later. Ovid cites nothing to show that those specific details are required to establish personal knowledge under FRE 602.

C. FRE 801/802

The Saporito Declarations are statements made by the Declarant testifying in this proceeding—not “hearsay” as defined in FRE 801(c), but rather sworn testimony that was subject to cross-examination. *See Actifio, Inc. v. Dephix Corp.*, IPR2015-00050, Paper 57 (PTAB Mar. 31, 2016). In fact, Ovid cross-examined Dr. Saporito regarding his testimony in both Exhibit 1015 and Exhibit 1033. Ex. 2016.

In the Motion, Ovid argues (untimely) only that “[b]ecause Petitioner offers no admissible evidence on which Dr. Saporito could base his opinions [(referencing the Saporito Posters)], they should be excluded under FRE 801/802.” Motion at 7–8. But even if the Saporito Posters were inadmissible (and they are not), Patent Owner provides no reason why the Saporito *Declarations* would be inadmissible hearsay.

III. EXHIBITS 1058 and 1060—Baughman Declarations

Ovid also moves to exclude the Baughman Declarations (Exhibits 1058 and 1060, referred to collectively as the “Baughman Declarations”). Exhibit 1058 is the first Declaration of Dr. Baughman, submitted along with Petitioner’s Reply.

Ovid objected to Exhibit 1058 under FRE 401–403, FRE 702(a), (b), (c), and (d), FRE 801/802, 37 C.F.R. § 42.65(b), and as allegedly improper reply evidence.

Paper 26 at 10. Exhibit 1060 is the supplemental Declaration of Dr. Baughman, timely served as supplemental evidence in response to Patent Owner’s objections to Petitioner’s Reply evidence, along with Exhibit 1061, which is cited in Exhibit 1060. (Ex. 1063). Exhibit 1060 is identical to Exhibit 1058 in substance, except for paragraph 16, to which the reference to Gasior 2024 (Exhibit 1061) was added. Ex. 2025 at 11:17–12:1.

A. FRE 702(a)

First, Ovid complains that Dr. Baughman did not provide an opinion in her expert declaration. Motion at 9. However, FRE 702 does not require expert testimony to be in the form of an opinion. “A witness who is qualified as an expert . . . may testify in the form of an opinion *or otherwise* . . .” (FRE 702, emphasis added). The remainder of Ovid’s arguments relate to the *content* of Dr. Baughman’s testimony, rather than her *scientific, technical, or other specialized knowledge*, which is the relevant inquiry for FRE 702(a). Ovid has not challenged Dr. Baughman’s bona fides; quite the opposite. Patent Owner’s Counsel said to Dr. Baughman: “So I don’t have any questions about your really impressive background and qualifications. So we’re going to skip right over that, but it was an enjoyable read. A long – a long and storied career.” Ex. 2025 at 16:19–23.

As to Ovid’s arguments regarding the *content* of Exhibits 1058 and 1060, this is a new and, once again, improper argument directed to *sufficiency* rather than *admissibility*. And, in any case, Dr. Baughman—as Ovid points out—provided simulations of dosing scenarios (Motion at 9; Ex. 1058 at 14–24, Ex. 1060 at 14–24) that *do* “help the trier of fact to understand the evidence or to determine a fact in issue” under FRE 701(a). Thus, they are highly relevant to Ovid’s allegedly “unexpected results.” Reply at 25–30.

B. FRE 401, 402, and 403

In the Motion, Ovid objects that “Dr. Baughman’s models are irrelevant to the claims at issue.” Motion at 10. Again, this is an improper *sufficiency* argument, not an *admissibility* argument. And, in any case, as Petitioner has described, these results are highly relevant to Ovid’s alleged evidence of “unexpected results.” Reply at 25-30. The Board is well positioned to determine and assign the appropriate weight to the Baughman Declarations without any danger of being unfairly prejudiced, confused, or misled.

C. FRE 702(b), (c), and (d)

In the Motion, Ovid provides *no evidence* to dispute that Dr. Baughman’s testimony is based on sufficient facts or data (FRE 702(b)) and is the product of reliable principles and methods (FRE 702(c)), or that an opinion of hers “reflects a

reliable application of the principles and methods to the facts of the case.” (FRE 702(d)).

Rather, Ovid states that “Dr. Baughman admitted that the ‘pharmacokinetic information related to ganaxolone that Marinus submitted to FDA,’ and that she used as the basis for her model, were provided to her by Marinus’s counsel and she was not aware whether it was publicly available.” Motion at 10 (citing Ex. 2025, 16:24-18:21). Ovid fails to articulate any reason why this would render Dr. Baughman’s testimony inadmissible under FRE 702(b), (c), or (d). And, as Dr. Baughman pointed out, she included the pharmacokinetic information directly into her declaration. Ex. 2025 at 16:24–17:24 (“The information I’m referring to is in Section 15.”) Ovid complains that “Marinus has not provided the Board with any source documents underlying these pharmacokinetic parameters.” Motion at 10. But FRE 702(b), (c), or (d) do not require as much, and Ovid does not cite to any authority suggesting that FRE 702(b), (c), or (d) require such source documents.

And, as noted above, Dr. Baughman included some of the pharmacokinetic information directly into her declaration (Ex. 1058). In response to Ovid’s objection to Dr. Baughman’s first declaration and before her deposition, Marinus timely served Ovid with Dr. Baughman’s supplemental declaration (Ex. 1060), as well as the reference cited within her supplemental declaration (Ex. 1061) that

contains additional data on which she relied in performing her pharmacokinetic modeling (Ex. 2025 at 19:13–20:12). Ex. 1063.

As Ovid noted during Dr. Baughman’s deposition, and Dr. Baughman confirmed, “[t]he only difference between the original declaration [Exhibit 1058] and the supplemental declaration [Exhibit 1060] is the addition of a citation to Gasior 2024.” Ex. 2025 at 11:17–12:1. Ovid then proceeded “to focus on the supplemental one [Ex. 1060] just to make things it’s easier for the rest of the day so we don’t have to go back and forth, considering that they’re almost identical,” noting that Exhibit 1060 is “the more complete version.” Ex. 2025 at 12:2–7.

Ovid also objects that “the development of Dr. Baughman’s models was guided by counsel,” in that she “did not model similar dosing scenarios . . . because counsel did not ask her to do so,” that she “did not compare her . . . model . . . with” similar dosing scenarios, and that the output was “plasma concentration” rather than “any measure of treatment efficacy.” There is no basis under FRE 702(b), (c), or (d) that an expert provide *particular* testimony—only that the testimony that *is* provided meets the requirements which, as noted above, Dr. Baughman’s Declarations do. Whether Dr. Baughman’s simulations were “adequately based on objective evidence goes to the weight [the Board] should accord [her] testimony,” not its admissibility. *Cardiovascular Systems, Inc. v. Shockwave Medical, Inc.*, IPR2019-00405, Paper 75, 87 (PTAB July 8, 2020).

D. FRE 801/802

The Baughman Declarations are statements made by the Declarant while testifying in this proceeding—not “hearsay” as defined in FRE 801(c), but rather sworn testimony that was subject to cross-examination. *See Actifio, Inc. v. Dephix Corp.*, IPR2015-00050, Paper 57 (PTAB Mar. 31, 2016).

Ovid argues that Dr. Baughman’s models are based on inadmissible hearsay and, therefore, should be excluded, citing *Wi-LAN Inc. v. Sharp Electronics Corporation*, 992 F.3d 1366, 1374–76 (Fed. Cir. 2021). *Wi-LAN* does not stand for this proposition. In that case, Wi-Lan sought to use source code as evidence of infringement. *Id.* at 1370. The district court granted summary judgment of no-infringement because the source code was inadmissible. *Id.* It was inadmissible because the declarants who provided written testimony to authenticate it as a business record were not available to testify at trial. *Id.* at 1372. Wi-LAN then argued that the source code data itself should be admissible because it was relied on by its expert. *Id.* at 1374. As the Federal Circuit Court explained, “Rule 703 does not make admissible otherwise inadmissible evidence.” *Id.* at 1374.

Here, however, Ovid is seeking to exclude a cross-examined expert witness’s testimony on the theory that the data underlying her models are inadmissible hearsay—without identifying or challenging the admissibility of any of it. *Wi-LAN* is unequivocal: “[d]ata relied on by the expert ‘need not be

admissible for the opinion to be admitted’ if experts in the field would reasonably rely on such data.” *Id.* at 1375. In that case, the expert’s declaration was not admitted because “Wi-LAN has not made a showing that source code experts reasonably rely on unauthenticated source code printouts.” *Id.* at 1376.

But in this case, Dr. Baughman’s declaration was based on data submitted to the FDA (Ex. 2025 at 16:24–17:20) and published in a scientific journal in the field (Ex. 1061; Ex. 2025 at 19:2–20:12)—data upon which experts in the field would reasonably rely. Ovid has not presented any arguments or evidence to the contrary.

E. 37 C.F.R. § 42.65(a)

Ovid argues that Dr. Baughman’s declarations should be excluded on the basis of 37 C.F.R. § 42.65(a) because they “fail to disclose the underlying facts or data on which” her models are based. This argument should be dismissed outright. The portion of § 42.65(a) that Ovid relies on “deals only with the weight that can be given evidence, not its admissibility,” and “is not a proper basis for a motion to exclude.” *Fox Factory, Inc. v. SRAM LLC*, IPR2016-01876, Paper 59 at 80 (PTAB Apr. 2, 2018). Furthermore, as described above, Dr. Baughman *did* disclose the underlying facts and data on which her models are based.

III. CONCLUSION

Exhibits 1013, 1014, 1015, 1033, 1058, and 1060 are highly relevant, and the Board is well equipped to evaluate them. Ovid’s Motion fails to articulate any

sound reasoning for their exclusion under the Federal Rules of Evidence. The Motion should be denied.

Respectfully submitted,

Dated: May 9, 2024

/Deanna Reichel/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) and 42.105(b), the undersigned certifies that on May 9, 2024 a complete and entire copy of this PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE and its supporting exhibits were provided via email to the Patent Owner as follows:

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