Paper No. 34
Filed: May 3, 2024

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 B2

PATENT OWNER'S MOTION TO EXCLUDE

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I. PRELIMINARY STATEMENT

Pursuant to the Board's Rules and the Federal Rules of Evidence ("FRE"), Patent Owner Ovid Therapeutics Inc. ("Ovid") moves to exclude the entirety of Exhibits 1013, 1014, 1015, 1033, 1058, and 1060.

II. EXHIBITS 1013 AND 1014 SHOULD BE EXCLUDED

Patent Owner timely objected to Exhibits 1013 (Saporito P1) and 1014 (Saporito P2) as irrelevant, prejudicial, confusing, and/or a waste of time under Federal Rules of Evidence ("FRE") 401, 402, and 403; as lacking authenticity under FRE 901; as hearsay without exception under FRE 801/802; and for failure to provide an original of a document to prove its contents under FRE 1002. Paper 11 at 6-9. Petitioner relies on Exhibits 1013 and 1014 for its arguments related to obviousness, specifically asserting Exhibits 1013 and 1014 as prior art, and for its arguments related to inherent anticipation. Petition at 5-7, 50-57; Reply at 10-11, 15-17.

A. Exhibits 1013 and 1014 Are Irrelevant, Prejudicial, Confusing, and/or a Waste of Time Under Federal Rules of Evidence 401, 402, and 403

Exhibits 1013 and 1014 should be excluded under FRE 401, 402, and 403 because they are irrelevant, prejudicial, confusing, and/or a waste of time. Petitioner has not demonstrated that Exhibits 1013 and 1014 were published or publicly available as of the relevant priority date. Saporito P1 and Saporito P2 are not dated, and there is no indication on their face that they were presented at the 2016 AAN

meeting. Ex. 2016, 48:8-22, 71:16-23; *see* Ex. 1013; Ex. 1014. Petitioner's Declaration of Dr. Michael Saporito (Ex. 1015) and Supplemental Declaration of Dr. Michael Saporito (Ex. 1033) (collectively, the "Saporito Declarations") do not indicate how many people attended the poster sessions other than the sessions being "well attended" (Ex. 1015, ¶¶ 10, 21) or that Dr. Saporito had "interacted with a number of meeting attendees" at Poster Session IV (*id*., ¶ 15). And Dr. Saporito admitted that he could not remember or provide a more specific number of attendees. Ex. 2016, 64:23-65:20 ("Q. … [D]id you pin down more of a specific number? … A. I didn't count them."), 66:17-67:23 ("Q. … [H]ow many would you estimate you interacted with? … A. Any -- it's a very rough estimate, right. … I really don't remember."), 79:15-80:21 ("Q. … How many people stopped to ask questions? A. It's hard. I can't put a specific number on the number of people who asked questions. … Q. Would you say the number of people that viewed the poster -- Poster 2 was comparable to the number of people that viewed Poster 1? A. It's hard to say. It was a long time ago.").

The authorship of Saporito P1 and Saporito P2 further call into question their public availability, which Petitioner fails to address. Specifically, Saporito P1 identifies an extra author (Donna Henry) who is not included in the AAN Meeting Brochure. *See* Ex. 1012 at 46 (P2.020). The Saporito Declarations do not address this discrepancy in authorship of Saporito P1. *See* Ex. 1015; Ex. 1033. Dr. Saporito

had no reason, other than a "guess," as to why this discrepancy existed. *See* Ex. 1015; Ex. 2016, 54:3-20 ("I don't remember specifically why Donna wasn't included . . . But my best guess . . . is that after we wrote and submitted it, we probably decided that Donna should be one of the authors."). That Saporito P1 contains a different set of authors than the meeting brochure that purportedly discusses the underlying poster begs the question—unanswered by Petitioner—as to whether Saporito P1 is the poster that was presented at the 2016 AAN meeting. *First Solar, Inc., v. Rovshan Sade*, IPR2023-00827, Paper 13 at 13-14 (PTAB Nov. 16, 2023) (burden is on the petitioner to identify with particularity evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent).

Saporito P2, on the other hand, does not provide the names of any authors on the poster itself, despite the AAN Meeting Brochure listing three authors (Michael Saporito, Julia Tsai, and Albena Patroneva). *See* Ex. 1012 at 97 (P4.212). The Saporito Declarations do not address this discrepancy in authorship of Saporito P2. *See* Ex. 1015; Ex. 1033. And during his deposition, Dr. Saporito explained that it was normal practice to print authors on a poster and that "[i]t should have had authors on it." Ex. 2016, 73:13-22. That Saporito P2 lists none of the authors listed in the AAN Meeting Brochure again demonstrates that Petitioner failed to show Saporito

P2 is the poster that was presented at the 2016 AAN meeting. *First Solar*, IPR2023-00827, Paper 13 at 13-14.

B. Exhibits 1013 and 1014 Should Be Excluded Under Federal Rules of Evidence 901 and 1002

Exhibits 1013 and 1014 should be excluded under FRE 901 and FRE 1002 as lacking authenticity and for failure to produce the original document. 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. *See* Pet., 5-7; Ex. 1015. While the Supplemental Saporito Declaration states without support that these exhibits are the same as the original posters, Dr. Saporito was unable to provide additional support for his conclusion other than that he labeled the version attached to his declaration as "the final version" of each poster. Ex. 1033 at ¶¶ 4, 7; Ex. 2016, 48:16-52:12 (admitting that there may be changes made to the final PDF version after it is sent for printing), 71:13-73:8.

The Saporito Declarations also do not provide any chain of custody for the files that Petitioner alleges are the posters that were presented and do not indicate whether Dr. Saporito possessed these files or if someone else did. And while Dr. Saporito clarified that these exhibits came from his files, as described above, he admitted that the only evidence connecting the exhibits to the as-presented versions is that the exhibits came from files labeled "final" in his files. Ex. 2016, 14:4-7,

48:16-52:12, 71:13-73:8. Moreover, the produced versions of Saporito P1 and Saporito P2 are provided in full on one page and followed by four "broken up" pages that are clearly not the posters as they would have been hung at the 2016 AAN meeting. *See* Ex. 1013; Ex. 1014.

C. Exhibits 1013 and 1014 Are Hearsay Without Exception Under Federal Rules of Evidence 801/802

Exhibits 1013 and 1014 should be excluded under FRE 802/803 because they include and rely on inadmissible hearsay without exception. Petitioner asserts that Exhibits 1013 and 1014 are prior art. Petition at 5-7, 50-57. But Petitioner fails to provide evidence that Exhibits 1013 and 1014 were published or publicly accessible on any certain date. Neither Exhibit 1013 nor Exhibit 1014 bear a date of publication, and while Petitioner asserts that they were publicly available as of the 2016 AAN meeting (*see* Reply at 15-16), the asserted date is inadmissible hearsay for the proposition that Exhibits 1013 and 1014 were published or publicly accessible as of those dates. The Saporito Declarations attempt to address this deficiency but fail for the reasons described above. *See* § II.B Additionally, 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. Therefore, Exhibits 1013 and 1014 should be excluded.

III. EXHIBITS 1015 AND 1033 SHOULD BE EXCLUDED

Patent Owner timely objected to Exhibit 1015 (Declaration of Dr. Michael Saporito) and Exhibit 1033 (Supplemental Declaration of Dr. Michael Saporito) as irrelevant, prejudicial, confusing, and/or a waste of time under FRE 401, 402, and 403; as lacking sufficient support to find that Dr. Michael Saporito has personal knowledge of the subject matter to which he is testifying under FRE 602; and as hearsay without exception under FRE 801/802. Paper 11 at 10; Paper 26 at 1. Petitioner relies on Exhibits 1015 and 1033 for its arguments related to obviousness, specifically to assert that Exhibits 1013 and 1014 are prior art. Petition at 5-7, 50-57.

A. Exhibits 1015 and 1033 Are Irrelevant, Prejudicial, Confusing, and/or a Waste of Time Under Federal Rules of Evidence 401, 402, and 403

Exhibits 1015 and 1033 should be excluded under FRE 401, 402, and 403 because they are irrelevant, prejudicial, confusing, and a waste of time. These declarations cite to and rely on Exhibits 1013 and 1014, which should be excluded for the reasons explained above. Because Petitioner offers no admissible evidence on which Dr. Saporito could base his opinions, they should be excluded under FRE 401, 402, and 403.

B. Exhibits 1015 and 1033 Lack Sufficient Support Under Federal Rule of Evidence 602

Exhibits 1015 and 1033 should be excluded under FRE 602 because they lack sufficient support to find that Dr. Michael Saporito has personal knowledge of the subject matter to which he is testifying. As one example, Dr. Saporito states that "The Scientific Abstract Listing and Meeting Information Brochure for each AAN meeting is generally available for viewing online before the meeting occurs," (Ex. 1033, ¶ 9) without providing any support to find that Dr. Saporito has personal knowledge of whether the brochure was actually available before the 2016 Annual meeting or is still available online today. And Dr. Saporito repeatedly admitted that there were many details in support of his declaration that he didn't remember or had to rely on other documents to refresh his recollection. *E.g.*, Ex. 2016, 54:3-13 ("I don't remember specifically why …"), 56:9-57:16 ("I don't remember how that decision was made. … I don't remember specifically what she did."), 63:7-9 ("Q. [H]ow did you remember or recall that date for this declaration? A. I looked at the program."), 66:17-67:23 ("I really don't remember."), 79:15-80:21 ("It's hard to say. It was a long time ago.").

C. Exhibits 1015 and 1033 Are Hearsay Without Exception Under Federal Rules of Evidence 801/802

Exhibits 1015 and 1033 should be excluded under FRE 802/803 because they include and rely on inadmissible hearsay without exception. Exhibits 1015 and 1033

rely on inadmissible hearsay evidence, including Exhibits 1013 and 1014, which should be excluded for the reasons explained above. Because Petitioner offers no admissible evidence on which Dr. Saporito could base his opinions, they should be excluded under FRE 801/802.

IV. EXHIBITS 1058 AND 1060 SHOULD BE EXCLUDED

Patent Owner timely objected to Exhibit 1058 (Declaration of Dr. Sharon Baughman) as irrelevant, prejudicial, confusing, and/or a waste of time under FRE 401, 402, and 403; 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 at issue under FRE 702(a); 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 under FRE 702(b), (c), and (d); as hearsay without exception under FRE 801/802; and for failing to disclose the underlying facts or data on which the opinion is based under 37 C.F.R. § 42.65(a). Paper 26 at 9-11. Petitioner relies on Exhibit 1058 (Declaration of Dr. Sharon Baughman) and Exhibit 1060 (Supplemental Declaration of Dr. Sharon Baughman) for its arguments related to Patent Owner's objective evidence of nonobviousness, specifically unexpected results. Reply at 25-26, 29-30.

A. Exhibits 1058 and 1060 Fail 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 at Issue Under FRE 702(a)

Exhibits 1058 and 1060 should be excluded under FRE 702(a) because Dr. Baughman's declarations do not help the trier of fact to understand the evidence or determine a fact at issue. Dr. Baughman does not provide an opinion in her declarations. Ex. 2025, 16:13-18 ("Q. You did not provide any opinions in this declaration; is that correct? A. … I did not provide an opinion. I just provided a simulation."). Dr. Baughman modeled two dosing scenarios administered by continuous intravenous infusion only. Ex. 1060, ¶17. Notably, Dr. Baughman did not model similar dosing scenarios using a bolus dose followed by continuous infusion as is relevant to the claims at issue because counsel did not ask her to do so. *Id*.; Ex. 2025, 24:15-25:13. Therefore, Dr. Baughman did not compare her continuous infusion-only model with a dosing model having a bolus dose with continuous infusion as relevant to the claims at issue. Additionally, Dr. Baughman's output is plasma concentration, not any measure of treatment efficacy, which the claims recite. *E.g.*, Ex. 1060, ¶¶18-22. Consequently, Dr. Baughman's declarations are of no help to the trier of fact in understanding the evidence or determining a fact at issue.

B. Exhibits 1058 and 1060 Are Irrelevant, Prejudicial, Confusing, and/or a Waste of Time Under Federal Rules of Evidence 401, 402, and 403

Exhibits 1058 and 1060 should be excluded under FRE 401, 402, and 403 because they are irrelevant, prejudicial, confusing, and a waste of time. As explained above, Dr. Baughman's models are irrelevant to the claims at issue. Consequently, this unsupported simulation is irrelevant to Ovid's evidence of unexpected results based on actual treatment outcomes. *See* Sur-reply at 15-17.

C. Exhibits 1058 and 1060 Fail 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 Under FRE 702(b), (c), and (d)

Exhibits 1058 and 1060 should be excluded under FRE 702(b), (c), and (d) because, as explained above, Dr. Baughman's declarations are not based on sufficient facts or data, are not the product of reliable principles and methods, and do not reflect a reliable application of the principles and methods to the facts of the case. Dr. Baughman's declarations fail to disclose the underlying facts or data on which Dr. Baughman's model is based. 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. Ex. 2025, 16:24-18:21. Moreover, Marinus has not provided the Board with any source documents underlying these pharmacokinetic parameters.

Additionally, the development of Dr. Baughman's models was guided by counsel. Ex. 2025, 13:22-14:5, 17:15-18:3, 20:1-3, 25:8-9. Dr. Baughman did not model similar dosing scenarios using a bolus dose followed by continuous infusion as is relevant to the claims at issue because counsel did not ask her to do so. *Id*.; Ex. 2025, 24:15-25:13. Dr. Baughman did not compare her continuous infusion-only model with a dosing model having a bolus dose with continuous infusion as relevant to the claims at issue. Additionally, Dr. Baughman's output is plasma concentration, not any measure of treatment efficacy, which the claims recite. *E.g.*, Ex. 1060, ¶¶18-22.

D. Exhibits 1058 and 1060 Are Hearsay Without Exception Under Federal Rules of Evidence 801/802

Exhibits 1058 and 1060 should be excluded under FRE 801 and 802 because they rely on inadmissible hearsay. 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. Ex. 2025, 16:24-18:21. Moreover, Marinus has not provided the Board with any source documents underlying these pharmacokinetic parameters. Dr. Baughman's models are thus based on inadmissible hearsay and do not fall within a hearsay exception. *Wi-LAN Inc. v. Sharp Electronics Corporation*, 992 F.3d 1366, 1374–76 (Fed. Cir.

2021) (finding that expert's reliance on inadmissible material does not translate to admissibility).

E. Exhibits 1058 and 1060 Fail to Disclose the Underlying Facts or Data on Which the Opinion Is Based Under 37 C.F.R. § 42.65(a)

Exhibits 1058 and 1060 should be excluded under 37 C.F.R. § 42.65(a) because they fail to disclose the underlying facts or data on which Dr. Baughman's model is based. Under 37 C.F.R. §42.65(a), expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a); *see also Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (holding that nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit unsupported assertions of an expert witness); Patent Trial and Appeal Board Consolidated Trial Practice Guide, 40-41 ("Affidavits expressing an opinion of an expert must disclose the underlying facts or data upon which the opinion is based."); 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) (updated Nov. 2019).

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. Ex. 2025, 16:24-18:21. Additionally, Dr. Baughman acknowledged that she has never communicated with anyone at Marinus. Ex. 2025,

15:7-9, 18:24-19:1. Moreover, Marinus has not provided the Board with any source documents underlying these pharmacokinetic parameters. This contravenes at least 37 C.F.R. § 42.65.

V. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board exclude the entirety of Exhibits 1013, 1014, 1015, 1033, 1058, and 1060.

Respectfully submitted,

Dated: May 3, 2024

/Anthony C. Tridico/
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Reg. No. 45,958

Counsel for Patent Owner
Ovid Therapeutics Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Motion to Exclude** was served electronically via email on May 3, 2024, in their entirety on the following:

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Petitioner has consented to electronic service by email.

Dated: May 3, 2024

/Mark A. Rosenberger/
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