

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 11,395,817 B2

Before JEFFREY N. FREDMAN, ZHENYU YANG, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON PATENT OWNER'S MOTION TO EXCLUDE
37 C.F.R. § 42.64

On May 3, 2024, Patent Owner filed a Motion to Exclude. Paper 34 (“PO Mot.”). On May 9, 2024, Petitioner filed an Opposition to Patent Owner’s Motion to Exclude. Paper 35 (“Pet. Opp.”). On May 13, 2024, Patent Owner filed a Reply in Support of its Motion to Exclude. Paper 36 (“PO Mot. Reply”).

In its Motion, Patent Owner moved to exclude the following evidence: Ex. 1013 (Saporito Poster 1 titled “Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus”); Ex. 1014 (Saporito Poster 2 titled “Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus”); Ex. 1015 (Declaration of Michael Saporito); Ex. 1033 (Supplemental Declaration of Michael Saporito); Ex. 1058 (Declaration of Sharon Baughman); and Ex. 1060 (Supplemental Declaration of Sharon Baughman).

Patent Owner’s Motion to Exclude is moot as to Ex. 1058 and Ex. 1060, as our Final Written Decision does not rely on either of these exhibits.

A. Patent Owner’s position

Patent Owner asserts that “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.” PO Mot. 1. Patent Owner asserts “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.” *Id.* at 1–2.

Patent Owner asserts that the “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.” PO Mot. 2. Patent Owner asserts this “begs the question—unanswered by Petitioner—as to whether Saporito P1 is the poster that was presented at the 2016 AAN meeting.” *Id.* at 3. Patent Owner also asserts “[t]hat 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.” *Id.* at 3–4.

Patent Owner also asserts, in support of an assertion that Exhibits 1013 and 1014 should be excluded under FRE 901 and 1002, that.

[w]hile 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.

PO Mot. 4. Patent Owner asserts “Exhibits 1013 and 1014 should be excluded under FRE 802/803 because they include and rely on inadmissible hearsay without exception. . . . [and] Petitioner fails to provide evidence that Exhibits 1013 and 1014 were published or publicly accessible on any certain date.” *Id.* at 5.

Patent Owner additionally asserts “[b]ecause Petitioner offers no admissible evidence on which Dr. Saporito could base his opinions, they should be excluded under FRE 401, 402, and 403.” PO Mot. 6. Patent Owner asserts “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.” *Id.* at 7. Patent Owner asserts “Exhibits 1015 and 1033 should be excluded under FRE 802/803 because they include and rely on inadmissible hearsay without exception.” *Id.*

B. Petitioner’s position

Petitioner asserts that Patent Owner “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.” Pet. Opp. 1. Petitioner asserts “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.” *Id.* at 2. Petitioner asserts

[a]long 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.

Id. Petitioner asserts that they “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.” *Id.* at 3. Petitioner asserts “as [Patent Owner] 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.” *Id.* Petitioner asserts “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.” *Id.* at 4.

Petitioner asserts that Patent Owner “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.” Pet. Opp. 4–5. Petitioner notes the “date the posters were presented appears in other exhibits that Ovid has not moved to strike (Ex. 2012).” *Id.* at 5. Petitioner asserts “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.” *Id.*

Petitioner asserts that Patent Owner’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.” Pet. Opp. 5. Petitioner asserts “Dr. Saporito is . . . offering facts based on his own personal knowledge.” *Id.* at 6. Petitioner asserts that Patent Owner “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.” *Id.* at 6–7. Petitioner asserts

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. . . . In fact, Ovid cross-examined Dr. Saporito regarding his testimony in both Exhibit 1015 and Exhibit 1033. Ex. 2016.

Id. at 7.

C. Analysis

As the movant, Patent Owner bears the burden of proof to show that the challenged exhibits should be excluded. 37 C.F.R. § 42.20(c). For reasons explained below, Patent Owner has not met that burden.

We do not find Patent Owner's arguments persuasive with regard to their Motion to Exclude. The posters in Exhibits 1013 and 1014 and supporting declarations in Exhibits 1015 and 1033 comprise relevant evidence. That evidence addresses particular limitations in claims 22 and 25–31 of the '817 patent, tending to show that certain facts in controversy are more probably true than not, supporting the factual underpinnings of Petitioner's obviousness challenge presented in this case. *See* FRE 401. Moreover, based on the record developed through trial, the pertinent fact is that Exhibits 1013 and 1014 are printed publications—supported, by example, by the testimony of the percipient witness who at minimum coauthored the slides and presented them at the 2016 AAN meeting. That fact is of consequence in our determination as to whether Petitioner has satisfied its burden on the patentability challenges involving these disclosures.

Patent Owner does not identify any statutory or constitutional basis for inadmissibility of this relevant evidence. *See* FRE 402. With respect to FRE 403, we agree with and adopt Petitioner's argument that the risks of unfair prejudice are minimal because the Board sits as a non-jury tribunal with administrative expertise, and as such is well-positioned to determine and assign appropriate weight to evidence. *See* Pet. Opp. 2. The evidentiary rule further requires, as a condition of exclusion, that the probative value of the evidence must be "*substantially outweighed*" by, for example, the risks

of unfair prejudice or misleading the fact-finder. FRE 403 (emphasis added). Patent Owner has not made such a showing—that the evidence tends to support Petitioner’s challenge and undercut Patent Owner’s substantive rebuttal falls short of what would justify exclusion under FRE 403.

We also are not persuaded by Patent Owner’s arguments regarding the authentication of Exhibits 1013 and 1014. Even if those exhibits are not self-authenticating under FRE 902, FRE 901 permits the proponent of the evidence to establish authenticity by testimony of a witness with knowledge stating that an item is what it is claimed to be. *See* FRE 901(b)(1). Petitioner has presented such testimony here. There are two declarations by Dr. Saporito that both attest, under penalty of perjury, that Exhibits 1013 and 1014 represent the actual posters presented at the AAN meeting in April 2016 and provide evidence regarding the public accessibility of these posters. Ex. 1015 ¶¶ 8, 13; Ex. 1033 ¶¶ 4, 8. In addition, Dr. Saporito points to the 2016 AAN meeting brochure and abstracts (*see* Ex. 1012), where the brochure lists the posters in Exhibits 1013 and Ex. 1014 and where Exhibits 1029 and 1030 show the abstracts of the posters presented at the meeting. Ex. 1012, 46, 99, 128; Ex. 1015 ¶¶ 7, 12; Ex. 1033 ¶ 10.

We are not persuaded by Patent Owner’s arguments that Exhibits 1015 and 1033 should be excluded under FRE 602 because these declarations facially state that Dr. Saporito was at the AAN meeting in April 2016 and Dr. Saporito testifies, *inter alia*, “I stood by Saporito Poster 1 to answer questions from meeting attendees.” Ex. 1015 ¶ 9. Similarly, Dr. Saporito testifies “I stood by Saporito Poster 2 at Poster Session IV to answer questions from meeting attendees.” *Id.* ¶ 14. Dr. Saporito provides

evidence “sufficient to support a finding that the witness has personal knowledge of the matter” under FRE 602.

Lastly, we are not persuaded by Patent Owner’s argument that Exhibits 1013, 1014, 1015, and 1033 are inadmissible hearsay under FRE 801 and 802. We agree with Petitioners on Exhibits 1013 and 1014 that “the Posters are offered as evidence of what the Posters say, not the truth of what the Posters say.” Pet. Opp. 5. That is, the posters are presented as prior art themselves and are offered as evidence of what they described at the AAN meeting in April 2016. *EMC Corp. v. Personal Web Techs., LLC*, IPR2013-00085, Paper 73 at 66 (PTAB May 15, 2014) (“[A] prior art document submitted as a ‘printed publication’ . . . is offered simply as evidence of what it described, not for proving the truth of the matters addressed in the document.”). We further agree with Petitioner on Exhibits 1015 and 1033 that 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.” Pet. Opp. 7.

We recognize that Patent Owner has asserted several instances of discrepancies, such as the omission of Donna Henry from one of the posters, alleged “chain of custody” issues with the files, and an inability of Dr. Saporito to recall specific numbers of people who participated in the poster sessions seven years before the deposition given in this case. PO Mot. 2–5. However, Patent Owner does not support these criticisms with evidence or testimony showing that either Exhibits 1013 or 1014 differed in any way from the posters presented at the 2016 AAN meeting in April 2016, nor does Patent Owner provide any evidence or testimony suggesting that any

statement made by Dr. Saporito was in error. During the trial, Patent Owner did not identify or provide any such rebuttal evidence. At most, we determine that Patent Owner's criticisms go to the weight of this evidence, not its admissibility.

We therefore deny Patent Owner's Motion to Exclude Ex. 1013, Ex. 1014, Ex. 1015, and Ex. 1033.

ORDER

Accordingly, it is

ORDERED that Patent Owner's Motion to Exclude Ex. 1013, Ex. 1014, Ex. 1015, and Ex. 1033 are DENIED; and

FURTHER ORDERED that Patent Owner's Motion to Exclude Ex. 1058 and Ex. 1060 is DISMISSED as moot.

PGR2023-00020
Patent 11,395,817 B2

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