

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JEISYS MEDICAL INC.,
Petitioner,

v.

SERENDIA, LLC
Patent Owner.

Case No. IPR2024-00386
U.S. Patent No. 9,480,836

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EVIDENCE

As provided by 37 C.F.R. § 42.64(b)(1), Petitioner Jeisys Medical Inc. hereby submits the following objections to evidence submitted by Patent Owner Serendia, LLC with its Response (Paper 28). To the extent Patent Owner subsequently relies on any of the evidence addressed herein, the objections set forth below shall continue to apply. In addition, Petitioner's Objections to Patent Owner's Evidence filed on August 5, 2024 (Paper 21) are incorporated herein by reference and shall continue to apply. These objections are timely served and filed within five business days of service of the evidence. 37 C.F.R. § 42.64(b)(1). Notwithstanding the objections set forth herein, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

A. Exhibit 2032

Petitioner objects to Exhibit 2032 (Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes, SCI. REP. published Nov. 13, 2015) as inadmissible hearsay and hearsay within hearsay under Federal Rules of Evidence (FRE) 801, 802, 803, and 805 not falling under any exception, as used and relied upon by Dr. Goldberg in his Declaration (Ex. 2142) and Dr. Daniel van der Weide in his Declaration (Ex. 2143), both of which were filed with Patent Owner's Response (Paper 28).

B. Exhibit 2142

Petitioner objects to Exhibit 2142 (Declaration of David Goldberg in Support of '836 Patent Owner's Response, dated November 04, 2024) ("Goldberg Decl.") under FRE 701-703 to the extent it contains improper expert testimony under FRE 702 and 703. Such testimony includes testimony based on conclusory statements and/or mischaracterizations of the patent, the state of/level of skill in the art, the cited prior art references, and/or any motivation to combine the references.

Objectionable testimony also includes that which is not based on sufficient facts or data and that ignores relevant facts or data, is irrelevant, is not based on a reliable foundation, constitutes conclusory opinion without sufficient support, and/or does not reliably apply the appropriate principles and methods to the facts of the case.

See also Daubert v. Merrell Dow Pharms, Inc., 509 U.S. 579 (1993).

Objectionable testimony further includes improper lay testimony under FRE 701 to the extent testimony is not based on scientific, technical, or other specialized knowledge within the scope of FRE 702 and the witness is not otherwise competent to provide such testimony.

A non-exhaustive example of such objectionable testimony includes Dr. Goldberg's irrelevant and immaterial conclusions purportedly based on Ex. 2032 (misleading referred to as the "Na Nature Paper"), which are set forth at, for example, paragraphs 15-16, 19, 33-37, 60, etc. This testimony, which compares the

prior art to an article, not to the '836 patent itself, is unreliable, lacks any scientific foundation, and is not probative.

In addition, testimony offered by Dr. Goldberg pertaining to “Objective Indicia of Non-Obviousness” (Ex. 2142, Section VIII, ¶¶ 42-71) should be excluded because Dr. Goldberg fails to show the existence of a nexus to the claimed invention. To the extent Dr. Goldberg relies on Dr. van der Weide’s opinion regarding nexus, such testimony should further be excluded because Dr. van der Weide’s opinion is itself unreliable and lacking in any scientific foundation. *See* objections to Ex. 2143, below.

Petitioner further objects to Exhibit 2142 as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception, and as inadmissible hearsay-within-hearsay under FRE 805.

Petitioner further to Exhibit 2142 under FRE 401 and 402 to the extent the exhibit contains analysis or opinions that are not relevant and/or not relied upon by Patent Owner.

C. Exhibit 2143

Petitioner objects to Exhibit 2143 (Declaration of Daniel van der Weide in Support of '836 Patent Owner's Response, dated November 04, 2024) (“VDW Decl.”) to the extent it contains improper expert testimony under FRE 702 and 703. Such testimony includes testimony based on conclusory statements and/or

mischaracterizations of the patent, the state of/level of skill in the art, the cited prior art references, and/or any motivation to combine the references.

Objectionable testimony also includes testimony not based on sufficient facts or data and that ignores relevant facts or data, is irrelevant, is not based on a reliable foundation, constitutes conclusory opinion without sufficient support, and/or does not reliably apply the appropriate principles and methods to the facts of the case.

See also Daubert v. Merrell Dow Pharms, Inc., 509 U.S. 579 (1993).

Objectionable testimony further includes improper lay testimony under FRE 701 to the extent testimony is not based on scientific, technical, or other specialized knowledge within the scope of FRE 702 and the witness is not otherwise competent to provide such testimony.

A non-exhaustive example of such objectionable testimony is included at, for example, paragraph 162 (referring to “heat mapping tests”). Dr. van der Weide relies on his “heat mapping” testing to support his conclusion that the Sylfirm X practices the challenged claims, but he has previously testified that his heat mapping tests did not use the actual components of the systems he tested – i.e., he did not use the Sylfirm X signal generator, utilized a cable in his testing apparatus that is not part of the Sylfirm X system (and for which he did not account for any power losses), and were not even designed to investigate coagulation. Furthermore, Dr. van der Weide’s use of “Oscar Mayer Lean White Turkey” in his heat mapping

tests as a proxy for the claimed skin tissue (*see* Ex. 2087 (also objected-to on the same grounds), cited at Ex. 2143, ¶ 162) lacks any scientific foundation. Dr. van der Weide's selection of a 133 millisecond time point for the thermal image capture (*see* Ex. 2087) is similarly arbitrary and lacking any scientific foundation or indicia of reliability.

Other non-exclusive examples of testimony that should be excluded on this basis include Dr. van der Weide's attempts to render opinions and conclusions regarding medical opinions or histology images, including at, for instance, paragraphs 43,73–80, 93-98, 101, and 107, because he is not qualified to offer such opinions as he is not a medical doctor and does not have any training in the examination of histological images. Additionally, Dr. van der Weide's testimony and conclusions regarding Ex. 2032 (Na article), including at paragraphs 43–44, 49, 77–80, and 107 should be excluded for the same reasons as set forth above with respect to Dr. Goldberg's declaration (Ex. 2142).

Dr. van der Weide's opinions (e.g., paragraphs 81, 84, 87, 89-90, 100-101, and 106) characterizing the alleged testimony of other witnesses, namely, Drs. Berube, Woloszko and Koch, is not proper admissible evidence under Rule 703. This is the province of the factfinder. Likewise, Dr. van der Weide's opinion (in paragraph 91) regarding the Board's prior decision, on a record different than that here, is inadmissible expert testimony under Rule 703.

Petitioner further objects to Exhibit 2143 as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception, and as inadmissible hearsay-within-hearsay under FRE 805.

Petitioner further objects to Exhibit 2143 under FRE 401 and 402 to the extent the exhibit contains analysis or opinions that are not relevant and/or not relied upon by Patent Owner.

D. Exhibit 2144

Petitioner objects to Exhibit 2144 (Deposition transcript of Jean Woloszko, M.D., Ph.D., *In re Certain Dermatological Treatment Devices & Components Thereof*, No. 337-TA-1356 (U.S.I.T.C.), taken September 14, 2023) under FRE 106 and 403 insofar as it is an incomplete excerpt and excludes relevant evidence, causing unfair prejudice and/or confusion of the issues. Petitioner reserves the right to require the introduction into evidence of any other part of the original material excerpted, or any other statement, that in fairness ought to be considered at the same time.

Petitioner preserves and restates its objections to specific portions of Dr. Woloszko's cross-examination testimony taken during the deposition. To the extent Patent Owner has relied or will rely on portions of the testimony that were objected to during the deposition, Petitioner maintains those objections and the grounds for such objections.

Petitioner further objects to Exhibit 2144 as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception.

Petitioner further objects to Exhibit 2144 as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

E. Exhibit 2145

Petitioner objects to Exhibit 2145 (Deposition transcript of Jean Woloszko, M.D., Ph.D., *Jeisys Medical Inc. v. Serendia, LLC*, IPR2024-00386, taken October 10, 2024) as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception.

Petitioner preserves and restates its objections to specific portions of Dr. Woloszko's cross-examination testimony taken during the deposition. To the extent Patent Owner has relied or will rely on portions of the testimony that were objected to during the deposition, Petitioner maintains those objections and the grounds for such objections.

Petitioner further objects to Exhibit 2145 as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or

needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

F. Exhibit 2146

Petitioner objects to Exhibit 2146 (Deposition transcript of R. James Koch, M.D., *Jeisys Medical Inc. v. Serendia, LLC*, IPR2024-00386, taken October 19, 2024) as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception.

Petitioner preserves and restates its objections to specific portions of Dr. Koch's cross-examination testimony taken during the deposition. To the extent Patent Owner has relied or will rely on portions of the testimony that were objected to during the deposition, Petitioner maintains those objections and the grounds for such objections.

Petitioner further objects to Exhibit 2146 as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

G. Exhibit 2147

Petitioner objects to Exhibit 2147 (Katarina Kesty & David J. Goldberg, *Radiofrequency Microneedling for Acne, Acne Scars, and More*, 1

DERMATOLOGICAL REVS. 33 (2020)) under FRE 901 and 902 because it lacks foundation, is not authenticated, and is not self-authenticating.

Petitioner further objects to Exhibit 2147 as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception.

H. Exhibit 2148

Petitioner objects to Exhibit 2148 (Andrew I. Brill, *Bipolar Electrosurgery: Convention and Innovation*, 51 CLINICAL OBSTETRICS GYNECOLOGY 153 (2008)) under FRE 901 and 902 because it lacks foundation, is not authenticated, and is not self-authenticating.

Petitioner further objects to Exhibit 2148 as inadmissible hearsay under FRE 801, 802, and 803 not falling under any exception.

Petitioner further objects to Exhibit 2148 as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

I. Exhibit 2149

Petitioner objects to Exhibit 2149 (Letter from Long Chen, U.S. Food & Drug Administration letter to Lisa Pritchard, Galvanize Therapeutics, Inc. (June 17, 2022), regarding K212871 (Aliya(TM) System, Aliya(TM) Generator,

Aliya(TM) Needle, Aliya(TM) Electrode; Regulation Number: 21 CPR 878.4400; Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories; Regulatory Class: Class II; Product Code: OAB; Dated: September 6, 2021; Received: September 9, 2021) (Ex. CX-2845 to the deposition of Dr. Jean Woloszko, taken October 10, 2024)) under FRE 901 and 902 because it lacks foundation, is not authenticated, and is not self-authenticating.

Petitioner further objects to Exhibit 2149 as inadmissible hearsay and hearsay within hearsay under FRE 801, 802, 803, and 805 not falling under any exception.

Petitioner further objects to Exhibit 2149 as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

Petitioner further objects to Exhibit 2149 under FRE 401 and 402 to the extent the exhibit contains analysis or opinions that are not relevant and/or not relied upon by Patent Owner.

J. Exhibit 2150

Petitioner objects to Exhibit 2150 (R. James Koch MD Inc., Legal & Medical Device Consulting: Stanford-trained, Double Board-Certified Facial

Plastic Surgeon, Practice Website (2024) (Ex. 1 to the deposition of Dr. R. James Koch, taken October 19, 2024)) as inadmissible hearsay and hearsay within hearsay under FRE 801, 802, 803, and 805 not falling under any exception.

Petitioner further objects to Exhibit 2150 as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

Petitioner further objects to Exhibit 2150 under FRE 401 and 402 to the extent the exhibit contains analysis or opinions that are not relevant and/or not relied upon by Patent Owner.

K. Exhibit 2151

Petitioner objects to Exhibit 2151 (U.S. Patent No. 9,510,899 B2 (“Manstein ’899”)) (Ex. 2 to the deposition of Dr. R. James Koch, taken October 19, 2024)) as not relevant under FRE 402. To the extent it is relevant, its probative value is outweighed by the danger of causing unfair prejudice, confusing the issues, causing undue delay, wasting time, and/or needlessly presenting cumulative evidence, and therefore is inadmissible under Rule 403.

Petitioner further objects to Exhibit 2151 under FRE 401 and 402 to the extent the exhibit contains analysis or opinions that are not relevant and/or not relied upon by Patent Owner.

Respectfully submitted,

Date: November 13, 2024

/s/ Wesley O. Mueller
Wesley O. Mueller (Reg. No. 33,976)
Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this Petitioner's Objections to Patent Owner's Evidence was served via electronic email on Patent Owner's counsel of record listed below, pursuant to its January 26, 2024 Mandatory Notices, on November 13, 2024:

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