

Filed: April 21, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AQUESTIVE THERAPEUTICS, INC.,  
Petitioner,

v.

NEURELIS, INC.,  
Patent Owner.

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Case IPR2019-00451  
Patent 9,763,876

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**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE**  
**37 C.F.R. §42.64**

## I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), Patent Owner respectfully moves to exclude Petitioner's reliance on EX1009, EX1013, EX1017, EX1021, EX1022, EX1033, EX1036, EX1038, paragraphs 29-63, 167-168, 171-191, 264-362, and Appendix A (pp. 197-224) of EX1041, EX1048, EX1050, EX1065, EX1069, EX1080, EX1081, EX1122, portions of EX1149, EX1150.

The Federal Rules of Evidence apply to *inter partes* proceedings. 37 C.F.R. § 42.62. This Motion addresses issues in Patent Owner's Objections to Evidence (Paper 11, 23) and the cross-examination of the parties' witnesses.

## II. ARGUMENT

### A. EX1009, EX1017, EX1021, EX1022, EX1033, EX1036, EX1038, EX1048, and EX1065 Should Be Excluded Under F.R.E. 402-403.

EX1009, EX1017, EX1021, EX1022, EX1033, EX1036, EX1038, EX1048, and EX1065 should be excluded under F.R.E. 402 and 403 because they are not discussed in the Petition or Reply, cannot be relevant to the Petition, and consequently would serve only to confuse and create prejudice through belated surprise.

### B. EX1013 Should be Excluded Under F.R.E. 402-403.

EX1013 should be excluded under F.R.E. 402 and 403. EX1013 (Sonne) was originally offered as the primary prior art reference for Ground 1 in Petition IPR2019-00450 (Paper 2)—which was denied institution (Paper 8)—and is

repeatedly misidentified by Dr. Peppas (Petitioner’s original expert) as ground reference EX1014 (Gwozdz). *See e.g.*, EX1041, Section XVI-XVII (“Gwozdz (Exhibit 1013)”); *see also* EX2011, 60:22-25 (“The important exhibits, Gwozdz 1013...”). Adding to the confusion is Dr. Peppas’ discussion of EX1013 as part of the prosecution history and general background. *See e.g.*, EX1041, IV.B.2 (“PO’s Inaccurate and Misleading Statements Regarding Sonne Generally and Sonne Example 11”); EX2011, 90:6-16, 93-97 (discussing opinions therein); *see also id.*, ¶¶126-127, 154 (citing EX1013 as background); *id.*, ¶366 (citing EX1013 as further support of disclosure in Meezan’962). Thus, EX1013 lacks relevance and risks unfair prejudice and confusing the issues. *Cf. LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 78 (Fed. Cir. 2012) (abuse of discretion to admit evidence with little relation to legal issue as probative value was greatly outweighed by the risk of unfair prejudice and confusion of the issues); *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (reversing for reliance on reference not cited in ground).

**C. Paragraphs 29-63, 167-168, 171-191, 264-362, and Appendix A (pp. 197-224) of EX1041 Should be Excluded Under F.R.E. 402-403, 602, 701-702, and 1006.**

Paragraphs 171-191, 264-362, and Appendix A (pages 197-224) of EX1041 should be excluded under F.R.E. 402 and 403 because they relate to non-instituted Ground 1 of IPR2019-00450 and are not relevant to any contested issue in this

proceeding. Thus, they lack relevance and risk unfair prejudice and confusing the issues. *LaserDynamics*, 694 F.3d at 78; *Magnum Oil*, 829 F.3d at 1381.

Paragraphs 29-63 and 167-168 of EX1041 should be excluded under F.R.E. 602 and 701-702 because they relate to statements and decisions made by the applicant during prosecution and Dr. Peppas testifies outside the scope of his expertise in analyzing what happened during the prosecution of the patent-at-issue. Indeed, Dr. Peppas admitted that he was not an expert on this subject matter. *See* EX2011, 70:13-89:6 (“I agree with you I did express on a matter that I was not an expert on.”). Paragraphs 29-63 and 167-168 are otherwise conclusory and unreliable as Dr. Peppas does not disclose the underlying facts or any basis in support of his opinions—including, *e.g.*, “the USPTO Examiner rejected the claims because (s)he believed that the rejected claims were very similar” and Applicants “admitt[ed] that the claims of the ’876 Patent ‘are not patentably distinct...’” or that “the ’439 application [] was ultimately abandoned because Applicants could not overcome the prior art...”. EX1041, ¶¶32, 36. Accordingly, paragraphs 29-63 and 167-168 are inadmissible under F.R.E. 602 and 701-702.

Paragraphs 186-191 and 264-362 of EX1041 should also be excluded for additional grounds under F.R.E. 701-702 and 1006 as they include conclusory and unreliable statements and otherwise rely on EX1050, which itself is an improper summary and chart with underlying documents not made available. Paragraphs

186-191 and 264-362 include Dr. Peppas’s opinions as to how a POSA would adjust Sonne’s (EX1013) Example 11 to meet the claim limitations of the patent-at-issue without providing sufficient facts or data as to how he reached his conclusions. Dr. Peppas does not set forth the principles used nor does he demonstrate the methods or calculations used in generating the combinations set forth in paragraphs 186-191 and 264-362 (or in EX1050). Accordingly, paragraphs 186-191 and 264-362 are inadmissible under F.R.E. 701-702 and 1006.

**D. EX1050 Should be Excluded Under F.R.E. 402-403 and 1006.**

EX1050 should be excluded under F.R.E. 402-403 because it relates to non-instituted Ground 1 of IPR2019-00450—specifically, EX1013—and is thus not relevant to any contested issue in this proceeding. *See* Section II.C. Thus, it lacks relevance and risks confusing the issues.

EX1050 should also be excluded under F.R.E. 1006 as it is an improper summary and chart with underlying documents not made available. *See* Section II.C. EX1050 is titled “Table of Various Diazepam Solutions Described in or Modified From Sonne’s Example 11 (DS11)” and includes Dr. Peppas’s unsubstantiated opinions as to various “DS11” diazepam solutions available by way of Sonne’s (EX1013) Example 11. EX1050 fails to include any facts or data showing how Dr. Peppas reached his combinations and otherwise does not set forth the principles used or demonstrate the methods or calculations used in generating

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