

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

U.S. Patent No. 9,763,876

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**NEURELIS, INC.'S REPLY TO PETITIONER'S OPPOSITION TO  
PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE**

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Each exhibit in Neurelis’s Motion to Exclude (“Motion”) (Paper 35) should be excluded for failure to comply with the FRE. Aquestive fails to show otherwise.

**I. Documents Not Cited in the Petition or Reply Should be Excluded**

Aquestive asserts that the uncited exhibits *might* have been relevant “[i]f PO filed a Motion to Amend,” effectively conceding irrelevance because “PO did not file a Motion to Amend.” Paper 38, 1. FRE 403 requires exclusion and Aquestive proves no exception to the rule. Pages 86-88 of EX1149 (discussing uncited-EX1065) should be excluded for the same reason.

**II. EX1013 and Dr. Peppas’ Reliance Thereon Should be Excluded**

Aquestive fails to show why EX1013—a document that is cited only in support of a *non-instituted* ground—(and Dr. Peppas’ discussion thereof, EX1041, ¶¶171-191, 264-362, Appendix A (pp. 197-224), and EX1050) is relevant to the *instituted* grounds. Aquestive’s assertion that EX1013 shows the state-of-the art is disingenuous given that Dr. Peppas’ extensive discussion of EX1013 relates to it being allegedly invalidating prior art. Moreover, Aquestive’s reliance on *Ariosa Diagnostics v. Verinata Health, Inc.* and *Genzyme Therapeutic Prod. Ltd. v. Biomarin Pharm. Inc.* is misplaced as neither addressed the relevance of an exhibit submitted in support of a *non-instituted* ground. 805 F.3d 1359, 1364 (Fed. Cir. 2015); 825 F.3d 1360, 1365-69 (Fed. Cir. 2016). Thus, EX1013 and Dr. Peppas’ testimony regarding EX1013 (including EX1050) should be excluded.

### **III. Dr. Peppas' Non-Expert Opinions Should be Excluded**

Aquestive fails to address Dr. Peppas' admission that he is not an expert in patent prosecution—the subject of EX1041 ¶¶29-63 and 167-168. These conclusory, non-expert opinions are of no value, and should be excluded.

### **IV. Belated and Unauthenticated EX1069 Should be Excluded**

Any purported relevance of EX1069—which Neurelis continues to dispute—is outweighed by the manifest prejudice to Neurelis caused by the belated submission of EX1069. Aquestive's reliance on *Genzyme Therapeutic* and/or *Ariosa Diagnostics* is disingenuous given that neither of those decisions involved the lack of notice, and resultant prejudice, that is present here. Paper 38 at 3, citing *Genzyme Therapeutic*, 825 F.3d at 1365 n.2 (exhibits were cited in institution decision); *Ariosa Diagnostics*, 805 F.3d at 1365 (exhibit included in petition).<sup>1</sup>

Additionally, Aquestive cites no actual evidence authenticating EX1069. Instead, Aquestive offers only the conclusory declaration of its own counsel, Mr.

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<sup>1</sup> Aquestive relies on the same decisions to argue relevance of EX1122, but they are inapplicable for the same reason—as EX1122 was not part of the petition.

Chakansky.<sup>2</sup> EX1152. The declaration does not provide any “personal knowledge” as required by FRE 901(b)(1), or any other evidence that EX1069 is what Aquestive purports it to be—a manual available to, and followed by, medical technicians in Florida prior to the priority date. *Phigenix, Inc. v. ImmunoGen, Inc.*, 845 F.3d 1168, 1175 n.6 (Fed. Cir. 2017) (reciting authentication standards for declaration). Moreover, whether “counsel was offered the opportunity to inspect the original” (Paper 38, 5) is not an authentication standard. *Multilayer Stretch Cling v. Berry Plastics Corp.*, 831 F.3d 1350, 1365 (Fed. Cir. 2016) (discovery sufficiency). EX1069 should be excluded, and pages 24-27 of EX1149 (discussing EX1069) should be excluded for the same reasons.

#### **V. EX1080 and EX1081 Should be Excluded**

Aquestive’s attempt to authenticate EX1080 and EX1081 through EX1152 fails for the same reasons as detailed, *supra*. §II.D.

As for hearsay, Aquestive’s argument that EX1080 is evidence of the “composition and characteristics of Valium<sup>®</sup>” (Paper 38, 6) confirms that Aquestive indeed submits the hearsay document to prove the truth of the matter

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<sup>2</sup> Aquestive discusses the “Fire Chiefs” website (Paper 38, 5), but fails to identify any link or relationship between said website and EX1069 that would satisfy the FRE 902 self-authentication requirements.

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