

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.
Patent Owner.

Case IPR2019-00451
Patent No. 9,763,876

**NEURELIS, INC.'S OPPOSITION TO
PETITIONER'S MOTION TO EXCLUDE
PURSUANT TO 37 C.F.R. § 42.64(c)**

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I. PRECISE RELIEF REQUESTED

Patent Owner (“Neurelis”) requests the Board to deny Petitioner’s (“Aquestive”) Motion to Exclude (Paper 34, “Motion”) because all exhibits challenged in Aquestive’s Motion fully comply with the Federal Rules of Evidence (“FRE”) as adopted in 37 CFR § 42.62. Aquestive has not met its burden to show that the evidence is inadmissible. 37 C.F.R. § 42.20(c); *Fanduel, Inc., et al. v. CG Tech. Development LLC*, IPR2017-00902, Paper 45, 83 n.21 (PTAB 2018) (“An opponent bears the burden of establishing *inadmissibility* of an exhibit by filing a motion to exclude the evidence”) (internal citations omitted).

Aquestive’s Motion is essentially *identical* to its objections and provides *no* explanation or rationale for excluding evidence apart from reciting the FRE. Neither Neurelis in responding, nor the Board in rendering its decision, should have to assume a reason to exclude when Aquestive failed to provide one. For this reason, as well as those below, Aquestive’s Motion should be denied in its entirety.

II. SHOWINGS AND ARGUMENT

A. Exhibit 2001 and Exhibit 2004

Aquestive fails to identify portions of EX2001 or EX2004 that allegedly are (1) irrelevant, (2) hearsay, or (3) not authentic, yet seeks to exclude these exhibits. The CDC publications are relevant to state the prevalence of epilepsy and need for treatment thereof. *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1407

(Fed. Cir. 1997) (recognizing “low threshold for relevancy” under FRE 104).

Aquestive fails to offer *any* evidence undermining relevance, and fails to identify any prejudice, much less prejudice that outweighs relevance.

For hearsay, Aquestive fails to identify any statement offered to prove the truth of the matter asserted in the statement. Nonetheless, EX2001 and EX2004 “are offered for what they describe, and not to prove the truth of the matter asserted,” and thus are not hearsay as defined under FRE 801(c). *EMC Corp. v. PersonalWeb Tech., LLC*, IPR2013-00087, Paper 69, 42-43 (PTAB 2014). The documents reflect the Federal government position on epilepsy and existing treatments. *See e.g., Biomarin Pharm., Inc. v. Genzyme Therapeutic Prods. Ltd.*, IPR2013-00537, 2015 WL 1009197, at *13 (PTAB 2015) (exhibits offered as evidence of what it describes to an ordinary artisan are not hearsay).

Lastly, EX2001 and EX2004 are properly authenticated. *See Ericsson Inc. v. Intellectual Ventures I, LLC*, IPR2014-01149, Paper 68, 12 (PTAB 2015) (“The burden of proof for authentication is ‘slight.’”). Specifically, EX2001 and EX2004 are self-authenticating as “Official Publications” under FRE 902(5)— publicly available on a government-based website—and are otherwise authenticated under 901(b)(4) as provided by a government agency, bearing official insignia, and including the agency’s contact information. Taken together, each of these exhibits are authenticated and should not be excluded.

B. Exhibit 2002

Aquestive fails to identify portions of EX2002 that allegedly are (1) irrelevant or (2) hearsay, yet seeks to exclude the exhibit. The FDA letter is relevant to express a need for intranasal epilepsy treatment. *See supra*, Section II.A. Aquestive fails to offer *any* evidence undermining relevance, and fails to identify any prejudice, much less prejudice that outweighs relevance.

Additionally, EX2002 is not relied on for the truth of the matter asserted therein but rather for what it describes to an ordinary artisan and, thus, is not hearsay as defined under FRE 801(c). *See supra*, Section II.A. The FDA letter otherwise falls under the “Records of a Regular Conducted Activity” hearsay exception. FRE 803(6).

C. Exhibit 2003 and Exhibit 2004

Aquestive fails to identify portions of EX2003 or EX2004 that allegedly are (1) irrelevant or (2) hearsay, yet seeks to exclude these exhibits. The exhibits are relevant documentation of a need for epilepsy treatment (and particularly, intranasal treatment). *See supra*, Section II.A. Aquestive fails to offer *any* evidence undermining relevance, and fails to identify any prejudice, much less prejudice that outweighs relevance.

Additionally, EX2003 and EX2004 are not relied on for the truth of the matter asserted but rather for what they describe to an ordinary artisan and, thus,

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