

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: IPR2019-00449

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

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**PETITIONER'S REQUEST FOR REHEARING**

**PURSUANT TO 37 C.F.R. § 42.71(d)**

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**PRELIMINARY STATEMENT**

Pursuant to 37 C.F.R. § 42.71(d), Petitioner Aquestive Therapeutics, Inc. respectfully requests rehearing of the Decision Denying Institution of *Inter Partes* Review of claims 8-10, 15 and 30-36 of U.S. Patent No. 9,763,876 (the ‘876 Patent”) entered August 1, 2019 (Paper 7) in IPR2019-00449 (“Decision”).<sup>1</sup>

In the Decision, the Board misapprehended and/or overlooked Petitioner’s “stand-alone” argument that claim 8 is obvious over Cartt ‘865 (Exhibit 1010) in view of Ueda (Exhibit 1019) – an argument that does not include unexpected results/criticality/optimization as its basis. Instead the Board appeared to conflate this argument with Petitioner’s arguments regarding obviousness over Cartt ‘865 in view of Ueda for claim 15 (among other claims) – arguments which do have unexpected results/criticality/optimization as their basis. A POSITA would have had ample motivation to expressly combine Cartt ‘865 with Ueda, given their respective teachings. Moreover, their combination expressly disclose all the limitations of claim 8 (as well as claim 1, from which it depends), rendering claim 8 unpatentable. The Board, in effect, added a criticality argument to Petitioner’s claim 8 obviousness argument of Cartt ‘865 in view of Ueda, and in so doing,

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<sup>1</sup> August 31<sup>st</sup> was a Saturday, September 1 and September 2 were a Sunday and Labor Day, respectively, so this request filed September 3<sup>rd</sup> is timely.

never addressed Petitioner's argument, and thus wrongly denied institution of claim 8 on the basis of "criticality." Decision, p. 21.

Petitioner's argument in the Petition as to why claim 8 is obvious is straightforward. See Petition, pp. 32-33, 60-63, 74-76. First, Cartt '865 in view of Ueda expressly discloses all the limitations of claim 1 of the '876 Patent. Ueda provides the express ethanol/benzyl alcohol combination. Second, claim 8 merely adds specified broad ranges to the ethanol/benzyl alcohol combination of claim 1. Claim 8 is therefore obvious over Cartt '865 in view of Ueda's express disclosure of combinations of ethanol and benzyl alcohol in amounts falling directly within the ethanol/benzyl alcohol ranges recited in claim 8. See Petition, pp. 61-63, 74-77, Paper 2 and discussion below. Thus, as discussed further below, Petitioner's stand-alone obviousness argument in its Petition demonstrates that at least claim 8 is obvious over Cartt '865 in view of Ueda. Therefore, Petitioner requests that IPR2019-00449 be instituted.

Due in part to space limitations, Petitioner is limiting its focus herein to claim 8. Petitioner understands that if the Board decides that Petitioner has demonstrated a reasonable likelihood that at least claim 8 is obvious, then in accordance with *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) and *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018), the Board will institute on all claims and grounds. However, while Petitioner is only addressing

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