

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 PRELIMINARY RESPONSE**  
35 U.S.C. § 313

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## I. PRECISE REQUESTED RELIEF

The patent owner (“Neurelis”) requests that institution be denied because the petitioner (“Aquestive”) has failed to demonstrate a reasonable likelihood that any challenged claim is unpatentable.

## II. STATEMENT OF REASONS TO DENY

### A. BACKGROUND

#### 1. *Epilepsy and epilepsy treatment*

Epilepsy is a general term for conditions with recurring seizures, involving abnormal electrical activity in the brain that causes an involuntary change in body movement or function, sensation, awareness, and/or behavior. A seizure may last from a few seconds to a few minutes. Causes of epilepsy include head or brain injury, brain tumor, central nervous system infection, stroke, and genetics, but in most cases the etiology is unknown. EX2004, 3; EX2001.

Epilepsy actively affects over 3.4 million people in the United States (about 1.2% of the total population), and ranks as the second most burdensome neurological disorder worldwide in terms of disability-adjusted life years, with associated stigma, psychiatric co-morbidity and high economic costs. EX2004, 3; EX2001; EX2005, 296. Nearly half a million children in the United States alone have active epilepsy. EX2001. Medications exist to help prevent seizures, but success varies and about one-third of epileptics receiving care still experience

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