

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

Case IPR2019-00449
Patent 9,763,876

PATENT OWNER PRELIMINARY RESPONSE
35 U.S.C. 313

Table of Contents

I. Precise Requested Relief	1
II. Statement of Reason to Deny	1
A. Background.....	1
1. Epilepsy and epilepsy treatments	1
2. The challenged patent and claims	2
B. Claim Construction.....	4
C. Denial Warranted Under Section 325(d).....	6
D. Denial Warranted Under Section 314(a).....	10
1. Claims 8-10 and 15 deserve their claimed priority	15
2. Claims 30-33 deserve their claimed priority	17
3. Claims 34-36 deserve their claimed priority	21
4. Without Cartt’865 as a reference the petition fails.....	25
III. Conclusion	25
Exhibit List.....	26
Type-Volume Certificate	27
Certificate of Service	28

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 REASON TO DENY

A. BACKGROUND

1. Epilepsy and epilepsy treatments

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

Uncontrolled seizures may result in injury, anxiety, depression, brain damage and

death, while also interfering with normal day-to-day activities, such as working, going to school, and socializing with friends and family. EX2004, 3. Better treatments are needed to control epileptic seizures, and nasal sprays could provide the best solution. EX2003. The United States Food and Drug Administration granted Neurelis, the patent owner, a Fast Track designation to develop a diazepam intranasal solution for this very purpose. EX2002.

2. The challenged patent and claims

Diazepam belongs to a family of drugs (benzodiazepines) that are useful for treating seizures. EX1001, 1:29-39. While other benzodiazepine formulations are available for treating seizures, they suffer from solubility problems. EX1001, 1:53-57. These existing formulations can also be very difficult to administer to a subject during a seizure, particularly if the person administering therapy is not a health professional. EX1001, 1:58-2:20. The present inventors realized that while nasal delivery would address the administration problem, solubility problems pose challenges for nasal administration. The present inventors developed the use of tocopherols and tocotrienols with alcohols as substantial fractions of the formulation to address the solubility problem, while still providing an acceptable nasal-delivery formulation. Claim 1, from which the challenged claims depend, defines the invention as (EX1001, 63:26-34):

A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising:

administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug,

one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);

ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and

an alkyl glycoside.

Challenged claims 8-10 depend from claim 1 and further specify that “the solution contains ethanol from 1 to 25% (w/v) and benzyl alcohol from 1 to 25% (w/v).” EX1001, 63:59-67.

Challenged claim 15 depends from claim 1 and further specifies that “the solution comprises ethanol from 10 to 22.5% (w/v) and benzyl alcohol from 7.5 to 12.5% (w/v).” EX1001, 64:16-18.

Challenged claims 30 and 31 depend from claim 1 and further specify that the solution contain “diazepam from 5 to 15% (w/v)” and “vitamin E from 45 to 65% (w/v), ethanol from 10 to 25% (w/v) and benzyl alcohol from 5 to 15% (w/v)”.

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