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Paper 7
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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 B2

Before ZHENYU YANG, JON B. TORNQUIST, and JAMIE T. WISZ, *Administrative Patent Judges.*

TORNQUIST, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Acquestive Therapeutics, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 8–10, 15, and 30–36 of U.S. Patent No. 9,763,876 B2 (Ex. 1001, "the '876 patent"). Neurelis, Inc. ("Patent Owner")[1] filed a Preliminary Response to the Petition (Paper 5, "Prelim. Resp.").

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless . . . the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For the reasons explained below, upon consideration of the Petition, Preliminary Response, and the evidence of record, we determine that the information presented in the Petition does not show that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we do not institute an *inter partes* review.

A. Related Proceedings

Patent Owner indicates that the '876 patent is also at issue in IPR2019-00450 and IPR2019-00451. Paper 4, 2.

B. The '876 Patent

The '876 patent is directed to nasally administered pharmaceutical solutions containing one or more benzodiazepine drugs. Ex. 1001, 9:14–17.

[1] Patent Owner informs us that subsequent to the filing of the Petition, Hale Biopharma Ventures, LLC, the originally named Patent Owner in this case, assigned its rights in the '876 patent to Neurelis, Inc. Paper 4, 2 (citing Reel 048271; Frame 0304).

The ’876 patent explains that solubility challenges associated with benzodiazepine drugs previously hindered the development of formulations intended for oral, rectal, or parenteral administration. *Id.* at 1:53–57, 19:12–15. It was discovered, however, that vitamin E (which includes tocopherols and tocotrienols) is an effective carrier for benzodiazepine drugs, as these compounds are soluble, or at least partially soluble, in vitamin E. *Id.* at 33:8–13, 33:42–45. The ’876 patent also reports that vitamin E “can have the added benefit of either avoiding irritation of sensitive mucosal membranes and/or soothing irritated mucosal membranes.” *Id.* at 33:47–49.

The ’876 patent discloses that one or more lower alcohols, such as ethanol and benzyl alcohol, may be used in the formulation. *Id.* at 2:57–64, 33:55–67 (noting that to “avoid the drawbacks of emulsions,” the disclosed solutions contain vitamin E and “one or more lower alkyl alcohols”). In addition, an alkyl glycoside may be added to the formulation to act as a penetration enhancer. *Id.* at 34:2–9.

C. Illustrative Claims

Claim 1 is the only independent claim in the ’876 patent, with challenged claims 8–10, 15, and 30–36 all depending directly or indirectly from claim 1. Claims 1 and 8 are illustrative of the challenged claims and are reproduced below:

> 1. 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.

Ex. 1001, 63:26–34.

> 8. The method of claim 1, wherein the solution contains ethanol from 1 to 25% (w/v) and benzyl alcohol from 1 to 25% (w/v).

Id. at 63:59–61.

D. The Asserted Grounds of Unpatentability

Petitioner contends claims 8–10, 15, and 30–36 of the '876 patent are unpatentable in view of the following grounds (Pet. 5–6):

Ground	Reference(s)	Basis	Claims
1	Cartt '865 [2]	§ 102	8–10, 15, 30–33
2	Cartt '865 or Cartt '865 and Ueda[3]	§ 103	8–10, 15, 30–33
3	Cartt '865, Meezan,[4] and Jamieson[5]	§ 103	34–36

In support of its obviousness arguments, Petitioner relies on the declaration testimony of Dr. Nicholas A. Peppas. Ex. 1041.

II. ANALYSIS

A. Claim Construction

In this *inter partes* review, claim terms are construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). Under this claim construction standard, claim terms are given their ordinary and customary meaning as would have been understood by one of ordinary skill

[2] US Pub. No. 2009/0258865 A1, published October 15, 2009 (Ex. 1010).

[3] US 4,657,901, issued April 14, 1987 (Ex. 1019).

[4] US Pub. No. 2006/0046962 A1, published March 2, 2006 (Ex. 1011).

[5] US Pub. No. 2008/0070904 A1, published March 20, 2008 (Ex. 1012).

in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). A patentee may define a claim term in a manner that differs from its ordinary and customary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner provides proposed constructions for the terms "vitamin E," "bioavailability," "% (w/w)," and "% (w/v)." Pet. 11–13. Patent Owner contends Petitioner's constructions "are consistent with the use of those terms in the specification and claims," but contends a proper understanding of the meaning of "about" in claim 1 is "critical" to understanding the scope of the challenged claims. Prelim. Resp. 4–5.

Upon review of the parties' arguments and the evidence of record, we determine that only the term "about" is in need of construction. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

"About"

The '876 patent provides an express definition of the term "about," which is:

> As used herein, the modifier "about" is intended to have its regularly recognized meaning of approximately. In some embodiments, the term may be more precisely interpreted as meaning within a particular percentage of the modified value, e.g., "about" may in some embodiments mean ±20%, ±10%, ±5%, ±2%, or ±1% or less.

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