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Paper 8
Entered: August 1, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

Case IPR2019-00450
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, 325(d)

I. INTRODUCTION

Aquestive Therapeutics, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–36 of U.S. Patent No. 9,763,876 B2 (Ex. 1001, "the '876 patent"). Neurelis, Inc.[1] ("Patent Owner") filed a Preliminary Response to the Petition (Paper 6, "Prelim. Resp.").

For the reasons explained below, we exercise our discretion under 35 U.S.C. §325(d) and decline to institute an *inter partes* review on the grounds set forth in the Petition.

A. Related Proceedings

The parties indicate that Petitioner has filed additional petitions against the '876 patent in IPR2019-00449 and IPR2019-00451. Pet. 2; Paper 7, 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. 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

[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 7, 2 (citing Reel 048271; Frame 0304).

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 Claim

Petitioner challenges claims 1–36 of the '876 patent. Independent claim 1 is illustrative of the challenged claims and is 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.

D. The Asserted Ground of Unpatentability

Petitioner contends the subject matter of claims 1–36 of the '876 patent would have been obvious in view of the combined disclosures of Sonne[2] and Meezan.[3] Pet. 5–6. In support of its obviousness arguments,

[2] US 6,193,985 B1, issued February 27, 2001 (Ex. 1013).

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

Petitioner relies on the declaration testimony of Dr. Nicholas A. Peppas. Ex. 1041; Pet. 5.

II. ANALYSIS

A. Claim Construction

In an *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 be understood by one of ordinary skill 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)," "% (w/v)," and "about 56.47% (w/v) vitamin E." Pet. 13–17. Patent Owner contends Petitioner's constructions for "vitamin E," "bioavailability," "% (w/w)," and "% (w/v)" are consistent with the use of those terms in the specification and claims of the '876 patent, but finds fault with the reasoning and support provided by Petitioner for its construction of the term "about 56.47% (w/v) vitamin E." Prelim. Resp. 3–5.

Upon review of the parties' arguments and supporting evidence, we determine that no claim terms require construction for purposes of this Decision. *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.")).

B. 35 U.S.C. § 325(d)

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). Pursuant to 35 U.S.C. § 325(d), the Board may take into account whether, and reject the petition because, "the same or substantially the same prior art or arguments previously were presented to the Office."

In evaluating whether to exercise our discretion under § 325(d), we consider several non-exhaustive factors, including:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
>
> (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
>
> (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
>
> (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

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