Trials@uspto.gov
Tel: 571-272-7822

Paper: 8
Entered: August 13, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

Case IPR2019-00451
Patent 9,763,876 B2

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

WISZ, *Administrative Patent Judge*.

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

I. INTRODUCTION

Aquestive Therapeutics, Inc. ("Petitioner") filed a Petition (Paper 3, "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 (Paper 7, "Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314, which provides that an *inter partes* review may be instituted only upon a showing that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). After considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all challenged claims of the '876 patent, based on all of the grounds identified in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the

[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 6, 2 (citing Reel 048271; Frame 0304).

full trial record, including any response timely filed by Patent Owner. Any arguments not raised by Patent Owner in a timely-filed response may be deemed waived, even if they were presented in the Preliminary Response.

A. Related Proceedings

The parties indicate that the '876 patent is being challenged by Petitioner in IPR2019-00449 and IPR2019-00450. Pet. 2; 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. 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 Claim

Petitioner challenges claims 1–36 of the '876 patent. Claim 1, which is the only independent claim of the '876 patent, 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 (formatting added). Challenged claims 2–36 depend from claim 1, either directly or indirectly.

D. The Asserted Grounds of Unpatentability

Petitioner contends claims 1–36 of the '876 patent are unpatentable in view of the following grounds. Pet. 5.

Ground	References	Basis	Claims Challenged
1	Gwozdz[2] and Meezan '962[3]	§ 103	1–16, 24–36
2	Gwozdz, Meezan '962, and Cartt '784[4]	§ 103	17–23

Petitioner also relies on the Declaration of Nicholas A. Peppas, Sc.D. 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 in the art at the time of the invention. *See id*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). 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

[2] PCT Pub. No. WO 2009/120933 A2, published October 1, 2009 (Ex. 1014, "Gwozdz").
[3] U.S. Pub. No. 2006/0046962 A1, published March 2, 2006 (Ex. 1011, "Meezan '962").
[4] U.S. Pub. No. 2008/0279784 A1, published November 13, 2008 (Ex. 1015, "Cartt '784").

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.