

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

AQUESTIVE THERAPEUTICS, INC.

Petitioner

v.

HALE BIOPHARMA VENTURES, LLC

Patent Owner

---

Case No.: IPR2019-00451

**U.S. Patent 9,763,876**

Issue Date: September 19, 2017

Title: Administration of Benzodiazepine Compositions

---

**PETITION FOR *INTER PARTES* REVIEW**

**UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.***

## TABLE OF CONTENTS

<b>TABLE OF CONTENTS .....</b>	<b>i</b>
<b>EXHIBIT LIST .....</b>	<b>v</b>
<b>I. THE PETITION.....</b>	<b>1</b>
<b>II. MANDATORY NOTICES (37 C.F.R. § 42.8).....</b>	<b>1</b>
<b>A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)) .....</b>	<b>1</b>
<b>B. Related Matters (37 C.F.R. § 42.8(b)(2)) .....</b>	<b>2</b>
<b>C. Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a)).....</b>	<b>2</b>
<b>D. Service Information (37 C.F.R. § 42.8(b)(4)).....</b>	<b>3</b>
<b>III. PAYMENT OF FEES.....</b>	<b>3</b>
<b>IV. ADDITIONAL REQUIREMENTS FOR <i>INTER PARTES</i> REVIEW ....</b>	<b>4</b>
<b>A. Grounds for Standing (37 C.F.R. § 42.104(a)) .....</b>	<b>4</b>
<b>B. Level of Ordinary Skill in the Art .....</b>	<b>4</b>
<b>C. Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1)) .....</b>	<b>5</b>
<b>1. Claims for which IPR is Requested (37 C.F.R. § 42.104(b)(1)) .....</b>	<b>5</b>
<b>2. Specific Statutory Grounds on Which the Challenge is Based (37 C.F.R. § 42.104(b)(2)) .....</b>	<b>5</b>

3. <b>35 U.S.C. § 325(d) Should Not Bar the Petition</b> .....	8
<b>V. CLAIM CONSTRUCTION</b> .....	9
A. <b>Ordinary and Customary Meaning (37 C.F.R. § 42.104(b)(3))</b> .....	9
B. <b>Claim Construction Summary Chart</b> .....	11
C. <b>Construction Of ‘876 Patent Claim Terms</b> .....	11
1. <b>“Vitamin E”</b> .....	11
2. <b>“Bioavailability”</b> .....	12
3. <b>“% (w/w)” and “% (w/v)”</b> .....	13
4. <b>“about 56.47% (w/v) vitamin E”</b> .....	14
<b>VI. ‘876 PATENT FAMILY HISTORY CHART</b> .....	15
<b>VII. EARLIEST EFFECTIVE PRIORITY DATE IS NO EARLIER THAN MARCH 27, 2009</b> .....	18
<b>VIII. SUMMARY OF ‘876 PATENT</b> .....	21
A. <b>Background of ‘876 Patent</b> .....	21
B. <b>Prosecution History of ‘876 Patent</b> .....	21
<b>IX. PRIOR ART REFERENCES RELIED ON BY PETITIONER</b> .....	23
A. <b>Gwozdz et al., WO 2009/120933 (“Gwozdz”, Exhibit 1014)</b> .....	23
1. <b>Benzodiazepines/Diazepam</b> .....	23
2. <b>Tocopherols/Tocotrienols and Alcohols</b> .....	23
3. <b>Intranasal Administration, Including Spraying</b> .....	27
4. <b>Bioavailability</b> .....	28

**B. Meezan et al., U.S. Publication No. 2006/0046962**  
 (“Meezan’962”, Exhibit 1011).....28

**1. General Teachings .....28**

**2. Combined With Gwozdz .....30**

**C. Cartt et al., US 2008/0279784 (“Cartt’784”, Exhibit 1015) .....31**

**D. Motivation to Combine.....33**

**1. Gwozdz Combined With Meezan’962 .....33**

**2. Addition of Cartt’784 to Gwozdz and Meezan’962.....34**

**X. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE OF THE CHALLENGED CLAIMS OF ‘876 PATENT IS UNPATENTABLE.....35**

**A. Grounds Chart .....36**

**B. Grounds 1 and 2.....36**

**1. Independent Claim 1.....37**

**2. Claim 2 .....41**

**3. Claims 3-4 .....42**

**4. Claims 5-6 .....42**

**5. Claim 7 .....43**

**6. Claims 8 and 15 .....44**

**7. Claims 9-10 .....46**

**8. Claims 11-12 .....46**

**9. Claims 13-14 .....47**

10. Claim 16 .....48

11. Claims 17-18 .....49

12. Claims 19-22 .....51

13. Claim 23 .....52

14. Claims 24-26 .....54

15. Claims 27 and 29 .....55

16. Claim 28 .....56

17. Claims 30-33 .....59

18. Claims 34-36 .....61

**XI. GROUNDS AND CLAIM CHART.....64**

**A. Grounds.....64**

**B. Claims Chart .....65**

        1. Ground 1 .....65

        2. Ground 2 .....87

**XII. CONCLUSION .....93**

**XIII. CERTIFICATE OF COMPLIANCE .....94**

# 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.