

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

U.S. Patent No. 9,763,876

DECLARATION OF MICHAEL I. CHAKANSKY

I, Michael I. Chakansky, declare as follows:

1. I am an attorney with Hoffmann & Baron, LLP, and Back Up Counsel for Petitioner Aquestive Therapeutics, Inc. in IPR2019-00451.

2. I submit this declaration pursuant to 37 C.F.R. § 42.64(b)(2) in response to Patent Owner's Objections dated February 4, 2020 (Paper 23).

3. Exhibit 1069 is a true and correct copy of the Florida Regional Common EMS Protocols Field Guide, Jones and Barlett Publishers, MA (2005). **If Patent Owner desires, Aquestive will make the original pamphlet available for inspection and copying at our offices.**

4. Exhibit 1072 is a true and correct copy of the Nayzilam Product Label and Instructions for Use obtained from the U.S. Food and Drug Administration's website and publically accessible at the following url:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211321s000lbl.pdf

5. Exhibit 1074 is a true and correct copy of the cover, the copyright page, and pages 1948, 1944, 1983 and 1976 of Hardman, et al, Editors, *Goodman & Gilman's, The Pharmacological Basis of Therapeutics*, 10th Edition (2001). Substitute Exhibit 1074, submitted contemporaneously with this declaration, is a clearer true and correct copy of the cover, the copyright page, and pages 1948, 1944, 1983 and 1976 of Hardman, et al, Editors, *Goodman & Gilman's, The Pharmacological Basis of Therapeutics*, 10th Edition (2001).

6. Exhibit 1076 is a true and correct copy of the cover, the inside cover page, the copyright page, and pages xiii-xviii, 508, 189, 641, 642 and 1712 of Budavari, et al, Editors, *The Merck Index*, 12th Edition (1996).

7. Exhibit 1077 is a true and correct copy of the cover, the inside cover page, the copyright page, and pages 367-368, 376-377, 386-389 of Ritchel, W.A., et al., *Handbook of Basic Pharmacokinetics Including Clinical Applications*, 6th Edition, 2004.

8. Exhibit 1078 is a true and correct copy of the cover, the inside cover page, the copyright page, and pages 59-60 of USP/NF 2003, *The Official Compendia of Standards, Ethanol*, Copyright 2002.

9. Exhibit 1080 is a true and correct copy of the Valium® Tablet Label, Roche, January 2008, obtained from the U.S. Food and Drug Administration's website and publically accessible at the following url:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/013263s083lbl.pdf.

10. Exhibit 1081 is a true and correct copy of the pages showing Drug Prices from Internet for: Diazepam), publically accessible at <https://www.webmd.com/rx/drug-prices/diazepam> (choose: form - syringe, dosage - 2ml of 5mg/ml); Diastat Acudial publically accessible at <https://www.webmd.com/rx/drug-prices/diazepam> (choose: form- gel, dosage 10mg); and "How much should I expect to pay for Nayzilam® (midazolam) nasal

spray, CIV?” publically accessible at <https://ucb-usa.com/Responsibility/Affordability/Nayzilam-Pricing-Info>.

11. Exhibit 1082 is a true and correct copy of the cover, the inside cover page, the copyright page, and pages 1-26 (Chapter 1, “*Anatomy and Physiology of the Nose*”) of Chien, Y.W., et al., “Nasal Systemic Drug Delivery”, Chapter 1, *Anatomy and Physiology of the Nose*, Drugs and the Pharmaceutical Sciences, Vol. 39, Marcel Decker, 1989.

12. Exhibit 1118 is a true and correct copy of Constantino HR, Illum L, Brandt G, et al., *Intranasal delivery: Physicochemical and therapeutic aspects*, Intl J Pharmaceutics 2007; 337: 1-24 publically accessible at <https://www.sciencedirect.com/science/article/pii/S0378517307002748> (available online March 25, 2007); also publically accessible at <https://www.ncbi.nlm.nih.gov/pubmed/17475423> (e published March 25, 2007).

13. Exhibit 1146 is a true and correct copy of the U.S. Food and Drug Administration’s publication FDA GUI FINAL, *Determining Whether to Submit an ANDA or a 505(b)(2) Application*, Published May 2019, obtained from the U.S. Food and Drug Administration’s website and publically accessible at <https://www.fda.gov/media/123567/download>. According to this publication, additional copies are available from the Office of Communications, Division of Drug Information Center for Drug Evaluation and Research, Food and Drug

Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor Silver Spring, MD 20993-0002.

14. Exhibit 1147 is a true and correct copy of the U.S. Food and Drug Administration's publication of CDER (Center for Drug Evaluation and Research) 2019-09-19- "*Abbreviated Approval Products: 505(b)(2) or ANDA?*", obtained from the U.S. Food and Drug Administration's website and publically accessible at <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-anda-september-19-2019-issue> (click "Download (PDF - 283KB)").

15. Exhibit 1148 is a true and correct copy of the U.S. Food and Drug Administration's publication FDA GUIDANCE FOR INDUSTRY (1999), *Applications Covered by Section 505(b)(2)*, obtained from the U.S. Food and Drug Administration's website and publically accessible at <https://www.fda.gov/media/72419/download>. According to this document, additional copies are available by contacting Drug Information Branch Division of Communications Management, HFD-210, Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857.

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