

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner

v.

HALE BIOPHARMA VENTURES, LLC
Patent Owner

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

Case IPR2019-00451

**EXPERT DECLARATION OF PROFESSOR SVEINBJÖRN GIZURARSON
IN SUPPORT OF PATENT OWNER'S RESPONSE TO PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 9,763,876**

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1. My name is Sveinbjörn Gizurarson. I am a Professor in the Faculty of Pharmaceutical Sciences, School of Health Science, University of Iceland, where I have worked on and developed pharmaceutical formulations for intranasal administration, including benzodiazepine formulations. Counsel for Patent Owner Neurelis, Inc. (“Neurelis”) retained me as a technical expert to provide my opinion regarding U.S. Patent No. 9,763,876 (the ’876 Patent) [Ex. 1001], specifically Aquestive Pharmaceuticals’ (“Aquestive”) challenge of claims 1-36 of the ’876 Patent based on the combination of Gwozdz [EX1014] and Meezan [EX1011] as it applies to claims 1-16 and 24-36, and the combination of Gwozdz, Meezan and Cartt’784 [EX1015], as it applies to claims 17-23.¹ My opinions in this expert declaration support Neurelis’ Response that all challenged claims of the ’876 Patent are valid.

¹ I understand from Neurelis’ counsel that while Dr. Nicholas Peppas’ declaration [EX1041] sets forth an additional ground for invalidity (Ground 1: Sonne [EX1013] and Meezan), that ground was rejected by the Patent Trials Appeal Board in a separate *inter partes* review petition filed by Aquestive. As such, my opinions relate to Dr. Nicholas Peppas’ positions only with regards to Ground 2 (Gwozdz and Meezan) as well as Ground 3 (Gwozdz, Meezan and Cartt’784).

I. Qualifications And Background

A. Education and Experience

2. I received my Masters degree and Ph.D in Pharmacy from the University of Copenhagen in 1986 and 1990, respectively, in the laboratory of Dr. Erik Bechgaard. The title of my Ph.D thesis was “Intranasal application of insulin. Pharmaceutical and physiological factors affecting successful absorption of insulin.” I completed my graduate work while employed as a Project Manager at Novo Nordisk, one of the world’s leading pharmaceutical companies. Novo Nordisk at the time was very interested in insulin delivery via intranasal administration, but my work as a Project Manager spanned a wide range of subject matter, and focused on intranasal delivery of benzodiazepines for the treatment of epileptic seizures, as well as the effects of various excipients on nasal membrane physiology.

3. After graduate school, I became a post-doctoral fellow from 1990-1991 at the National Institute of Health in Tokyo, Japan. When working at Novo Nordisk, I became interested in some of the immunological side-effects that occurred following nasal administration, which introduced me to the field of mucosal vaccines and mucosal immunizations. It was there that I learned to know the newly developed intranasal product, Rhinocort[®] (budesonide nasal spray) for relief of hay fever or other

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