

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

LIQUIDIA TECHNOLOGIES, Inc.,  
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,  
Patent Owner.

---

IPR2021-00406  
U.S. Patent No. 10,716,793

---

**DECLARATION OF AARON WAXMAN, M.D., PH.D**

**Table of Contents**

I.	INTRODUCTION .....	1
A.	Scope of Analysis.....	1
B.	Qualifications .....	1
C.	Materials Considered.....	3
II.	PERSON OF ORDINARY SKILL IN THE ART .....	4
III.	LEGAL STANDARDS PROVIDED BY COUNSEL.....	6
A.	Claim Construction .....	6
B.	Anticipation .....	7
C.	Obviousness.....	8
IV.	BACKGROUND .....	11
A.	The '793 Patent and Priority Date.....	11
B.	General Overview of Pulmonary Hypertension.....	12
C.	General Overview of Inhalation Therapies .....	14
D.	Overview of the Claimed Invention .....	17
V.	VALIDITY OF THE '793 PATENT .....	19
A.	Overview of the Challenged Grounds and Cited References.....	19
1.	The '212 Patent (EX1006).....	22
2.	Voswinckel JESC (EX1007).....	31
3.	Voswinckel JAHA (EX1008) .....	35
B.	Ground 1: the '212 Patent, Voswinckel JESC, and Voswinckel JAHA Fail to Render Claims 1-8 Obvious.....	37

1.	“wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof” .....	38
2.	“delivered in 1 to 3 breaths” .....	39
C.	Ground 2: the '212 Patent and Voswinckel JESC Fail to Render Claims 1-8 Obvious .....	44
VI.	OBJECTIVE INDICIA OF NON-OBVIOUSNESS.....	46
VII.	CONCLUSION.....	52

## **I. INTRODUCTION**

### **A. Scope of Analysis**

1. I, Aaron Waxman, M.D., Ph.D., submit this declaration on behalf of United Therapeutics Corporation (“UTC” or “Patent Owner”) in connection with responding to the Petition for *Inter Partes* Review (“IPR” or “Petition”) of U.S. Patent No. 10,716,793 (“the ’793 patent”) filed by Liquidia Technologies, Inc. (“Liquidia” or “Petitioner”). I am over the age of eighteen and otherwise competent to make this declaration.

2. I am being compensated at my standard consulting rate for my time in connection with this matter. My compensation is not contingent on the substance of my opinions or the outcome of the proceedings.

3. I understand that Petitioner has asserted six grounds of unpatentability in this IPR challenging claims 1 to 8 of the ’793 patent by relying upon allegations that the claims are anticipated and/or obvious. I further understand that the scope of issues to be considered in an IPR are limited to those grounds disclosed in the Petition, and so I limit my opinions to those grounds.

### **B. Qualifications**

4. I am a pulmonary critical physician in Boston, Massachusetts. I have been practicing as a pulmonary and critical care doctor for over 20 years. As a practicing physician, one of the areas in which I specialize includes all aspects of

pulmonary vascular disease including pulmonary hypertension, and more specifically pulmonary arterial hypertension. I have treated thousands of patients with pulmonary hypertension using intravenous, subcutaneous, oral and inhaled forms of medications. Importantly, dosing between all the various forms of administration has shown great variability, ranging from nanograms to milligrams.

5. I am Executive Director of the Center for Pulmonary and Heart Disease in the Heart and Vascular and Lung Centers, and Director of the Pulmonary Vascular Disease Program at Brigham and Women's Hospital in Boston, Massachusetts. I am board certified in Internal Medicine, Pulmonary Disease and Critical Care Medicine. I am also a member of the American College of Chest Physicians, The American Thoracic Society, the Pulmonary Hypertension Association, and the Pulmonary Vascular Research Institute.

6. I am an Associate Professor of Medicine at Harvard Medical School and have dual appointments in the Pulmonary Critical Care and Cardiovascular Medicine divisions at Brigham and Women's Hospital. I have previously served as an assistant professor in Medicine at the Yale University School of Medicine and Tufts University School of Medicine.

7. I received my Bachelor's degree from George Washington University. I received a Ph.D. in Anatomy and Neuroscience at the Albany Medical College, and an M.D. from Yale University School of Medicine. I completed my internship

# 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.