

Reply Declaration of Nicholas Hill in Support of
Petition for *Inter Partes* Review
of U.S. Patent No. 10,716,793 B2

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 B2

REPLY DECLARATION OF NICHOLAS HILL, M.D.

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. QUALIFICATIONS	2
A. Qualifications and Experience	2
B. Materials Considered.....	3
III. PERSON OF ORDINARY SKILL IN THE ART	8
IV. STATEMENT OF LEGAL PRINCIPLES.....	8
V. THE '793 PATENT.....	9
VI. APPLICATION OF THE PRIOR ART TO THE CLAIMS.....	11
A. Public Availability of Prior Art: A POSA in May 2006 Would Have Found and Relied upon Voswinckel JAHA and Voswinckel JESC.....	12
1. Voswinckel JAHA	12
2. Voswinckel JESC.....	19
B. Ground 1: Claims 1-8 Are Obvious Over the '212 Patent in View of Voswinckel JAHA and Voswinckel JESC.....	26
1. Dr. Waxman's Isolated Critique of the '212 Patent Fails to Rebut My Obviousness Opinions	39
2. Dr. Waxman's Isolated Critique of Voswinckel JESC Fails to Rebut My Obviousness Opinions	51
3. Dr. Waxman's Isolated Critique of Voswinckel JAHA Fails to Rebut My Obviousness Opinions	56
4. Dr. Waxman Never Considers the Combination of the Prior Art Disclosures.....	58
C. Ground 2: Claims 1-8 Are Obvious Over the '212 Patent and Voswinckel JESC	66
D. Grounds 3-6: Dr. Waxman Provides No Opinions Regarding Invalidity Based on Ghofrani and/or Voswinckel 2006.....	68
E. Dr. McConville Like Dr. Waxman Fails to Rebut My Obviousness Opinions.....	69

VII. SECONDARY CONSIDERATIONS DO NOT SUPPORT THE
NON-OBVIOUSNESS OF CLAIMS 1-876

VIII. CONCLUSION.....85

Reply Declaration of Nicholas Hill in Support of
Petition for *Inter Partes* Review
of U.S. Patent No. 10,716,793 B2

I, Nicholas Hill, M.D., declare as follows:

I. INTRODUCTION

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. Counsel for Liquidia Technologies, Inc. (“Liquidia” or “Petitioner”) retained me to offer technical opinions with respect to U.S. Patent No. 10,716,793 (“the ’793 Patent”) and the prior art references cited in the inter partes review (IPR) proceedings for the ’793 Patent, Ex. 1001.

3. I am being compensated for my time in connection with this IPR at my standard consulting rate of \$550 per hour for review of materials and report preparation, and \$650 per hour for any time I might spend testifying. For any weekend review and report preparation, I will be paid \$600 per hour, and I will be paid \$750 per hour for any time spent testifying on a weekend. My compensation does not depend on the outcome of, or the content of my testimony in, the current IPR.¹

4. I incorporate by reference the opinions set forth in my First Declaration

¹ Any allegation by UTC that I am being “paid by Liquidia to say the opposite” of what I believe or to provide testimony is baseless. *See* Patent Owner Response at 35. As Dr. Waxman explained, I am “well regarded” within the field of pulmonary hypertension. Ex. 1108 at 141:3-5. Additionally, I am currently working on clinical trials sponsored by UTC. UTC’s arguments regarding the non-obviousness of the ’793 Patent claims, however, lack merit, so UTC instead stoops to denigration.

Reply Declaration of Nicholas Hill in Support of
Petition for *Inter Partes* Review
of U.S. Patent No. 10,716,793 B2

submitted as Ex. 1002 on January 7, 2021 (“Hill First Decl.”), as well as the exhibits cited therein.

5. I have assessed the ’793 Patent. In doing so, I have considered the teachings of the scientific literature before May 15, 2006, in light of general knowledge in the art before that date.

6. Counsel informs me that the Patent Trial and Appeal Board (“the Board”) has instituted *inter partes* review of the ’793 Patent based on the petition submitted by Liquidia. Since IPR institution, I understand that United Therapeutics Corporation (“UTC”) has filed a Patent Owner Response as well as declarations from Dr. Aaron Waxman, Dr. Jason McConville, and Ms. Pilar Wyman in support thereof.

7. This declaration presents my additional expert opinions considering UTC’s Patent Owner Response and Supporting Declarations of Dr. Waxman, Dr. McConville, and Ms. Wyman, that Claims 1-8 of the ’793 Patent would have been obvious to a person of ordinary skill in the art (“POSA”) before May 15, 2006.

II. QUALIFICATIONS

A. Qualifications and Experience

8. I summarized my background, qualifications, and experience relevant to the issues raised in the present IPR in Exhibit 1002, which I incorporate by reference. As part of my first declaration, I also provided a copy of my curriculum vitae, which includes a full description of my background and qualifications as Exhibit 1003. The

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.