

Declaration of Igor Gonda 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

U.S. Patent No. 10,716,793 B2

DECLARATION OF IGOR GONDA, Ph.D.

TABLE OF CONTENTS

	Page
I. INTRODUCTION AND QUALIFICATIONS.....	1
A. Qualifications and Experience	1
B. Materials Considered.....	4
II. PERSON OF ORDINARY SKILL IN THE ART	11
III. STATEMENT OF LEGAL PRINCIPLES.....	12
IV. RELEVANT TECHNICAL BACKGROUND	14
A. History of Inhalation Therapy	15
B. Inhaled Treprostinil and Its Analogues	17
C. Well Known Considerations for Inhalation Therapies	21
V. THE '793 PATENT.....	26
A. The Specification.....	26
B. The Claims of the '793 Patent.....	28
VI. SUMMARY OF PRIOR ART.....	29
A. '212 Patent [Ex. 1006]	29
B. Voswinckel JESC [Ex. 1007].....	31
C. Voswinckel JAHA [Ex. 1008]	33
D. Voswinckel 2006 [Ex. 1009].....	36
VII. APPLICATION OF THE PRIOR ART TO THE CLAIMS	37
A. Ground 1: Claims 1–8 are Obvious over '212 Patent in Combination with Voswinckel JESC Voswinckel JAHA	38
1. Independent Claim 1	38
2. Dependent Claim 2	38
3. Dependent Claim 3	40
4. Dependent Claim 4	41
5. Dependent Claim 5	43
6. Dependent Claim 6	44
7. Dependent Claim 7	45
8. Dependent Claim 8	45

TABLE OF CONTENTS
(continued)

	Page
B. Ground 2: Claims 1–8 are Obvious over '212 Patent in Combination with Voswinckel JESC	47
1. Independent Claim 1	47
2. Dependent Claims 2-8.....	48
C. Ground 4: Claims 1, 3, and 8 are Rendered Obvious by Voswinckel JAHA in Combination with Ghofrani.....	49
1. Independent Claim 1	49
2. Dependent Claim 3	49
3. Dependent Claim 8	49
D. Ground 5: Claims 1 and 3 Are Anticipated by Voswinckel 2006	50
1. Independent Claim 1	50
2. Dependent Claim 3	50
E. Ground 6: Claims 2 and 4-8 are Obvious Over Voswinckel 2006 in Combination with the '212 Patent	51
1. Motivation to Combine With a Reasonable Expectation of Success.....	51
2. Dependent Claim 2	53
3. Dependent Claim 4	54
4. Dependent Claim 5	55
5. Dependent Claim 6	56
6. Dependent Claim 7	57
7. Dependent Claim 8	58
VIII. NO SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS	60
IX. CONCLUSION.....	63

Declaration of Igor Gonda in Support of
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I, Igor Gonda, Ph.D. declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

A. Qualifications and Experience

1. I am currently the founder and CEO of Respidex LLC, which has offered consulting services to pharmaceutical and medical device companies since 2018. Before founding Respidex LLC, I held leadership positions at several pharmaceutical companies, including Aradigm Corporation, a company that focused on developing inhalation therapies for the prevention and treatment of serious respiratory and systemic diseases.

2. In 1971, I received my Bachelor of Science in Chemistry from the University of Leeds. In 1974, I received my Ph.D. in Physical Chemistry from the University of Leeds. After working as a Project Chemist for Nicholas Research Laboratories, I served as a Lecturer at the University of Aston's Pharmacy Department, located in Birmingham, U.K., from 1975 to 1982. My research was primarily on inhalation therapies, including dry powder inhaler and liquid formulations. I taught undergraduate and graduate courses in Physical Pharmacy and Pharmaceutical Sciences, which included lectures on inhalation products. Then, from 1983 to 1992, I served as a Lecturer and later Senior Lecturer at the University of Sydney's Department of Pharmacy. While at the University of Sydney, my

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research on inhalation expanded into human studies and investigations of liquid aerosolized products. During my time at the University of Aston and University of Sydney, I also consulted for pharmaceutical companies, compendial bodies, and pharmaceutical regulatory authorities.

3. After leaving the University of Sydney in 1992, I served as a Senior Scientist and Group Leader in Genentech, Inc.'s Aerosol Drug Delivery Group and later Pharmaceutics department where I prepared and executed the development plan for pulmonary delivery of the first human recombinant protein administered by inhalation (Pulmozyme[®]), which is an aqueous formulation delivered via a nebulizer. *See* Ex. 1050 (Pulmozyme[®] Label). During that time, I also led the selection of potential technologies for inhalation delivery of Genentech's development candidates, which included nebulizers, soft mist inhalers, and dry powder inhalers. In particular, the group that I led put a significant effort into the development of a "metered dose" dry powder inhaler for recombinant human rhDNase.

4. Later, in 1995, I joined Aradigm Corporation as Vice President of Research and Development. Five years later, I was promoted to Chief Scientific Officer of Aradigm where I led the New Product Research Department, which focused on preclinical and clinical exploration of new therapeutic and technological

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