

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS, INC.,
Patent Owner.

Case No. IPR2017-01621
Patent No. 9,358,240

**PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,358,240**

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
United States Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22313-1450
Submitted Electronically via the Patent Review Processing System

TABLE OF CONTENTS

I. INTRODUCTION.....	1
II. MANDATORY NOTICES – 37 C.F.R. § 42.8	3
A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)	3
B. Related Matters Under 37 C.F.R. § 42.8(b)(2).....	4
C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3).....	4
D. Service Information Under 37 C.F.R. § 42.8(b)(4)	5
III. REQUIREMENTS FOR IPR – 37 C.F.R. § 42.104.....	5
A. Grounds for Standing Under 37 C.F.R. § 42.104(a)	5
B. Identification of the Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested.....	5
C. Claim Construction Under 37 C.F.R. §§ 42.100(b), 42.104(b)(3).....	6
D. How the Construed Claims are Unpatentable Under 37 C.F.R. § 42.104(b)(4).....	7
E. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)	7
IV. THE CHALLENGED CLAIMS	7
V. LEVEL OF ORDINARY SKILL IN THE ART	8
VI. DETAILED EXPLANATION UNDER 37 C.F.R. § 42.104(B)	9
A. All References Relied Upon as Grounds for Trial Are Prior Art to the ‘240 Patent	9
1. Applicable Legal Standards.....	9
2. Based On The Record of Proceedings Before the PTO, The Date of Invention is No Earlier than May 15, 2006	10
a. For Purposes of this Petition, Petitioner Assumes That Each Claim is Supported by the Provisional Application.....	10
b. The Efforts to Antedate Prior Art Found In the File History Do Not Show a Date of Invention for the ’240 Patent Claims Before May 15, 2006	
11	
3. The Prior Art References Relied Upon Are Printed Publications	12
a. Voswinckel Is a Prior Art Printed Publication	12
b. Ghofrani Is a Prior Art Printed Publication.....	14

i.	Ghofrani Was Publicly Accessible More Than 1 Year Before the Earliest Possible Filing Date	14
ii.	Ghofrani Is “By Another”	15
c.	Patton Is a Prior Art Printed Publication	16
d.	The OptiNeb® User Manual Is a Printed Publication.....	16
e.	EU Community Register Is a Printed Publication.....	18
B.	Ground 1: Claims 1-9 are Invalid as Obvious Under § 103(a) Over Voswinckel in view of Patton and Ghofrani	21
1.	Claim 1 Would Have Been Obvious Over Voswinckel in View of Patton and Ghofrani	22
a.	Preamble: “A method of treating pulmonary hypertension”.....	22
i.	Limitation [A]: “administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising from 200 to 1000 µg/ml of treprostinil or a pharmaceutically acceptable salt thereof”	23
ii.	Limitation [B]: “with a pulsed ultrasonic nebulizer [B1] that aerosolizes a fixed amount of treprostinil or a pharmaceutically acceptable salt thereof per pulse,”	24
iii.	Limitation [C]: “said pulsed ultrasonic nebulizer comprising an opto-acoustical trigger which allows said human to synchronize each breath to each pulse”	26
iv.	Limitation [D]: “said therapeutically effective single event dose comprising from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 18 breaths.”	28
2.	Claim 2 Would Have Been Obvious Over Voswinckel in view of Patton and Ghofrani	30
3.	Claim 3 Would Have Been Obvious Over Voswinckel in view of Patton and Ghofrani	31
4.	Claim 4 Would Have Been Obvious Over Voswinckel in view of Patton, and Ghofrani	32
5.	Claim 5 Would Have Been Obvious Over Voswinckel in view of Patton and Ghofrani	33
6.	Claim 6 Would Have Been Obvious Over Voswinckel in view of Patton and Ghofrani	34

7.	Claim 7 Would Have Been Obvious Over Voswinckel in view of Patton and Ghofrani	34
8.	Claim 8 Would Have Been Obvious Over Voswinckel in view of Patton, and Ghofrani	34
9.	Claim 9 Would Have Been Obvious Over Voswinckel in view of Patton and Ghofrani	35
C.	Ground 2: Claims 1-9 are Invalid as Obvious Under § 103(a) Over Voswinckel in view of Patton and the OptiNeb® User Manual	35
1.	Claim 1 Would Have Been Obvious Over Voswinckel in view of Patton and the OptiNeb® User Manual	36
i.	Limitation [D]: “said therapeutically effective single event dose comprising from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 18 breaths.”	36
2.	Claims 2, 3, 7, and 8 Would Have Been Obvious Over Voswinckel in view of Patton, and the OptiNeb® User Manual.....	39
3.	Claim 4 Would Have Been Obvious Over Voswinckel in view of Patton and the OptiNeb® User Manual	39
4.	Claim 5 Would Have Been Obvious Over Voswinckel in view of Patton, and the OptiNeb® User Manual	40
5.	Claim 6 Would Have Been Obvious Over Voswinckel in view of Patton, and the OptiNeb® User Manual	41
D.	Ground 3: Claims 1-9 are Invalid as Obvious Under § 103(a) Over Voswinckel in view of Ghofrani and the EU Community Register.....	42
1.	Claim 1 Would Have Been Obvious Over Voswinckel in view of Ghofrani and the EU Community Register	42
i.	Limitation [B]: “with a pulsed ultrasonic nebulizer [B1] that aerosolizes a fixed amount of treprostinil or a pharmaceutically acceptable salt thereof per pulse,”	43
ii.	Limitation [C]: “said pulsed ultrasonic nebulizer comprising an opto-acoustical trigger which allows said human to synchronize each breath to each pulse”	45
2.	Claims 2-9 Would Have Been Obvious Over Voswinckel in view of Ghofrani and the EU Community Register.	47

a. Alleged Evidence Regarding Secondary Considerations Does Not
Render the Claimed Subject Matter Non-Obvious.....47

VII. CONCLUSION.....50

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.