

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner

v.

UNITED THERAPEUTICS CORP.

Patent Owner

Patent No. 9,358,240

Issue Date: June 7, 2016

Title: TREPROSTINIL ADMINISTRATION BY INHALATION

Inter Partes Review No. 2017-01621

SECOND DECLARATION OF DR. AARON WAXMAN

I, Dr. Aaron Waxman, hereby declare as follows:

1. I am a pulmonary critical physician in Boston, Massachusetts. I am the Executive Director of the Center for Pulmonary and Heart Disease in the Heart and Vascular Center at Brigham and Women's Hospital in Boston, Massachusetts. I am board certified in Internal Medicine, Pulmonary Disease, and Critical Care Medicine. I have been practicing as a pulmonary and critical care doctor for over 20 years. I am a member of the American College of Chest Physicians, the American Thoracic Society, the Pulmonary Hypertension Association, and the Pulmonary Vascular Research Institute.

2. 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 the Brigham and Women's Hospital. I have previously served as assistant professor in Medicine at the Yale University School of Medicine and Tufts University School of Medicine. I have authored or co-authored more than 100 peer-reviewed journal articles, book chapters and reviews.

3. 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 and residency in Internal Medicine at Yale New Haven Hospital. I also completed

a Fellowship in Pulmonary and Critical Care at the Yale School of Medicine. My *curriculum vitae* is provided as Exhibit 2041.

4. I am a paid consultant for United Therapeutics, the assignee of U.S. Patent No. 9,358,240 (“the ’240 patent”), in connection with IPR2017-01621. My compensation does not depend on the content of my opinions or the disposition of this proceeding. I have been retained by United Therapeutics to provide technical expertise and my expert opinion on the ’240 patent.

5. I understand that the Petition brought forward by Watson Laboratories, Inc. (“Watson”) challenges claims 1-9 of the ’240 patent. In my previous declaration (Ex. 2040), I addressed “Ground 1” of the Petition – *i.e.* whether these claims are obvious over the combination of Voswinckel (Ex. 1003), Ghofrani (Ex. 1005), and Patton (Ex. 1012). I understand the Patent Trial and Appeal Board (“the Board”) has now changed the scope of the proceeding to also consider whether the claims are obvious over two additional combinations – “Ground 2” and “Ground 3” – summarized below. The testimony provided below supplements my previous declaration (Ex. 2040) and specifically relates to Ground 2 and Ground 3.

6. For reference, below is a list of the Exhibits that are cited herein:

Exhibit No.	Description
1001	U.S. Patent No. 9,358,240
1002	Declaration of Dr. Maureen Donovan
1003	Robert Voswinckel, et al. "Inhaled treprostinil sodium for the treatment of pulmonary hypertension" Abstract #1414, <i>Circulation</i> , 110, 17, Supplement (Oct. 2004): III-295
1006	Opti-Neb-ir® Operating Instructions, Model ON-100/2 (2005)
1005	Hossein Ardeschir Ghofrani, Robert Voswinckel, et al., "Neue Therapieoptionen in der Behandlung der pulmonalerteriellen Hypertonie," <i>Herz</i> , 30,4 (June 2005): 296-302
1009	Annexes to Commission Decision C(2005)3436 of 05 September 2005: Annex III – Ventavis® Labelling and Package Leaflet
1012	WO 93/00951
1014	Declaration of Christopher Butler
1060	William F. Ganong, <i>Review of Medical Physiology</i> 591-92 (17th ed. 1995).
1099	FDA Drug Details Website, Ventavis, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (accessed 5/17/2017)
2003	Newman, Stephen P. <i>Respiratory drug delivery: essential theory and practice</i> . Respiratory Drug Delivery Online, 2009 (excerpt).
2008	"Mechanical Ventilation." <i>American Journal of Respiratory and Critical Care Medicine</i> 196(2):P3-4 (2017).
2040	Declaration of Dr. Aaron Waxman
2041	<i>Curriculum vitae</i> of Dr. Aaron Waxman
2113	Merck Manual – Professional Version – Evaluation of the Pulmonary Patient (accessed July 6, 2018)
2114	FDA Ventavis Label under Action Date 12/29/2004 (accessed July 2, 2018)
2115	FDA Ventavis Label under Action Date 8/24/2005 (accessed July 2, 2018)

7. I have been informed that in order for a patent claim to be considered obvious, each and every limitation of the claim must be present within the prior art

or within the prior art in combination with the general knowledge held by a POSA at the time an invention was made, and that such a person would have a reason for and reasonable expectation of success in combining these teachings to achieve the claimed invention. I understand there may be a variety of rationales that can demonstrate the reason for and reasonable expectation of success in combining selected teachings, but, regardless of the rationale used, it must be supported by evidence.

8. I understand that the Board was previously only considering whether claims 1-9 are obvious over the references provided in “Ground 1,” but is now also considering whether claims 1-9 are obvious over the references provided in “Ground 2” and “Ground 3” noted below.

Ground	References
Ground 2	Robert Voswinckel, et al. “Inhaled treprostinil sodium for the treatment of pulmonary hypertension” Abstract #1414, <i>Circulation</i> , 110, 17, Supplement (Oct. 2004): III-295 (“Voswinckel,” Ex. 1003)
	WO 93/00951 (“Patton,” Ex. 1012)
	Opti-Neb-ir® Operating Instructions, Model ON-100/2 (2005) (“the OptiNeb-ir Manual,” Ex. 1006)
Ground 3	Voswinckel

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