

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. RICHARD DALBY

I, Dr. Richard Dalby, hereby declare as follows:

1. I am a Professor in the Department of Pharmaceutical Sciences at the University of Maryland School of Pharmacy. I received my Bachelor's degree in Pharmacy with honors from the Nottingham University School of Pharmacy and my Ph.D. in Pharmaceutical Sciences from the University of Kentucky College of Pharmacy. I have over 25 years of experience working and consulting in the field of inhaled and nasal medications and devices. My *curriculum vitae* is provided as Exhibit 2022.

2. I am a paid consultant for United Therapeutics, the assignee of U.S. Patent No. 9,358,240 (Ex. 1001, "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.

3. While I am neither a patent lawyer nor an expert in patent law, I have been informed of the applicable legal standards for obviousness of patent claims. I understand that the Petition brought forward by Watson Laboratories, Inc. ("Petitioner" or "Watson") challenges claims 1-9 of the '240 patent and that the Patent Trial and Appeal Board ("the Board") is now considering whether these claims are obvious over the combination of Voswinckel (Ex. 1003), Ghofrani (Ex.

1005), and Patton (Ex. 1012). The testimony provided below supplements my prior declaration (Ex. 2001).

4. 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
1005	Hossein Ardeschir Ghofrani, Robert Voswinckel, et al., "Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie," <i>Herz</i> , 30,4 (June 2005): 296-302
1012	WO 93/00951
2001	Declaration of Dr. Richard Dalby
2003	Newman, Stephen P. <i>Respiratory drug delivery: essential theory and practice</i> . Respiratory Drug Delivery Online, 2009 (excerpt).
2022	<i>Curriculum vitae</i> of Dr. Richard Dalby
2039	US 4,319,155 ("Nakai")

5. 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.

6. I understand that Board is reviewing whether claims 1-9 are obvious over the references provided in “Ground 1” noted below.

Ground	References
Ground 1	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)
	Hossein Ardeschir Ghofrani, Robert Voswinckel, et al., “Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie,” <i>Herz</i> , 30,4 (June 2005): 296-302 (“Ghofrani,” Ex. 1005)

I further understand that Board has relied on both the references cited under “Ground 1” and Dr. Donovan’s declaration (Ex. 1002) in its decision to “institute trial” on this ground. In this section, I provide my opinions about Voswinckel (Ex. 1003), Ghofrani (Ex. 1005), and Patton (Ex. 1012) in relation to the Board’s decision, Watson’s arguments, and the supporting testimony provided in Dr. Donovan’s declaration.

7. I understand that the Board summarized the critical question with regard to the combination of Voswinckel, Ghofrani, and Patton as follows (emphasis added):

The relevant question is not whether Patton employs **a nebulizer that requires breath synchronization – i.e. a pulsed nebulizer.**

Voswinckel expressly discloses a pulsed nebulizer. Ex. 1003. Rather, the relevant question is whether it would have been obvious to use a light and sound signal, like that taught in Patton, in Voswinckel's pulsed nebulizer.

Paper 10, 29. But the Board's framing of the question is based on Watson's incorrect assumption that a "pulsed nebulizer" **requires** (or is synonymous with, as indicated by the "i.e.") synchronization of individual breaths by the patient to individual pulses of aerosol. This assumption appears to be based on parts of paragraphs 127 to 128 of Dr. Donovan's declaration, which state:

The primary purpose of using a pulsed nebulizer is to avoid wasting the drug that gets aerosolized while the patient is exhaling. Thus, the patient must synchronize their breath to the pulse of drug that is being delivered. [...] A POSA would therefore appreciate that when using a pulsed nebulizer, the patient needs to know when the drug is ready to be inhaled, otherwise the efficiency gains from the pulsed nebulizer would be lost. Thus, by necessity, a POSA would implement some sort of signal to demonstrate to the patient that the device is generating aerosol and is ready for the patient to inhale. **Without this sort of trigger, the patient would be unable**

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