

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2019-00688
U.S. Patent No. 9,468,747

SECOND DECLARATION OF KENNETH A. WILLIAMS, M.D.

DECLARATION OF KENNETH A. WILLIAMS

TABLE OF CONTENTS

I. OVERVIEW4

II. LEGAL STANDARDS5

 A. Obviousness.....5

 B. Objective Indicia of Nonobviousness8

III. SUMMARY OF MY FIRST DECLARATION AND SCOPE OF MY SECOND DECLARATION.....9

IV. THE POSA WOULD HAVE CHOSEN AN INTRANASAL NALOXONE DOSE OF 2 MG OR LESS12

 A. The POSA’s Goal Would Have Been To Mimic the Established Clinical Practice of Administering a Low Initial Dose of Naloxone14

 B. The POSA Would Have Accounted for the Serious Withdrawal and Adverse Effects of Naloxone Administration in Opioid-Dependent Individuals.....17

 C. Dr. Donovan and Dr. Hochhaus, Who Have No Clinical Experience, Misconstrued the POSA’s Clinical Goal22

 1. The Problem Dr. Donovan and Dr. Hochhaus Opine the POSA Would Have Sought To Solve Did Not Exist.....22

 2. Dr. Donovan and Dr. Hochhaus Conflate the Prior Art’s Discussion of a Total Dose of Naloxone with an Initial Dose of Naloxone.....29

 D. The Prior Art Did Not Recognize Re-dosing as a Problem To Be Solved32

 1. Lay Persons Can Readily Re-dose When Necessary.....32

 2. The Clinical Prior Art Did Not Identify Re-dosing as a Problem To Be Solved.....35

V. NARCAN® NASAL SPRAY SATISFIED A LONG-FELT BUT UNMET NEED42

 A. There Was a Long-Felt but Unmet Need for a Needle-Free Community-Use Naloxone Product42

DECLARATION OF KENNETH A. WILLIAMS

B. Naloxone Products Available as of March 16, 2015, Did Not Meet the Long-Felt Need52

 1. Evzio® Did Not Satisfy the Long-Felt But Unmet Need.....52

 2. Unapproved MAD Kits Did Not Satisfy the Long-Felt but Unmet Need54

 3. Intranasal Products that Did Not Receive FDA Approval Did Not Satisfy the Long-Felt but Unmet Need.....58

C. Narcan® Nasal Spray Satisfied the Long-Felt but Unmet Need59

VI. NARCAN® NASAL SPRAY WAS INITIALLY THE SUBJECT OF SIGNIFICANT SKEPTICISM.....61

VII. NARCAN® NASAL SPRAY HAS RECEIVED SIGNIFICANT THIRD-PARTY PRAISE.....62

I, Kenneth A. Williams, M.D., declare as follows:

I. OVERVIEW

1. I am over the age of 18 and competent to make this declaration. This declaration is based on my personal knowledge as an expert in the fields of emergency and pre-hospital medicine. I understand that this declaration is being submitted in support of the Response of Patent Owners Opiant Pharmaceuticals, Inc. (“Opiant”) and Adapt Pharma Operations Limited (“Adapt”) to petitions for *inter partes* review (“IPR”) filed by Nalox-1 Pharmaceuticals, LLC (“Nalox-1”), challenging U.S. Patent Nos. 9,211,253 (“the ’253 patent”), 9,468,747 (“the ’747 patent”), and 9,629,965 (“the ’965 patent”).

2. This is my second declaration in this proceeding. Earlier this year, I submitted a declaration in support of Opiant’s preliminary responses to Nalox-1’s petitions challenging the ’253, ’747, and ’965 patents. *See* IPR2019-00685, Exhibit 2001; IPR201900688, Exhibit 2001; IPR201900694, Exhibit 2001. I refer to that declaration hereinafter as “my first declaration.”

3. In preparing this declaration, I have reviewed the ’253, ’747, and ’965 patents and their file histories; the petitions for *inter partes* review filed by Nalox-1 challenging those patents; the exhibits submitted in support of Nalox-1’s petitions, including the declarations and deposition transcripts of Maureen Donovan, Ph.D. and Günther Hochhaus, Ph.D; Patent Owner Opiant Pharmaceuticals, Inc.’s

DECLARATION OF KENNETH A. WILLIAMS

preliminary responses to Nalox-1's petitions and the exhibits submitted in support thereof; and the Board's orders instituting trial on the petitions. I have considered the materials cited herein, as well as in my first declaration. I have also relied on my professional judgment and expertise.

4. I understand that each of the three IPR proceedings at issue has its own set of exhibit numbers. I will therefore refer to the exhibits by name; a chart of the relevant exhibit numbers in each proceeding and the short names I use to refer to different documents is attached to the end of this declaration.

5. I am being compensated at the rate of \$500 per hour for my time spent working on this matter. My compensation is not contingent on my findings, testimony rendered, or on the outcome of this proceeding.

II. LEGAL STANDARDS

A. Obviousness

6. I understand that a patent claim is "obvious," and thus invalid, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill ("POSA") in the art to which said subject matter pertains. I understand that factual determinations relevant to the obviousness inquiry include (a) the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, (c) the level of

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