

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,

Petitioner

v.

OPIANT PHARMACEUTICALS, INC.,

Patent Owner

IRP2019-00688

Patent No. 9,468,747

DECLARATION OF MAUREEN DONOVAN, Ph.D.

*Inter Partes Review of U.S. Patent No. 9,468,747
Declaration of Maureen Donovan, Ph.D. (Nalox1002)*

TABLE OF CONTENTS

I.	OVERVIEW	1
II.	MY BACKGROUND AND QUALIFICATIONS	9
III.	LEGAL STANDARDS	11
	A. Person of ordinary skill in the art.....	11
	B. Claim construction	13
	C. Anticipation or obviousness	15
	D. Written description and priority	17
IV.	THE '747 PATENT AND ITS CLAIMS	18
	A. Background of the art pertinent to the '747 Patent	19
	1. Opioid overdose	20
	2. Prior intranasal formulations of naloxone	21
	3. Development of a new intranasal naloxone formulation.....	23
	(a) Physical and chemical properties of naloxone	23
	(b) Stability of the formulation.....	26
	(c) Nasal physiology	29
	(d) Drug exposure attributes for an improved intranasal formulation of naloxone.....	30
	(e) Choice of pharmaceutical excipients to achieve the desired exposure and stability attributes.....	32
	(f) Choice of delivery device	49
	(g) The properties of the nasal spray delivered by the spray device	50

*Inter Partes Review of U.S. Patent No. 9,468,747
Declaration of Maureen Donovan, Ph.D. (Nalox1002)*

B.	Independent claims 1 and 30.....	57
C.	Dependent claims 2–29 and 31–45	59
D.	The '747 patent lacks priority to U.S. Provisional Application No. 61/953,379.....	64
E.	Orange Book listing of the '747 patent.....	67
V.	CLAIM CONSTRUCTION	67
1.	“pre-primed”	68
2.	“delivery time”	69
3.	“90% confidence interval for dose delivered per actuation is ±about 2.0%,” and “95% confidence interval for dose delivered per actuation is ±about 2.5%”	69
VI.	PUBLIC ACCESSIBILITY OF THE PRIOR ART.....	70
VII.	BASIS OF MY ANALYSIS WITH RESPECT TO OBVIOUSNESS.....	70
A.	A Formulator POSA reading Wyse in view of HPE would have had ample reason and know-how to arrive at the subject matter of claims 1–3, 16–24, and 30–33.....	70
1.	Claim 1	70
(a)	Preamble: “A method of treatment of opioid overdose or a symptom thereof, comprising”	71
(b)	1.1: “nasally administering to a patient in need thereof a dose of naloxone hydrochloride using a single-use, pre-primed device adapted for nasal delivery of a pharmaceutical composition to a patient by one actuation of said device into one nostril of said patient, having a single reservoir comprising”	72

***Inter Partes Review of U.S. Patent No. 9,468,747
Declaration of Maureen Donovan, Ph.D. (Nalox1002)***

(c)	1.2: “a pharmaceutical composition which is an aqueous solution of about 100 µL comprising:”	75
(d)	1.3: “about 4 mg naloxone hydrochloride or a hydrate thereof;”	77
(e)	1.4: “between about 0.2 mg and about 1.2 mg of an isotonicity agent;”	80
(f)	1.5: “between about 0.005 mg and about 0.015 mg of a compound which is at least one of a preservative, a cationic surfactant, and a permeation enhancer;”	81
(g)	1.6: “between about 0.1 mg and about 0.5 mg of a stabilizing agent;”	88
(h)	1.7: “and an amount of an acid sufficient to achieve a pH of 3.5-5.5.”	90
2.	Claim 2	91
(a)	“the isotonicity agent is NaCl;”	91
(b)	“the preservative is benzalkonium chloride;”	91
(c)	“the stabilizing agent is disodium edetate;”	95
(d)	“and the acid is hydrochloric acid.”	95
3.	Claim 3	95
(a)	“about 4.4 mg naloxone hydrochloride dihydrate;”	95
(b)	“about 0.74 mg NaCl;”	96
(c)	“about 0.01 mg benzalkonium chloride;”	100
(d)	“about 0.2 mg disodium edetate;”	100
(e)	“and an amount of hydrochloric acid sufficient to	

***Inter Partes Review of U.S. Patent No. 9,468,747
Declaration of Maureen Donovan, Ph.D. (Nalox1002)***

	achieve a pH of 3.5 to 5.5.”	101
4.	Claim 16	102
5.	Claim 17	103
6.	Claim 18	105
7.	Claim 19	105
8.	Claims 20–23	107
9.	Claim 24	111
10.	Claim 30	114
11.	Claim 31	115
12.	Claim 32	115
13.	Claim 33	116
B.	A Formulator POSA reading Wyse in view of Djupesland and HPE would have had ample reason and know-how to arrive at the subject matter of claims 4–7 and 10–14.....	117
1.	Claim 4	117
2.	Claim 5	120
3.	Claim 6	123
4.	Claim 7	124
5.	Claims 10–11	125
6.	Claims 12–14	128
C.	A Formulator POSA reading Wyse in view of Djupesland, HPE, and the '291 patent would have had ample reason and know-how to arrive at the subject matter of claims 8–9.	131

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