

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,

Petitioner

v.

OPIANT PHARMACEUTICALS, INC.,

Patent Owner

IRP2019-00690

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)*

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(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

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(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
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(b)	“the preservative is benzalkonium chloride;”	91
(c)	“the stabilizing agent is disodium edetate;”	95
(d)	“and the acid is hydrochloric acid.”	95
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(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	

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