UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,

Petitioner,

v.

ADAPT PHARMA LIMITED,
OPIANT PHARMACEUTICALS, INC.,

Patent Owners

IPR2019-00697
U.S. Patent No. 9,775,838

DECLARATION OF MAUREEN DONOVAN, Ph.D.

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1. Claim 1 72

(a) Preamble: "A method of treating opioid overdose, the method comprising:" 72

(b) 1.1: "delivering a 25-200 µL spray of a pharmaceutical solution" 73

(c) 1.2: "from a pre-primed device into a nostril of a patient, wherein the device is adapted for nasal delivery," 75

(d) 1.3: "wherein the spray delivers between about 4 mg and about 10 mg naloxone," 78

(e) 1.4: "an isotonicity agent," 80

(f) 1.5: "and between about 0.005% and about 0.015% (w/v) of benzalkonium chloride," 81

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2. Claim 2 84

3. Claim 3 85

(a) "the spray delivers about 100 µL of the pharmaceutical solution comprising" 86

(b) "about 4% (w/v) naloxone hydrochloride;" 86

(c) "about 0.74% (w/v) sodium chloride" 88

(d) "about 0.01% (w/v) benzalkonium chloride" 92

(e) "about 0.1% (w/v) disodium edetate." 94

4. Claim 4 96

5. Claim 18 98

6. Claim 19 99

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12. Claim 32 108

(a) "the pharmaceutical solution further comprises between about 0.1% and about 0.5% (w/v) of a stabilizing agent" 108

(b) "and an amount of an acid sufficient to achieve a pH between about 3.5 and about 5.5." 110

13. Claim 33 111

(a) "the isotonicity agent is sodium chloride;" 111

(b) "the stabilizing agent is disodium edetate;" 112

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(c) "and the acid is hydrochloric acid." 112

14. Claim 34 112

15. Claim 36 113

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B. A Formulator POSA reading Wyse in view of HPE and Wang would have had a reason and the know-how to arrive at the subject matter of claims 5–12 120

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C. A Formulator POSA reading Wyse in view of HPE and the '291 patent would have had a reason and the know-how to arrive at the subject matter of claims 13–17 and 41 127

1. Claims 13–17 127

2. Claim 41 131

(a) "wherein the patient is in a lying, supine, or recovery position." 133

(b) "the patient experiences a geometric mean naloxone C_{max} not less than about 3 ng/mL following a single spray." 136

D. A Formulator POSA reading Wyse in view of HPE and Djupesland would have had a reason and the know-how to arrive at the subject matter of claims 24, 35, and 37 137

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E. A Formulator POSA reading Wyse in view of HPE, Djupesland, and Zomig Review would have had a reason and the know-how to arrive at the subject matter of claim 38 145

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