UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,

Petitioner

v.

OPIANT PHARMACEUTICALS, INC.
Patent Owner

IPR2019-00687
U.S. Patent No. 9,211,253

DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.

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1. Wyse (U.S. Patent No. 9,192,570) 27

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3. Davies (PCT Patent Publication WO 00/62757) 28

B. In view of the prior art, a Pharmacologist POSA would have been motivated to design a concentrated solution of naloxone in a ready-to-use nasal delivery device, with a reasonable expectation

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of success.....28

1. The known physical, chemical, biopharmaceutical and pharmacological properties of naloxone and prior art would have motivated a Pharmacologist POSA to use a range of 2 to 10 mg naloxone per dose, if not up to 20 mg per dose, in an intranasal solution with a reasonable expectation of success...29

2. The nasal physiology would have motivated a Pharmacologist POSA to use an intranasal solution volume of up to 100 µL per dose with a reasonable expectation of success. 30

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   (b) A Pharmacologist POSA would have expected the inclusion of hydrochloric acid in a naloxone intranasal formulation to achieve high exposure levels, consistent with the Wyse intranasal formulations.....40

   (c) A Pharmacologist POSA would have expected the

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inclusion of disodium EDTA in a naloxone intranasal formulation to achieve high exposure levels, consistent with the Wyse intranasal formulations. 41

(d) A Pharmacologist POSA would have expected the inclusion of benzalkonium chloride (BAC) in a naloxone intranasal formulation to achieve high exposure levels, and may serve to slightly improve the exposure seen with the Wyse formulations. 41

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