

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

**PETITIONER NALOX-1 PHARMACEUTICALS, LLC'S REPLY
TO PATENT OWNERS' RESPONSE**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE CHALLENGED CLAIMS ARE UNPATENTABLE.....	2
A.	Wyse would not have directed a POSA away from using BAC in an intranasal naloxone formulation.....	2
1.	A POSA would have known that naloxone degradants in Wyse's formulations could <i>not</i> have been caused by BAC, and therefore would have dismissed Wyse's conclusion.	3
2.	A POSA would have known that Wyse's prototyping studies were not designed to identify any single ingredient as the cause of naloxone degradation, and would have further investigated the root cause of the degradation.....	6
B.	No other prior art cited by Adapt would have directed a POSA away from using BAC in an intranasal naloxone formulation.....	9
C.	A POSA would have been highly motivated to use BAC as a preservative in an intranasal naloxone formulation.	11
D.	The claimed dose of 4 mg of naloxone would have been obvious to a POSA.	12
1.	Wyse discloses a range of naloxone content that includes 4 mg, and does not teach away from such a dose.....	12
2.	A POSA seeking to develop a community-use intranasal naloxone formulation would have been motivated to choose a naloxone dose of greater than 2 mg.	13
3.	Concerns over inducing acute withdrawal would not have outweighed the risks of administering a less than effective dose of naloxone.	15
4.	A POSA would have tried to achieve a rapid onset of action and high drug exposure with an intranasal naloxone formulation, and would have known that a naloxone dose higher than 2 mg could achieve these goals.	16

IPR2019-00688 - U.S. Patent No. 9,468,747
Petitioner's Reply to Patent Owners' Response

5.	A POSA would <i>not</i> have expected substantial differences in pK between Wyse's intranasal formulations and the claimed formulation, and would have expected Wyse's exposure parameters to remain dose proportional at least at 4 mg.....	17
E.	The claimed naloxone formulation does not have unexpected properties.....	18
1.	The claimed naloxone formulation does not have "unexpected" stability – a POSA would have expected the claimed formulation to be stable.....	18
2.	The C _{max} and relative bioavailability differences between Wyse and the claimed formulation are not statistically significant.....	19
3.	In an "apples-to-apples" comparison, the terminal half-lives of the Wyse formulation and the claimed formulation are not different.....	20
F.	Adapt's evidence of "skepticism" and alleged "failure of others" is based on hearsay or irrelevant facts, and should be ignored.....	20
G.	Adapt has not shown commercial success and satisfaction of a long-felt need because Narcan's adoption by the community and sales are attributable to factors other than the claims.....	22
III.	CONCLUSION.....	25

TABLE OF EXHIBITS

Exhibit No.	Description
Nalox1002	Expert Declaration of Maureen Donovan
Nalox1003	Expert Declaration of Günther Hochhaus
Nalox1007	U.S. Patent No. 9,192,570 (Wyse)
Nalox1009	PCT International App. Pub. No. WO00/62757 (Davies)
Nalox1010	Djupestrand, P., Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review, 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupestrand)
Nalox1012	Handbook of Pharmaceutical Excipients, 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Rowe, R. et al. eds., 6th ed. 2009) (HPE)
Nalox1015	U.S. Patent No. 8,198,291 (the '291 patent)
Nalox1022	Bitter, C. et al., Nasal Drug Delivery in Humans, 40 Curr. Probl. Dermatol. 20–35 (2011) (Bitter)
Nalox1023	Boyer, E., Management of Opioid Analgesic Overdose, 367(2) N. Engl. J. Med. 146–55 (2012) (Boyer)
Nalox1044	Physicians' Desk Reference, NARCAN [Naloxone Hydrochloride Injection, USP], IMITREX Nasal Spray [Sumatriptan], 1300–02, 1546–50 (57th ed., 2003) (PDR 2003)
Nalox1049	<i>Role of Naloxone in Opioid Overdose Fatality Prevention</i> FDA Meeting Transcript (Apr. 12, 2012) (2012 FDA Meeting)
Nalox1201	Supplemental Expert Declaration of Maureen Donovan
Nalox1202	Supplemental Expert Declaration of Günther Hochhaus

IPR2019-00688 - U.S. Patent No. 9,468,747
Petitioner's Reply to Patent Owners' Response

Exhibit No.	Description
Nalox1203	Agency for Healthcare Research & Quality, H.H.S., <i>Comparative Effectiveness Review, Management of Suspected Opioid Overdose With Naloxone by Emergency Medical Services Personnel</i> No. 193 (2017) (AHRQ 2017)
Nalox1204	Asali, L.A. & Brown, K.F., <i>Naloxone Protein Binding in Adult and Foetal Plasma</i> , 27 Eur. J. Clin. Pharmacol. 459–63 (1984) (Asali)
Nalox1205	Intentionally Left Blank
Nalox1206	Bureš, F., <i>Quaternary Ammonium Compounds: Simple in Structure, Complex in Application</i> , 377(14) Topics in Current Chemistry (2019) (Bureš)
Nalox1207	Committee on Drugs, American Academy of Pediatrics, <i>Naloxone Dosage and Route of Administration for Infants and Children: Addendum to Emergency Drug Doses for Infants and Children</i> , 86(3) Pediatrics 484–85 (1990) (Pediatrics 1990)
Nalox1208	Connors, K. et al., <i>Oxidation and Photolysis, in Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists</i> 82–114 (2d ed. 1986) (Connors)
Nalox1209	Intentionally Left Blank
Nalox1210	Ehrick, J. et al., <i>Considerations for the Development of Nasal Dosage Forms, in Sterile Product Development: Formulation, Process, Quality and Regulatory Considerations</i> 99–144 (Parag Kolhe, et al., eds., 2013) (Ehrick)
Nalox1211	<i>Exploring Naloxone Uptake and Uses</i> , FDA Meeting Transcript (July 1, 2015) (2015 FDA Meeting)
Nalox1212	Intentionally Left Blank



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