

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA LTD,
OPIANT PHARMACEUTICALS, INC.
Patent Owners

IPR2019-00691
U.S. Patent No. 9,561,177

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,561,177
AS OBVIOUS OVER WYSE**

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 A. “pre-primed”26

 B. “patient”26

 C. “wherein no more than about [x]% of the droplets have a diameter less than 10 μm,” “wherein the median droplet size is between about [x] μm and about [y] μm,” and “wherein approximately 90% of droplets have a diameter less than about 100 μm.”27

 D. “wherein the patient experiences a geometric mean naloxone C_{max}” and “wherein the patient experiences a plasma naloxone concentration such that the geometric mean of area under a plasma concentration versus time curve (AUC_{0-∞})” 27

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 A. Wyse (U.S. Patent No. 9,192,570)29

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 1. Claim 133

 2. Claim 237

 3. Claim 337

 4. Claim 438

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 6. Claims 10 and 1142

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 1. Claim 644

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TABLE OF EXHIBITS

Exhibit Number	Description
Nalox1001	U.S. Patent No. 9,561,177 (the '177 patent)
Nalox1002	Expert Declaration of Maureen Donovan
Nalox1003	Expert Declaration of Günther Hochhaus
Nalox1004	Excerpt of File History of U.S. Patent No. 9,561,177, Aug. 22, 2016 Office Action, Non-Final Rejection (Aug. 22, 2016 Non-Final Rejection)
Nalox1005	Excerpt of File History of U.S. Patent No. 9,561,177, Oct. 21, 2016 Amendment and Response to Office Action (Oct. 21, 2016 Response to Office Action)
Nalox1006	Excerpt of File History of U.S. Patent No. 9,561,177, Dec. 21, 2016 Office Action, Notice of Allowance and Fees Due (Notice of Allowance)
Nalox1007	U.S. Patent No. 9,192,570 (Wyse)
Nalox1008	Chinese Patent No. 1,575,795 (Wang)
Nalox1009	PCT International App. Pub. No. WO00/62757 (Davies)
Nalox1010	Djupesland, P., <i>Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review</i> , 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupesland)
Nalox1011	Grassin-Delyle, S. et al., <i>Intranasal Drug Delivery: An Efficient and Non-invasive Route for Systemic Administration, Focus on Opioids</i> , 134 Pharm. & Ther. 366–79 (2012) (Grassin-Delyle)
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)
Nalox1013	Kushwaha, S. et al., <i>Advances in Nasal Trans-Mucosal Drug Delivery</i> , (1)7 J. Applied Pharm. Sci. 21–28 (2011) (Kushwaha)
Nalox1014	U.S. Patent No. 5,866,154 (Bahal)
Nalox1015	U.S. Patent No. 8,198,291 (the '291 patent)

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