

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 IPR2019-00694

U.S. Patent No. 9,629,965

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

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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	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)
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., <i>Nasal Drug Delivery in Humans</i> , 40 Curr. Probl. Dermatol. 20–35 (2011) (Bitter)
Nalox1023	Boyer, E., <i>Management of Opioid Analgesic Overdose</i> , 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

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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 <i>Eur. J. Clin. Pharmacol.</i> 459–63 (1984) (Asali)
Nalox1205	Intentionally Left Blank
Nalox1206	Bureš, F., <i>Quaternary Ammonium Compounds: Simple in Structure, Complex in Application</i> , 377(14) <i>Topics in Current Chemistry</i> (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) <i>Pediatrics</i> 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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