

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
UPDATED EXHIBIT LIST**

TABLE OF EXHIBITS

Exhibit Number	Description
Nalox1001	U.S. Patent No. 9,468,747 (the '747 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)

Exhibit Number	Description
Nalox1016	Wermeling, D., <i>A Response to the Opioid Overdose Epidemic: Naloxone Nasal Spray</i> , 3 Drug Deliv. & Transl. Res. 63–74 (2013) (Wermeling 2013)
Nalox1017	Alabama Department of Public Health, <i>Alabama EMS Patient Care Protocols</i> (7th ed., Oct. 2013) (Alabama EMS Protocols)
Nalox1018	Aptar Pharma, Press Release, Aptar Pharma Provides Unit-Dose Nasal Spray Technology for Treatment of Opioid Overdose (Apr. 20, 2016) (Aptar Press Release)
Nalox1019	Ashton, H. et al., <i>Best Evidence Topic Report Intranasal Naloxone in Suspected Opioid Overdose</i> , 23(3) Emerg. Med. J. 221–23 (2006) (Ashton)
Nalox1020	Barton, E. et al., <i>Intranasal Administration of Naloxone by Paramedics</i> , 6 Prehosp. Em. Care 54–58 (Barton 2002)
Nalox1021	Barton, E. et al., <i>Efficacy of Intranasal Naloxone as a Needleless Alternative for Treatment of Opioid Overdose in the Prehospital Setting</i> , 29(3) J. Emerg. Med. 265–71 (2005) (Barton 2005)
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)
Nalox1024	CDC, NDA No. 21-450 Clinical Pharmacology & Biopharmaceutics Review (2002) (Zomig Review)
Nalox1025	Excerpt of Commonwealth of Kentucky, <i>Kentucky Patient Care Protocols</i> (Mar. 13, 2015) (Kentucky Patient Care Protocols)
Nalox1026	Costantino, H. et al., <i>Intranasal Delivery: Physiochemical and Therapeutic Aspects</i> , 337 Int'l. J. of Pharm. 1–24 (2007) (Constantino)
Nalox1027	Dowling, J. et al., <i>Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers</i> , 30(4) Ther. Drug. Monit. 490–96 (2008) (Dowling)
Nalox1028	FDA, Center for Drug Evaluation and Research, Guidance for Industry, <i>Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation</i> (2002) (2002 FDA Guidance)

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Exhibit Number	Description
Nalox1029	FDA, Center for Drug Evaluation and Research, Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action</i> (2003) (2003 FDA Guidance)
Nalox1030	Freise, K. et al., <i>Naloxone Reversal of an Overdose of a Novel, Long-Acting Transdermal Fentanyl Solution in Laboratory Beagles</i> , 35(2) J. Vet. Pharmacol. Therap. 45–51 (2012) (Freise)
Nalox1031	Glende, O., <i>Development of non-injectable naloxone for pre-hospital reversal of opioid overdose: A Norwegian project and a review of international status</i> (May 2016) (unpublished M.A. thesis, Norwegian University of Science and Technology) (on file with Norwegian University of Science and Technology) (Glende)
Nalox1032	Hertz, S., <i>Naloxone for Outpatient Use: Data Required to Support an NDA</i> , PowerPoint Presentation (Hertz Presentation)
Nalox1033	Intentionally left blank
Nalox1034	Kelly, A-M. et al., <i>Randomised Trial of Intranasal Versus Intramuscular Naloxone in Prehospital Treatment for Suspected Opioid Overdose</i> , 182(1) Med. J. Austl. 24–27 (2005) (Kelly)
Nalox1035	Kerr, D. et al., <i>Intranasal Naloxone for the Treatment of Suspected Heroin Overdose</i> , 103 Addiction 379–86 (2008) (Kerr 2008)
Nalox1036	Kerr, D. et al., <i>Randomized Controlled Trial Comparing the Effectiveness & Safety of Intranasal & Intramuscular Naloxone for the Treatment of Suspected Heroin Overdose</i> , 104 Addiction 2067–74 (2009) (Kerr 2009)
Nalox1037	Kleiman-Wexler, R. et al., <i>Pharmacokinetics of Naloxone-An Insight into the Locus of Effect on Stress-Ulceration</i> , 251(2) J. Pharmacol. Exp. Ther. 435–38 (1989) (Kleiman-Wexler)
Nalox1038	Marple, B. et al., <i>Safety Review of Benzalkonium Chloride Used as a Preservative in Intranasal Solutions: An Overview of Conflicting Data and Opinions</i> , 130 Otolaryngol Head Neck Surg. 131–41 (2004) (Marple)
Nalox1039	Merck Index, <i>Isotonic Solutions</i> , MISC-47–69 (Windholz, M. et al. eds., 10th ed. 1983) (Merck Index)

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Exhibit Number	Description
Nalox1040	Merlin, M. et al., <i>Intranasal Naloxone Delivery is an Alternative to Intravenous Naloxone for Opioid Overdoses</i> , 28 Am. J. Emerg. Med. 296–303 (2010) (Merlin)
Nalox1041	Middleton, L. et al., <i>The Pharmacodynamic & Pharmacokinetic Profile of Intranasal Crushed Buprenorphine & Buprenorphine/Naloxone Tablets in Opioid Abusers</i> , 106(8) Addiction 1460–73 (2011) (Middleton)
Nalox1042	Monitto, C. et al., <i>The Optimal Dose of Prophylactic Intravenous Naloxone in Ameliorating Opioid-Induced Side Effects in Children Receiving Intravenous Patient-Controlled Analgesia Morphine for Moderate to Severe Pain: A Dose Finding Study</i> , 113(4) Anesthesia & Analgesia 834–42 (2011) (Monitto)
Nalox1043	<i>Pharmacodynamic Agents</i> , in Foye’s Principles of Medicinal Chemistry, 670 (Lemke, T. et al. eds., 6th ed. 2008) (Lemke)
Nalox1044	Physicians’ Desk Reference, <i>NARCAN [Naloxone Hydrochloride Injection, USP]</i> , <i>IMITREX Nasal Spray [Sumatriptan]</i> , 1300–02, 1546–50 (57th ed., 2003) (PDR 2003)
Nalox1045	Physicians’ Desk Reference, <i>ZOMIG Nasal Spray [Zolmitriptan]</i> , 768–78 (64th ed., 2010) (PDR 2010)
Nalox1046	Robertson, T. et al., <i>Intranasal Versus Intravenous Naloxone for Prehospital Narcotic Overdose</i> , Abstract, 12(5)(1) Acad. Emerg. Med. 166–67 (2005) (Robertson 2005)
Nalox1047	Robertson, T. et al., <i>Intranasal Naloxone is a Viable Alternative to Intravenous Naloxone for Prehospital Narcotic Overdose</i> , 13 Prehosp. Emerg. Care 512–15 (2009) (Robertson 2009)
Nalox1048	<i>Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop; Request for Comments</i> , 76 Fed. Reg. 71,348 (Nov. 17, 2011) (Role of Naloxone Fed. Reg. Notice)
Nalox1049	<i>Role of Naloxone in Opioid Overdose Fatality Prevention</i> FDA Meeting Transcript (Apr. 12, 2012) (2012 FDA Meeting)
Nalox1050	Rosanske, T., <i>Morphine</i> , in Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 604–11 (Connors, K. et al. eds., 2d ed. 1986) (Rosanske)
Nalox1051	Sabzghabae, A. et al., <i>Naloxone Therapy in Opioid Overdose Patients: Intranasal or Intravenous? A Randomized Clinical Trial</i> , 10(2) Arch. Med. Sci. 309–14 (2014) (Sabzghabae)

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