

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NALOX-1 PHARMACEUTICALS, LLC,  
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and  
OPIANT PHARMACEUTICALS, INC.,  
Patent Owners.

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Case IPR2019-00688  
U.S. Patent No. 9,468,747

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**PATENT OWNERS' EXHIBIT LIST**

Exhibit	Short Name	Description
2001	Williams POPR Decl.	Declaration of Kenneth A. Williams, M.D.
2002	Amphastar Press Release	<i>Amphastar Announces the Receipt of a CRL for Intranasal Naloxone for the Emergency Treatment of Opioid Overdose</i> (Feb. 21, 2017), available at <a href="http://ir.amphastar.com/static-files/19b13150-7ff8-4d3b-8e3f-452578083dbb">http://ir.amphastar.com/static-files/19b13150-7ff8-4d3b-8e3f-452578083dbb</a>
2003	Aquina	Christopher T. Aquina et al., OxyContin® Abuse and Overdose, <i>Postgraduate Medicine</i> (2009) 121(2):163–67
2004	Baca	Catherine T. Baca et al., Take-home Naloxone to Reduce Heroin Death, <i>Addiction</i> (2005) 100:1823–31
2005	Belz	Daniel Belz et al., Naloxone Use in a Tiered-Response Emergency Medical Services System, <i>Prehosp. Emerg. Care</i> (2006) 10(4):468–71
2006	Buajordet	Ingebjorg Buajordet, Adverse Events After Naloxone Treatment of Episodes of Suspected Acute Opioid Overdose, <i>Eur. J. Emerg. Med.</i> (2004) 11:19–23
2007	Burford Press Release	<i>Burford Capital Closes \$500 Million Complex Strategies Investment Fund</i> (July 3, 2017), available at <a href="https://www.burfordcapital.com/wp-content/uploads/2017/06/2017.07.03-Burford-Complex-Strategies-fund-close-FINAL.pdf">https://www.burfordcapital.com/wp-content/uploads/2017/06/2017.07.03-Burford-Complex-Strategies-fund-close-FINAL.pdf</a>
2008	Evzio® Label	Evzio® (naloxone hydrochloride injection) Auto-Injector for intramuscular or subcutaneous use, Prescribing Information (Revised Apr. 2014), available at <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205787Orig1s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205787Orig1s000lbl.pdf</a>

Exhibit	Short Name	Description
2009	FDA Teva Press Release	<i>FDA Approves First Generic Naloxone Nasal Spray to Treat Opioid Overdose</i> (Apr. 19, 2019), available at <a href="https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-naloxone-nasal-spray-treat-opioid-overdose">https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-naloxone-nasal-spray-treat-opioid-overdose</a>
2010	Gaddis	Gary M. Gaddis et al., <i>Naloxone-Induced Patient Violence: An Overlooked Toxicity?</i> , <i>Annals of Pharmacotherapy</i> (1992) 26:196–97
2011	Goldfrank's	Goldfrank's Toxicologic Emergencies 579–85 (9th ed. 2010)
2012	Indivior Press Release	<i>Indivior Receives Complete Response Letter from FDA Not Approving Naloxone Nasal Spray New Drug Application for Opioid Overdose</i> (Nov. 24, 2015), available at <a href="http://www.indivior.com/wpcontent/uploads/2015/11/Nasal-Naloxone-Final-Release-112415.pdf">http://www.indivior.com/wpcontent/uploads/2015/11/Nasal-Naloxone-Final-Release-112415.pdf</a>
2013	Kelly 2002	A-M. Kelly et al., <i>Intranasal Naloxone for Life Threatening Opioid Toxicity</i> , <i>Emerg. Med. J.</i> (2002) 19:375
2014	Letter from Ten Congressmen to Michelle K. Lee, Director of U.S. PTO	Letter from Nydia M. Velasquez et al. to Michelle K. Lee, Director, U.S. Patent and Trademark Office (Dec. 5, 2016), available at <a href="http://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/12/Letter-to-Director-Lee-Regarding-IPR-Petitions.pdf">http://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/12/Letter-to-Director-Lee-Regarding-IPR-Petitions.pdf</a>
2015	Loimer 1992	Norbert Loimer et al., <i>Nasal Administration of Naloxone for Detection of Opiate Dependence</i> , <i>Journal of Psychiatric Research</i> (1992) 26(1):39–43
2016	Narcan® Nasal Spray Label	NARCAN® (naloxone hydrochloride) nasal spray, Prescribing Information (Revised Jan. 2017), available at <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208411s001lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208411s001lbl.pdf</a>

Exhibit	Short Name	Description
2017	Osterwalder	Joseph J. Osterwalder, Naloxone—For Intoxications with Intravenous Heroin and Heroin Mixtures—Harmless or Hazardous? A Prospective Clinical Study, <i>Journal of Toxicology: Clinical Toxicology</i> (1996) 34(4):409–16
2018	Pallasch	Thomas J. Pallasch et al., Naloxone-Associated Morbidity and Mortality, <i>Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology</i> (1981) 52:602–03
2019	Popper	Caroline Popper et al., Naloxone Hazard In Drug Abuser, <i>Lancet</i> (1989)
2020	Schwartz	Jeffrey A. Schwartz et al., Naloxone-Induced Pulmonary Edema, <i>Annals of Emergency Medicine</i> (1987) 16:1294–96
2021	Sporer 1996	Karl A. Sporer et al., Out-of-hospital Treatment of Opioid Overdoses in an Urban Setting, <i>Academic Emergency Medicine</i> (1996) 3(7):660–67
2022	Sporer 2007	Karl A. Sporer et al., Prescription Naloxone: A Novel Approach to Heroin Overdose Prevention, <i>Annals of Emergency Medicine</i> (2007) 49(2):172–17
2023	Stoove	Mark A. Stoove et al., Overdose Deaths Following Previous Non-Fatal Heroin Overdose: Record Linkage of Ambulance Attendance and Death Registry Data, <i>Drug and Alcohol Review</i> (2009) 28: 347–52
2024	Terman Slides	G. Terman PowerPoint Presentation “Naloxone: Effects and Side Effects” at FDA 2012 Workshop
2025	Teva Case Claim Construction Opinion	Opinion, <i>Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.</i> , No. 2:16-cv-07721, D.I. 200 (Apr. 24, 2019)

Exhibit	Short Name	Description
2026	Teva Case Schedule Stipulation	Stipulation and Order Regarding Expert Discovery Schedule, <i>Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.</i> , No. 2:16-cv-07721, D.I. 210 (May 13, 2019)
2027	van Dorp	Eveline L.A. van Dorp et al., Naloxone Treatment in Opioid Addiction: the Risks and Benefits, <i>Expert Opinion Drug Safety</i> (2007) 6(2):125–32
2028	Walley	A.Y. Walley et al., Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis, <i>BMJ</i> (2013) 346:174
2029	Wermeling 2015	Daniel P. Wermeling, Review of Naloxone Safety for Opioid Overdose: Practical Considerations for New Technology and Expanded Public Access, <i>Ther. Adv. Drug Safety</i> (2015) 6(1):20-31
2030	Wermeling '354	U.S. Patent Application No. 2010/0331354
2031	Williams	Kenneth Williams et al., Evidence-Based Guidelines for EMS Administration of Naloxone, <i>Prehosp. Emerg. Care</i> (2019)
2032	Yealy	Donald M. Yealy et al., The Safety of Prehospital Naloxone Administration by Paramedics, <i>Annals of Emergency Medicine</i> (1990) 19(8):902–05
2033	Zuckerman	Matthew Zuckerman et al., Pitfalls of Intranasal Narcan – Response to a Letter to the Editor, <i>Prehosp. Emerg. Care</i> (2015) 19:138–39
2034	'253 patent	U.S. Patent No. 9,211,253
2035	'747 patent	U.S. Patent No. 9,468,747
2036	'177 patent	U.S. Patent No. 9,561,177
2037	Teva Case Status Conference Minute Entry	Minute Entry, <i>Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.</i> , No. 2:16-cv-07721, D.I. 221 (June 26, 2019)

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