Paper 1 Filed: February 19, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC, Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,
Patent Owner

IPR2019-00695 U.S. Patent No. 9,629,965

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,629,965 AS OBVIOUS OVER WANG



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B. A POSA Would Have Had the Know-How to Readily Develop an Improved Intranasal Naloxone Formulation.
1. The volume of the nasal cavity naturally limits the volume of a naloxone nasal spray to about 100 μL per spray17
2. A POSA would have been motivated to use a 4–6 mg naloxone dose to achieve desirable naloxone exposure levels.



3. A POSA would have had adequate know-how and ability commonplace excipients to make a stable, well-tolerated intranasal formulation.	naloxone
4. A POSA would have been motivated to load an intranasal a formulation into an easy-to-use single-dose, pre-primed nasal sprayer.	
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TABLE OF EXHIBITS

Exhibit Number	Description
Nalox1001	U.S. Patent No. 9,629,965 (the '965 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., Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review, 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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