Paper 1 Filed: February 19, 2019

#### UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC, Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,
Patent Owner

IPR2019-00696

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

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



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A. Nalo	A POSA Would Have Been Motivated to Develop Improved Intranoxone Formulations to Combat the Opioid Epidemic	
B. Intra	A POSA Would Have Had the Know-How to Readily Develop an Impronasal Naloxone Formulation.	
1. na	The volume of the nasal cavity naturally limits the volume of a nalox sal spray to about 100 μL per spray	
2. ac	A POSA would have been motivated to use a 4–6 mg naloxone dos hieve desirable naloxone exposure levels.	



	. A POSA would have had adequate know-how and ability to ommonplace excipients to make a stable, well-tolerated intranasal na ormulation	loxone
4. fo	. A POSA would have been motivated to load an intranasal na ormulation into an easy-to-use single-dose, pre-primed nasal sprayer	
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D. and	"90% confidence interval for dose delivered per actuation is $\pm$ about 195% confidence interval for dose delivered per actuation is $\pm$ about 2.	.5%"
	"yields, when intranasally administered to a patient, a mean naloxone pentration" and "yields a mean naloxone plasma concentration itent"	plasma in said
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10. Claim 25
11. Claims 29 and 3044
B. Ground 2: Claims 3–5 and 14–16 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007)
1. Claims 3–5 and 14-16
C. Ground 3: Claims 6–8 and 13 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007) or Wang (Nalox1008) and Pharmacologist POSA Knowledge or Wermeling 2013 (Nalox1016)
1. Claims 6–8 and 1347
D. Ground 4: Claim 24 is obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), and Kushwaha (Nalox1013)
E. Ground 5: Claims 27–28 are obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and the '291 patent (Nalox1015)
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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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