Paper 1 Filed: February 19, 2019

#### 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 LTD,
OPIANT PHARMACEUTICALS, INC.,
Patent Owners

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IPR2019-00692 U.S. Patent No. 9,561,177

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,561,177
AS OBVIOUS OVER WANG



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1. na	The volume of the nasal cavity naturally limits the volume of a naloxone sal spray to about 100 μL per spray19
2. acl	A POSA would have been motivated to use a 4–6 mg naloxone dose to hieve desirable naloxone exposure levels
	A POSA would have had adequate know-how and ability to select mmonplace excipients to make a stable, well-tolerated intranasal naloxone mulation



4. for	A POSA would have been motivate rmulation into an easy-to-use single-dose	
VI. CI A.	LAIM CONSTRUCTION UNDER 37 C. "pre-primed"	
B.	"patient"	25
μm,"	"wherein no more than about [x]% of the median droplet size is and "wherein approximately 90% of droum."	between about [x] µm and about [y] oplets have a diameter less than about
"whe	"wherein the patient experiences a generic the patient experiences a plasma metric mean of area under a plasma condition and the second	aloxone concentration such that the
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(Nalo	Ground 8: Claim 28 is obvious over Wang (Nalox1008) in view of HPE 1012), Djupesland (Nalox1010), the '291 patent (Nalox1015), and Wyse 1007), and optionally Wang (Nalox1008) and Pharmacologist POSA edge, or Wermeling 2013 (Nalox1016)



### IPR2019-00692

# Petition for Inter Partes Review of U.S. Patent No. 9,561,177

I.	Ground 9: Claim 30 is obvious over Wang (Nalox1008) in	view of HPE
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