UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC, Petitioner,

v.

OPIANT PHARMACEUTICALS, INC., Patent Owner.

Case IPR2019-00696 Patent 9,629,965

OPIANT PHARMACEUTICALS, INC.

PRELIMINARY RESPONSE OF PATENT OWNER



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	A.		The POSA Would Not Have Been Motivated to Use a Single Intranasal Naloxone Dose of 4 mg		
		1.	Petitioner Ignores Clinical Evidence and Provides No Testimony from a Clinician		
		2.	The Prior Art Taught That an Initial Intranasal Dose of 2 mg or Less Was Therapeutically Effective		
		3.	The Prior Art Disclosed That Too Much Liquid Was a Problem for Nasal Delivery, Not Lack of Efficacy25		
		4.	The Art Taught, and the POSA Would Have Understood, That Higher Doses of Naloxone Risked Withdrawal Symptoms and Other Significant Negative Effects		
		5.	Davies Does Not Teach 4 mg Doses of Naloxone		
		6.	Contrary to Petitioner's Misreading, Wyse Does Not Teach 4 mg Doses of Naloxone		



		7.	The Pharmacokinetic Data in Wyse Would Not Lead the POS to a Single 4 mg Dose of Intranasal Naloxone		
	B.		The POSA Would Not Have Been Motivated To Use BZK or the Combination of BZK with EDTA		
		1.	Davies Does Not Teach the Use of BZK and a Stabilizing Agent—or EDTA—at the Claimed Amounts	.46	
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