UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,

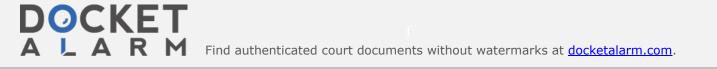
Petitioner

v.

OPIANT PHARMACEUTICALS, INC., Patent Owner

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

DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.



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		2. Wang (Chinese Patent Publication CN 1575795)					
		3. Davies (PCT Patent Publication WO 00/62757)28					
	B.	In view of the prior art, a Pharmacologist POSA would have been motivated to design a concentrated solution of naloxone in a					

-		e nasal delivery device, with a reasonable expectation				
1.	The known physical, chemical, biopharmaceutical and pharmacological properties of naloxone and prior art would have motivated a Pharmacologist POSA to use a range of 2 to 10 mg naloxone per dose, if not up to 20 mg per dose, in an intranasal solution with a reasonable expectation of success29					
2.	POS	The nasal physiology would have motivated a Pharmacologist POSA to use an intranasal solution volume of up to 100 $\mu$ L per dose with a reasonable expectation of success				
3.	A Pharmacologist POSA would have been motivated to design an intranasal solution of naloxone that met or exceeded the exposure levels of the approved Narcan® 2 mg injection protocol, and would have determined that approximately 4-6 mg intranasally would work, with a reasonable expectation of success					
4.	an in abou	A Pharmacologist POSA would have been motivated to design an intranasal solution of naloxone that achieved a $T_{max}$ within about 20-30 minutes, with a reasonable expectation of success. 				
5.	A Pharmacologist POSA would have been able to choose the routine pharmaceutical excipients disclosed in prior a naloxone formulations, to achieve high exposure levels, y reasonable expectation of success					
	(a)	A Pharmacologist POSA would have expected the inclusion of sodium chloride in a naloxone intranasal formulation to achieve high exposure levels, consistent with the Wyse intranasal formulations				
	(b)	A Pharmacologist POSA would have expected the inclusion of hydrochloric acid in a naloxone intranasal formulation to achieve high exposure levels, consistent with the Wyse intranasal formulations				

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			(c)	A Pharmacologist POSA would have expected the inclusion of disodium EDTA in a naloxone intranasal formulation to achieve high exposure levels, consistent with the Wyse intranasal formulations.	41	
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