UNITED STATES PATENT AND TRADEMARK OFFIC	Ŀ
BEFORE THE PATENT TRIAL AND APPEAL BOARD)

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner

v.

OPIANT PHARMACEUTICALS, INC., Patent Owner

IPR2019-00694 U.S. Patent No. 9,629,965

DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.



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	A.	Prior art patent applications disclose concentrated solutions of naloxone administered intranasally to treat opioid overdose					
		1. Wyse (U.S. Patent No. 9,192,570)	27				
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	B.	In view of the prior art, a Pharmacologist POSA would have been motivated to design a concentrated solution of naloxone in a					



-	to-use nasal delivery device, with a reasonable expectation cess				
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				
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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.	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 from the routine pharmaceutical excipients disclosed in prior art naloxone formulations, to achieve high exposure levels, with a 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				



			(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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