UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner

v.

OPIANT PHARMACEUTICALS, INC.
Patent Owner

IPR2019-00686 U.S. Patent No. 9,211,253

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			
		2. Wang (Chinese Patent Publication CN 1575795)	27			
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	В.	In view of the prior art, a Pharmacologist POSA would have been motivated to design a concentrated solution of naloxone in a ready-to-use nasal delivery device, with a reasonable expectation				



of suc	ccess	28			
1.	pharm have:	known physical, chemical, biopharmaceutical and nacological properties of naloxone and prior art would motivated a Pharmacologist POSA to use a range of 2 to g naloxone per dose, if not up to 20 mg per dose, in an assal solution with a reasonable expectation of success29			
2.	POSA	asal physiology would have motivated a Pharmacologist A to use an intranasal solution volume of up to 100 μL per with a reasonable expectation of success30			
3.	an interpretation expose protocome in	armacologist POSA would have been motivated to design ranasal solution of naloxone that met or exceeded the sure levels of the approved Narcan® 2 mg injection col, and would have determined that approximately 4-6 stranasally would work, with a reasonable expectation of ss			
4.	an int	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.	the ro	armacologist POSA would have been able to choose from outine pharmaceutical excipients disclosed in prior art one formulations, to achieve high exposure levels, with a nable 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
			(d)	A Pharmacologist POSA would have expected the inclusion of benzalkonium chloride (BAC) in a naloxone intranasal formulation to achieve high exposure levels, and may serve to slightly improve the exposure seen with the Wyse formulations	41
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