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

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner

v.

ADAPT PHARMA LTD., OPIANT PHARMACEUTICALS,

Patent Owners

IPR2019-00693 U.S. Patent No. 9,561,177

DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.



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		2. Wang (Chinese Patent Publication CN 1575795)	28			
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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	29		
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 success30		
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 success31		
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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.	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.	42		
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