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

IPR2019-00697 U.S. Patent No. 9,775,838

DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.



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VI.	FOR	IVATION TO DESIGN A NALOXONE NASAL MULATION HAVING HIGH BIOAVAILABILITY, WITH A SONABLE EXPECTATION OF SUCCESS					
	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)					
		2. Wang (Chinese Patent Publication CN 1575795)					
		3. Davies (PCT Patent Publication WO 00/62757)30					
	B.	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					

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of s	uccess.					
1.	phar have 10 n	known physical, chemical, biopharmaceutical and macological properties of naloxone and prior art would e motivated a Pharmacologist POSA to use a range of 2 to ng naloxone per dose, if not up to 20 mg per dose, in an masal solution with a reasonable expectation of success31				
2.	POS	nasal physiology would have motivated a Pharmacologist A to use an intranasal solution volume of up to 100 μ L per with a reasonable expectation of success				
3.	an ir expo prote mg i	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 ir 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.	the r nalo	harmacologist POSA would have been able to choose from routine pharmaceutical excipients disclosed in prior art exone formulations, to achieve high exposure levels, with a sonable 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				

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				inclusion of disodium EDTA in a naloxone intranasal formulation to achieve high exposure levels, consistent with the Wyse intranasal formulations			
			(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 formulations43			
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