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

IPR2019-00692 U.S. Patent No. 9,561,177

DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.



TABLE OF CONTENTS

I.	OVE	ERVIEW1				
II.	MY :	BACKGROUND AND QUALIFICATIONS				
III.	LEGAL STANDARDS					
	A.	Person of ordinary skill in the art	.10			
	B.	Claim construction				
	C.	Anticipation and obviousness	13			
	D.	Written description and priority	15			
IV.	THE '177 PATENT AND ITS CLAIMS16					
	A.	Independent claims 1, 12, and 22	17			
	B.	Remaining dependent claims: claims 2–11, 13–21, and 23–30	19			
	C.	The '177 patent lacks priority to U.S. Provisional Application No. 61/953,379.				
	D.	Orange Book listing of the '177 patent	22			
V.	STA	TE OF THE ART	23			
VI.	FOR	TIVATION TO DESIGN A NALOXONE NASAL MULATION HAVING HIGH BIOAVAILABILITY, WITH A SONABLE EXPECTATION OF SUCCESS	26			
	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)	28			
		2. Wang (Chinese Patent Publication CN 1575795)	28			
		3. Davies (PCT Patent Publication WO 00/62757)	29			
	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		
3.	an interpretation expose protocome in	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 intranasal 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.	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	
			(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	42	
		6.	a sing	armacologist POSA would have been motivated to employle-dose device for an intranasal formulation of naloxone a reasonable expectation of success	,	
VII.	CLAI	М СО	NSTR	UCTION	14	
	A.	"patie	ent"		45	
	В.	"wherein the patient experiences a geometric mean naloxone C _{max} "				
	C.	conce	entratio	the patient experiences a plasma naloxone on such that the geometric mean of area under a centration versus time curve $(AUC_{0-\infty})$ "	46	
	D.	"bioa	vailabl	e"	48	
VIII.		UBLIC ACCESSIBILITY OF THE APRIL 12, 2012 FDA [ATERIALS49				
IX.	CLAIMS 10, 11, 16, 22 AND 28 OF THE '177 PATENT ARE OBVIOUS IN VIEW OF THE PRIOR ART					
	A.	Claim	n 28 is	obvious in view of the prior art	51	
		1.		dditional limitations of claim 28 are obvious over Wyse.		
		2.		dditional limitations of claim 28 are obvious over Wang w of the knowledge of a Pharmacologist POSA	53	
		3.	The a	dditional limitations of claim 28 are obvious over		



		Wermeling 2013	55
	B.	Claim 10 and the C _{max} limitations of claim 22 are obvious over Wyse.	56
	C.	The additional limitations of claim 11 are obvious over Wyse	58
	D.	The additional limitations of claim 16 are obvious over Wyse	60
X.	SEC	ONDARY CONSIDERATIONS OF NON-OBVIOUSNESS	62
	A.	No teaching away	63
	B.	No unexpected superior results	64
VΙ	CON	CLUSION	65



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