#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re <i>Inter Partes</i> Review of:	)
U.S. Patent No. 8,573,210	)
Issued: Nov. 5, 2013	)
Application No.: 13/677,483	)
U.S. Filing Date: Nov. 15, 2011	)

For: Nitric Oxide Delivery Device

**FILED VIA PRPS** 

DECLARATION OF WARREN P. HEIM, P.E. IN SUPPORT OF PATENT OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,573,210



### TABLE OF CONTENTS

			<u>Page</u>	
I.	INTRODUCTION AND QUALIFICATIONS			
II.	UND	ERSTANDING OF THE GOVERNING LAW	8	
	A.	A Person of Ordinary Skill in the Art		
	В.	Anticipation		
	C.	Obviousness		
	D.	Claim Construction	13	
III.	MAT	ERIALS RELIED UPON IN FORMING OPINIONS	14	
IV.	OVERVIEW OF THE '210 PATENT			
V.	OVE	RVIEW OF ALLEGED PRIOR ART	18	
	A.	Bathe '083	19	
	B.	Peters '510	22	
	C.	French Patent Publication No. 2 917 804 ("FR '804")	30	
	D.	The IR Standard	35	
	E.	Lebel '533	37	
VI.	LEVI	EL OF ORDINARY SKILL IN THE ART	37	
VII.	NO E	DELIVERY DEVICES OFFERED FOR SALE	38	
	A.	INOmax DSIR® NO Delivery Systems	39	
	B.	Other NO Delivery Systems		
VIII.	MOT	TVATION TO COMBINE	41	
	A.	The Motivation of a Person of Ordinary Skill in the Art		
		Designing Medical Devices		
	B.	The Influence of MAUDE and FDA Guidance		
	C.	Motivation to Combine Bath '083 and Peters '510	52	
	D.	Motivation to Combine FR '804 with Bathe '083 and/or Peters	_	
	-	'510	56	
	E.	Motivation to Combine the IR Standard with the Other Cited		
		References	64	



IX.		MPARISON OF '210 CLAIMS TO ASSERTED MBINATIONS	64
X.	ADDITIONAL REFERENCES		
		The INOMAX Label	
XI.	CO	NCLUSION	71



I, Warren P. Heim, P.E. resident of Boulder, Colorado, hereby declare as follows:

### I. INTRODUCTION AND QUALIFICATIONS

- 1. I have been retained by INO Therapeutics, LLC ("INO") to provide my opinions concerning certain claims of U.S. Patent No. 8,573,210 (the "'210 patent") in support of INO's Response to the Institution of *Inter Partes* Review of the '210 patent. I have not previously been employed or retained by INO in any capacity.
- I am a Registered Professional Engineer with three college degrees: A.B.
  1973 with a major in engineering from Dartmouth College, B.E. 1974 and
  M.E. 1975, both from Dartmouth College's Thayer School of Engineering.
- 3. I have been a product development consultant or engineer for the medical device and energy industries since 1975. In my projects I have designed mechanical, electromechanical, and electronic products and been the system architect for medical devices that incorporated mechanical, electromechanical, electronic, and software subsystems.
- 4. My medical device experience includes infusion pumps when I was employed between 1982 and 1987 by Valleylab when it is was a unit of Pfizer. I worked on new products and improving existing products including remote communication and control between pumps and computers at nursing



- stations using wired connections. The precision and accuracy of the pumps made them particularly well suited to deliver medications to neonates.
- 5. I was one of the founders and the president of The Larren Corporation ("Larren"), a contract medical device product development firm that was eventually sold to Battelle Memorial Institute after Battelle approached us about purchasing the firm.
- 6. Among the projects at Larren in which I was involved was a locator for endotracheal tubes that was recognized for design excellence as a finalist in the Medical Device and Diagnostic Industry Medical Device Excellence Awards.
- 7. As a product development consultant I have managed and been an engineer on many projects including ambulatory infusion pumps, cardiac monitors, hemodialysis systems, catheters, and electrosurgical instruments.
- 8. These projects frequently involved multiple microprocessor CPUs exchanging and comparing data. One project for an automated assembly line had over 15 control modules with CPUs using communication protocols that I developed and implemented as the system architect and lead engineer.
- 9. Another project was a hemodialysis system for which I was the system architect and lead engineer that had multiple microprocessor CPUs exchanging information, including using radio telemetry to an external



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