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

PAR PHARMACEUTICAL, INC. Petitioner

V.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

.....

CASE IPR: <u>Unassigned</u> Patent 8,772,306

DECLARATION OF JOHN W. WINKELMAN, M.D., Ph.D.



TABLE OF CONTENTS

I.	OVE	/ERVIEW1				
II.	MY	BACKGROUND AND QUALIFICATIONS				
III.	PER	PERSON OF ORDINARY SKILL IN THE ART10				
IV.	THE '306 PATENT AND ITS CLAIMS					
	A.	Overview of the '306 Patent	12			
	B.	Claim Construction – "Concomitant" and "Concomitantly"1				
	C.	Orange Book listing of the '306 patent				
V.	STATE OF THE ART					
	A.	Narcolepsy and GHB20				
	B.	Valproic Acid/Divalproex Sodium				
	C.	Drug Interactions				
	D.	GHB Metabolism and Valproate Interactions				
VI.	BASIS OF MY ANALYSIS WITH RESPECT TO OBVIOUSNESS					
	A.	The Scope and Content of the Prior Art	40			
		1. The Xyrem 2005 Label (PAR1006)	40			
		2. The Depakote 2011 Label (PAR1007)	42			
		3. Cagnin (PAR1008)	43			
		4. Waszkielewicz (PAR1009)	44			
		5. Weiss (PAR1010)	45			
		6. The FDA Guidance (PAR1011)	46			
	B.	Comparison of the Prior Art to the Claims	47			



		1.	Claim 1	49	
		2.	Claim 11	63	
		3.	Claim 19	73	
		4.	Claims 30 and 33.	82	
		5.	Claims 2, 4, 12, 13, 18, and 28	98	
		6.	Claims 3 and 8	100	
		7.	Claims 5 and 16	100	
		8.	Claim 6, 17, and 27	101	
		9.	Claims 7, 9, and 10	102	
		10.	Claims 14, 15, 20, and 21	103	
		11.	Claims 22 and 24.	104	
		12.	Claim 25	105	
		13.	Claim 26	105	
		14.	Claim 31	105	
		15.	Claims 23, 29, 32 and 34	106	
VII.	SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS				
	A.	No c	commercial success.	107	
	B.	No le	ong-felt but unmet need or failure of others.	108	
	C.	No u	nexpected superior results.	110	
VIII.	CON	ICLUS	SION	112	



I, John W. Winkelman, M.D., Ph.D., do hereby declare as follows:

I. OVERVIEW

- 1. I am over the age of eighteen (18) and otherwise competent to make this declaration. This declaration is based on my personal knowledge as an expert in treatment of sleep disorders with extensive experience treating patients for both excessive daytime sleepiness and cataplexy in narcolepsy. I understand that this declaration is being submitted together with a petition for an *Inter Partes* Review ("IPR") of claims 1-34 of U.S. Patent No. 8,772,306 ("the '306 patent," PAR1001.)
- 2. I have been retained as an expert witness on behalf of Par Pharmaceutical, Inc. ("Par") for this IPR. I am being compensated for my time in connection with this declaration at my standard consulting rate of \$600 per hour and \$900 per hour for time at deposition or at trial. I have no personal or financial interest in the outcome of this proceeding.
- 3. I understand that the '306 patent issued on July 8, 2014, and resulted from U.S. Ser. No. 13/872,997, filed on April 29, 2013. I also understand that the U.S. Patent and Trademark Office ("**USPTO**") records state that the '306 patent is currently assigned to Jazz Pharmaceuticals, Inc. ("**Jazz**").

- 4. The face page of the '306 patent lists another patent application. I understand that the '306 patent is related to this patent application, which was filed on March 1, 2013.
- 5. In preparing this declaration, I have reviewed the '306 patent (PAR1001) and its file history (PAR1002). I have also considered each of the documents listed in the table below, in light of general knowledge in the art as of March 1, 2013.

Par Exhibit #	Description
1001	Eller, M., U.S. Patent No. 8,772,306 (filed Apr. 29, 2013; issued Jul. 8, 2014)
1002	File History for U.S. Patent No. 8,772,306 (filed Apr. 29, 2013; issued Jul. 8, 2014)
1005	Orange Book Patent Exclusivity Listing for XYREM (http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew .cfm?Appl_No=021196∏_No=001&table1=OB_Rx)
1006	Jazz Pharmaceuticals, Inc., Prescribing Information and Medication Guide for XYREM (sodium oxybate) (Nov. 18, 2005)
1007	Abbvie, Inc., Prescribing Information and Medication Guide for DEPAKOTE (divalproex sodium) (Oct. 7, 2011)
1008	Cagnin, A. et al., γ-Hydroxybutyric Acid-Induced Psychosis and Seizures, 21(2) Epilepsy Behav. 203–05 (2011) ("Cagnin")
1009	Waszkielewicz, A. et al., γ-Hydroxybutyric Acid (GHB) and Its Chemical Modifications: A Review of the GHBergic System, 56(1) Pol. J. Pharmacol. 43–49 (2004) ("Waszkielewicz")



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