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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC., Petitioners,

v.

INDIVIOR UK LIMITED, Patent Owner.

Patent No. 8,475,832
Issue Date: July 2, 2013
Title: SUBLINGUAL AND BUCCAL FILM COMPOSITIONS
Inter Partes Review No. IPR2016-XXXXX

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,475,832



## **TABLE OF CONTENTS**

		<u>Pag</u>	<u>e</u>	
I.	INTE	RODUCTION	1	
II.	BACKGROUND1			
	A.	Brief Overview of the '832 Patent	1	
	B.	Brief Overview of the Prosecution History	3	
III.	GRO	OUNDS FOR STANDING (§ 42.104(A))	6	
IV.	MAN	NDATORY NOTICES UNDER 37 C.F.R. § 42.8	6	
	A.	Real Party-in-Interest (§ 42.8(b)(1)	6	
	B.	Related Proceedings (§ 42.8(b)(2))	6	
	C.	Lead and Backup Counsel (§ 42.8(b)(3))1	0	
V.		STATEMENT OF THE PRECISE RELIEF REQUESTED AND IDENTIFICATION OF THE CHALLENGE (§ 42.104(B))11		
VI.	LEV	EL OF ORDINARY SKILL IN THE ART1	3	
VII.	THE	CHALLENGED CLAIMS OF THE '832 PATENT1	3	
VIII.	CLAIM CONSTRUCTION		5	
IX.	SCO	PE AND CONTENT OF THE PRIOR ART1	5	
	A.	WO2008/040534 ("LabTec") (Ex. 1007)	5	
	B.	WO 2008/025791 ("Oksche") (Ex. 1005)	6	
	C.	U.S. Patent No. 7,357,891 ("Yang") (Ex. 1006)1	6	
	D.	Suboxone® Sublingual Tablets (Label and SBOA, Exs. 1008 and 1009)	7	
	E.	U.S. Patent Publication 2005/0085440 ("Birch") (Ex. 1004)2	2	
	F.	The '055 Publication (Ex. 1010)2	.3	



Χ.		AILED EXPLANATION OF THE GROUNDS FOR ATENTABILITY2	4
	A.	Ground 1: Claims 1-2, 4-7, and 9-10 are Invalid Under 35 U.S.C. § 103(a) as Being Obvious Over LabTec in View of Yang, the Suboxone® 2002 Label, SBOA, and Birch	4
		1. The film dosage limitations2	4
		2. The buffer and pH range limitations2	7
	В.	Ground 2: Claims 3 and 11-12 are Invalid Under 35 U.S.C. § 103(a) as Being Obvious Over LabTec in View of Yang, the Suboxone® 2002 Label, SBOA, Birch, and the '055 Publication3	9
	C.	Ground 3: Claims 1-2, 4-7, and 9-10 are Invalid Under 35 U.S.C. § 103(a) as Being Obvious Over Oksche in View of Yang, Birch, the Suboxone® 2002 Label, and SBOA	0
		1. The film dosage limitations4	0
		2. The buffer and pH range limitations4	3
	D.	Ground 4: Claims 3 and 11-12 are Invalid Under 35 U.S.C. § 103(a) as Being Obvious Over Oksche in View of Yang, Birch, the Suboxone® 2002 Label, SBOA, and the '055 Publication4	9
XI.	CON	ICLUSION5	0



## **PETITIONERS' EXHIBIT LIST**

Exhibit No.	Reference
1001	U.S. Patent No. 8,475,832 (filed August 7, 2009) ("'832 patent")
1002	File History, U.S. Patent No. 8,475,832
1003	Expert Declaration of Metin Çelik, Ph.D., Relating to U.S. Patent No. 8,475,832 ("Çelik Decl.")
1004	U.S. Patent Application Publication 2005/0085440 (published April 21, 2005) ("Birch")
1005	WO 2008/025791 (published March 6, 2008) ("Oksche")
1006	U.S. Patent No. 7,357,891 (published December 23, 2004) (issued April 15, 2008) ("Yang")
1007	WO 2008/040534 (published April 10, 2008) ("LabTec")
1008	Suboxone <sup>®</sup> Label
1009	Suboxone® Tablet Summary Basis of Approval ("SBOA")
1010	U.S. Patent Application Publication No. 2005/0037055 ("the '055 publication")
1011	European Medicines Agency Initial Marketing-Authorisation Document, Scientific Discussion, Oct. 19, 2006 for Suboxone® sublingual tablets ("EMEA")
1012	J.P. Cassidy et al., <i>Controlled Buccal Delivery of Buprenorphine</i> , 25 J. Controlled Release 21 (1993)
1013	Rex M. C. Dawson et al., <i>Data for Biochemical Research</i> (3d ed. 1986)
1014	Domenic A. Ciraulo et al., <i>Pharmacokinetics and Pharmacodynamics of Multiple Sublingual Buprenorphine Tablets</i>



	in Dose-Escelation Trials, 46 J. Clinical Pharmacology 179 (2006)
1015	C. Nora Chiang & Richard L. Hawks, <i>Pharmacokinetics of the Combination Tablet of Buprenorphine and Naloxone</i> , 70 Drug & Alcohol Dependence S39 (2003)
1016	Campbell et al., <i>The History of the Development of Buprenorphine as an Addiction Therapeutic</i> , 1248 Ann. N.Y. Acad. Sc. (Issue: Addiction Reviews), 124 (2012) ("Campbell")
1017	Bullingham et al., Sublingual Buprenorphine Used Postoperatively: Clinical Observations and Preliminary Pharmacokinetic Analysis, 12 Br. J. Clinical Pharmacology 117 (1981)
1018	U.S. Patent App. Pub. No. US 2010/0087470
1019	U.S. Patent No. 4,582,835
1020	Center for Drug Evaluation and Research, Approval Package for App. No. 22-410/S006/S007 (approval date 8/10/12) ("Film Approval Package")
1021	Encyclopedia of Pharmaceutical Technology, 2nd ed., Vol. I, Drug Delivery—Buccal Route (McElnay et al.) ("McElnay")
1022	U.S. Patent No. 5,288,497 ("Stanley")
1023	Declaration by Marlene Bobka ("Bobka Decl.")
1024	Parkhurst A. Shore et al., The Gastric Secretion of Drugs: A pH Partition Hypothesis, 119 J. Pharmacology Exp. Ther. 361 (1957)
1025	Curriculum Vitae of Metin Çelik, Ph.D.
1026	List of Materials Considered by Metin Çelik, Ph.D.
1027	The Theory and Practice of Industrial Pharmacy (L. Lachman, Ph.D.) (1986)



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