

Paper No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Petitioner

v.

RB PHARMACEUTICALS LIMITED

Patent Owner

Case No. IPR2014-00325

Patent 8,475,832

**PETITIONER'S FIRST UPDATED EXHIBIT LIST
ACCOMPANYING REPLY**

Exhibit No.	Description
1001	US Patent 8,475,832
1002	<i>Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited, and MonoSol, RX, LLC.</i> , WDNC Civil Action No. 5:13-cv-760, Complaint filed October 29, 2013 (“ Complaint ”)
1003	2012 Reckitt Annual Report (“ Annual Report ”)
1004	Declaration of Maureen Reitman, Sc.D. (“ Reitman ”)
1005	Declaration of Phillip T. Lavin, Ph.D. (“ Lavin ”)
1006	First Office Action mailed August 31, 2011 (“ First OA ”)
1007	Response filed February 29, 2012 (“ First Response ”)
1008	Second Office Action mailed May 2, 2012 (“ Second OA ”)
1009	Response to filed October 22, 2012 (“ Second Response ”)
1010	Third Office Action mailed November 6, 2012 (“ Third OA ”)
1011	Response to filed April 30, 2013 (“ Third Response ”)
1012	Notice of Allowance mailed May 24, 2013, including the attached Interview Summary (“ NOA ”)
1013	Suboxone® tablet label, Revised September 2006 (“Suboxone Tablet Label”)
1014	Merriam-Webster’s Collegiate Dictionary (10 th ed. 2000)
1015	European Medicines Agency (EMA) Study Report on Suboxone® tablets, 2006 (“ Suboxone Tablet Study Report ”)
1016	US Patent No. 7,357,891, published December 23, 2004, to Yang <i>et al.</i> (“ Yang ”)
1017	International Patent Publication No. WO 2008/040534, published April 10, 2008, to Applicant Labtec GmbH (“ Labtec ”)
1018	International Patent Publication No. WO 2008/025791, published March 6, 2008, to Applicant Euro-Celtique S.A. (“ Euro-Celtique ”)

1019	US Patent Publication No. 2005/0085440, published April 21, 2005, to Birch <i>et al.</i> (" Birch ")
1020	Power of Attorney
1021	Assignment from Reckitt Benckiser Healthcare (UK) Limited to RB Pharmaceuticals Limited
1022	Assignment from MonoSol Rx, LLC to Reckitt Benckiser Healthcare (UK) Limited
1023	US Patent No. 7,425,292, published September 16, 2008, to Yang <i>et al.</i>
1024	M.Voet, THE GENERIC CHALLENGE (Brown Walker Press 2d ed. 2008)
1025	P.J. Tiseo, <i>et al.</i> , Br J Clin Pharmacol. Nov 1998; 46 (Suppl 1): 51–55, <i>An evaluation of the pharmacokinetics of Donepezil HCL and patients with impaired hepatic function</i> (marked as exhibit during deposition, but not filed)
1026	Zyprexa Prescribing Information, Copyright © 1997, 2003, Eli Lilly and Company (marked as exhibit during deposition, but not filed)
1027	IPR2014-00325, Institution Decision, Paper No. 17 (marked as exhibit during deposition, but not filed)
1028	Full Transcript Deposition of Dr. Johnston dated January 23, 2015
1029	Declaration of David W. Feigal, MD, MPH
1030	David W. Feigal, MD, MPH CV
1031	Declaration of Christine Siegwarth Meyer, Ph.D.
1032	Christine Siegwarth Meyer, Ph.D. CV & Materials Considered
1033	IPR2014-000998, Paper No. 2, Petition
1034	IPR2014-00998, Paper No. 12, Institution Decision
1035	IPR2014-00998, Paper No. 6, Motion for Joinder
1036	US 2014/0005218, Publication of USSN 13/964,975, published January 2, 2014

1037	Non-final Rejection of USSN 13/964,975, mailed November 7, 2013
1038	Amendment and Response of USSN 13/964,975, filed January 2, 2014
1039	Final Rejection of USSN 13/964,975, mailed March 7, 2014
1040	RB Press Release, "US FDA Marketing Approval For Reckitt Benckiser's Subutex® & Suboxone®," October 9, 2002 available at: https://www.rb.com/documentdownload.axd?documentresourceid=8
1041	FDA Website, "Developing Products for Rare Diseases & Conditions" available at: http://www.fda.gov/forindustry/DevelopingProduCTsforrareDiseasesConditions/default.htm
1042	FDA Website, "Frequently Asked Questions on Patents and Exclusivity" available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm
1043	FDA National Drug Code Database Search Results, available at: http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm (Type: Active Ingredient; Name: buprenorphine)
1044	2013 Reckitt Benckiser Group Annual Report
1045	Federal Register 2013-13446 (FDA re Suboxone Withdrawal)
1046	RB Press Release, "Proposed Demerger of the RB Pharmaceuticals business," November 17, 2014 available at: https://www.rb.com/proposed-demerger-of-the-rb-pharmaceuticals-business
1047	Paul Ragusa and Dennis Bissonnette, <i>Product Improvements and Life Cycle Management – Antitrust Pitfalls</i> , New Jersey Intellectual Property Law Association, available at: http://www.njipla.org/Resources/Documents/event_proceedings/2012-12-05-26th-Annual-Pharmaceutical-Chemical/NJIPLA%20Presentation%20on%20Product%20Switching--Final%20Paper%20NY02%20760911%201-2.pdf
1048	Jessie Cheng, <i>An Antitrust Analysis of Product Hopping in the</i>

	<i>Pharmaceutical Industry</i> , COLUM. L. REV., Issue 6, October 2008
1049	Sean Royall, Ashely E. Johnson, and Jason C. McKenney, <i>Antitrust Scrutiny of Pharmaceutical “Product Hopping,”</i> ANTITRUST, Vol. 28, No. 1, Fall 2013
1050	2010 Reckitt Benckiser Group Annual Report
1051	2011 Reckitt Benckiser Group Annual Report
1052	Lachman Consultant Services, Inc. Citizen Petition, September 27, 2012 (Docket No. FDA-2012-P-1034)
1053	RB Press Release, <i>Further US RB Pharmaceuticals Announcement</i> , September 25, 2012 available at: http://www.rb.com/site/rkbr/templates/mediainvestorsgeneral2.aspx?pageid=1332&cc=GB

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