

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
Petitioner

v.

RB PHARMACEUTICALS LIMITED  
Patent Owner.

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Case IPR2014-00325  
Patent 8,475,832

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**PATENT OWNER'S TRANSMITTAL LETTER AND UPDATED EXHIBIT  
LIST ACCOMPANYING DEMONSTRATIVE EXHIBIT FOR ORAL  
HEARING**

Pursuant to the Trial Hearing Order, Paper 36, filed herewith is Patent Owner's demonstrative exhibit (Exhibit 2053). An updated list of exhibits appears below.

Exhibit No.	Description
2001	Affidavit of Daniel A. Ladow in Support of Motion for <i>Pro Hac Vice</i> Admission
2002	U.S. Patent No. 7,598,343
2003	Declaration of Thomas P. Johnston, Ph.D.
2004	Thomas P. Johnston, Ph.D. <i>curriculum vitae</i>
2005	Lewis and Readhead, "Novel analgesics and molecular rearrangements in the morphine-thebaine group. XVIII. 3- deoxy-6,14-endo-etheno-6,7,8,14-tetrahydrooripavines," <i>J Med Chem</i> 13:525-7, (1970)
2006	Stoller et al., "Effects of buprenorphine/naloxone in opioid-dependent humans," <i>Psychopharmacology</i> 154:230-242, 230 (2001) ("Stoller")
2007	SUBOXONE® Tablet Data Sheet, 2006
2008	U.S. Patent No. 4,464,378
2009	Brewster et al., "The systemic bioavailability of buprenorphine by various routes of administration," <i>J. Pharm. Pharmacol.</i> 33:500-506, 504-5 (1981) (Brewster)

Exhibit No.	Description
2010	Bullingham et al., "Sublingual buprenorphine used postoperatively: ten hour plasma drug concentration analysis," <i>Br. J. Clin. Pharmac.</i> 13:665-673, 665 (1982) (Bullingham 1982)
2011	Kuhlman et al., "Human pharmacokinetics of intravenous, sublingual, and buccal buprenorphine," <i>Journal of Analytical Toxicology</i> 20:369-378, 369 (1996)
2012	Mendelson et al., "Bioavailability of sublingual buprenorphine," <i>J. Clin. Pharmacol.</i> 37:31-37, 31 (1997) ("Mendelson 1997")
2013	Robinson, "Buprenorphine: An analgesic with an expanding role in the treatment of opioid addiction," <i>CNS Drug Reviews</i> 8:377-390, 381 (2002)
2014	Chiang and Hawks "Pharmacokinetics of the combination tablet of buprenorphine and naloxone," <i>Drug and Alcohol Dependence</i> 70:S39-S47, S40 (2003)
2015	Harris et al, "Pharmacokinetics and subjective effects of sublingual buprenorphine alone or in combination with naloxone," <i>Clin. Pharmacokinet.</i> 76:329-340, 330 (2004)
2016	Elkader and Sproule "Buprenorphine Clinical pharmacokinetics in the treatment of opioid dependence," <i>Clin. Pharmacokinet.</i> 44:661-680, 663 (2005) (Elkader)
2017	Welsh and Valadez-Meltzer "Buprenorphine: a (relatively) new treatment for opioid dependence," <i>Psychiatry (Edgmont)</i> 2:29-39, 32 (2005) (Welsh)

Exhibit No.	Description
2018	Rance and Shillingford “The metabolism of phenolic opiates by rat intestine,” <i>Xenobiotica</i> 7:529-536, 534 (1977) (Rance)
2019	Iribarne et al., “Involvement of cytochrome P450 3A4 in n-dealkylation of buprenorphine in human liver microsomes,” <i>Life Sci.</i> 60:1953-64 (1997) (Iribarne)
2020	Chang et al., “Novel metabolites of buprenorphine detected in human liver microsomes and human urine,” <i>Drug Metab. and Disp.</i> 34:440-448, 446 (2006) (“Chang”)
2021	Bullingham et al., “Buprenorphine kinetics” <i>Clin. Pharmacol.</i> 28:667-672, 670-671 (1980) (“Bullingham 1980”)
2022	McQuay and Moore “Buprenorphine Kinetics in Humans,” In: <i>Buprenorphine: Combatting Drug Abuse With A Unique Opioid</i> Cowan, Lewis (Eds.) (1995) pp. 137-147, 140-41, Table II
2023	Tam “Individual Variation in First-Pass Metabolism,” <i>Clin. Pharmacokinet.</i> 25:300-328, 300 (1993) (Tam)
2024	Rowland and Tozer “Therapeutic relevance,” In: <i>Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications</i> , Rowland, Tozer (Eds.), 4th Edition, Lippincott Williams & Wilkins, New York (2011) pp. 3-16 (Rowland)
2025	Shargel et. al., “Relation of Dose to Pharmacologic Effect” In: <i>Applied Bi pharmaceuticals &amp; Pharmacokinetics</i> , Shargl, Wu-Pong, Yu (Eds.), 5 <sup>th</sup> Edition, McGraw Hill, New York (2005) pp.577-580

Exhibit No.	Description
2026	Rowland and Tozer "Variability," In: <i>Clinical Pharmacokinetics: Concepts and Applications</i> , Rowland, Tozer (Eds.), 3rd Edition, Lippincott Williams & Wilkins, New York (1995) pp. 203-219 (Rowland 1995).
2027	Walter and Inturrisi "Absorption, distribution, metabolism, and excretion of buprenorphine in animals and humans," In: <i>Buprenorphine: Combatting Drug Abuse with a Unique Opioid</i> . Cowan, Lewis (Eds.) (1995) pp. 113-135, 127
2028	Bullingham et al., "Sublingual buprenorphine used postoperatively: clinical observations and preliminary pharmacokinetic analysis," <i>Br. J. Clin. Pharmacology</i> 12:117-122, 121 (1981)
2029	Johnson et al., "Buprenorphine: considerations for pain management," <i>J. Pain and Symptom Management</i> 3:297-326, 302
2030	Summary of Product Characteristics for Subutex 0.4 mg, 2 mg, and 8 mg Sublingual tablets at <a href="http://www.medicines.ie/medicine/1658/SPC/Subutex+0.4mg%2c+2mg+and+8mg+Sublingual+Tablets/">http://www.medicines.ie/medicine/1658/SPC/Subutex+0.4mg%2c+2mg+and+8mg+Sublingual+Tablets/</a> downloaded on Nov. 2, 2014
2031	Washington and Fanciullo "Buprenorphine: Side-Effects and Tolerability," In: <i>Handbook of Methadone Prescribing and Buprenorphine Therapy</i> , Cruciani, Knotkova (Eds.) (2013) pp. 201-212, 203
2032	Fishman et al., "Disposition of naloxone-7,8- <sup>3</sup> H in normal and narcotic-dependent men," <i>J. Pharmacol. Exp. Ther.</i> 187:575-580, 577-579 (1973) (Fishman)
2033	Chamberlain and Klein, "A comprehensive review of naloxone for the emergency physician," <i>American J. Emergency Medicine</i> 12:650-660, 650 (1994)

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