

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 EXHIBIT LIST**

Exhibit No.	Description
2001	Affidavit of Daniel A. Ladow in Support of Motion for <i>Pro Hac Vice</i> Admission
2002 (NEW)	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 routs of administration," <i>J. Pharm. Pharmacol.</i> 33:500-506, 504-5 (1981) (Brewster)
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)
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
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)
2034	Martin et al., “Bioavailability investigation of a new tilidine/naloxone liquid formulation compared to a reference formulation,” <i>Arzneim.-Forsch./Drug Res.</i> 49:599-607, 604-606 (Table 4 and Fig. 5)
2035	Smith et al., “Low absolute bioavailability of oral naloxone in healthy subjects” <i>Int. J. Clin. Pharm. And Thera.</i> 50:360-367, 362-364 (2012)
2036	Shargel et. al., “Physiological factors related to drug absorption” In: <i>Applied Biopharmaceuticals &amp; Pharmacokinetics</i> , Shargel, Wu-Pong, Yu (Eds.), 5 <sup>th</sup> Edition, McGraw Hill, New York (2005) pp. 371-409,

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