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Filed on behalf of Petitioners,

Lupin Limited and Lupin Pharmaceuticals, Inc.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LIMITED
AND LUPIN PHARMACEUTICALS INC.,
Petitioners

v.

iCEUTICA PTY LTD.

Patent Owner

Case No. IPR2016-00399

U.S. Patent No. 9,017,721

PETITIONERS' UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioners Lupin Limited and Lupin Pharmaceuticals, Inc. hereby provide a current list of its exhibits.

| Exhibit No. | Description | Short Citation |
|--------------------|--|-------------------------|
| 1001 | U.S. Patent No. 9,017,721 | '721 patent |
| 1002 | Declaration of Mansoor Amiji, Ph.D. | |
| 1003 | Curriculum Vitae of Mansoor Amiji, Ph.D. | |
| 1004 | List of documents reviewed by Mansoor Amiji, Ph.D. in preparation of his declaration | |
| 1005 | PCT Publication No. WO2008/000042, published January 3, 2008 | Meiser |
| 1006 | Novartis Package Insert for Cataflam®, Voltaren®, and Voltaren®-XR, dated May 2000 | Novartis Package Insert |
| 1007 | United States Pharmacopeia 30, Section <711> (2007) | USP <711> |
| 1008 | United States Pharmacopeia 30, Section <1092> (2007) | USP <1092> |
| 1009 | Chuasuwana <i>et al.</i> , "Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms Diclofenac Sodium and Diclofenac Potassium," 98(4):1206-1219 (2009) | Chuasuwana |
| 1010 | PCT Publication No. WO2006/133954, published December 21, 2006 | Reiner |
| 1011 | PCT Publication No. WO2006/069419, published July 6, 2006 | Payne |

| Exhibit No. | Description | Short Citation |
|-------------|--|------------------|
| 1012 | Moore, "Diclofenac Potassium 12.5mg Tablets for Mild to Moderate Pain and Fever: A Review of Its Pharmacology, Clinical Efficacy and Safety," 27(3):163-195 (2007) | Moore |
| 1013 | U.S. Patent No. 5,256,699 to Murphy <i>et al.</i> | |
| 1014 | Dokoumetzidis <i>et al.</i> , "A century of dissolution research: From Noyes and Whitney to the Biopharmaceutics Classification System," Int'l Journal of Pharmaceutics 321:1-11 (2006) | Dokoumetzidis |
| 1015 | Kesisoglou <i>et al.</i> , "Nanosizing – Oral Formulation Development and Biopharmaceutical Evaluation," Advanced Drug Delivery Reviews, 59:631-644 (2007) | Kesisoglou |
| 1016 | U.S. Patent No. 5,202,129 to Samejima <i>et al.</i> | Samejima |
| 1017 | U.S. Patent Publication 2006/0159628 to Liversidge | Liversidge '628 |
| 1018 | Vogt <i>et al.</i> , "Dissolution enhancement of Fenofibrate by Micronization, Cogrinding and Spray-drying: Comparison with Commercial Preparations," European Journal of Pharmaceutics and Biopharmaceutics 68:283-288 (2008) | Vogt |
| 1019 | U.S. Patent Publication 2006/0204588 to Liversidge <i>et al.</i> | Liversidge '588 |
| 1020 | U.S. Patent No. 8,808,751 to Cammarano, <i>et al.</i> | Cammarano |
| 1021 | Iroko F-1 Prospectus filed with the Securities and Exchange Commission on June 18, 2013 | Iroko Prospectus |

| Exhibit No. | Description | Short Citation |
|-------------|--|------------------------|
| 1022 | Khazaeinia et al., “A Comparison of Gastrointestinal Permeability Induced by Diclofenac-phospholipid complex with Diclofenac Acid and its Sodium Salt,” <i>Journal of Pharmaceutical Sciences</i> 6(3):352-359 (2003) | Khazaeinia |
| 1023 | iCeutica Press Release, “iCeutica Receives Key Patent for SoluMatrix Fine Particle Technology Platform” (September 24, 2014) | iCeutica Press Release |
| 1024 | Memorandum dated April 6, 2005, from John Jenkins, M.D., at FDA re: “Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk” | Jenkins Memo |
| 1025 | U.S. Dep’t of Health & Human Servs., Food and Drug Admin., CDER, Guidance for Indus., <i>Dissolution Testing of Immediate Release Solid Oral Dosage Forms</i> (1997) | FDA Guidance |
| 1026 | Royal Hanson <i>et al.</i> Handbook of Dissolution Testing 1-53 (3 rd ed. 2004) | Handbook |
| 1027 | ’721 Patent Reduced File History | File History |
| 1028 | iCeutica Press Release dated April 28, 2011: iCeutica Announces Sale to Partner Iroko; 10X uplift on original value | |
| 1029 | FDA Orangebook listing for Zorvolex; available at: http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=204592&TABLE1=OB_Rx ; and http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=204592&Product_No=001&table1=OB_Rx (accessed November 2, 2015) | |

| Exhibit No. | Description | Short Citation |
|--------------------|---|-----------------------|
| 1030 | Loewenstein and Roberts "The Ionization of Citric Acid Studied by the Nuclear Magnetic Resonance Technique" J. of Am. Chem. Soc. 82(11) 2705-2710 (1960) | |
| 1031 | Rune and Viskum, "Duodenal pH values in normal controls and in patients with duodenal ulcer," <i>Gut</i> 10:569-571 (1969) | |
| 1032 | Countdown to the 10th Anniversary Scrip Awards, available at: https://ibiawards.com/scrip-awards/wp-content/uploads/sites/41/2014/11/script_shottlist_ad6_141125_16.pdf (accessed November 2, 2015) | |
| 1033 | U.S. Patent No. 3,558,690 | |
| 1034 | United States Pharmacopeia 30, Official Monographs for Diclofenac Potassium and Diclofenac sodium, pp. 1921-1924 (2007) | |
| 1035 | Remington's Pharmaceutical Handbook Excerpt, 18th ed., pp. 715-716 (1990) | |
| 1036 | HPPS Operators Guide, Malvern Instruments, 2.0 (2003) | |
| 1037 | U.S. Provisional Application No. 61/172,291 | |
| 1038 | Australian Provisional Application No. 2009901748 | |

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