

Filed on behalf of Lupin Limited

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LIMITED
Petitioner

v.

JANSSEN SCIENCES IRELAND UC
Patent Owner, based on Public Filings
JANSSEN R&D IRELAND
Patent Owner, based on Electronic Records of PTO
U.S. Patent No. 8,518,987 B2 to Vermeersch et al.
Issue Date: August 27, 2013
Title: Pseudopolymorphic Forms of a HIV Inhibitor

Inter Partes Review Trial No. TBD

Petition for *Inter Partes* Review of U.S. Patent No. 8,518,987 B2

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**EXHIBIT LIST PURSUANT TO 37 C.F.R. § 42.63(e) AND
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Lupin Exhibit No.	Description of Exhibit
1001	U.S. Patent No. 8,518,987 B2 (“the ‘987 patent”)
1002	Arun K. Ghosh et al., <i>Potent HIV Protease Inhibitors Incorporating High-Affinity P₂-Ligands and (R)-(Hydroxyethylamino)sulfonamide Isostere</i> , 8 BIOORGANIC & MEDICINAL CHEMISTRY LETTERS 687 (1998) (“Ghosh 1998”)
1003	U.S. Patent No. 6,248,775 B1 (“the ‘775 patent”)
1004	Stephen Byrn et al., <i>Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations</i> , 12 PHARMACEUTICAL RES. 945 (1995) (“Byrn 1995”)
1005	Gautam R. Desiraju, <i>Hydration in Organic Crystals: Prediction from Molecular Structure</i> , 6 J. CHEMICAL SOC’Y CHEMICAL COMM. 426 (1991) (“Desiraju 1991”)
1006	Elke Van Gyseghem et al., <i>Solid State Characterization of the Anti-HIV Drug TMC114: Interconversion of Amorphous TMC114 Ethanolate and Hydrate</i> , 38 EUR. J. PHARMACEUTICAL SCI. 489 (2009) (“Van Gyseghem”)
1007	U.S. Application Serial No. 12/536,807 (“the ‘807 application”) Prosecution History (“PH”), 8/6/2009 Transmittal of New Application
1008	‘807 application PH, 7/2/2010 Preliminary Amendment
1009	‘807 application PH, 9/12/2011 Office Action
1010	‘807 application PH, 3/12/2012 Reply
1011	‘807 application PH, 5/22/2012 Final Office Action
1012	‘807 application PH, 7/20/2012 Reply
1013	‘807 application PH, 9/17/2012 Pre-Appeal Brief Request for Review
1014	‘807 application PH, 10/25/2012 Notice of Panel Decision from Pre-Appeal Brief Review
1015	‘807 application PH, 1/25/2013 Appeal Brief
1016	European Patent Application No. EP 02076929.5 (“EP ‘929”)
1017	International Publication No. WO 95/06030 A1 (“WO ‘030”)
1018	European Patent No. 1 567 529 B1 (“EP ‘529”)
1019	EP ‘529 PH, 12/3/2004 Entry into European Phase Request
1020	EP ‘529 PH, 1/29/2013 Communication to EPO

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1021	EP '529 PH, 1/29/2013 Experimental Report
1022	U.S. Patent No. 7,700,645 B2 (“the related ‘645 patent”)
1023	3/12/2014 Summ. J. Op. (public version), <i>Janssen Prods., L.P. et al. v. Lupin Ltd. et al.</i> , No. 10-cv-5954 (D.N.J. Sept. 23, 2014), ECF No. 997 (“Summ. J. Op.”)
1024	Excerpts of Trial Transcripts from March 18, 2014 – April 2, 2014 trial proceedings in <i>Janssen Products, L.P. et al. v. Lupin Ltd. et al.</i> , Consolidated Case No. 10-5954 (D.N.J.) (“Trial Tr.”)
1025	Declaration of Terence L. Threlfall, Ph.D. in Support of Lupin Limited’s Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,518,987 B2 (“Threlfall Decl.”)
1026	Curriculum Vitae of Terence L. Threlfall, Ph.D.
1027	List of Documents Reviewed and Relied Upon by Terence L. Threlfall, Ph.D.
1028	<i>Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances</i> , FOOD & DRUG ADMINISTRATION (1987) (“FDA Guidelines”)
1029	<i>Preface, in</i> POLYMORPHISM IN PHARMACEUTICAL SOLIDS iii (Harry G. Brittain ed., 1999) (“Brittain”)
1030	David J.W. Grant, <i>Theory and Origin of Polymorphism, in</i> POLYMORPHISM IN PHARMACEUTICAL SOLIDS 8 (Harry G. Brittain ed., 1999) (“Grant”)
1031	John Haleblian & Walter McCrone, <i>Pharmaceutical Applications of Polymorphism</i> , 58 J. PHARMACEUTICAL SCI. 911 (1969) (“McCrone”)
1032	J. Keith Guillory, <i>Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids, in</i> POLYMORPHISM IN PHARMACEUTICAL SOLIDS 183 (Harry G. Brittain ed., 1999) (“Guillory”)
1033	Örn Almarsson & Michael J. Zaworotko, <i>Crystal Engineering of the Composition of Pharmaceutical Phases. Do Pharmaceutical Co-crystals Represent a New Path to Improved Medicines?</i> , CHEMICAL COMM. 1889 (2004) (“Almarsson”)
1034	Stephen R. Byrn et al., <i>Hydrates and Solvates, in</i> SOLID-STATE CHEMISTRY OF DRUGS 233 (2d ed. 1999) (“Byrn 1999”)
1035	Steven S. Zumdahl, CHEMISTRY 31-59, 295-347, 383-433, 559-613 (1986) (“Zumdahl”)
1036	R. Docherty, <i>The Application of Computational Chemistry to the Study of Molecular Materials, in</i> CRYSTAL GROWTH OF ORGANIC MATERIALS 2 (Allan S. Myerson et al. eds., 1996) (“Docherty”)
1037	Terence L. Threlfall, <i>Analysis of Organic Polymorphs: A Review</i> , 120

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