

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., and
SUN PHARMACEUTICALS INDUSTRIES LTD.,
Petitioners,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

IPR2020-00040¹
Patent 7,326,708

PATENT OWNER'S EIGHTH AMENDED EXHIBIT LIST

¹ Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. were joined as parties to this proceeding via a Motion for Joinder in IPR2020-01060; and Sun Pharmaceuticals Industries Ltd. was joined as a party to this proceeding via Motion for Joinder in IPR2020-01072.

Exhibit	Description
EX2001	Declaration of Bruce R. Genderson in Support of <i>Pro Hac Vice</i> Admission
EX2002	Declaration of Vicky K. Vydra
EX2003	Declaration of Robert M. Wenslow, Ph.D.
EX2004	Declaration of Russell R. Ferlita
EX2005	Declaration of Joanne Diddle
EX2006	Scheduling Order, <i>In re Sitagliptin Phosphate ('708 & '921) Patent Litigation</i> , No. 1:19-md-02902-RGA (D. Del. Aug. 23, 2019)
EX2007	Order, <i>Merck Sharp & Dohme Corp. v. Mylan Pharmaceuticals, Inc.</i> , No. 1:19-cv-00101-IMK (N.D. W. Va. Aug. 2, 2019)
EX2008	Defendants' Initial Invalidity Contentions, <i>In re Sitagliptin Phosphate ('708 & '921) Patent Litigation</i> , No. 1:19-md-02902-RGA (D. Del. Oct. 25, 2019) (Excerpt)
EX2009	Certified Assignment Record – US 7,326,708
EX2010	Certified Assignment Record – WO 03/004498
EX2011	U.S. Patent No. 9,718,880 (cited in <i>Amgen Inc. v. Alexion Pharms. Inc.</i> , IPR2019-00740, Paper 15 (P.T.A.B. Aug. 20, 2019))
EX2012	U.S. Patent No. 7,919,499 (cited in <i>Anneal Pharmaceuticals LLC v. Alkermes Pharma Ireland Limited</i> , IPR2018-00943, Paper 8 (P.T.A.B. Nov. 7, 2018))
EX2013	U.S. Patent No. 9,182,027 (cited in <i>Fox Factory, Inc. v. SRAM, LLC</i> , IPR2016-01876, Paper 8 (P.T.A.B. Apr. 3, 2017))
EX2014	Declaration of Anthony H. Sheh
EX2015	U.S. District Court for the District of Delaware, Civil Docket for Case # 1:19-md-2902-RGA (as of April 13, 2020)
EX2016	Stipulation and [Proposed] Order to Amend Scheduling Order, <i>In re Sitagliptin Phosphate ('708 & '921) Patent Litigation</i> , No. 19-2902-RGA (D. Del. Mar. 16, 2020), ECF No. 83
EX2017	U.S. District Court for the Northern District of West Virginia, Civil Docket for Case # 1:19-cv-00101-IMK (as of April 13, 2020)
EX2018	Defendant's Answer to Plaintiff's Complaint and Counterclaims, <i>Merck Sharp & Dohme Corp. v. Mylan Pharmaceuticals Inc.</i> , No. 19-cv-101-IMK (N.D. W. Va. May 31, 2019), ECF No. 32
EX2019	Joint Quarterly Status Report, <i>Merck Sharp & Dohme Corp. v. Mylan Pharmaceuticals Inc.</i> , No. 19-cv-101-IMK (N.D. W. Va. Jan. 3, 2020), ECF No. 50

Exhibit	Description
EX2020	REDACTED VERSION, Brief in Support of Mylan Pharmaceuticals Inc. and Mylan Inc.'s Motion to Dismiss for Improper Venue and Failure to State a Claim, <i>Merck Sharp & Dohme Corp. v. Mylan Pharmaceuticals, Inc.</i> , No. 19-cv-315-RGA (D. Del. Mar. 28, 2019), ECF No. 15
EX2021	U.S. Judicial Panel on Multidistrict Litigation, Civil Docket for Case # MDL No. 2902
EX2022	Memorandum in Support of Motion to Transfer, <i>In re Sitagliptin Phosphate ('708 & '921) Patent Litigation</i> , MDL No. 2902 (J.P.M.L. May 15, 2019), ECF No. 1-1
EX2023	<i>In re Sitagliptin Phosphate ('708 & '921) Patent Litigation</i> , 402 F. Supp. 3d 1366 (J.P.M.L. 2019)
EX2024	Oral Order, <i>Plastic Omnium Advanced Innovation and Research v. Donghee America Inc.</i> , No. 16-187-LPS (D. Del. Oct. 27, 2017), ECF No. 196
EX2025	Declaration of Alexander S. Zolan in Support of <i>Pro Hac Vice</i> Admission
EX2026	Declaration of Elise M. Baumgarten in Support of <i>Pro Hac Vice</i> Admission
<i>EX2027 TO EX2031 Reserved</i>	
EX2032	U.S. Patent No. 8,309,724
EX2033	WO 2013/001457
<i>EX2033 to EX2040 Reserved</i>	
EX2041	Transcript of July 15, 2020 Telephonic Hearing
EX2042	A.T.M. Serajuddin & Pudipeddi, <i>Salt-Selection Strategies</i> , in HANDBOOK OF PHARMACEUTICAL SALTS (P.H. Stahl & C.G. Wermuth, eds., 2002)
EX2043	U.S. Patent No. 8,329,696
EX2044	WO 2012/166420
EX2045	Pandey et al., <i>Importance of Polymorphs and Salts in the Pharmaceutical Industry</i> , in DRUG DISCOVERY AND DEVELOPMENT, VOLUME 2: DRUG DEVELOPMENT (Mukund S. Chorghade ed., 2007)
EX2046	Vippagunta et al., <i>Crystalline Solids</i> , 48 ADVANCED DRUG DELIVERY REVIEWS 3 (2001)
EX2047	Reutzel-Edens et al., <i>Anhydrates and Hydrates of Olanzapine: Crystallization, Solid-State Characterization, and Structural Relationships</i> , 3 CRYSTAL GROWTH & DESIGN 897 (2003)

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EX2048	U.S. Patent No. 7,056,942
EX2049	Bernstein, <i>Crystal Growth, Polymorphism and Structure-Property Relationships in Organic Crystals</i> , 26 J. PHYS. D. APPL. PHYS. B66 (1993)
EX2050	Bernstein, POLYMORPHISM IN MOLECULAR CRYSTALS (2002) (Chapter 3)
EX2051	Transcript of Aug. 6, 2020 Deposition of Mukund Chorghade, Ph.D.
EX2101	Declaration of Allan S. Myerson, Ph.D.
EX2102	Curriculum Vitae of Allan S. Myerson, Ph.D.
EX2103	Declaration of Adam J. Matzger, Ph.D.
EX2104	Curriculum Vitae of Adam J. Matzger, Ph.D.
EX2105	Declaration of Lou Ann Eader
EX2106	Synopsis and Comprehensive Study Summary from the Clinical Study Report for Protocol 005, dated November 15, 2005 (excerpt)
EX2107	Synopsis and Comprehensive Study Summary from the Clinical Study Report for Protocol 006, dated April 1, 2005 (excerpt)
EX2108	Module 3.2.P.5.4 Batch Analyses from Januvia® NDA, dated November 14, 2005 (excerpt)
EX2109	Declaration of Gary Herman, M.D.
EX2110	Email Summary of December 9, 2002, Meeting Re: Clinical Development of MK-0431
EX2111	January 3, 2003 Email Re: DRAFT Preliminary Interim Analysis Memo/RMC Background Slides - L-224715
EX2112	Demuth et al., <i>Single Dose Treatment of Diabetic Patients by the DP IV Inhibitor P32/98</i> , 49 DIABETES A102 (2000)
EX2113	Pospisilik et al., <i>Long-Term Treatment with the Dipeptidyl Peptidase IV Inhibitor P32/98 Causes Sustained Improvements in Glucose Tolerance, Insulin Sensitivity, Hyperinsulinemia, and β-Cell Glucose Responsiveness in VDF (fa/fa) Zucker Rats</i> , 51 DIABETES 943 (2002)
EX2114	Thornberry & Weber, <i>Discovery of JANUVIA (Sitagliptin), a Selective Dipeptidyl Peptidase IV Inhibitor for the Treatment of Type 2 Diabetes</i> , 7 CURRENT TOPICS IN MEDICINAL CHEMISTRY 557 (2007)
EX2115	Rothenberg et al., <i>Treatment with a DPP-IV Inhibitor, NVP-DPP728, Increases Prandial Intact GLP-1 Levels and Reduces Glucose Exposure in Humans</i> , 49 DIABETES 160-OR (2000)

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EX2116	Second Declaration of Robert M. Wenslow, Ph.D.
EX2117	WO 2005/020920
EX2118	WO 2005/072530
EX2119	Compilation of L-224715 Phosphate Salt Anhydrous Polymorph Data
EX2120	Physical Characterization of L-224715-66839-113 (115) and -125 (from ISAA)
EX2121	L-000224715 Monohydrate Evaluation
EX2122	Parallel Development of Multiple Crystal Forms for a New Drug Candidate: Selection of the Final Form via Integrated Chemical and Pharmaceutical Process Evaluation
EX2123	L-000224715 (MK-0431) Preliminary Market Formulation Development Report
EX2124	Declaration of Stephen Howard Cypes
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EX2127	Declaration of Karl B. Hansen, Ph.D.
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EX2131	K. Hansen Weekly Reports
EX2132	Email from M. Palucki to K. Hansen re Acid Salt Screen of L-224715 Free Base (and Attachment)
EX2133	Email from L. Shultz to K. Hansen re L-224715 salt selection
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