

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS
LLC, ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA,
INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN
PHARMACEUTICAL INDUSTRIES, INC., AND SUN PHARMA GLOBAL
FZE,
Petitioners,

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-00854¹
Patent No. 9,187,405

PETITIONERS' UPDATED EXHIBIT LIST

¹ Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined
with this proceeding.

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,187,405, “S1P Receptor Modulators for Treating Relapsing-Remitting Multiple Sclerosis” (filed April 21, 2014) (issued November 17, 2015)
1002	Declaration of Dr. Barbara S. Giesser
1003	<i>Curriculum Vitae</i> of Dr. Barbara S. Giesser
1004	John Kovarik and Silke Appel-Dingemane: International Publication No. WO 2006/058316 (published June 1, 2006)
1005	Thomson, <i>FTY720 in Multiple Sclerosis: The Emerging Evidence of its Therapeutic Value</i> , CORE EVIDENCE, 1(3):157-167 (2006)
1006	U. S. Patent No. 6,004,565 (Chiba) “Compositions and Methods of Using Compositions with Accelerated Lymphocyte Homing Immunosuppressive Properties” (filed September 23, 1997) (issued December 21, 1999)
1007	Kappos, L., <i>et al.</i> , <i>FTY720 in Relapsing MS: Results of a Double-Blind Placebo-Controlled Trial with a Novel Oral Immunomodulator</i> , JOURNAL OF NEUROLOGY 252(Suppl 2):11/41, Abstract O141 (2005)
1008	Budde, <i>et al.</i> , <i>First Human Trial of FTY720, a Novel Immunomodulatory, in Stable Renal Transplant Patients</i> , JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY, 13:1073-1083 (2002)
1009	File History U.S. Patent Application No. 12/303,765
1010	File History U.S. Patent Application No. 13/149,468
1011	File History U.S. Patent Application No. 14/257,342
1012	GB 0612721.1
1013	U.S. Pat. No. 8,741,963 “S1P Receptor Modulators for Treating Multiple Sclerosis” (filed May 31, 2011) (issued June 3, 2014)

1014	File History of U.S. Patent Application No. 11/720,205
1015	Provisional Patent Application No. 60/631,483 (filed November 29, 2004)
1016	Virley, <i>Developing Therapeutics for the Treatment of Multiple Sclerosis</i> , NEURORX, 2:638-649 (2005)
1017	Adachi, <i>et al.</i> , <i>Design, Synthesis, and Structure-Activity Relationships of 2-Substituted-2-amino-1,3-propanediols: Discovery of a Novel Immunosuppressant, FTY720</i> , BIOORGANIC AND MEDICINAL CHEMISTRY LETTERS, 5(8):853-856 (1995)
1018	Dumont, <i>Fingolimod Mitsubishi Pharma/Novartis</i> , IDRUGS, 8(3):236-253 (2005)
1019	Park, <i>et al.</i> , <i>Pharmacokinetic/Pharmacodynamic Relationships of FTY720 in Kidney Transplant Patients</i> , BRAZILIAN JOURNAL OF MEDICAL AND BIOLOGICAL RESEARCH, 38: 683-694 (2005)
1020	Yanagawa, <i>et al.</i> , <i>FTY720, a Novel Immunosuppressant, Induces Sequestration of Circulating Mature Lymphocytes by Acceleration of Lymphocyte Homing in Rats, III. Increase in Frequency of CD62L-Positive T Cells in Peyer's Patches by FTY720-Induced Lymphocyte Homing</i> , IMMUNOLOGY, 95: 591-594 (1998)
1021	"Clinical Pharmacology in the Critically Ill Child," in CRITICAL CARE PEDIATRICS, Zimmerman and Gildea eds. (Saunders Company 1985)
1022	Chiba, <i>FTY720, a New Class of Immunomodulatory, Inhibits Lymphocyte Egress from Secondary Lymphoid Tissues and Thymus by Agonistic Activity at Sphingosine 1-Phosphate Receptors</i> , PHARMACOLOGY & THERAPEUTICS, 108:308-319 (2005)
1023	MCALPINE'S MULTIPLE SCLEROSIS, 4 th Edition, Compston, ed (Elsevier, Inc., December 2005)
1024	Frohman, <i>et al.</i> , <i>Multiple Sclerosis – The Plaque and its Pathogenesis</i> , NEW ENGLAND JOURNAL OF MEDICINE, 354: 942-955 (2006)

1025	Inglese, <i>Multiple Sclerosis: New Insights and Trends</i> , AMERICAN JOURNAL OF NEURORADIOLOGY, 27: 954-957 (2006)
1026	Dragun, D., <i>et al.</i> , <i>FTY720: Early Clinical Experience</i> , TRANSPLANT. PROC., 36 (Suppl 2S), 554S-548S (2004)
1027	Kahan, B.D., <i>FTY720: A New Dimension in Transplantation</i> , TRANSPLANT. PROC., 33, 3081-3083 (2001)
1028	Fujino, <i>et al.</i> , <i>Amelioration of Experimental Autoimmune Encephalomyelitis in Lewis Rats by FTY720 Treatment</i> , JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, 305(1):70-77 (2003)
1029	Kataoka, <i>et al.</i> , <i>FTY720, Sphingosine 1-Phosphate Receptor Modulator, Ameliorates Experimental Autoimmune Encephalomyelitis by Inhibition of T Cell Infiltration</i> , CELLULAR AND MOLECULAR IMMUNOLOGY, 2(6):439-448 (2005)
1030	Kahan, B.D., <i>Sirolimus and FTY720: New Approaches to Transplant Immunosuppression</i> , TRANSPLANT. PROC., 34, 2520-2522 (2002)
1031	Kahan, <i>et al.</i> , <i>Pharmacodynamics, Pharmacokinetics, and Safety of Multiple Doses of FTY720 in Stable Renal Transplant Patients: A Multicenter, Randomized, Placebo-Controlled, Phase I Study</i> , TRANSPLANTATION, 76(7): 1079-1084 (2003)
1032	Final Written Decision, Paper 112, IPR2014-00784
1033	PHYSICIAN'S DESK REFERENCE, 59 th Edition (Thomson PDR, January 1, 2005)
1034	"Introduction to Pharmacokinetics" in BIOPHARMACEUTICS AND CLINICAL PHARMACOKINETICS, Gibaldi (Lea & Febiger, 1991)
1035	Orange Book entry for Fingolimod (http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=022527&Appl_type=N) (last accessed February 2, 2017)

1036	FDA approval letter for Tysabri, obtained from the Food and Drug Administration website http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=125104 (last accessed January 30, 2017)
1037	U. S. Pat. No. 8,324,283 (Oomura) <i>Solid Pharmaceutical Compositions Comprising a SIP Receptor Agonist and a Sugar Alcohol</i> (filed August 11, 2008) (issued December 4, 2012)
1038	Kappos, L., <i>et al.</i> , <i>A Placebo-Controlled Trial of Oral Fingolimod in Relapsing Multiple Sclerosis</i> , NEW ENGLAND JOURNAL OF MEDICINE, 362(5):387-401 (2010)
1039	LaMontagne, <i>et al.</i> , “Antagonism of Sphingosine-1-Phosphate Receptors by FTY720 Inhibits Angiogenesis,” <i>Cancer Res.</i> , 66:221-231 (Jan. 2006)
1040	Thomson, <i>FTY720 in Multiple Sclerosis: The Emerging Evidence of its Therapeutic Value</i> , CORE EVIDENCE, 1(3):157-167 (2006)
1041 (served but not filed)	“Clinical Pharmacology in the Critically Ill Child,” in CRITICAL CARE PEDIATRICS, Zimmerman and Gildea eds. (Saunders Company 1985)
1042	PROTECTIVE ORDER MATERIAL: Transcript of December 15, 2017 Deposition of Fred D. Lublin, M.D.
1042	REDACTED: Transcript of December 15, 2017 Deposition of Fred D. Lublin, M.D.
1043	PROTECTIVE ORDER MATERIAL: Transcript of January 10, 2018 Conference Call with the Patent Trial and Appeal Board
1043	REDACTED: Transcript of January 10, 2018 Conference Call with the Patent Trial and Appeal Board
1044	PROTECTIVE ORDER MATERIAL: December 5, 2017 Email regarding document production
1045	PROTECTIVE ORDER MATERIAL: January 4, 2018 Email regarding discovery

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