

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,

Petitioner

v.

ELI LILLY AND COMPANY,

Patent Owner

U.S. Patent 7,772,209

Issue Date: Aug. 10, 2010

Title: Antifolate Combination Therapies

Inter Partes Review No. 2016-00318

**PETITIONER SANDOZ INC.'S
CURRENT EXHIBIT LIST UNDER 37 C.F.R. § 42.63(e)**

EXHIBIT LIST

Exhibit No.	Description	Referred To In The Petition As
Exhibit 1001:	U.S. Patent No. 7,772,209	“209 patent”
Exhibit 1002:	File History of U.S. Patent Application No. 11/776,329, which issued as U.S. Patent No. 7,772,209 on August 10, 2010	“209 file history”
Exhibit 1003:	Findings Of Fact And Conclusions Of Law Following Bench Trial August 19, 2013, in <i>Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.</i> , Case No. 1:10-cv-1376, Dkt. 336 (S.D. Ind. March 31, 2014)	“Teva Decision”
Exhibit 1004:	Declaration of Ron D. Schiff, M.D., Ph.D.	“Schiff Decl.”
Exhibit 1005:	U.S. Patent No. 5,217,974	“974 patent”
Exhibit 1006:	C. Niyikiza, <i>et al.</i> , <i>MTA (LY231514): Relationship of vitamin metabolite profile, drug exposure, and other patient characteristics to toxicity</i> , <i>Annals Oncology</i> 9 (Suppl. 4): 125-140, Abstract 609P, (1998)	“Niyikiza I”
Exhibit 1007:	Hilary Calvert, <i>An Overview of Folate Metabolism: Features Relevant to the Action and Toxicities of Antifolate Anticancer Agents</i> , <i>Seminars Oncology</i> , 26: 3-10 (1999)	“Calvert”
Exhibit 1008:	<i>Textbook of Small Animal Medicine</i> (John K. Dunn ed. 1999)	“Animal Medicine”
Exhibit 1009:	Sidney Farber, <i>et al.</i> , <i>Temporary Remissions in acute leukemia in children produced by folic</i>	“Farber”

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	<i>acid antagonist, 4-aminopteroylglutamic acid (aminopterin), New Eng. J. Med., 238(23): 787-793</i>	
Exhibit 1010:	Sarah L. Morgan, <i>et al.</i> , <i>Supplementation with Folic Acid during Methotrexate Therapy for Rheumatoid Arthritis</i> , <i>Annals Internal Med.</i> , 121: 833-841 (1994)	“Morgan”
Exhibit 1011:	G.B. Grindey, <i>et al.</i> , <i>Reversal of the toxicity but not the antitumor activity of Lometrexol by folic acid</i> , <i>Am. Ass’n Cancer Res.</i> , 32: 324, Abstract 1921 (1991)	“Grindey”
Exhibit 1012:	Laurane G. Mendelsohn, <i>et al.</i> , <i>Preclinical and Clinical Evaluation of the Glycinamide Ribonucleotide Formyltransferase Inhibitors Lometrexol and LY309887</i> , in <i>Anticancer Drug Dev. Guide: Antifolate Drugs Cancer Therapy</i> , (Ann L. Jackman, ed.) Ch. 12: 261-80 (1999)	“Mendelsohn”
Exhibit 1013	John F. Worzalla, <i>et al.</i> , <i>Role of Folic Acid in Modulating the Toxicity and Efficacy of the Multitargeted Antifolate, LY231514</i> , <i>Anticancer Res.</i> , 18: 3235-3240 (1998)	“Worzalla”
Exhibit 1014	L. Hammond, <i>et al.</i> , <i>A Phase I and Pharmacokinetic (PK) Study of the Multitargeted Antifol (MTA) LY231514 with Folic Acid</i> , <i>Proc. Am. Soc’y Clinical Oncology</i> , 17: Abstract 866 (1998)	“Hammond II”
Exhibit 1015	L. Hammond, <i>et al.</i> , <i>A phase I and pharmacokinetic (PK) study of the multitargeted antifolate (MTA, LY231514) with folic acid (FA)</i> , <i>Annals Oncology</i> , 9: 129, Abstract 620P (1998)	“Hammond I”

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Exhibit 1016	C. Niyikiza, <i>et al.</i> , <i>LY231514 (MTA): Relationship of vitamin metabolite profile to toxicity</i> , Proc. Am. Ass'n Cancer Res., 17: 558a, Abstract 2139 (1998)	"Niyikiza II"
Exhibit 1017	R. Thödtmann, <i>et al.</i> , <i>Preliminary Results of a Phase I Study with MTA (LY231415) in Combination with Cisplatin in Patients with Solid Tumors</i> , Seminars Oncology, 26 (2, Suppl. 6): 89-93 (1999)	"Thödtmann I"
Exhibit 1018	U.S. Patent No. 5,563,126	"126 patent"
Exhibit 1019	Ernest Beutler & James K. Weick, <i>Blood and Neoplastic Disorders</i> , in <i>Current Clinical Practice</i> (Messerli, ed., 1987), Ch. 1: 291-302	"Beutler"
Exhibit 1020	Lars Brattström, <i>Vitamins as Homocysteine-Lowering Agents</i> , J. Nutrition, 126: 1276S-1280S (1996)	"Brattström"
Exhibit 1021	Chuan Shih, <i>et al.</i> , <i>LY231514, a Pyrrolo[2,3-d]pyrimidine-based Antifolate That Inhibits Multiple Folate-requiring Enzymes</i> , Cancer Res., 57, 1116- 1123 (1997)	"Shih"
Exhibit 1022	G. Robbin Westerhof, <i>et al.</i> , <i>Carrier- and Receptor-Mediated Transport of Folate Antagonists Targeting Folate-Dependent Enzymes: Correlates of Molecular-Structure and Biological Activity</i> , Am. Soc'y Pharmacology Experimental Therapeutics, 48: 459-471 (1995)	"Westerhof"
Exhibit 1023	F. G. Arsenyan, <i>et al.</i> , <i>Influence of Methylcobalamin on the Antineoplastic Activity of Methotrexate</i> , Pharmaceutical Chemistry J.,	"Arsenyan"

Exhibit No.	Description	Referred To In The Petition As
	12(10): 1299-1303 (1978)	
Exhibit 1024	File History of U.S. Patent Application No. 11/288,807, Abandoned	“807 File History”
Exhibit 1025	U.S. Food & Drug Administration, <i>Approved Drug Products with Therapeutic Equivalents Evaluations</i> (30th ed. 2010)	“Orange Book Listing for Alimta®”
Exhibit 1026	Z.P. Sofyina, <i>et al.</i> , <i>Possibility to Increase the Antitumor Effect of Folic Acid Antagonist with the Help of Methylcobalamine Analogs</i> , <i>Sci. Center Oncology</i> 1:72-78 (1979)	“Sofyina”
Exhibit 1027	Victor Herbert, <i>The Role of Vitamin B₁₂ and Folate in Carcinogenesis</i> , <i>Advances Experimental Med. Biology</i> , 206: 293-311 (1986)	“Herbert”
Exhibit 1028	Glenn Tisman, <i>et al.</i> , <i>Overcoming Colon Cancer Resistance to Hepatic Artery Infusional 5FUdR Chemotherapy with Folinic Acid</i> , <i>Clinical Res.</i> , 33(2): 459A (1985)	“Tisman”
Exhibit 1029	J.D. Kinloch, <i>Maintenance Treatment of Pernicious Anaemia by Massive Parenteral Doses of Vitamin B₁₂ at Intervals of Twelve Weeks</i> , <i>Brit. Med. J.</i> , 1:99-100 (1960)	“Kinloch”
Exhibit 1030	D. Wray, <i>et al.</i> , <i>Recurrent Aphthae: Treatment with Vitamin B₁₂, Folic Acid, and Iron</i> , <i>Brit. Med. J.</i> , 2:490-93 (1975)	“Wray”
Exhibit 1031	J. Tamura, <i>et al.</i> , <i>Immunomodulation by Vitamin B12: Augmentation of CD8⁺ T Lymphocytes and Natural Killer (NK) Cell Activity in Vitamin B12-Deficient Patients by Methyl-B12 Treatment</i> , <i>Clin. Experimental Immunology</i> ,	“Tamura”

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