

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SANDOZ INC.,  
APOTEX INC., APOTEX CORP.,  
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HERITAGE PHARMACEUTICALS INC.,  
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GLENMARK HOLDING SA,  
GLENMARK PHARMACEUTICALS, LTD.,  
MYLAN LABORATORIES LIMITED,  
TEVA PHARMACEUTICALS USA, INC.,  
FRESENIUS KABI USA, LLC, and WOCKHARDT BIO AG,

Petitioners

v.

ELI LILLY AND COMPANY,

Patent Owner.

Case IPR2016-00318<sup>1</sup>

U.S. Patent 7,772,209

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**PETITIONER'S UPDATED EXHIBIT LIST**

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<sup>1</sup> Cases IPR2016-01429, IPR2016-01393, and IPR2016-01340 have been joined with the instant proceeding.

<b>Exhibit No.</b>	<b>Description</b>	<b>Filing Date</b>
<b>Exhibit 1001</b>	U.S. Patent No. 7,772,209	12/14/2015
<b>Exhibit 1002</b>	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	12/14/2015
<b>Exhibit 1003</b>	Findings Of Fact And Conclusions Of Law Following Bench Trial August 19, 2013, in <i>Eli Lilly &amp; Co. v. Teva Parenteral Medicines, Inc.</i> , Case No. 1:10-cv-1376, Dkt. 336 (S.D. Ind. March 31, 2014)	12/14/2015
<b>Exhibit 1004</b>	Declaration of Ron D. Schiff, M.D., Ph.D.	12/14/2015
<b>Exhibit 1005</b>	U.S. Patent No. 5,217,974	12/14/2015
<b>Exhibit 1006</b>	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)	12/14/2015
<b>Exhibit 1007</b>	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)	12/14/2015
<b>Exhibit 1008</b>	<i>Textbook of Small Animal Medicine</i> (John K. Dunn ed. 1999)	12/14/2015

Exhibit No.	Description	Filing Date
<b>Exhibit 1009</b>	Sidney Farber, <i>et al.</i> , <i>Temporary Remissions in acute leukemia in children produced by folic acid antagonist, 4-aminopteroylglutamic acid (aminopterin)</i> , <i>New Eng. J. Med.</i> , 238(23): 787-793 (Ex. 2042 in IPR2016-00237, -240) <sup>2</sup>	12/14/2015
<b>Exhibit 1010</b>	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)	12/14/2015
<b>Exhibit 1011</b>	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)	12/14/2015
<b>Exhibit 1012</b>	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)	12/14/2015
<b>Exhibit 1013</b>	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)	12/14/2015

<sup>2</sup> Pursuant to the parties' December 6, 2016 stipulation that the transcript of Dr. Steven Zeisel's deposition in IPR2016-00237 and -240 may be filed in the above-captioned proceeding, cross-references to the corresponding exhibit numbers in IPR2016-00237, and -240 are provided. (Paper 48, Stipulation Regarding the Deposition of Dr. Steven H. Zeisel, M.D., Ph.D.)

<b>Exhibit No.</b>	<b>Description</b>	<b>Filing Date</b>
<b>Exhibit 1014</b>	L. Hammond, <i>et al.</i> , <i>A Phase I and Pharmacokinetic (PK) Study of the Multitargeted Antifol (MTA) LY231514 with Folic Acid</i> , Proc. Am. Soc’y Clinical Oncology, 17: Abstract 866 (1998)	12/14/2015
<b>Exhibit 1015</b>	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> , Annals Oncology, 9: 129, Abstract 620P (1998)	12/14/2015
<b>Exhibit 1016</b>	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)	12/14/2015
<b>Exhibit 1017</b>	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)	12/14/2015
<b>Exhibit 1018</b>	U.S. Patent No. 5,563,126	12/14/2015
<b>Exhibit 1019</b>	Ernest Beutler & James K. Weick, <i>Blood and Neoplastic Disorders, in Current Clinical Practice</i> (Messerli, ed., 1987), Ch. 1: 291-302	12/14/2015
<b>Exhibit 1020</b>	Lars Brattström, <i>Vitamins as Homocysteine-Lowering Agents</i> , J. Nutrition, 126: 1276S-1280S (1996)	12/14/2015
<b>Exhibit 1021</b>	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)	12/14/2015

<b>Exhibit No.</b>	<b>Description</b>	<b>Filing Date</b>
<b>Exhibit 1022</b>	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)	12/14/2015
<b>Exhibit 1023</b>	F. G. Arsenyan, <i>et al.</i> , <i>Influence of Methylcobalamin on the Antineoplastic Activity of Methotrexate</i> , Pharmaceutical Chemistry J., 12(10): 1299-1303 (1978)	12/14/2015
<b>Exhibit 1024</b>	File History of U.S. Patent Application No. 11/288,807, Abandoned	12/14/2015
<b>Exhibit 1025</b>	U.S. Food & Drug Administration, <i>Approved Drug Products with Therapeutic Equivalents Evaluations</i> (30th ed. 2010)	12/14/2015
<b>Exhibit 1026</b>	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> , Sci. Center Oncology 1:72-78 (1979)	12/14/2015
<b>Exhibit 1027</b>	Victor Herbert, <i>The Role of Vitamin B<sub>12</sub> and Folate in Carcinogenesis</i> , Advances Experimental Med. Biology, 206: 293-311 (1986)	12/14/2015
<b>Exhibit 1028</b>	Glenn Tisman, <i>et al.</i> , <i>Overcoming Colon Cancer Resistance to Hepatic Artery Infusional 5FUdR Chemotherapy with Folinic Acid</i> , Clinical Res., 33(2): 459A (1985)	12/14/2015
<b>Exhibit 1029</b>	J.D. Kinloch, <i>Maintenance Treatment of Pernicious Anaemia by Massive Parenteral Doses of Vitamin B<sub>12</sub> at Intervals of Twelve Weeks</i> , Brit. Med. J., 1:99-100 (1960)	12/14/2015

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