

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ELI LILLY AND COMPANY,
Patent Owner.

Case IPR2016-00318
Patent 7,772,209

PETITIONER'S UPDATED EXHIBIT LIST

| Exhibit No. | Description | Filing Date |
|----------------------|--|-------------|
| Exhibit 1001: | U.S. Patent No. 7,772,209 | 12/14/2015 |
| 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 | 12/14/2015 |
| 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) | 12/14/2015 |
| Exhibit 1004: | Declaration of Ron D. Schiff, M.D., Ph.D. | 12/14/2015 |
| Exhibit 1005: | U.S. Patent No. 5,217,974 | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| Exhibit 1008: | <i>Textbook of Small Animal Medicine</i> (John K. Dunn ed. 1999) | 12/14/2015 |
| Exhibit 1009: | 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 | 12/14/2015 |

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| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| Exhibit 1016 | C. Niyikiza, <i>et al.</i> , <i>LY231514 (MTA): Relationship of vitamin metabolite profile to toxicity</i> , <i>Proc. Am. Ass'n Cancer Res.</i> , 17: 558a, Abstract 2139 (1998) | 12/14/2015 |

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| 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> , <i>Seminars Oncology</i> , 26 (2, Suppl. 6): 89-93 (1999) | 12/14/2015 |
| Exhibit 1018 | U.S. Patent No. 5,563,126 | 12/14/2015 |
| Exhibit 1019 | 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 |
| Exhibit 1020 | Lars Brattström, <i>Vitamins as Homocysteine-Lowering Agents</i> , <i>J. Nutrition</i> , 126: 1276S-1280S (1996) | 12/14/2015 |
| 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> , <i>Cancer Res.</i> , 57, 1116-1123 (1997) | 12/14/2015 |
| 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> , <i>Am. Soc'y Pharmacology Experimental Therapeutics</i> , 48: 459-471 (1995) | 12/14/2015 |
| Exhibit 1023 | F. G. Arsenyan, <i>et al.</i> , <i>Influence of Methylcobalamin on the Antineoplastic Activity of Methotrexate</i> , <i>Pharmaceutical Chemistry J.</i> , 12(10): 1299-1303 (1978) | 12/14/2015 |
| Exhibit 1024 | File History of U.S. Patent Application No. 11/288,807, Abandoned | 12/14/2015 |

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| Exhibit 1025 | U.S. Food & Drug Administration, <i>Approved Drug Products with Therapeutic Equivalents Evaluations</i> (30th ed. 2010) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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) | 12/14/2015 |
| 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> , 116:28-32 (1999) | 12/14/2015 |
| Exhibit 1032 | Carrasco <i>et al.</i> , <i>Acute Megaloblastic Anemia: Homocysteine Levels Are Useful for Diagnosis and Follow-Up</i> , <i>Haematologica</i> , 84: 767- 768 (1999) | 12/14/2015 |

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