Case IPR2016-00318 Patent 7,772,209

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ELI LILLY & COMPANY, Patent Owner.

Case No: IPR2016-00318¹ Patent No. 7,772,209

PATENT OWNER'S UPDATED EXHIBIT LIST

¹ Cases IPR2016-01429, IPR2016-01393, and IPR2016-01340 have been joined

with the instant proceeding.

DOCKET

EXHIBIT	DESCRIPTION
2001	Lilly Eli & Co. Form 10-k Annual Report filed February 19, 2016 for the Period Ending December 31, 2015
2002	Alimta Prescribing Information revised September 2013
2003	<i>Eli Lilly and Co. v. Teva Parenteral Medicines Inc. et al.</i> , Civil Action No. 1:10-cv-01376, Defendants' Opening Post-Trial Brief Regarding the Invalidity of U.S. Patent No. 7,772,209, dated October 11, 2013
2004	<i>Eli Lilly and Co. v. Teva Parenteral Medicines Inc. et al.</i> , Civil Action No. 1:10-cv-01376, Plaintiff's Post-Trial Brief, dated November 22, 2013
2005	Exhibit Number Not Used
2006	<i>Eli Lilly and Co. v. Teva Parenteral Medicines Inc. et al.</i> , Civil Action No. 1:10-cv-01376, Joint Trial Exhibit List, dated August 18, 2013
2007	Exhibit Number Not Used
2008	<i>Eli Lilly and Co. v. Teva Parenteral Medicines et al.</i> , United States Court of Appeals for the Federal Circuit Case 15-2067, Notice of Docketing, dated September 25, 2015
2009	Exhibit Number Not Used
2010	United States Court of Appeals for the Federal Circuit Internal Operating Procedures
2011	Exhibit Number Not Used
2012	Exhibit Number Not Used
2013	<i>Eli Lilly and Co. v. Teva Parenteral Medicines Inc. et al.</i> , Civil Action No. 1:10-cv-01376, Defendants' Reply Post-Trial Brief Regarding the Invalidity of U.S. Patent No. 7,772,209, dated December 17, 2013
2014	<i>Eli Lilly and Co. v. Teva Parenteral Medicines Inc. et al.</i> , Civil Action No. 1:10-cv-01376, Entry on Claim Construction, dated June 20, 2012
2015	<i>Eli Lilly and Co. v. Teva Parenteral Medicines et al.</i> , United States Court of Appeals for the Federal Circuit Case 15-2067 Docket, dated March 16, 2016

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

n

EXHIBIT	DESCRIPTION
2016	The New Shorter Oxford English Dictionary on Historical Principles [excerpt] Vol. 2, pg. 2123 (1993)
2017	Random House Unabridged Dictionary [excerpt], 2nd Ed., pg. 1421 (1993)
2018	Affidavit of Adam L. Perlman In Support of Motion for <i>Pro Hac Vice</i> Admission Pursuant to 37 C.F.R. § 42.10(c)
2019	Transcript of July 22, 2016 Teleconference with the Board
2020	PDR 53rd (1999)
2021	ABPI COMPENDIUM OF DATA SHEET AND SUMMARIES OF PRODUCT CHARACTERISTICS 1998-99:1542-45 (1998) ("ABPI Compendium of Data Sheets")
2022	Rinaldi, et al., A phase I evaluation of LY231514, a novel multitargeted antifolate, administered every 21 days, AMERICAN SOCIETY OF CLINICAL ONCOLOGY, 15: 489, Abstract 1559 (1996) ("Rinaldi I")
2023	Declaration of W. Archie Bleyer, M.D., FRCP [GLASG] (IPR2016-00237 Proceeding) [Not Filed]
2024	Declaration of W. Archie Bleyer, M.D., FRCP [GLASG] (IPR2016-00240 Proceeding) [Not Filed]
2025	PDR 52nd (1998)
2026	Schiff Deposition Transcript

2

EXHIBIT	DESCRIPTION
2027	Bleyer Deposition Transcript Part I (August 30, 2016) [Not Filed]
2028	Bleyer Deposition Transcript Part II (August 31, 2016) [Not Filed]
2029	O'Dwyer, <i>et al., Overview of Phase II Trials of MTA in Solid Tumors</i> , SEMINARS IN ONCOLOGY, 26(2 :6): 99-104 (1999) (Stamped Univ. Wisconsin Health Sciences Library) ("O'Dwyer")
2030	Rinaldi, Overview of Phase I Trials of Multitargeted Antifolate (MTA, LY 231514), SEMINARS IN ONCOLOGY, 26 (2:6): 82-88 (1999) (Stamped Univ. Wisconsin Health Sciences Library) ("Rinaldi II")
2031	Laohavinij, et al., A Phase I clinical study of the antipurine antifolate lometrexol (DDATHF) given with oral folic acid, INVESTIGATIONAL NEW DRUGS, 14: 325-335 (1996) ("Laohavinij")
2032	VIDAL LE DICTIONNAIRE, 21, 30 & 1985-1986 (1998) [w/ Translation] ("Vidal 1998")
2033	Quinn et al., Evaluation of Homocysteine and Excitatory Amino Acid Neurotransmitters in the CSF of Children Who Received Methotrexate for the Treatment of Cancer, JOURNAL OF CLINICAL ONCOLOGY, 15: 2800-2806 (1997) ("Quinn")
2034	Exhibit Number Not Used
2035	Exhibit Number Not Used

EXHIBIT	DESCRIPTION
2036	Exhibit Number Not Used
2037	Dierkes, et al., Supplementation With Vitamin B12 Decreases Homocysteine and Methylmalontc, / Acid But Also Serum Folate in Patients With End-Stage Renal Disease, METABOLISM, 48(5): 631-635 (1999) (Stamped Univ. of Wisconsin Health Sciences Library) ("Dierkes")
2038	Gulati, <i>et al., Posttranscriptional Regulation of Mammalian Methionine Synthase by B 12,</i> BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, 259: 436-442 (1999) ("Gulati")
2039	Savage, et al., Sensitivity of Serum Methylmalonic Acid and Total Homocysteine Determinations for Diagnosing Cobalamin and Folate Deficiencies, AMERICAN JOURNAL OF MEDICINE, 96: 239-246 (1994) ("Savage")
2040	Smith, et al., Enhanced Antitumor Activity for the Thymidylate Synthase Inhibitor 1843U89 through Decreased Host Toxicity with Oral Folic Acid, CANCER RESEARCH, 55:6117-6125 (1995) ("Smith & Amyx")
2041	Z.P. Sofyina, et al., Possibility to Increase the Antitumor Effect of Folic Acid Antagonist with the Help of Methylcobalamine Analogs, SCIENTIFIC CENTER ONCOLOGY, 1:72-78 (1979) ("Sofyina") (Lilly Translation)
2042	Exhibit Number Not Used
2043	Exhibit Number Not Used

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.