

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
APOTEX INC., APOTEX CORP.,
TEVA PHARMACEUTICALS USA, INC.,
and FRESENIUS KABI USA, LLC,

PETITIONERS,

V.

ELI LILLY & COMPANY,

PATENT OWNER.

Case IPR2016-00240¹
Patent 7,772,209

**PETITIONER'S CURRENT EXHIBIT LIST AS OF DECEMBER 22, 2016
PURSUANT TO 37 C.F.R. § 42.63(e)**

¹ Cases IPR2016-01191 and IPR2016-01343 have been joined with the instant proceeding.

PETITIONER'S CURRENT EXHIBIT LIST

(Updated December 22, 2016)

Exhibit No.	Description
Exhibit 1001	U.S. Patent No. 7,772,209 to Clet Niyikiza, filed on July 11, 2007, and issued on Aug. 10, 2010 (“the ’209 patent”)
Exhibit 1002	U.S. Patent No. 7,772,209 Prosecution History (“’209 prosecution history”)
Exhibit 1003	U.S. Patent No. 5,344,932 to Edward C Taylor, issued on Sep. 6, 1994 (“ <i>Taylor</i> ”)
Exhibit 1004	Claim Chart for Niyikiza ’209 Petition (Attachment 2 to Bleyer Declaration)
Exhibit 1005	Worzalla et al., “Role of Folic Acid in Modulating the Toxicity and Efficacy of the Multitargeted Antifolate, LY231514.” <i>Anticancer Research</i> 18:3235-3240 (1998) (“ <i>Worzalla</i> ”)
Exhibit 1006	U.S. Patent No. 4,140,707 to Cleare et al., issued on Feb. 20, 1979 (“ <i>Cleare</i> ”)
Exhibit 1007	Tsao CS, “Influence of Cobalamin on the Survival of Mice Bearing Ascites Tumor.” <i>Pathobiology</i> 1993;61:104-108 (“ <i>Tsao</i> ”)
Exhibit 1008	Niyikiza et al., “MTA (LY231514): Relationship of vitamin metabolite profile, drug exposure, and other patient characteristics to toxicity.” <i>Annals of Oncology</i> , Vol. 9, Suppl. 4, 1998, Abstract 609P, pg. 126 (“ <i>Niyikiza</i> ”)
Exhibit 1009	Curriculum Vitae of W. Archie Bleyer, M.D., FRCP[Glasg] (Attachment 1 to Bleyer Declaration)
Exhibit 1010	European Patent Application No. 0,595,005 A1 (“ <i>EP 005</i> ”)
Exhibit 1011	Rusthoven et al., “Multitargeted Antifolate LY231514 as First-Line Chemotherapy for Patients with Advanced Non-Small-Cell Lung Cancer: A Phase II Study.” <i>Journal of Clinical Oncology</i> , Vol. 17, No. 4, (April 1999), pp. 1194-1199 (“ <i>Rusthoven</i> ”)
Exhibit 1012	Refsum H & Ueland PM, “Clinical significance of pharmacological modulation of homocysteine metabolism.” <i>Trends in Pharmacol. Sci.</i> , Vol. 11, No. 10, 1990, pp. 411-416 (“ <i>Refsum</i> ”)

Exhibit No.	Description
Exhibit 1013	Calvert AH & Walling JM, "Clinical studies with MTA." British Journal of Cancer (1998) 78 (Suppl. 3), 35-40 (" <i>Calvert 1998</i> ")
Exhibit 1014	Calvert H, "An Overview of Folate Metabolism: Features Relevant to the Action and Toxicities of Antifolate Anticancer Agents," Seminars in Oncology, Vol. 26, No. 2, Suppl 6 (April), 1999, pp.3-10 (" <i>Calvert 1999</i> ")
Exhibit 1015	O'Dwyer et al., "Overview of Phase II Trials of MTA in Solid Tumors." Seminars in Oncology, Vol. 26, No. 2, Suppl 6 (April), 1999, pp. 99-104 (" <i>O'Dwyer</i> ")
Exhibit 1016	Zervos et al., "Functional folate status as a prognostic indicator of toxicity in clinical trials of the multitargeted antifolate LY231514." Proceedings of ASCO, Vol. 16, 1997, pg. 256a (" <i>Zervos</i> ")
Exhibit 1017	Allen et al., "Diagnosis of Cobalamin Deficiency I: Usefulness of Serum Methylmalonic Acid and Total Homocysteine Concentrations." American Journal of Hematology, 34, 1990, 90-98 (" <i>Allen</i> ")
Exhibit 1018	Savage et al., "Sensitivity of Serum Methylmalonic Acid and Total Homocysteine Determinations for Diagnosing Cobalamin and Folate Deficiencies. The American Journal of Medicine, 96: 1994, 239-246 (" <i>Savage</i> ")
Exhibit 1019	Brönstrup et al., "Effects of folic acid and combinations of folic acid and vitamin B-12 on plasma homocysteine concentrations in healthy, young women." Am. J. Clin. Nutr. Vol. 68, 1998, 1104-10 (" <i>Bronstrup</i> ")
Exhibit 1020	Carrasco et al., "Acute megaloblastic anemia: homocysteine levels are useful for diagnosis and follow-up." Haematologica, Vol. 84(8), August 1999, 767-768 (" <i>Carrasco</i> ")
Exhibit 1021	Thödttmann et al., "Phase I study of different sequences of MTA (LY231514) in combination with cisplatin in patients with solid tumours." Annals of Oncology, Vol. 9, Suppl. 4, 1998, Abstract 618P, pg. 129 (" <i>Thodtman</i> ")

Exhibit No.	Description
Exhibit 1022	Hammond et al., “A Phase I and pharmacokinetic (PK) study of the multitargeted antifolate (MTA, LY231514) with folic acid (FA).” <i>Annals of Oncology</i> , Vol. 9, Suppl. 4, 1998, Abstract 620P, pg. 129 (“ <i>Hammond</i> ”)
Exhibit 1023	Morgan et al., “The Effect of Folic Acid Supplementation on the Toxicity of Low-Dose Methotrexate in Patients with Rheumatoid Arthritis.” <i>Arthritis and Rheumatism</i> , Vol. 33, No. 1, January 1990, pp. 9-18 (“ <i>Morgan</i> ”) (Ex. 1023)
Exhibit 1024	Declaration of W. Archie Bleyer, M.D., FRCP[Glasg]
Exhibit 1025	<i>Eli Lilly and Company v. Teva Parental Medicines, Inc., et al.</i> , INSD-1:10-cv-01376 Markman Order (June 20, 2012) (“ <i>Teva</i> ”)
Exhibit 1026	<i>Eli Lilly and Company v. Teva Parental Medicines, Inc., et al.</i> , INSD-1:10-cv-01376 Joint Claim Construction Brief (April 19, 2012) (“ <i>Teva Claim Construction</i> ”)
Exhibit 1027	<i>Eli Lilly and Company v. Teva Parental Medicines, Inc., et al.</i> , INSD-1:10-cv-01376 Decision (March 31, 2014) (“ <i>Teva Decision</i> ”)
Exhibit 1028	Curriculum Vitae of Scott Bennett, Ph.D.
Exhibit 1029	Declaration of Scott Bennett, Ph.D.
Exhibit 1030	Online copy of Rusthoven from the Web site of the Journal of Clinical Oncology
Exhibit 1031	University of Illinois at Urbana-Champaign Library directory entry for the Journal of Clinical Oncology
Exhibit 1032	Statewide Illinois Library Catalog record for the Journal of Clinical Oncology
Exhibit 1033	Copy of Rusthoven from the University of Illinois at Chicago Library
Exhibit 1034	Web of Science entry for Rusthoven
Exhibit 1035	Online copy of <i>Carrasco</i> from the Highwire Press
Exhibit 1036	University of Illinois at Urbana-Champaign Library directory entry for <i>Haematologica</i>
Exhibit 1037	Statewide Illinois Library Catalog record for <i>Haematologica</i>

Exhibit No.	Description
Exhibit 1038	Copy of <i>Carrasco</i> from the University of Michigan Taubman Medical Library
Exhibit 1039	Web of Science entry for <i>Carrasco</i>
Exhibit 1040	Declaration of Mieke K. Malmberg
Exhibit 1041	Declaration of Paul J. Skiermont
Exhibit 1042	Transcript of October 31, 2016 Telephone Hearing
Exhibit 1043	Tashjian, AH J, and BA Chabner. "Commentary on Clinical Safety of Recombinant Human Parathyroid Hormone 1-34 in the Treatment of Osteoporosis in Men and Postmenopausal Women." <i>Journal of Bone and Mineral Research : the Official Journal of the American Society for Bone and Mineral Research</i> . 17.7 (2002): 1151-61. Print. (Previously introduced as Ex. 1043 in Dr. Chabner's deposition.)
Exhibit 1044	Tefferi, A, H Kantarjian, S V. Rajkumar, L H. Baker, J L. Abkowitz, J W. Adamson, R H. Advani, J Allison, K H. Antman, and R C. Bast. "In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs." <i>Mayo Clinic Proceedings</i> . 90.8 (2015): 996-1000. Print. (Previously introduced as Ex. 1044 in Dr. Chabner's deposition.)
Exhibit 1045	Singh, H, D L. Longo, and B A. Chabner. "Improving Prospects for Targeting Ras." <i>Journal of Clinical Oncology</i> . 33.31 (2015): 3650-3659. Print. (Previously introduced as Ex. 1045 in Dr. Chabner's deposition.)
Exhibit 1046	Information for Contributors, theoncologist.alphamedpress.org/site/misc/InfoForContributors.xhtml#_Toc374525716 (viewed on 11/15/2016). (Previously introduced as Ex. 1046 in Dr. Chabner's deposition.)
Exhibit 1047	Hanuske, AR, V Chen, P Paoletti, and C Niyikiza. "Pemetrexed Disodium: a Novel Antifolate Clinically Active against Multiple Solid Tumors." <i>The Oncologist</i> . 6.4 (2001): 363-73. Print. (Previously introduced as Ex. 1047 in Dr. Chabner's deposition.)
Exhibit 1048	Chabner BA., hand drawn sketch. (Previously introduced as Ex. 1048 in Dr. Chabner's deposition.)

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.