

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

PETITIONERS,

V.

ELI LILLY & COMPANY,  
PATENT OWNER.

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Case IPR2016-00240<sup>1</sup>  
Patent 7,772,209

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**PETITIONER'S CURRENT EXHIBIT LIST AS OF NOVEMBER 9, 2016  
PURSUANT TO 37 C.F.R. § 42.63(e)**

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<sup>1</sup> Cases IPR2016-01191 and IPR2016-01343 have been joined with the instant proceeding.

**PETITIONER'S CURRENT EXHIBIT LIST**

(Updated November 9, 2016)

<b>Exhibit No.</b>	<b>Description</b>
<b>Exhibit 1001</b>	U.S. Patent No. 7,772,209 to Clet Niyikiza, filed on July 11, 2007, and issued on Aug. 10, 2010 (“the ’209 patent”)
<b>Exhibit 1002</b>	U.S. Patent No. 7,772,209 Prosecution History (“’209 prosecution history”)
<b>Exhibit 1003</b>	U.S. Patent No. 5,344,932 to Edward C Taylor, issued on Sep. 6, 1994 (“ <i>Taylor</i> ”)
<b>Exhibit 1004</b>	Claim Chart for Niyikiza ’209 Petition (Attachment 2 to Bleyer Declaration)
<b>Exhibit 1005</b>	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> ”)
<b>Exhibit 1006</b>	U.S. Patent No. 4,140,707 to Cleare et al., issued on Feb. 20, 1979 (“ <i>Cleare</i> ”)
<b>Exhibit 1007</b>	Tsao CS, “Influence of Cobalamin on the Survival of Mice Bearing Ascites Tumor.” <i>Pathobiology</i> 1993;61:104-108 (“ <i>Tsao</i> ”)
<b>Exhibit 1008</b>	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> ”)
<b>Exhibit 1009</b>	Curriculum Vitae of W. Archie Bleyer, M.D., FRCP[Glasg] (Attachment 1 to Bleyer Declaration)
<b>Exhibit 1010</b>	European Patent Application No. 0,595,005 A1 (“ <i>EP 005</i> ”)
<b>Exhibit 1011</b>	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> ”)
<b>Exhibit 1012</b>	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
<b>Exhibit 1013</b>	Calvert AH & Walling JM, "Clinical studies with MTA." British Journal of Cancer (1998) 78 (Suppl. 3), 35-40 (" <i>Calvert 1998</i> ")
<b>Exhibit 1014</b>	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> ")
<b>Exhibit 1015</b>	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> ")
<b>Exhibit 1016</b>	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> ")
<b>Exhibit 1017</b>	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> ")
<b>Exhibit 1018</b>	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> ")
<b>Exhibit 1019</b>	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> ")
<b>Exhibit 1020</b>	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> ")
<b>Exhibit 1021</b>	Thödtmann 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>Thodtmann</i> ")

Exhibit No.	Description
<b>Exhibit 1022</b>	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> ”)
<b>Exhibit 1023</b>	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)
<b>Exhibit 1024</b>	Declaration of W. Archie Bleyer, M.D., FRCP[Glasg]
<b>Exhibit 1025</b>	<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> ”)
<b>Exhibit 1026</b>	<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> ”)
<b>Exhibit 1027</b>	<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> ”)
<b>Exhibit 1028</b>	Curriculum Vitae of Scott Bennett, Ph.D.
<b>Exhibit 1029</b>	Declaration of Scott Bennett, Ph.D.
<b>Exhibit 1030</b>	Online copy of Rusthoven from the Web site of the Journal of Clinical Oncology
<b>Exhibit 1031</b>	University of Illinois at Urbana-Champaign Library directory entry for the Journal of Clinical Oncology
<b>Exhibit 1032</b>	Statewide Illinois Library Catalog record for the Journal of Clinical Oncology
<b>Exhibit 1033</b>	Copy of Rusthoven from the University of Illinois at Chicago Library
<b>Exhibit 1034</b>	Web of Science entry for Rusthoven
<b>Exhibit 1035</b>	Online copy of <i>Carrasco</i> from the Highwire Press
<b>Exhibit 1036</b>	University of Illinois at Urbana-Champaign Library directory entry for <i>Haematologica</i>
<b>Exhibit 1037</b>	Statewide Illinois Library Catalog record for <i>Haematologica</i>

Exhibit No.	Description
<b>Exhibit 1038</b>	Copy of <i>Carrasco</i> from the University of Michigan Taubman Medical Library
<b>Exhibit 1039</b>	Web of Science entry for <i>Carrasco</i>
<b>Exhibit 1040</b>	Declaration of Mieke K. Malmberg
<b>Exhibit 1041</b>	Declaration of Paul J. Skiermont
<b>Exhibit 1042</b>	Transcript of October 31, 2016 Telephone Hearing

November 9, 2016

Respectfully Submitted,

/Sarah E. Spires/

Sarah E. Spires (Reg. No. 61,501)  
**SKIERMONT DERBY LLP**  
 2200 Ross Ave., Ste. 4800W  
 Dallas, Texas 75201  
 P: 214-978-6600/F: 214-978-6601  
**Lead Counsel for Petitioner**

Dr. Parvathi Kota (Reg. No. 65,122)  
 Paul J. Skiermont (*pro hac vice*  
 requested)  
**SKIERMONT DERBY LLP**  
 2200 Ross Ave., Ste. 4800W  
 Dallas, Texas 75201  
 P: 214-978-6600/F: 214-978-6621

Mieke K. Malmberg (*pro hac vice*  
 requested)  
**SKIERMONT DERBY LLP**  
 800 Wilshire Boulevard  
 Los Angeles, CA 90017  
 P: 213-788-4500/F: 213-788-4545  
**Back-Up Counsel for Petitioner**

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