UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner

v.

The Johns Hopkins University,
Patent Owner

IPR2024-00650
Patent No. 11,634,491

PETITIONER'S CURRENT LIST OF EXHIBITS

LIST OF EXHIBITS

Ex. No.	Description	Previously Submitted
EX1001	U.S. Patent No. 11,634,491 (the "'491 patent")	X
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EX1003	Declaration of Dr. Alfred I. Neugut, M.D., Ph.D., M.P.H.	X
EX1004	Curriculum Vitae of Dr. Alfred I. Neugut, M.D., Ph.D., M.P.H.	X
EX1005	ClinicalTrials.gov, NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," (June 10, 2013) available at https://clinicaltrials.gov/study/NCT01876511?tab=history&a=1 ("MSI-H Study Record"); also available at Merck Sharp & Dohme LLC v. The Johns Hopkins University, 1:22-cv-03059-BPG, ECF 1, Complaint, Exhibit B (11/29/22)	X
EX1006	Pernot et al, *Colorectal Cancer and Immunity: What We Know and Perspectives*, 20(14) World J. Gastroenterology 3738 (April 2014)	X
EX1007	Chapelle et al, *Clinical Relevance of Microsatellite Instability in Colorectal Cancer*, 28(20) J. Clinical Oncology 3380 (2010)	X
EX1008	Reserved	
EX1009	Benson et al, *Colon Cancer, Version 3.2014: Clinical Practice Guidelines in Oncology*, 12(7) J. Nat'l Comprehensive Cancer Network 1028 (July 2014)	X
EX1010	Salipante et al, *Microsatellite Instability Detection by Next Generation Sequencing*, 60(9) Clinical Chemistry 1192 (June 2014)	X

EX1011	Hamid et al, *Safety and Tumor Responses with Lambrolizumab (Anti-PD-1) in Melanoma*, 369(2) New Eng. J. Medicine 134 (July 2013)	X
EX1012	Laheru et al, *Immunotherapy for Pancreatic Cancer Science Driving Clinical Progress*, 5 Nature Revs. 459 (June 2005)	X
EX1013	Topalian et al, Safety, *Activity, and Immune Correlates of Anti–PD-1 Antibody in Cancer*, 366(26) New Eng. J. Med. 2443 (June 28, 2012)	X
EX1014	Pardoll, *The Blockade of Immune Checkpoints in Cancer Immunotherapy*, 12 Nature Revs. 252 (April 2012)	X
EX1015	Kang et al, *Pembrolizumab KEYNOTE-001: An Adaptive Study Leading to Accelerated Approval for Two Indications and a Companion Diagnostic*, 28(6) Annals of Oncology 1388 (2017)	X
EX1016	ClinicalTrials.gov, NCT01848834, "Study of MK-3475 in Participants With Advanced Solid Tumors (MK-3475-012)," (October 18, 2013) available at https://classic.clinicaltrials.gov/ct2/history/NCT01848834?A=12&B=12&C=merged#StudyPageTop	X
EX1017	ClinicalTrials.gov, NCT02054806, "Study of Pembrolizumab (MK-3475) in Participants With Advanced Solid Tumors (MK-3475-028/KEYNOTE-28)," (July 7, 2014) available at https://clinicaltrials.gov/study/NCT02054806?tab=history&a=14	X
EX1018	Robinson et al, *Lynch Syndrome (Hereditary Nonpolyposis Colorectal Cancer) Diagnostics*, 99(4) J. Nat'l Cancer Inst. 291 (2007)	X

EX1019	Fujiwara et al, *Accumulated Clonal Genetic Alterations in Familial and Sporadic Colorectal Carcinomas with Widespread Instability in Microsatellite Sequences*, 153(4) Am. J. Pathology 1063 (1998)	X
EX1020	National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Colon Cancer Version 3.2014 (January 27, 2014)	X
EX1021	Press Release, National Institutes of Health Launches "ClinicalTrials.gov" (February 20, 2000), Available at https://www.nlm.nih.gov/archive/20040831/news/press_releases/clntrlpr00.html	X
EX1022	File History of the '356 patent (U.S. Patent Application No. 16/144,549)	X
EX1023	July 27, 2017 Keytruda Package Insert, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125514s014lbl.pdf	X
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EX1026	ClinicalTrials.gov, NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," (May 21, 2014) available at https://www.clinicaltrials.gov/study/NCT01876511?tab=history&a=4	X

EX1027	ClinicalTrials.gov, NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," (June 25, 2014) available at https://www.clinicaltrials.gov/study/NCT01876511?tab=history&a=5	X
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EX1030	U.S. Provisional Patent App. No. 61/931,512	X
EX1031	Le et al, *PD-1 Blockade in Tumors with Mismatch-Repair Deficiency*, 372(26) New Eng. J. Medicine 2509 (June 25, 2015)	X
EX1032	Champiat et al, *Exomics and Immunogenics Bridging Mutational Load and Immune Checkpoints Efficacy*, 3(1) OncoImmunology e27817-1(January 2014)	X
EX1033	Gatalica et al, *Programmed Cell Death 1 (PD-1) and Its Ligand (PD-L1) in Common Cancers and Their Correlation with Molecular Cancer Type, Cancer*, Epidemiology, 23(12) Biomarkers & Prevention 2965 (November 12, 2014)	X
EX1034	Brown et al, *Neo-Antigens Predicted by Tumor Genome Meta-Analysis Correlate with Increased Patient Survival*, 24(5) Genome Research 743 (May 2014)	X
EX1035	Ogino et al, *Cancer Immunology - Analysis of Host and Tumor Factors for Personalized Medicine*, 8(12) Nature Revs. Clinical Oncology 711 (2011)	X

EX1036	Tougeron et al, *Tumor-Infiltrating Lymphocytes in Colorectal Cancers with Microsatellite Instability Are Correlated with the Number and Spectrum of Frameshift Mutations*, 22(9) Modern Pathology 1186 (2009)	X
EX1037	Nosho et al, *Tumour-infiltrating T-cell Subsets, Molecular Changes in Colorectal Cancer and Prognosis: Cohort Study and Literature Review*, 222(4) J. Pathology 350 (2010)	X
EX1038	Kim et al, *Prospects for Targeting PD-1 and PD-L1 in Various Tumor Types*, 28(supp.3) Oncology 15 (November 10, 2014)	X
EX1039	Llosa et al, *Immune Checkpoints Expression in MSI Versus MSS Colorectal Cancers and Their Potential Therapeutic Implications*, J. 32(15) Clinical Oncology 243s (May 2014)	X
EX1040	Loi et al, *Host Antitumor Immunity Plays a Role in the Survival of Patients With Newly Diagnosed Triple-Negative Breast Cancer*, 32(27) J. Clinical Oncology 2935 (July 28, 2014)	X
EX1041	Donnard et al, *Mutational Analysis of Genes Coding for Cell Surface Proteins in Colorectal Cancer Cell Lines Reveal Novel Altered Pathways, Druggable Mutations and Mutated Epitopes for Targeted Therapy*, 5(19) OncoTarget 199 (October 15, 2014)	X
EX1042	Kansara et al, *Translational Biology of Osteosarcoma*, 14(11) Nature Revs. Cancer 722 (October 16, 2014)	X
EX1043	U.S. Provisional Patent App. No. 62/190,977	X
EX1044	Tay et al, *A Combined Comparative Genomic Hybridization and Expression Microarray Analysis of Gastric Cancer Reveals Novel Molecular Subtypes1,2*, 63(12) Cancer Research 3309 (2003)	X

EX1045	Wahlberg et al, *Evaluation of Microsatellite Instability and Immunohistochemistry for the Prediction of Germ-Line MSH2 and MLH1 Mutations in Hereditary Nonpolyposis Colon Cancer Families*, 62(12) Cancer Research 3485 (2002)	X
EX1046	Taggart et al, *High-level Microsatellite Instability in Appendiceal Carcinomas*, 37(8) Am. J. Surgical Pathology 1192 (August 2013)	X
EX1047	Stintzing et al, *Management of Colorectal Cancer*, 6 F1000 Prime Reports 1 (November 4, 2014)	X
EX1048	Eisenhauer et al, *New Response Evaluation Criteria in Solid Tumours: Revised RECIST Guideline (Version 1.1)*, 45(2) Eur. J. Cancer 228 (2009)	X
EX1049	Matikas et al, *The Place of Targeted Agents in the Treatment of Elderly Patients with Metastatic Colorectal Cancer*, 7(1) Cancers 439 (March 13, 2015)	X
EX1050	Lee et al, *Novel Therapies in Development for Metastatic Colorectal Cance*r, 7(4 Supp. 1) Gastrointestinal Cancer Research 1 (September 2015)	X
EX1051	Lal et al, *An Immunogenomic Stratification of Colorectal Cancer: Implications for Development of Targeted Immunotherapy*, 4(3) OncoImmunology 1 (April 2, 2015)	X
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EX1053	ClinicalTrials.gov, NCT02060188, "Study of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Colon Cancer (CheckMate 142)," (February 10, 2014) available at https://clinicaltrials.gov/study/NCT02060188?tab=history&a=1	X

EX1054	Ascierto et al, *Future Perspectives in Melanoma Research: Meeting Report from the "Melanoma Bridge", Napoli, December 5th-8th 2013*, 12 J. Translational Medicine 277 (October 2024)	X
EX1055	September 4, 2014 Keytruda Package Insert, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125514lbl.pdf	X
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EX1057	Lipson et al, *Durable Cancer Regression Off-Treatment and Effective Reinduction Therapy with an Anti-PD-1 Antibody*, 19(2) Clinical Cancer Research 462 (January 2015)	X
EX1058	Drescher et al, *Lymphocyte Recruitment into the Tumor Site is Altered in Patients with MSI-H Colon Cancer*, 8(3) Familial Cancer 231 (2009)	X
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EX1064	Le et al, Supplementary Appendix to *PD-1 Blockade in Tumors with Mismatch-Repair Deficiency*, 372(26) New Eng. J. Medicine 2509 (June 25, 2015), available at https://www.nejm.org/doi/suppl/10.1056/NEJMoa1500596/suppl_file/nejmoa1500596_appendix_1.pdf	X

EX1065	June 21, 2022 Memo From Katherine Vidal on Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022), available at https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf	X
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EX1068	Henry et al, *Cancer Biomarkers*, 6(2) Molecular Oncology 140 (2012)	X
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EX1070	World Health Organization, *International Nonproprietary Names for Pharmaceutical Substances (INN)*, 27(2) WHO Drug Information (2013)	X
EX1071	Roth, *Frameshift Mutations*, 8 Annual Review of Genetics 319 (1974)	X
EX1072	Excerpt from Julien Taieb Citations, Google Scholar, available at https://scholar.google.ca/citations?user=niwd5qgAAAAJ&hl=en (accessed 8/25/23)	X

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EX1078	Young et al, *Treatment of Advanced Disease*, 321 British Medical J. 1278 (2000)	X
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EX1080	Poster presented at ASCO, Le et al, *Phase 2 Study of Programmed Death-1 Antibody (Anti-PD-1, MK-3475) in Patients with Microsatellite Unstable (MSI) Tumors* (Jun. 1, 2014)	X
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EX1082	Charles Fuchs, Research.com, available at https://research.com/u/charles-s-fuchs (accessed 8/25/23)	X
EX1083	Excerpt from Jerome Galon Citations, Google Scholar, available at https://scholar.google.com/citations?user=coRgZqUAAAAJ&hl=fr (accessed 8/25/23)	X
EX1084	Press Release, *Caris Life Sciences Research Provides Key Clinical Insights on Immunotherapeutic Targets in a Broad Range of Cancers* (June 10, 2014), available at https://www.carislifesciences.com/about/news-and-media/caris-life-sciences-research-provides-key-clinical-insights-on-immunotherapeutic-targets-in-a-broad-range-of-cancers/?gad_source=1&gclid=EAIaIQobChMIzba8u6LlggMVGlBHAR1ZPAHNEAAYASAAEgIaFvD_BwE	X
EX1085	Imai et al, *Carcinogenesis and Microsatellite Instability: the Interrelationship Between Genetics and Epigenetics*, 29(4) Carcinogenesis 673 (2008)	X
EX1086	Cheung et al, *Current Advance in Small Bowel Tumors*, 44(1) Clinical Endoscopy 13 (2011)	X
EX1087	Duval et al, *The Mutator Pathway is a Feature of Immunodeficiency-Related Lymphomas*, 101(14) Proceedings of the National Academy of Sciences 5002 (2004)	X
EX1088	National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Esophageal and Esophagogastric Junction Cancers Version 1.2014 (May 30, 2014)	X

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EX1091	Kim et al, *Microsatellite Instability Status in Gastric Cancer: A Reappraisal of Its Clinical Significance and Relationship with Mucin Phenotypes*, 47(1) Korean J. Pathology 28 (February 2013)	X
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EX1096	Ajani et al, *Gastric Cancer, Version 2.2013: Featured Updates to the NCCN Guidelines*, 11(5) J. Nat'l Comprehensive Cancer Network 531 (May 2013)	X
EX1097-1101	Reserved	

EX1102	Benson et al, *Colon Cancer, Version 3.2014: Clinical Practice Guidelines in Oncology*, 12(7) J. Nat'l Comprehensive Cancer Network 1028 (July 2014)	Not Filed
EX1103	Brown et al, *Neo-Antigens Predicted by Tumor Genome Meta-Analysis Correlate with Increased Patient Survival*, 24(5) Genome Research 743 (May 2014)	Not Filed
EX1104	Chapelle et al, *Clinical Relevance of Microsatellite Instability in Colorectal Cancer*, 28(20) J. Clinical Oncology 3380 (2010)	Not Filed
EX1105	Duval et al, *The Mutator Pathway is a Feature of Immunodeficiency-Related Lymphomas*, 101(14) Proceedings of the National Academy of Sciences 5002 (2004)	Not Filed
EX1106	Hamid et al, *Safety and Tumor Responses with Lambrolizumab (Anti-PD-1) in Melanoma*, 369(2) New Eng. J. Medicine 134 (July 2013)	Not Filed
EX1107	Reserved	
EX1108	Steinert et al, *Immune Escape and Survival Mechanisms in Circulating Tumor Cells of Colorectal Cancer*, 74(6) Cancer Research OF1 (March 2014)	Not Filed
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EX1121	RESERVED	

EX1122	Overman, M, Nivolumab in patients with metastatic DNA mismatch repair deficient/microsatellite instability–high colorectal cancer (CheckMate 142): results of an open-label, multicentre, phase 2 study, Lancet Oncol. 2017 September; 18(9): 1182–1191	
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Respectfully submitted,

Dated: May 6, 2025 By: /Preston K. Ratliff II/

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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2025, I caused a true and correct copy of the foregoing Petitioner's Current List of Exhibits to be served by electronic mail on Patent Owner at the following correspondence address of record:

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