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

IPR2024-00240
Patent No. 11,591,393

PETITIONER'S CURRENT LIST OF EXHIBITS

LIST OF EXHIBITS

Ex. No.	Description	Previously Submitted
EX1001	U.S. Patent No. 11,591,393 (the "'393 patent")	X
EX1002	File History of the '393 patent (U.S. Patent Application No. 17/465,101)	X
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	Steinert et al, *Immune Escape and Survival Mechanisms in Circulating Tumor Cells of Colorectal Cancer*, 74(6) Cancer Research OF1 (March 2014)	X
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 U.S. Patent No. 10,9394,356 (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
EX1024	ClinicalTrials.gov, NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," (June 12, 2013) available at https://www.clinicaltrials.gov/study/NCT01876511?tab=history&a=2	X
EX1025	ClinicalTrials.gov, NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," (September 20, 2013) available at https://www.clinicaltrials.gov/study/NCT01876511?tab=history&a=3	X
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
EX1028	Reserved	
EX1029	*Merck Sharp & Dohme LLC v. The Johns Hopkins University*, 1:22-cv-03059-BPG, ECF 40, The Johns Hopkins University's First Amended Answer and Counterclaims to Merck's Complaint for Declaratory Relief (Filed 5/22/23)	X
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
EX1052	Reserved	
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
EX1056	Reserved	
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
EX1059	Reserved	
EX1060	Reserved	
EX1061	Reserved	
EX1062	Reserved	
EX1063	Dimasi et al, *Clinical Approval Success Rates for Investigational Cancer Drugs*, 94(3) Clinical Pharmacology & Therapeutics 329 (September 2013)	X
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
EX1066	*Merck Sharp & Dohme LLC v. The Johns Hopkins University*, 1:22-cv-03059-BPG, ECF 57, Scheduling Order (Filed 10/16/23)	X
EX1067	Maryland, U.S. District Court – Judicial Caseload Profile, available at https://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile0630.2023.pdf	X
EX1068	Henry et al, *Cancer Biomarkers*, 6(2) Molecular Oncology 140 (2012)	X
EX1069	Garon et al, *Antitumor Activity of Pembrolizumab (Pembro; Mk-3475) and Correlation with Programmed Death Ligand 1 (Pd-L1) Expression in a Pooled Analysis of Patients (Pts) with Advanced Non–Small Cell Lung Carcinoma (Nsclc)*, 25(4) Annals of Oncology September 2014	X
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

EX1073	Excerpt from Alexander Eggermount Citations, Google Scholar, available at https://scholar.google.com/citations?user=NWWkhzoAAAAJ&hl=en (accessed 8/25/23)	X
EX1074	Excerpt from Jean-Charles Soria Citations, Google Scholar, available at https://scholar.google.com/citations?user=wyFxnccAAAAJ (accessed 8/25/23)	X
EX1075	Henry Lynch, Research.com, available at https://research.com/u/henry-t-lynch (accessed 8/25/23)	X
EX1076	Excerpt from Daniel Van Hoff Citations, Google Scholar, available at https://scholar.google.com/citations?user=-NTa4oUAAAAJ&hl=en (accessed 8/25/23)	X
EX1077	Excerpt from Robert A. Holt, Google Scholar, available at https://scholar.google.com/citations?user=CXPlI08AAAAJ&hl=en (accessed 11/27/23)	X
EX1078	Young et al, *Treatment of Advanced Disease*, 321 British Medical J. 1278 (2000)	X
EX1079	Le et al, *Phase 2 Study of Programmed Death-1 Antibody (Anti-PD-1, MK-3475) in Patients with Microsatellite Unstable (MSI) Tumors*, 32 (15) J. Clinical Oncology (May 2014)	X
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
EX1081	Excerpt from Shuji Ogino, Google Scholar, available at https://scholar.google.com/citations?user=87TPyfoAAAAJ&hl=en (accessed 8/25/23)	X

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
EX1083-1101	Reserved	
EX1102	Contents Volume 20 Issue 14, World J. Gastroenterology 3738 (April 2014), https://web.archive.org/web/20140710041915/http:/www.wjgnet.com/1007-9327/journal/v20/i14/index.htm	Not filed
EX1103	Chapelle et al, Clinical Relevance of Microsatellite Instability in Colorectal Cancer, 28(20) J. Clinical Oncology 3380 (2010) (library stamped on July 28, 2010)	Not filed
EX1104	Steinert et al, Immune Escape and Survival Mechanisms in Circulating Tumor Cells of Colorectal Cancer, 74(6) Cancer Research OF1 (March 2014) (library stamped on March 26, 2014)	Not filed
EX1105	Benson et al, Colon Cancer, Version 3.2014: Clinical Practice Guidelines in Oncology, 12(7) J. Nat'l Comprehensive Cancer Network 1028 (July 2014) (library stamped on July 17, 2014)	Not filed

EX1106	Salipante et al, Microsatellite Instability Detection by Next Generation Sequencing, 60(9) Clinical Chemistry 1192 (June 2014) (library stamped on September 25, 2014)	Not filed
EX1107	Hamid et al, Safety and Tumor Responses with Lambrolizumab (Anti-PD-1) in Melanoma, 369(2) New Eng. J. Medicine 134 (July 2013) (library stamped on July 22, 2013)	Not filed
EX1108	Phase 2 study of programmed death-1 antibody (anti-PD-1, MK-3475) in patients with microsatellite unstable (MSI) tumors, Program Guide –ASCO Meeting Program Guide, https://meetings.asco.org/abstracts-presentations/98450 (last visited July 8, 2024)	Not filed
EX1109	Email Correspondence	
EX1110	Excerpts of transcript of the February 2019 earnings call https://s21.q4cdn.com/488056881/files/doc_financials/2018/Q4/MRK-USQ_Transcript_2019-02-01-Final.pdf	
EX1111	Excerpts of Merck's patent webpage listing Keytruda® patents: https://www.merck.com/products/patent/	
EX1112	Declaration of Jessica Stauring in Support of Motion for Pro Hac Vice	

Respectfully submitted,

Dated: November 25, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on November 25, 2024, 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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