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

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EX1001	U.S. Patent No. 11,591,393 (the "'393 patent")	X
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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
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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
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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
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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	X
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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	X

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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
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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
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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
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EX1211	Breakthrough Therapy definition, FDA, available at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (last accessed January 29, 2025)	
EX1212	Continuity Data of U.S. Patent Application No. 17/465,101 https://patentcenter.uspto.gov/applications/17465101/continuity?application= (last accessed January 29, 2025)	
EX1213	Merck U.S. patent rights for products, Merck, available at https://www.merck.com/products/patent/ (last accessed January 29, 2025)	
EX1214	U.S. Patent No. 8,900,587	

EX1215	U.S. Patent No. 9,834,605	
EX1216	U.S. Patent No. 11,117,961	
EX1217	U.S. Patent No. 9,220,776	
EX1218	Edited Transcript, MRK - Q3 2014 Merck & Co Inc Earnings Call dated October 27, 2014	
EX1219	Merck 10-Q filing for the quarterly period ended September 30, 2014	
EX1220	Success Multiplied: Launch Excellence for Multi-Indication Assets, IQVIA (2023)	
EX1221	"KEYTRUDA (pembrolizumab) from Merck Awarded Prix Galien USA 2015 Best Biotechnology Product Award," Merck, October 28, 2015, available at https://www.merck.com/news/keytruda-pembrolizumab-from-merck-awarded-prix-galien-usa-2015-best-biotechnology-product-award/ (last accessed January 29, 2025)	
EX1222	In the Eye of the Storm: PD-(L)1 Inhibitors Weathering Turbulence," IQVIA Whitepaper (2022)	
EX1223	"Keytruda wins second place in the race to approval for neo-adjuvant NSCLC," Clinical Trials Arena, October 23, 2023, available at https://www.clinicaltrialsarena.com/analyst-comment/keytruda-approval-nsclc/?cf-view (last accessed January 29, 2025)	

EX1224	"Merck & Co., Roche, and BMS Among Leading Players in the Non-Small Cell Lung Cancer Drugs Market," Global Data, July 20, 2022, available at https://www.globenewswire.com/news-release/2022/07/20/2482864/0/en/Merck-Co-Roche-and-BMS-Among-Leading-Players-in-the-Non-Small-Cell-Lung-Cancer-Drugs-Market-GlobalData-Plc.html (last accessed January 29, 2025)	
EX1225	Summary of "PD-1 Non-Small Cell Lung Cancer Market Insight," Delve Insight, available at https://www.delveinsight.com/report-store/pd-1-non-small-cell-lung-cancer-market (last accessed January 29, 2025)	
EX1226	Opdivo Package Insert, available at https://packageinserts.bms.com/pi/pi_opdivo.pdf (last accessed January 29, 2025)	
EX1227	"Cancer Stat Facts: Colorectal Cancer," National Cancer Institute, available at https://seer.cancer.gov/statfacts/html/colorect.html (last accessed January 29, 2025)	
EX1228	"Cancer Stat Facts: Colorectal Cancer," National Cancer Institute, archived October 28, 2023, available at https://web.archive.org/web/20231028215159/https://seer.cancer.gov/statfacts/html/colorect.html (last accessed January 29, 2025)	
EX1229	"Cancer Stat Facts: Colorectal Cancer," National Cancer Institute, archived March 17, 2023, available at https://web.archive.org/web/20230317191901/https://seer.cancer.gov/statfacts/html/colorect.html (last accessed January 29, 2025)	

EX1230	"Cancer Stat Facts: Colorectal Cancer," National Cancer Institute, archived March 8, 2022, available at https://web.archive.org/web/20220308124217/https://seer.cancer.gov/statfacts/html/colorect.html (last accessed January 29, 2025)	
EX1231	"Cancer Stat Facts: Colorectal Cancer," National Cancer Institute, archived March 18, 2021, available at https://web.archive.org/web/20210318013225/https://seer.cancer.gov/statfacts/html/colorect.html (last accessed January 29, 2025)	
EX1232	"Cancer Stat Facts: Lung and Bronchus Cancer," National Cancer Institute, archived March 8, 2022, available at https://web.archive.org/web/20220308124230/http://seer.cancer.gov/statfacts/html/lungb.html (last accessed January 29, 2025)	
EX1233	"Cancer Stat Facts: Lung and Bronchus Cancer," National Cancer Institute, archived March 21, 2023, available at https://web.archive.org/web/20230321152735/https://seer.cancer.gov/statfacts/html/lungb.html (last accessed January 29, 2025)	
EX1234	"Cancer Stat Facts: Lung and Bronchus Cancer," National Cancer Institute, archived October 26, 2023 available at https://web.archive.org/web/20231026195403/https://seer.cancer.gov/statfacts/html/lungb.html (last accessed January 29, 2025)	
EX1235	"Cancer Stat Facts: Lung and Bronchus Cancer," National Cancer Institute, available at https://seer.cancer.gov/statfacts/html/lungb.html (last accessed January 29, 2025)	

EX1236	"Cancer Stat Facts: Lung and Bronchus Cancer," National Cancer Institute, archived March, 18, 2021, available at https://web.archive.org/web/20210318000630/https://seer.cancer.gov/statfacts/html/lungb.html (last accessed January 29, 2025)	
EX1237	"Non-Small Cell Lung Cancer," Yale Medicine, available at https://www.yalemedicine.org/conditions/non-small-cell-lung-cancer (last accessed January 29, 2025)	
EX1238	U.S. Patent No. 8,354,509	

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