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

IPR2024-00623
Patent No. 11,325,974

PETITIONER'S CURRENT LIST OF EXHIBITS

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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
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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
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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
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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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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
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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
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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
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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
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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
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EX1208	NCCN Guidelines, Colon Cancer, Version 5.2024 - August 22, 2024	
EX1209	NCCN Guidelines, Rectal Cancer, Version 4.2024 - August 22, 2024	
EX1210	MSI-H CRC, Opdivo, available at https://www.opdivo.com/msi-h-crc (last accessed January 29, 2025)	
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EX1214	U.S. Patent No. 8,900,587	
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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)	
EX1226-1237	Reserved	
EX1238	U.S. Patent No. 8,354,509	
EX1239-1241	Reserved	
EX1242	Deposition Transcript of Jennifer Newberger, taken on April 10, 2025	
EX1243	Deposition Transcript of Richard . Goldberg, taken on April 15, 2025	
EX1244	[HIGHLY CONFIDENTIAL ATTORNEY EYES ONLY – PROTECTIVE ORDER MATERIAL] Deposition Transcript of Brian J. Segers, taken on April 21, 2025	
EX1245	[HIGHLY CONFIDENTIAL ATTORNEY EYES ONLY – PROTECTIVE ORDER MATERIAL] Deposition Transcript of Nils Lonberg, taken on April 17, 2025	
EX1246	Deposition Transcript of Dung Thi Le, M.D., taken on April 18, 2025	
EX1247	Reserved	
EX1248	Reserved	

EX1249	"FDA Converts to Full Approval Indication for KEYTRUDA® (pembrolizumab) for Certain Adult and Pediatric Patients With Advanced Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors" (March 29, 2023) (https://www.merck.com/news/fda-converts-to-full-approval-indication-for-keytruda-pembrolizumab-for-certain-adult-and-pediatric-patients-with-advanced-microsatellite-instability-high-msi-h-or-mismatch-repair-deficient/)	
EX1250	NCCN Clinical Practice Guidelines in Oncology - Uterine Neoplasms (Version 3.2025-March 7, 2025), available at www.nccn.org/patients	
EX1251	NCCN Clinical Practice Guidelines in Oncology - Small Bowel Adenocarcinoma (Version 3.2025-March 31, 2025), available at www.nccn.org/patients	
EX1252	NCCN Clinical Practice Guidelines in Oncology - Gastric Cancer (Version 2.2025-April 4, 2025), available at www.nccn.org/patients	
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EX1260	NCCN Clinical Practice Guidelines in Oncology - Vaginal Cancer (Version 5.2025-February 28, 2025), available at www.nccn.org/patients	
EX1261	Keytruda Label	
EX1262	"FDA grants nivolumab accelerated approval for MSI-H or dMMR colorectal cancer" (https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-nivolumab-accelerated-approval-msi-h-or-dmmr-colorectal-cancer)	
EX1263	"FDA Grants Accelerated Approval to Ipilimumab for MSI-H or dMMR Metastatic Colorectal Cancer" (https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-ipilimumab-msi-h-or-dmmr-metastatic-colorectal-cancer)	
EX1264	Yervoy Label	
EX1265	Opdivo Label	

EX1266	"GSK - GSK Receives FDA Accelerated Approval for JEMPERLI dostarlimab-gxly for Adult Patients with dMM" (https://www.gsk.com/en-gb/media/press-releases/gsk-receives-fda-accelerated-approval-for-jemperli-dostarlimab-gxly-for-adult-patients-with-mismatch-repair-deficient-dmmr-recurrent-or-advanced-solid-tumours/)	
EX1267	Jemperli Label	
EX1268	FDA Approves Pembrolizumab for Adults and Children with TMB-H Solid Tumors, available at	
EX1269	[HIGHLY CONFIDENTIAL ATTORNEY EYES ONLY – PROTECTIVE ORDER MATERIAL] Confidential Declaration of Brian J Segers in IPR2024-00625 - Ex. 2191 – (U.S. 11,339,219)	
EX1270	[HIGHLY CONFIDENTIAL ATTORNEY EYES ONLY – PROTECTIVE ORDER MATERIAL] Confidential Declaration of Brian J Segers in IPR2024-00647 - Ex. 2191 - (11,649,287)	
EX1271-1272	Reserved	
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EX1277	NCCN Clinical Practice Guidelines in Oncology - Ovarian Cancer (Version 1.2025-March 5, 2025), available at www.nccn.org/patients	
EX1278	NCCN Clinical Practice Guidelines in Oncology - Rectal Cancer (Version 2.2025-March 31, 2025), available at www.nccn.org/patients	
EX1279	June 29, 2020 first-line CRC approval (FDA approves pembrolizumab for first-line treatment of MSI-H/dMMR colorectal cancer | FDA) https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-pembrolizumab-first-line-treatment-msi-hdmmr-colorectal-cancer	
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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 1, 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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