

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

IPR2024-00647
Patent No. 11,649,287

PETITIONER'S CURRENT LIST OF EXHIBITS

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EX1001	U.S. Patent No. 11,649,287 (the “’287 patent”)	X
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EX1006	Pernot et al, <i>Colorectal Cancer and Immunity: What We Know and Perspectives</i> , 20(14) World J. Gastroenterology 3738 (April 2014)	X
EX1007	Chapelle et al, <i>Clinical Relevance of Microsatellite Instability in Colorectal Cancer</i> , 28(20) J. Clinical Oncology 3380 (2010)	X
EX1008	Steinert et al, <i>Immune Escape and Survival Mechanisms in Circulating Tumor Cells of Colorectal Cancer</i> , 74(6) Cancer Research OF1 (March 2014)	X
EX1009	Benson et al, <i>Colon Cancer, Version 3.2014: Clinical Practice Guidelines in Oncology</i> , 12(7) J. Nat’l Comprehensive Cancer Network 1028 (July 2014)	X

EX1010	Salipante et al, <i>Microsatellite Instability Detection by Next Generation Sequencing</i> , 60(9) Clinical Chemistry 1192 (June 2014)	X
EX1011	Hamid et al, <i>Safety and Tumor Responses with Lambrolizumab (Anti-PD-1) in Melanoma</i> , 369(2) New Eng. J. Medicine 134 (July 2013)	X
EX1012	Laheru et al, <i>Immunotherapy for Pancreatic Cancer Science Driving Clinical Progress</i> , 5 Nature Revs. 459 (June 2005)	X
EX1013	Topalian et al, <i>Safety, Activity, and Immune Correlates of Anti-PD-1 Antibody in Cancer</i> , 366(26) New Eng. J. Med. 2443 (June 28, 2012)	X
EX1014	Pardoll, <i>The Blockade of Immune Checkpoints in Cancer Immunotherapy</i> , 12 Nature Revs. 252 (April 2012)	X
EX1015	Kang et al, <i>Pembrolizumab KEYNOTE-001: An Adaptive Study Leading to Accelerated Approval for Two Indications and a Companion Diagnostic</i> , 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, <i>Lynch Syndrome (Hereditary Nonpolyposis Colorectal Cancer) Diagnostics</i> , 99(4) J. Nat'l Cancer Inst. 291 (2007)	X
EX1019	Fujiwara et al, <i>Accumulated Clonal Genetic Alterations in Familial and Sporadic Colorectal Carcinomas with Widespread Instability in Microsatellite Sequences</i> , 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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EX1031	Le et al, <i>PD-1 Blockade in Tumors with Mismatch-Repair Deficiency</i> , 372(26) New Eng. J. Medicine 2509 (June 25, 2015)	X
EX1032	Champiat et al, <i>Exomics and Immunogenics Bridging Mutational Load and Immune Checkpoints Efficacy</i> , 3(1) OncoImmunology e27817-1(January 2014)	X
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EX1035	Ogino et al, <i>Cancer Immunology - Analysis of Host and Tumor Factors for Personalized Medicine</i> , 8(12) Nature Revs. Clinical Oncology 711 (2011)	X
EX1036	Tougeron et al, <i>Tumor-Infiltrating Lymphocytes in Colorectal Cancers with Microsatellite Instability Are Correlated with the Number and Spectrum of Frameshift Mutations</i> , 22(9) Modern Pathology 1186 (2009)	X
EX1037	Nosho et al, <i>Tumour-infiltrating T-cell Subsets, Molecular Changes in Colorectal Cancer and Prognosis: Cohort Study and Literature Review</i> , 222(4) J. Pathology 350 (2010)	X
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EX1039	Llosa et al, <i>Immune Checkpoints Expression in MSI Versus MSS Colorectal Cancers and Their Potential Therapeutic Implications</i> , J. 32(15) Clinical Oncology 243s (May 2014)	X
EX1040	Loi et al, <i>Host Antitumor Immunity Plays a Role in the Survival of Patients With Newly Diagnosed Triple-Negative Breast Cancer</i> , 32(27) J. Clinical Oncology 2935 (July 28, 2014)	X
EX1041	Donnard et al, <i>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</i> , 5(19) OncoTarget 199 (October 15, 2014)	X
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EX1044	Tay et al, <i>A Combined Comparative Genomic Hybridization and Expression Microarray Analysis of Gastric Cancer Reveals Novel Molecular Subtypes</i> 1,2, 63(12) Cancer Research 3309 (2003)	X
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EX1048	Eisenhauer et al, <i>New Response Evaluation Criteria in Solid Tumours: Revised RECIST Guideline (Version 1.1)</i> , 45(2) Eur. J. Cancer 228 (2009)	X
EX1049	Matikas et al, <i>The Place of Targeted Agents in the Treatment of Elderly Patients with Metastatic Colorectal Cancer</i> , 7(1) Cancers 439 (March 13, 2015)	X
EX1050	Lee et al, <i>Novel Therapies in Development for Metastatic Colorectal Cancer</i> , 7(4 Supp. 1) Gastrointestinal Cancer Research 1 (September 2015)	X
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EX1064	Le et al, Supplementary Appendix to <i>PD-1 Blockade in Tumors with Mismatch-Repair Deficiency</i> , 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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EX1079	Le et al, <i>Phase 2 Study of Programmed Death-1 Antibody (Anti-PD-1, MK-3475) in Patients with Microsatellite Unstable (MSI) Tumors</i> , 32 (15) J. Clinical Oncology (May 2014)	X
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EX1087	Duval et al, <i>The Mutator Pathway is a Feature of Immunodeficiency-Related Lymphomas</i> , 101(14) Proceedings of the National Academy of Sciences 5002 (2004)	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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EX1196	BLA Supplement Approval Letter, FDA, 10-16-2023	
EX1197	BLA Supplement Approval Letter, FDA, 10-21-2023	
EX1198	BLA Supplement Approval Letter, FDA, 10-24-2016	
EX1199	BLA Supplement Approval Letter, FDA, 10-30-2018	
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EX1202	BLA Supplement Approval Letter, FDA, 12-3-2021	
EX1203	BLA Supplement Approval Letter, FDA, 12-15-2023	
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EX1239-1241	Reserved	
EX1242	Deposition Transcript of Jennifer Newberger, taken on April 10, 2025	
EX1243	Deposition Transcript of Richard M. 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	
EX1247-1274	Reserved	
EX1275	NCCN Clinical Practice Guidelines in Oncology - Colon Cancer (Version 3.2025-April 24, 2025), available at www.nccn.org/patients	
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EX1282	Declaration of Ms. Jennifer Newberger, in IPR2024-00623, Ex. 2137 (11,325,974)	

EX1283	[HIGHLY CONFIDENTIAL ATTORNEY EYES ONLY – PROTECTIVE ORDER MATERIAL] Deposition Transcript of Paul E. Oberstein, M.D., taken on February 19, 2025	
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Respectfully submitted,

Dated: May 6, 2025

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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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