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.

Case IPR2024-00647
Patent 11,649,287 B2

PATENT OWNER'S UNOPPOSED MOTION FOR *PRO HAC VICE*

ADMISSION OF

CAROLINE (GRACIE) KOONCE UNDER 37 C.F.R. § 42.10(c)

PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit Number	Description
2001	RESERVED
2002	Curriculum Vitae of Dr. Nils Lonberg
2003	Dung T. Le, Sidney Kimmel Comprehensive Cancer Center, PD-1 Blockade in Tumors with Mismatch Repair Deficiency, Presentation at 2015 ASCO Annual Meeting (May 30, 2015) (abstract available at https://meetings.asco.org/abstracts-presentations/109904)
2004	FDA News Release, FDA, FDA Approves First Cancer Treatment for Any Solid Tumor with a Specific Genetic Feature (May 23, 2017) available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-cancer-treatment-any-solid-tumor-specific-genetic-feature
2005	Gina Kolata, Cancer Drug Proves to Be Effective Against Multiple Tumors, N.Y. Times (June 8, 2017), https://www.nytimes.com/2017/06/08/health/cancer-drug-keytruda-tumors.html
2006	Laurie McGinley, 'This is not the end': Using immunotherapy and a genetic glitch to give cancer patients hope, Wash. Post (May 28, 2017), https://www.washingtonpost.com/national/health-science/this-is-not-the-end-experimental-therapy-that-targets-genes-gives-cancer-patients-hope/2017/05/28/cdce31de-365c-11e7-b373-418f6849a004_story.html
2007	News Release, Merck, Merck Receives Accelerated Approval of KEYTRUDA® (Pembrolizumab), the First FDA-Approved Anti-PD-1 Therapy (Sept. 4, 2014) available at https://www.merck.com/news/merck-receives-accelerated-approval-of-keytruda-pembrolizumab-the-first-fda-approved-anti-pd-1-therapy/
2008	News Release, Merck, Merck Announces Fourth-Quarter and Full-Year 2023 Financial Results (Feb. 1, 2024) available at https://s2.q4cdn.com/584635680/files/doc_news/Merck-Announces-Fourth-Quarter-and-Full-Year-2023-Financial-Results-2024.pdf
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2022	Bacher et al., Development of a Fluorescent Multiplex Assay for Detection of MSI-High Tumors, 20(4-5) Disease Markers 237-50 (2004)
2023	Diaz et al., Liquid Biopsies: Genotyping Circulating Tumor DNA, 32(6) J. Clinical Oncology 579-86 (Feb. 20, 2014)
2024	Brahmer et al., Phase I Study of Single-Agent Anti–Programmed Death-1 (MDX-1106) in Refractory Solid Tumors: Safety, Clinical Activity, Pharmacodynamics, and Immunologic Correlates, 28(19) J. Clinical Oncology 3167-75 (July 1, 2010)
2025	RESERVED
2026	Mandrekar et al., All-Comers versus Enrichment Design Strategy in Phase II Trials, 6(4) J. Thoracic Oncology 658-60 (Apr. 1, 2011)
2027	Freidlin et al., Randomized Clinical Trials With Biomarkers: Design Issues, 102(3) J. Nat'l Cancer Inst. 152-60 (Feb. 3, 2010)
2028	Malik et al., Consensus Report of a Joint NCI Thoracic Malignancies Steering Committee: FDA Workshop on Strategies for Integrating Biomarkers into Clinical Development of New Therapies for Lung Cancer Leading to the Inception of "Master Protocols" in Lung Cancer, 9(10) J. Thoracic Oncology 1443-48 (Oct. 2014)
2029-2031	RESERVED
2032	NIH National Cancer Institute, What is Cancer? (last updated Oct. 11, 2021), https://www.cancer.gov/about-cancer/understanding/what-is-cancer
2033	Weiss, Open Questions: Knowing Who's Who in Multicellular Animals is Not Always as Simple as We Imagine, 16 BMC Biology Article number: 115 (Oct. 15, 2018)
2034	Mumphrey et al., Distinct Mutational Processes Shape Selection of MHC Class I and Class II Mutations Across Primary and Metastatic Tumors, 42(8) Cell Reports 112965 1-20 (Aug. 29, 2023)
2035	Jenkins et al., Antigen Presentation by Chemically Modified Splenocytes Induces Antigen-Specific T Cell Unresponsiveness In Vitro and In Vivo, 165(2) J. Experimental Med. 302-19 (Feb. 1, 1987)
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2037	Lotze et al., Lysis of Fresh and Cultured Autologous Tumor by Human Lymphocytes Cultured in T-Cell Growth Factor, 41 Cancer Research 4420-25 (Nov. 1981)
2038	Briukhovetska et al., Interleukins in Cancer: From Biology to Therapy, 21 Nature Reviews Cancer 481-99 (June 3, 2021)
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2040	Wang et al., CD19+CD24hiCD38hiBregs Involved in Downregulate Helper T Cells and Upregulate Regulatory T Cells in Gastric Cancer, 6(32) Oncotarget 33486-99 (Sept. 10, 2015)
2041	Michaud et al., Regulatory B Cells in Cancer, 299(1) Immunological Reviews 74-92 (Dec. 23, 2020)
2042	Nakhoda et al., Addressing Recent Failures in Immuno-Oncology Trials to Guide Novel Immunotherapeutic Treatment Strategies, 34 Pharmaceutical Medicine 83-91 (Mar. 10, 2020)
2043	Korman et al., The Foundations of Immune Checkpoint Blockade and the Ipilimumab Approval Decennial, 21 Nature Reviews Drug Discovery 509-28 (July 2022)
2044	NIH National Cancer Institute, Immune Checkpoint Inhibitors (last updated Apr. 7, 2022), https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/checkpoint-inhibitors
2045	Boland et al., Microsatellite Instability in Colorectal Cancer, 138(6) Gastroenterology 2073-87 (May 2010)
2046	Branch et al., Immune Surveillance in Colorectal Carcinoma, 9 Nature Genetics 231-32 (Mar. 1995)
2047	Kloor et al., Immune Evasion of Microsatellite Unstable Colorectal Cancers, 127(5) Int'l J. Cancer 1001-10 (Sept. 1, 2010)
2048	Zhong et al., Comparison of the Molecular and Cellular Phenotypes of Common Mouse Syngeneic Models with Human Tumors, 21 BMC Genomics Article number: 2 (Jan. 2, 2020)
2049	Thomas et al., Advancing Translational Research for Colorectal Immuno-Oncology, 129 British J. Cancer 1442-50 (Aug. 10, 2023)
2050	Lacombe et al., The Dream and Reality of Histology Agnostic Cancer Clinical Trials, 8(6) Molecular Oncology 1057-63 (Sept. 12, 2014)

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2051	David Shaywitz, The Startling History Behind Merck's New Cancer Blockbuster, Forbes (July 26, 2017)
2052-2059	RESERVED
2060	News Release, Merck, FDA Approves Merck's KEYTRUDA® (pembrolizumab) for Adult and Pediatric Patients with Unresectable or Metastatic, Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors (May 25, 2017)
2061	News Release, Merck, First Study Evaluating DNA Mismatch Repair as Genetic Guide for Immunotherapy Treatment with Merck's KEYTRUDA® (pembrolizumab) Presented at 2015 ASCO Annual Meeting and Published in the New England Journal of Medicine (May 29, 2015)
2062	News Release, Merck, Merck Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for KEYTRUDA® (pembrolizumab) in Advanced Colorectal Cancer (Nov. 2, 2015)
2063	Thomson Reuters Streetevents, Edited Transcript MRK - Q4 2018 Merck & Co Inc Earnings Call, event date Feb. 1, 2019
2064	News Release, Merck, Merck Announces Fourth-Quarter and Full-Year 2022 Financial Results (Feb. 2, 2023)
2065	News Release, Merck, Merck Announces Fourth-Quarter and Full-Year 2021 Financial Results (Feb. 3, 2022)
2066	News Release, Merck, Merck Announces Fourth-Quarter and Full-Year 2020 Financial Results (Feb. 4, 2021)
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2069	Exhibit 22 to Johns Hopkins University Corrected Answer and Counterclaims to Complaint, Merck Sharp & Dohme LLC v. The Johns Hopkins University, Case No. 1-22-cv-03059-JRR, D.I. 17-12 (D. Md. April 21, 2023)
2070	Statista, Leading drugs worldwide based on projected 2024 sales (in billion of U.S. dollars), released December 2023, available at https://www.statista.com/statistics/973523/top-drugs-by-year-on-year-sales-increase/

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2072	Declaration of Dr. Nils Lonberg
2073	Connolly et al., Novel Mouse Models for Cancer Immunology, Annual Review of Cancer Biology 6:269-91 (2022)
2074	Sun et al., Immune checkpoint therapy for solid tumours: clinical dilemmas and future trends, Signal Transduction Targeted Therapy, 8:320 (2023)
2075	Dobosz et al., Challenges of the Immunotherapy: Perspectives and Limitations of the Immune Checkpoint Inhibitor Treatment Int. J. Mol. Sci., 23, 2847:1-17 (2022)
2076	Jonathan Gardner, Merck suffers bad week as 3 Keytruda combination trials fail, BioPharma Dive (Dec. 8, 2023), https://www.biopharmadive.com/news/merck-keytruda-combination-trials-fail-patent-cliff/701975/
2077	Angus Liu, Merck's Keytruda flunks pivotal studies in lung and skin cancers, Fierce Pharma (Aug. 29, 2024), https://www.fiercepharma.com/pharma/mercks-keytruda-flunks-early-stage-lung-and-skin-cancer-tests
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2079	Merck's trial of Keytruda regimen fails to meet primary endpoint, Clinical Trials Arena (May 10, 2024), https://www.clinicaltrialsarena.com/news/merck-trial-keytruda-regimen/?cf-view
2080	Study of Pembrolizumab (MK-3475) in Participants With Advanced Solid Tumors (MK-3475-028/KEYNOTE-28), ClinicalTrials.gov (Oct. 10, 2023), https://clinicaltrials.gov/study/NCT02054806
2081	van der Bruggen et al., A gene encoding an antigen recognized by 7cytolytic T lymphocytes on a human melanoma, Science 254:1643-47 (Dec. 13, 1991)
2082	Lawrence et al., Mutational heterogeneity in cancer and the search for new cancer-associated genes, Nature 499:214-18 (July 11, 2013)

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2083	Shigehisa Kitano et al., Myeloid-derived suppressor cell quantity prior to treatment with ipilimumab at 10mg/kg to predict for overall survival in patients with metastatic melanoma, J. of Clin. Oncology 30(15), 2518 (May 20, 2012)
2084	Snyder et al., Genetic basis for clinical response to CTLA-4 blockade in melanoma, N. Engl. J. Med. 371(23):2189-99 (Dec. 4 2014)
2085	Chan et al., Genetic Basis for Clinical Response to CTLA-4 Blockade in Melanoma, N. Engl. J. Med. 373(20):1984 (Nov. 12, 2015)
2086	McGranahan et al., Clonal neoantigens elicit T cell immunoreactivity and sensitivity to immune checkpoint blockade, Science 351(6280):1463-69 (Mar. 25, 2016)
2087	Hellmann et al., Tumor Mutational Burden and Efficacy of Nivolumab Monotherapy and in Combination with Ipilimumab in Small-Cell Lung Cancer, Cancer Cell 33, 853-861 (May 14, 2018)
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2089	Boyiadzis et al., Significance and implications of FDA approval of pembrolizumab for biomarker-defined disease, J. ImmunoTher. Cancer 6:35 (May 14, 2018)
2090	Declaration of Dr. Richard Goldberg
2091	Bray et al., Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries, CA Cancer J. Clin. 74:229-263 (2024)
2092	Zeineddine et al., Survival improvement for patients with metastatic colorectal cancer over twenty years, NPJ Precis. Oncol. 7:16 (2023)
2093	Patel et al., The rising tide of early-onset colorectal cancer: a comprehensive review of epidemiology, clinical features, biology, risk factors, prevention, and early detection, Lancet Gastroenterol Hepatol. 7: 262–74 (2022)
2094	Frank A. Sinicrope, Increasing Incidence of Early-Onset Colorectal Cancer, N. Engl. J. Med. 86:1547-58 (Apr. 21, 2022)
2095	Frank A. Sinicrope, Lynch Syndrome-Associated Colorectal Cancer, N. Engl. J. Med. 379:764-73 (Aug. 23, 2018)
2096	Sargent et al., Defective mismatch repair as a predictive marker for lack of efficacy of fluorouracil-based adjuvant therapy in colon cancer, J. Clin. Oncol. 28:3219-3226 (July 10, 2010)
2097	Keung et al., The eighth edition American Joint Committee on Cancer (AJCC) melanoma staging system: implications for melanoma

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2098	Ogunwobi et al., Biomarkers in Colorectal Cancer: Current Research and Future Prospects, Int. J. Mol. Sci. 21, 5311 (2020)
2099	Kong et al., Prolonged surveillance of colorectal cancer patients after curative surgeries beyond five years of follow-up, Ann. Transl. Med. 7(21):608 (2019)
2100	Modulation of fluorouracil by leucovorin in patients with advanced colorectal cancer: evidence in terms of response rate, Advanced Colorectal Cancer Meta-Analysis Project 10:896:903 (1992)
2101	Dy et al., Long-term survivors of metastatic colorectal cancer treated with systemic chemotherapy alone: a North Central Cancer Treatment Group review of 3811 patients, N0144, Clin. Colorectal Cancer 8(2):88-93 (2009)
2102	Saltz et. al., Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer, Irinotecan Study Group, N. Engl. J. Med. 343(13):905-13 (2000)
2103	Sanoff et al., Five-year data and prognostic factor analysis of oxaliplatin and irinotecan combinations for advanced colorectal cancer: N9741, J. Clin. Oncol. 26:5721-5727 (2008)
2104	Hurwitz et al., Bevacizumab plus irinotecan, fluorouracil, and leucovorin for metastatic colorectal cancer, N. Engl. J. Med. 350(23):35-42 (June 3, 2004)
2105	Saltz et al., Phase II trial of cetuximab in patients with refractory colorectal cancer that expresses the epidermal growth factor receptor, J. Clin. Oncol. 22:1201-1208 (Apr. 1, 2004)
2106	Van Cutsem at al., Cetuximab and chemotherapy as initial treatment for metastatic colorectal cancer, N. Engl. J. Med. 360(14):1408-17 (Apr. 2, 2009)
2107	Van Cutsem et al., Open-label phase III trial of panitumumab plus best supportive care compared with best supportive care alone in patients with chemotherapy-refractory metastatic colorectal cancer, J. Clin. Oncol. 25(13):1658-64 (May 1, 2007)
2108	Tabernero et al., Aflibercept versus placebo in combination with fluorouracil, leucovorin and irinotecan in the treatment of previously treated metastatic colorectal cancer: prespecified subgroup analyses from the VELOUR trial, Eur. J. Cancer 50:320-331 (2014)

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2109	Venook et al., Effect of First-Line Chemotherapy Combined With Cetuximab or Bevacizumab on Overall Survival in Patients With KRAS Wild-Type Advanced or Metastatic Colorectal Cancer: A Randomized Clinical Trial, JAMA 317(23):2392-2401 (2017)
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2111	Lucas et al., A decade of advances in cytotoxic chemotherapy for metastatic colorectal cancer, Clin. Colorectal Cancer 10(4):238-44 (Dec. 2011)
2112	Modest et al., Treatment sequencing in metastatic colorectal cancer, Eur. J. Cancer 109:70-83 (2019)
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2118	Le et al., Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade, Science 357:409–413 (July 28, 2017)
2119	Ethical Guidelines, Ethics in Clinical Research, NIH Clinical Center, https://www.cc.nih.gov/recruit/ethics (last accessed Sept. 26, 2024)
2120	The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research (April 18, 1979)
2121	The Cancer Letter, Vol. 43, No. 38, Oct. 13, 2017
2122	The Cancer Letter, Vol. 48, No. 23, June 10, 2022
2123	How Beth Carner went from six weeks left to live with stage 4 colon cancer to complete remission, Cancer History Project (June 10, 2022), https://cancerhistoryproject.com/article/how-beth-carner-went-from-six-weeks-left-to-live-with-stage-4-colon-cancer-to-complete-remission/

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2124	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information (May 23, 2017)
2125	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information (Oct. 2015)
2126	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information (Aug. 2016)
2127	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information (Mar. 2017)
2128	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information (May 18, 2017)
2129	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information (June 2020)
2130	Declaration of Dung Le, M.D.
2131	Investigator Initiated Clinical Trial Research Agreement between The Johns Hopkins University and Merck Sharp & Dohme Corp., dated August 14, 2013
2132	O'Neil et al, Safety and antitumor activity of the anti-PD-1 antibody pembrolizumab in patients with advanced colorectal carcinoma, PLoS One (Dec. 28, 2017)
2133	FDA Grants Priority Review to Merck's Supplemental Biologics License Application (sBLA) Seeking Approval for KEYTRUDA® (pembrolizumab) for NewIndication in Microsatellite Instability-High Cancer. merck.com/news/fda-grants-priority-review-to-mercks-supplemental-biologics-license-application-sbla-seeking-approval-for-keytruda-pemb…
2134	News Release, Merck Makes $3 Million Charitable Donation to Support Swim Across America, Merck (Oct. 10, 2017), https://www.merck.com/news/merck-makes-3-million-charitable-donation-to-support-swim-across-america/
2135	ASCO 2015: Mismatch Repair Deficiency Predicts Response to Pembrolizumab Among Patients With Colorectal and Other Cancers, The ASCO Post (May 29, 2015), https://ascopost.com/News/27670
2136	Video interview, Dung T. Le, MD, and Axel Grothey, MD, on PD-1 Blockade in Tumors With Mismatch Repair Deficiency, 2015 ASCO Annual Meeting, recorded on May 31, 2015, https://ascopost.com/archive/meetings/2015-asco-annual-

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2137	Declaration of Ms. Jennifer Newberger
2138	K. Dickersin, Report from the panel on the Case for Registers of Clinical Trials at the Eighth Annual Meeting of the Society for Clinical Trials, Controlled Clinical Trials 9:76-81 (1988)
2139	D. Moher, Clinical-trial registration: a call for its implementation in Canada, CMAJ 149(11):1657-58 (Dec. 1, 1993)
2140	International Clinical Trials Registry Platform (ICTRP), World Health Organization, https://www.who.int/clinical-trials-registry-platform (last accessed Oct. 3. 2024)
2141	The Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115, Nov. 21, 1997
2142	Laine et al., Update on Trials Registration: Clinical Trial Registration: Looking Back and Moving Ahead, ICMJE (June 2007)
2143	Food and Drug Administration Amendments Act of 2007, Pub. L. 110–85, Sept. 27, 2007, 121 Stat. 823
2144	RESERVED
2145	About ClinicalTrials.gov, Nat'l Library of Medicine, ClinicalTrials.gov, https://clinicaltrials.gov/about-site/about-ctg
2146	Krleza-Jerić et al., 7th Revision of the Declaration of Helsinki: Good News for the Transparency of Clinical Trials, Croat. Med. J. 50:105-10 (2009)
2147	42 C.F.R. Pt. 11 (2024)
2148	42 U.S.C. § 282(j)
2149	Protocol Registration Data Element Definitions for Interventional and Observational Studies, Nat'l Library of Medicine, ClinicalTrials.gov, https://clinicaltrials.gov/policy/protocol-definitions
2150	21 U.S.C. § 331 - Prohibited acts
2151	21 U.S.C. § 333 - Penalties
2152	De Angelis et al., Clinical trial registration: a statement from the International Committee of Medical Journal Editors, Editorial, Clinical Trial Registration (2004)
2153	Response, The American Heritage dictionary of the English Language (5th ed. 2011)
2154	Response, Collins Dictionary (10th ed. 2009)
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2156	Response, The Chambers Dictionary (13th ed. 2016)
2157	Response, Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2158	Response, Cambridge Advanced Learner's Dictionary (4th ed. 2013)
2159	Response, Webster's Third New International Dictionary of the English Language (2002)
2160	Plaintiff Merck Sharp & Dohme LLC's Opening Brief Regarding Claim Construction, Merck Sharp & Dohme LLC v. The Johns Hopkins University, Case No. 1-22-cv-03059-JRR, D.I. 82 (D. Md. May 1, 2024)
2161	The Johns Hopkins University's Opening Claim Construction Brief, Merck Sharp & Dohme LLC v. The Johns Hopkins University, Case No. 1-22-cv-03059-JRR, D.I. 81 (D. Md. May 1, 2024)
2162	Plaintiff Merck Sharp & Dohme LLC's Responsive Brief Regarding Claim Construction, Merck Sharp & Dohme LLC v. The Johns Hopkins University, Case No. 1-22-cv-03059-JRR, D.I. 107 (D. Md. May 1, 2024)
2163	Stenographic Deposition of Alfred I. Neugut, M.D., Ph.D., MPH taken on August 8, 2024, Merck Sharp & Dohme LLC, v. The Johns Hopkins University, Case IPR2024-00240 (PTAB)
2164	EX1096 from '187 proceeding, IPR2024-00649, Ajani et al., National Comprehensive Cancer Network. Gastric cancer, version 2.2013: featured updates to the NCCN Guidelines, J. Natl Compr. Canc. Netw., 11(5):531-46 (May 1, 2013)
2165	Record History Tab, Study of MK03475 in Patients with Microsatellite Unstable (MSI) Tumors (Cohorts A, B, and C), National Library of Medicine, ClinicalTrials.gov (Jan. 4, 2016), https://clinicaltrials.gov/study/NCT01876511?tab=history&a=12#version-content-panel
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2167	Highly Confidential Attorney Eyes Only Document 1 – Protective Order Material

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2168	Highly Confidential Attorney Eyes Only Document 2 – Protective Order Material
2169	Highly Confidential Attorney Eyes Only Document 4 – Protective Order Material
2170	Highly Confidential Attorney Eyes Only Document 5 – Protective Order Material
2171	Highly Confidential Attorney Eyes Only Document 6 – Protective Order Material
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2174	Highly Confidential Attorney Eyes Only Document 9 – Protective Order Material
2175	André et al., KEYNOTE-177 Investigators. Pembrolizumab in Microsatellite-Instability-High Advanced Colorectal Cancer, N. Engl. J. Med., 383(23):2207-2218 (Dec. 3, 2023)
2176	Robin Marantz Henig, Could Immunotherapy Lead the Way to Fighting Cancer?, Smithsonian Magazine (April 2018), https://www.smithsonianmag.com/innovation/immunotherapy-lead-way-fighting-cancer-180968392/
2177	Exhibit 8, The Johns Hopkins University's Infringement of U.S. Patent No. 11,649,387 by KEYTRUDA claim chart, Merck Sharp & Dohme LLC v. The Johns Hopkins University, Case No. 1-22-cv-03059-JRR
2178	Marques et al., Tumor mutational burden in colorectal cancer: Implications for treatment, Crit. Rev. Oncol. Hematol. (Apr. 12, 2024)
2179	Le et al., Phase II Open-label study of pembrolizumab in treatment-refractory, microsatellite instability-high/mismatch repair-deficient metastatic colorectal cancer: Keynote-164, J. Clin. Oncol. (38:1(1-19) (2019)
2180	Anagha Nair, High Impact Journals 2024 – Key to deciding the right journal?, Enago Academy (Feb. 19, 2024), https://www.enago.com/academy/top-high-impact-factor-journals/
2181	Highly Confidential Attorney Eyes Only Document 3 – Protective Order Material

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2182	Highly Confidential Attorney Eyes Only Document 10 – Protective Order Material
2183	Email correspondence from Luis Diaz to Amy Meister and Mr. Robert Iannone dated December 27, 2012, production document Bates stamped JHU_MERCK00027065
2184	Breakthroughs in Immunotherapy, Swim Across America, https://www.swimacrossamerica.org/site/SPageNavigator/Breakthroughs_35.html (last accessed Sept. 26, 2024)
2185	RESERVED
2186	Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics, U.S. Dept. of HHS, FDA (May 2014)
2187	Highly Confidential Attorney Eyes Only Document 11 – Protective Order Material
2188	Highly Confidential Attorney Eyes Only Document 12 – Protective Order Material
2189	Email correspondence from Preston K. Ratliff to Nicholas Stephens and Casey Kraning dated August 20, 2024
2190	RESERVED
2191	Segers Declaration (Highly Confidential Attorney Eyes Only – Protective Order Material)
2192	How Does KEYTRUDA® Work?, KEYTRUDA, https://www.keytruda.com/how-does-keytruda-work/#how-keytruda-works (last accessed Oct. 2, 2024)
2193	Merck & Co., Inc. 2014 SEC Form 10-K, dated February 27, 2015
2194	Merck & Co., Inc. 2023 SEC Form 10-K, dated February 26, 2024
2195	Merck Sharp & Dohme LLC Private Company Profile at S&P Capital IQ
2196	Johns Hopkins University Educational Institution Profile at S&P Capital IQ
2197	Research & Faculty, Johns Hopkins University, https://www.jhu.edu/research/ (last accessed Oct. 3, 2024)
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2199	Is KEYTRUDA® Right for You?, KEYTRUDA, https://www.keytruda.com/msi-h/treatment-options (last accessed Oct. 3, 2024)

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2201	Boland et al., Microsatellite Instability in Colorectal Cancer Boland, Gastroenterology Volume 138, Issue 6, 2073 - 2087.e3 (2010)
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2203	Immune Checkpoint Inhibitors and Their Side Effects, American Cancer Society, https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/immune-checkpoint-inhibitors.html (last accessed Oct. 3, 2024)
2204	How KEYTRUDA® is Given, KEYTRUDA, https://www.keytruda.com/taking-keytruda/ (last accessed Oct. 3, 2024)
2205	Accelerated Approval Letter to Nahid Latif of Merck Sharp and Dohme, Corp. from Patricia Keegan of the Department of Health and Human Services dated May 23, 2017 (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/125514Orig1s014ltr.pdf)
2206	News Release, 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, Merck (March 29, 2023)
2207	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information. August 2024
2208	Merck & Co., Inc., Q2 2018 Earnings Call, dated July 27, 2018
2209	Merck & Co., Inc., Q3 2018 Earnings Call, dated October 25, 2018
2210	Merck & Co., Inc., Q4 2018 Earnings Call, dated February 01, 2019
2211	Merck & Co., Inc., Q1 2019 Earnings Call, dated April 30, 2019
2212	List of Targeted Therapy Drugs Approved for Specific Types of Cancer, National Cancer Institute, https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/approved-drug-list (last accessed Oct. 3, 2024)
2213	Bristol-Myers Squibb Company, Q2 2018 Earnings Call, dated July 26, 2018

Exhibit Number	Description
2214	Bristol-Myers Squibb Company, Q3 2018 Earnings Call, dated October 25, 2018
2215	Bristol-Myers Squibb Company, Q1 2019 Earnings Call, dated April 25, 2019
2216	Merck & Co., Inc. 2017 SEC Form 10-K, dated February 27, 2018
2217	Merck & Co., Inc. 2018 SEC Form 10-K, dated February 27, 2019
2218	Merck & Co., Inc. 2019 SEC Form 10-K, dated February 26, 2020
2219	Merck & Co., Inc. 2020 SEC Form 10-K, dated February 25, 2021
2220	Merck & Co., Inc. 2021 SEC Form 10-K, dated February 25, 2022
2221	Merck & Co., Inc. 2022 SEC Form 10-K, dated February 24, 2023
2222	RESERVED
2223	Siegel et al., Cancer Statistics, 2017, CA Cancer J. Clin., 67(1):7-30 (Jan-Feb 2017)
2224	Siegel et al., Cancer Statistics, 2018, CA Cancer J. Clin., 68(1):7-30 (Jan-Feb 2018)
2225	Siegel et al., Cancer Statistics, 2019, CA Cancer J. Clin., 69(1):7-34 (Jan-Feb 2019)
2226	Siegel et al., Cancer Statistics, 2020, CA Cancer J. Clin., 70(1):7-30 (Jan-Feb 2020)
2227	Siegel et al., Cancer Statistics, 2021, CA Cancer J. Clin., 71(1):7-33 (Jan-Feb 2021)
2228	Siegel et al., Cancer Statistics, 2022, CA Cancer J. Clin., 72(1):7-33 (Jan-Feb 2022)
2229	Siegel et al., Cancer Statistics, 2023, CA Cancer J. Clin., 73(1):17-48 (2023)
2230	Microsatellite Instability Biomarker (MSI-H), Colorectal Cancer Alliance, colorectalcancer.org/treatment/types-treatment/why-biomarkers-matter/types-biomarkers/microsatellite-instability (last accessed Oct. 3, 2024)
2231	Merck Q2 2017 Earnings Call, dated July 28, 2017
2232	Abel et al., Cancer-Related Direct-to-Consumer Advertising: Awareness, Perceptions, and Reported Impact Among Patients Undergoing Active Cancer Treatment, J. Clin. Oncol., 27(25):4182-7 (Sept. 1, 2009)
2233	Cost Information and Financial Help, KEYTRUDA (pembrolizumab), https://www.keytruda.com/financial-support/ (last accessed Oct. 3, 2024)

Exhibit Number	Description
2234	Pricing Information for OPDIVO®, Bristol Myers Squibb, https://www.bmspricinginformation.com/opdivo (last accessed Oct. 3, 2024)
2235	Pricing Information for OPDIVO® + YERVOY®, Bristol Myers Squibb, https://www.bmspricinginformation.com/opdivo (last accessed Oct. 3, 2024)
2236	Bristol Myers Squibb. YERVOY® (ipilimumab) Full Prescribing Information. February 2024
2237	Alex Watt, Keytruda and Opdivo: a decade review, Pharmaceutical Technology (Sept. 30, 2024), https://www.pharmaceutical-technology.com/analyst-comment/keytruda-opdivo-decade-review/
2238	Merck 2015 SEC Form 10-K, dated February 26, 2016 (Excerpt)
2239	Merck 2016 SEC Form 10-K, dated February 28, 2017 (Excerpt)
2240	Bristol-Myers Squibb 2017 SEC Form 10-K (Excerpt)
2241	Bristol-Myers Squibb 2018 SEC Form 10-K (Excerpt)
2242	Bristol-Myers Squibb 2019 SEC Form 10-K (Excerpt)
2243	Bristol-Myers Squibb 2020 SEC Form 10-K (Excerpt)
2244	Bristol-Myers Squibb 2021 SEC Form 10-K (Excerpt)
2245	Bristol-Myers Squibb 2022 SEC Form 10-K (Excerpt)
2246	Bristol-Myers Squibb 2023 SEC Form 10-K (Excerpt)
2247	Merck SEC Form 10-Q, for quarterly period ended March 31, 2018 (Excerpt)
2248	Merck SEC Form 10-Q, for quarterly period ended March 31, 2023 (Excerpt)
2249	Merck SEC Form 10-Q, for quarterly period ended June 30, 2023 (Excerpt)
2250	Merck SEC Form 10-Q, for quarterly period ended September 30, 2023 (Excerpt)
2251-2300	RESERVED
2301	U.S. Patent No. 11,591,393
2302	Excerpts from Prosecution History of U.S. Patent No. 11,591,393
2303-2499	RESERVED
2500	Declaration of Frank E. Scherkenbach in support of Motion for Pro Hac Vice Admission

Exhibit Number	Description
2501	Declaration of Corrin N. Drakulich in support of Motion for Pro Hac Vice Admission
2502	Declaration of Dr. Christina D. Brown-Marshall in support of Motion for Pro Hac Vice Admission
2503	Declaration of Dr. Casey M. Kraning in support of Motion for Pro Hac Vice Admission
2504	Declaration of Madelyn S. McCormick in support of Motion for Pro Hac Vice Admission
2505	Declaration of Sarah E. Jack in support of Motion for Pro Hac Vice Admission
2506	Declaration of Caroline (Gracie) Koonce

Pursuant to 37 C.F.R. § 42.10(c), Patent Owner, The Johns Hopkins University ("Patent Owner" or "JHU") respectfully requests that the Board recognize Caroline (Gracie) Koonce as counsel *pro hac vice* in this proceeding. Patent Owner seeks the counsel of Ms. Koonce due to her experience in representing JHU in other patent-related matters and particularly due to her familiarity with the substantive and technical issues involved in this proceeding. This motion is authorized by the Notice of Filing Date Accorded to Petition and Time for Filing Patent Owner Preliminary Response that was mailed on April 11, 2024.

Petitioner does not oppose this motion.

Statement of Facts

Ms. Koonce is a patent litigation attorney with 2 years of experience representing clients in cases involving, *inter alia*, biochemistry and a variety of chemical and pharmaceutical innovations. Ms. Koonce regularly litigates patent cases before federal district courts and through her practice in such cases, Ms. Koonce has gained substantial experience in the various phases of patent litigation. Ms. Koonce's biography is attached as Appendix A of Exhibit 2506.

Ms. Koonce also has particular experience and familiarity with the substantive and technical issues involved in this inter partes review proceeding. In a related matter, Merck Sharp & Dohme LLC v. The Johns Hopkins University,

Case No. 1:22-CV-03059-JRR at the United States District Court for the District of Maryland, Ms. Koonce served as counsel for and specifically handled the patent-at-issue in this proceeding.

Declaration of Individual Seeking to Appear

This Motion for *Pro Hac Vice* Admission is accompanied by a Declaration of Caroline (Gracie) Koonce.

Accordingly, JHU submits that there is good cause under 37 C.F.R. § 42.10(c) for the Board to recognize Caroline (Gracie) Koonce as counsel *pro hac vice* during this proceeding.

Respectfully submitted,

Date: 03/18/2025

/Nicholas W. Stephens/

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e)(4), the undersigned certifies that on March 18, 2025, a complete and entire copy of this Patent Owner's Motion for Pro Hac Vice and Exhibit 2506 were provided via email, to the Petitioner by serving the email correspondence addresses of record as follows:

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