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 IPR2024-00625
Patent 11,339,219 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
2009	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Mar. 6, 2022) retrieved from File History of U.S. Patent No. 11,325,974 (U.S. Patent Application No. 17/131,326)

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2010	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Feb. 28, 2022) retrieved from File History of U.S. Patent No. 11,325,975 (U.S. Patent Application No. 17/131,339)
2011	RESERVED
2012	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Mar. 23, 2022) retrieved from File History of U.S. Patent No. 11,629,187 (U.S. Patent Application No. 17/354,656)
2013	RESERVED
2014	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Mar. 21, 2022) retrieved from File History of U.S. Patent No. 11,643,462 (U.S. Patent Application No. 17/354,653)
2015	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Dec. 17, 2021) retrieved from File History of U.S. Patent No. 11,649,287 (U.S. Patent Application No. 17/465,096)
2016-2017	RESERVED
2018	Office Action (Nov. 29, 2017) retrieved from File History of U.S. Patent Application No. 15/611,017
2019	Reply to Action of November 29, 2017 (May 29, 2018) retrieved from File History of U.S. Patent Application No. 15/611,017
2020	Information Disclosure Statement Signed by Examiner Mark Halvorson (Date Considered: Oct. 6, 2019) retrieved from File History of U.S. Patent Application No. 15/523,451
2021	Sidney Kimmel Comprehensive Cancer Center (Clinical Trial Announcement NCT01876511) (June 12, 2013) (updated Oct. 6, 2017)
2022	Bacher et al., Development of a Fluorescent Multiplex Assay for Detection of MSI-High Tumors, 20(4-5) Disease Markers 237-50 (2004)
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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)
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2031	Plaintiff Merck's Local Rule 804.1(C) Initial Disclosure of Invalidity Contentions, Civil Action No. JRR-22-3059
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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2045	Boland et al., Microsatellite Instability in Colorectal Cancer, 138(6) Gastroenterology 2073-87 (May 2010)
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2047	Kloor et al., Immune Evasion of Microsatellite Unstable Colorectal Cancers, 127(5) Int'l J. Cancer 1001-10 (Sept. 1, 2010)
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2055	Maryland, U.S. District Court – Judicial Caseload Profile, updated Dec. 2023, available at https://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile1231.2023.pdf
2056-2059	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)
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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/
2071	Letter to Magistrate Judge Aslan from The Johns Hopkins University, Merck Sharp & Dohme LLC v. The Johns Hopkins University, Case No. 1-22-cv-03059-JRR, D.I. 100 (D. Md. May 14, 2024)
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)
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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/
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2078	Jared S. Hopkins, Merck Keeps Striking Out on Expanding Its Cancer-Drug Juggernaut, The Wall Street Journal (April 26, 2023), https://www.wsj.com/articles/merck-keeps-striking-out-on-expanding-its-cancer-drug-juggernaut-637c83d4
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
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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)
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)
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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)
2088	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
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)

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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)
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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)
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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)

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2116	Robert et al., Pembrolizumab versus Ipilimumab in Advanced Melanoma, N. Engl. J. Med. 372(26):2521-32 (June 25, 2015)
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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/
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)
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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-

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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-meeting/dung-t-le-md-and-axel-grothey-md-on-pd-1-blockade-in-tumors-with-mismatch-repair-deficiency/
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)
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2141	The Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115, Nov. 21, 1997
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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)
2153-2162	RESERVED
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
2166	Record History Tab, Study of MK03475 in Patients with Microsatellite Unstable (MSI) Tumors (Cohorts A, B, and C), National Library of Medicine, ClinicalTrials.gov, Compare between June 10, 2013 and Jan. 4, 2016, https://clinicaltrials.gov/study/NCT01876511?tab=history&a=1&b=12#version-content-panel
2167	Highly Confidential Attorney Eyes Only Document 1 – Protective Order Material
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

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2171	Highly Confidential Attorney Eyes Only Document 6 – Protective Order Material
2172	Highly Confidential Attorney Eyes Only Document 7 – Protective Order Material
2173	Highly Confidential Attorney Eyes Only Document 8 – Protective Order Material
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2191	Declaration of Mr. Brian Segers (Highly Confidential Attorney Eyes Only – Protective Order Material)
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2207	Merck & Co., Inc. KEYTRUDA® (pembrolizumab), Full Prescribing Information. August 2024
2208	Merck & Co., Inc., Q2 2018 Earnings Call, dated July 27, 2018
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Exhibit Number	Description
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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)
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2282	Stenographic Deposition of Alfred I. Neugut, M.D., Ph.D., MPH taken on January 6, 2025
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2287	Support & Resources | JEMPERLI (dostarlimab-gxly), available at https://jemperli.com/endometrial-cancer/support-resources/
2288	GSK 2021 Annual Report
2289	GSK 2022 Annual Report
2290	GSK 2023 Annual Report
2291	Yearly average currency exchange rates, Internal Revenue Service
2292	RESERVED
2293	Segers Declaration in IPR2024-00240 (Highly Confidential Attorney Eyes Only – Protective Order Material)
2294-2400	RESERVED
2401	Copy of EX1001, U.S. Pat. No. 10,934,356, marked at January 6th Deposition of Dr. Neugut
2402	Copy of EX1005, ClinicalTrials.gov, NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," (June 10, 2013), marked at January 6th Deposition of Dr. Neugut
2403	Board Email regarding Motion to Seal dated October 4, 2024
2404-2499	RESERVED
2500	Declaration of Frank E. Scherkenbach in Support of Notice of Intent to Designate a Provisionally Recognized PTAB Attorney
2501	Declaration of Corrin N. Drakulich in Support of Notice of Intent to Designate a Provisionally Recognized PTAB Attorney
2502	Declaration of Christina D. Brown-Marshall in Support of Notice of Intent to Designate a Provisionally Recognized PTAB Attorney

Exhibit Number	Description
2503	Declaration of Casey M. Kraning in Support of Notice of Intent to Designate a Provisionally Recognized PTAB Attorney
2504	Declaration of Madelyn S. McCormick in Support of Notice of Intent to Designate a Provisionally Recognized PTAB Attorney
2505	Declaration of Sarah E. Jack in Support of Notice of Intent to Designate a Provisionally Recognized PTAB Attorney
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 March 26, 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

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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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