

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 IPR2024-00622
Patent 10,934,356

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, <i>Cancer Drug Proves to Be Effective Against Multiple Tumors</i> , N.Y. TIMES (June 8, 2017), https://www.nytimes.com/2017/06/08/health/cancer-drug-keytruda-tumors.html
2006	Laurie McGinley, <i>'This is not the end': Using immunotherapy and a genetic glitch to give cancer patients hope</i> , 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/
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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)
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	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Mar. 6, 2022) retrieved from File History of U.S. Patent No. 11,339,219 (U.S. Patent Application No. 17/131,328)
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	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: July 16, 2022) retrieved from File History of U.S. Patent No. 11,634,491 (U.S. Patent Application No. 17/739,278)
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	Information Disclosure Statement Signed by Examiner Lisa V. Cook (Date Considered: Sept. 10, 2022) retrieved from File History of U.S. Patent No. 11,718,668 (U.S. Patent Application No. 17/739,274)
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Exhibit Number	Description
	History of U.S. Patent No. 11,753,468 (U.S. Patent Application No. 17/952,919)
2018	Office Action (Nov. 29, 2017) retrieved from File History of U.S. Patent Application No. 15/611,017
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2023	Diaz et al., <i>Liquid Biopsies: Genotyping Circulating Tumor DNA</i> , 32(6) J. Clinical Oncology 579-86 (Feb. 20, 2014)
2024	Brahmer et al., <i>Phase I Study of Single-Agent Anti-Programmed Death-1 (MDX-1106) in Refractory Solid Tumors: Safety, Clinical Activity, Pharmacodynamics, and Immunologic Correlates</i> , 28(19) J. Clinical Oncology 3167-75 (July 1, 2010)
2025	The Cancer Genome Atlas Network, <i>Comprehensive Molecular Characterization of Human Colon and Rectal Cancer</i> , 487 Nature 330-37 (July 19, 2012)
2026	Mandrekar et al., <i>All-Comers versus Enrichment Design Strategy in Phase II Trials</i> , 6(4) J. Thoracic Oncology 658-60 (Apr. 1, 2011)
2027	Freidlin et al., <i>Randomized Clinical Trials With Biomarkers: Design Issues</i> , 102(3) J. Nat'l Cancer Inst. 152-60 (Feb. 3, 2010)
2028	Malik et al., <i>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</i> , 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

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2032	NIH NATIONAL CANCER INSTITUTE, <i>What is Cancer?</i> (last updated Oct. 11, 2021), https://www.cancer.gov/about-cancer/understanding/what-is-cancer
2033	Weiss, <i>Open Questions: Knowing Who's Who in Multicellular Animals is Not Always as Simple as We Imagine</i> , 16 BMC Biology Article number: 115 (Oct. 15, 2018)
2034	Mumphrey et al., <i>Distinct Mutational Processes Shape Selection of MHC Class I and Class II Mutations Across Primary and Metastatic Tumors</i> , 42(8) Cell Reports 112965 1-20 (Aug. 29, 2023)
2035	Jenkins et al., <i>Antigen Presentation by Chemically Modified Splenocytes Induces Antigen-Specific T Cell Unresponsiveness In Vitro and In Vivo</i> , 165(2) J. Experimental Med. 302-19 (Feb. 1, 1987)
2036	Wherry et al., <i>Viral Persistence Alters CD8 T-Cell Immunodominance and Tissue Distribution and Results in Distinct Stages of Functional Impairment</i> , 77(8) J. Virology 4911-27 (Apr. 2003)
2037	Lotze et al., <i>Lysis of Fresh and Cultured Autologous Tumor by Human Lymphocytes Cultured in T-Cell Growth Factor</i> , 41 Cancer Research 4420-25 (Nov. 1981)
2038	Briukhovetska et al., <i>Interleukins in Cancer: From Biology to Therapy</i> , 21 Nature Reviews Cancer 481-99 (June 3, 2021)
2039	Bod et al., <i>B-Cell-Specific Checkpoint Molecules That Regulate Anti-Tumour Immunity</i> , 619 Nature 348-56 (June 21, 2023)
2040	Wang et al., <i>CD19⁺CD24^{hi}CD38^{hi}Bregs Involved in Downregulate Helper T Cells and Upregulate Regulatory T Cells in Gastric Cancer</i> , 6(32) Oncotarget 33486-99 (Sept. 10, 2015)
2041	Michaud et al., <i>Regulatory B Cells in Cancer</i> , 299(1) Immunological Reviews 74-92 (Dec. 23, 2020)
2042	Nakhoda et al., <i>Addressing Recent Failures in Immuno-Oncology Trials to Guide Novel Immunotherapeutic Treatment Strategies</i> , 34 Pharmaceutical Medicine 83-91 (Mar. 10, 2020)
2043	Korman et al., <i>The Foundations of Immune Checkpoint Blockade and the Ipilimumab Approval Decennial</i> , 21 Nature Reviews Drug Discovery 509-28 (July 2022)

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2045	Boland et al., <i>Microsatellite Instability in Colorectal Cancer</i> , 138(6) <i>Gastroenterology</i> 2073-87 (May 2010)
2046	Branch et al., <i>Immune Surveillance in Colorectal Carcinoma</i> , 9 <i>Nature Genetics</i> 231-32 (Mar. 1995)
2047	Kloor et al., <i>Immune Evasion of Microsatellite Unstable Colorectal Cancers</i> , 127(5) <i>Int'l J. Cancer</i> 1001-10 (Sept. 1, 2010)
2048	Zhong et al., <i>Comparison of the Molecular and Cellular Phenotypes of Common Mouse Syngeneic Models with Human Tumors</i> , 21 <i>BMC Genomics</i> Article number: 2 (Jan. 2, 2020)
2049	Thomas et al., <i>Advancing Translational Research for Colorectal Immuno-Oncology</i> , 129 <i>British J. Cancer</i> 1442-50 (Aug. 10, 2023)
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2052	IPR2024-00240, Paper No. 1 (PTAB, Nov. 30, 2023)
2053	<i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , 1:22-cv-03059-JRR, ECF 67, Claim Construction Order
2054	Information Disclosure Statement Signed by Examiner Mark Halvorson (Date Considered: Dec. 17, 2021) retrieved from File History of U.S. Patent Application No. 17/465,101
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

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	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 13 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. 17-13 (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/
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., <i>Novel Mouse Models for Cancer Immunology</i> , Annual Review of Cancer Biology 6:269-91 (2022)
2074	Sun et al., <i>Immune checkpoint therapy for solid tumours: clinical dilemmas and future trends</i> , Signal Transduction Targeted Therapy, 8:320 (2023)

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2075	Dobosz et al., <i>Challenges of the Immunotherapy: Perspectives and Limitations of the Immune Checkpoint Inhibitor Treatment</i> Int. J. Mol. Sci., 23, 2847:1-17 (2022)
2076	Jonathan Gardner, <i>Merck suffers bad week as 3 Keytruda combination trials fail</i> , BioPharma Dive (Dec. 8, 2023), https://www.biopharmadive.com/news/merck-keytruda-combination-trials-fail-patent-cliff/701975/
2077	Angus Liu, <i>Merck's Keytruda flunks pivotal studies in lung and skin cancers</i> , Fierce Pharma (Aug. 29, 2024), https://www.fiercepharma.com/pharma/mercks-keytruda-flunks-early-stage-lung-and-skin-cancer-tests
2078	Jared S. Hopkins, <i>Merck Keeps Striking Out on Expanding Its Cancer-Drug Juggernaut</i> , The Wall Street Journal (April 26, 2023), https://www.wsj.com/articles/merck-keeps-striking-out-on-expanding-its-cancer-drug-juggernaut-637c83d4
2079	<i>Merck's trial of Keytruda regimen fails to meet primary endpoint</i> , 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., <i>A gene encoding an antigen recognized by 7cytolytic T lymphocytes on a human melanoma</i> , Science 254:1643-47 (Dec. 13, 1991)
2082	Lawrence et al., <i>Mutational heterogeneity in cancer and the search for new cancer-associated genes</i> , Nature 499:214-18 (July 11, 2013)
2083	Shigehisa Kitano et al., <i>Myeloid-derived suppressor cell quantity prior to treatment with ipilimumab at 10mg/kg to predict for overall survival in patients with metastatic melanoma</i> , J. of Clin. Oncology 30(15), 2518 (May 20, 2012)
2084	Snyder et al., <i>Genetic basis for clinical response to CTLA-4 blockade in melanoma</i> , N. Engl. J. Med. 371(23):2189-99 (Dec. 4 2014)

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2085	Chan et al., <i>Genetic Basis for Clinical Response to CTLA-4 Blockade in Melanoma</i> , N. Engl. J. Med. 373(20):1984 (Nov. 12, 2015)
2086	McGranahan et al., <i>Clonal neoantigens elicit T cell immunoreactivity and sensitivity to immune checkpoint blockade</i> , Science 351(6280):1463-69 (Mar. 25, 2016)
2087	Hellmann et al., <i>Tumor Mutational Burden and Efficacy of Nivolumab Monotherapy and in Combination with Ipilimumab in Small-Cell Lung Cancer</i> , 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., <i>Significance and implications of FDA approval of pembrolizumab for biomarker-defined disease</i> , J. ImmunoTher. Cancer 6:35 (May 14, 2018)
2090	Declaration of Dr. Richard Goldberg
2091	Bray et al., <i>Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries</i> , CA Cancer J. Clin. 74:229-263 (2024)
2092	Zeineddine et al., <i>Survival improvement for patients with metastatic colorectal cancer over twenty years</i> , NPJ Precis. Oncol. 7:16 (2023)
2093	Patel et al., <i>The rising tide of early-onset colorectal cancer: a comprehensive review of epidemiology, clinical features, biology, risk factors, prevention, and early detection</i> , Lancet Gastroenterol Hepatol. 7: 262–74 (2022)
2094	Frank A. Sinicrope, <i>Increasing Incidence of Early-Onset Colorectal Cancer</i> , N. Engl. J. Med. 86:1547-58 (Apr. 21, 2022)
2095	Frank A. Sinicrope, <i>Lynch Syndrome-Associated Colorectal Cancer</i> , N. Engl. J. Med. 379:764-73 (Aug. 23, 2018)
2096	Sargent et al., <i>Defective mismatch repair as a predictive marker for lack of efficacy of fluorouracil-based adjuvant therapy in colon cancer</i> , J. Clin. Oncol. 28:3219-3226 (July 10, 2010)
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2100	<i>Modulation of fluorouracil by leucovorin in patients with advanced colorectal cancer: evidence in terms of response rate</i> , Advanced Colorectal Cancer Meta-Analysis Project 10:896:903 (1992)
2101	Dy et al., <i>Long-term survivors of metastatic colorectal cancer treated with systemic chemotherapy alone: a North Central Cancer Treatment Group review of 3811 patients</i> , N0144, Clin. Colorectal Cancer 8(2):88-93 (2009)
2102	Saltz et. al., <i>Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer</i> , Irinotecan Study Group, N. Engl. J. Med. 343(13):905-13 (2000)
2103	Sanoff et al., <i>Five-year data and prognostic factor analysis of oxaliplatin and irinotecan combinations for advanced colorectal cancer: N9741</i> , J. Clin. Oncol. 26:5721-5727 (2008)
2104	Hurwitz et al., <i>Bevacizumab plus irinotecan, fluorouracil, and leucovorin for metastatic colorectal cancer</i> , N. Engl. J. Med. 350(23):35-42 (June 3, 2004)
2105	Saltz et al., <i>Phase II trial of cetuximab in patients with refractory colorectal cancer that expresses the epidermal growth factor receptor</i> , J. Clin. Oncol. 22:1201-1208 (Apr. 1, 2004)
2106	Van Cutsem et al., <i>Cetuximab and chemotherapy as initial treatment for metastatic colorectal cancer</i> , N. Engl. J. Med. 360(14):1408-17 (Apr. 2, 2009)
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2108	Tabernero et al., <i>Aflibercept versus placebo in combination with fluorouracil, leucovorin and irinotecan in the treatment of previously treated metastatic colorectal cancer: prespecified</i>

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2109	Venook et al., <i>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</i> , JAMA 317(23):2392-2401 (2017)
2110	McRee et al., <i>Optimal management of metastatic colorectal cancer: current status</i> , Drugs 71(7):869-884 (2011)
2111	Lucas et al., <i>A decade of advances in cytotoxic chemotherapy for metastatic colorectal cancer</i> , Clin. Colorectal Cancer 10(4):238-44 (Dec. 2011)
2112	Modest et al., <i>Treatment sequencing in metastatic colorectal cancer</i> , Eur. J. Cancer 109:70-83 (2019)
2113	Grothey et al., <i>Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial</i> , Lancet 381: 303–12 (Jan. 26, 2013)
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2116	Robert et al., <i>Pembrolizumab versus Ipilimumab in Advanced Melanoma</i> , 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

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2123	<i>How Beth Carner went from six weeks left to live with stage 4 colon cancer to complete remission</i> , 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)
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, <i>Safety and antitumor activity of the anti-PD-1 antibody pembrolizumab in patients with advanced colorectal carcinoma</i> , PLoS One (Dec. 28, 2017)
2133	FDA Grants Priority Review to Merck’s Supplemental Biologics License Application (sBLA) Seeking Approval for KEYTRUDA® (pembrolizumab) for New Indication 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, <i>Merck Makes \$3 Million Charitable Donation to Support Swim Across America</i> , Merck (Oct. 10, 2017), https://www.merck.com/news/merck-makes-3-million-charitable-donation-to-support-swim-across-america/
2135	<i>ASCO 2015: Mismatch Repair Deficiency Predicts Response to Pembrolizumab Among Patients With Colorectal and Other</i>

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	<i>Cancers</i> , 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, <i>Controlled Clinical Trials</i> 9:76-81 (1988)
2139	D. Moher, <i>Clinical-trial registration: a call for its implementation in Canada</i> , <i>CMAJ</i> 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., <i>Update on Trials Registration: Clinical Trial Registration: Looking Back and Moving Ahead</i> , <i>ICMJE</i> (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., <i>7th Revision of the Declaration of Helsinki: Good News for the Transparency of Clinical Trials</i> , <i>Croat. Med. J.</i> 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

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2151	21 U.S.C. § 333 - Penalties
2152	De Angelis et al., <i>Clinical trial registration: a statement from the International Committee of Medical Journal Editors</i> , 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, <i>Merck Sharp & Dohme LLC, v. The Johns Hopkins University</i> , Case IPR2024-00240 (PTAB)
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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 25, 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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