

Filed: December 2, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC.,
Petitioner,

v.

MODERNA TX, INC.,
Patent Owner.

Case IPR2023-01358
Patent No. 10,702,600

PATENT OWNER'S CORRECTED EXHIBIT LIST

Patent Owner contacted the Board on November 26, 2024 seeking leave to file an updated Exhibit List in IPR2023-01358 (U.S. Patent No. 10,702,600) to correct typographical errors in the recent Exhibit List filed with Patent Owner's Sur-Reply on October 16, 2024 (Paper 72 Sealed, Paper 73 Redacted). In an email dated November 27, 2024 (attached as Appendix A), the Board granted Patent Owner's request. The corrected Exhibit List is hereby submitted for IPR2023-01358 in accordance with the Board's email.

Exhibit	Description
2001	Stanley A. Plotkin, <i>Vaccines: Past, Present and Future</i> , 11 Nature Medicine Supplement 55 (2005)
2002	Lynne Cassimeris et al., <i>Lewin's Cells</i> (2d ed.) Jones & Bartlett Publishers (2011)
2003	National Human Genome Research Institute, <i>Central Dogma</i> , https://www.genome.gov/genetics-glossary/Central-Dogma
2004	National Human Genome Research Institute, <i>Double Helix</i> , https://www.genome.gov/genetics-glossary/Double-Helix
2005	Luis A. Brito et al., <i>A Cationic Nanoemulsion for the Delivery of Next-Generation RNA Vaccines</i> , 22 Molecular Therapy 2118 (2014)
2006	<i>Reserved</i>
2007	S Withoff et al., <i>Replication-defective Recombinant Semliki Forest Virus Encoding GM-CSF as a Vector System for Rapid and Facile Generation of Autologous Human Tumor Cell Vaccines</i> , 20 Gene Therapy 1515 (2001)
2008	Alexander E. Gorbalenya, <i>The Species Severe Acute Respiratory Syndrome-Related Coronavirus: Classifying 2019-nCoV and Naming It SARS-CoV-2</i> , 5 Nature Microbiology 536 (2020)
2009	Andrew M.Q. King et al., <i>Virus Taxonomy: Classification and Nomenclature of Viruses</i> , Elsevier Academic Press (2012)
2010	Package Insert for Spikevax (COVID-19 Vaccine, mRNA) – 2023-2024 Formula
2011	Civil Docket Report for <i>ModernaTX, Inc. et al. v. Pfizer Inc. et al.</i> , C.A. No. 22-11378-RGS (D. Mass.)
2012	Complaint, <i>ModernaTX, Inc. et al. v. Pfizer Inc et al.</i> , C.A. No. 22-11378, Dkt. No. 1 (D. Mass, Aug. 26, 2022)

Exhibit	Description
2013	United States District Courts – National Judicial Caseload Profile, Federal Court Management Statistics (June 2023), https://www.uscourts.gov/sites/default/files/data_tables/fcms_na_dist_profile0630.2023.pdf
2014	Excerpts from Defendants’ Supplemental Patent-Related Disclosures, Exhibit C – Invalidity Contentions of U.S. Patent No. 10,702,600 (June 27, 2023)
2015	<i>Reserved</i>
2016	U.S. Patent No. 10,933,127 File History
2017	Excerpts from U.S. Patent No. 10,702,599 File History
2018	Excerpts from U.S. Patent No. 10,064,934 File History
2019	U.S. Patent Application Publication No. 2014/0193482 (“the ’482 Publication”)
2020	International Patent Publication No. WO 2005/027963 (“Nabel”)
2021	Andrew J. Geall, <i>Nonviral Delivery of Self-Amplifying RNA Vaccines</i> , 109 Proceedings of the Nat’l Acad. of Sci. 14604 (2012) (“Geall 2012”)
2022	International Patent Publication No. WO 2003/072720 (“Haller”)
2023	<i>Reserved</i>
2024	Karl-Josef Kallen et al., <i>A Novel, Disruptive Vaccination Technology: Self-Adjuvanted RNActive Vaccines</i> , 9 Human Vaccines & Immunotherapeutics 2263 (2013)
2025	Benjamin Petsch, <i>Protective Efficacy of In Vitro Synthesized, Specific mRNA Vaccines Against Influenza A Virus Infection</i> , 30 Nature Biotechnology 1210 (2012)
2026	U.S. Patent No. 10,487,332 File History

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2027	Norbert Pardi et al., <i>mRNA Vaccine – A New Era in Vaccinology</i> , 17 Nature Reviews 261 (2018)
2028	Laura DeFrancesco, <i>The ‘Anti-Hype’ Vaccine</i> , 35 Nature Biotechnology 193 (2017)
2029	Harry Vennema et al., <i>Early Death After Feline Infectious Peritonitis Virus Challenge due to Recombinant Vaccinia Virus Immunization</i> , 64 Journal of Virology 1407 (1990) (“Vennema”)
2030	Martial Jaume et al., <i>Anti-Severe Acute Respiratory Syndrome Coronavirus Spike Antibodies Trigger Infection of Human Immune Cells via a pH- and Cysteine Protease-Independent FcγR Pathway</i> , 85 J. Virology 10582 (2011) (“Jaume”)
2031	Amarendra Pegu et al., <i>Durability of mRNA-1273 Vaccine-Induced Antibodies Against SARS-CoV-2 Variants</i> , 373 Science 1372 (2021)
2032	European Medicines Agency, Assessment Report for COVID-19 Vaccine Moderna (Mar. 11, 2021)
2033	Japanese Package Insert for Spikevax Intramuscular Injection (Monovalent: Omicron XBB.1.5)
2034	Moderna, Inc., <i>Patents</i> , https://www.modernatx.com/patents
2035	E.J. Anderson et al., <i>Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults</i> , 383 The New England Journal of Medicine 2427 (2020)
2036	Spyros Chalkias et al., <i>Safety, Immunogenicity and Antibody Persistence of a Bivalent Beta-Containing Booster Vaccine Against COVID-19: A Phase 2/3 Trial</i> , 28 Nature Med. (2022)
2037	Denise Grady, <i>Vaccine’s Early Test Result Elevates Hopes and Stocks</i> , 169 N.Y. Times, May 19, 2020, at A1
2038	Peter Loftus, <i>Moderna Says Initial Covid-19 Vaccine Results Are Positive</i> , Wall St. J. (May 18, 2020)

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2039	Carolyn Y. Johnson, <i>Moderna's coronavirus vaccine shows encouraging early results</i> , The Washington Post (2020)
2040	<i>'Heroes of Chemistry' recognized for contributions to health, medicine and more</i> , American Chemical Society (2022)
2041	<i>The Galien Foundation Announces Winners of the 2022 Prix Galien UK Awards at the Natural History Museum, London</i> (2022)
2042	<i>Pharma Awards 2022: The Winners Interviews</i>
2043	Jeffrey M. Jacobson et al., <i>Dendritic Cell Immunotherapy for HIV-1 Infection Using Autologous HIV-1 RNA: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial</i> , 72 J. Acquired Immune Deficiency Syndromes 31 (2016)
2044	Wesley de Jong, <i>Therapeutic Vaccine in Chronically HIV-1-Infected Patients: A Randomized, Double-Blind, Placebo-Controlled Phase IIa Trial with HTI-TriMix</i> , 209 Vaccines (2019)
2045	Nick Paul Taylor, <i>Translate Bio's mRNA Fails to Improve Lung Function in Cystic Fibrosis Patients</i> , Biotech (2021)
2046	Martin Alberer et al., <i>Safety and Immunogenicity of a mRNA Rabies Vaccine in Healthy Adults: an Open-label, Non-randomised, Prospective, First-in-human Phase 1 Clinical Trial</i> , 390 The Lancet 1511 (2017)
2047	Excerpts from Defendants' Patent-Related Disclosures, Exhibit C – Invalidity Contentions of U.S. Patent No. 10,702,600 (Mar. 31, 2023)
2048	<i>Reserved</i>
2049	Excerpts from Matthew G. Stanton & Kerry E. Murphy-Benenato, <i>Messenger RNA as a Novel Therapeutic Approach</i> , Topics in Medicinal Chemistry RNA Therapeutics 237 (2017); MOD_000773684-MOD_000773700 at MOD_000773688

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2050	Excerpts from Investigator's Brochure mRNA-1325 (Sept. 23, 2016) (PROTECTIVE ORDER MATERIAL); MOD_001416753-MOD_001416784 at MOD_001416764-MOD_001416765
2051	Excerpts from Pre-IND Meeting Background Document, mRNA-1325 (PROTECTIVE ORDER MATERIAL); MOD_001417294-MOD_001417512 at MOD_001417309, MOD_001417492
2052	Excerpts from mRNA-1893 Investigator's Brochure (June 4, 2019) (PROTECTIVE ORDER MATERIAL); MOD_000337172-MOD_000337198 at MOD_000337182, MOD_000337183
2053	Excerpts from Division of Microbiology and Infectious Diseases (DMID) Protocol (Mar. 30, 2020); MOD_000477134-MOD_000477212 at MOD_000477149
2054	Excerpts from Division of Microbiology and Infectious Diseases (DMID) Protocol (Feb. 14, 2020); MOD_000477491-MOD_000477561 at MOD_000477497, MOD_000477505
2055	Excerpts from Division of Microbiology and Infectious Diseases (DMID) Protocol (May 20, 2020); MOD_000471975-MOD_000472059 at MOD_000471981, MOD_000471991
2056	Excerpts from Type B Pre-IND Meeting Request for mRNA-1273 (PROTECTIVE ORDER MATERIAL); MOD_000205848-MOD_000205881 at MOD_000205868
2057	Excerpts from SARS-CoV-2, Disease Enhancement & Vaccination (Apr. 7, 2020) (PROTECTIVE ORDER MATERIAL); MOD_000329613-MOD_000329628 at MOD_000329616-MOD_000329617
2058	Redline Stipulated Protective Order
2059	Stipulated Protective Order
2060	Petitioner's Chart (PROTECTIVE ORDER MATERIAL)

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2061	Petitioner's Chart – Redacted
2062	Electronic Order re Trial Timing, <i>ModernaTX, Inc. et al. v. Pfizer Inc. et al.</i> , C.A. No. 22-11378, Dkt. No. 225 (D. Mass. Feb. 7, 2024)
2063	National Human Genome Research Institute, <i>Central Dogma</i> , https://www.genome.gov/genetics-glossary/Central-Dogma [https://web.archive.org/web/20231208025319/https://www.genome.gov/genetics-glossary/Central-Dogma].
2064	National Human Genome Research Institute, <i>Double Helix</i> , https://www.genome.gov/genetics-glossary/Double-Helix [https://web.archive.org/web/20231202221904/https://www.genome.gov/genetics-glossary/Double-Helix].
2065	<i>The Galien Foundation Announces Winners of the 2022 Prix Galien UK Awards at the Natural History Museum, London</i> (2022) [https://web.archive.org/web/20220513120111/https://www.prnewswire.co.uk/news-releases/the-galien-foundation-announces-winners-of-the-2022-prix-galien-uk-awards-at-the-natural-history-museum-london-852118296.html].
2066	Jeffrey M. Jacobson et al., <i>Dendritic Cell Immunotherapy for HIV-1 Infection Using Autologous HIV-1 RNA: A Randomized, Double-Blind, Placebo- Controlled Clinical Trial</i> , 72 J. Acquired Immune Deficiency Syndromes 31 (2016).
2067	Peter Loftus, <i>The Coronavirus Pandemic: Moderna Says Data Show Promise</i> , The Wall Street Journal, Lexis+, May 19, 2020, A6.
2068	Denise Grady, <i>Vaccine's Early Test Result Elevates Hopes and Stocks</i> , 169 N.Y. Times, Lexis+, May 19, 2020, at A1.
2069	Carolyn Y. Johnson, <i>Moderna's coronavirus vaccine shows encouraging early results</i> , The Washington Post, Lexis+ (2020).

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2070	Moderna, Inc., <i>Patents</i> , https://www.modernatx.com/en-US/patents [https://web.archive.org/web/20231116100458/https://www.modernatx.com/en-US/patents].
2071	<i>'Heroes of Chemistry' recognized for contributions to health, medicine and more</i> , American Chemical Society (2022) [https://web.archive.org/web/20230529045839/https://www.acs.org/pressroom/newsreleases/2022/july/heroes-of-chemistry-recognized-for-contributions-to-health-medicine-and-more.html].
2072	<i>Pharma Awards 2022: The Winners Interviews</i> [https://web.archive.org/web/20230513204114/https://www.cphi-online.com/pharma-awards-2022-page000610.html].
2073	Declaration of Anastasia Greenberg
2074	Declaration of Kevin S. Prussia
2075	Declaration of Amy K. Wigmore
2076	Declaration of Joshua L. Stern
2077	Preety Sahdev et al., <i>Biomaterials for Nanoparticle Vaccine Delivery Systems</i> , 31 <i>Pharmaceutical Research</i> 2563 (2014)
2078	Kyung Soo Park et al., <i>Non-Viral COVID-19 Vaccine Delivery Systems</i> , 169 <i>Advanced Drug Delivery Reviews</i> 137 (2021)
2079	Chemical Structure of DOTMA (1,2-di-O-octadecenyl-3-trimethylammonium propane)
2080	Chemical Structure of DOTAP (Dioleoyl-3-trimethylammonium propane)
2081	Chemical Structure of Cholesterol
2082	Lena M. Kranz et al., <i>Systemic RNA Delivery to Dendritic Cells Exploits Antiviral Defence for Cancer Immunotherapy</i> , 534 <i>Nature</i> 396 (2016)

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2083	Enzo Paoletti et al., <i>Applications of Pox Virus Vectors to Vaccination: An Update</i> , 93 Proceedings of the Nat'l Acad. of Sci. 11349 (1996)
2084	Ling-Yan Zhou et al., <i>Current RNA-Based Therapeutics in Clinical Trials</i> , 19 Current Gene Therapy 172 (2019)
2085	Rajesh T. Gandhi et al., <i>Immunization of HIV-1-Infected Persons with Autologous Dendritic Cells Transfected with mRNA Encoding HIV-1 Gag and Nef: Results of a Randomized, Placebo-Controlled Clinical Trial</i> , 71 J. Acquired Immune Deficiency Syndrome 246 (2016)
2086	<i>FDA Approves First COVID-19 Vaccine</i> (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine
2087	<i>Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine</i> (Jan. 31, 2022), https://www.prnewswire.com/news-releases/coronavirus-covid-19-update-fda-takes-key-action-by-approving-second-covid-19-vaccine-301471678.html
2088	Shan Lu et al., <i>Immunogenicity of DNA Vaccines Expressing Human Immunodeficiency Virus Type 1 Envelope Glycoprotein With and Without Deletions in the V1/2 and V3 Regions</i> , 14 AIDS Research & Human Retroviruses 151 (1998)
2089	Yanmin Wan et al., <i>Comparison of Immunogenicity Between Codon Optimized HIV-1 Thailand Subtype B gp140 and gp145 Vaccines</i> , 25 Vaccine 4949 (2007)
2090	<i>Reserved</i>
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2092	Chung-ke Chang et al., <i>Recent Insights into the Developments of Therapeutics Against Coronavirus Disease by Targeting N Protein</i> , 21 Drug Discovery Today 562 (2016)
2093	Tae Woo Kim et al., <i>Generation and Characterization of DNA Vaccines Targeting the Nucleocapsid Protein of Severe Acute Respiratory Syndrome Coronavirus</i> , 78 J. Virology 4638 (2004)
2094	Rimanshee Arya et al., <i>Structural Insights into SARS-Cov-2 Proteins</i> , 433 J. Molecular Biology 1 (2021)
2095	Jun Liu, et al., <i>The Membrane Protein of Severe Acute Respiratory Syndrome Coronavirus Acts as a Dominant Immunogen Revealed by a Clustering Region of Novel Functionally and Structurally Defined Cytotoxic T-Lymphocyte Epitopes</i> , 202 J. Infectious Diseases 1171 (2010)
2096	Dongwan Yoo et al., <i>Synthesis and Processing of the Haemagglutinin-Esterase Glycoprotein of Bovine Coronavirus Encoded in the E3 Region of Adenovirus</i> , 73 J. Gen. Virology 2591 (1992)
2097	<i>Reserved</i>
2098	<i>Reserved</i>
2099	<i>Reserved</i>
2100	FDA, <i>Vaccines Licensed for Use in the United States</i> (Apr. 26, 2019), https://web.archive.org/web/20190427211808/https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states
2101	<i>Reserved</i>
2102	Peter J.M. Openshaw et al., <i>Immune Responses and Disease Enhancement During Respiratory Syncytial Virus Infection</i> , 18 Clinical Microbiology Reviews 541 (2005)

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2103	Christine A. Shaw et al., <i>The Path to an RSV Vaccine</i> , 3 Current Opinion in Virology 332 (2013)
2104	FDA, <i>Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry</i> (June 2020), https://web.archive.org/web/20201001013504/https://www.fda.gov/media/139638/download
2105	<i>Reserved</i>
2106	Joe Miller et al., <i>The Vaccine: Inside the Race to Conquer the COVID-19 Pandemic</i> , Ch. 3: The Unknowns (2022)
2107	Joe Miller et al., <i>The Vaccine: Inside the Race to Conquer the COVID-19 Pandemic</i> , Ch. 8: On Our Own (2022)
2108	BioNTech, Investigator's Brochure, BNT162/PF-07302048 (Oct. 27, 2021), https://assets.publishing.service.gov.uk/media/65f164dbff11700019615ac7/FOI_23-583_PDF_attachment__2_.pdf
2109	Yoshikazu Nakayama et al., <i>Comparison of Current Regulatory Status for Gene-Based Vaccines in the U.S., Europe and Japan</i> , 3 Vaccines 186 (2015)
2110	Samantha L. Ginn et al., <i>Gene Therapy Clinical Trials Worldwide to 2017: An Update</i> , 20 J. Gene Med. e3015 (2018)
2111	D. Allan Drummond et al., <i>The Evolutionary Consequences of Erroneous Protein Synthesis</i> , 10 Nature Reviews Genetics 715 (2009)
2112	Jose A. Regla-Nava et al., <i>Severe Acute Respiratory Syndrome Coronaviruses with Mutations in the E Protein Are Attenuated and Promising Vaccine Candidates</i> , 89 J. Virology 3870 (2015)
2113	Deposition of James J. Moon, Ph.D. (May 10, 2024), in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.)

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2114	Deposition of Daniel O. Griffin, M.D., Ph.D. (May 22, 2024), in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.)
2115	FDA, Vaccines and Related Biological Products Advisory Committee Meeting: FDA Briefing Document, Pfizer-BioNTech COVID-19 Vaccine (Dec. 10, 2020), https://www.fda.gov/media/144245/download
2116	FDA, Vaccines and Related Biological Products Advisory Committee Meeting Presentation: mRNA-1273 Sponsor Briefing Document (Dec. 17, 2020), https://www.fda.gov/media/144452/download
2117	<i>Reserved</i>
2118	Katalin Karikó, <i>Modified Uridines Are the Key to a Successful Message</i> , 21 Nature Reviews Immunology 619 (2021)
2119	<i>Reserved</i>
2120	BioNTech SE 2021 Form 20-F
2121	BioNTech SE 2023 Form 20-F
2122	Pfizer Inc. 2021 Form 10-K
2123	Pfizer Inc. 2023 Form 10-K
2124	Moderna, Inc. 2020 Form 10-K
2125	Moderna, Inc. 2023 Form 10-K

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2126	Moderna, <i>Moderna Announces First Participant Dosed in NIH-Led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus</i> (Mar. 16, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-First-Participant-Dosed-in-NIH-led-Phase-1-Study-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx
2127	Pfizer, <i>Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program</i> (May 5, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_dose_first_participants_in_the_u_s_as_part_of_global_covid_19_mrna_vaccine_development_program
2128	Pfizer, <i>Pfizer and BioNtech Choose Lead mRNA Vaccine Candidate Against COVID-19 and Commence Pivotal Phase 2/3 Global Study</i> (Jul. 27, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate
2129	FDA, <i>Vaccines Licensed for Use in the United States</i> , https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (last updated Dec. 1, 2023)
2130	Ian Jaffe et al., <i>A Decade On: Systematic Review of ClinicalTrials.gov Infectious Disease Trials, 2007-2017</i> , 6 Open Forum Infectious Diseases 1 (2019)
2131	<i>Reserved</i>
2132	Michele A. Kutzler et al., <i>DNA Vaccines: Ready for Prime Time?</i> , 9 Nature Reviews Genetics 776 (2008)
2133	Ellen F. Fynan et al., <i>One Group's Historical Reflections on DNA Vaccine Development</i> , 29 Human Gene Therapy 966 (2018)

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2134	Rebekah Griesenauer et al., <i>An Overview of FDA-Approved Vaccines & Their Innovators</i> , 16 Expert Rev. Vaccines 1253 (2017)
2135	Guangwen Lu et al., <i>Bat-to-Human: Spike Features Determining ‘Host Jump’ of Coronaviruses SARS-CoV, MERS-CoV, and Beyond</i> , 23 Trends in Microbiology 468 (2015)
2136	Paul-Henri Lambert et al., <i>Consensus Summary Report for CEPI/BC March 12-13, 2020 Meeting: Assessment of Risk of Disease Enhancement with COVID-19 Vaccines</i> , 38 Vaccine 4783 (2020)
2137	Zhi-yong Yang et al., <i>Evasion of Antibody Neutralization in Emerging Severe Acute Respiratory Syndrome Coronaviruses</i> , 102 PNAS 797 (2005)
2138	Julie E. Martin et al., <i>A SARS DNA Vaccine Induces Neutralizing Antibody and Cellular Immune Responses in Healthy Adults in a Phase I Clinical Trial</i> , 26 Vaccine 6338 (2008)
2139	<i>Reserved</i>
2140	Marion F. Gruber & Valerie B. Marshall, <i>Ch. 79: Regulation and Testing of Vaccines</i> , in Plotkin’s Vaccines 1547 (7th ed. 2018)
2141	Excerpts from Pre-IND Meeting Background Document, mRNA-1325 (PROTECTIVE ORDER MATERIAL); MOD_001417294-MOD_001417512 at MOD_001417324-MOD_001417325, MOD_001417495, MOD_001417497-MOD_001417498, MOD_001417508-MOD_001417509
2142	Kizzmekia S. Corbett et al., <i>SARS-CoV-2 mRNA Vaccine Design Enabled by Prototype Pathogen Preparedness</i> , 586 Nature 567 (2020)
2143	Excerpts from Type B Pre-IND Meeting Request for mRNA-1273 (PROTECTIVE ORDER MATERIAL); MOD_000205848-MOD_000205881 at MOD_000205851-MOD_000205856, MOD_000205861- MOD_000205864

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2144	FDA, <i>E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)</i> (Mar. 2018)
2145	FDA, <i>Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance</i> (Apr. 1996)
2146	Excerpts from Investigator's Brochure mRNA-1325 (Sept. 23, 2016) (PROTECTIVE ORDER MATERIAL); MOD_001416753-MOD_001416784 at MOD_001416768, MOD_001416770-MOD_001416771, MOD_001416780-MOD_001416781
2147	Excerpts from mRNA-1893 Investigator's Brochure (June 4, 2019) (PROTECTIVE ORDER MATERIAL); MOD_000337172-MOD_000337198 at MOD_000337185, MOD_000337187-MOD_000337189
2148	<i>Reserved</i>
2149	Excerpts from Division of Microbiology and Infectious Diseases (DMID) Protocol (Mar. 30, 2020); MOD_000477134-MOD_000477212 at MOD_000477134- MOD_000477139, MOD_000477148- MOD_000477154
2150	Excerpts from Division of Microbiology and Infectious Diseases (DMID) Protocol (Feb. 14, 2020); MOD_000477491-MOD_000477561 at MOD_000477491- MOD_000477498; MOD_000477504- MOD_000477509
2151	Excerpts from Division of Microbiology and Infectious Diseases (DMID) Protocol (May 20, 2020); MOD_000471975-MOD_000472059 at MOD_000471975-MOD_000471983; MOD_000471990- MOD_000471992; MOD_000471994-MOD_000471997
2152	Kayvon Modjarrad et al., <i>Safety and Immunogenicity of an Anti-Middle East Respiratory Syndrome Coronavirus DNA Vaccine: A Phase 1, Open-Label, Single-Arm, Dose-Escalation Trial</i> , 19 The Lancet Infectious Diseases 1013 (2019)

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2153	Ralf Wagner et al., <i>Accelerated Development of COVID-19 Vaccines: Technology Platforms, Benefits, and Associated Risks</i> , 9 Vaccines (Basel) 747 (2021)
2154	Sudhakar Agnihothram, Review Committee Chair, Summary Basis for Regulatory Action, STN 125752/0 (Jan. 30, 2022)
2155	Elijah N. Mulabbi et al., <i>The History of the Emergence and Transmission of Human Coronaviruses</i> , 88 Onderstepoort J. Veterinary Research 1 (2021)
2156	James D. Cherry et al., <i>SARS: The First Pandemic of the 21st Century</i> , 56 Pediatric Research 1 (2004)
2157	Yongshi Yang et al., <i>The Deadly Coronaviruses: The 2003 SARS Pandemic and the 2020 Novel Coronavirus Epidemic in China</i> , 109 J. Autoimmunity 102434 (2020)
2158	Wenjie Tan et al., <i>A Novel Coronavirus Genome Identified in a Cluster of Pneumonia Cases — Wuhan, China 2019-2020</i> , 2 China CDC Weekly 61 (2020)
2159	<i>COVID-19 Weekly Epidemiological Case Count</i> , World Health Organization, https://www.who.int/publications/m/item/weekly-epidemiological-update---29-december-2020
2160	Moderna, <i>Moderna Announces FDA Authorization of Moderna COVID-19 Vaccine in U.S.</i> (Dec. 19, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-FDA-Authorization-of-Moderna-COVID-19-Vaccine-in-U.S/default.aspx
2161	Vrinda Gote et al., <i>A Comprehensive Review of mRNA Vaccines</i> , 24 Int'l J. Molecular Sci. 2700 (2023)
2162	A.A. Ilyichev et al., <i>mRNA Technology as One of the Promising Platforms for the SARS-CoV-2 Vaccine Development</i> , 24 Vavilov J. Genetics & Breeding 802 (2020)

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2163	BioNTech, <i>BioNTech and Pfizer Announce Regulatory Approval from German Authority Paul-Ehrlich-Institut to Commence First Clinical Trial of COVID-19 Vaccine Candidates</i> (Apr. 22, 2020), https://investors.biontech.de/news-releases/news-release-details/biontech-and-pfizer-announce-regulatory-approval-german
2164	Moderna, <i>Moderna Announces Positive Interim Phase 1 Data for Its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus</i> (May 18, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Positive-Interim-Phase-1-Data-for-its-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx
2165	L.A. Jackson et al., <i>An mRNA Vaccine Against SARS-CoV-2—Preliminary Report</i> , 383 New England J. Med. 1920 (2020)
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2168	Gábor Tamás Szabó et al., <i>COVID-19 mRNA Vaccines: Platforms and Current Developments</i> , 30 Molecular Therapy 1850 (2022)
2169	Karin Bok et al., <i>Accelerated COVID-19 Vaccine Development: Milestones, Lessons, and Prospects</i> , 54 Immunity 1636 (2021)
2170	Li Liu et al., <i>Anti-spike IgG Causes Severe Acute Lung Injury by Skewing Macrophage Responses During Acute SARS-CoV Infection</i> , 4 J. Clinical Invest. Insight 1 (2019)
2171	Pureum Lee et al., <i>Current Status of COVID-19 Vaccine Development: Focusing on Antigen Design and Clinical Trials on Later Stages</i> , 21 Immune Network e4 (2021)

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2172	Monika Kumari et al., <i>A Critical Overview of Current Progress for COVID-19: Development of Vaccines, Antiviral Drugs, and Therapeutic Antibodies</i> , 29 J. Biomed. Sci. 1 (2022)
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2174	Novavax, <i>U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted for Individuals Aged 18 and Over</i> (July 13, 2022), https://ir.novavax.com/press-releases/2022-07-13-U-S-FDA-Grants-Emergency-Use-Authorization-for-Novavax-COVID-19-Vaccine%2C-Adjuvanted-for-Individuals-Aged-18-and-Over
2175	Berkeley Lovelace Jr. & Noah Higgins-Dunn, <i>Dr. Anthony Fauci Says Chance of Coronavirus Vaccine Being Highly Effective Is 'Not Great'</i> , CNBC.com (last updated Aug. 8, 2020), https://www.cnbc.com/2020/08/07/coronavirus-vaccine-dr-fauci-says-chances-of-it-being-highly-effective-is-not-great.html
2176	Jon Cohen, <i>'Absolutely Remarkable': No One Who Got Moderna's Vaccine in Trial Developed Severe COVID-19</i> , Science (Nov. 30, 2020), https://www.science.org/content/article/absolutely-remarkable-no-one-who-got-modernas-vaccine-trial-developed-severe-covid-19
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Exhibit	Description
2178	Morgan Frey, <i>Pharma Peers Cheer Moderna's Unexpectedly Strong COVID-19 Vaccine Results</i> , S&P Global Market Intelligence (Nov. 16, 2020), https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/pharmapeers-cheer-moderna-s-unexpectedly-strong-covid-19-vaccine-results-61302444
2179	H.M. El Sahly et al., <i>Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase</i> , 385 New England J. Med. 1774 (2021)
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2186	Nicole Roth et al., <i>Assessment of Immunogenicity and Efficacy of CV0501 mRNA-Based Omicron COVID-19 Vaccination in Small Animal Models</i> , 11 Vaccines 318 (2023)
2187	Benjamin Weide et al., <i>Results of the First Phase I/II Clinical Vaccination Trial with Direct Injection of mRNA</i> , 31 J. Immunotherapy 180 (2008)
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2194	3.2.S.1.2. Structure CX-038839 Excerpt (PROTECTIVE ORDER MATERIAL)
2195	3.2.P.1. BLA Description and Composition of the Drug Product Excerpt (PROTECTIVE ORDER MATERIAL); MOD_001515874
2196	3.2.S.2.2 BLA Structure of LNP Excerpt (PROTECTIVE ORDER MATERIAL); MOD_000104820

Exhibit	Description
2197	Declaration of James E. Malackowski
2198	Declaration of Warren C.W. Chan, Ph.D.
2199	Declaration of Deborah H. Fuller, Ph.D. (PROTECTIVE ORDER MATERIAL)
2200	Declaration of Philip Krause, M.D. (PROTECTIVE ORDER MATERIAL)
2201	PUBLIC Declaration of Deborah H. Fuller, Ph.D. (redacted version of Ex. 2199)
2202	PUBLIC Declaration of Philp Krause, M.D. (redacted version of Ex. 2200)
2203	Spyros Chalkias et al., <i>Interim Report of the Reactogenicity and Immunogenicity of Severe Acute Respiratory Syndrome Coronavirus 2 XBB-Containing Vaccines</i> , J. Infectious Diseases (2024)
2204	Moderna, Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Moderna COVID-19 Vaccine (2023-2024 Formula), for Individuals 6 Months Through 11 Years of Age (Nov. 1, 2023)
2205	Package Insert for Spikevax (COVID-19 Vaccine, mRNA) – 2023-2024 Formula (Apr. 2024)
2206	Moderna, Vaccines and Related Biological Products Advisory Committee Presentation: Moderna COVID-19 Variant Vaccines (June 15, 2023); MOD_000767652-MOD_000767686
2207	Juleen Gayed et al., <i>Safety and Immunogenicity of the Monovalent Omicron XBB.1.5-Adapted BNT162b2 COVID-19 Vaccine in Individuals ≥ 12 Years Old: A Phase 2/3 Trial</i> , 12 Vaccines (Basel) 118 (2024)
2208	European Medicines Agency, Assessment Report for COMIRNATY (Aug. 30, 2023)

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2210	Pfizer-BioNTech, Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), for 6 Months Through 11 Years of Age (Sept. 11, 2023); MOD_001483910- MOD_001483970
2211	Kayvon Modjarrad et al., <i>Preclinical Characterization of the Omicron XBB.1.5-Adapted BNT162b2 COVID-19 Vaccine</i> , bioRxiv (2023) (preprint), https://www.biorxiv.org/content/10.1101/2023.11.17.567633v1.full.pdf+html
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2214	Avanti Polar Lipids, ALC-0315 Safety Data Sheet Version 8.1 (Nov. 8, 2022)
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2216	Avanti Polar Lipids, Cholesterol Safety Data Sheet Version 5.0 (Nov.15, 2018)
2217	Avanti Polar Lipids, 1,2-distearoyl-sn-glycero-3-phosphocholine Safety Data Sheet Version 5.2 (Nov. 15, 2018)
2218	European Medicines Agency, Assessment Report for Spikevax (Sept. 14, 2023)
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2220	Angus Liu, <i>AstraZeneca Withdraws US COVID Vaccine Application, Shifts Focus to Antibody Treatments</i> , Fierce Pharma (Nov. 10, 2022), https://www.fiercepharma.com/pharma/astrazeneca-withdraws-us-covid-vaccine-application-focus-shifts-antibody-treatments
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2230	FDA, <i>Vaccines Licensed for Use in the United States</i> (Apr. 26, 2019), https://web.archive.org/web/20190427211808/https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states [SERVICE ONLY]
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2232	Pfizer, <i>Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program</i> (May 5, 2020), https://web.archive.org/web/20240528163740/https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_dose_first_participants_in_the_u_s_as_part_of_global_covid_19_mrna_vaccine_development_program [SERVICE ONLY]
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2234	Moderna, <i>Moderna Announces FDA Authorization of Moderna COVID-19 Vaccine in U.S.</i> (Dec. 19, 2020), https://web.archive.org/web/20221221101553/https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-FDA-Authorization-of-Moderna-COVID-19-Vaccine-in-U.S/default.aspx [SERVICE ONLY]
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2236	Moderna, <i>Moderna Announces Positive Interim Phase 1 Data for Its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus</i> (May 18, 2020), https://web.archive.org/web/20230927221332/https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Positive-Interim-Phase-1-Data-for-its-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx [SERVICE ONLY]
2237	Pfizer, <i>Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19</i> (Dec. 11, 2020), https://web.archive.org/web/20240221190048/https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-celebrate-historic-first-authorization [SERVICE ONLY]

Exhibit	Description
2238	Fraiser Kansteiner, <i>It's the End of the Line for J&J's COVID Shot in the US, CDC Says</i>, Fierce Pharma (May 16, 2023), https://web.archive.org/web/20240521135506/https://www.fiercepharma.com/pharma/its-end-line-jjs-covid-shot-us-cdc-says [SERVICE ONLY]
2239	Novavax, <i>U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted for Individuals Aged 18 and Over</i> (July 13, 2022), https://web.archive.org/web/20240510233937/https://ir.novavax.com/press-releases/2022-07-13-U-S-FDA-Grants-Emergency-Use-Authorization-for-Novavax-COVID-19-Vaccine%2C-Adjuvanted-for-Individuals-Aged-18-and-Over [SERVICE ONLY]
2240	Morgan Frey, <i>Pharma Peers Cheer Moderna's Unexpectedly Strong COVID-19 Vaccine Results</i>, S&P Global Market Intelligence (Nov. 16, 2020), https://web.archive.org/web/20201124071818/https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/pharma-peers-cheer-moderna-s-unexpectedly-strong-covid-19-vaccine-results-61302444 [SERVICE ONLY]
2241	CureVac, <i>CureVac Provides Update on Phase 2b/3 Trial of First-Generation COVID-19 Vaccine Candidate, CVnCoV</i> (June 16, 2021), https://web.archive.org/web/20240520142553/https://www.curevac.com/en/curevac-provides-update-on-phase-2b-3-trial-of-first-generation-covid-19-vaccine-candidate-cvncov/ [SERVICE ONLY]

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2242	Angus Liu, <i>AstraZeneca Withdraws US COVID Vaccine Application, Shifts Focus to Antibody Treatments</i> , Fierce Pharma (Nov. 10, 2022), https://web.archive.org/web/20240516162312/https://www.fiercepharma.com/pharma/astrazeneca-withdraws-us-covid-vaccine-application-focus-shifts-antibody-treatments [SERVICE ONLY]
2243	Chemical Structure of DOTMA [SERVICE ONLY]
2244	Chemical Structure of DOTAP [SERVICE ONLY]
2245	Chemical Structure of Cholesterol [SERVICE ONLY]
2246	FDA, <i>Vaccines Licensed for Use in the United States</i> (last updated Dec. 1, 2023) https://web.archive.org/web/20240523161036/https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states [SERVICE ONLY]
2247	Declaration of Wenli Gu regarding Exhibits 2079-2081, 2086-2087, 2100, 2104, 2115-2116, 2126-2129, 2144-2145, 2154, 2158-2160, 2163-2164, 2166, 2173-2178, 2184-2185, 2204-2206, 2209-2211, 2214-2217, 2219-2220, 2229-2246 [SERVICE ONLY]
2248	Declaration of Aaron Fier regarding Exhibits 2194-2196 [SERVICE ONLY]
2249	Declaration of Annaleigh E. Curtis
2250	Declaration of Andrew J. Danford

Exhibit	Description
2251	Declaration of Claire M. Specht
2252	<i>Reserved</i>
2253	Deposition of Daniel O. Griffin, M.D., Ph.D. (September 20, 2024) in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.)
2254	Deposition of James J. Moon, Ph.D. (September 13, 2024) in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.)
2255	Deposition of W. Christopher Bakewell (October 3, 2024) in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.)
2256	Deposition of L. Ross Pierce, M.D. (October 4, 2024) in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.) (PROTECTIVE ORDER MATERIAL)
2257	PUBLIC Deposition of L. Ross Pierce, M.D. (October 4, 2024) in <i>BioNTech SE and Pfizer Inc. v. Moderna TX, Inc.</i> , No. IPR2023-01358 (P.T.A.B.) (redacted version of Ex. 2256)

Respectfully submitted,

Date: December 2, 2024

By: /Emily R. Whelan/
Emily R. Whelan (Reg. No. 50,391)

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2024, I caused a true and correct copy of the following documents:

- Patent Owner's Corrected Exhibit List

to be served via e-mail, as consented to by Petitioners, upon the following:

COVIDPatentPfizer@wc.com
BioNTech-Moderna-IPR@paulhastings.com

By: /Wenli Gu/
Wenli Gu (Reg. No. 72,124)
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Appendix A

From: [Trials](#)
To: [Gu, Wenli](#); [Trials](#)
Cc: [WH Moderna IPR](#); [Whelan, Emily](#); [BioNTech-Moderna-IPR@paulhastings.com](#); [COVIDPatentPfizer](#)
Subject: RE: IPR2023-01358 / Corrected Exhibit List
Date: Wednesday, November 27, 2024 8:20:21 AM

EXTERNAL SENDER

Counsel,

From the Board –

Patent Owner is authorized to file an updated Exhibit List correcting typographical errors in the Exhibit List filed with Patent Owner's Sur-Reply on October 16, 2024.

Regards,

Esther Goldschlager
Supervisory Paralegal Specialist
Patent Trial & Appeal Board
U.S. Patent & Trademark Office

From: Gu, Wenli <Wenli.Gu@wilmerhale.com>
Sent: Tuesday, November 26, 2024 3:15 PM
To: Trials <Trials@USPTO.GOV>
Cc: WH_Moderna_IPR <WH_Moderna_IPR@wilmerhale.com>; Whelan, Emily <Emily.Whehan@wilmerhale.com>; BioNTech-Moderna-IPR@paulhastings.com; COVIDPatentPfizer <COVIDPatentPfizer@wc.com>
Subject: IPR2023-01358 / Corrected Exhibit List

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Re: Corrected Exhibit List
IPR2023-01358 // U.S. Patent No. 10,702,600

Dear Board,

Patent Owner respectfully requests to file an updated Exhibit List in IPR2023-01358 to correct typographical errors in the recent Exhibit List filed with Patent Owner's Sur-Reply on October 16, 2024 (Paper 72 Sealed, Paper 73 Redacted). Patent Owner has conferred with Petitioners and Petitioners do not object.

Many thanks,

Wenli Gu
Back-up Counsel for Patent Owner

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