

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MODERNA THERAPEUTICS, INC.,  
Petitioner,

v.

PROTIVA BIOTHERAPEUTICS, INC.,  
Patent Owner.

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Case IPR2018-00739  
Patent No. 9,364,435

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**PATENT OWNER'S UPDATED EXHIBIT LIST**

## LIST OF EXHIBITS

EXHIBIT NO.	DESCRIPTION
2001	Declaration of Edward R. Reines in Support of Patent Owner's Motion for <i>Pro Hac Vice</i> Admission
2002	<i>In re Reines</i> , No. 14-MA004 (14-4) (Fed. Cir. Nov. 5, 2014)
2003	Personal Statement of Edward R. Reines
2004	Tam P. et al., <i>Stabilized Plasmid-Lipid Particles for Systemic Gene Therapy</i> 7 GENE THERAPY 1867-1874 (2000)
2005	Huang L. et al., <i>Liposomal Gene Delivery: A Complex Package</i> 15 NATURE BIOTECHNOLOGY 620-621 (1997)
2006	Pak C.C., Erukulla R.K., Ahl, P.L., Janoff, A.S. and Meers, P., <i>Elastase-Activated Liposomal Delivery to Nucleated Cells</i> . 1419 BIOCHIM. BIOPHY. ACTA 111-126 (1999)
2007	U.S. Patent No. 7,491,409
2008	Transcript of October 2, 2018 Conference Call
2009	Declaration of David H. Thompson, Ph.D.
2010	<i>Curriculum Vitae</i> of David H. Thompson, Ph.D.
2011	Charles W. Schmidt, <i>Therapeutic Interference: Small RNA Molecules Act as Blockers of Disease Metabolism</i> AM. CHEM. SOC'Y 37 (2003)

2012	C. Russell Middaugh & Joshua D. Ramsey, <i>Analysis of Cationic-Lipid-Plasmid-DNA Complexes</i> , ANALYTICAL CHEMISTRY 7240 (2007)
2013	<i>Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation, Guidance for Industry</i> , FOOD AND DRUG ADMINISTRATION (2018)
2014	Erika Check, <i>RNA to the Rescue?</i> 425 NATURE 10 (2003)
2015	Dirk Hausseker, <i>The Business of RNAi Therapeutics in 2012</i> , 2 AM. SOC'Y OF GENE & CELL THERAPY (2012)
2016	Luke Timmerman, <i>Merck's Alan Sachs, on RNAi's Big Challenge: Delivery, Delivery, Delivery</i> , XCONOMY (Jan. 21, 2010), <a href="https://xconomy.com/national/2010/01/21/mercks-alan-sachs-on-rnais-big-challenge-delivery-delivery-delivery/">https://xconomy.com/national/2010/01/21/mercks-alan-sachs-on-rnais-big-challenge-delivery-delivery-delivery/</a>
2017	U.S. Patent No. 8,236,943
2018	U.S. Publication No. 2013/0116307
2019	U.S. Publication No 2017/0307608
2020	Combined Declaration for Patent Application and Power of Attorney in U.S. Patent Application No. 90/914,615.
2021	Sean C. Semple, et al., <i>Rational Design of Cationic Lipids for siRNA Delivery</i> , 28 NATURE BIOTECH. 172 (2010)
2022	Supplementary Figures to Sean C. Semple, et al., <i>Rational Design of Cationic Lipids for siRNA Delivery</i> , 28 NATURE BIOTECH. 172 (2010)
2023	Heidi Ledford, <i>Gene-Silencing Drug Approved: US Government Okays First RNA-Interference Drug — After a 20-Year Wait</i> 560 NATURE 291 (2018)

2024	<i>FDA Approves First-of-its Kind Targeted RNA-based Therapy to Treat a Rare Disease</i> , FOOD AND DRUG ADMIN. (2018), <a href="https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616518.htm">https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616518.htm</a>
2025	<i>New Medicine for Hereditary Rare Disease</i> , EUROPEAN MED. AGENCY (2018), <a href="https://www.ema.europa.eu/en/news/new-medicine-hereditary-rare-disease">https://www.ema.europa.eu/en/news/new-medicine-hereditary-rare-disease</a>
2026	<i>Arbutus' LNP Licensee Alnylam Announces FDA Approval of ONPATTRO™ (patisiran), for the Treatment of ATTR Amyloidosis</i> , ARBUTUS BIOPHARMA (2018), <a href="https://investor.arbutusbio.com/news-releases/news-release-details/arbutus-lnp-l-icensee-alnylam-announces-fda-approval-onpattrotm">https://investor.arbutusbio.com/news-releases/news-release-details/arbutus-lnp-l-icensee-alnylam-announces-fda-approval-onpattrotm</a>
2027	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, <i>Patent and Exclusivity for: N210922</i> , FOOD AND DRUG ADMIN. available at <a href="https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=210922&amp;Appl_type=N">https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=210922&amp;Appl_type=N</a> (last visited Dec. 19, 2018)
2028	Deposition Transcript of Andrew S. Janoff, December 4, 2018
2029	U.S. Patent No. 9,404,127
2030	Intentionally Left Blank
2031	Intentionally Left Blank
2032	Ian MacLachlan & Pieter Cullis, <i>Diffusible-PEG-Lipid Stabilized Pasmid Lipid Particles</i> , 53 ADVANCES IN GENETICS 157 (2005)
2033	Sean C. Semple et al., <i>Immunogenicity and Rapid Blood Clearance of Liposomes Containing Polyethylene Glycol-Lipid Conjugates and Nucleic Acid</i> , 312 THE JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 1020 (2005)
2034	Doxil Label – FDA (Revised May, 2007), <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/050718s029lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/050718s029lbl.pdf</a>

2035-2039	Intentionally Left Blank
2040	Declaration of David H. Thompson, Ph.D. in Support of Patent Owner's Contingent Motion to Amend
2041	U.S. Provisional Patent Application Number 61/045,228
2042	U.S. Patent Application Number 12/424,367
2043	U.S. Patent Application Number 13/253,917
2044	U.S. Patent Application Number 13/928,309
2045	U.S. Patent Application Number 14/462,441
2046	Listing of Example Formulations Falling Within the Scope of the '435 Patent Claims
2047	International Publication No. WO 2010/088537
2048	Maja Sedic et al., <i>Safety Evaluation of Lipid Nanoparticle-Formulated Modified mRNA in the Sprague-Dawley Rat and Cynomolgus Monkey</i> , VETERINARY PATHOLOGY (2017)
2049	International Publication No. WO 2013/090648
2050	Kapil Bahl et al., <i>Preclinical and Clinical Demonstration of Immunogenicity by mRNA Vaccines against H10N8 and H7N9 Influenza Viruses</i> , MOLECULAR THERAPY (2017)
2051	International Publication No. WO 2017/223135
2052	International Publication No. WO 2018/232357
2053	Intentionally Left Blank
2054	Intentionally Left Blank
2055	Deposition Transcript of Andrew S. Janoff, April 15, 2019
2056	April 2, 2019 Email from Trials

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