IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC., Plaintiff, v. MODERNA, INC., MODERNA TX, INC., and MODERNA US, INC., Defendants.	C.A. No. 22-cv-335-CFC (CONSOLIDATED)

MODERNA'S COUNTERCLAIMS AND ANSWER TO THE COMPLAINT

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants/Counterclaim-Plaintiffs Moderna, Inc., Moderna TX, Inc., and Moderna US, Inc. (collectively, "Moderna") by and through their attorneys, bring the following Counterclaims against Plaintiff/Counterclaim-Defendant Alnylam Pharmaceuticals, Inc. ("Alnylam"):

FACTUAL BACKGROUND

1. Moderna brings these Counterclaims in response to Alnylam's Complaint, which baselessly seeks to profit from Moderna's innovations that led to its groundbreaking mRNA-1273 COVID-19 Vaccine ("SPIKEVAX®"). Specifically, Moderna asks this Court to declare the following: (a) SPIKEVAX® does not infringe U.S. Patent No. 11,246,933 ("the '933 Patent"); (b) the '933 Patent

is invalid; and (c) Alnylam has no claim against Moderna to the extent Moderna used or manufactured SPIKEVAX® "for the Government" and "with the authorization or consent of the Government" under 28 U.S.C. § 1498. In short, this lawsuit will confirm that Moderna and its scientists, employees, and collaborators are the true innovators of the mRNA delivery technology that led to the lifesaving SPIKEVAX® vaccine. Alnylam played no role in Moderna's significant accomplishments.

A. Moderna's Development of mRNA Medicines Using Lipid Nanoparticle Technology

2. For a decade before COVID-19 emerged, Moderna had been pioneering a new class of medicines made of messenger RNA, or mRNA, and developed its own platform technologies that could deliver mRNA in a variety of therapeutic and prophylactic applications, including vaccines. These mRNA medicines have the potential to treat and prevent a wide range of diseases—from infectious diseases like influenza and HIV, to autoimmune and cardiovascular diseases and rare forms of cancer. Over the past twelve years, Moderna has worked diligently in its laboratories to pioneer a number of fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines—from the characteristics and design of the mRNA itself and the protein it encodes, to the technologies to deliver mRNA to patients safely and effectively.

3. Included among the mRNA advancements that Moderna developed over years of extensive work is its proprietary lipid nanoparticle ("LNP") delivery

technologies to provide the mRNA for delivery. The LNPs function to protect the mRNA and deliver it into cells. Critical to the LNP delivery technology used in SPIKEVAX® is Moderna's proprietary lipid, SM-102. Moderna scientist Dr. Kerry Benenato discovered SM-102. Dr. Benenato and her team conducted extensive work to discover a lipid for use in an LNP that would address the issues of being able to protect the delivery of fragile mRNA to the right location in the body, effectively deliver the mRNA to the cells of interest, and then biodegrade so as not to cause tolerability issues. This was no small feat.

4. Moderna invested years of work and resources to develop LNPs that are tailored to work with mRNA. Those efforts included developing novel proprietary lipids, including SM-102, and improving LNP manufacturing processes.

B. Moderna's development and Sale of SPIKEVAX®

5. The SARS-CoV2 virus, which causes COVID-19, was first detected in December 2019. On January 10, 2020, the genetic sequence of the SARS-CoV-2 virus became public. Leveraging its decade of research and proprietary technologies, Moderna quickly responded when the pandemic struck, swiftly developing, manufacturing, and providing doses of SPIKEVAX® to people around the world. SPIKEVAX®, also referred to as the mRNA-1273 vaccine, uses Moderna's proprietary LNP delivery technology that Moderna developed years earlier. For that groundbreaking work, Moderna's scientists were recently honored by the American

Chemistry Society's 2022 Heroes of Chemistry Award, the highest honor for industrial chemical scientists, recognizing their "work developing formulations that protect against . . . COVID-19."[1]

6. Following the declaration of a public health emergency, Moderna entered into numerous agreements with the U.S. Government regarding SPIKEVAX®. In April 2020, Moderna entered into a grant agreement with the Biomedical Advanced Research and Development Authority ("BARDA")—an office of HHS—to support clinical development of the mRNA-1273 vaccine. BARDA chose to partner with Moderna to develop SPIKEVAX® because "Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus."[2]

7. Once Moderna had obtained promising clinical results, on August 9, 2020, ModernaTX, Inc. entered into a supply contract with the Army Contracting Command of the U.S. Department of Defense, Contract No. W911QY20C0100

[1] Nina Notman, Chemists are Recognized for Their Contributions to Sustainable Packaging, Dental Cements, Breast Cancer Treatments, and Formulations that Protect Against or Treat COVID-19, C&EN, https://pubs.acs.org/doi/10.1021/cen-10028-acsnews2.

[2] Contract No. 75A50120000034 Development of an mRNA Vaccine for SARS-CoV-2, § C.1 at 9, https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf.

("C0100 Contract").[3] Under the C0100 Contract, Moderna was obligated to produce and deliver doses of SPIKEVAX® to the U.S. Government, with the option to supply additional doses.[4] The C0100 Contract specifically states that Moderna manufactured SPIKEVAX® doses "for the United States Government."[5] The C0100 contract also incorporates by reference FAR 52.227-1, entitled "Authorization and Consent."[6]

8. Moderna received emergency use authorization for SPIKEVAX® in the U.S. from the Food & Drug Administration ("FDA") on December 16, 2020, less than a year after beginning development. Promptly thereafter, Moderna shipped SPIKEVAX® doses to the U.S. Government pursuant to the C0100 Contract. On January 31, 2022, Moderna received full approval from the FDA for its Biologics License Application for SPIKEVAX®.[7]

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[3] Army Contracting Command of the U.S. Department of Defense, Contract No. W911QY20C0100, https://www.hhs.gov/sites/default/files/moderna-large-scale-production-sars-cov-2-vaccine.pdf.
[4] *Id.*
[5] *Id.* at 19.
[6] *Id.* at 46 (also incorporating FAR clause 52.227-1 Alternate I).
[7] Colleen Hussey, Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine SPIKEVAX, https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

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