IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	)	C.A. No. 22-252-MSG
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	)	

PLAINTIFFS ARBUTUS BIOPHARMA CORPORATION AND GENEVANT SCIENCES GMBH'S ANSWER TO DEFENDANTS MODERNA, INC. AND MODERNATX, INC.'S COUNTERCLAIMS

Plaintiffs/Counterclaim-Defendants Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs"), by their attorneys, answer the counterclaims of Defendants/Counterclaim-Plaintiffs Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") as follows. This Answer reproduces Defendants' counterclaims followed by Plaintiffs' responses.

INTRODUCTION

1. Moderna brings these counterclaims in response to Arbutus and Genevant's lawsuit, which baselessly seeks to profit from Moderna's innovations that led to its ground-breaking mRNA-1273 "COVID-19 Vaccine." Specifically, Moderna asks this Court to declare that Moderna's COVID-19 Vaccine does not infringe the Asserted Patents, and that those patents

are invalid. In short, this lawsuit will confirm that Moderna and its scientists, employees, and collaborators are the true innovators in the mRNA delivery technology that led to its lifesaving COVID-19 Vaccine. Plaintiffs played no role in Moderna's significant accomplishments.

ANSWER: The allegations of Paragraph 1 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that they filed a Complaint against Moderna on February 28, 2022, and an Amended Complaint against Moderna on May 1, 2024. Otherwise, **DENIED**.

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.

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief about the allegations in Paragraph 2, and therefore **DENY** them.

3. Included among the mRNA advancements that Moderna developed over years of extensive work, is its proprietary lipid nanoparticle ("LNP") delivery technologies to encapsulate the mRNA for delivery. The LNPs function to protect the mRNA and deliver it into cells.

ANSWER: Plaintiffs **ADMIT** that lipid nanoparticles ("LNPs") can function to protect mRNA and deliver it into cells. Plaintiffs lack knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 3, and therefore **DENY** them.

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 and optimal lipid compositions, and improving LNP manufacturing processes. Moderna's inventions in this area have been recognized with multiple U.S. patents.

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 and therefore **DENY** them.

5. Moderna's innovative proprietary LNP formulation technology, developed to address the complex problem of reliably delivering mRNA to a patient, goes well beyond the rudimentary, early technology for delivery of siRNA described in Arbutus's Asserted Patents, nor is it covered by those patents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 5.

6. In contrast to Moderna's proprietary LNP technology to deliver mRNA, Arbutus (and its predecessor Protiva Biotherapeutics, Inc., "Protiva") conducted research relating to delivery of small interfering RNA ("siRNA"), small pieces of RNA "about 15–60 . . . nucleotides in length" as defined by Arbutus. *See, e.g.*, U.S. Patent No. 8,058,069 ("'069 Patent") at 6:55–66. siRNA is a far cry from the long, complex mRNA that Moderna's technology is designed to deliver. By way of example, Moderna's COVID-19 Vaccine delivers mRNA that is approximately 4,000 nucleotides—over 60 times the length contemplated by the Arbutus patents.

ANSWER: Plaintiffs **ADMIT** that some research conducted by Arbutus and Protiva included work on siRNA. Plaintiffs **ADMIT** that U.S. Patent No. 8,058,069 ("'069 Patent") includes the following statement: "Interfering RNA includes 'small-interfering RNA' or 'siRNA,' e.g., interfering RNA of about 15-60, 15-50, or 15-40 (duplex) nucleotides in length, more typically about 15-30, 15-25, or 19-25 (duplex) nucleotides in length, and is preferably about 20-24, 21-22, or 21-23 (duplex) nucleotides in length . . . ." '069 Patent at 6:55–60. Plaintiffs **DENY** the remaining allegations in Paragraph 6.

7. None of the Asserted Patents focus on mRNA. For example, the specification of the '069 Patent (and related Asserted Patents) focuses on siRNA, not mRNA, discussing "Selection of siRNA Sequences," "Generating siRNA Molecules," "Modifying siRNA Sequences," and "Target Genes" of siRNA. *See, e.g.*, '069 Patent at cols. 29, 32, 33, and 35. Indeed, all 11 examples of the '069 Patent (and its asserted family members) are directed to "nucleic acid-lipid particles" comprising siRNA—none involve mRNA. *Id.* at 67:64–86:18; *see also* U.S. Patent 9,504,651 at cols. 14–19 (Examples 1–8, none of which are directed to mRNA formulations). This is consistent with Arbutus predecessor Protiva's public statements at the time that the company was "focused on" "formulations for RNAi therapeutics." As another example, the '651 Patent focuses on plasmid DNA, rather than mRNA. *See* '651 Patent at 2:17–19 ("The present invention can be used to form lipid vesicles that contain encapsulated plasmid DNA or small molecule drugs."), and cols. 14–15.

ANSWER: Plaintiffs **ADMIT** that the '069 Patent contains headings titled "Selection of siRNA Sequences," "Generating siRNA Molecules," "Modifying siRNA Sequences," and

"Target Genes." '069 Patent at cols. 29, 32, 33, and 35. Plaintiffs **ADMIT** that the website cited by Defendants states that "Tekmira and Protiva each have liposome formulations suitable for a range of nucleic acid-based drugs, although both are focused on and have several formulations for RNAi therapeutics. Protiva's liposomal platform is called SNALP (for stable nucleic acid-lipid particles)." Plaintiffs **ADMIT** that the '651 Patent states that "[t]he present invention can be used to form lipid vesicles that contain encapsulated plasmid DNA or small molecule drugs." Otherwise, **DENIED.**

8. Tellingly, Plaintiffs/Counterclaim Defendants never developed an LNP capable of delivering mRNA, let alone manufactured or sold any approved products of their own, whether siRNA or mRNA-based.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 8.

9. Failing to develop any products of its own, Arbutus instead improperly expanded the scope of its patent estate in an attempt to cover the inventions of others, including pioneers like Moderna. Consequently, the purported inventions that Arbutus lays claim to in the Asserted Patents bear no resemblance to the rudimentary technology described in the specifications.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 9.

10. 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 its COVID-19 vaccine to people around the world. The COVID-19 Vaccine, also referred to as the mRNA-1273 vaccine, uses Moderna's proprietary LNP delivery technology that Moderna developed and described 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."

ANSWER: Plaintiffs **ADMIT** that the SARS-CoV2 virus, which causes COVID-19, was first detected in December 2019. Plaintiffs **ADMIT** that on January 10, 2020, the genetic sequence of the SARS-CoV-2 virus became public. Plaintiffs lack knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 and therefore **DENY** them.

11. Following the declaration of a public health emergency, Moderna entered into numerous agreements with the U.S. Government regarding its COVID-19 Vaccine. 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 the COVID-19 vaccine 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."

ANSWER: Plaintiffs **ADMIT** that the COVID-19 pandemic was declared a public health emergency. Plaintiffs **ADMIT** that the document cited by Defendants states that "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." Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11 and therefore **DENY** them.

12. 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 ("C0100 Contract"). Under the C0100 Contract, Moderna was obligated to produce and deliver doses of its COVID-19 Vaccine to the U.S. Government, with the option to supply additional doses. The C0100 Contract specifically states that Moderna manufactured the COVID-19 Vaccine doses "for the United States Government." The C0100 contract also incorporates by reference FAR 52.227-1, entitled "Authorization and Consent," and FAR 52.227-1 Alt 1, entitled "Authorization And Consent (JUN 2020) - Alternate I."

ANSWER: On information and belief, Plaintiffs **ADMIT** that the document cited by Defendants, D.I. 17-1, Ex. A, is listed as "Contract No. W911QY20C0100" with an Effective Date listed as August 9, 2020. D.I. 17-1, Ex. A at 1. Plaintiffs **ADMIT** that ModernaTX, Inc. is listed as the contractor on the document cited by Defendants, and the contract states that it is administered by the Defense Contract Management Agency of Boston, MA. *Id*. Plaintiffs

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