

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. \_\_\_\_\_

**JURY TRIAL DEMANDED**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Arbutus Biopharma Corporation (“Arbutus”) and Genevant Sciences GmbH (“Genevant”) file this Complaint seeking patent infringement damages against Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, “Moderna”) and allege the following:

**INTRODUCTION**

1. The impact of the COVID-19 pandemic, one of the greatest public health challenges in modern history, would be immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna’s. Moderna brought its vaccine from lab bench to arms in record speed. That unprecedented accomplishment was made possible by Moderna’s use of breakthrough technology Arbutus had already created and patented—a revolutionary lipid nanoparticle (“LNP”) delivery platform that took the scientists of Arbutus years of painstaking work to develop and refine. Moderna was well aware of Arbutus’s LNP patents and licensed them for other product programs, but it chose not to do so for its COVID-19 vaccine. Instead, it attempted to invalidate several of the patents before the United States Patent

and Trademark Office, and when those efforts largely failed, Moderna simply used the patented technology without paying for it or even asking for a license. Plaintiffs do not seek an injunction or any relief in this case that would impede the sale or manufacture of Moderna's life-saving vaccine. They seek only fair compensation for the use of patented technology they developed with great effort and at great expense, without which Moderna's COVID-19 vaccine would not have been successful.

2. Medicines using messenger ribonucleic acid (or "mRNA") technology, like Moderna's COVID-19 vaccine, rely on synthetic mRNA that enters the body's cells and instructs them to make proteins they would not necessarily make on their own. Moderna's COVID-19 vaccine, in particular, uses mRNA to cause cells to make a small piece of the virus that causes COVID-19 called the "spike protein." That small piece, which is harmless in isolation, prompts the body's immune system to produce antibodies that will recognize the spike protein if it is encountered in the future and destroy it. In this way, the vaccine equips a person's body ahead of time with antibodies to fight the COVID-19 virus if that person experiences a subsequent exposure.

3. Ever since the vast potential for mRNA-based vaccines and other mRNA-based medicines began to catch the attention of scientists more than two decades ago, the biggest technological hurdle to developing and deploying them has been devising a safe and effective way to deliver the mRNA to the cell. Without adequate protection, mRNA quickly degrades in the body. For mRNA vaccines like Moderna's to work, they must incorporate a mechanism for protecting the fragile mRNA, delivering it through cell membranes, and then releasing it inside

the cell. In the words of one Nobel Prize winning scientist, the secret for making RNA-based products work has always been “delivery, delivery, delivery.”<sup>1</sup>

4. Having vexed experts in the field for years, that problem eventually found a solution in the innovative research of Arbutus scientists. Their solution was ingenious: microscopic particles built from four carefully selected types of fat-like molecules, so small that they are measured in nanometers but still stable enough to shelter and protect an RNA molecule on a voyage through the human body to a target cell, and then through the target cell’s membrane, before finally releasing the RNA. These tiny fat-like particles are called “lipid nanoparticles,” or “LNPs.” The United States Patent and Trademark Office has granted Arbutus several patents for its groundbreaking LNP technologies.

5. LNPs identified through Arbutus’s pioneering work have been described as “crucial” to Moderna’s COVID-19 vaccine, the first mRNA product the company was able to commercialize and the keystone of its financial success.<sup>2</sup> Without the LNPs Arbutus invented to safeguard the mRNA and deliver it into cells, the mRNA in Moderna’s vaccine would degrade before ever reaching the cells it needs to enter and the vaccine would not work.

6. Moderna has long been aware of Arbutus’s LNP intellectual property and its importance as a component of mRNA-based vaccines and other mRNA-based medicines. Several years before the pandemic, Moderna obtained licenses to use Arbutus’s LNP patents for certain mRNA products directed to specific viral targets. But those licenses did not grant Moderna rights to use the technology for products targeting SARS-CoV-2, the virus that causes

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<sup>1</sup> Erika Check, “RNA to the Rescue,” *Nature* 425:10-12 (2003), available at <https://www.nature.com/articles/425010a>.

<sup>2</sup> Nathan Vardi, “Moderna’s Mysterious Coronavirus Vaccine Delivery System,” *Forbes.com*, July 29, 2020, available at <https://www.forbes.com/sites/nathanvardi/2020/07/29/modernas-mysterious-coronavirus-vaccine-delivery-system/>.

COVID-19 and that the vaccines at issue here target. Before it decided to use Arbutus's proven and patented technology as a crucial part of its COVID-19 vaccine, Moderna did not ask for a license to do so. Instead, it tried to convince the United States Patent and Trademark Office and, later, the United States Court of Appeals for the Federal Circuit to cancel several of Arbutus's LNP-related patents. But despite the failure of Moderna's attempts to eliminate Arbutus's patents, and despite Plaintiffs' efforts to resolve this dispute without litigation, Moderna has remained unwilling to pay for its use of Arbutus's technology in a vaccine that has earned Moderna billions of dollars in profits.

7. Moderna's intransigence has forced Arbutus and Genevant, a company spearheaded by former Arbutus scientists, to bring this infringement action. Plaintiffs are proud that their LNP technology has had such a profound impact on the heroic fight against the COVID-19 pandemic, and they do not seek to impede by an injunction or otherwise the production or distribution of Moderna's COVID-19 vaccine, including boosters. All Plaintiffs seek is the compensation due to them under the patent laws of the United States and as a matter of simple fairness.

#### **NATURE OF THE ACTION**

8. This is a civil action under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, seeking damages for Moderna's infringing manufacture, use, sale, offer for sale, and/or importation of its mRNA-1273 COVID-19 mRNA LNP vaccine product ("Moderna's COVID-19 vaccine") or any supplemental or booster COVID-19 mRNA LNP vaccine product (collectively, the "Accused Product").

9. As alleged herein, the manufacture, use, sale, offer to sell, and/or importation of the Accused Product infringes or will infringe, actively induces or will actively induce

infringement of, or contributes or will contribute to the infringement of, one or more claims of the following patents relating to nucleic acid-lipid particles, compositions thereof, and their use to deliver nucleic acid-based medicines: U.S. Patent Nos. 8,058,069 (Exhibit A), 8,492,359 (Exhibit B), 8,822,668 (Exhibit C), 9,364,435 (Exhibit D), 9,504,651 (Exhibit E), and 11,141,378 (Exhibit F) (collectively, the “Asserted Patents”). At all relevant times, Arbutus owned the Asserted Patents and licensed exclusive rights to sublicense, practice, and sue for infringement of them to Genevant in certain fields of use that include the vaccine application at issue in this Complaint, with certain exceptions not relevant here (hereinafter, Genevant’s “Exclusive Rights”).

### THE PARTIES

10. Plaintiff Arbutus Biopharma Corporation is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974. The company’s research and development efforts include discovering, developing, and commercializing a cure for chronic hepatitis B virus, as well as drug discovery and development efforts for treating coronaviruses, including SARS-CoV-2, which causes COVID-19.

11. Plaintiff Genevant Sciences GmbH is a company organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. Genevant is a technology-focused nucleic acid delivery solutions company with cutting-edge LNP platforms. Genevant owns or licenses the industry’s most important LNP intellectual property—that of Arbutus—and has decades of experience and expertise in nucleic acid drug delivery and development. Genevant, together with its affiliated companies, maintains offices in Cambridge, Massachusetts and Vancouver, British Columbia, Canada. Genevant’s

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