EXHIBIT 21

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 **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

DECLARATION OF ALLISON P. GRISWOLD IN SUPPORT OF MODERNA'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

I, Allison P. Griswold, hereby declare as follows:

1. I am the Senior Manager, Quality Strategic Operations at ModernaTX, Inc. ("Moderna"). In this role, I am familiar with Moderna's Quality Control ("QC") procedures, including Moderna's compliance with Current Good Manufacturing Practice ("CGMP") standards, FDA criteria and regulations which apply to drugs like Moderna's COVID-19 Vaccine "SpikeVax." I have personal knowledge of the facts stated in this declaration or have become aware of such facts through my role at Moderna. If called upon to testify, I could and would competently testify thereto.

2. I write this declaration in support of Moderna's opposition to Plaintiffs' Motion to Compel production of samples from every drug product batch manufactured of SpikeVax.

3. I understand this case relates to Moderna's COVID-19 Vaccine, known as mRNA-1273 or "SpikeVax." SpikeVax is comprised of messenger RNA (mRNA) which is encased in lipid nanoparticles (LNPs). [redacted]

A. SpikeVax is a Regulated Drug Product that is Approved by the FDA

4. SpikeVax is an FDA-approved drug product, which was initially authorized pursuant to Emergency Use Authorization No. 27073, and later pursuant to Biologics License Application No. 125752. During the FDA approval process, Moderna submits specifications for the drug product and certain of its components, which provide limits for various physical and chemical characteristics. Moderna's specifications for its [redacted] mRNA-LNP, and drug product include lipid content specifications. Each time a batch of [redacted] and drug product is manufactured, Moderna tests a sample to ensure that the batch complies with the specification, including lipid content. A Certificate of Analysis or "COA" is produced each time those tests are carried out, which reports the results of each test to confirm whether it complies with the specification. COAs are also included in Moderna's submissions to the FDA.

5. Because SpikeVax is an FDA-approved drug product, it is subject to regulations. Inventory of batches and samples of drug product and its components is carefully controlled and documented.

B. Request for Samples of Drug Product

6. I have been asked to describe the steps that would need to be taken to be able to produce samples from each batch manufactured of SpikeVax.

7. Retained samples of these batches may be held at Moderna's Norwood location or at third-party manufacturer sites across the United States.

8. I have been part of a cross-functional team that has been working to prepare samples from approximately 400 batches that were manufactured by third-party Catalent to produce to Plaintiffs' external laboratory. The majority of the samples have now arrived at Moderna's facilities, but were previously stored at Catalent's facility in Indiana. The samples had to be driven for over 12 hours under strict cold storage conditions to allow Moderna's team to prepare the samples for production.

9. The team that has been working for weeks to prepare these samples is comprised of at least 15 individuals from various departments, including Quality Control, Quality Assurance, Supply Chain, Compliance, and Regulatory. I expect that an additional 8 individuals will be involved in inventorying the samples, packing the samples for shipment, and documenting their removal from sample retention and processing for shipment.

10. Every process carried out in relation to an approved drug product like SpikeVax requires an approved written Standard Operating Procedure or "SOP." Collection and production of samples for litigation, including by removing regulatory retained samples, is not a standard process that we carry out at Moderna, and as such there is no approved SOP. SpikeVax is Moderna's first commercial product and prior to this request, the company has not had to produce samples for patent infringement litigation.

11. To remove a sample that was reserved for regulatory retain for litigation purposes, the removal must be documented through a change control process, which describes the deviation from normal processes. The change control must be assessed and approved by other stakeholders, including individuals from various departments including Quality Assurance (either internal Quality Assurance, or External Quality Assurance where a contract manufacturing organization is involved), Quality Control, Regulatory, Supply Chain, and Compliance. The change control documentation records the deviation, who evaluated and approved the deviation, and describes the oversight that was involved and what process was followed. The process to be followed is described in a protocol, which for this sample collection must include details on how employees will be trained to follow the protocol, where the samples are being transported to, how they are maintained at required temperatures, and how the temperatures will be monitored.

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