## **Exhibit D**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

MODERNATX, INC. and MODERNA US, INC.,	) ) )
Plaintiffs,	) ) 
v.	) C.A. No
PFIZER INC., BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC.,	) ) JURY TRIAL DEMANDED )
Defendants.	) ) _)

## **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs ModernaTX, Inc. and Moderna US, Inc. (collectively, "Moderna" or the "Company"), by and through their attorneys, hereby allege for their patent infringement Complaint against Defendants Pfizer Inc. ("Pfizer"), BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. ("BioNTech US," together with BioNTech SE and BioNTech Manufacturing GmbH, "BioNTech") as follows:

### NATURE OF THE CASE

- A. Moderna Was Founded in 2010 on the Promise of Developing mRNA Technology to Create a New Generation of Transformative Medicines
- 1. Just twelve years ago, messenger RNA ("mRNA") medicines were a new and unproven technology. Although many doubted that this technology could ever be used to treat or prevent disease, Moderna recognized early on that it had great potential to improve patients' lives. Since Moderna's founding in 2010 in Cambridge, Massachusetts, the Company has been singularly focused on making mRNA medicines a reality through substantial investment and years of research and development.



- 60. The '574 patent claims Moderna's mRNA platform technology, which utilizes mRNA encoding for a polypeptide that comprises a modified uracil, including 1-methylpseudouridine, in a lipid nanoparticle formulation. The '574 patent claims both methods of producing a polypeptide of interest and pharmaceutical compositions.
- 61. Moderna practices the '574 patent through its Spikevax® vaccine, and Moderna marks Spikevax® with a reference to its patent marking website (https://www.modernatx.com/patents [https://perma.cc/B6AG-6URD]), which identifies the '574 patent for Spikevax®.

#### B. Coronavirus Vaccines

- 62. Before COVID-19 first emerged, Moderna made significant breakthroughs in the development of coronavirus vaccines. Coronaviruses are a class of viruses that are enveloped in a protein shell that is covered on the surface by a "spike" protein. A coronavirus spike protein allows the virus to attach to and infect host cells.
- 63. When another coronavirus, MERS, first emerged in the mid-2010s, Moderna carefully studied, designed and tested a vaccine for MERS. The MERS vaccine that Moderna developed was based on mRNA encoding for the virus's spike protein. However, coronavirus spike proteins are large molecules, and no one had previously developed an mRNA vaccine targeting an antigen protein of that size before.
- 64. Moderna was the first to discover that using mRNA encoding for a full-length coronavirus spike protein in a lipid nanoparticle formulation was highly effective at producing neutralizing antibodies to the coronavirus. Moderna's research showed that its coronavirus vaccine produced neutralizing antibodies that prevented infection and confirmed that targeting the spike protein was a successful vaccine design that could be applied to other coronaviruses. Moderna's '600 and '127 patents describe and claim the results of that research.



- 65. When COVID-19 first emerged, this prior research allowed Moderna to design a vaccine for SARS-CoV-2 in record time. Moderna used the coronavirus vaccine design described and claimed in the '600 and '127 patents to develop an mRNA vaccine for COVID-19 by using mRNA encoding for the full-length spike protein for SARS-CoV-2 in a lipid nanoparticle formulation. Although Pfizer and BioNTech initially considered alternative vaccine designs, they ultimately chose to follow Moderna's path of using mRNA encoding for the full-length spike protein of SARS-CoV-2—the exact same design used in Moderna's Spikevax®.
- 66. The '600 patent is titled "Betacoronavirus mRNA vaccine." The '600 patent names as inventors Moderna scientists Giuseppe Ciaramella and Sunny Himansu. The '600 patent claims priority to provisional patent applications filed in October 2015 and a PCT application filed on October 21, 2016. The '600 patent issued on July 7, 2020, and is assigned to Moderna. A true and correct copy of the '600 patent is attached as Exhibit 2.
- 67. The '600 patent claims compositions comprising mRNA comprising an open reading frame encoding a betacoronavirus S protein or S protein subunit formulated in a lipid nanoparticle.
- 68. Moderna practices the '600 patent through its Spikevax® vaccine, and Moderna marks Spikevax® with a reference to its patent marking website (https://www.modernatx.com/patents [https://perma.cc/B6AG-6URD]), which identifies the '600 patent for Spikevax®.
- 69. The '127 patent is titled "Betacoronavirus mRNA vaccine." The '127 patent names as inventors Moderna scientists Giuseppe Ciaramella and Sunny Himansu. The '127 patent claims priority to provisional patent applications filed in October 2015 and a PCT application filed on October 21, 2016. The '127 patent issued on March 2, 2021, and is assigned to Moderna. A true and correct copy of the '127 patent is attached as Exhibit 3.



- 70. The '127 patent claims methods of administering to a subject mRNA comprising an open reading frame encoding a betacoronavirus S protein or S protein subunit formulated in a lipid nanoparticle to induce in the subject an immune response to the S protein or S protein subunit, wherein the lipid nanoparticle comprises certain specified percentages of ionizable cationic lipid, neutral lipid, cholesterol, and PEG-modified lipid.
- 71. The administration of Moderna's Spikevax® in accordance with its approved package insert practices the methods claimed in the '127 patent.

## PFIZER AND BIONTECH'S COVID-19 VACCINE

72. Prior to the emergence of COVID-19, Pfizer and BioNTech had begun researching an mRNA vaccine for influenza, but lacked Moderna's expertise in developing mRNA vaccines for coronaviruses and other infectious diseases. Indeed, BioNTech's CEO, Uğur Şahin, had stated that infectious disease targets were "not a priority" for his company before COVID-19.9 Upon information and belief, Pfizer lacked any candidates in clinical trials using mRNA technology before COVID-19, and BioNTech did not have any such candidates in clinical trials for infectious diseases. <sup>10</sup> By contrast, Moderna had six mRNA candidates for infectious diseases in clinical trials by the time COVID-19 arrived.

BioNTech, Fourth Quarter and Full Year 2019 Corporate Update and Financial Results 10-11 (Mar. 31, 2020), https://investors.biontech.de/static-files/a718a9ec-53cd-42b6-a6e0-8dd21ca4d907.



Asher Mullard, COVID-19 Vaccine Success Enables a Bolder Vision for mRNA Cancer Vaccines, Says BioNTech CEO, 20 Nature Revs.: Drug Discovery 500 (June 17, 2021), available at https://www.nature.com/articles/d41573-021-00110-x ("[Q.] Prior to the pandemic, your first priority was cancer therapies. How much will you now focus on infectious disease vaccines? [A.] We were always interested in infectious diseases, but they were not a priority.") [https://perma.cc/GV6C-UD74].

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