IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

MODERNATX, INC. and MODERNA US, INC., Plaintiffs, v. PFIZER INC., BIONTECH SE, BION-TECH MANUFACTURING GMBH, and BIONTECH US INC., Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

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.

2. Moderna embodies the American ethos of innovation. Its founders are scientists who challenged the status quo and took a chance on developing this unproven technology to treat and prevent some of the deadliest diseases and medical conditions. They came together to create Moderna, a name created from combining "modified" and "RNA." Throughout its history, Moderna has prioritized science above all else, with a focus on helping patients who do not have other options.

3. Over the past twelve years, Moderna has worked diligently in its laboratories to pioneer several 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.

4. Built on that research, Moderna is developing medicines that could 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.

5. Part of Moderna's foundational research in this area included advancing the solution to one of the fundamental challenges with mRNA medicines—namely that the body's own immune system can recognize mRNA as a foreign substance and attack it. In 2010, Moderna scientists began studying new chemical modifications to the mRNA that could better avoid provoking an immune response. That work led to the discovery that mRNA molecules with a specific modification in which uridine is replaced with 1-methylpseudouridine were surprisingly superior to other chemically-modified mRNAs. A former top vaccine official at the U.S. Food and Drug

Administration ("FDA") was recently quoted as saying that the chemical change Moderna pioneered is "the most important thing that people have done with mRNA vaccines."[1]

6. Moderna scientists then studied how to deliver that chemically-modified mRNA to cells in the body. In 2011, they tested whether chemically-modified mRNAs could be delivered to cells when formulated in a lipid nanoparticle. These experiments showed for the first time that cells could successfully express the protein encoded by 1-methylpseudouridine modified mRNA when formulated in a lipid nanoparticle. After those successful experiments, Moderna began using 1-methylpseudouridine modified mRNA in a lipid nanoparticle formulation as the foundation of its mRNA platform.

7. In 2014, around the time that a coronavirus that caused "Middle East Respiratory Syndrome" or "MERS" first emerged, Moderna created a division that was focused exclusively on developing mRNA vaccines for infectious disease. In 2015, Company scientists developed an mRNA vaccine for MERS, which encoded for the full-length spike protein of the MERS coronavirus in a lipid nanoparticle. Animal challenge studies showed that the new vaccine successfully resulted in the production of neutralizing antibodies and prevented MERS infection. Those experimental results provided proof of concept that mRNA encoding for the full-length spike protein in a lipid nanoparticle could be used successfully to prevent coronavirus infection.

8. To protect Moderna's substantial investment of time and resources in developing its innovations, Moderna sought and obtained patents protecting the inventions underlying its mRNA platform and disease-specific vaccine designs, including for coronaviruses. These patents were filed between 2011 and 2016.

---

[1] Jon Cohen, *New Crop of mRNA Vaccines Aim for Accessibility*, 376 Science 120, 121 (2022), *available at* https://www.science.org/doi/epdf/10.1126/science.abq3935 [https://perma.cc/JBM9-9FLH].

9. As a company that had no commercial products at the time, these patents were among Moderna's most valuable business assets and enabled Moderna, as a startup biotech company, to attract investors who could help the Company fulfill its promise and bring its technologies to patients. Indeed, Pfizer's CEO, Albert Bourla, has stated that patents are crucial to "small biotech innovators that are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected."[2]

B. Moderna Was Uniquely Prepared to Respond to the COVID-19 Pandemic Based on Its Existing mRNA Platform and Coronavirus Vaccine Work on MERS

10. When the COVID-19 pandemic struck, Moderna had already conducted a decade of foundational research in the area of mRNA medicines, including specifically on coronaviruses, and was uniquely positioned to respond to the crisis.

11. Following Moderna's initial patented discoveries, the Company began partnering in 2017 with scientists at the National Institutes of Health ("NIH") to further develop its MERS vaccine. This experience partnering with the NIH would later prove vital in quickly responding to the COVID-19 pandemic.

12. Moderna was not planning to bring its first product to market—a vaccine for mothers that could prevent birth defects—until the mid-2020s. Prior to COVID-19, almost all of Moderna's employees worked in research and development. But when it became clear that the virus that causes COVID-19 had the potential to create a pandemic, Moderna answered the call. For a company as small as Moderna, with fewer than 1,000 employees at the time, this was no small feat. Nor was it one that came without risk. Moderna diverted resources away from other

[2] Open Letter from Albert Bourla to Pfizer Employees (May 7, 2021), https://www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines [https://perma.cc/6HSM-QDM5].

projects and hired and built new teams in order to take on the challenge presented by COVID-19. Moderna also issued new stock to raise the funds it would need to manufacture the vaccine. The Company took all of these actions because Moderna had done the research and believed that its mRNA platform could take on this new coronavirus.

13. As a result, in early 2020, Moderna was able to quickly leverage its existing mRNA technology to address the crisis. With its partnership with the U.S. government and in particular the NIH, the Company was able to develop a COVID-19 vaccine that was ready to test in clinical trials within a matter of weeks.

14. While others were predicting that vaccine development could take years, Moderna's COVID-19 vaccine was first administered by the NIH in clinical trials on March 16, 2020, just two months after the genetic sequence for the virus that causes COVID-19 was published. *See, e.g.*, *infra* ¶¶ 48-50.

15. Regulatory authorities set a bar by which to measure COVID-19 vaccines, requiring that they be at least 50% effective in preventing infection. On November 16, 2020, less than a year after COVID had first been identified, Moderna blew away those expectations and was able to show that its vaccine was 94% effective against infection by the strain of the COVID virus then circulating. Other companies using more traditional technology were not able to submit their data until much later and fell short of the bar Moderna had set. Some even abandoned their efforts at a vaccine altogether. Without mRNA vaccines and Moderna's technology, many more months and lives might have been lost.

16. The FDA authorized the use of Moderna's COVID-19 vaccine, which is now marketed under the name Spikevax®, in individuals 18 years of age and older under an emergency

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.