

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

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

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

use authorization on December 18, 2020, and the FDA fully approved Spikevax® for use in that population on January 31, 2022.

C. Pfizer and BioNTech Followed the Trail Moderna Blazed for mRNA Vaccines and Copied Moderna’s Innovations Without Ever Requesting a License

17. Pfizer and BioNTech also developed an mRNA vaccine for COVID-19, marketed under the brand name Comirnaty®. As explained more fully below, the Pfizer/BioNTech vaccine uses the technology Moderna developed and patented.

18. When COVID-19 emerged, neither Pfizer nor BioNTech had Moderna’s level of experience with developing mRNA vaccines for coronaviruses. Upon information and belief, before the emergence of COVID-19, unlike Moderna, neither Pfizer nor BioNTech had ever developed an mRNA vaccine for a coronavirus.

19. Pfizer and BioNTech started with a number of different options when they considered how to design their vaccine. In fact, they took four different candidates into clinical testing, including options that would have steered clear of Moderna’s innovative path by using unmodified mRNA. *See, e.g., infra* ¶¶ 73-74. Ultimately, however, Pfizer and BioNTech discarded those alternatives and copied Moderna’s patented technology. *See, e.g., infra* ¶¶ 75-76.

20. And they did so knowing that they were following Moderna’s lead. Pfizer’s CEO, Albert Bourla, acknowledged that the vaccine design Pfizer and BioNTech ultimately chose to pursue uses “the entire spike protein, which . . . Moderna is using.” Ex. 4, Transcript of Goldman Sachs Virtual 41st Annual Global Healthcare Conference at 3 (June 9, 2020).

21. Pfizer and BioNTech copied two critical features of Moderna’s patented mRNA technology platform. First, out of numerous possible choices, they decided to make the exact same chemical modification to their mRNA that Moderna scientists first developed years earlier, and which the Company patented and uses in Spikevax®. Second, and again despite having many

different options, the Pfizer and BioNTech vaccine encoded for the exact same type of coronavirus protein (i.e., the full-length spike protein), which is the coronavirus vaccine design that Moderna had pioneered based off its earlier work on coronaviruses and which the company patented and uses in Spikevax®. The Moderna inventions that Pfizer and BioNTech chose to copy were foundational for the success of their vaccine.

D. Moderna Is the Only Vaccine Manufacturer to Have Made a Global Commitment to Intellectual Property Never Being a Barrier to COVID-19 Vaccine Access

22. Given the unprecedented challenges of the COVID-19 pandemic, Moderna voluntarily pledged on October 8, 2020 that, “*while the pandemic continues*, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.”³ Moderna refrained from asserting its patents earlier so as not to distract from efforts to bring the pandemic to an end as quickly as possible.

23. By early 2022, however, the collective fight against COVID-19 had entered a new endemic phase and vaccine supply was no longer a barrier to access in many parts of the world, including the United States. In view of these developments, Moderna announced on March 7, 2022, that it expected companies such as Pfizer and BioNTech to respect Moderna’s intellectual

³ Press Release, Moderna, Inc., Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (Oct. 8, 2020), <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx> (emphasis added) [<https://perma.cc/EMU7-9JAT>].

property and would consider a commercially-reasonable license should they request one.⁴ This announcement was widely publicized, including through coverage in *The Wall Street Journal*.⁵ Critically, however, and to further its belief that intellectual property should never be a barrier to access, as part of this announcement, Moderna committed to never enforce its patents for any COVID-19 vaccine used in the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (“AMC”). This includes any product manufactured outside the AMC-92 countries, such as the World Health Organization’s project in South Africa, with respect to COVID-19 vaccines destined for and used in the AMC-92 countries. Although they have continued to use Moderna’s intellectual property, Pfizer and BioNTech have not reached out to Moderna to discuss a license.

E. Moderna Brings This Action to Protect the Company’s mRNA Technology Platform and Ensure its Innovations Are Respected

24. Despite recognizing the importance of patents to innovators such as Moderna, Pfizer and BioNTech have copied Moderna’s intellectual property and have continued to use Moderna’s inventions without permission.

25. Moderna therefore brings this lawsuit to protect the mRNA technology platform it innovated, invested in, and patented and to ensure that intellectual property is respected.

26. In non-AMC 92 countries, where vaccine supply is no longer a barrier to access, Moderna expects Pfizer and BioNTech to stop infringing the Company’s intellectual property. Compensating Moderna with monetary damages for using its patented technology will enable the

⁴ Press Release, Moderna, Inc., Moderna’s Updated Patent Pledge (Mar. 7, 2022), <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx> [<https://perma.cc/R7KP-74FJ>].

⁵ See Peter Loftus, *Moderna Signals It May Enforce Covid-19 Vaccine Patents in Wealthy Nations*, Wall Street J., (Mar. 7, 2022, 7:33 PM), <https://www.wsj.com/articles/moderna-signals-it-may-enforce-covid-19-vaccine-patents-in-wealthy-nations-11646699609> [<https://perma.cc/CC7N-2JPS>].

Company to continue investing in its mRNA technology platform so that it can develop medicines that can treat and prevent a wide range of diseases.

27. This lawsuit is based on three patents that claim priority to applications filed between 2011 and 2016 covering Moderna's foundational intellectual property, and the Company is seeking damages for revenue Pfizer and BioNTech derived from sales in the United States that are not subject to 28 U.S.C. § 1498 and from its domestic manufacture for supply to non-AMC 92 countries outside the United States.

28. This lawsuit does not relate to any patent rights generated during Moderna and NIH's collaboration to combat COVID-19. In addition, in recognition of the need for ensuring access to these critical vaccines, this lawsuit is narrowly drawn in terms of the relief it seeks. Moderna is not seeking an injunction: it is not seeking to remove Comirnaty® from the market or to prevent its future sale. Consistent with Moderna's patent pledge, Moderna is not seeking damages for activities occurring before March 8, 2022. And Moderna is not seeking damages related to Pfizer and BioNTech's sales to the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment.

PARTIES

29. ModernaTX, Inc. ("ModernaTX") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 200 Technology Square, Suite 300, Cambridge, MA 02139. ModernaTX is a wholly-owned subsidiary of Moderna, Inc. ModernaTX is the owner by assignment of the patents asserted in this litigation.

30. Moderna US, Inc. ("Moderna US") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 200 Technology Square, Suite 300, Cambridge, MA 02139. Moderna US is a wholly-owned subsidiary of Moderna, Inc. Moderna

US is the exclusive licensee of the patents asserted in this litigation, and Moderna US sells Spikevax® in the United States.

31. Moderna is a pioneer in the field of mRNA medicines. Since its founding in 2010, Moderna has through years of research and development created the most advanced platform for mRNA medicines in the world. In addition to Spikevax®, Moderna has a pipeline of several dozen mRNA vaccines and therapeutic medicines for a wide range of diseases.

32. Upon information and belief, Pfizer is a corporation organized and existing under the laws of Delaware, with its principal place of business at 235 East 42nd Street, New York, NY 10017. Pfizer has regular and established places of business at 1 Portland Street, Cambridge, MA 02139 and 1 Burt Road, Andover, MA 01810.

33. Upon information and belief, BioNTech SE is a corporation organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

34. Upon information and belief, BioNTech Manufacturing GmbH, a wholly-owned subsidiary of BioNTech SE, is a limited liability company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany. BioNTech Manufacturing GmbH is the Biologics License Application (“BLA”) holder for Comirnaty® in the United States.

35. Upon information and belief, BioNTech US, a wholly-owned subsidiary of BioNTech SE, is a corporation organized and existing under the laws of Delaware, with its principal place of business at 40 Erie St., Suite 110, Cambridge, MA 02139. BioNTech US’s office in

Cambridge, MA serves as BioNTech's North American headquarters.⁶ BioNTech US is BioNTech's agent for service of process in the United States.⁷

36. Upon information and belief, Pfizer and BioNTech together developed and commercialize Comirnaty®.

JURISDICTION AND VENUE

37. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et. seq. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

38. This Court has personal jurisdiction over Defendants because of their systematic and continuous contacts with Massachusetts. For example, both Pfizer and BioNTech regularly conduct business within Massachusetts, including at Pfizer's facilities located at 1 Portland Street, Cambridge, MA 02139 and 1 Burt Road, Andover, MA 01810, and at BioNTech's facility located at 40 Erie St, Suite 110, Cambridge, MA 02139, which serves as BioNTech US's North American headquarters. Both Pfizer and BioNTech have specifically directed their business activities making and selling Comirnaty® to Massachusetts, including by manufacturing the mRNA drug substance for Comirnaty® at Pfizer's facility in Andover, Massachusetts. Defendants' actions that give rise to personal jurisdiction further include, but are not limited to: making, using, selling, and offering for sale Comirnaty® in Massachusetts; knowing and intending that Comirnaty® would be used in Massachusetts; deriving substantial revenue from the use of Comirnaty® in Massachusetts; and expecting their infringing actions to have consequences in Massachusetts.

⁶ See, e.g., BioNTech SE, Annual Report (Form 20-F) 179, F-12 (Mar. 30, 2021), available at <https://investors.biontech.de/static-files/e862a8ea-5d90-4672-acfb-34de57b58806>.

⁷ See, e.g., BioNTech SE, Annual Report (Form 20-F) 81 (Mar. 30, 2022), available at <https://investors.biontech.de/static-files/50d0cafc-b2c1-4392-a495-d252f84be105>.

39. Pfizer and BioNTech have also purposefully availed themselves of the benefits and protections of the courts in Massachusetts, including by initiating litigation relating to Comirnaty® before this Court. *See BioNTech SE v. CureVac AG*, C.A. No. 22-11202 (D. Mass.) (filed July 25, 2022).

40. Venue is proper as to BioNTech SE and BioNTech Manufacturing GmbH in this District pursuant to, *inter alia*, 28 U.S.C. § 1391(c)(3).

41. Venue also is proper as to all Defendants in this District under 28 U.S.C. § 1400(b). Both Pfizer and BioNTech have regular and established places of business in this District, including Pfizer's facilities located at 1 Portland Street, Cambridge, MA 02139 and 1 Burt Road, Andover, MA 01810, and at BioNTech's facility located at 40 Erie St, Suite 110, Cambridge, MA 02139, which serves as the North American headquarters for BioNTech. Defendants have committed acts of infringement and, upon information and belief, will commit further acts of infringement in Massachusetts.

MODERNA'S PIONEERING WORK ON mRNA MEDICINES

42. Long before COVID-19 first emerged, Moderna recognized that mRNA had the potential to revolutionize the field of medicine. mRNA is a molecule that instructs cells to make particular proteins. Unlike traditional vaccines and therapeutics, mRNA medicines harness the body's own cellular machinery to make proteins themselves that can treat or prevent disease. mRNA medicines use a specific nucleotide sequence to encode instructions to make the exact protein needed for a particular disease. This makes mRNA medicines a powerful tool that can be programmed to target specific diseases. However, before Moderna began its research, nobody had figured out how to make or use mRNA medicines successfully. Moderna was founded in 2010 with the sole focus on solving those challenges to make mRNA medicines a reality for patients.

43. Along the way, Moderna encountered many technical challenges as it attempted to develop an entirely new way to treat and prevent disease. The problems that Moderna faced started with the mRNA itself. mRNA is an unstable molecule that is quickly destroyed inside the body. Moderna scientists had to develop novel ways to stabilize mRNA by modifying its chemical structure so that it could be used in vaccines and therapeutics. Moderna also optimized its mRNA platform to make it more effective at producing the proteins needed to fight and prevent disease. And Moderna developed new techniques for manufacturing mRNA medicines so that they could be made on a large scale. All told, Moderna invested billions of dollars over the course of nearly a decade of research to develop an mRNA platform that could be applied across a variety of therapeutic and prophylactic applications.

44. Moderna was also at the forefront of applying its mRNA medicines to new diseases as they emerged. For example, Moderna had previously developed an mRNA vaccine against a coronavirus that caused Middle Eastern Respiratory Syndrome, or “MERS.” Through that work on MERS, Moderna demonstrated the effectiveness of mRNA vaccines to prevent coronavirus infection and developed a template that could be used for vaccines against future coronaviruses.

MODERNA’S COVID-19 VACCINE

45. When COVID-19 first emerged, nobody was better positioned to respond than Moderna. Moderna had already developed the world’s most advanced platform for mRNA medicines. And Moderna had experience developing mRNA vaccines to prior coronaviruses through its research on MERS.

46. Unlike Pfizer and BioNTech, Moderna did not struggle with different approaches before designing its COVID-19 vaccine. Instead, working from its research completed years earlier, Moderna knew how to design an effective COVID-19 vaccine and was able to respond rapidly

with a vaccine specifically targeting COVID-19 in early 2020 when reports of COVID-19 first began to emerge from China.

47. Moderna partnered with leading scientists from the NIH to test and develop Moderna's COVID-19 vaccine. The NIH had access to laboratories to conduct pre-clinical testing of Moderna's COVID-19 vaccine, including through challenge studies demonstrating the ability of Moderna's new vaccine to prevent COVID-19 infection. Moderna and the NIH also met regularly to develop a clinical trial strategy to evaluate the safety and efficacy of Moderna's COVID-19 vaccine.

48. The genomic sequence for SARS-CoV-2 was first published on January 11, 2020, and, within a matter of days, Moderna took that information to create an mRNA sequence encoding for the virus's spike protein. The first clinical batch of Moderna's COVID-19 vaccine was manufactured on February 7, 2020—just four weeks after the genome sequence for SARS-CoV-2 was published. Moderna provided clinical samples to its partners at the NIH. Moderna and the NIH then worked together to conduct clinical trials of Moderna's vaccine on an expedited basis.

49. Moderna's new mRNA technology dramatically changed the pace of vaccine development. While other leading pharmaceutical companies thought that it could take "several years" or more before a vaccine would be ready, Moderna's CEO, Stéphane Bancel, predicted in March 2020 that Moderna could have its vaccine in Phase II and III clinical trials in just a "few months."⁸

⁸ See Remarks by President Trump and Members of the Coronavirus Task Force in Meeting with Pharmaceutical Companies (Mar. 2, 2020), <https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/> [<https://web.archive.org/web/20200303160403/https://www.whitehouse.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/>].

50. He was right. Spikevax® has had a significant effect in preventing infections, transmission, hospitalizations, and deaths resulting from COVID-19. Spikevax® was approved for clinical trials on March 4, 2020 and became the first COVID-19 vaccine candidate to enter Phase I clinical trials in humans in the United States. On March 16, 2020, the first participant in the Phase I study of Spikevax® was dosed, with a Phase II trial beginning in May 2020 and a Phase III trial in July 2020. Those clinical trials showed that Spikevax® was 94% effective at preventing a COVID-19 infection from the original coronavirus strain after completing a two-dose regimen, and it remained 93% effective six months after administration.

51. The FDA authorized the use of Spikevax® in individuals 18 years of age and older under an emergency use authorization on December 18, 2020, and the FDA fully approved Spikevax® for use in that population on January 31, 2022.

52. On October 20, 2021, the FDA expanded its emergency use authorization for Moderna's COVID-19 vaccine to permit the administration of a booster dose in certain individuals who previously completed their primary two-dose regimen with Moderna's COVID-19 vaccine. On November 19, 2021, the FDA amended its emergency use authorization to permit individuals to receive a booster dose of Moderna's COVID-19 vaccine six months after completion of their primary dosing regimen with any FDA-authorized or approved COVID-19 vaccine. After the Omicron variant of COVID-19 emerged, the FDA on January 7, 2022 shortened the dosing interval for a booster dose of Moderna's COVID-19 vaccine to five months after the completion of the individual's primary vaccination series. On March 29, 2022, the FDA expanded Moderna's emergency use authorization to permit the administration of a second booster dose to individuals 50 years of age and older and to immunocompromised individuals 18 years of age and older. On June

17, 2022, the FDA expanded Moderna's emergency use authorization to permit the use of Moderna's COVID-19 vaccine in children six months and older.

53. Moderna has supplied the United States with over 299 million doses of Moderna's COVID-19 vaccine, and over 77 million people in the United States have received a complete primary vaccine series with Moderna's COVID-19 vaccine to date.

MODERNA'S PATENTS

54. The success of Spikevax® is a result of the groundbreaking innovations that Moderna made in the years before COVID-19 first emerged. Moderna has sought to protect its substantial investment in research and development by obtaining patents that cover its inventions. Three of those patents are at issue here: U.S. Patent Nos. 10,898,574 (the "574 patent"), 10,702,600 (the "600 patent"), and 10,933,127 (the "127 patent") (collectively, the "Asserted Patents").

A. Moderna's mRNA Platform Technology

55. mRNA is a molecule that typically is composed of four different nucleosides: adenosine, guanosine, cytidine, and uridine. The nucleoside sequence in an mRNA molecule provides instructions that cells use to create particular proteins.

56. One of the early challenges that Moderna faced in developing mRNA medicines was that administering them to people can result in the body's own immune system attacking the mRNA molecule. This immune response destroys the mRNA before it can have its intended effect. To solve that problem, Moderna studied numerous different potential chemical modifications to the mRNA molecule itself to disguise the mRNA from the body's immune system. By substituting one of the typical nucleosides in mRNA with a chemically-modified version, Moderna hoped that it could prevent the body's immune system from recognizing and destroying the mRNA molecule.

While certain chemical modifications had been tested before, Moderna set out to improve upon that work to identify the best chemical modifications to use in an mRNA vaccine.

57. Moderna's scientists made the groundbreaking discovery that replacing uridine in the mRNA molecule with 1-methylpseudouridine resulted in surprisingly superior protein production—a severalfold increase over chemically-modified mRNAs studied before—with a significantly reduced immune response against the mRNA itself. Moderna further discovered that packaging that chemically-modified mRNA in a lipid nanoparticle formulation allowed for the efficient delivery of the mRNA to cells.

58. This work became the foundation of Moderna's mRNA platform. Moderna's '574 patent describes and claims the results of that research. Moderna's early discovery captured in the '574 patent has been critical to the success of mRNA vaccines for COVID-19. Although Pfizer and BioNTech initially considered alternative vaccine designs without a chemical modification, they ultimately chose to use one, and not just any one. They chose to use the very same 1-methylpseudouridine modification first pioneered by Moderna years earlier.

59. The '574 patent is titled "Delivery and formulation of engineered nucleic acids." The '574 patent names Moderna scientists Antonin de Fougères and Sayda M. Elbashir as inventors. The '574 patent claims priority to a provisional patent application filed on March 31, 2011 and a non-provisional patent application filed on April 2, 2012. The '574 patent issued on January 26, 2021, and is assigned to Moderna. A true and correct copy of the '574 patent is attached as Exhibit 1.

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.¹⁰ By contrast, Moderna had six mRNA candidates for infectious diseases in clinical trials by the time COVID-19 arrived.

⁹ 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>].

¹⁰ 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>.

73. Although Pfizer and BioNTech initially started their development of an mRNA vaccine for COVID-19 behind Moderna technologically, they quickly made up ground by co-opting Moderna's patented inventions. Pfizer and BioNTech had many choices for how they could design their COVID-19 vaccine. Indeed, upon information and belief, Pfizer and BioNTech's COVID-19 vaccine program—named “Project Lightspeed”—started with more than twenty vaccine candidates representing different mRNA constructs and target antigens that BioNTech took into preclinical testing. By April 23, 2020, Pfizer and BioNTech had narrowed that field down to four vaccine candidates that they chose to take into clinical testing.¹¹

74. Not all of Pfizer and BioNTech's COVID-19 vaccine candidates used Moderna's patented inventions. For example, upon information and belief, Pfizer and BioNTech investigated a vaccine candidate called “BNT162a1,” which used mRNA containing unmodified uridine. Pfizer and BioNTech also studied a vaccine candidate called “BNT162c2,” which used a self-amplifying mRNA technology.¹² Neither BNT162a1 nor BNT162c2 use Moderna's patented mRNA platform containing 1-methylpseudouridine modified mRNA in a lipid nanoparticle formulation.

75. However, as Pfizer and BioNTech got further along in their clinical development, they ultimately focused exclusively on vaccine designs that used Moderna's patented technologies.

¹¹ BioNTech, *BNT162 COVID-19 Vaccine Program Update* 6, 13 (Apr. 23, 2020), <https://investors.biontech.de/static-files/398d9bd8-e2cb-49ca-9d6d-7dfd01c66b8a>.

¹² Pfizer, *COVID-19 Vaccine Development Program* 6 (July 1, 2020), https://s28.q4cdn.com/781576035/files/doc_presentation/2020/07/01/COVID-Vaccine-Analyst-Call-Deck-v15-presentation.pdf [<https://perma.cc/B269-RQ2K>]; Pfizer, *Pfizer Inc to Discuss Data From an Ongoing Phase 1/2 Study of mRNA-Based Vaccine Candidate Against SARS-CoV-2 Call 3* (July 1, 2020), https://s28.q4cdn.com/781576035/files/doc_downloads/event-announcement/2020/07/01/PFE-USQ_Transcript_2020-07-01.pdf [<https://perma.cc/5BS7-GY45>]; BioNTech, *Second Quarter 2020 Corporate Update and Financial Results* 19 (Aug. 11, 2020), <https://investors.biontech.de/static-files/ed9d3efd-2dfb-4f48-955a-69718604d604>.

In doing so, Pfizer and BioNTech were aware of Moderna’s COVID-19 vaccine design, and they chose to copy it. *See* Ex. 4 at 3 (Pfizer’s CEO, Albert Bourla, stating: “We are using an mRNA, modified RNA technology. . . . [O]ne antigen that we’re using it [sic] is the entire spike protein, which . . . Moderna is using.”); Ex. 5, Transcript of RBC Capital Markets Global Healthcare Conference at 5 (May 19, 2020) (Pfizer’s Vice President of Investor Relations, Chuck Triano, stating: “[W]e’re testing, not just the spike protein . . . that’s Moderna’s approach, but in addition, we’re testing both the spike and the receptor binding domain.”); Ex. 6, Transcript of BioNTech Q2 2020 Earnings Call at 22 (Aug. 11, 2020) (BioNTech’s CEO, Uğur Şahin, stating: “[The] modified messenger RNA platform . . . used for the candidate[s] b1 and b2 . . . w[as] selected based on the experience of the field in the past with MERS and [] SARS[.]”).

76. On July 27, 2020, Pfizer and BioNTech announced they had chosen to advance a single COVID-19 vaccine candidate called “BNT162b2” to Phase II/III clinical trial.¹³ BNT162b2 uses the exact same 1-methylpseudouridine chemical modification in a lipid nanoparticle formulation as Moderna’s patented COVID-19 vaccine. Moreover, BNT162b2 contains mRNA encoding for the exact same full-length spike protein for SARS-CoV-2 as Moderna’s patented COVID-19 vaccine.

77. Pfizer and BioNTech’s strategy of copying Moderna’s COVID-19 vaccine design has proven highly successful. On November 18, 2020, Pfizer and BioNTech announced that BNT162b2 showed 95% efficacy against the original coronavirus strain in study participants who

¹³ Pfizer Inc., Press Release, Pfizer and BioNTech Choose Lead mRNA Vaccine Candidate Against COVID-19 and Commence Pivotal Phase 2/3 Global Study (July 27, 2020), <https://biontechse.gcs-web.com/news-releases/news-release-details/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate-against> [<https://web.archive.org/web/20200730054155/https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate-0>].

had no prior SARS-CoV-2 infection. On December 11, 2020, the FDA granted emergency use authorization for the use of BNT162b2 in individuals over 16 years of age. On August 23, 2021, the FDA approved the BLA for Comirnaty® (BNT162b2) for use in individuals over 16 years of age. Upon information and belief, BioNTech Manufacturing GmbH is the BLA holder for Comirnaty®.

78. On October 29, 2021, the FDA authorized the use of Pfizer and BioNTech's COVID-19 vaccine in children between 5 and 11 years of age pursuant to an emergency use authorization. On June 17, 2022, the emergency use authorization for Pfizer and BioNTech's vaccine was expanded to include the use of the vaccine in individuals between six months and 4 years of age.

79. On September 22, 2021, the FDA amended its emergency use authorization for Comirnaty® to permit administration of a booster dose in certain individuals six months after completing their primary two-dose series with Comirnaty®. On November 19, 2021, the FDA expanded its emergency use authorization to permit a booster dose of Comirnaty® for individuals who are at least 18 years old and allowed for the administration of a Comirnaty® booster in individuals who completed their primary vaccination series with any FDA-authorized or approved COVID-19 vaccine. The FDA further expanded its emergency use authorization to permit a booster dose of Comirnaty® in 16- and 17-year-olds on December 9, 2021 and for individuals 12-years-old or older on January 3, 2022. On January 3, 2022, the FDA also shortened the time period for administration of the third booster dose of Comirnaty® to five months after completion of the primary vaccination series. On March 29, 2022, the FDA authorized individuals who are over the age of 50 or immunocompromised patients who are 12-years-old or older to receive a second booster dose of Comirnaty® four months after receiving a first booster dose. Pfizer and BioNTech

encourage the administration of booster doses of Comirnaty® in accordance with its emergency use authorization, including through the website for their COVID-19 vaccine: <https://www.comirnaty.com/booster-dose/> [<https://perma.cc/7WHG-LZ3B>].

80. Pfizer and BioNTech have enjoyed a substantial financial windfall from their use of Moderna's patented technologies. To date, Pfizer and BioNTech have provided over 472 million doses of their COVID-19 vaccine for use in the United States. Pfizer reported that it earned \$7.8 billion in revenues from the sale of Comirnaty® in the United States in 2021, and Pfizer recently announced that it expects an additional \$32 billion in global revenues from Comirnaty® in 2022. *See* Rachel Arthur, *Pfizer Predicts \$54bn in 2022 Revenue from Comirnaty and Paxlovid*, BioPharma-Reporter.com (Feb. 8, 2022, 15:45 GMT), <https://www.biopharma-reporter.com/Article/2022/02/08/Pfizer-predicts-54bn-in-2022-sales-from-Comirnaty-and-Paxlovid> [<https://perma.cc/9T43-3JHT>]; *see also* Press Release, Pfizer, Pfizer Reports Fourth-Quarter and Full-Year 2021 Results 35 (Feb. 8, 2022), https://s28.q4cdn.com/781576035/files/doc_financials/2021/q4/Q4-2021-PFE-Earnings-Release.pdf [<https://perma.cc/LLJ4-566V>].

81. Moderna is not seeking any relief in this lawsuit for sales that Pfizer and BioNTech have made to the U.S. government that are covered by 28 U.S.C. § 1498. But Pfizer and BioNTech have made clear that they intend to continue to reap profits from their use of Moderna's patented technology in 2022 and beyond, including by making product in the United States to serve the global market. For example, in December 2021, the Committee for Medicinal Products for Human Use of the European Medicines Agency approved Pfizer and BioNTech's request to scale up pro-

duction at Pfizer’s facility in Andover, Massachusetts “to support the continued supply of Comirnaty in the European Union.”¹⁴ Pfizer and BioNTech have also made clear that they intend to sell additional booster doses of Comirnaty®. For example, on March 29, 2022, the FDA authorized certain people to receive a second booster dose of Pfizer and BioNTech’s COVID-19 vaccine.¹⁵ Pfizer and BioNTech actively promote the use of booster doses for their COVID-19 vaccine, including through their website for Comirnaty®: <https://www.comirnaty.com/booster-dose/> [<https://perma.cc/7WHG-LZ3B>].

82. In the face of that ongoing infringement, Moderna filed this lawsuit so that it may obtain fair compensation for Pfizer and BioNTech’s continued use of Moderna’s patented technologies. That fair compensation will translate into an opportunity for Moderna to reinvest in its leading mRNA platform that allowed both Moderna and Pfizer/BioNTech to address the COVID-19 pandemic. Indeed, were Pfizer and BioNTech allowed to freely copy Moderna’s patented technology for their own benefit, the next generation of biotech startups would lose their ability to rely on the patent system that is the bedrock upon which future medicines will be discovered.

COUNT I – INFRINGEMENT OF THE ’574 PATENT

83. Moderna incorporates each of the above paragraphs 1-82 as though fully set forth herein.

¹⁴ European Medicines Agency, *Increase in Manufacturing Capacity for COVID-19 Vaccines from Janssen, Moderna, and BioNTech/Pfizer* (Dec. 16, 2021), <https://www.ema.europa.eu/en/news/increase-manufacturing-capacity-covid-19-vaccines-janssen-moderna-biontech-pfizer> [<https://perma.cc/43DL-YXK9>].

¹⁵ Pfizer, Inc., Press Release, *Pfizer and BioNTech Receive Expanded U.S. Emergency Use Authorization for an Additional COVID-19 Vaccine Booster in Individuals Aged 50 Years and Older* (Mar. 29, 2022), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-receive-expanded-us-emergency-use> [<https://perma.cc/BRL9-NX8P>].

84. Upon information and belief, Defendants have directly infringed and continue to directly infringe one or more of the claims of the '574 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Comirnaty® in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

85. Upon information and belief, the use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization infringes one or more of the claims of the '574 patent. Defendants have induced infringement and continue to induce infringement of one or more of the claims of the '574 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to make and use Comirnaty® in the United States and in this District in a manner that would directly infringe the '574 patent. Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '574 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

86. Upon information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '574 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants have contributorily infringed and continue to contributorily infringe one or more of the claims of the '574 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '574 patent, in violation of 35 U.S.C. § 271(c).

87. Upon information and belief, Defendants have infringed or will infringe one or more of the claims of the '574 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), including by supplying the global market for Comirnaty® with components, such as mRNA, manufactured in the United States.

88. Comirnaty® satisfies each and every element of one or more claims of the '574 patent. Defendants' actions with respect to Comirnaty® have infringed, induced infringement, or contributorily infringed at least claims 1-4 and 6-10 of the '574 patent.

89. For example, claim 2 of the '574 patent is representative and recites:

A pharmaceutical composition comprising:

a plurality of lipid nanoparticles comprising a cationic lipid, a sterol, and a PEG-lipid,

wherein the lipid nanoparticles comprise an mRNA encoding a polypeptide,

wherein the mRNA comprises one or more uridines, one or more cytidines, one or more adenosines, and one or more guanosines and wherein substantially all uridines are modified uridines.

90. Comirnaty® is a pharmaceutical composition comprising a plurality of lipid nanoparticles comprising a cationic lipid, a sterol, and a PEG-lipid, wherein the lipid nanoparticles comprise an mRNA encoding a polypeptide, wherein the mRNA comprises one or more uridines, one or more cytidines, one or more adenosines, and one or more guanosines and wherein substantially all uridines are modified uridines.

91. For example, Section 12 of the package insert for Comirnaty® states that “[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen.” Section 11 of the package insert for Comirnaty® states that “[e]ach 0.3 mL dose of the COMIRNATY . . .

also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose.” Section 11 of the package insert for Comirnaty® further states that “[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein.” A true and correct copy of the package insert from July 2022 for Comirnaty® is attached as Exhibit 7.

92. Defendants’ own publications confirm that the uridines in Comirnaty® are modified uridines—namely, 1-methylpseudouridine. For example, Defendants published an article in the journal *Nature*, which describes making Comirnaty® (BNT162b2) using 1-methylpseudouridine instead of uridine: “Here we report the preclinical development of lipid-nanoparticle-formulated, N¹-methyl-pseudouridine (m¹Ψ) nucleoside-modified mRNA (modRNA) BNT162b vaccine candidates (BNT162b1 and BNT162b2) that encode immunogens derived from the S of SARS-CoV-2.” Annette B. Vogel et al., *BNT162b Vaccines Protect Rhesus Macaques from SARS-CoV-2*, 592 *Nature* 283, 284 (2021). A true and correct copy of this publication is attached as Exhibit 8.

93. Claim 9 of the ’574 patent recites:

The pharmaceutical composition of claim 2, wherein the modified uridine is 1-methyl-pseudouridine.

94. Comirnaty® satisfies all of the limitations of claim 9 of the ’574 patent for all of the reasons described in paragraphs 90-92 above.

95. Defendants promote the use of Comirnaty® to infringe one or more claims of the '574 patent. For example, Sections 1 and 2 of the package insert for Comirnaty® instruct how to use the vaccine.

96. Defendants further promote the use of Comirnaty® booster shots to infringe one or more claims of the '574 patent. For example, among other things, Pfizer and BioNTech maintain a website (<https://www.comirnaty.com/booster-dose/> [<https://perma.cc/7WHG-LZ3B>]) that promotes the use of Comirnaty® booster shots in accordance with the FDA's emergency use authorization. Pfizer and BioNTech also provide a "Fact Sheet" that instructs the use of Comirnaty® booster shots to infringe one or more claims of the '574 patent. *See* Ex. 9, Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use in Individuals 12 Years of Age and Older (revised July 8, 2022).

97. Defendants have knowledge of the '574 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '574 patent.

98. Comirnaty® constitutes a material part of the invention claimed in the '574 patent, is especially adopted for use in infringing the claims of the '574 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Indeed, the only use of Comirnaty® instructed in its package insert infringes the claims of the '574 patent. *See* Ex. 7 at 2 ("COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.").

99. The '574 patent is listed on Moderna's patent marking website for Spikevax®. Pursuant to 35 U.S.C. § 287, Defendants have constructive notice of the '574 patent through Moderna's patent marking.

100. Defendants' infringement of the '574 patent has been willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it utilized the same chemically-modified mRNA as Moderna's patent-protected Spikevax®. Defendants have continued to use the invention claimed in the '574 patent in deliberate disregard for Moderna's patent rights.

101. Moderna has suffered damages as a result of Defendants' infringement of the '574 patent. Moderna is entitled to an award of compensatory damages, including reasonable royalties and/or lost profits, for Defendants' infringement of the '574 patent.

102. Defendants have engaged in egregious infringement behavior with respect to the '574 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

103. Defendants' conduct with respect to '574 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II – INFRINGEMENT OF THE '600 PATENT

104. Moderna incorporates each of the above paragraphs 1-82 as though fully set forth herein.

105. Upon information and belief, Defendants have directly infringed and continue to directly infringe one or more of the claims of the '600 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Comirnaty® in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

106. Upon information and belief, the use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization infringes one or more of the claims of

the '600 patent. Defendants have induced infringement and continue to induce infringement of one or more of the claims of the '600 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to make and use Comirnaty® in the United States and in this District in a manner that would directly infringe the '600 patent. Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '600 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

107. Upon information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '600 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants have contributorily infringed and continue to contributorily infringe one or more of the claims of the '600 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '600 patent, in violation of 35 U.S.C. § 271(c).

108. Upon information and belief, Defendants have infringed or will infringe one or more of the claims of the '600 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), including by supplying the global market for Comirnaty® with components, such as mRNA, manufactured in the United States.

109. Comirnaty® satisfies each and every element of one or more claims of the '600 patent. Defendants' actions with respect to Comirnaty® have infringed, induced infringement, or contributorily infringed at least claims 1-2, 4-6, 8-12, 16-17, 20-21, and 26 of the '600 patent.

110. For example, claim 1 of the '600 patent is representative and recites:

A composition, comprising:

a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit

formulated in a lipid nanoparticle.

111. Comirnaty® is a composition comprising a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.

112. For example, Section 11 of the package insert for Comirnaty® states that “[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.” Ex. 7 at 19. Section 12 of the package insert for Comirnaty® states that “[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen.” Ex. 7 at 20. The “SARS-CoV-2 S antigen” encoded by the mRNA in Comirnaty® is a betacoronavirus S protein.

113. Defendants promote the use of Comirnaty® to infringe one or more claims of the '600 patent. For example, Sections 1 and 2 of the package insert for Comirnaty® instruct how to use the vaccine.

114. Defendants further promote the use of Comirnaty® booster shots to infringe one or more claims of the '600 patent. For example, among other things, Pfizer and BioNTech maintain

a website (<https://www.comirnaty.com/booster-dose/> [<https://perma.cc/7WHG-LZ3B>]) that promotes the use of Comirnaty® booster shots in accordance with the FDA’s emergency use authorization. Pfizer and BioNTech also provide a “Fact Sheet” that instructs the use of Comirnaty® booster shots to infringe one or more claims of the ’600 patent. *See* Ex. 9 at 5.

115. Defendants have knowledge of the ’600 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the ’600 patent.

116. Comirnaty® constitutes a material part of the invention claimed in the ’600 patent, is especially adopted for use in infringing the claims of the ’600 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Indeed, the only use of Comirnaty® instructed in its package insert infringes the claims of the ’600 patent.

117. The ’600 patent is listed on Moderna’s patent marking website for Spikevax®. Pursuant to 35 U.S.C. § 287, Defendants have constructive notice of the ’600 patent through Moderna’s patent marking.

118. Defendants’ infringement of the ’600 patent has been and continues to be willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it utilized the same target antigen as Moderna’s patent-protected Spikevax®. Defendants continued to use the invention claimed in the ’600 patent in deliberate disregard for Moderna’s patent rights.

119. Moderna has suffered damages as a result of Defendants’ infringement of the ’600 patent. Moderna is entitled to an award of compensatory damages, including reasonable royalties and/or lost profits, for Defendants’ infringement of the ’600 patent.

120. Defendants have engaged in egregious infringement behavior with respect to the '600 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

121. Defendants' conduct with respect to '600 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III – INFRINGEMENT OF THE '127 PATENT

122. Moderna incorporates each of the above paragraphs 1-82 as though fully set forth herein.

123. Upon information and belief, Defendants have directly infringed and continue to directly infringe one or more of the claims of the '127 patent, either literally or under the doctrine of equivalents, by using Comirnaty® in the United States and in this District, in violation of 35 U.S.C. § 271(a).

124. Upon information and belief, the use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization infringes one or more of the claims of the '127 patent. Defendants have induced infringement and continue to induce infringement of one or more of the claims of the '127 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to make and use Comirnaty® in the United States and in this District in a manner that would directly infringe the '127 patent. Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '127 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

125. Upon information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '127 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants have contributorily infringed and continue

to contributorily infringe one or more of the claims of the '127 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '127 patent, in violation of 35 U.S.C. § 271(c).

126. Upon information and belief, Defendants have infringed or will infringe one or more of the claims of the '127 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), including by supplying the global market for Comirnaty® with components, such as mRNA, manufactured in the United States.

127. The use of Comirnaty® as instructed in its package insert satisfies each and every element of one or more claims of the '127 patent. Upon information and belief, Defendants and others, including but not limited to healthcare providers and patients, have used Comirnaty® in the United States and in this District as instructed in Comirnaty®'s package insert to practice the methods claimed in the '127 patent. Defendants' actions with respect to Comirnaty® have infringed, induced infringement, or contributorily infringed at least claims 1-3, 6-9, 11-13, 17-18, and 20 of the '127 patent.

128. For example, claim 1 of the '127 patent is representative and recites:

A method comprising administering to a subject

a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit

formulated in a lipid nanoparticle

in an effective amount to induce in the subject an immune response to the BetaCoV S protein or S protein subunit

wherein the lipid nanoparticle comprises 20-60 mol% ionizable cationic lipid, 5-25 mol% neutral lipid, 25-55 mol% cholesterol, and 0.5-15 mol% PEG-modified lipid.

129. The use of Comirnaty® as instructed in its package insert is a method comprising administering to a subject a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle in an effective amount to induce in the subject an immune response to the BetaCoV S protein or S protein subunit wherein the lipid nanoparticle comprises 20-60 mol% ionizable cationic lipid, 5-25 mol% neutral lipid, 25-55 mol% cholesterol, and 0.5-15 mol% PEG-modified lipid.

130. For example, Section 2.2 of the package insert for Comirnaty® instructs users to “[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly.” Ex. 7 at 6. Section 11 of the package insert for Comirnaty® states that “[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein SARS-CoV-2.” Ex. 7 at 19. Section 12 of the package insert for Comirnaty® states that “[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen.” Ex. 7 at 20. The “SARS-CoV-2 S antigen” encoded by the mRNA in Comirnaty® is a betacoronavirus S protein. Section 12 of the package insert for Comirnaty® further states that “[t]he vaccine elicits an immune response to the S antigen, which protects against COVID-19.” *Id.* Section 11 of the package insert for Comirnaty® further states that “[e]ach 0.3 mL dose of the COMIRNATY . . . also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potas-

sium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose.” Ex. 7 at 19-20. The lipid nanoparticle composition of Comirnaty® falls within the ranges specified in the claims of the ’127 patent.

131. The use of Comirnaty® booster shots pursuant to Pfizer and BioNTech’s emergency use authorization infringes the claims of the ’127 patent for the same reasons. For example, Pfizer and BioNTech have published a “Fact Sheet” that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Pfizer and BioNTech’s vaccine “has been shown to prevent COVID-19.” Ex. 9 at 5. Booster doses are identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing> [<https://perma.cc/94KH-8R2B>].

132. Defendants have knowledge of the ’127 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the ’127 patent.

133. Comirnaty® constitutes a material part of the invention claimed in the ’127 patent, is especially adopted for use in infringing the claims of the ’127 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Indeed, the only use of Comirnaty® instructed in its package insert infringes the claims of the ’127 patent.

134. Defendants’ infringement of the ’127 patent has been willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it utilized the same target antigen as Moderna’s patent-protected Spikevax®. Defendants continue

to promote the use the invention claimed in the '127 patent in deliberate disregard for Moderna's patent rights.

135. Moderna has suffered damages as a result of Defendants' infringement of the '127 patent. Moderna is entitled to an award of compensatory damages, including reasonable royalties and/or lost profits, for Defendants' infringement of the '127 patent.

136. Defendants have engaged in egregious infringement behavior with respect to the '127 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

137. Defendants' conduct with respect to '127 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Moderna prays that this Court grant the following relief:

- a. A judgment that Defendants have infringed one or more claims of the Asserted Patents, induced infringement of one or more claims of the Asserted Patents, and/or contributorily infringed one of more claims of the Asserted Patents;
- b. A judgment that Defendants' infringement is willful;
- c. An award to Moderna of monetary damages for Defendants' infringement occurring on or after March 8, 2022 other than for sales to the U.S. government that are subject to 28 U.S.C. § 1498 or to the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), including reasonable royalties and/or lost profits, together with interest, costs, expenses, disbursements, and an accounting and/or ongoing royalty for any post-judgment infringement;
- d. An award to Moderna of all other damages permitted by 35 U.S.C. § 284, including enhanced damages up to three times the amount of compensatory damages found;

e. A declaration that this is an exceptional case and an award to Moderna of its attorneys' fees, costs, and expenses, pursuant to 35 U.S.C. § 285; and

f. Such other relief as this Court may deem just and proper, except Moderna does not seek injunctive relief against Comirnaty®.

DEMAND FOR JURY TRIAL

Moderna respectfully requests a trial by jury on all issues so triable in accordance with Rule 38 of the Federal Rules of Civil Procedure.

Date: August 26, 2022

Respectfully submitted,

/s/ William F. Lee

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