IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MODERNATX, INC. and MODERNA US, INC., Plaintiffs, v. PFIZER INC., BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC., Defendants.	Case No. 1:22-cv-11378-RGS **JURY TRIAL DEMANDED**
PFIZER INC., BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC., Counterclaim-Plaintiffs, v. MODERNATX, INC. and MODERNA US, INC., Counterclaim-Defendants.	

DEFENDANTS PFIZER INC., BIONTECH SE, BIONTECH MANUFACTURING GMBH, AND BIONTECH US INC.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Pfizer Inc. ("Pfizer"), BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US, Inc. (collectively, "BioNTech") answer and respond to each of the allegations in the complaint of Plaintiffs and Counterclaim-Defendants ModernaTX, Inc. and Moderna US, Inc. (collectively "Moderna") (D.I. 1). Any allegations not expressly admitted are denied. This answer follows the numbering provided in Moderna's complaint. To the extent that the section headings of Moderna's complaint contain allegations, those allegations

are denied. Moderna's complaint contains various footnoted citations not reproduced herein. To the extent Moderna's footnotes contain allegations, those allegations are denied.

GENERAL DENIAL

1. Except as may be expressly admitted below, Pfizer and BioNTech (collectively, "Defendants") generally deny any averment in Moderna's complaint. Defendants particularly deny Moderna's allegations that it has exclusive patent rights in either (1) the fundamental discovery of an mRNA platform technology that utilizes modified mRNA, or (2) the idea of encasing modified mRNA in a lipid nanoparticle for delivery of the mRNA to cells. For the reasons explained in the paragraphs that follow and Counterclaim Paragraphs 1 to 57, Moderna did not contribute to the development of Defendants' COVID-19 vaccine, which is different from Moderna's vaccine. Moderna will fail in its attempt to stretch already overbroad (and, as contended herein, invalid) patents to try to claim credit for others' work.

2. SARS-CoV-2, the respiratory virus that causes COVID-19, first emerged in 2019. Within months, COVID-19 became a devastating pandemic. Thankfully, independent intensive medical research by teams at BioNTech and Pfizer, and separately at Moderna, led to the development and regulatory approval of two different mRNA-based vaccines.

3. In its complaint against BioNTech and Pfizer, Moderna rewrites that story to eliminate the contributions of many brilliant and dedicated scientists and place itself in the single, starring role. Ignoring the contributions of all these others—including Defendants' scientists and those working for the National Institutes of Health ("NIH")—Moderna now alleges that it developed ***both*** the Moderna vaccine ***and*** the technology behind Pfizer and BioNTech's vaccine, and that Moderna deserves credit for the hard work and creative experiments performed by an entire field of researchers in the years before COVID-19 emerged. Moderna avers that it ***alone***—

not BioNTech, not Pfizer, and not the U.S. Government—holds critical patent rights to ***both*** parties' COVID-19 vaccines.

4. Moderna is wrong, and its revisionist history is not based on fact. Pfizer and BioNTech did *not* copy Moderna's technology. Nor do Pfizer and BioNTech infringe Moderna's patents-in-suit. Rather, Pfizer and BioNTech independently developed their vaccine by utilizing innovation from their respective scientists and relying upon decades of research conducted by others before the pandemic began. Unlike Moderna, however, Pfizer and BioNTech are not seeking a financial windfall for the work of others. Moderna's patent claims far exceed its actual contributions to the field, and its present lawsuit will discourage further development of the remarkable science that made accelerated COVID-19 vaccines possible in the first place. Pfizer and BioNTech deny Moderna's allegations, and, by their Counterclaims, seek to prevent that unjust and anti-scientific outcome.

5. On December 11, 2020, Pfizer and BioNTech first received emergency use authorization ("EUA") from the Food and Drug Administration ("FDA") for their vaccine against the COVID-19 virus. One week later, Moderna received EUA for its vaccine. Both vaccines have since received full FDA approval. The Moderna vaccine and the BioNTech/Pfizer vaccine are both "mRNA vaccines"—that is, they include biological material generically called messenger ribonucleic acid ("mRNA") that encodes and causes the body to make certain proteins that cause the beneficial immune response that leads to COVID-19 protection. Both vaccines also use a type of delivery vehicle—generically called a "lipid nanoparticle" or "LNP"— to deliver mRNA into the cells of patients. Despite these high-level similarities, the Pfizer and BioNTech vaccine is undeniably different from Moderna's. For example, the Pfizer and BioNTech vaccine uses a

different mRNA structure—with a different sequence—from the one in the Moderna vaccine. The vaccines also use different lipids to deliver their respective mRNA into patients' cells.[1]

6. In view of the "unprecedented challenges of the COVID-19 pandemic"—not to mention the more than one billion dollars the U.S. Government committed to developing Moderna's vaccine—Moderna 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."[2] Moderna reaffirmed and broadened these representations repeatedly while taking in more than $30 billion from COVID-19 vaccine sales. At the same time it was making these promises, Moderna was also quietly expanding its patent portfolio in a manner apparently intended to lay claim not to the vaccine it actually developed, but rather to fundamental science that Moderna did not create (and that nonetheless still fails to capture the different Pfizer and BioNTech vaccine). Now Moderna breaks its promises and seeks to leverage fundamental research done by others for more financial gain.

7. Moderna's effort to write other scientists out of the history books is particularly egregious with respect to Drs. Katalin Karikó and Drew Weissman of the University of Pennsylvania. Drs. Karikó and Weissman made foundational discoveries that overcame critical problems plaguing the use of mRNA in drugs before Moderna was even founded. Exs. 1, 22; *see also* Ex. 26. In particular, Drs. Karikó and Weissman discovered that by replacing a particular component of mRNA—the nucleoside "uracil"—with naturally occurring uracil variants

[1] Although BioNTech and Pfizer published the sequence of the mRNA structure that they use in their vaccine, Moderna declined to do so. Third parties, however, have sequenced the mRNA structure that Moderna uses in its vaccine. Such reports demonstrate that the two vaccines use different mRNA sequences. *See, e.g.*, Ex. 16.

[2] Complaint ¶ 22.

(including "pseudouridine" and "1-methyl-pseudouridine"), *and* by using particular techniques to purify mRNA, mRNA that could do its job in the body (instead of being disposed of too quickly by the body's natural immune response or creating a dangerous immune response). *Id.* Drs. Karikó and Weissman have been honored by numerous national and international institutions for their "trailblazing" and "champion[ing]" work, which "laid the foundation for the creation of [an] incredibly effective COVID-19 vaccine[.]" Exs. 2, 3; *see also* Exs. 4–8.

8. Moderna used to agree. Before Moderna had the present patent litigation in its sights, Moderna's co-founder, Derrick Rossi, lauded Drs. Karikó and Weissman's work as "fundamental to this entire field" of mRNA vaccines and therapeutics. Ex. 9 at 2. In Dr. Rossi's estimation, Drs. Karikó and Weissman's work was "going to earn them a Nobel Prize because it really is what allows these mRNA vaccines and any mRNA therapeutic down the road[,]" *id.*, and Moderna's founder reiterated that, "[i]f anyone asks [him] whom to vote for some day down the line, [he] would put them front and center," Ex. 10 at 7. According to Dr. Rossi, Drs. Karikó and Weissman's "fundamental discovery is going to go into medicines that help the world." *Id.* In fact, Moderna backed up Dr. Rossi's belief with its pocketbook, and took a license from the University of Pennsylvania's successor-in-interest, Cellscript, LLC so that it could practice patents embodying Drs. Karikó and Weissman's "fundamental discovery", including patents disclosing the modified uridine that Moderna's mRNA vaccine uses. *Id.*; Ex. 11.

9. Now Moderna tries to forget Drs. Karikó and Weissman's groundbreaking work. According to Moderna's complaint, Moderna alone "pioneer[ed] several fundamental breakthroughs in the field of mRNA technology."[3] But Moderna cannot dispute that Drs. Karikó and Weissman pioneered uridine modification in mRNA technology, not Moderna. Indeed, soon

[3] Complaint ¶ 3.

after Moderna filed this lawsuit, "Weissman and Karikó noted in separate emails to *Science* that they have an issued patent, filed 6 years *earlier* than Moderna's, that explicitly includes the 1-methylpseudouridine modification." Ex. 12 at 2 (emphasis added).

10. Drs. Karikó and Weissman are not the only scientists Moderna wants to forget. Moderna *also* asserts that it is *solely* responsible for creating the particular COVID-19 protein—a modified "spike" protein—that is made by the mRNA used in its vaccine. In doing so, Moderna ignores the NIH scientists who were recognized for their discovery of a particular alteration to the sequence of the coronavirus spike protein (*i.e.*, the protein structures covering the exterior of the COVID-19 virus) that (1) stabilizes the spike protein and (2) allows it to be used by human cells to elicit the bodily response that results in immunity.[4] Ex. 13. Indeed, when Moderna filed patent applications during its time working with the NIH, Moderna *excluded* the NIH scientists who NIH asserts "design[ed] the genetic sequence that prompts the vaccine to produce an immune response."[5] In its complaint, Moderna tries to head off scrutiny of the contributions of these other scientists by stating that it is not asserting patents "generated during Moderna and NIH's collaboration to combat COVID-19."[6] But this careful wording fails to account for the credit Moderna seeks to take in its other patents that continue to rely on the NIH work, including on information and belief those at issue in this case. The allegations reflect yet another example of Moderna's effort to place itself in the spotlight alone.

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[4] Bob Herman, *The NIH Claims Joint Ownership of Moderna's Coronavirus Vaccine*, AXIOS (Jun. 20, 2020), https://www.axios.com/2020/06/25/moderna-nih-coronavirus-vaccine-ownership-agreements.

[5] S.G. Stolberg & R. Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, NEW YORK TIMES (Nov. 11, 2021), https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html?_sm_au_=iHV8nvZffSvHttQQvMFckK0232C0F.

[6] Complaint ¶ 28.

11. Finally, Moderna attempts to take credit for a broad discovery of lipid nanoparticles that it did not make. The lipid nanoparticles in the COVID-19 vaccines are generally microscopic particles that encase mRNA structures for delivery into cells. Because Pfizer and BioNTech's vaccine and Moderna's vaccine use different lipid nanoparticles, Moderna cannot accuse Pfizer and BioNTech of infringing patents that are limited to the lipid nanoparticle that Moderna's vaccines use. Instead, Moderna must rely, again, on patents seeking to broadly claim technology that Moderna did not invent, and which still cannot reach as far as would be necessary to capture Pfizer and BioNTech's different vaccine. The record belies Moderna's statements that its scientists "discovered that packaging [its] chemically-modified mRNA in a lipid nanoparticle formulation allowed for the efficient delivery of the mRNA to cells."[7]

12. Even the lipid nanoparticles in Moderna's own vaccine rely on third-party technology. Dr. Robert Langer, an MIT professor, Moderna board member, and founder of numerous biotech companies, purportedly told Moderna's CEO, Stéphane Bancel, "that Moderna was too underfunded and small to create its own delivery system." Ex. 14 at 3–4. Accordingly, Moderna in-licensed lipid nanoparticle technology for its vaccine program from third party Acuitas Therapeutics. After litigation between Acuitas and another company, Arbutus, regarding whether Acuitas had the right to license the lipid nanoparticle technology at issue to Moderna in the first place, Acuitas terminated its license with Moderna in 2018 leading to continued disputes. Ex. 15 at 7. Moderna's complaint fails to discuss the actual history relating to its use of lipid nanoparticle technology, which will be directly relevant to its efforts to broadly co-opt credit for the lipid nanoparticles used in mRNA technology generally.

[7] Complaint ¶ 57.

13. For these reasons, and as set forth more fully in this Answer and Counterclaims, Defendants deny Moderna's allegations, deny that Moderna is entitled to any relief, and seek the relief for Defendants/Counterclaim Plaintiffs described below.

NATURE OF THE CASE

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.

ANSWER: To the extent Paragraph 1 alleges that Moderna was the first to realize the potential of mRNA medicines for treating or preventing disease or improving patient lives—or that Moderna was the only company focused on mRNA technology—Defendants deny those allegations. Defendants deny the remaining allegations of Paragraph 1 on the basis that that they are subjective and vague, and because Defendants lack knowledge of what "Moderna recognized" and what was Moderna's "focus."

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.

ANSWER: Defendants deny that "Moderna embodies the American ethos of innovation" because, for example, this lawsuit reflects Moderna's effort to lay claim to fundamental mRNA technologies discovered and developed by others. Defendants otherwise lack sufficient information and understanding of the allegations in the remainder of Paragraph 2 and therefore deny them.

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.

ANSWER: Defendants are not aware of any "fundamental breakthroughs" that Moderna has made in the field of mRNA technology that relate to Defendants' vaccine. Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 3 and therefore deny them.

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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 4 and therefore deny them. Defendants further deny that Moderna's future research efforts have relevance to Defendants' vaccine.

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."

ANSWER: Defendants admit that "one of the fundamental challenges with mRNA medicines" was "that the body's own immune system can recognize mRNA as a foreign substance." As set forth herein, Defendants deny that Moderna "pioneered" the nucleoside modification(s) that addressed this problem. Defendants further deny the assertion that "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,'" and Defendants note that Moderna mischaracterizes the cited document. Rather, that document, an April 2022 article in the journal *Science*, characterizes the "replac[ement] of uridine—one of the four basic building blocks of RNA—with methylpseudouridine" as an invention made at the University of Pennsylvania—*i.e.*, by Drs. Karikó and Weissman.[8] Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 and therefore deny them.

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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 6 and therefore deny them.

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.

ANSWER: Defendants deny that Moderna's research "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." Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 and therefore deny them.

[8] Jon Cohen, *New Crop of mRNA Vaccines Aim for Accessibility*, 376 SCIENCE 120, 121 (2022), https://www.science.org/doi/epdf/10.1126/science.abq3935 ("Science 2022").

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.

ANSWER: Defendants are unaware of Moderna's alleged "innovations" or "inventions underlying its mRNA platform and disease-specific vaccine designs" and are presently unaware of the motivations of the different individuals within Moderna over the span of five years who created and supervised Moderna's patent filing strategy. Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 8 and therefore deny them.

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."

ANSWER: Defendants admit that publicly available sources suggest Moderna had no commercial products in 2011-2016.[9] Defendants deny that Moderna's patents served as a basis for Moderna's revenue, particularly given Moderna's patent pledge announcing nonenforcement of the patents. Defendants are not aware of Moderna having patents that are "valuable business assets" and Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in the first sentence of Paragraph 9 and therefore deny them. The second sentence of Paragraph 9 purports to partially quote a letter from Dr. Albert Bourla that is not about

[9] Peter Loftus and Gregory Zuckerman, *Inside Moderna: The Covid Vaccine Front-Runner With No Track Record and an Unsparing CEO*, WALL STREET JOURNAL (Jul. 1, 2020, 10:53 AM), https://www.wsj.com/articles/inside-moderna-the-covid-vaccine-front-runner-with-no-track-record-and-an-unsparing-ceo-11593615205.

this litigation and which speaks for itself.[10] Defendants deny the remaining allegations in the second sentence of Paragraph 9.

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.

ANSWER: Defendants deny that Moderna was "uniquely positioned to respond to the [coronavirus] crisis." Defendants are not aware of Moderna having "conducted a decade of foundational research in the area of mRNA medicines" and thus deny this allegation. Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 and therefore deny them.

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.

ANSWER: Defendants understand based on publicly available information that NIH claims its scientists made discoveries relevant to Moderna's vaccine for which Moderna denied NIH credit, but otherwise lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 11 and therefore deny them.

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 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.

[10] 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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 12 and therefore deny them.

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.

ANSWER: Defendants understand that the U.S. Government and NIH scientists were involved in aspects of Moderna's work but otherwise lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 13 and therefore deny them.

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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 14 and therefore deny them.

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.

ANSWER: Defendants admit that June 2020 FDA Guidance for Industry stated that "[t]o ensure that a widely deployed COVID-19 vaccine is effective, the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%." Defendants further admit that on November 16, 2020 (updated March 16, 2021), the *New York Times* reported that Moderna became "the second company to report preliminary results from a large trial testing a vaccine" and "announced . . . that its coronavirus vaccine was 94.5 percent effective" thereby "joining Pfizer as

a front-runner in the global race to contain a raging pandemic that has killed 1.2 million people worldwide." Defendants admit that certain other companies failed to develop successful mRNA vaccines. Defendants otherwise deny the allegations in Paragraph 15.

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.

ANSWER: Defendants admit the allegations of Paragraph 16.

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.

ANSWER: Defendants admit that they developed an mRNA vaccine for COVID-19 that is currently sold under the name Comirnaty®. Defendants deny that their COVID-19 vaccine uses any technology Moderna developed and patented. Defendants deny any remaining allegations in Paragraph 17.

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.

ANSWER: Defendants deny the allegations of Paragraph 18.

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.

ANSWER: Defendants admit that they considered more than one mRNA candidate. Defendants deny that any candidate involved any "innovative path" of Moderna, that Moderna was a basis for any decisions with respect to clinical development of Defendants' COVID-19 vaccine, or that Defendants copied Moderna's "patented technology." Indeed, Defendants' mRNA vaccine uses a

different mRNA sequence from the one reported by a third party as being what Moderna uses, information which Moderna itself chose not to publish. Defendants deny any remaining allegations of Paragraph 19.

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).

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 20. Defendants observe that the quote from Exhibit 4 has been altered and taken out of context. Defendants admit that Exhibit 4 to Moderna's complaint is a document that purports to be a transcript of "Goldman Sachs Virtual 41st Annual Global Healthcare Conference" and bears the date June 9, 2020. Defendants further admit that Exhibit 4 purports to report a statement from Dr. Albert Bourla stating "[w]e are using four different approaches, that include the two different antigens, one antigen that we're using it is the entire spike protein, which is I think the same like the Moderna is using." Defendants deny that their mRNA vaccine is composed of the spike protein or that the "entire spike protein" is technology owned by Moderna. Defendants deny any remaining allegations of Paragraph 20.

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.

ANSWER: Defendants deny that they "copied" any of Moderna's technology. Defendants deny the remaining allegations of Paragraph 21.

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." 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.

ANSWER: Defendants admit that in an October 8, 2020 press release, Moderna stated that, "while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic." Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegation that Moderna made this pledge "[g]iven the unprecedented challenges of the COVID-19 pandemic" and therefore deny it. Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 22 and therefore deny them. Defendants deny any remaining allegations in Paragraph 22.

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 property and would consider a commercially-reasonable license should they request one. This announcement was widely publicized, including through coverage in *The Wall Street Journal*. 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.

ANSWER: Defendants deny that by early 2022, "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." Defendants admit that Moderna issued a statement on

March 7, 2022, which speaks for itself and is different from the wording in Paragraph 23.[11] Defendants admit that the *Wall Street Journal* published an article online on March 8, 2022 titled "Moderna Signals It May Enforce Covid-19 Vaccine Patents in Wealthy Nations."[12] Defendants admit that Moderna sued Defendants, and that Defendants have not contacted Moderna to request a license from Moderna regarding the patents asserted in Moderna's complaint (the "Asserted Patents"). Defendants deny that a license is necessary, and deny that they have used or continue to use Moderna's intellectual property. Defendants deny any remaining allegations in Paragraph 23, including on the basis that they lack information and knowledge sufficient to form a belief as to the truth of the allegations.

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.

ANSWER: Defendants deny the allegations of Paragraph 24.

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.

ANSWER: Defendants deny that the Asserted Patents reflect a "mRNA technology platform" that Moderna "innovated" and deny that the Asserted Patents are valid, enforceable, and/or infringed. Defendants further deny that Moderna is entitled to any of the relief that it seeks. Defendants lack information and knowledge sufficient to form a belief as to Moderna's motivations and therefore deny the remaining allegations in Paragraph 25.

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[11] Statement & Perspective Details, Moderna, Updated Patent Pledge (Mar. 7, 2020), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx.

[12] Peter Loftus, *Moderna Signals It May Enforce Covid-19 Vaccine Patents in Wealthy Nations*, WALL STREET JOURNAL (Mar. 7, 2022, 7:33 PM), https://www.wsj.com/articles/moderna-signals-it-may-enforce-covid-19-vaccine-patents-in-wealthy-nations-11646699609.

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 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.

ANSWER: Defendants deny that they are infringing Moderna's intellectual property, deny that Moderna is entitled to monetary compensation from Defendants, and further deny that Moderna is entitled to any of the relief that it seeks. Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 26 and therefore deny them.

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.

ANSWER: The allegations of Paragraph 27 purport to characterize Moderna's complaint, which contains only the specific allegations made, and set forth legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Asserted Patents recite, on their faces, priority claims to applications filed between 2011 and 2016, although Defendants deny that Moderna has proven entitlement to such priority claims. Defendants deny that the Asserted Patents cover "foundational" intellectual property properly belonging to Moderna and deny that the Asserted Patents are valid, enforceable, and/or infringed. Defendants understand that Moderna asserts that it is not seeking damages for revenue from sales of COVID-19 vaccines to the U.S. Government that are subject to 28 U.S.C. § 1498 and from its domestic manufacture for supply to non-AMC 92 countries outside the United States. Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 27 and therefore deny them.

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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 28. The allegations of Paragraph 28 purport to characterize Moderna's complaint, which contains only the specific allegations made, and set forth legal conclusions to which no response is required. To the extent a response is required, Defendants understand that Moderna asserts it is not seeking to remove Comirnaty® from the market or to prevent its future sale; not seeking damages for activities occurring before March 8, 2022; and not seeking damages related to any sales to the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment. To the extent a response is required, Defendants deny that Moderna's complaint is "[c]onsistent with Moderna's patent pledge" and further deny that Moderna is entitled to any of the relief it seeks. Defendants deny any remaining allegations of Paragraph 28.

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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 29 and therefore deny them.

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.

ANSWER: Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 30 and therefore deny them.

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.

ANSWER: Defendants deny that Moderna is a pioneer in the manner described in the complaint. Defendants deny the allegations of the second sentence of Paragraph 31. Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in the third sentence of Paragraph 31 and therefore deny them. Defendants deny any remaining allegations in Paragraph 31.

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 Burtt Road, Andover, MA 01810.

ANSWER: Defendants admit the allegations of Paragraph 32.

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.

ANSWER: Defendants admit the allegations of Paragraph 33.

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.

ANSWER: Defendants admit the allegations of Paragraph 34.

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. BioNTech US is BioNTech's agent for service of process in the United States.

ANSWER: Defendants admit the allegations of Paragraph 35.

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

ANSWER: Defendants admit the allegations of Paragraph 36.

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).

ANSWER: The allegations of paragraph 37 purport to characterize Moderna's complaint, which speaks for itself, and set forth legal conclusions, to which no response is required. To the extent a response is required, Defendants deny that they have infringed the Asserted Patents.

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 Burtt 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.

ANSWER: The allegations of Paragraph 38 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction in the District of Massachusetts for purposes of this case only. Defendants admit that Pfizer has facilities located at 1 Portland Street, Cambridge, MA 02139 and 1 Burtt Road, Andover, MA

01810. Defendants admit that BioNTech has North American Headquarters located at 40 Erie Street, Suite 110, Cambridge, MA 02139. Defendants admit that certain manufacture associated with Comirnaty® occurs at an Andover, Massachusetts facility, and that Comirnaty® has been administered in Massachusetts. Defendants deny that any "infringing actions" have taken place in Massachusetts. Defendants deny any remaining allegations of Paragraph 38.

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).

ANSWER: The allegations of Paragraph 39 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants admit Defendants filed a declaratory judgment complaint against CureVac AG in this district on July 25, 2022, and that Defendants do not contest personal jurisdiction in the District of Massachusetts for purposes of this case only.

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).

ANSWER: The allegations of Paragraph 40 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest that venue is proper in the District of Massachusetts for purposes of this case only.

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 Burtt 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.

ANSWER: The allegations of Paragraph 41 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest that venue is proper in the District of Massachusetts for purposes of this case only. Defendants admit that Pfizer has

facilities located at 1 Portland Street, Cambridge, MA 02139 and 1 Burtt Road, Andover, MA 01810. Defendants admit that BioNTech has North American Headquarters located at 40 Erie Street, Suite 110, Cambridge, MA 02139. Defendants deny that they have committed or will commit 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.

ANSWER: Defendants lack knowledge and information sufficient to form a belief regarding the truth of the allegations in the first sentence of Paragraph 42 and therefore deny them. Defendants admit that mRNA refers to "messenger ribonucleic acid," and that, in nature, mRNA contains instructions or recipes that function to direct cells to make proteins using their natural machinery. Defendants further admit that "[f]or decades, scientists have studied mRNA, looking for ways to unlock its potential to prevent and treat disease," that "once inside cells, [mRNA] instructs them to build proteins" and that "researchers have had to work for years [to] develop technologies to allow mRNA to work in the real world."[13] Defendants further admit that "mRNA has proved to be a great platform for vaccine development (and potentially therapeutics), so that our own cells can do the hard work of producing proteins, resulting in an immune response which helps protect

[13] Pfizer, Unleashing the Next Wave of Scientific Innovations to Fight Viruses and More, https://www.pfizer.com/science/innovation/mrna-technology (last accessed Dec. 5, 2022).

us against diseases."[14] Defendants deny that Moderna was the first to figure out "how to make or use mRNA medicines successfully" and further deny any remaining allegations in the sixth sentence of Paragraph 42. Defendants lack knowledge and information sufficient to form a belief regarding the truth of the allegations in the seventh sentence of Paragraph 42 and therefore deny them. Defendants deny any remaining allegations in Paragraph 42.

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.

ANSWER: Defendants deny the allegation that it was Moderna scientists who first developed "novel ways to stabilize mRNA by modifying its chemical structure so that it could be used in vaccines and therapeutics." Defendants admit that scientific literature, including the journal *Vaccines*, describes "naked mRNA" as "unstable, and easily destroyed."[15] Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 43, which purport to characterize Moderna's internal work, and therefore deny them.

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.

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[14] *Id.*

[15] Subbiah Jeeva *et al*., *An Update on mRNA-Based Viral Vaccines*, 9 VACCINES 965 (2021), https://doi.org/10.3390/vaccines9090965.

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 44. Defendants lack knowledge and information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 44 and therefore deny them.

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.

ANSWER: Defendants deny the allegations of Paragraph 45.

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.

ANSWER: Defendants deny that they "struggle[d] with different approaches before designing [their] COVID-19 vaccine." Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 46 and therefore deny them.

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.

ANSWER: Defendants admit that an August 2022 article in the journal *Nature* reports that Moderna and NIH "work[ed] together on producing a vaccine" that "contains mRNA that encodes a modified form of the SARS-CoV-2 spike protein[,]" that NIH has asserted that it—not Moderna—developed those modifications and published them in 2017, and that NIH disputes Moderna's decision to exclude three NIH scientists from at least one of Moderna's patent

applications.[16] Defendants deny that any such Moderna patent is valid, enforceable, and/or would be infringed. Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 47 and therefore deny them.

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.

ANSWER: Defendants admit that public sources, including the journal *Science*, reported on January 11, 2020, that the genomic sequence for SARS-CoV-2 had been published.[17] Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 48 and therefore deny them.

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."

ANSWER: Defendants deny the allegations in the first sentence of Paragraph 49. For example, Defendants are not aware of Moderna developing "new mRNA technology [that] dramatically changed the pace of vaccine development." Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 49 and therefore deny them.

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[16] Heidi Ledford, *What the Moderna–NIH COVID vaccine patent fight means for research*, 600 NATURE 200–01 (Nov. 20, 2021), https://www.nature.com/articles/d41586-021-03535-x#:~:text=In%20an%20August%20statement%20to,mRNA%20sequence%20for%20the%20vaccine.

[17] Jon Cohen, *Chinese researchers reveal draft genome of virus implicated in Wuhan pneumonia outbreak*, SCIENCE (Jan. 11, 2020), https://www.science.org/content/article/chinese-researchers-reveal-draft-genome-virus-implicated-wuhan-pneumonia-outbreak.

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.

ANSWER: Defendants admit that on November 16, 2020, the *New York Times* reported that Moderna became "the second company to report preliminary results from a large trial testing a vaccine" and "announced . . . that its coronavirus vaccine was 94.5 percent effective."[18] Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 50 and therefore deny them.

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.

ANSWER: Defendants admit the allegations of Paragraph 51.

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.

[18] Denise Grady, *Early Data Show Moderna's Coronavirus Vaccine Is 94.5% Effective*, NEW YORK TIMES (Mar. 16, 2021), https://www.nytimes.com/2020/11/16/health/Covid-moderna-vaccine.html.

ANSWER: Defendants admit the allegations of Paragraph 52.

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.

ANSWER: Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 53 and therefore deny them.

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").

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 54. Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 54 and therefore deny them. The third sentence of Paragraph 54 purports to characterize Moderna's complaint, which speaks for itself, and sets forth legal conclusions, to which no response is required. To the extent that a response is required, Defendants admit that the Asserted Patents are at issue in this lawsuit, and deny the remaining allegations of the third sentence of Paragraph 54.

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.

ANSWER: Defendants deny that "mRNA" connotes "a molecule," admit that mRNA refers to "messenger ribonucleic acid," that, in nature, mRNA contains instructions or recipes that function to direct cells to make proteins using their natural machinery, and that mRNA can include naturally occurring nucleosides including adenosine, guanosine, cytidine, and uridine. Defendants deny any remaining allegations of Paragraph 55.

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.

ANSWER: To the extent Paragraph 56 alleges that Moderna was the first to identify particular chemical modifications that helped avoid deleterious immune responses, or that Moderna properly has been credited with first proposing such chemical modifications, Defendants deny those allegations. Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 56 and therefore deny them.

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.

ANSWER: Defendants deny the allegations of Paragraph 57.

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.

ANSWER: Defendants deny the allegations of the first and second sentences of Paragraph 58. Defendants admit that they considered certain mRNA vaccine candidates and selected as their clinical vaccine candidate an mRNA vaccine containing nucleosides among which are 1-methyl-pseudouridine, but deny the allegation that Moderna "pioneered" this modification. Defendants deny the remaining allegations of Paragraph 58.

59. The ’574 patent is titled “Delivery and formulation of engineered nucleic acids.” The ’574 patent names Moderna scientists Antonin de Fougerolles 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.

ANSWER: Defendants admit that the ’574 Patent, on its face, is titled “Delivery and formulation of engineered nucleic acids” and lists Antonin de Fougerolles and Sayda M. Elbashir as inventors. Defendants further admit the face of the ’574 Patent lists a priority claim to an application filed on April 2, 2012 and an issuance date of January 26, 2021, and an assignee of “ModernaTX, Inc.” Defendants admit that Exhibit 1 to Moderna’s complaint is a document that purports to be a copy of the ’574 Patent. Defendants deny any remaining allegations of Paragraph 59.

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.

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 60. The second sentence of paragraph 60 purports to characterize the claims of the ’574 Patent, which is an issue of law to which no response is required. To the extent a response is required, Defendants deny that the claims of the ’574 Patent are valid, enforceable, and/or infringed.

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®.

ANSWER: Paragraph 61 sets forth legal conclusions, to which no response is required. To the extent a response is required, Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 61 and therefore deny them.

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.

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 62. Defendants admit that, in general, coronaviruses include a family of viruses, some of which cause respiratory illnesses in humans, that the name coronavirus is derived from the fact that under electron microscopic examination, the virions are surrounded by a "corona," or halo, and that this is due to the presence of protein spikes emanating from the exterior of the virus. Defendants admit that the coronavirus spike protein plays a role in receptor recognition and membrane fusion. Defendants deny any remaining allegations of Paragraph 62.

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.

ANSWER: Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations of Paragraph 63 and therefore deny them.

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.

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 64. Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations of the second sentence of Paragraph 64 and therefore deny them. The third sentence of Paragraph 64 purports to characterize the specification and claims of the '600 and '127 Patents, and thus set forth legal conclusions to which no response is required. To the extent a response is required,

Defendants deny that the claims of the ’600 and ’127 Patents claim inventions made by Moderna and deny that the claims of the ’600 and ’127 Patents are valid, enforceable, and/or infringed.

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®.

ANSWER: Defendants deny the allegations of Paragraph 65.

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.

ANSWER: Defendants admit that the ’600 Patent, on its face, is titled “Betacoronavirus mRNA vaccine” and lists Giuseppe Ciaramella and Sunny Himansu as inventors. Defendants further admit the face of the ’600 Patent lists a priority claim to October 2015 provisional applications and an October 21, 2016 PCT application, an issuance date of July 7, 2020, and an assignee of “ModernaTX, Inc.” Defendants admit that Exhibit 2 to Moderna’s complaint is a document that purports to be a copy of the ’600 Patent. Defendants deny any remaining allegations of Paragraph 66.

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.

ANSWER: The allegations of Paragraph 67 purport to characterize the claims of the ’600 Patent, and set forth legal conclusions, to which no response is required. To the extent a response is required, Defendants deny that the claims of the ’600 Patent are valid, enforceable, and/or infringed.

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®.

ANSWER: Paragraph 68 sets forth legal conclusions, to which no response is required. To the extent a response is required, Defendants lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 68 and therefore deny them.

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.

ANSWER: Defendants admit that the ’127 Patent, on its face, is titled “Betacoronavirus mRNA vaccine” and lists Giuseppe Ciaramella and Sunny Himansu as inventors. Defendants further admit the face of the ’127 Patent lists a priority claim to October 2015 provisional applications and an October 21, 2016 PCT application, an issuance date of March 2, 2021, and an assignee of “ModernaTX, Inc.” Defendants admit that Exhibit 3 to Moderna’s complaint is a document that purports to be a copy of the ’127 Patent. Defendants deny any remaining allegations of Paragraph 69.

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.

ANSWER: The allegations of Paragraph 70 purport to characterize the claims of the ’127 Patent, and thus set forth legal conclusions, to which no response is required. To the extent a response is required, Defendants deny that the claims of the ’127 Patent are valid, enforceable, and/or infringed by Defendants’ conduct.

71. The administration of Moderna's Spikevax® in accordance with its approved package insert practices the methods claimed in the '127 patent.

ANSWER: Paragraph 71 sets forth legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 71.

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

ANSWER: Defendants admit that they began work on an influenza vaccine using mRNA before COVID-19, but otherwise deny the allegations of the first sentence of Paragraph 72. Defendants admit that Uğur Şahin was quoted as stating, in the greater context of a 2021 *Nature* article, that "[w]e were always interested in infectious diseases, but they were not a priority" and otherwise deny the allegations of the second and third sentences of Paragraph 72.[19] Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations in the fourth sentence of Paragraph 72, and therefore deny them.

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.

[19] Asher Mullard, *COVID-19 Vaccine Success Enables a Bolder Vision for mRNA Cancer Vaccines, Says BioNTech CEO*, 20 NATURE REVS.: DRUG DISCOVERY 500 (Jun. 17, 2021), https://www.nature.com/articles/d41573-021-00110-x.

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 73. Defendants admit that they had choices in the design of a COVID-19 vaccine, and otherwise deny the allegations in the second sentence of Paragraph 73. Defendants admit that Pfizer-BioNTech's vaccine program was internally dubbed "Project Lightspeed" and involved, among other things, analysis of different mRNA constructs and target antigens. Defendants admit that on April 22, 2020, Pfizer issued a press release stating, among other things, that "[f]our vaccine candidates" would "enter clinical development."[20] Defendants deny any remaining allegations of Paragraph 73.

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. Neither BNT162a1 nor BNT162c2 use Moderna's patented mRNA platform containing 1-methylpseudouridine modified mRNA in a lipid nanoparticle formulation.

ANSWER: Defendants deny that any of Defendants' vaccine candidates used Moderna's "patented inventions" or that Moderna properly holds any such valid and/or enforceable patents. Defendants admit that BNT162a1 was a potential vaccine candidate that included unmodified uridine. Defendants further admit that BNT162c2 was a potential vaccine candidate that included self-amplifying mRNA. Defendants deny that *any* of Defendants' vaccine candidates utilized any invention of Moderna's. Defendants deny any remaining allegations of Paragraph 74.

[20] Pfizer, *Press Release: BioNTech and Pfizer announce regulatory approval from German authority Paul-Ehrlich-Institut to commence first clinical trial of COVID-19 vaccine candidates,* https://www.pfizer.com/news/press-release/press-release-detail/biontech_and_pfizer_announce_regulatory_approval_from_german_authority_paul_ehrlich_institut_to_commence_first_clinical_trial_of_covid_19_vaccine_candidates.

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. 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[.]").

ANSWER: Defendants deny that any of Defendants' vaccine candidates used Moderna's "patented technologies" or that Moderna properly holds any such valid and/or enforceable patents. Defendants also deny that they "were aware of Moderna's COVID-19 vaccine design, and they chose to copy it." As subsequent publication by a third-party of Moderna's COVID-19 vaccine has shown, Defendants and Moderna use mRNAs with different structures and different lipid nanoparticles ("LNP"). Defendants further admit that Exhibit 4 purports to report a truncated comment from Dr. Albert Bourla that, in full, was observing aspects of what Defendants and Moderna had each been reported to be using, and does not state or suggest that either company had copied the other: "We are using an mRNA, modified RNA technology. I know that there is, but Moderna also is using the same technology. We are using 4 different approaches, that include the 2 different antigens, one antigen that we're using it is the entire spike protein, which is I think the same like the Moderna is using [*sic*]. [T]hen we are using also the [*sic*] [what] we call the RBD, which is the head of the spike, the antigen. So we are using both just in case." Defendants further admit that Exhibit 5 purports to report a truncated comment from Mr. Chuck Triano that, in full, does not state or suggest that either company copied the other: "So we're testing, not just the spike protein, which we are testing, but we're not just testing that–that's Moderna's approach,

and I'm not saying that that's a bad approach at all, but in addition, we're testing, both the spike and the receptor binding domain. So which offers a different hypothesis and allows us then to select based on clinical data, the best one or two hypotheses to move forward here." Defendants further admit that Exhibit 6 purports to report a truncated comment from Dr. Uğur Şahin which, in full, does not state or suggest that either company had copied the other: "So, the rationale for starting with four different vaccines was on the one hand to evaluate our three different vaccine platforms. This is that modified messenger RNA platform which were now used for the candidate bl and b2 and here bl and b2 were selected based on the experience of the field in the past with MERS and the SARS, where both antigens had been evaluated but never benchmarked side by side." Defendants deny any remaining allegations of Paragraph 75.

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. 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.

ANSWER: Defendants admit that on July 27, 2020, BioNTech issued a press release stating, "Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the start of a global (except for China) Phase 2/3 safety and efficacy clinical study to evaluate a single nucleoside-modified messenger RNA (modRNA) candidate from their BNT162 mRNA-based vaccine program, against SARS-CoV-2." Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations in Paragraph 76 and therefore deny them.

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 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®.

ANSWER: Defendants deny that they had a "strategy of copying Moderna's COVID-19 vaccine." Defendants admit the allegations of the second, third, and fourth sentences of Paragraph 77. Defendants admit that BioNTech Manufacturing GmbH is the BLA holder for Comirnaty®. Defendants deny any remaining allegations of Paragraph 77.

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.

ANSWER: Defendants admit the allegations of Paragraph 78.

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 competition 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].

ANSWER: Defendants admit the allegations of the first, second, third, and fifth sentences of Paragraph 79. Defendants admit that 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. Defendants admit that they maintain a website https://www.comirnaty.com/booster-dose/, which speaks for itself. Defendants deny any remaining allegations of Paragraph 79.

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].

ANSWER: Defendants deny that they have used "Moderna's patented technologies" and deny the remaining allegations of the first sentence of Paragraph 80. Defendants admit that an unaudited Pfizer financial report states that $7.809 billion were earned from the direct sales and alliance revenues of Comirnaty® to the U.S. Government in 2021. Defendants admit that a February 8, 2022 article published on BioPharma-Reporter.com stated that "Pfizer forecasts $32bn in revenue for COVID-19 vaccine Comirnaty" and that a Pfizer press release stated that Pfizer "Raises 2022 Revenue Guidance for Comirnaty(1) to Approximately $32 Billion." Defendants deny any remaining allegations in Paragraph 80.

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 production at Pfizer's facility in Andover, Massachusetts "to support the continued supply of Comirnaty in the European Union." 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. 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].

ANSWER: Defendants admit that 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. Defendants deny that Moderna is entitled to any relief whatsoever. Defendants deny the allegation in the second sentence of Paragraph 81. Defendants admit that the European Medicines Agency ("EMA") reported that in December 2021, its Committee for Medicinal Products for Human Use approved "[a]n increase in production of the active substance of Comirnaty, the COVID-19 vaccine from BioNTech/Pfizer, at the manufacturing site operated by Wyeth BioPharma Division of Wyeth Pharmaceuticals, located in Andover, MA, USA."[21] Defendants admit that they maintain a website at https://www.comirnaty.com/booster-dose/, which speaks for itself. Defendants admit that on March 29, 2022, the FDA authorized second booster doses of Defendants' COVID-19 vaccine in certain individuals. Defendants deny any remaining allegations of Paragraph 81.

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.

ANSWER: Defendants deny the allegations of Paragraph 82 and deny that Moderna is entitled to any compensation whatsoever.

[21] EMA, *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.

COUNT I – INFRINGEMENT OF THE '574 PATENT

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

ANSWER: Defendants reallege and incorporate by reference all paragraphs in its Answer above as if fully set forth herein.

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).

ANSWER: Defendants deny the allegations of Paragraph 84.

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).

ANSWER: Defendants deny the allegations of Paragraph 85.

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).

ANSWER: Defendants deny the allegations of Paragraph 86.

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.

ANSWER: Defendants deny the allegations of Paragraph 87.

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.

ANSWER: Defendants deny the allegations of Paragraph 88.

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.

ANSWER: Defendants acknowledge that Moderna alleges that Claim 2 is representative of the claims of the '574 patent, and admit that Claim 2 of the '574 patent 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.

The remaining allegations of Paragraph 89 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations of Paragraph 89.

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.

ANSWER: Paragraph 90 appears to recite language from Claim 2 from the '574 patent, and therefore sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 90 and deny that Comirnaty® infringes any claim of the '574 Patent.

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.

ANSWER: Defendants admit that Exhibit 7 to Moderna's complaint is a document that purports to be a package insert for Comirnaty® from July 2022. Defendants admit that Section 12 of Exhibit 7 states, among other things "[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." Defendants admit that Section 11 of Exhibit 7 states, among other things, 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." Defendants admit that Section 11 of Exhibit 7 states, among other things, 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." Defendants deny any remaining allegations of Paragraph 91.

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 SARSCoV-2*, 592 Nature 283, 284 (2021). A true and correct copy of this publication is attached as Exhibit 8.

ANSWER: The allegations of Paragraph 92 purport to characterize publications by Defendants, which speak for themselves. Defendants further admit that Exhibit 8 to Moderna's complaint is a document that purports to be to be an article by Annete B. Vogel published in *Nature* in 2021, titled "BNT162b Vaccines Protect Rhesus Macaques from SARSCoV-2." Defendants admit that Exhibit 8 states, among other things: "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." Defendants deny any remaining allegations of Paragraph 92.

93. Claim 9 of the '574 patent recites:

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

ANSWER: Defendants admit the allegations of Paragraph 93.

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.

ANSWER: Defendants deny the allegations of Paragraph 94.

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.

ANSWER: Defendants deny the allegations of Paragraph 95.

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).

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 96. Defendants admit that they maintain a website https://www.comirnaty.com/booster-dose/, which speaks for itself. Defendants admit that Exhibit 9 to Moderna's complaint is a document that purports to be a "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" bearing a revision date of July 8, 2022. Defendants deny that Exhibit 9 instructs infringement of the '574 Patent and deny any remaining allegations of Paragraph 96.

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.

ANSWER: Defendants deny the allegations of Paragraph 97.

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.").

ANSWER: Defendants deny the allegations of Paragraph 98.

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.

ANSWER: The allegations of Paragraph 99 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 99.

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.

ANSWER: Defendants deny the allegations of Paragraph 100.

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.

ANSWER: Defendants deny the allegations of Paragraph 101.

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.

ANSWER: Defendants deny the allegations of Paragraph 102.

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.

ANSWER: Defendants deny the allegations of Paragraph 103.

COUNT II – INFRINGEMENT OF THE '600 PATENT

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

ANSWER: Defendants reallege and incorporate by reference all paragraphs in its Answer above as if 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).

ANSWER: Defendants deny the allegations of Paragraph 105.

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).

ANSWER: Defendants deny the allegations of Paragraph 106.

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).

ANSWER: Defendants deny the allegations of Paragraph 107.

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.

ANSWER: Defendants deny the allegations of Paragraph 108.

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.

ANSWER: Defendants deny the allegations of Paragraph 109.

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.

ANSWER: Defendants acknowledge that Moderna alleges that Claim 1 is representative of the claims of the ’600 patent, and admit that Claim 1 of the ’600 patent 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.

The remaining allegations of Paragraph 110 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations of Paragraph 110.

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.

ANSWER: Paragraph 111 appears to recite language from Claim 1 of the ’600 patent, and therefore sets forth legal conclusions to which no response is required. To the extent a response is required Defendants deny the allegations of Paragraph 111 and deny that Comirnaty® infringes any claim of the ’600 Patent.

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.

ANSWER: Defendants admit that Exhibit 7 to Moderna’s complaint is a document that purports to be a package insert for Comirnaty® from July 2022. Defendants admit that Section 12 of

Exhibit 7 states, among other things, 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." Defendants admit that Section 12 of Exhibit 7 states, among other things, 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." The final sentence of Paragraph 112 appears to recite language from Claim 1 of the '600 patent, and therefore sets forth legal conclusions to which no response is required. To the extent a response is required Defendants deny the allegations of the final sentence of Paragraph 112 and deny Comirnaty® infringes any claim of the '600 Patent. Defendants deny any remaining allegations of Paragraph 112.

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.

ANSWER: Defendants deny the allegations of Paragraph 113.

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 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.

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 114. Defendants admit that they maintain a website https://www.comirnaty.com/booster-dose/, which speaks for itself. Defendants deny the allegations of the third sentence of Paragraph 114 and deny any remaining allegations of Paragraph 114.

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.

ANSWER: Defendants deny the allegations of Paragraph 115.

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.

ANSWER: Defendants deny the allegations of Paragraph 116.

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.

ANSWER: Paragraph 117 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 117.

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.

ANSWER: Defendants deny the allegations of Paragraph 118.

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.

ANSWER: Defendants deny the allegations of Paragraph 119.

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.

ANSWER: Defendants deny the allegations of Paragraph 120.

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.

ANSWER: Defendants deny the allegations of Paragraph 121.

COUNT III – INFRINGEMENT OF THE '127 PATENT

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

ANSWER: Defendants reallege and incorporate by reference all paragraphs in its Answer above as if 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).

ANSWER: Defendants deny the allegations of Paragraph 123.

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).

ANSWER: Defendants deny the allegations of Paragraph 124.

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).

ANSWER: Defendants deny the allegations of Paragraph 125.

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.

ANSWER: Defendants deny the allegations of Paragraph 126.

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.

ANSWER: Defendants deny the allegations of Paragraph 127.

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.

ANSWER: Defendants acknowledge that Moderna alleges that Claim 1 is representative of the claims of the '127 patent, and admit that Claim 1 of the '127 patent 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.

The remainder of Paragraph 128 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations of Paragraph 128.

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.

ANSWER: Paragraph 129 appears to recite language from Claim 1 of the '127 patent, and therefore sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 129 and deny that Comirnaty® infringes any claim of the '127 Patent.

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 potassium 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.

ANSWER: Defendants admit that Exhibit 7 to Moderna's complaint is a document that purports to be a package insert for Comirnaty® from July 2022. Defendants admit that Section 2.2 of Exhibit 7 states, among other things, "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly." Defendants admit that Section 11 of Exhibit 7 states "[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." Defendants admit that Section 12 of Exhibit 7 states, among other things, "[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." Defendants admit that Section 12 of Exhibit 7 states, among other things, that "[t]he vaccine elicits an immune response to the S antigen, which protects against COVID-19."

Defendants admit that Section 11 of Exhibit 7 states, among other things, 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." The remainder of Paragraph 130 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that administration of Comirnaty® in accordance with its package insert infringes any claim of the '127 Patent. Defendants deny any remaining allegations of Paragraph 130.

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-announcephase-3-trial-data-showing [https://perma.cc/94KH-8R2B].

ANSWER: Defendants deny the allegations of the first sentence of Paragraph 131. Defendants admit that Exhibit 9 to Moderna's complaint is a document that purports to be a "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" bearing a revision date of July 8, 2022. Defendants admit that Exhibit 9 states, among other things, that Defendants' vaccine "has been shown to prevent COVID-19." The allegations of the third sentence of Paragraph 141 are

vague as to the precise booster and primary vaccination series, and Defendants deny the allegations on that basis. Defendants deny any remaining allegations in Paragraph 131.

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.

ANSWER: Defendants deny the allegations of Paragraph 132.

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.

ANSWER: Defendants deny the allegations of Paragraph 133.

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.

ANSWER: Defendants deny the allegations of Paragraph 134.

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.

ANSWER: Defendants deny the allegations of Paragraph 135.

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.

ANSWER: Defendants deny the allegations of Paragraph 136.

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.

ANSWER: Defendants deny the allegations of Paragraph 137.

MODERNA'S PRAYER FOR RELIEF

The "WHEREFORE" paragraphs following paragraph 137 state Moderna's Prayer for Relief, to which no response is required. To the extent a response is required, Defendants deny that Moderna is entitled to any of the relief in the Prayer for Relief, or any relief whatsoever.

* * *

Any allegation in Moderna's complaint not expressly admitted herein is denied. All allegations in the section headers and footnotes of Moderna's complaint are denied.

AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the complaint not otherwise admitted. Defendants do not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Defendants reserve the right to assert other defenses and/or to supplement or amend its Answer, Affirmative Defenses, and Counterclaims to the complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE
(Invalidity of the '574 Patent)

1. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

2. Claims 1–4 and 6–10 of the '574 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of the ’600 Patent)

3. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

4. Claims 1–2, 4–6, 8–12, 16–17, 20–21, and 26 of the ’600 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of the ’127 Patent)

5. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

6. Claims 1–3, 6–9, 11–13, 17–18, and 20 of the ’127 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

FOURTH AFFIRMATIVE DEFENSE
(Non-infringement of the ’574 patent)

7. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

8. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® does not infringe any valid claim of the ’574 patent.

FIFTH AFFIRMATIVE DEFENSE
(Non-infringement of the ’600 patent)

9. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

10. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® does not infringe any valid claim of the ’600 patent.

SIXTH AFFIRMATIVE DEFENSE
(Non-infringement of the ’127 patent)

11. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

12. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® does not infringe any valid claim of the ’127 patent.

SEVENTH AFFIRMATIVE DEFENSE
(Implied License)

13. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

14. Moderna’s claims for infringement against Defendants are barred by the doctrine of implied license.

EIGHTH AFFIRMATIVE DEFENSE
(Waiver)

15. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

16. Moderna’s claims for infringement against Defendants are barred by the doctrine of waiver.

NINTH AFFIRMATIVE DEFENSE
(Implied Waiver)

17. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

18. Moderna's claims for infringement against Defendants are barred by the doctrine of implied waiver.

TENTH AFFIRMATIVE DEFENSE
(Acquiescence)

19. Defendants incorporate by reference paragraphs 1–57 of its Counterclaims as if fully set forth herein.

20. Defendants' claims for infringement against Defendants are barred by the doctrine of acquiescence.

* * *

WHEREFORE, Defendants respectfully request the following relief:

a. An order dismissing each of Moderna's claims with prejudice;

b. A judgment that Defendants have not infringed any claim of any of the '600, '574, and '127 patents;

c. A judgment that each of the '600, '574, and '127 patents is invalid;

d. A judgment that each of the '600, '574, and '127 patents is unenforceable;

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

f. An award of Defendants' costs and expenses in this action; and

g. Such further and other relief as this Court may deem just and proper.

COUNTERCLAIMS

Without admitting any of the allegations of Counterclaim-Defendants ModernaTX Inc. and Moderna U.S., Inc. (collectively, "Moderna") other than those expressly admitted herein, and without prejudice to the right of Counterclaim-Plaintiffs Pfizer Inc. ("Pfizer"), BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US, Inc. (collectively, "BioNTech") to plead additional counterclaims as the facts of the matter warrant, Counterclaim-Plaintiffs assert the following counterclaims against Counterclaim-Defendant Moderna.

Parties

1. Counterclaim-Plaintiff Pfizer is a company organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, NY 10017.

2. Counterclaim-Plaintiff BioNTech SE is a company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

3. Counterclaim-Plaintiff BioNTech Manufacturing GmbH 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.

4. Counterclaim-Plaintiff BioNTech US is a corporation organized and existing under the laws of Delaware, with its principal place of business at 40 Erie Street, Suite 110, Cambridge, MA 02139.

5. Upon information and belief, and based on Counterclaim-Defendant's allegations, Counterclaim-Defendant ModernaTX, Inc. 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.

6. Upon information and belief, and based on Counterclaim-Defendant's allegations, Counterclaim-Defendant Moderna US, Inc. 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.

Background, Jurisdiction, and Venue

7. Pfizer seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202. The Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterclaim-Defendant's choice of forum.

9. This action is based upon an actual controversy between the parties arising from allegations of infringement of U.S. Patent Nos. 10,898,574 (the "'574 Patent"), 10,702,600 (the "'600 Patent"), and 10,933,127 (the "'127 Patent").

mRNA Vaccines for COVID-19 are Built on Decades of Foundational Research

10. This action is about two vaccines, Comirnaty® and Spikevax®, that were independently developed to combat the greatest public health challenge in recent memory: COVID-19. BioNTech and Pfizer's Comirnaty® was the world's first mRNA vaccine approved for public use—deployed in record time against the COVID-19 pandemic. Approval for Moderna's Spikevax® followed soon thereafter. Both groups of companies answered the bell by developing a new type of vaccine containing mRNA packaged in a lipid nanoparticle ("LNP") for delivery into the patient's cells to elicit a protective immune response.

11. Despite these broad similarities, the two vaccines were developed independently and are different. For example, they use different mRNA structures and LNP formulations.

12. While Moderna has not publicly disclosed the complete mRNA sequence that its vaccine uses, Pfizer and BioNTech have. In 2021, a third party reported that it had sequenced the mRNA in Moderna's vaccine and published the results. Ex. 16. As Moderna can confirm based on its own and publicly available information, Comirnaty®'s mRNA sequence is different from Spikevax®'s mRNA sequence.

13. The development of Comirnaty® could not have been achieved without the innovation, ingenuity, and hard work of Pfizer and BioNTech's scientists and employees. Comirnaty® also stands as a testament to decades of foundational research at public institutions, universities, and other research organizations that was lawfully available to Pfizer and BioNTech through public sources and licenses.

14. Since the 1970s, scientists have recognized that mRNA can induce protein expression and has the potential to treat or prevent disease in humans. By the 1990s, researchers demonstrated that mRNA could be used to elicit antiviral immune responses in animal models and encode proteins expressed by cancer cells.

15. One vexing problem encountered by researchers, however, was that synthetic mRNA can trigger proteins known as toll-like receptors, which can lead to an undesirable immune and inflammatory response in the body. Despite such challenges, Dr. Katalin Karikó was convinced mRNA structures could be used to instruct cells to make their own therapeutic proteins. As Dr. Anthony Fauci acknowledged, Dr. Karikó "was, in a positive sense, kind of obsessed with the concept of messenger RNA." Ex. 17 at 1. Despite her tenacity, Dr. Karikó struggled to stay afloat in academia, as she sought—and was denied—grant after grant to pursue ideas that seemed

wild and fanciful to many in the academic community. *Id.* at 1–2. As one of her colleagues explained, "[w]hen your idea is against the conventional wisdom that makes sense to the star chamber, it is very hard to break out." *Id.* at 1. Yet, Dr. Karikó's focus and drive never wavered. Her genius was a "willingness to accept failure and keep trying, and her ability to answer questions people were not smart enough to ask." *Id.* at 3.

16. After years of painstaking research, Dr. Karikó and her collaborator Dr. Drew Weissman at the University of Pennsylvania made a key breakthrough in the mid-2000s—they discovered that making certain chemical modifications to RNA nucleosides could reduce or eliminate the inflammatory reaction. A clue as to why mRNA triggered an inflammatory reaction in the body came when they noticed that the mRNA they expressed induced an immune response, while the controls—transfer RNA or tRNA—did not. They discovered that a nucleoside called pseudouridine in tRNA allowed it to evade the immune response. *Id.* at 3–4.

17. Drs. Karikó and Weissman had the idea to modify mRNA with naturally occurring pseudouridines found in tRNA and found that the uridine modification protected the modified mRNA from the body's immune system. Drs. Karikó and Weissman taught about their insights in a series of research papers, including a seminal 2005 paper titled "Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA." Ex. 1. These findings led Drs. Karikó and Weissman to believe that mRNA could be used to alter the functions of cells without prompting an undesirable immune system response.

18. Drs. Karikó and Weissman brought their ideas to pharmaceutical companies and venture capitalists to discuss the promise of their discovery. At first, no one was interested. As Dr. Weissman later recounts, "[w]e were screaming a lot, but no one would listen." Ex. 17 at 4.

Eventually, however, both BioNTech and Moderna took notice of Drs. Karikó and Weissman's work. BioNTech partnered with and began funding Dr. Weissman's laboratory. *Id.* In 2013, Dr. Karikó joined BioNTech full-time as a Vice President.

19. Drs. Karikó and Weissman's discovery that modified mRNA nucleosides could evade toll-like receptors is a critical innovation behind both Comirnaty® and Spikevax®. In fact, Moderna's co-founder, Derrick Rossi, recognized this discovery as "fundamental to this entire field" of mRNA vaccines and therapeutics. Ex. 9 at 2. He "believe[s] it's going to earn [Drs. Karikó and Weissman] a Nobel Prize because it really is what allows these mRNA vaccines and any mRNA therapeutics down the road," *id.*, and "[i]f anyone asks me whom to vote for some day down the line, I would put them front and center." Ex. 10 at 7. According to Dr. Rossi, Drs. Karikó and Weissman's "fundamental discovery is going to go into medicines that help the world." *Id.*

20. Recognizing the importance of their discovery, Drs. Karikó and Weissman have already been honored on several occasions from institutions such as Columbia University Irving Medical Center and the European Patent Office for their "trailblazing" work, which "laid the foundation for the creation of [an] incredibly effective COVID-19 vaccine[.]" Exs. 2, 3. Drs. Karikó and Weissman have also been distinguished through a variety of other awards, such as the Princess of Asturias Award, the Albany Medical Center Prize in Medicine and Biomedical Research, the 2022 Breakthrough Prize in Life Sciences, and the 2021 Lasker Award—America's top biomedical research prize. Exs. 4, 7, 18, 19, 20, and 21.

21. The University of Pennsylvania patented Drs. Karikó and Weissman's groundbreaking research by submitting, in 2005, Provisional Patent Application No. 60/710,164 titled "RNA Containing Modified Nucleosides and Methods of Use Thereof." Ex. 22. The '164

Application describes how "[t]his invention provides RNA . . . comprising pseudouridine or a modified nucleoside" and expressly identifies N1-methyl-pseudouridine. Ex. 22 at 1, 14. The '164 Application further "provides methods of reducing the immunogenicity of RNA." *Id.* at 1. The U.S. Patent Office eventually granted U.S. Patent No. 8,691,966 (the "'966 Patent") to Drs. Karikó and Weissman, which claims priority to the '164 Application. Ex. 28. The '966 Patent expressly claims a modified mRNA containing 1-methyl-pseudouridine—the modification that Moderna's complaint now alleges to have first discovered years later. D.I. 1 ¶ 5.

22. Dr. Karikó continued her research on modified mRNA at BioNTech, where she helped determine that an mRNA vaccine could elicit antibodies against the Zika virus. In 2017, Dr. Karikó co-authored a paper in *Nature* (the "2017 *Nature* Paper") demonstrating that "a single low-dose intradermal immunization with lipid-nanoparticle-encapsulated nucleoside modified mRNA (mRNA–LNP) encoding the pre-membrane and envelope glycoproteins of a strain from the ZIKV outbreak in 2013 elicited potent and durable neutralizing antibody responses" in animal models. Ex. 23 at 1. The mRNA Zika vaccine developed by BioNTech and the University of Pennsylvania used mRNA that contained the modified nucleoside 1-methyl-pseudouridine (m1Ψ), which is the same modified nucleoside that would later be used in Comirnaty®. *Id.* at 2–3.

23. BioNTech's scientists, including Dr. Karikó, soon demonstrated that modified mRNA vaccines successfully conferred immunity against HIV, Zika, and influenza in animal models; and published these results in the *Journal of Experimental Medicine* (the "2018 JEM Paper"). *See* Ex. 24. The 2018 JEM Paper recognized that BioNTech's mRNA vaccine platform has the "advantages of a favorable safety profile, potentially inexpensive manufacturing, and the *capacity for rapid development in emerging epidemics*." *Id.* at 1580 (emphasis added).

24. That same year, Pfizer and BioNTech partnered to develop an mRNA-based vaccine for influenza. As part of the agreement, BioNTech and Pfizer would jointly conduct research and development to advance mRNA-based flu vaccines. In announcing the collaboration, the head of Pfizer's vaccine research and development unit, Dr. Kathrin Jansen, noted that "[i]nnovative vaccine approaches are urgently needed to provide improved protection against seasonal flu, and to *respond rapidly and in quantity to pandemic influenza threats*." Ex. 25 at 1 (emphasis added). Dr. Jansen further emphasized that "mRNA vaccines offer a novel approach to code for any protein or multiple proteins, and the potential to manufacture higher potency flu vaccines more rapidly and at a lower cost than contemporary flu vaccine." *Id.*

25. In December 2019, SARS-CoV-2 first appeared in Wuhan, China. At the emergence of this novel coronavirus, Pfizer and BioNTech were well-positioned to respond rapidly by constructing a vaccine around their existing modified mRNA platform, which had already been tested against viruses such as HIV, Zika, and influenza. Leveraging decades of foundational research, BioNTech rapidly identified several candidates for clinical testing as mRNA-based vaccines to protect against COVID-19.

26. By March 2020, Pfizer and BioNTech began a collaborative effort focused on developing an mRNA based COVID-19 vaccine. That same month, the World Health Organization ("WHO") declared the COVID-19 outbreak a global pandemic. Clinical trials of BioNTech/Pfizer vaccine candidates began in late April 2020, with preliminary results demonstrating their safety and efficacy published in merely six months. This rapid development and launch of clinical trials of product candidates was not a chance event, the result of sudden inspiration, or copying of someone else's work. It was the result of the relentless work of dedicated scientists and the vision of BioNTech and Pfizer.

27. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted its clinical trial data as part of its Emergency Use Authorization ("EUA") request to the Food and Drug Administration ("FDA") for administering its mRNA vaccine to people 16 years of age and older.

28. On December 11, 2020, the FDA granted the first EUA for a COVID-19 disease vaccine to Pfizer and BioNTech's mRNA vaccine with vaccinations rolling out immediately thereafter,[22] reflecting the fastest development of a vaccine in history.

Moderna Erroneously Claims Exclusive Credit for mRNA COVID-19 Vaccines

29. The founders of Moderna were aware of the work of Drs. Karikó and Weissman on modified mRNA. Several months after its launch in 2010, Moderna's investment capital firm, Flagship Pioneering ("Flagship"), sent one of its patent attorneys, Greg Sieczkiewicz, to visit Drs. Karikó and Weissman at the University of Pennsylvania and obtain a license to Drs. Karikó and Weissman's patent.[23]

30. In 2011, at Flagship's request, Drs. Karikó and Weissman gave a lecture at Moderna regarding mRNA technology. During the lecture, they explained, among other things, the importance of purifying nucleosides for therapeutic applications. Drs. Karikó and Weissman also published a paper that same year describing how high-performance liquid chromatography

[22] FDA Memorandum, Emergency Use Authorization ("EUA") for an Unapproved Product Review (Dec. 11, 2020), https://www.fda.gov/media/144416/download; Press Release, FDA, FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

[23] Peter Loftus, *The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World* 36 (2022); *see also* Gregory Zuckerman, *A Shot to Save the World: The Inside Story of the Life-or-Death Race for a COVID-19 Vaccine* 107–10 (2021).

("HPLC") purification reduces immune activation and improves translation for certain modified mRNAs, including those with modified uridine. *See* Ex. 26. Upon information and belief, Moderna utilizes HPLC purification in manufacturing the mRNA used in Spikevax®.

31. The University of Pennsylvania sold the rights to modified RNA technologies that Drs. Karikó and Weissman developed to mRNA RiboTherapeutics, which licensed non-gene therapy applications of that technology to Cellscript, LLC ("Cellscript"). Ex. 11. In 2017, and, upon information and belief, recognizing that Moderna was, in fact, in need of the University of Pennsylvania patents, Moderna took a license from Cellscript regarding the modified RNA technologies developed by Drs. Karikó and Weissman. On information and belief, this license includes the '966 Patent that expressly claims a modified mRNA containing 1-methyl-pseudoruridine. *Id*. That license is an admission that Moderna was not the first to discover mRNAs comprising modified uridines, including 1-methyl-pseudouridine, as it now alleges.

32. After Moderna filed the present lawsuit, Drs. Karikó and Weissman "noted in separate emails to *Science* [magazine] that they have an issued patent, filed 6 years earlier than Moderna's, that explicitly includes the 1-methyl-pseudouridine modification." Ex. 12 at 2. Moderna did not, in response, produce any contemporaneous information to show that Drs. Karikó and Weissman were wrong.

33. Moderna's complaint also boasts that it "discovered that packaging that chemically-modified mRNA in a lipid nanoparticle formulation allowed for the efficient delivery of the mRNA to cells." D.I. 1 ¶ 57. But Moderna did not make this discovery, and the Asserted Patents do not specifically claim the LNPs that Spikevax® actually uses.

34. The same components claimed in the Asserted Patents—and even the ratio of those components—were already described in the literature. For example, International Patent

Publication No. 2010/144740 describes introducing nucleic acid into cells using lipid particles, and lists the same components at the same ratios claimed in Moderna's patents. Ex. 27 at 1, 6.

35. Drs. Karikó and Weissman's '966 Patent also claims a formulation of a 1-methyl-pseudouridine modified mRNA "encapsulated in a nanoparticle, polymer, lipid, cholesterol, or a cell penetrating peptide." *See* Ex. 28 at Claim 15.

36. Moderna's attempt to portray itself as a leader in the field of lipid nanoparticle-based delivery of mRNA to the cell (*see* D.I. 1, ¶¶ 6, 57) also does not withstand scrutiny. At its inception, Moderna had no experience in the formulation or development of lipid nanoparticle carriers used to transport mRNA. Ex. 29 at 3–4. Dr. Robert Langer, an MIT professor, a Moderna board member, and founder of numerous biotech companies, allegedly told Moderna's CEO, Stéphane Bancel, "that Moderna was too underfunded and small to create its own delivery system." Ex. 14 at 3–4. Accordingly, Moderna in-licensed lipid nanoparticle technology for its vaccine program from third party Acuitas Therapeutics. This led to litigation between Acuitas and another company Arbutus regarding whether Acuitas had the right to license certain LNP technology to Moderna. *Id.* at 3. Ultimately, the litigations were resolved with Acuitas terminating its license with Moderna in 2018. Ex. 15 at 7.

37. Nor can Moderna seek to claim ownership of the broad concept of encoding for the full-length spike protein. While SARS-COV-2 only emerged recently, scientists have long been concerned about the broader threat posed by coronaviruses, especially after the early 2000s SARS outbreak. By 2009, "[s]everal vaccines that are based on the full-length S protein of SARS-CoV ha[d] been reported," and scientists understood that "the full-length S protein is highly immunogenic and induces protection against SARS-CoV challenge." Ex. 30 at 229. In other

words, the spike protein is a good antigen for the development of an effective vaccine—and this was well known by 2009, a decade before the COVID-19 pandemic.

38. Because Defendants' and Moderna's mRNA vaccines have different structures and different LNP formulations, Moderna does not and cannot assert any patents that actually disclose or describe Moderna's COVID-19 vaccine.

39. Instead, Moderna discusses COVID-19 throughout the complaint, while failing to disclose that the '600 and '127 Patents do not mention SARS-CoV-2 or disclose an actual mRNA vaccine that encodes a SARS-CoV-2 protein at all.

40. None of the Asserted Patents discloses the complete mRNA sequence that Moderna used for Spikevax®.

41. No claim of any Asserted Patent specifically recites the complete mRNA sequence that Moderna used for Spikevax®.

42. During prosecution of the '127 Patent, the examiner expressly stated that the claims "are interpreted as be[ing] directed to betacoronaviruses that were known as of October 21, 2016 (e.g., OC43, HKU1, MERS and SARS-CoV) and not SARS-CoV-2 (COVID-19)." Ex. 31.

43. In aggressively pursuing broad patents, irrespective of whether Moderna actually invented the underlying technology, Moderna also failed to properly credit scientists at the NIH. Scientists at the NIH worked with Moderna to stabilize the coronavirus spike protein, which had been developed by scientists at the National Institute of Allergy and Infectious Diseases—an institute of the NIH—and their collaborators at Scripps Research, Dartmouth College and the University of Texas at Austin.[24] Ex. 13. Moderna has stated that NIH scientists Dr. John Mascola,

[24] Herman, *supra* note 4.

Dr. Barney Graham, and Dr. Kizzmekia Corbett played a "substantial role" in the development of its COVID-19 vaccine.[25]

44. Despite the crucial role of the NIH scientists, Moderna filed patent applications that excluded the NIH scientists who are reported to have "design[ed] the genetic sequence that prompts the vaccine to produce an immune response."[26] Moderna named only its own scientists as the inventors of the genetic sequence that instructs the body's cells to make a harmless version of the spike proteins that stud the coronavirus's surface, which prompts a powerful immune response.

45. Moderna also accepted $1.4 billion from the federal government to develop and test its vaccine. Ex. 32. Moderna then failed to disclose that it received this federal funding for its vaccines in its patent applications, which would have given the federal government certain rights in any resulting patents.[27] In August 2020, the U.S. Department of Defense's research arm, the Defense Advanced Research Projects Agency ("DARPA"), began investigating Moderna's "compliance with federal law that requires companies to disclose any government funding to the U.S. Patent and Trademark Office."[28]

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[25] Chris Lange, *NIH sues Moderna over COVID-19 vaccine Patent*, FISMTV (Nov. 11, 2021), https://fism.tv/nih-sues-moderna-over-covid-19-vaccine-patent/.

[26] Stolberg & Robbins, *supra* note 5.

[27] Ed Silverman, *Moderna failed to disclose federal funding for vaccine patent applications, advocates say*, STATNEWS (Aug. 28, 2020), https://www.statnews.com/pharmalot/2020/08/28/moderna-covid19-vaccine-coronavirus-patents-darpa/.

[28] Kevin Stawicki, *DOD Investigating Moderna's Vaccine Patents*, LAW360 (Aug. 31, 2020, 9:56 PM), https://www.law360.com/articles/1305849/dod-investigating-moderna-s-vaccine-patents; *see also* James Love, *KEI asks DOD to investigate failure to disclose DARPA funding in Moderna patents*, KEIONONLINE (Aug. 28, 2020), https://www.keionline.org/33763; Luis Gil Abinader, *KEI Series on inventors that fail to disclose U.S. government funding in patented*

46. In sum, the Asserted Patents reach beyond the scope of any purported invention that Moderna has made and attempt to misappropriate discoveries relating to mRNA technology made by others, such as Drs. Karikó and Weissman. Moderna's plan appears to be to co-opt the use of fundamental technology that Moderna did not itself discover, burdening research and development by other companies.

Moderna's Pledge to Not Enforce Its Patents

47. Moderna's attempt to patent the mRNA COVID-19 vaccine without disclosing the government's role in funding and developing the vaccine became public by mid-2020.[29] On information and belief, to mollify public ire and avoid further disputes with government agencies such as the NIH and the DARPA, Moderna's senior executives, led by CEO Stéphane Bancel and Chairman Noubar Afeyan, made numerous public statements expressing that Moderna would not enforce its COVID-19 related patents.

48. In particular, Moderna first published a statement that, "while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic." Ex. 33. Moderna's CEO Stéphane Bancel later emphasized that "we never wanted our patents to be a barrier to others bringing forward mRNA vaccines." Ex. 34.

49. Moderna's other senior executives likewise committed not to sue other COVID-19 vaccine makers for patent infringement. Moderna's Chairman, Noubar Afeyan, expressly stated that "[w]e decided not to enforce our patent during the pandemic." Ex. 36 at 1; *see also* Ex. 35.

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inventions, KEIONONLINE (Aug. 27, 2020), https://www.keionline.org/wp-content/uploads/RN-2020-3.pdf.

[29] Silverman, *supra* note 27; Herman, *supra* note 4.

And during an interview on CNN, Mr. Afeyan noted that "[w]e believe that [the voluntary pledge] has enabled others to make mRNA vaccines, and if others do that even further, that's great . . . . So combined by adding production capacity and *allowing others to use our intellectual property*, we've taken steps voluntarily to do the maximum we can. And in fact, we invite everyone to do the same." Ex. 37 at 6–7 (Transcript of Fareed Zakaria, *Interview With Moderna CEO And Co-Founder Noubar Afeyan*, CNN (Dec. 5, 2021), https://www.cnn.com/videos/tv/2021/12/05/exp-gps-1205-noubar-afeyan-moderna-omicron.cnn) (emphasis added).

50. Moderna's CEO, Stéphane Bancel, in reference to other vaccine makers, stated that "we will not sue them. We made that public and we wrote that on our website. Our boss talked about it. So people will not worry *if they wanted to invest money and time, that they will not get the lawsuit from Moderna because we care about getting as many vaccine[s] as we can get through the door*." Ex. 38 at 42–43 (Transcript of Podcast interview with Bancel (52:30, 58:07) https://www.modernatx.com/media-center/all-media/podcasts/the-future-of-vaccines-with-moderna-ceo-stephane-bancel) (emphasis added).

51. In addition, Moderna's executives also indicated that its pledge was binding. When asked whether "there was any kind of agreement that goes beyond [Moderna] not enforcing [its] intellectual property rights," Mr. Afeyan replied that "*I think you don't need an agreement if you have some sort of voluntary statement that that's our position.* We've had that stance and we welcome others to join." Ex. 36 at 4 (emphasis added).

52. On March 7, 2022, Moderna declared that "vaccine supply is no longer a barrier to access" in certain countries. Ex. 39 at 1. Moderna stated that, "[i]n these countries, the Company expects those using Moderna-patented technologies will respect the Company's intellectual property." *Id.*

53. The COVID-19 pandemic was still ongoing as of March 7, 2022. The same week Moderna posted its statement, the CDC reported that there were 9,085 new deaths and 3,185 new hospital admissions due to COVID-19 infections.[30] As of the filing date of these Counterclaims, the WHO still considers COVID-19 to be a pandemic.[31]

54. In an interview with 60 Minutes in September 2022, President Joe Biden remarked that the pandemic was over. President Biden later clarified that his comments meant the pandemic "basically is not where it was."[32] Infectious disease experts have agreed with this latter statement that the pandemic is not in fact over. [33] The Department of Health and Human Services ("HHS") recently renewed its determination "that a public health emergency exists and has existed since January 27, 2020, nationwide."[34] HHS is allowing the federal public health emergency status for

[30] CDC, COVID DATA TRACKER, https://covid.cdc.gov/covid-data-tracker/#trends_dailycases_select_00 (last accessed Dec. 5, 2022).

[31] WHO, CORONAVIRUS DISEASE (COVID-19) PANDEMIC, https://www.who.int/emergencies/diseases/novel-coronavirus-2019 (last accessed Dec. 5, 2022); Cecelia Smith-Schoenwalder, *WHO Says COVID-19 Pandemic Isn't Over After Biden's Controversial Remarks*, U.S. NEWS (Sept. 22, 2022, 12:42 PM), https://www.usnews.com/news/health-news/articles/2022-09-22/who-says-covid-19-pandemic-isnt-over-after-bidens-controversial-remarks.

[32] Brett Samuels, *Biden Clarifies COVID comments: Pandemic 'basically is not where it was'*, NEWS10 (Sep. 20, 2022), https://www.news10.com/news/coronavirus/biden-clarifies-covid-comments-pandemic-basically-is-not-where-it-was/.

[33] Eric Berger, *Biden's claim that Covid pandemic is over sparks debate over future*, THE GUARDIAN (Sept. 24, 2022), https://www.theguardian.com/world/2022/sep/24/covid-not-over-biden-remarks-cbs-60-minutes.

[34] HHS, RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (Oct. 13, 2022), https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx.

COVID-19 to remain in place until at least mid-January 2023, with HHS officials not yet signaling an end date.[35]

55. On September 16, 2022, Moderna's Chairman Noubar Afeyan explained:

> This was and still is a major battle between a code-based pathogen that is preying on our social nature, the very social nature we're hearing about today, to transmit itself against -- fighting against a distributed individual immune system in each and every one of us trying to protect us even as the enemy mutates relentlessly to escape detection. *That's the battle that produced the -- the pandemic that we're experiencing.*

Ex. 40 at 6 (Transcript of Flagship Pioneering Founder and CEO and Moderna Co-founder and Chairman Dr. Noubar Afeyan, *Presentation at the 2022 Code Conference*, Recode (5:14, 6:50, 25:42) (Sept. 16, 2022), https://www.youtube.com/watch?v=cgmn4vJ6pCg) (emphasis added). Mr. Afeyan further noted that "[a]nd just this past weekend, *because the fight's still going on*, both Moderna and our colleagues at Pfizer BioNTech, began rolling out updated bivalent boosters that are reprogrammed to address the new Omicron variants." *Id*. at 7.

56. Moderna knows that the pandemic was not over as of March 7, 2022.

57. After March 7, 2022, Moderna continued to reassure the public that it did not intend to sue other vaccine makers. Two months after Moderna's March 2022 statement, Moderna's Chairman Noubar Afeyan stated that "we pledged in October 2020 to give away our patents and not enforce them in the pandemic to anybody working on a vaccine . . . we're doing this because it's the right thing to do." Ex. 41 at 15 (Transcript of Noubar Afeyan, Moderna Co-Founder and

[35] *See* Spencer Kimball, *U.S. will keep Covid public health emergency in place at least until mid January*, CNBC (Nov. 11, 2022, 4:24 PM), https://www.cnbc.com/2022/11/11/us-will-keep-covid-public-health-emergency-in-place-until-at-least-mid-january.html; Nathaniel Weixel, *US to keep COVID public health emergency through January*, THE HILL (Nov. 14, 2022, 4:39 PM), https://thehill.com/policy/healthcare/3735058-u-s-to-continue-covid-public-health-emergency-through-january/; Lawrence Gostin and James Hodge, *Renewing Covid's Status As A Public Health Emergency Was The Right Call. Here's Why*, FORBES (Nov. 14, 2022, 3:29 PM), https://www.forbes.com/sites/coronavirusfrontlines/2022/11/14/renewing-covids-status-as-a-public-health-emergency-was-the-right-call-heres-why/?sh=4d7423794425.

Chairman, Moderna, *Discussing Ethical Innovation at Solve at MIT 2022* (May 5, 2022) (16:00), https://www.youtube.com/watch?v=XwPM3SKaOMQ). Chairman Afeyan then unequivocally declared: "*Every company has an implicit license to operate and that's the most precious thing it has.*" *Id*. at 15 (emphasis added).

COUNT I – DECLARATION OF INVALIDITY OF THE '574 PATENT

58. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

59. Claims 1–4 and 6–10 of the '574 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

COUNT II – DECLARATION OF INVALIDITY OF THE '600 PATENT

60. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

61. Claims 1–2, 4–6, 8–12, 16–17, 20–21, and 26 of the '600 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

COUNT III – DECLARATION OF INVALIDITY OF THE '127 PATENT

62. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

63. Claims 1–3, 6–9, 11–13, 17–18, and 20 of the ’127 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

COUNT IV – DECLARATION OF NONINFRINGEMENT OF THE ’574 PATENT

64. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

65. Counterclaim Defendant Moderna has accused Pfizer and BioNTech of activities that it claims infringe the ’574 Patent. Pfizer and BioNTech deny that they have infringed any valid and/or enforceable claim of the ’574 Patent.

66. Pfizer and BioNTech are entitled to a judicial determination that it has not infringed and will not infringe any valid claim of the ’574 Patent.

COUNT V – DECLARATION OF NONINFRINGEMENT OF THE ’600 PATENT

67. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

68. Counterclaim Defendant Moderna has accused Pfizer and BioNTech of activities that it claims infringe the ’600 Patent. Pfizer and BioNTech deny that they have infringed any valid and/or enforceable claim of the ’600 Patent.

69. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe any valid claim of the ’600 Patent.

COUNT VI – DECLARATION OF NONINFRINGEMENT OF THE ’127 PATENT

70. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

71. Counterclaim Defendant Moderna has accused Pfizer and BioNTech of activities that it claims infringe the ’574 Patent. Pfizer and BioNTech deny that they have infringed any valid and/or enforceable claim of the ’127 Patent.

72. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe any valid claim of the ’127 Patent.

COUNT VII– DECLARATION THAT PFIZER AND BIONTECH ARE LICENSED TO PRACTICE THE ASSERTED PATENTS

73. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

74. Moderna has granted an implied license to practice (in the words of Moderna Chairman “an implicit license to operate”) the ’574, ’600, and ’127 Patents to Pfizer and BioNTech. In addition to Moderna’s express statements that it would not enforce its COVID-19 related patents, as noted above, Pfizer and BioNTech may also properly infer from Moderna’s statements and/or conduct that Moderna consents to any use of their COVID-19 related patents.

COUNT VIII – DECLARATION OF UNENFORCEABILITY BASED ON WAIVER

75. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

76. The ’574, ’600, and ’127 Patents are unenforceable against Pfizer and BioNTech based on the doctrine of waiver. During the pandemic, Moderna intentionally and expressly relinquished its right to enforce these patents.

COUNT IX – DECLARATION OF UNENFORCEABILITY BASED ON IMPLIED WAIVER

77. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

78. The ’574, ’600, and ’127 Patents are unenforceable against Pfizer and BioNTech based on the doctrine of implied waiver. Moderna’s numerous public statements pledging not to enforce its patents, along with Moderna’s conduct, demonstrates that Moderna relinquished its rights to enforce its patents.

COUNT X – DECLARATION OF UNENFORCEABILITY BASED ON ACQUIESCENCE

79. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 57 of its Counterclaims as if fully set forth herein.

80. The ’574, ’600, and ’127 Patents are unenforceable against Pfizer and BioNTech based on the doctrine of acquiescence.

DEMAND FOR JUDGMENT

WHEREFORE, Counterclaim Plaintiffs Pfizer and BioNTech prays for the following relief:

a) That the Court order Moderna's complaint be dismissed with prejudice and judgment be entered in favor of Pfizer and BioNTech;

b) That a judgment be entered declaring that Pfizer and BioNTech's conduct has not infringed the '574, '600, and '127 patents;

c) That a judgment be entered declaring Claims 1–4 and 6–10 of the '574 Patent; Claims 1–2, 4–6, 8–12, 16–17, 20–21, and 26 of the '600 Patent; and Claims 1–3, 6–9, 11–13, 17–18, and 20 of the '127 Patent invalid;

d) That a judgment be entered declaring that the '574, '600, and '127 Patents are unenforceable against Pfizer and BioNTech;

e) That Moderna and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Pfizer and BioNTech or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Pfizer and BioNTech, or charging any of them either orally or in writing with infringement of the '574, '600, and '127 Patents;

f) That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Pfizer and BioNTech are therefore entitled to recover their reasonable attorneys' fees upon prevailing in this action;

g) That Pfizer and BioNTech be awarded costs, attorney's fees, and other relief, both legal and equitable, to which they may be justly entitled; and

h) That Pfizer and BioNTech be awarded such other and further relief as is just and proper.

Dated: December 5, 2022

Respectfully submitted:

DEFENDANT AND COUNTERCLAIM-PLAINTIFF PFIZER INC.

By their Counsel,

/s/ Lee Carl Bromberg

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