IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

PLAINTIFFS MODERNATX, INC. AND MODERNA US, INC.'S
ANSWER TO DEFENDANTS' COUNTERCLAIMS

1. COVID-19 presented an unprecedented public health crisis that required an unprecedented response. Due to Moderna's decade-long investment in foundational research to develop its own innovative mRNA vaccine platform technology, with a specific focus on infectious disease, Moderna was uniquely poised to respond to that challenge.

2. Pfizer and BioNTech assert that they "independently" developed their own COVID-19 vaccine and tout the speed with which they developed their vaccine. But Pfizer and BioNTech's development of their COVID-19 vaccine was clearly aided by Moderna's technology. Indeed, after initially pursing an alternative vaccine design in Phase I/II clinical trials,[1] Pfizer and BioNTech made a late switch to pursue a different candidate in Phase III clinical trials.[2] The vaccine design that Pfizer and BioNTech ultimately settled on had the same chemical modification to mRNA encoding for the same spike protein as Moderna's vaccine—features that Moderna had disclosed in patent applications years earlier. It is no coincidence that the only two mRNA vaccines for COVID-19 that have had any success to date are Pfizer and BioNTech's Cominarty® and Moderna's Spikevax®; both utilize Moderna's patented inventions.

3. Rather than acknowledge Moderna's innovative research, Pfizer and BioNTech seek to distract from the issues in this case by pointing to the work done by scientists at the University of Pennsylvania and the NIH. Moderna acknowledges and respects the work that others

[1] Exhibit A (*Pfizer and BioNTech Announce Early Positive Data from an Ongoing Phase 1/2 Study of mRNA-based Vaccine Candidate Against SARS-CoV-2*, Pfizer.com (July 1, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-early-positive-data-ongoing); Exhibit B (*Pfizer and BioNTech Announce Early Positive Update from German Phase 1/2 COVID-19 Vaccine Study, Including First T-Cell Response Data*, Pfizer.com (July 20,2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-early-positive-update-german).

[2] Exhibit C (*Pfizer and BioNTech Choose Lead mRNA Vaccine Candidate Against COVID-19 and Commence Pivotal Phase 2/3 Global Study*, Pfizer.com (July 27, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate).

have done in innovating in the mRNA field, and nothing in this lawsuit seeks to detract from or diminish the contributions by others. No inventor acts in a vacuum, and great leaps in science and medicine often result from the innovations of multiple parties which, taken together, advance the field. But Moderna's inventions are critical contributions that are appropriately protected by patents Moderna earned through the creative and persevering work of its scientists. Pfizer and BioNTech cannot excuse their use of Moderna's inventions simply because Moderna is not the only innovator in this space.

4. Lacking any actual defense to their infringement, Pfizer and BioNTech instead seek to twist Moderna's promise to not enforce its patents during the pandemic into a perpetual right to use Moderna's inventions. But there is no support for that extreme position. Moderna's patent pledge was for the specific purpose of ensuring that patent rights were not a barrier to access to life saving medicines. And Moderna still stands behind that principle today; indeed, Moderna has promised never to enforce its patents for COVID-19 vaccines against companies manufacturing in or for 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment. Now that vaccine supply is no longer a barrier to access in the United States and elsewhere, Moderna expects others will not continue to profit from their unlicensed use of Moderna's patented inventions, as Pfizer and BioNTech have continued to do.

ANSWER TO COUNTERCLAIMS[3]

Plaintiffs/Counterclaim-Defendants ModernaTX, Inc. and Moderna US, Inc. (collectively, "Moderna" or the "Company"), by and through their attorneys, hereby respond to the counter-claims of Defendants/Counterclaim-Plaintiffs Pfizer Inc. ("Pfizer"), BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. (collectively, "BioNTech") as follows:

[3] Moderna does not reproduce the headings or footnotes from Defendants' Counterclaims and denies any allegations contained in those headings or footnotes.

Moderna denies all allegations in Defendants' Counterclaims not expressly admitted.

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.

ANSWER: Upon information and belief, and as admitted by Defendants in their Answer, Moderna admits the allegations of Paragraph 1.

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.

ANSWER: Upon information and belief, and as admitted by Defendants in their Answer, Moderna admits the allegations of Paragraph 2.

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.

ANSWER: Upon information and belief, and as admitted by Defendants in their Answer, Moderna admits the allegations of Paragraph 3.

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.

ANSWER: Upon information and belief, and as admitted by Defendants in their Answer, Moderna admits the allegations of Paragraph 4.

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.

ANSWER: Moderna admits the allegations of Paragraph 5.

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.

ANSWER: Moderna admits the allegations of Paragraph 6.

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Moderna admits that Defendants' Counterclaims purport to seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202. Moderna does not contest the Court's jurisdiction over Defendants' Counterclaims.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Moderna admits that it filed its Complaint in the District of Massachusetts. Moderna does not contest that this Court is a proper venue for Defendants' Counterclaims.

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").

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Moderna admits that it has accused Defendants of infringing the '574 Patent, the '600 Patent, and the '127 Patent. Moderna does not contest that there is an actual controversy between the parties regarding Defendants' infringement of those patents.

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.

ANSWER: Moderna admits that COVID-19 is the greatest public health challenge in recent memory. Moderna admits that BioNTech and Pfizer's Comirnaty® was approved for public use under an Emergency Use Authorization on December 11, 2020, and that one of the reasons it

was able to be deployed quickly was because Defendants took advantage of Moderna's many years of published and patented research and development. Moderna admits that Spikevax® was approved under an Emergency Use Authorization on December 18, 2020, seven days following the approval of Comirnaty® under an Emergency Use Authorization on December 11, 2020. Moderna admits that Moderna developed a new type of vaccine containing mRNA packaged in a lipid nanoparticle for delivery into the patient's cells to elicit a protective immune response. Moderna denies the remaining allegations in Paragraph 10.

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

ANSWER: Moderna admits that Comirnaty® and Spikevax® are similar and include mRNA strands using the same modified nucleoside that encode for the same antigen. Moderna denies that Comirnaty® and Spikevax® were developed independently. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11, and therefore denies them.

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.

ANSWER: Moderna denies that it has not publicly disclosed the complete mRNA sequence in Spikevax®. Moderna denies that Exhibit 16 reports the mRNA sequence of Comirnaty® or Spikevax®. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 12 and therefore denies them.

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.

ANSWER: Moderna acknowledges and respects the work that others have done in the mRNA field, but denies that Comirnaty® is the result of independent research by Pfizer and BioNTech. Moderna denies the remaining allegations of Paragraph 13.

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.

ANSWER: Moderna admits that scientists have been studying mRNA for many years. Moderna denies that research sufficient to create a real-world, safe, and effective mRNA coronavirus vaccine existed prior to Moderna's work. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the vague allegations in Paragraph 14, and therefore denies them.

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.

ANSWER: Moderna admits that it is now known that unmodified synthetic mRNA can trigger proteins known as toll-like receptors, which can lead to an undesirable immune and inflammatory response in the body. Moderna admits that Exhibit 17 purports to be a news article in which Dr. Anthony Fauci is reported to have stated that Dr. Karikó "was, in a positive sense, kind of obsessed with the concept of messenger RNA." Dkt. 45 Ex. 17 at 1. Moderna admits that Exhibit 17 purports to be a news article in which Dr. David Langer is reported to have stated that "[w]hen your idea is against the conventional wisdom that makes sense to the star chamber, it is

very hard to break out." *Id.* Moderna admits that Exhibit 17 purports to be a news article in which Dr. David Langer is reported to have stated that "Kate's 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. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15, and therefore denies them.

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.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 16, and therefore denies them.

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.

ANSWER: Moderna admits that Exhibit 1 purports to be a paper authored by Katalin Karikó, Michael Buckstein, Houpin Ni, and Drew Weissman, titled "Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA," and dated August 2005. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17 and therefore denies them.

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.

ANSWER: Moderna admits that Exhibit 17 purports to be a news article in which Dr. Weissman is reported to have stated that "[w]e were screaming a lot, but no one would listen." Dkt. 45 Ex. 17 at 4. Moderna denies that it "took notice of Drs. Karikó and Weissman's work." Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18 and therefore denies them.

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*.

ANSWER: Moderna denies that "Drs. Karikó and Weissman's discovery that modified mRNA nucleosides could evade toll-like receptors is a critical innovation behind both Comirnaty® and Spikevax®." Comirnaty® and Spikevax® both use mRNA modified with 1-methylpseudouridine. Drs. Karikó and Weissman published no data for 1-methylpseudouridine prior to the publication of Moderna's data.[4] Moderna was the first to discover that 1-methylpseudouridine was not only effective in evading toll-like receptors, but significantly more effective than the pseudouridine that Drs. Karikó and Weissman tested.

Moderna admits that Derrick Rossi was a Moderna co-founder. Moderna admits that Exhibit 9 purports to be a newsletter stating: "Kariko and Weissman's discovery is 'fundamental to this entire field,' says Derrick Rossi, a co-founder of mRNA vaccine maker Moderna. 'I believe it's going to earn them a Nobel Prize because it really is what allows these mRNA vaccines and any mRNA therapeutic down the road.'" Dkt. 45 Ex. 9 at 2. Moderna admits that Exhibit 10

[4] *E.g.*, Exhibit D (WO 2012/045075); Exhibit E (WO 2012/135805).

purports to be a news article stating that Derrick Rossi "now says Karikó and Weissman deserve the Nobel Prize in chemistry" and reported that Mr. Rossi stated: "'If anyone asks me whom to vote for some day down the line, I would put them front and center,' he said. 'That fundamental discovery is going to go into medicines that help the world.'" Dkt. 45 Ex. 10 at 7. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19 and therefore denies them.

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.

ANSWER: Moderna admits that Exhibit 2 purports to be a news release from Columbia University stating that "Columbia will award the 2021 Louisa Gross Horwitz Prize to Katalin Karikó, PhD, and Drew Weissman, MD, PhD, for trailblazing work on messenger RNA (mRNA) vaccines for COVID-19" and "[d]ecades of research on messenger RNA by Karikó and Weissman laid the foundation for the creation of incredibly effective COVID-19 vaccines." Dkt. 45 Ex. 2 at 3. Moderna admits that Exhibits 3, 4, 7, 18, 19, and 20 purport to describe Drs. Karikó and Weissman as the recipient of certain awards. Moderna denies that Exhibit 21 purports to refer to Dr. Karikó or Dr. Weissman. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 20, and therefore denies them.

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.

ANSWER: Moderna admits that Exhibit 22 purports to be a copy of Provisional Patent Application No. 60/710,164, titled "RNA Containing Modified Nucleosides and Methods of Use Thereof," dated August 23, 2005, and listing Drew Weissman and Katalin Karikó as inventors. Dkt. 45 Ex. 22 at cover sheet. Moderna admits that the first page of Exhibit 22 states: "This invention provides RNA, oligoribonucleotide, and polyribonucleotide molecules comprising pseudouridine or a modified nucleoside . . . ." *Id.* at 1. Moderna admits that pages 13-15 of Exhibit 22 contain a paragraph listing ninety-five modified nucleosides and that "1-methylpseudouridine" is buried in the middle of that list. *Id.* at 13-15. Moderna denies that 1-methylpsuedouridine is expressly identified in the '164 Application. Although the '164 Application purports to include twenty-five experimental examples, not a single one purports to have tested 1-methylpseudouridine. *Id.* at 43-79.

Moderna admits that Exhibit 28 purports to be a copy of U.S. Patent No. 8,691,966, issued on April 8, 2014, listing the '164 Application under "Related U.S. Application Data," listing Drs. Karikó and Weissman as inventors, and listing the Trustees of the University of Pennsylvania as the assignee. Moderna admits that claim 1 of the '966 Patent purports to claim "A composition comprising an in vitro-synthesized modified RNA comprising an open reading frame that encodes a protein of interest for translation in a mammalian cell, wherein said in vitro-synthesized modified RNA comprises a modified nucleoside selected from the group consisting of (i) 1-methylpseudouridine ($m^1\Psi$) and (ii) pseudouridine (Ψ)." Dkt. 45 Ex. 28 at 67:29-34. Moderna denies any allegation that Drs. Karikó and Weissman first discovered 1-methylpseudouridine modified mRNA. The '164 Application that Defendants assert the '966 Patent claims priority to did not include any data or information about 1-methylpseudouridine

modified mRNA. Further, the original claim 1 in the '164 Application did ***not*** recite 1-methylpseudouridine. The claim that became claim 1 of the '966 patent was amended on December 19, 2013, to include 1-methylpseudouridine ***only after*** the publication of Moderna's patent applications containing data showing the superiority of 1-methylpseudouridine.[5]

Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21, and therefore denies them.

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.

ANSWER: Moderna admits that Exhibit 23 purports to be a letter in Nature, dated March 9, 2017, listing Dr. Karikó as one of thirty-seven authors (of which Dr. Karikó is the only author listed as affiliated with "BioNTech RNA Pharmaceuticals, An der Goldgrube 12, 55131 Mainz, Germany"), and stating: "Here we demonstrate 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 mice and non-human primates." Dkt. 45 Ex. 23 at 1. Moderna admits that Exhibit 23 states that the anti-ZIKV vaccine described contained 1-methylpseudouridine. *Id.* Moderna denies any allegation that Dr. Karikó was first to discover that 1-methylpseudouridine-modified mRNA encapsulated in lipid

[5] *Compare* Exhibit F (Dec. 19, 2013 claim amendment to U.S. Patent Application No. 13/585,517), *with* Exhibit D (WO 2012/045075 (published Apr. 5, 2012)); Exhibit E (WO 2012/135805 (published Oct. 4, 2012)).

nanoparticles could be immunogenic. Moderna admits that Comirnaty® uses 1-methylpseudouridine. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22, and therefore denies them.

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).

ANSWER: Moderna admits that Exhibit 24 purports to be an article in the Journal of Experimental Medicine. Dkt. 45 Ex. 24 at 1571. Moderna admits that Exhibit 24 lists Dr. Karikó as one of thirty-nine authors, and that Dr. Karikó's affiliation is listed as "BioNTech RNA Pharmaceuticals, Mainz, Germany." *Id.* Moderna denies that any of the other authors of Exhibit 24 are listed as affiliated with BioNTech. *Id.* Moderna denies that Exhibit 24 makes any reference to "BioNTech's mRNA vaccine platform." Moderna admits that Exhibit 24 states that "the m1Ψ-mRNA-LNP vaccine platform . . . has the additional advantages of a favorable safety profile, potentially inexpensive manufacturing, and the capacity for rapid development in emerging epidemics." *Id.* at 1577-1578, 1580. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 23, and therefore denies them.

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*.

ANSWER: Moderna admits that Exhibit 25 purports to be a press release from BioNTech and Pfizer dated August 16, 2018, in which Kathrin Jansen is reported to have stated:

"Innovative vaccine approaches are urgently needed to provide improved protection against seasonal flu, and to respond rapidly and in quantity to pandemic influenza threats. 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 vaccines." Dkt. 45 Ex. 25 at 1. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 24, and therefore denies them.

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.

ANSWER: Moderna admits that SARS-CoV-2 was first identified in Wuhan, China, in December 2019. Moderna denies that Pfizer and BioNTech were well-positioned to respond rapidly by constructing a vaccine around their existing modified mRNA platform. Pfizer and BioNTech were positioned to respond rapidly because they took advantage of Moderna's longstanding research in mRNA vaccines for infectious diseases. Moderna lacks knowledge and information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 25 and therefore denies them.

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.

ANSWER: Moderna admits that the World Health Organization declared the COVID-19 outbreak a global pandemic in March 2020. Moderna denies that the rapid development and launch of Pfizer and BioNTech's product candidates was not the result of copying someone else's

work and denies that it was result of the vision of Pfizer and BioNTech. Pfizer and BioNTech were able to rapidly develop and launch their product because they copied critical features of Moderna's vaccine including the use of 1-methylpseudouridine modified mRNA and the use of mRNA encoding for the full-length coronavirus spike protein. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 26, and therefore denies them.

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.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 27, and therefore denies them.

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, reflecting the fastest development of a vaccine in history.

ANSWER: Moderna admits that on December 11, 2020, the FDA granted the first EUA for a COVID-19 disease vaccine to Pfizer and BioNTech's mRNA vaccine. The development timeline for Pfizer and BioNTech's vaccine relied on Moderna's work. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 28, and therefore denies them.

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.

ANSWER: Moderna admits that it is aware of the research involving pseudouridine by Drs. Karikó and Weissman. Moderna admits that "A Shot to Save The World: The Inside Story of the Life-or-Death Race for a COVID-19 Vaccine," by Gregory Zuckerman, and "The

Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World," by Peter Loftus, report that a Flagship patent attorney discussed a potential patent license with Drs. Karikó and Weissman. Moderna denies that it obtained a license in 2010 to any University of Pennsylvania patent. Moderna developed its own chemically-modified mRNA technologies. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 29, and therefore denies them.

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 ("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®.

ANSWER: Moderna admits that Drs. Karikó and Weissman presented at Moderna regarding mRNA technology in 2011. Moderna admits that Exhibit 26 purports to be a paper authored by Katalin Karikó, Hiromi Muramatsu, János Ludwig, and Drew Weissman; dated September 2, 2011; and titled "Generating the optimal mRNA for therapy: HPLC purification eliminates immune activation and improves translation of nucleoside-modified, protein-encoding mRNA." Dkt. 45 Ex. 26 at 1. Moderna admits that Exhibit 26 purports to describe experiments using pseudouridine, but denies any allegation that it describes experiments using 1-methylspeudouridine. *Id.* at 2. Moderna denies the allegations regarding the Spikevax® manufacturing process. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 30, and therefore denies them.

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-

methylpseudoruridine. *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.

ANSWER: Modena admits that it has a license from Cellscript, LLC to certain intellectual property relating to the use of modified RNA technology, which Cellscript in turn had licensed from the Trustees of the University of Pennsylvania. Moderna denies that it was "in need of" the University of Pennsylvania patents. By the time Moderna entered into the license agreement with Cellscript, Moderna had made its own inventions relating to chemically-modified mRNAs and had filed patent applications on those discoveries.

Moderna admits that claim 1 of the '966 Patent purports to claim "A composition comprising an in vitro-synthesized modified RNA comprising an open reading frame that encodes a protein of interest for translation in a mammalian cell, wherein said in vitro-synthesized modified RNA comprises a modified nucleoside selected from the group consisting of (i) 1-methylpseudouridine ($m^1\Psi$) and (ii) pseudouridine (Ψ)." Dkt. 45 Ex. 28 at 67:29-34. Moderna denies any allegation that Drs. Karikó and Weissman first discovered 1-methylpseudouridine modified mRNA. The '164 Application that Defendants assert the '966 Patent claims priority to did not include any data or information about 1-methylpseudouridine modified mRNA. Further, the original claim 1 in the '164 Application did ***not*** recite 1-methylpseudouridine. The claim that became claim 1 of the '966 patent was amended on December 19, 2013, to include 1-methylpseudouridine ***only after*** the publication of Moderna's patent applications containing data showing the superiority of 1-methylpseudouridine.[6]

Moderna denies that the license from Cellscript is an admission that Moderna was not the first to discover 1-methylpseudouridine modified mRNA and its superior performance. Moderna

[6] *See supra* note 5.

denies any allegation that Moderna was not the first to discover 1-methylpseudouridine modified mRNA.

Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 31, and therefore denies them.

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.

ANSWER: Moderna admits that Exhibit 12 purports to be a news article in ScienceInsider dated August 29, 2022, that states: "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." Dkt. 45 Ex. 12 at 2. To the extent they were referring to the '966 Patent, the '164 Application that Defendants assert the '966 Patent claims priority to did not include any data or information about 1-methylpseudouridine modified mRNA. Further, the original claim 1 in the '164 Application did ***not*** recite 1-methylpseudouridine. The claim that became claim 1 of the '966 patent was amended on December 19, 2013, to include 1-methylpseudouridine ***only after*** the publication of Moderna's patent applications containing data showing the superiority of 1-methylpseudouridine.[7] Moderna admits that it did not respond to those emails to *Science*. Moderna denies any allegation or implication that it had any obligation to respond to those emails to *Science*. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 32, and therefore denies them.

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

[7] *See supra* note 5.

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.

ANSWER: Moderna admits that paragraph 57 of its Complaint states: "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." Moderna stands by its allegations that it was the first to discover that packaging 1-methylpseudouridine modified mRNA in lipid nanoparticles allowed for efficient delivery of the mRNA to cells. Moderna denies the remaining allegations in Paragraph 33.

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.

ANSWER: Moderna admits that Exhibit 27 purports to be International Patent Publication No. 2010/144740, which published on December 16, 2010. Dkt. 45 Ex. 27 at cover. Moderna denies that International Patent Publication No. 2010/144740 describes introducing nucleic acids to cells using lipid particles using the same components at the same ratios claimed in Moderna's patents. Moderna denies the remaining allegations in Paragraph 34.

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

ANSWER: Moderna admits that claim 1 of the '966 Patent purports to claim "[a] composition comprising an in vitro-synthesized modified RNA comprising an open reading frame that encodes a protein of interest for translation in a mammalian cell, wherein said in vitro-synthesized modified RNA comprises a modified nucleoside selected from the group consisting of

(i) 1-methylpseudouridine ($m^1\Psi$) and (ii) pseudouridine (Ψ)" and that claim 15 of the '966 Patent purports to claim "[t]he composition of claim 1, wherein said in vitro-synthesized modified RNA is encapsulated in a nanoparticle, polymer, lipid, cholesterol, or a cell penetrating peptide." Dkt. 45 Ex. 28 at 67:29-34, 70:11-13. Moderna denies that the '966 Patent claims recite mRNA. Moderna denies any allegation that Drs. Karikó and Weissman first discovered 1-methylpseudouridine modified mRNA encapsulated in a nanoparticle, polymer, lipid, cholesterol, or a cell penetrating peptide. The '966 patent does not contain any data for 1-methylpseudouridine modified mRNA, nor does it contain any data for mRNA encapsulated in a lipid nanoparticle. Moderna denies the remaining allegations in Paragraph 35.

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.

ANSWER: Moderna denies the allegations in the first two sentences of Paragraph 36. Moderna admits that Stéphane Bancel is the CEO of Moderna. Moderna admits Exhibit 14 is a news article that states that "Robert Langer, an MIT professor, Moderna board member and founder of dozens of biotech companies, told Bancel that Moderna was too underfunded and small to create its own delivery system." Dkt. 45 Ex. 29 at 3-4. Moderna admits that it obtained certain limited patent licenses from Acuitas Therapeutics. Moderna denies that Acuitas terminated its licenses with Moderna in 2018. Moderna denies that it uses any of the intellectual property licensed from Acuitas in its vaccine program. Moderna developed its own lipid nanoparticle technology, and Spikevax® incorporates Moderna's own, proprietary lipid nanoparticle

formulation, as claimed by, for example, the '127 Patent. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 36 and therefore denies them.

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.

ANSWER: Moderna denies the allegations in the first sentence of Paragraph 37. Moderna was the first to make an mRNA vaccine using a complete coronavirus spike protein and demonstrate that it could produce an immunogenic response, and its patents appropriately claim ownership of that invention. Moderna admits that SARS-COV-2 emerged recently. Moderna admits that Exhibit 30 purports to be a review article published in 2009 stating "[s]everal vaccines that are based on the full-length S protein of SARS-CoV have been reported" and certain "reports suggest that the full-length spike protein is highly immunogenic and induces protection against SARS-CoV challenge." Dkt. 45 Ex. 30 at 229. Moderna denies the allegations in the last sentence of Paragraph 37. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 37 and therefore denies them.

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.

ANSWER: Moderna denies the allegations in Paragraph 38.

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.

ANSWER: Moderna admits that the Complaint includes allegations that discuss COVID-19. Moderna admits that the '600 and '127 patents describe betacoronaviruses generally, which includes SARS-CoV-2, and disclose mRNA vaccines that induce an immune response to such betacoronaviruses. The '600 and '127 patents exemplify the claimed inventions with respect to the MERS coronavirus specifically, but Moderna's groundbreaking work that led to the Asserted Patents is not limited to vaccines for the MERS coronavirus. Instead, Moderna developed a platform technology that can be used to create mRNA vaccines against betacoronaviruses generally. The speed at which Moderna was able to create a vaccine for SARS-CoV-2 confirms that Moderna's patents provided an adaptable platform that allowed the incorporation of the novel coronavirus spike sequence. Further proof comes from the fact that Spikevax® was again quickly adapted into a bivalent vaccine that targeted both the initially circulating strain of SARS-CoV-2

and the variant that came to be known as omicron.[8] Moderna denies the remaining allegations in Paragraph 39.

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

ANSWER: Moderna admits the allegations in Paragraph 40, but they are irrelevant to this case. Moderna's groundbreaking work that led to the Asserted Patents is not limited to the precise mRNA sequence that Moderna used for Spikevax®. Instead, Moderna developed a platform technology that can be used to create mRNA vaccines against betacoronaviruses generally, regardless of the precise sequence of their spike proteins. The speed at which Moderna was able to create a vaccine for SARS-CoV-2 confirms that Moderna's patents provided an adaptable platform that allowed the incorporation of the novel coronavirus spike sequence. Further proof comes from the fact that Spikevax® was again quickly adapted into a bivalent vaccine that

[8] Exhibit G (*Moderna Announces Strategy to Address Omicron (B.1.1.529) SARS-Co-V-2 Variant*, Moderna.com (Nov. 26, 2021), https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Strategy-to-Address-Omicron-B.1.1.529-SARS-CoV-2-Variant/default.aspx (explaining that Moderna planned to develop an omicron-specific booster and stating that it "has repeatedly demonstrated the ability to advance new candidates to clinical testing in 60-90 days)); Exhibit H (*Moderna Announces First Participant Dosed in Phase 2 Study of Omicron-Specific Booster Candidate and Publication of Data on Booster Durability Against Omicron Variant*, Moderna.com (Jan. 26, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Announces-First-Participant-Dosed-in-Phase-2-Study-of-Omicron-Specific-Booster-Candidate-and-Publication-of-Data-on-Booster-Durability-Against-Omicron-Variant/default.aspx); Exhibit I (*Moderna Announces First Participant Dosed in Phase 2 Study of Omicron-Specific Bivalent Booster Candidate*, Moderna.com (Mar. 10, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Announces-First-Participant-Dosed-in-Phase-2-Study-of-Omicron-Specific-Bivalent-Booster-Candidate/default.aspx); Exhibit J *Moderna Receives FDA Authorization for Emergency Use of Omicron-Targeting Bivalent COVID-19 Booster Vaccine for Adults 18 Years and Older*, Moderna.com (Aug. 31, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-FDA-Authorization-for-Emergency-Use-of-Omicron-Targeting-Bivalent-COVID-19-Booster-Vaccine-for-Adults-18-Years-and-Older/default.aspx).

targeted both the initially circulating strain of SARS-CoV-2 and the variant that came to be known as omicron.[9]

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

ANSWER: Moderna admits the allegations in Paragraph 41, but they are irrelevant to this case. Moderna's groundbreaking work that led to the Asserted Patents is not limited to the precise mRNA sequence that Moderna used for Spikevax®. Instead, Moderna developed a platform technology that can be used to create mRNA vaccines against betacoronaviruses generally, regardless of the precise sequence of their spike proteins. The speed at which Moderna was able to create a vaccine for SARS-CoV-2 confirms that Moderna's patents provided an adaptable platform that allowed the incorporation of the novel coronavirus spike sequence. Further proof comes from the fact that Spikevax® was again quickly adapted into a bivalent vaccine that targeted both the initially circulating strain of SARS-CoV-2 and the variant that came to be known as omicron.[10]

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.

ANSWER: Moderna admits that Exhibit 31 purports to be a Notice of Allowability for U.S. Patent Application 16/880,829 in which the examiner stated in a "Note" that "the current method claims and claims directed to compositions comprising mRNA encoding a betacoronavirus S protein or S protein subunit formulated in a lipid nanoparticle are interpreted as begin [sic] 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)." Dkt. 45 Ex. 31 at 4. Moderna denies that

[9] *Supra* note 8.
[10] *Supra* note 8.

its claims are so limited. As Moderna explained in its Response to the Examiner's Note, the '127 Patent encompasses all betacoronaviruses, including SARS-CoV-2. The Examiner never disagreed with Moderna's Response. The disclosure in the '127 Patent's specification supports the full scope of the claimed genus of betacoronaviruses, which includes SARS-CoV-2.

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. Ex. 13. Moderna has stated that NIH scientists Dr. John Mascola, Dr. Barney Graham, and Dr. Kizzmekia Corbett played a "substantial role" in the development of its COVID-19 vaccine.

ANSWER: Moderna denies that it has failed to properly credit the contributions of government and academic scientists. Moderna acknowledges and respects the work that others have done in the mRNA field. Moderna denies the remaining allegations in Paragraph 43.

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." 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.

ANSWER: Moderna admits that it filed patent applications properly naming only its own scientists as inventors of certain patents. Moderna also acknowledges that certain NIH scientists played a role in the development of Spikevax®, and Moderna has filed patent applications naming scientists from the NIH as joint inventors with Moderna in recognition of their contributions where appropriate. Moderna denies the remaining allegations in Paragraph 44.

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. 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."

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Moderna admits that it received federal funding related to the development of its COVID-19 vaccine years after the inventions described and claimed in the patents-in-suit had been conceived and reduced to practice. Moderna admits that it reviewed, in consultation with DARPA, patents and patent applications to determine whether any of them described inventions that were developed with the assistance of DARPA awards. Moderna denies that any of the patents-in-suit were conceived or reduced to practice using DARPA funding. Moderna denies the remaining allegations in Paragraph 45.

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.

ANSWER: Moderna denies the allegations of Paragraph 46.

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. 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.

ANSWER: Moderna admits that its CEO Stéphane Bancel and Chairman Noubar Afeyan made public statements expressing that, while the pandemic continued, Moderna would not enforce its COVID-19 related patents against those making vaccines to combat the pandemic. Moderna was the only vaccine manufacturer to have made a global commitment to intellectual property never being a barrier to COVID-19 vaccine access. Moderna denies the remaining allegations of Paragraph 47.

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.

ANSWER: Moderna admits that, on October 8, 2020, Moderna published a statement that: "Beyond Moderna's vaccine, there are other COVID-19 vaccines in development that may use Moderna-patented technologies. We feel a special obligation under the circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period. Moderna is proud that its mRNA technology is poised to be used to help end the current pandemic." Dkt. 45 Ex. 33. One year later, on October 8, 2021, Moderna published a statement that: "[T]o support global access of vaccines, in October 2020 and before we had our Phase 3 data, we announced that we would not enforce our COVID-19 related patents during the pandemic. As a small company, we are still limited in our capacity to help and focused on scaling our manufacturing, but we never wanted our patents to be a barrier to others bringing forward mRNA vaccines." Dkt. 45 Ex. 34. Moderna denies the remaining allegations of Paragraph 48.

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. 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/expgps-1205-noubar-afeyan-moderna-omicron.cnn) (emphasis added).

ANSWER: Moderna admits that it committed not to sue other COVID-19 vaccine makers for patent infringement while the pandemic continued. Moderna denies that it or its senior executives ever committed not to sue other COVID-19 vaccine makers for patent infringement indefinitely. As Moderna's public statements make clear, the driving force behind Moderna's commitment was to ensure that its intellectual property was never a barrier to vaccine access. Moderna could not, from a business perspective, give away its intellectual property rights entirely and indefinitely, and no one reading or listening to its statements would have reasonably understood Moderna to have done so.

Moderna admits that Noubar Afeyan is its Chairman. Moderna admits that Exhibit 36 purports to be a news article in which Mr. Afeyan is reported to have stated: "We decided not to enforce our patent during the pandemic" and "we publicly stated that we would not voluntarily enforce any of our patents during the pandemic on anyone making a vaccine." Dkt. 45 Ex. 36 at 1, 3. Moderna admits that Exhibit 37 purports to be a transcript of a video interview with Mr. Afeyan in which Mr. Afeyan is reported to have stated: "Well, Fareed, the first time we spoke was around the time a year ago when we voluntarily pledged – the only company to have done that voluntarily pledged not to enforce our patents against anybody who uses our patents to make a vaccine against the pandemic. At that time, there had been no proof to the vaccine will work, but we did that because we thought it's the right thing to do from a vaccine access standpoint. We believe that that has enabled others to make mRNA vaccines, and if others do that even further that's great. In addition, we've added to our production capacity. So this year we will have produced about 800 million doses. Next year, we've said we will produce 2 to 3 billion doses. 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." Dkt. 45 Ex. 37 at 6-7.

Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 49, and therefore denies them.

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-withmoderna-ceo-stephane-bancel) (emphasis added).

ANSWER: Moderna admits that Stéphane Bancel is Moderna's CEO. Moderna admits that Exhibit 38 purports to be a transcript of an interview of Mr. Bancel dated October 25, 2021, in which Mr. Bancel is reported to have stated, in reference to a hypothetical vaccine manufacturer in India who had a factory ready to come online quickly: "And as I said, 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 as we can through the door." Dkt. 45 Ex. 38 at 42-43. Moderna denies that Mr. Bancel committed never to sue any other vaccine makers. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 50, and therefore denies them.

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).

ANSWER: Moderna admits that Exhibit 36 purports to be a news article in which the interviewer is reported to have asked "But is there any kind of agreement that goes beyond you not enforcing your intellectual property rights?" and Mr. Afeyan is reported to have stated: "There

are many companies currently making mRNA vaccines that would need the intellectual property that Moderna has developed for 10 years. Two years ago there was no one working on mRNA as a vaccine of the type that we do and now obviously several companies are making it. 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." Dkt. 45 Ex. 36 at 4. Moderna denies any allegation that Moderna's voluntary statement amounted to an enforceable agreement not to sue other COVID-19 vaccine makers for patent infringement indefinitely. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 51, and therefore denies them.

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*.

ANSWER: Moderna admits that on March 7, 2022, Moderna issued a press release stating: "To underscore our commitment to low- and middle-income countries, Moderna is now updating our patent pledge to never enforce our patents for COVID-19 vaccines against companies manufacturing in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries . . . . In non-AMC 92 countries, vaccine supply is no longer a barrier to access. In these countries, the Company expects that those using Moderna-patented technologies will respect the Company's intellectual property. Moderna remains willing to license its technology for COVID-19 vaccines to manufacturers in these countries on commercially reasonable terms. Doing so enables Moderna to continue to invest in research to develop new vaccines, prepare for the next pandemic, and meet other pressing areas of unmet medical need." Dkt. 45 Ex. 39 at 1-2. Moderna denies the remaining allegations in Paragraph 52.

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. As of the filing date of these Counterclaims, the WHO still considers COVID-19 to be a pandemic.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief as to the truth of the statements concerning the CDC and WHO in Paragraph 53, and therefore denies them. Moderna denies the remaining allegations in Paragraph 53.

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." Infectious disease experts have agreed with this latter statement that the pandemic is not in fact over. 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." HHS is allowing the federal public health emergency status for COVID-19 to remain in place until at least mid-January 2023, with HHS officials not yet signaling an end date.

ANSWER: Moderna admits that in an interview with 60 Minutes in September 2022, President Joe Biden remarked that the pandemic was over. Moderna admits that President Biden later stated that the pandemic "basically is not where it was." Moderna denies any allegation that President Biden stated that the pandemic is not in fact over. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 54 and therefore denies them.

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.

ANSWER: Moderna admits that Noubar Afeyan is Moderna's Chairman. Moderna admits that Exhibit 40 purports to be a transcript of an interview with Mr. Afeyan in which Mr. Afeyan is reported to have stated: "The COVID pandemic impacted the whole world resulting in more than 15 million deaths worldwide, massive economic destruction, and potentially tens of millions who are currently living with the after-effects with long COVID. 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." Dkt. 45 Ex. 40 at 6. Moderna admits that Exhibit 40 purports to be a transcript of an interview with Mr. Afeyan in which Mr. Afeyan is reported to have stated: "And 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. Moderna denies any allegation that Mr. Afeyan stated that the pandemic was not over. Moderna denies any allegation that Mr. Afeyan committed Moderna to not enforcing its patents in non-AMC countries after March 7, 2022. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 55 and therefore denies them.

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

ANSWER: Moderna denies the allegations in Paragraph 56.

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 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).

ANSWER: Moderna denies the allegation in the first sentence of Paragraph 57. Moderna admits that Noubar Afeyan is Moderna's Chairman. Moderna admits that Exhibit 41 purports to be a transcript of an interview with Mr. Afeyan stating: "Then we pledged in October 2020 to give away our patents and not enforce then in the pandemic to anybody working on a vaccine. A month ago, we declared that we will forever pledge our vaccines never to be applied in the COVID case in low- and middle-income countries. Well, it's – I mean, look, we're not – frankly, we're not doing this to be – to do – we're doing this because it's the right thing to do. Every company – I'll say this one lastly. Every company has an implicit license to operate and that's the most precious thing it has. And if it loses that, then it cannot have the kind of impact it's worked years and years to have." Dkt. 45 Ex. 41 at 15. Moderna denies any allegation that Mr. Afeyan unequivocally stated that every company has an implicit license to use Moderna's intellectual property. In context, the statement Defendants quote is referring to Moderna's pledge not to enforce its vaccine patents against those manufacturing in or for the low- and middle-income AMC 92 countries. Moderna lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 57, and therefore denies them.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna denies the allegations in Paragraph 59.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna denies the allegations in Paragraph 61.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna denies the allegations in Paragraph 63.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna admits the allegations in the first sentence in Paragraph 65. Moderna admits that Pfizer and BioNTech filed an answer denying 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.

ANSWER: Moderna denies the allegations in Paragraph 66.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna admits the allegations in the first sentence of Paragraph 68. Moderna admits that Pfizer and BioNTech filed an answer denying 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.

ANSWER: Moderna denies the allegations in Paragraph 69.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna admits the allegations in the first sentence of Paragraph 71. Moderna has also accused Pfizer and BioNTech of infringing the '127 Patent. Moderna admits that Pfizer and BioNTech filed an answer denying 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.

ANSWER: Moderna denies the allegations in Paragraph 72.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna denies the allegations in Paragraph 74.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna denies the allegations in Paragraph 76.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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.

ANSWER: Moderna denies the allegations in Paragraph 78.

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.

ANSWER: Moderna repeats and incorporates by reference its responses to Paragraphs 1-57 of Defendants' Counterclaims.

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

ANSWER: Moderna denies the allegations in Paragraph 80.

ANSWER TO DEFENDANTS' DEMAND FOR JUDGMENT

Moderna denies that Defendants are entitled to any of the relief sought in their Counterclaims or to any relief whatsoever. WHEREFORE Moderna respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

A. a judgment that Defendants are not entitled to any relief under the Counterclaims;

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

C. such other relief as this Court may deem just and proper.

Date: December 21, 2022

Respectfully submitted,

/s/ William F. Lee

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