THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIONTECH SE, BIONTECH MANUFACTURING GMBH, AND PFIZER INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 1:22-cv-11202
	)	**JURY TRIAL DEMANDED**
CUREVAC AG,	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY JUDGMENT OF NONINFRINGEMENT

Plaintiffs BioNTech SE and BioNTech Manufacturing GmbH ("BioNTech Manufacturing," and with BioNTech SE collectively, "BioNTech") and Pfizer Inc. ("Pfizer") (collectively, "Plaintiffs"), by their undersigned attorneys, respectfully submit this Complaint for Declaratory Judgment of Noninfringement against CureVac AG ("CureVac" or "Defendant"), and hereby allege as follows:

INTRODUCTION

1. This is an action brought by BioNTech and Pfizer who partnered together, and continue to work together, to address the greatest public health threat the United States and the world has faced in at least a century: the COVID-19 pandemic. Now, BioNTech and Pfizer must also face threats of a groundless patent infringement suit by a company, CureVac, who has been unable to bring to market any product to help in the fight against COVID-19.

2. BioNTech and Pfizer partnered together to develop, manufacture, and secure regulatory approval for a vaccine that proved to be effective in preventing severe disease, hospitalization, and death from COVID-19 infection. BioNTech and Pfizer did so at great risk to their companies, by investing considerable sums of money and countless hours in an effort to address this global pandemic. BioNTech and Pfizer successfully developed a product, proved its efficacy, established global manufacturing and supply chains, and gained regulatory approval in record time. Through their efforts they were able to help the United States and the world begin to move past the COVID-19 public health crisis.

3. Unlike BioNTech's and Pfizer's efforts, CureVac's failed, as it was unable to develop a COVID-19 vaccine product. After this failure, CureVac turned its attention to an attempt to profit from the success of BioNTech and Pfizer through threats of patent infringement.

4. BioNTech and Pfizer bring this action to resolve CureVac's meritless allegations.

NATURE OF THE ACTION

5. This is a civil action for a declaratory judgment that U.S. Patent Nos. 11,135,312, 11,149,278, and 11,241,493 (collectively, "the patents-in-suit" and attached as Exhibits 1 to 3 of this Complaint) are not infringed by the manufacture, use, offer to sell, and sale in the United States, and the importation into the United States, of the mRNA vaccine against COVID-19 that BioNTech created and made available to doctors and patients with Pfizer.

6. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 and the patent laws of the United States, including Title 35, United States Code.

THE PARTIES

7. Plaintiff BioNTech SE is a company organized and existing under the laws of Germany, having a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

8. Plaintiff BioNTech Manufacturing is a company organized and existing under the laws of Germany, having a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

9. BioNTech Manufacturing is a wholly owned subsidiary of BioNTech SE.

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

11. Upon information and belief, Defendant CureVac is a company organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201.

13. As described in detail below, an actual, immediate, substantial, and justiciable controversy exists between Plaintiffs and CureVac as to whether the Pfizer-BioNTech COVID-19 vaccine (sold commercially as "COMIRNATY® vaccine") has infringed or will infringe the patents-in-suit.

14. This Court has personal jurisdiction over CureVac under Fed. R. Civ. P. 4(k)(2).

15. This Court also has personal jurisdiction over CureVac, because, *inter alia*, upon information and belief, CureVac: (1) maintains pervasive, continuous, and systematic contacts with Massachusetts; (2) conducts business in Massachusetts through its office and agents located in Massachusetts; (3) sends agents into Massachusetts on a regular basis to conduct business; and (4) holds itself out as doing business in Massachusetts.

16. Upon information and belief, since at least November 2017, CureVac has entered into agreements and conducted business with multiple entities located in Massachusetts.

17. Upon information and belief, in 2020, in connection with its initial public offering, (a) CureVac N.V. was incorporated and became the holding company of CureVac and (b) the historical consolidated financial statements of CureVac became part of the historical consolidated financial statements of CureVac N.V. (Exhibit 4.)

18. Upon information and belief, CureVac is a wholly owned subsidiary of CureVac N.V.

19. Upon information and belief, CureVac also conducts business in Massachusetts, *inter alia*, through its wholly owned subsidiary CureVac, Inc.

20. Upon information and belief, CureVac, Inc. acts as an agent for CureVac for conducting business in the United States, including Massachusetts.

21. Upon information and belief, CureVac N.V. has designated CureVac, Inc. as its agent for service of process in the United States.

22. Upon information and belief, CureVac, Inc. maintains a lease on a property of more than 12,000 square feet at 250 Summer Street, 3rd Floor, Boston, Massachusetts 02210.

23. Upon information and belief, CureVac, Inc. is registered with the Commonwealth of Massachusetts as a business in Massachusetts.

24. Upon information and belief, the Foreign Corporation Certificate of Registration filed by CureVac, Inc. with the Commonwealth of Massachusetts lists the CEO of CureVac as a corporate officer and director of CureVac, Inc.

25. Upon information and belief, CureVac sends employees and agents into Massachusetts, including to CureVac, Inc.'s office located at 250 Summer Street, 3rd Floor, Boston, Massachusetts 02210, on a regular basis.

26. Upon information and belief, CureVac lists Boston, USA as one of its offices. For example, CureVac holds itself out as a "Tübingen, Germany/Boston, MA, USA" entity, *inter alia*, on its corporate website and in press releases. CureVac has also stated that it "employs more than 900 people at its sites in Tübingen, Frankfurt, and Boston, USA." (Exhibit 20.)

27. This Court also has personal jurisdiction over CureVac because, *inter alia*, it sent communications regarding CureVac's assertion of intellectual property ("IP") rights in connection with COMIRNATY® vaccine to individuals at BioNTech US Inc., which is located in Cambridge, Massachusetts.

28. This Court also has personal jurisdiction over CureVac because, *inter alia*, the group of representatives who were involved in CureVac's assertion of IP rights in connection with COMIRNATY® vaccine included the Director IP Management US of CureVac, Inc., which is located in Boston, Massachusetts.

29. This Court has personal jurisdiction over CureVac for at least the reasons set forth above and for other reasons that will be presented to the Court if such personal jurisdiction were to be challenged.

30. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because CureVac is a foreign corporation and is subject to this Court's personal jurisdiction for at least the reasons set forth above.

31. Venue is proper for at least the reasons set forth above and for other reasons that will be presented to the Court if such venue were to be challenged.

32. This Court is authorized to issue declaratory judgments pursuant to 28 U.S.C. § 2201.

BACKGROUND

BioNTech

33. BioNTech SE is a global biotechnology company specializing in the development of novel medicines. BioNTech SE scientists have been researching and developing proprietary mRNA-based technologies for more than 20 years, achieving expertise in, *inter alia*, translational drug discovery and development, GMP manufacturing, and commercial capabilities.

34. BioNTech SE has been using its proprietary technologies across multiple technology platforms—including not only mRNA vaccines, but also small molecules, protein therapeutics, and other cell and gene therapies—to address human diseases with unmet medical need and major health burdens, such as cancer and infectious disease.

35. Since its foundation, BioNTech SE has worked on mRNA-based vaccine candidates, earning itself a reputation as an industry leader in mRNA technology. BioNTech partnered with several companies and research institutes to develop mRNA-based vaccines.

36. BioNTech Manufacturing is the holder of Biologics License Application No. 125742 for COMIRNATY® vaccine.

Pfizer

37. Pfizer Inc. is a research-based biopharmaceutical company. Pfizer applies science and its global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development, manufacture, marketing, sale, and distribution of biopharmaceutical products.

38. Pfizer works across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Pfizer collaborates with healthcare providers, governments, and local communities to support and expand

access to reliable, affordable healthcare around the world. Pfizer was incorporated under the laws of the State of Delaware on June 2, 1942.

39. Research and development ("R&D") is at the heart of fulfilling Pfizer's purpose to deliver breakthroughs that change patients' lives as Pfizer works to translate advanced science and technologies into the therapies that may be the most impactful for patients. The discovery and development of drugs, vaccines, and biological products are time consuming, costly, and unpredictable.

The Development of COMIRNATY® Vaccine

40. In December 2019, reports began circulating about an outbreak of pneumonia resulting in severe illness and death among people who were linked to the Huanan Seafood Wholesale Market in Wuhan, China.

41. By January 2020, it was discovered that the cause of this pneumonia outbreak was a novel coronavirus, eventually designated by the World Health Organization ("WHO") as SARS-CoV-2 with the disease it causes reclassified as Coronavirus disease 2019 ("COVID-19").

42. On March 11, 2020, the WHO designated COVID-19 an international pandemic as the disease quickly spread worldwide and tore through immunologically naïve populations, threatening the collapse of the healthcare system and loss of life at scales not seen since the advent of modern medicine.

43. In response, countries around the world instituted society-shaking restrictions on movement, requiring people to temporarily stay confined and isolated to their homes in an attempt to slow transmission of disease, save lives, and gain time to develop a fulsome response.

44. To date, COVID-19 has infected at least 508 million people around the world, resulting in more than 6 million deaths. (Exhibit 4.)

45. In the midst of the COVID-19 pandemic, many saw the development of highly effective and safe vaccines that successfully targeted and neutralized COVID-19 as the path out of the pandemic without a continuing, massive loss of life.

46. By early January of 2020, BioNTech initiated "Project Lightspeed," an accelerated vaccine development program to fight COVID-19. BioNTech's COVID-19 vaccine development program leveraged BioNTech's experience and expertise with mRNA technologies. For example, BioNTech has developed innovative, proprietary mRNA-based technologies to achieve effective translational performance and direction of the immune response.

47. BioNTech rapidly developed and performed numerous toxicological and pharmacological studies to determine the safety and efficacy of the COVID-19 vaccine. For example, BioNTech's studies showed, *inter alia*, that its COVID-19 vaccine is highly immunogenic in animal models and provided the needed confirmation to quickly move into Phase 1 clinical studies.

48. BioNTech and Pfizer decided to partner together on the development, clinical testing, manufacturing, distribution, and regulatory approval of the Pfizer-BioNTech COVID-19 vaccine. (Exhibit 6.)

49. BioNTech and Pfizer agreed to share the costs of developing the COVID-19 vaccine. By the end of the first quarter of 2020, Pfizer had increased its yearly R&D budget by $500 million to reflect investments in combatting COVID-19. (Exhibit 7.)

50. On May 5, 2020, BioNTech and Pfizer announced that the first participants had been dosed in the United States in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. (Exhibit 9.) After attaining promising Phase 1 clinical study results, BioNTech and Pfizer rapidly moved the Pfizer-BioNTech COVID-19 vaccine into the pivotal Phase 2 and 3

studies—on a global scale encompassing more than 44,000 patients—to determine its safety and efficacy in humans. (Exhibit 8.)

51. Meanwhile, Pfizer was also working on the logistics and infrastructure needed to successfully manufacture and distribute the Pfizer-BioNTech COVID-19 vaccine. Pfizer activated its extensive manufacturing network and invested at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible for those most in need around the world. Pfizer-owned sites in three U.S. states (Massachusetts, Michigan, and Missouri) and Puurs, Belgium were identified as manufacturing centers for COVID-19 vaccine production, with more sites to be selected. (Exhibit 10.)

52. On July 13, 2020, BioNTech SE and Pfizer announced that investigational vaccine candidates from their BNT162 mRNA-based vaccine program being developed to help protect against SARS-CoV-2 (the virus that causes COVID-19) received Fast Track designation from the U.S. Food and Drug Administration ("FDA"). (Exhibit 11.)

53. On July 27, 2020, BioNTech and Pfizer began a Phase 2/3 clinical study of their advanced nucleoside-modified messenger RNA candidate BNT162b2. (Exhibit 12.)

54. In about November of 2020, the Pfizer-BioNTech COVID-19 vaccine was shown to have met all the primary efficacy endpoints in a Phase 3 clinical trial, demonstrating an efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and in participants with and without prior SARS-CoV-2 infection (second primary objective), as measured from seven days after the second dose of the vaccine. (Exhibit 13.)

55. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted clinical trial data as part of an Emergency Use Authorization ("EUA") request to the FDA for administering the Pfizer-BioNTech COVID-19 vaccine to people 16 years of age and older.

56. On December 11, 2020, the FDA granted an EUA for the Pfizer-BioNTech COVID-19 vaccine for use in individuals 16 years of age and older.

57. The Pfizer-BioNTech COVID-19 vaccine was the first mRNA drug product, and the first vaccine to target COVID-19, authorized for emergency use in the United States.

58. As part of the fastest development of a vaccine in history, doses of the Pfizer-BioNTech COVID-19 vaccine were distributed immediately after the FDA granted an EUA.

59. On May 11, 2021, the FDA expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include children as young as 12 years of age.

60. On October 29, 2021, the FDA also expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include children as young as 5 years of age.

61. On June 17, 2022, the FDA further expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include children as young as 6 months of age.

62. Based on a comprehensive data package and real-world results demonstrating the overwhelming safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine, on August 23, 2021, the FDA granted full approval of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older.

63. In 2021, Pfizer manufactured more than three billion doses of the Pfizer-BioNTech COVID-19 vaccine. (Exhibit 14.) BioNTech and Pfizer expect to manufacture up to four billion doses in total by the end of 2022. *Id*.

64. The Pfizer-BioNTech COVID-19 vaccine fully approved by the FDA is marketed under the trade name COMIRNATY®.

65. COMIRNATY® vaccine was the first mRNA drug product, and the first COVID-19 vaccine to receive full FDA approval.

66. COMIRNATY® vaccine is indicated for "active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)." (Exhibit 15.)

67. Since receiving the first EUA from the FDA, COMIRNATY® vaccine has contributed to saving at least 14 million lives that otherwise may have been lost due to the pandemic. (Exhibit 16.) Furthermore, widespread vaccination of populations with COMIRNATY® vaccine allowed Massachusetts and other jurisdictions to remove restrictions on movement, easing the burdens countless individuals suffered during forced isolation.

CureVac

68. Upon information and belief, CureVac was founded in 2000 and holds itself out to be a clinical stage biotechnology company.

69. Upon information and belief, CureVac had undertaken efforts aimed at developing at least one COVID-19 vaccine.

70. Upon information and belief, on or about June 16, 2021, a pivotal Phase 2b/3 clinical trial showed that CureVac's COVID-19 vaccine candidate, "CVnCoV," had an interim vaccine efficacy of only about 47% against COVID-19 of any severity and did not meet the pre-specified statistical success criteria. (Exhibit 4.)

71. Upon information and belief, in the day following the publication of the unsuccessful Phase 2b/3 clinical trial data of CVnCoV, the price of CureVac N.V.'s stock, which is publicly traded in the United States, fell by about 50%. (Exhibit 17.)

72. Upon information and belief, in about October of 2021, based on the disappointing results of its clinical studies, CureVac withdrew its CVnCoV vaccine candidate from the approval process with the European Medicines Agency. (Exhibit 18.)

73. Upon information and belief, CureVac N.V.'s consolidated net losses for the years ending December 31, 2021 and December 31, 2020 were approximately €411.7 million and €129.1 million, respectively. As of December 31, 2021, CureVac N.V.'s accumulated deficit was approximately €1.06 billion. (Exhibit 4.)

74. Upon information and belief, in January 2022, CureVac N.V.'s Chief Technology Officer resigned from the company. (Exhibit 5.)

75. Upon information and belief, CureVac N.V. has reported an expectation of continued losses in the future. (Exhibit 4.)

76. Upon information and belief, CureVac has reported that it has no history of commercializing pharmaceutical products, including any COVID-19 vaccine. (Exhibit 4.)

77. Upon information and belief, CureVac has reported that it cannot give any assurance that any of its product candidates will receive regulatory approval in the future. (Exhibit 4.)

78. Upon information and belief, CureVac licensed from Acuitas Therapeutics, Inc. ("Acuitas") lipid nanoparticle ("LNP") technology developed by Acuitas.

79. Upon information and belief, as of January 2020, CureVac was aware that BioNTech had licensed LNPs from Acuitas for use with mRNA therapeutic products.

80. Upon information and belief, CureVac used the LNP technology it licensed from Acuitas in its failed COVID-19 vaccine candidate.

CureVac's Assertion of the Patents-in-Suit against BioNTech and Pfizer

81. In about February 2022, after CureVac had withdrawn its CVnCoV vaccine candidate from the regulatory approval process, CureVac N.V. contacted BioNTech SE, Pfizer's collaboration partner, seeking to initiate discussions between the IP counsel of CureVac and BioNTech SE regarding the potential licensing of certain IP rights from CureVac.

82. Upon information and belief, CureVac N.V. had at that time a deadline to report financial results and provide business updates for the fourth quarter and full-year of 2021 on April 28, 2022.

83. CureVac contacted the Senior Patent Counsel of BioNTech US Inc., which is located in Cambridge, Massachusetts, regarding the licensing of certain IP rights from CureVac in connection with COMIRNATY® vaccine. At that time, it was publicly known that BioNTech and Pfizer were collaborating on the manufacture of COMIRNATY® vaccine and that Pfizer manufactured COMIRNATY® vaccine in the United States.

84. Upon information and belief, at all relevant times since the initial contact described above, CureVac was aware that Pfizer manufactures and is responsible for the distribution and sale of COMIRNATY® vaccine in the United States, including in Massachusetts.

85. At all relevant times, BioNTech and Pfizer have worked together with respect to CureVac's accusations.

86. CureVac and BioNTech SE held a videoconference on April 4, 2022, and an in-person meeting on April 7, 2022.

87. On March 29, 2022, CureVac sent BioNTech SE a document identifying CureVac's purported IP portfolio. This document included the patents-in-suit and related patents, of which the patents-in-suit are representative family members.

88. On June 9, 2022, CureVac and BioNTech SE conducted a meeting relating to CureVac's threat to assert its patents in connection with COMIRNATY® vaccine. Such threat included both United States patents and their European counterparts.

89. Upon information and belief, CureVac was aware that BioNTech SE was acting in the discussions with the knowledge of both BioNTech and Pfizer.

90. The parties did not reach an amicable resolution of CureVac's threats. CureVac has stated that the parties' "out-of-court dispute resolution efforts have not been successful." (Exhibit 19.)

91. Upon information and belief, individuals from CureVac who were involved in the communications regarding CureVac's IP rights in connection with COMIRNATY® vaccine included the Chief Business Officer and Chief Commercial Officer of CureVac, the Vice President, Patents of CureVac, the Head of IP Management of CureVac, and the Director IP Management US of CureVac, Inc.

92. On June 29, 2022, following the failed dispute resolution efforts, CureVac submitted an infringement complaint to the German Regional Court in Düsseldorf against BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH, alleging, *inter alia*, that the manufacture and sale of COMIRNATY® vaccine infringes European counterparts to the patents-in-suit. (Exhibit 19.)

93. On July 5, 2022, CureVac N.V. issued a press release announcing that "it has moved to assert its intellectual property rights" against BioNTech. (Exhibit 20.)

94. That same day, following CureVac's announcement of its lawsuit against BioNTech and that it intended to assert its intellectual property rights against COMIRNATY® vaccine, news reports indicated that Pfizer's stock fell over 3.5%. (Exhibit 21.)

95. The German infringement complaint does not name Pfizer. Pfizer does not manufacture or sell COMIRNATY® vaccine in Germany. According to news reports, however, when asked in a media call, CureVac's chief executive said that he was not ruling out further legal action against BioNTech partner Pfizer. (Exhibit 22.)

96. Based on, at a minimum, CureVac's assertion of the patents-in-suit and commencement of litigation with respect to European counterparts of such patents in connection with COMIRNATY® vaccine, an actual, immediate, substantial, and justiciable controversy exists between BioNTech, Pfizer, and CureVac as to whether COMIRNATY® vaccine has infringed or will infringe the patents-in-suit.

97. Plaintiffs fund pharmaceutical research and development in part with revenues from COMIRNATY® vaccine. CureVac's assertion of the patents-in-suit in connection with COMIRNATY® vaccine has created a cloud of uncertainty, *inter alia*, with respect to what portion of the revenues from COMIRNATY® vaccine Plaintiffs may invest into that research and development.

THE PATENTS-IN-SUIT

U.S. Patent No. 11,135,312 ("the '312 patent")

98. Upon information and belief, the '312 patent, titled "Pharmaceutical Composition Containing a Stabilised mRNA Optimised for Translation in its Coding Regions," issued on October 5, 2021. The '312 patent names Florian Von Der Mülbe, Ingmar Hoerr, and Steve Pascolo as inventors. Upon information and belief, CureVac appears to be the assignee of the '312 patent. A true and correct copy of the '312 patent is attached to this Complaint as Exhibit 1.

99. The '312 patent contains an independent claim 1 that recites a "method for producing a stabilized mRNA molecule encoding a polypeptide, wherein the stabilized mRNA molecule encoding the polypeptide comprises a coding sequence that has an increased Guanine/Cytosine (G/C) content relative to the original coding sequence encoding the polypeptide, said relative G/C content being increased by at least 7 percentage points compared to the original coding sequence encoding the polypeptide, to thereby produce a stabilized mRNA molecule, wherein said increase in

relative G/C content results in the elimination of at least one destabilizing sequence element (DSE), wherein the stabilized mRNA molecule exhibits enhanced expression of the polypeptide compared to mRNA having the original coding sequence encoding the polypeptide."

U.S. Patent No. 11,149,278 ("the '278 patent")

100. Upon information and belief, the '278 patent, titled "Artificial Nucleic Acid Molecules for Improved Protein Expression," issued on October 19, 2021. The '278 patent names Andreas Thess, Thomas Schlake, and Stefanie Grund as inventors. Upon information and belief, CureVac appears to be the assignee of the '278 patent. A true and correct copy of the '278 patent is attached to this Complaint as Exhibit 2.

101. The '278 patent contains an independent claim 1 that recites a "method for treating or preventing an infectious disease, the method comprising administering an RNA molecule comprising: a) at least one open reading frame (ORF) encoding an antigen from a pathogen associated with the infectious disease; and b) a 3'-untranslated region (3'-UTR) comprising at least two poly(A) sequences, wherein at least one of the poly(A) sequences comprises at least 70 adenine nucleotides, wherein the at least two poly(A) sequence elements are separated by a nucleic acid sequence comprising from 10 to 90 nucleotides, wherein the RNA molecule is administered intramuscularly."

U.S. Patent No. 11,241,493 ("the '493 patent")

102. Upon information and belief, the '493 patent, titled "Coronavirus Vaccine," issued on February 8, 2022. The '493 patent names Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch as inventors. Upon information and belief, CureVac appears to be the assignee of the '493 patent. A true and correct copy of the '493 patent is attached to this Complaint as Exhibit 3.

103. The ’493 patent contains an independent claim 1 that recites a “composition comprising a mRNA comprising,” *inter alia,* “at least one coding sequence encoding a SARS-CoV-2 spike protein (S)” and “at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles.” Claim 1 also recites that “the LNP comprises” “at least one cationic lipid according to formula III-3,” “at least one neutral lipid, comprising 1,2-distearoylsn-glycero-3-phosphocholine (DSPC),” “at least one steroid, comprising cholesterol,” and “at least one PEG-lipid according to formula IVa.” Claim 1 further recites that the lipids comprising the LNP “are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-15% PEG-lipid.”

COUNT I: NONINFRINGEMENT OF THE ’312 PATENT

104. Plaintiffs incorporate by reference herein all of the allegations of paragraphs 5 to 103.

105. There is an actual case or controversy between Plaintiffs and CureVac as to whether COMIRNATY® vaccine is manufactured by a method that meets all of the limitations of any claim of the ’312 patent and whether the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, infringes any claim of the ’312 patent.

106. The manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the ’312 patent.

107. For example, COMIRNATY® vaccine is not manufactured by a method that comprises “synthesizing a stabilized mRNA molecule encoding a polypeptide, wherein the stabilized mRNA molecule encoding the polypeptide comprises a coding sequence that has an increased

Guanine/Cytosine (G/C) content relative to the original coding sequence encoding the polypeptide," as required by all of the claims of the '312 patent to the extent understood.

108. Plaintiffs are entitled to a judgment that COMIRNATY® vaccine is not manufactured by a method that meets all of the limitations of any claim of the '312 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '312 patent.

COUNT II: NONINFRINGEMENT OF THE '278 PATENT

109. Plaintiffs incorporate by reference herein all of the allegations of paragraphs 5 to 108.

110. There is an actual case or controversy between Plaintiffs and CureVac as to whether COMIRNATY® vaccine meets all the limitations of any claim of the '278 patent and whether the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, infringes any claim of the '278 patent.

111. The manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '278 patent.

112. For example, COMIRNATY® vaccine does not comprise "a 3'-untranslated region (3'-UTR) comprising at least two poly(A) sequences," as required by all of the claims of the '278 patent to the extent understood.

113. Plaintiffs are entitled to a judgment that COMIRNATY® vaccine does not meet all of the limitations of any claim of the '278 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '278 patent.

COUNT III: NONINFRINGEMENT OF THE '493 PATENT

114. Plaintiffs incorporate by reference herein all of the allegations of paragraphs 5 to 113.

115. There is an actual case or controversy between Plaintiffs and CureVac as to whether COMIRNATY® vaccine meets all the limitations of any claim of the '493 patent and whether the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, infringes any claim of the '493 patent.

116. The manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '493 patent.

117. For example, COMIRNATY® vaccine does not comprise a "composition comprising a mRNA comprising . . . at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles," as required by all of the claims of the '493 patent to the extent understood.

118. Plaintiffs are entitled to a judgment that COMIRNATY® vaccine does not meet all of the limitations of any claim of the '493 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '493 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter:

A. a Judgment that the commercial manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, has not infringed and will not infringe any claim of U.S. Patent Nos. 11,135,312, 11,149,278, and 11,241,493 under 35 U.S.C. § 271;

B. an Order enjoining and restraining CureVac and its officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from pursuing further assertions of infringement or acts of enforcement based on U.S. Patent Nos. 11,135,312, 11,149,278, and 11,241,493 against Plaintiffs or their actual and prospective business partners, customers, suppliers, clinical investigators, and anyone in privity with Plaintiffs;

C. a Judgment that this case is exceptional, and that Plaintiffs are entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285;

D. an award to Plaintiffs of costs and expenses in this action;

E. an award of taxable costs;

F. an award of interest; and

G. such other and further relief as the Court may deem just and proper.

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