

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

CUREVAC SE, and CUREVAC
MANUFACTURING GMBH,

Plaintiffs,

v.

MODERNA, INC., MODERNATX, INC.,
and MODERNA US, INC.,

Defendants.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs CureVac SE and CureVac Manufacturing GmbH (collectively “CureVac”), by their undersigned attorneys, respectfully submit this Complaint against Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively “Moderna”), and allege as follows:

INTRODUCTION

1. Founded in 2000 in Tübingen, Germany, CureVac was the pioneer in the development of a new class of medicines based on messenger RNA (mRNA). These medicines use the mRNA molecule as a carrier of information to allow the body to produce its own active substances to treat or prevent disease. Although many doubted that this technology could ever be used to treat or prevent disease, CureVac recognized that mRNA had the potential to improve patients’ lives. Over the last quarter-century, CureVac has been singularly focused on making mRNA medicines a reality through substantial investment and decades of research and development.

2. As a molecule found within all forms of cellular life, mRNA is central to biology: it is literally the “messenger” between DNA, the body’s genetic blueprint, and proteins, the molecules responsible for the structure, function, and regulation of essentially all processes in the

body. For many years after its discovery, mRNA was considered too unstable to be used as a medicine (mRNA is quickly destroyed both outside and inside the body), and was therefore relegated to the shadow of its much-more stable parent molecule, DNA. But in the late 1990s, CureVac's founders, Drs. Florian von der Mülbe, Ingmar Hoerr, and Steve Pascolo (although only graduate students at the time), made a completely unexpected discovery: despite being unstable, mRNA can be directly administered to animals, without complicated reformulations or molecular packaging, and their cells will produce the protein encoded by the mRNA.

3. With this groundbreaking discovery in 2000, Drs. von der Mülbe, Hoerr, and Pascolo and others founded CureVac and began to challenge the status quo by developing the unproven mRNA technology into therapeutics to prevent and treat some of the deadliest diseases and medical conditions, including cancer. CureVac was the first company in the world to harness mRNA for medical purposes—because CureVac's scientists saw opportunities where others saw only obstacles.

4. Convinced of mRNA's unparalleled potential as a medicine, CureVac's scientists worked tirelessly to pioneer numerous fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines, including methods to stabilize and modify mRNA, to manufacture it on a commercial scale, to increase the yield of the protein it encodes, and to formulate it for safe and effective administration to patients.

5. Based on that research, CureVac developed novel medicines with the goal of treating and preventing a wide range of diseases—infectious diseases like COVID-19 (caused by severe acute respiratory syndrome coronavirus 2 (“SARS-CoV-2”)), influenza, liver and eye diseases, and treatment-resistant cancers. CureVac also invented commercial-scale processes to

manufacture mRNA and licensed several global biopharmaceutical companies to use those processes.

6. All told, CureVac invested decades of effort and more than a billion dollars to build an mRNA medicines platform that could be applied across a variety of therapeutic and prophylactic (e.g., vaccine) applications. CureVac protected its innovations by developing an intellectual property portfolio, including by obtaining patents on its breakthroughs related to mRNA stabilization and manufacturing, as well as for its design of mRNA medicines.

7. Moderna has taken advantage of CureVac's pioneering inventions to develop and manufacture its Spikevax[®] COVID-19 vaccine product without paying for a license to CureVac's patents. Moderna's deliberate and willful infringement of CureVac's patents has generated and continues to generate billions of dollars in revenue for Moderna at CureVac's expense. CureVac brings this suit to recover a reasonable royalty for Moderna's sales of Spikevax[®] that exploited and continue to exploit CureVac's patented technologies.

NATURE OF THE ACTION

8. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., seeking damages for Moderna's infringing manufacture, use, sale, marketing, offer for sale, and/or importation of its Spikevax[®] mRNA vaccine (as further described and exemplified in paragraphs 31–51, *infra*) (collectively "the Accused Products").

9. As alleged herein, Moderna's activities with respect to the Accused Products have and continue to directly infringe, actively induce infringement of, and/or contribute to the infringement of, one or more claims of the following CureVac patents: U.S. Patent No. 10,760,070 ("the '070 Patent") (Exhibit 1); U.S. Patent No. 11,667,910 ("the '910 Patent") (Exhibit 2); U.S. Patent No. 11,760,992 ("the '992 Patent") (Exhibit 3); U.S. Patent No. 11,834,651 ("the '651

Patent”) (Exhibit 4); U.S. Patent No. 12,221,605 (“the ’605 Patent”) (Exhibit 5)¹; U.S. Patent No. 11,135,312 (“the ’312 Patent”) (Exhibit 6); U.S. Patent No. 11,576,966 (“the ’966 Patent”) (Exhibit 7); U.S. Patent No. 11,596,686 (“the ’686 Patent”) (Exhibit 8); U.S. Patent No. 12,194,089 (“the ’089 Patent”) (Exhibit 9); and U.S. Patent No. 12,390,523 (“the ’523 Patent”) (Exhibit 10)² (collectively the “Patents-in-Suit”).

10. At all relevant times, CureVac has owned, and continues to own, all rights, title, and interest in the Patents-in-Suit, including the right to sue and recover for past infringement.

PARTIES

11. CureVac SE is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany.

12. CureVac Manufacturing GmbH is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany.

13. On information and belief, Defendant Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. Moderna, Inc., itself and through its subsidiaries, including ModernaTX, Inc. and Moderna US, Inc., and business partners, develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused Products in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

¹ The ’070, ’910, ’992, ’651, and ’605 Patents are collectively referred to herein as the “TFF Patents.”

² The ’966, ’686, ’089, and ’523 Patents are collectively referred to herein as the “COVID Vaccine Patents.”

14. On information and belief, Defendant ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc., is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. ModernaTX, Inc. holds the Biologics License Application (BLA) for the Accused Products (BLA 125752) in the United States. Exhibit 11 (January 31, 2022, FDA Spikevax[®] (original monovalent) vaccine Approval Letter) at 1. ModernaTX, Inc., itself and through its parent company, Moderna, Inc., and sister company, Moderna US, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused Products for use in the State of Delaware and throughout the United States.

15. On information and belief, Defendant Moderna US, Inc. is a wholly owned subsidiary of Moderna, Inc., is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. Moderna US, Inc., itself and through its parent company, Moderna, Inc., and sister company, ModernaTX, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused Products for use in the State of Delaware and throughout the United States.

16. On information and belief, Defendants Moderna Inc., ModernaTX, Inc., and Moderna US, Inc. are agents of one another and/or work in concert with each other regarding the development, regulatory approval, manufacturing, use, offering for sale, sale, and importation of the Accused Products in the United States.

JURISDICTION AND VENUE

17. This action arises under the patent laws of the United States, including 35 U.S.C. § 100 et seq. generally and 35 U.S.C. § 271 et seq. specifically.

18. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

19. This Court has personal jurisdiction over Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. because each is organized under the laws of Delaware.

20. This Court also has personal jurisdiction over Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. because, on information and belief, each has conducted and continues to conduct business in Delaware at least by offering for sale and/or selling the Accused Products in Delaware, and because each has committed and continues to commit acts of infringement in Delaware. For example, as reported by the United States Center for Disease Control and Prevention (“CDC”), by May 10, 2023, Moderna had delivered to the State of Delaware over one million doses of Spikevax[®] (original monovalent) and over 160 thousand doses of Spikevax[®] (bivalent BA.4/5) products (as described in paragraphs 35–41, and 44–45, *infra*). (https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdiction/unsk-b7fc/data_preview, archived at <https://perma.cc/NH7C-PEV3>). And, on information and belief, Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. continue to deliver doses of Spikevax[®] products into the State of Delaware. Therefore, Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. have transacted and continue to transact business within Delaware relating to and giving rise to CureVac’s claims herein. This Court also has personal jurisdiction over Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. because, in connection with their offers for sale and sales of the Accused Products, they have engaged in and maintain systematic and continuous business contacts in Delaware.

21. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. have consented to this Court’s exercise of personal jurisdiction in other litigations involving the

Accused Products, including in *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al.*, C.A. No. 22-cv-252-MSG; *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 22-335-CFC, *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 23-580-CFC; *GlaxoSmithKline Biologicals SA et al v. Moderna, Inc. et al.*, C.A. No. 24-1135-GBW; and *Northwestern University v. Moderna, Inc. et al.*, C.A. No. 24-1151-RGA.

22. Under 28 U.S.C. § 1400(b), venue is proper in Delaware because Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. are Delaware corporations.

CUREVAC'S PATENTS

23. The realization of mRNA vaccines has long been hampered by, for example, mRNA instability, the difficulty getting it inside the target cells in the body, its inability to produce sufficient quantities of the desired protein once it is inside those cells, the insufficient stimulation of the immune system by the expressed protein, and various undesirable side effects (called “reactogenicity”). In its more than quarter-century of developing mRNA technologies, CureVac encountered and developed solutions to the technical challenges presented by this entirely new way to treat and prevent disease. CureVac protected its innovations and substantial investment in research and development in the field of mRNA medicines by obtaining patents that cover its inventions.

24. To overcome instability issues so that mRNA can be used in vaccines and other medicines, CureVac’s scientists developed novel ways to stabilize mRNA. mRNA typically is composed of four different subunits, called nucleotides: adenosine, guanosine, cytidine, and uridine. The sequence of these nucleotides in an mRNA molecule provides instructions that cells use to create the particular protein the mRNA encodes. CureVac’s scientists discovered that increasing the relative proportions of guanosine and cytidine nucleotides in the protein-coding

region of an mRNA stabilizes the molecule and increases expression of the protein it encodes. In 2001, CureVac filed its first patent application directed to this advance in mRNA technology.

25. On October 5, 2021, the U.S. Patent & Trademark Office (“the Patent Office”) issued the ’312 Patent titled “Pharmaceutical Composition Containing a Stabilised mRNA Optimised for Translation in its Coding Regions.” The ’312 Patent names CureVac’s co-founders, Florian von der Mülbe, Ingmar Hoerr, and Steve Pascolo, as inventors. The ’312 Patent reflects the inventors’ pioneering work to develop an mRNA molecule stable enough to use as a therapeutic in the treatment and prevention of disease. A true and correct copy of the ’312 Patent is attached as Exhibit 6.

26. The development of mRNA into a viable alternative to traditional drug products required the development of a commercially viable, efficient, and effective method of producing and purifying mass quantities of mRNA. To generate a sufficient supply of mRNA for use as a therapeutic, CureVac’s scientists developed new methods to purify mRNA, as well as the DNA template that encodes the mRNA, using a technique called Tangential Flow Filtration (“TFF”). In 2015, CureVac filed its first patent application directed to this advance in mRNA technology.

27. On September 1, 2020, the Patent Office issued the ’070 Patent titled “Method for Producing and Purifying RNA, Comprising at Least One Step of Tangential Flow Filtration.” A true and correct copy of the ’070 Patent is attached as Exhibit 1. On June 6, 2023, the Patent Office issued the ’910 Patent titled “Method for Producing and Purifying RNA, Comprising at Least One Step of Tangential Flow Filtration.” A true and correct copy of the ’910 Patent is attached as Exhibit 2. On September 19, 2023, the Patent Office issued the ’922 Patent titled “Method for Producing and Purifying RNA, Comprising at Least One Step of Tangential Flow Filtration.” A true and correct copy of the ’922 Patent is attached as Exhibit 3. On December 5, 2023, the Patent

Office issued the '651 Patent titled "Method for Producing and Purifying RNA, Comprising at Least One Step of Tangential Flow Filtration." A true and correct copy of the '651 Patent is attached as Exhibit 4. On February 11, 2025, the Patent Office issued the '605 Patent titled "Method for Producing and Purifying RNA, Comprising at Least One Step of Tangential Flow Filtration." A true and correct copy of the '605 Patent is attached as Exhibit 5. The '070, '910, '922, '651, and '605 Patents list Andreas Funkner, Stefanie Dorner, Stefanie Sewing, Johannes Kamm, Norbert Broghammer, Thomas Ketterer, and Thorsten Mutzke as inventors.

28. When the COVID-19 pandemic struck, the U.S. Government asked the scientists at CureVac if they could develop an mRNA vaccine against the SARS-CoV-2 virus. CureVac's scientists leveraged their resources and expertise built over decades to find the optimal mRNA sequence encoding the full-length COVID-19 spike protein, which is expressed on the surface of the SARS-CoV-2 virus. Building on their rapid response, CureVac developed full-length mRNA vaccine candidates for its innovative coronavirus vaccine designs. In February 2020, CureVac filed its first patent application directed to these advanced mRNA vaccines.

29. On February 14, 2023, the Patent Office issued the '966 Patent titled "Coronavirus Vaccine." A true and correct copy of the '966 Patent is attached as Exhibit 7. On March 7, 2023, the Patent Office issued the '686 Patent titled "Coronavirus Vaccine." A true and correct copy of the '686 Patent is attached as Exhibit 8. On January 14, 2025, the Patent Office issued the '089 Patent titled "Coronavirus Vaccine." A true and correct copy of the '089 Patent is attached as Exhibit 9. On August 19, 2025, the Patent Office issued the '523 Patent titled "Coronavirus vaccine." A true and correct copy of the '523 Patent is attached as Exhibit 10. The '686, '966, '089, and '523 Patents list Susanne Rauch, Hans Wolfgang Grosse, and Benjamin Petsch as inventors.

30. CureVac SE owns the '312, '966, '686, '089, and '523 Patents. CureVac Manufacturing GmbH owns the '070, '910, '922, '651, and '605 Patents.

MODERNA'S COVID-19 VACCINES

31. In early 2020, Moderna also began to develop an mRNA-based vaccine to address the COVID-19 pandemic, and developed the Accused Products over the ensuing years. On information and belief, the mRNA component of the Accused Products includes “a 7'-methylguanosine and a first 5' ribonucleotide, the 7'-methylguanosine being linked 5'-to-5' to the first 5' ribonucleotide, and the first 5' ribonucleotide comprising a 2'-methylated ribose.” Exhibit 12 (Application for Patent Term Extension) at 2, 11 (“[T]he molecular sequence of the mRNA component of SPIKEVAX includes the 5'-cap1 structure m7G-5'-ppp-5'-Gm.”), 13, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the structure of the “Cap” (“m7G-5'-ppp-5'-Gm”), the sequence of the “5' UTR” (position 3–58), the sequence of the “ORF” (position 59–3880), the sequence of the “3' UTR” (position 3881–3996), and the length of the “PolyA tail” (“100-nucleotide”)). On information and belief, the mRNA component of the Accused Products includes a poly(A) tail comprising 100 adenine nucleotides. *Id.* at 4.

32. The mRNA component of the Accused Products is encapsulated in tiny fat-like particles called “lipid nanoparticles,” or “LNPs.” The lipids that form the LNP component of the Accused Products include SM-102, polyethylene glycol 2000 dimyristoyl glycerol (“DMG”), cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine (“DSPC”). Exhibit 12 (Application for Patent Term Extension) at 4. SM-102 is an ionizable lipid, which under acidic conditions is a cationic lipid. *Id.*

33. On information and belief, Moderna uses the same processes to manufacture the mRNA component across all versions of the Spikevax[®] vaccine. Exhibit 13 (August 22, 2024, FDA Spikevax[®] (monovalent KP.2) vaccine EUA Review Memo) at 21 (“Effectiveness and safety

data accrued with the Moderna COVID-19 Vaccine (Original monovalent), Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), and Moderna COVID-19 Vaccine (2023-2024 Formula) are relevant to Moderna COVID-19 Vaccine (2024-2025 Formula), because all these vaccines are manufactured using the same process.”); Exhibit 14 (August 31, 2022, FDA Spikevax[®] (bivalent BA.4/BA.5) EUA Review Memo) at 6, 14–15, 41, 48; Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 19; Exhibit 16 (October 19, 2022, EMA Spikevax[®] (bivalent BA.4/BA.5) Assessment Report) at 14 and 41; Exhibit 17 (January 2, 2024, EMA Spikevax[®] EPAR Product Information) at 142, 146, 150; Exhibit 18 (Transcript of January 18, 2023, CNBC Television Interview) at 2:15 (original video available at <https://www.youtube.com/watch?v=FzgSE3yG-7E>) (“Moderna CEO: “And the other great news about mRNA is because all the products use the same manufacturing process. We don't have capacity constraint because we can use exactly the same equipment, people, and raw material as with the COVID shot.”).

34. On information and belief, as described *infra*, the Accused Products used and continue to use the same composition of mRNA (apart from differences in the coding sequences), composition of lipid particles, and methods of manufacture in both the United States (as approved by the U.S. Food and Drug Administration (“FDA”)) and in Europe (as approved by the European Medicines Agency (“EMA”)).

Spikevax[®] (original monovalent)

35. Moderna did not develop its Spikevax[®] COVID-19 vaccine products from a blank slate. Moderna developed its vaccines using mRNA technologies that incorporate CureVac’s pioneering inventions—Moderna’s COVID-19 vaccine program utilized the very technological advances that CureVac disclosed and claimed in the Patents-in-Suit.

36. Moderna's development of its COVID-19 vaccine was also heavily subsidized by the United States government. On April 16, 2020, the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services, awarded Moderna approximately \$483 million to accelerate the development and manufacturing of its COVID-19 vaccine candidate. On July 26, 2020, the U.S. government awarded an additional \$472 million to Moderna to support the Phase III clinical trial and other development activities. On August 11, 2020, the U.S. government awarded Moderna up to \$1.525 billion to support large-scale manufacturing and to secure the first 100 million doses of its mRNA-1273 vaccine candidate. Thus, Moderna leveraged CureVac's patented inventions while receiving \$2.5 billion in federal funding to bring its vaccine products to market.

37. Moderna used CureVac's inventions with great success. On information and belief, Moderna's development of its first COVID-19 vaccine, designated "mRNA-1273," began following the release of the SARS-CoV-2 genetic sequence by Chinese authorities on January 11, 2020. According to Moderna's SEC filings, Moderna and the National Institutes of Health finalized the sequence for the original version of the vaccine by January 13. Exhibit 19 (Moderna SEC Filing) at 1. On November 30, 2020, Moderna submitted an Emergency Use Authorization ("EUA") request to the FDA. On December 18, 2020, the FDA granted the EUA for Spikevax[®] (original monovalent) to prevent COVID-19 caused by SARS-CoV-2. The authorized regimen was a two-dose primary vaccination series administered one month apart, for use in adults 18 and older.

38. On August 12, 2021, the FDA expanded the EUA for Spikevax[®] (original monovalent) to a third primary dose (at least 1 month after the second dose) for certain immunocompromised individuals 18 years of age and older. On October 20, 2021, the FDA

expanded the EUA for Spikevax[®] (original monovalent) to a third dose (a first booster) six months after completion of the primary two-dose vaccination series for individuals 65 years of age or older, or certain other higher-risk individuals 18 to 64 years of age. On November 19, 2021, the FDA expanded the EUA for Spikevax[®] (original monovalent) to a third dose (a first booster) for all individuals 18 years and older six months after completion of any authorized primary vaccination regimen.

39. On January 31, 2022, the FDA granted full approval of Moderna’s BLA for Spikevax[®] (original monovalent) two-dose primary vaccination series in individuals 18 years of age and older. On March 29, 2022, the FDA expanded the EUA for Spikevax[®] (original monovalent) to a fourth dose (second booster) at least four months after receipt of a first booster dose of any FDA-authorized or -approved COVID-19 vaccine for individuals over 50 years of age and for immunocompromised patients 18 years of age and older. On June 17, 2022, the FDA expanded the EUA for Spikevax[®] (original monovalent) to a two-dose primary vaccination series for children 6 months through 17 years of age.

40. The mRNA component in Spikevax[®] (original monovalent) was referred to by Moderna as “CX-024414,” and was given the recommended name “elasomeran” in the World Health Organization’s register of International Nonproprietary Names for Pharmaceutical Substances. Exhibit 20 (Proposed International Nonproprietary Names List 125 – COVID-19) at 3. On information and belief, elasomeran/CX-024414 is 4,100 nucleotides in length.³

³ Sequence of elasomeran/CX-024414 is available at <https://gsrs.ncats.nih.gov/ginas/app/ui/substances/EPK39PL4R4>, archived at <https://perma.cc/YK42-2QP4>.

41. Moderna also referred to Spikevax[®] (original monovalent) containing elasomeran as “mRNA-1273,” and on information and belief, Moderna sold this version of the vaccine under the brand name Spikevax[®].⁴

Spikevax[®] (bivalent BA.1)

42. On September 1, 2022, the European Medicines Agency (EMA) recommended approval of Moderna’s bivalent COVID-19 vaccine targeting both the original SARS-CoV-2 strain and the Omicron BA.1 variant. The European Commission subsequently granted marketing authorization for Spikevax[®] (bivalent BA.1) for use as a booster in individuals 12 years of age and older who had completed a primary vaccination series with any COVID-19 vaccine.

43. Spikevax[®] (bivalent BA.1) contains two mRNA components: (1) the mRNA in Spikevax[®] (original monovalent), and (2) an mRNA designed specifically for the Omicron BA.1 variant. Moderna referred to the mRNA component targeting the Omicron BA.1 variant in Spikevax[®] (bivalent BA.1) as “CX-031302,” and it was given the recommended name “imelasomeran” in the World Health Organization’s register of International Nonproprietary Names for Pharmaceutical Substances. Exhibit 21 (Proposed International Nonproprietary Names List 127 – COVID-19) at 2. On information and belief, imelasomeran/CX-031302 is 4,091 nucleotides in length.⁵ Moderna also referred to Spikevax[®] (bivalent BA.1) containing elasomeran

⁴ For ease of reference, we refer herein to the monovalent version of Spikevax[®] containing elasomeran as “Spikevax[®] (original monovalent).”

⁵ Sequence of imelasomeran/CX-031302, available at <https://gsrs.ncats.nih.gov/ginias/app/ui/substances/b04ecc09-83fe-4c25-9dcc-d362648ef076>, archived at <https://perma.cc/29XG-8EKL>.

and imelasomeran as mRNA-1273.214, and on information and belief, sold this version of the vaccine under the brand name Spikevax[®].⁶

Spikevax[®] (bivalent BA.4/BA.5)

44. On August 23, 2022, Moderna announced the completion of its submission to the FDA for an EUA on a bivalent form of Spikevax for use as a COVID-19 booster vaccine. On August 31, 2022, the FDA granted Moderna an EUA for Spikevax[®] (bivalent BA.4/BA.5) as a single booster dose in patients 18 years of age and older who had received a primary series, or primary series and first booster, of any FDA-authorized or -approved COVID-19 vaccine. The FDA also revised the EUA for Spikevax[®] (original monovalent) to no longer include use as a first or second booster dose. On October 12, 2022, the FDA expanded the EUA for Spikevax[®] (bivalent BA.4/BA.5) as a booster dose in children and adolescents 6 through 17 years of age who had received a primary series, or primary series and booster, of any authorized or approved COVID-19 vaccine. On December 8, 2022, the FDA expanded the EUA for Spikevax[®] (bivalent BA.4/BA.5) as a single booster dose in children 6 months through 5 years of age who had received a primary series of Spikevax[®] (original monovalent). On April 18, 2023, the FDA expanded the EUA for Spikevax[®] (bivalent BA.4/BA.5) to be used for all doses (primary and booster) in most adults and pediatric populations as well as other dosage regimes for certain individuals based on age or immunocompromised status. The FDA also rescinded all authorizations for use of Spikevax[®] (original monovalent) vaccine in the United States.

45. Spikevax[®] (bivalent BA.4/BA.5) contains two mRNA components: (1) the same mRNA in Spikevax[®] (original monovalent), and (2) an mRNA designed for the Omicron variants

⁶ For ease of reference, we refer herein to the bivalent version of Spikevax[®] containing elasomeran and imelasomeran as “Spikevax[®] (bivalent BA.1).”

B.1.1.529.4 and B.1.1.529.5 (also known as BA.4 and BA.5, respectively). Moderna referred to the mRNA component designed for the Omicron BA.4 and BA.5 variants in Spikevax[®] (bivalent BA.4/BA.5) as “CX-034476,” and it was given the recommended name “davesomeran” in the World Health Organization’s register of International Nonproprietary Names for Pharmaceutical Substances. Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2. On information and belief, davesomeran/CX-034476 is 4,088 nucleotides in length.⁷ Moderna also referred to Spikevax[®] (bivalent BA.4/BA.5) containing elasomeran and davesomeran as “mRNA-1273.222,” and on information and belief, sold this version of the vaccine under the brand name Spikevax[®].⁸

Spikevax[®] (2023-2024 Formula)

46. On June 22, 2023, Moderna submitted an amendment to its existing EUA request for authorization of a monovalent COVID-19 vaccine targeting the Omicron XBB.1.5 variant. On September 11, 2023, the FDA granted full approval of Moderna’s supplemental BLA for Spikevax[®] (2023-2024 Formula) single-dose regimen for individuals 6 months through 11 years of age, and individuals 12 years of age and older.

47. Moderna referred to the mRNA component in the Omicron XBB.1.5 version of Spikevax[®] (2023-2024 Formula) as “CX-038839,” and it was given the recommended name “andusomeran” in the World Health Organization’s register of International Nonproprietary Names for Pharmaceutical Substances. Exhibit 23 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2. On information and belief, andusomeran/CX-038839 is 4,101

⁷ Sequence of davesomeran/CX-034476 available at <https://gsrs.ncats.nih.gov/ginas/app/ui/substances/TYF7YW7ENF>, archived at <https://perma.cc/X2W9-EGSQ>.

⁸ For ease of reference, we refer herein to the bivalent version of Spikevax[®] containing elasomeran and davesomeran as “Spikevax[®] (bivalent BA.4/BA.5).”

nucleotides in length.⁹ Moderna also referred to Spikevax[®] (2023-2024 Formula) containing andusomeran as “mRNA-1273.815,” and on information and belief, sold this version of the vaccine under the brand name Spikevax[®].¹⁰

Spikevax[®] (2024-2025 Formula)

48. On June 7, 2024, Moderna submitted an amendment to its existing EUA request for authorization of a monovalent COVID-19 vaccine targeting the Omicron JN.1 variant, which was later modified to target the Omicron KP.2 variant. On August 22, 2024, the FDA granted full approval of Moderna’s supplemental BLA for Spikevax[®] (2024-2025 Formula) single-dose regimen for individuals 6 months through 11 years of age, and individuals 12 years of age and older.

49. Moderna referred to the mRNA targeting the Omicron KP.2 variant in Spikevax[®] (2024-2025 Formula) as “CX-046684.” On information and belief, CX-046684 is 4,092 nucleotides in length.¹¹ Moderna also referred to Spikevax[®] (2024-2025 Formula) as “mRNA-1273.712,” and on information and belief, sold this version of the vaccine under the brand name Spikevax[®].¹²

⁹ Sequence of andusomeran/CX-038839 available at <https://gsrs.ncats.nih.gov/ginas/app/ui/substances/4F9QRS7ZV2>, archived at <https://perma.cc/2UZ4-ZAAH>.

¹⁰ For ease of reference, we refer herein to the version of Spikevax[®] containing andusomeran, an mRNA targeting the XBB 1.5 variant, as “Spikevax[®] (2023-2024 Formula).”

¹¹ Sequence of CX-046684, available at <https://gsrs.ncats.nih.gov/ginas/app/ui/substances/6a4684df-509a-4de1-bbdd-ec48890d7da9>, archived at <https://perma.cc/9XP9-XA7Y>.

¹² For ease of reference, we refer herein to the 2024-2025 formula version of Spikevax[®] containing mRNA-1273.712, an mRNA targeting the Omicron KP.2 variant, as “Spikevax[®] (2024-2025 Formula).”

Spikevax[®] (2025-2026 Formula)

50. On May 23, 2025, Moderna submitted a supplemental BLA for authorization of a monovalent COVID-19 vaccine targeting the Omicron LP.8.1 variant. On August 27, 2025, the FDA granted full approval of Moderna’s supplemental BLA for Spikevax[®] (2025-2026 Formula) single-dose regimen for individuals 6 months through 11 years of age, and individuals 12 years of age and older.

51. Moderna referred to the mRNA targeting the Omicron LP.8.1 variant in Spikevax[®] (2025-2026 Formula) as “CX-051869.” On information and belief, CX-051869 is 4,088 nucleotides in length.¹³ Moderna also refers to Spikevax[®] (2025-2026 Formula) as “mRNA-1273.251,” and on information and belief, sells this version of the vaccine under the brand name Spikevax[®].^{14,15}

MODERNA’S FINANCIAL WINDFALL FROM SPIKEVAX[®]

52. Moderna profited significantly from its use of CureVac’s patented technologies. From December 2020 through April 2023, Moderna provided over 353 million doses of Spikevax[®] for use in the United States. Exhibit 24 (April 26, 2023, archival form of CDC data, archived site available at <https://perma.cc/2Y4U-KPSU>) at 5. In its Annual Reports (Forms 10-K) and as shown

¹³ Sequence of CX-051869, available at <https://gsrs.ncats.nih.gov/ginas/app/ui/substances/e8e99376-ca51-42c4-a44e-698b01648f0e>, archived at <https://perma.cc/L75A-6RYK>.

¹⁴ For ease of reference, we refer herein to the 2025-2026 Formula version of Spikevax[®] containing mRNA-1273.215, an mRNA targeting the Omicron LP.8.1 variant, as “Spikevax[®] (2025-2026 Formula).”

¹⁵ The use of the terms “Spikevax[®]” and “Accused Products” without reference to a specific version of Moderna’s COVID-19 vaccine refers to all versions of Moderna’s Spikevax[®]: Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), Spikevax[®] (2024-2025 Formula), and Spikevax[®] (2025-2026 Formula).

in the chart below, Moderna reported more than \$14 billion in total U.S. revenue (and over \$47 billion globally) for the fiscal period from 2020 through 2025:

Fiscal Year	U.S. Revenue	Global Revenue
2020	\$200 million	
2021	\$5.4 billion	\$17.7 billion
2022	\$4.4 billion	\$18.4 billion
2023	\$1.7 billion	\$6.7 billion
2024	\$1.7 billion	\$3.1 billion
2025	\$1.2 billion	\$1.8 billion
Total	\$14.6 billion	\$47.7 billion

Exhibit 25 (excerpts from February 26, 2021, Moderna, Inc. FY2020 Annual Report (Form 10-K)) at 165–66; Exhibit 26 (excerpts from February 25, 2022, Moderna, Inc. FY2021 Annual Report (Form 10-K)) at 100, 107, 129; Exhibit 27 (excerpts from February 24, 2023, Moderna, Inc. FY2022 Annual Report (Form 10-K)) at 18, 127; Exhibit 28 (excerpts from February 23, 2024, Moderna, Inc. FY2023 Annual Report (Form 10-K)) at 6, 87; Exhibit 29 (Moderna, Inc. FY2024 Annual Report (Form 10-K) dated February 21, 2025) at 86; Exhibit 30 (Moderna, Inc. FY2025 Annual Report (Form 10-K) dated February 20, 2026) at 86.

53. On information and belief, Moderna intends to continue profiting from CureVac’s patented technologies, including by continuing to manufacture its infringing mRNA vaccines in the United States for sale and use throughout the global market. On November 19, 2025, Moderna announced that it “will now operate full end-to-end manufacturing for its mRNA medicines in the U.S.” Exhibit 31 (November 19, 2025, Moderna Press Release) at 1. Moderna’s CEO, Stephan

Bancel, stated “[b]y onshoring Drug Product manufacturing to our campus in Norwood, Massachusetts, we have completed the full manufacturing loop under one roof in the U.S.” *Id.*

54. On information and belief, all Spikevax[®] sold and administered in the United States was distributed by Moderna, or through a Moderna distributor, to hospitals, pharmacies, clinics, and numerous other entities, for the benefit of individual vaccine recipients in the United States.

55. On information and belief, and as explained below, Moderna manufactures the mRNA component in each of the Accused Products with the materially same process and purification steps. *See, e.g.*, Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 10 (noting that “[t]he manufacturing process and process controls [for Moderna’s mRNA imelasomeran in its bivalent vaccine] are the same as currently approved [by the EMA] for the manufacture of elasomeran [the mRNA in the Spikevax[®] monovalent vaccine]”); *id.* at 11 (noting use of the same raw materials and starting materials for the mRNAs in the monovalent and bivalent vaccines, and further noting that Moderna uses the same manufacturing method for both mRNAs); *id.* at 19 (noting “there are no changes in the manufacturing process” as it relates to encapsulation of the mRNAs for the bivalent vaccine relative to the monovalent vaccine).

56. Moderna made and continues to make (and/or have third parties make) the mRNA component in the Accused Products, as well as the finished drug product, in the United States for use in the United States and Europe. As explained in the FDA’s 2022 CMC Review Memo, for example, the mRNA component in Spikevax[®] is made by ModernaTX, Inc. in Norwood, Massachusetts, by Lonza Biologics, Inc. in Portsmouth, New Hampshire, and by Aldevron in Fargo, North Dakota, while the finished drug product is made by Catalent Biologics, LLC, and Baxter Pharmaceutical Solutions, LLC, both in Bloomington, Indiana:

The on-site pre-licensure inspections of ModernaTX, Inc. (Norwood, MA), Lonza Biologics, Inc. (Portsmouth, NH), and Aldevron (Fargo, ND) manufacturing facilities that are involved in the manufacture, controls, and storage of CX-024414 mRNA, [] and mRNA-1273 LNP DS were accomplished by the FDA inspection team ... For the subject BLA, inspections for Catalent Biologics, LLC (Bloomington, IN) and Baxter Pharmaceutical Solutions, LLC (Bloomington, IN) facilities used for the fill/finish, in-process testing, release testing (sterility), and storage of mRNA-1273 DP were waived as these facilities were determined to have an acceptable compliance history for manufacturing of previously approved FDA licensed products

Exhibit 32 (January 28, 2022, FDA Chemistry, Manufacturing, and Controls (CMC) Review Memo) at vii; *see also id.* at 2, 8, 62, 63, 86, 90, 93, 94, 96, 97. This is consistent with the FDA’s January 2022 Approval Letter:

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA, drug substance at ModernaTX, Inc., 1 Moderna Way, Norwood, MA, and Lonza Biologics, Inc., 101 International Drive, Portsmouth, NH. The final formulated product will be manufactured, filled, labeled and packaged at Catalent Indiana, LLC (a subsidiary of Catalent Pharma Solutions, LLC), 1300 S. Patterson Drive, Bloomington, IN, and Baxter BioPharma Solutions, 927 S. Curry Pike, Bloomington, IN.

Exhibit 11 (January 31, 2022, FDA Spikevax[®] (original monovalent) Approval Letter) at 1; *see also* Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 17–18; Exhibit 33 (September 11, 2023, FDA Spikevax[®] (monovalent XBB.1.5) Approval Letter) at 1 (identifying as manufacturers for “COVID-19 Vaccine, mRNA (SPIKEVAX)”, Catalent Indiana, LLC); Exhibit 34 (August 22, 2024, FDA Spikevax[®] (monovalent KP.2) Approval Letter) at 1 (identifying as manufacturers for “COVID-19 Vaccine, mRNA (SPIKEVAX)”, Catalent Indiana, LLC); Exhibit 35 (September 4, 2024 EMA Spikevax (monovalent JN.1)) Assessment Report) at 133 (identifying ModernaTX as the “manufacturers of the biological active substances ... ModernaTX, Inc. One Moderna Way Norwood, MA 02062 USA”); Exhibit 27 (excerpts from February 24, 2023, Moderna, Inc. FY2022 Annual Report (Form 10-K)) at 32–33 (“[W]e have

built a dedicated in-house multi-building manufacturing campus in Norwood, MA, the Moderna Technology Center (MTC); Exhibit 28 (excerpts from February 23, 2024, Moderna, Inc. FY2023 Annual Report (Form 10-K)) at 24–25 (similar).

57. On information and belief, Moderna manufactured the Accused Products in the United States and shipped the same to other countries. Exhibit 36 (Wingrove et al. “Vaccine Exports from U.S. Accelerate as Moderna Ships Abroad,” Bloomberg, May 20, 2021) at 2.

58. Moderna also made and continues to make (and/or have third parties make) the mRNA component in the Accused Products, as well as the finished drug product, outside of the United States, and on information and belief imports those products into the United States. As explained in the EMA’s January 2024 Product Information document, for example, the mRNA component in Spikevax[®] is made by several manufacturers in Europe.

THE INVENTIONS DESCRIBED AND CLAIMED IN CUREVAC’S TFF PATENTS

59. The inventions described and claimed in CureVac’s TFF Patents satisfied a long-felt need (as of May 29, 2015, when CureVac filed the first priority patent application) by providing a solution to the problem of producing mRNA at quantities and purities sufficient (a) for late-stage clinical development of vaccines and (b) to meet the demand for such vaccines against new infectious diseases.

60. As of May 29, 2015, there were no established manufacturing processes that could be easily adapted to rapidly produce a vaccine, such as an mRNA vaccine, against an emergent or genetically modified infectious organism at the scale needed to address the demands of the military or the general population during a public health crisis. Thus, there was a need in the art to develop new and better methods for manufacturing vaccines, like mRNA vaccines, at sufficient scale and purity to respond to such situations.

61. As part of a consortium of companies, CureVac was awarded a multi-year grant from the U.S. Defense Advanced Research Projects Agency (“DARPA”) that could provide as much as €150 million over four years to allow CureVac “to strengthen its technology platform and scale it up for commercial use.” Exhibit 37 (November 15, 2011, Genetic Engineering News Article, “CureVac, Sanofi Pasteur, and In-Cell-Art Collaborate on €33.1M DARPA-Supported Vaccine Program”) at 2. CureVac’s TFF Patents, initially filed on May 29, 2015, are one result of that work. DARPA funds research that reaches for “transformational breakthroughs” instead of “incremental advances.” Exhibit 38 (DARPA Mission) at 2. These research projects, like the project pursued by CureVac, often involve significant risks of failure, but have the potential to yield enormous rewards if successful.

62. In CureVac’s case, pilot-scale experiments conducted to develop new purification and production processes for nucleic acid-based vaccines required significant quantities of linear DNA and large mRNA molecules. As of the May 29, 2015, priority date of CureVac’s TFF patents, making such large quantities of DNA and mRNA was difficult, time-consuming, and labor-intensive. Further, the equipment needed to generate such quantities of materials requires significant capital investments and skilled-labor commitments, all for highly speculative success.

63. Against this backdrop, CureVac’s TFF project led to key advances in mRNA production and purification. For example, the inventors on the TFF Patents demonstrated (and described in the common specification of the TFF Patents) the advancement that TFF unit operations can be used to effectively process shear-sensitive molecules, such as transcribed (soluble) mRNA, with membrane cassettes. Exhibit 1 (’070 Patent) at 11:15-22.

64. The inventors on the TFF Patents discovered how to purify shear-sensitive molecules using TFF membrane cassettes and scale-up that process for the development of mRNA-

based vaccines. These critical and transformational discoveries are described and claimed in CureVac's TFF Patents.

MODERNA'S PRODUCTION AND PURIFICATION OF mRNA

65. Moderna's manufacture, use, sale, marketing, offer for sale, and/or importation of the Accused Products—including Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), Spikevax[®] (2024-2025 Formula), and Spikevax[®] (2025-2026 Formula)—directly and indirectly infringed and/or continue to infringe the TFF Patents.

66. On January 28, 2022, the FDA published a Chemistry, Manufacturing, and Controls (CMC) Review Memo recommending approval of Moderna's Biological License Application (BLA File STN 125752) to market its COVID-19 Vaccine, mRNA (SPIKEVAX). Exhibit 32 (January 28, 2022, FDA Chemistry, Manufacturing, and Controls (CMC) Review Memo). That memo is more than 120 pages in length, but is heavily redacted. The unredacted information includes the identities and locations of Moderna's and its partners' facilities where they manufacture both the mRNA component in the Accused Products, and the finished Accused Products, as explained below. The redacted information includes (i) how Moderna manufactures the mRNA, (ii) the raw materials and starting materials Moderna uses to manufacture the mRNA, and (iii) how Moderna developed its manufacturing process. *Id.* at 2–18.

67. Portions of Moderna's BLA describing its manufacturing process are disclosed in its Marketing Authorisation Application that Moderna appears to have submitted to the European Medicines Agency (EMA) to support its request for regulatory approval to market Spikevax[®] in Europe. Exhibit 39 (Moderna BLA § 3.2.S.2.5 Process Validation and/or Evaluation {CX-024414,

Lonza Portsmouth}}) at 4 (“Detailed descriptions of the manufacturing process, including the process flow diagram, are provided in [BLA] Section 3.2.S.2.2.”).

68. This BLA document shows that Moderna’s mRNA manufacturing process for Spikevax[®] involves several “major steps,” including *in vitro* transcription (“IVT”) of a template DNA to produce an uncapped mRNA; filtration to purify the transcribed mRNA; capping the mRNA; and subsequent “additional purification and filtration steps”:

The manufacturing process for CX-024414 mRNA involves several major steps. The uncapped mRNA is transcribed from linear DNA utilising an *in vitro* transcription (IVT) reaction followed by purification and filtration steps. Next, mRNA is enzymatically capped followed by additional purification and filtration steps. Finally, CX-214414 mRNA is filtered, dispensed and stored.

Exhibit 40 (March 11, 2021, EMA Spikevax[®] (original monovalent) Assessment Report) at 17.

69. On information and belief, Moderna’s manufacturing activities include manufacturing a master cell bank (MCB) and a working cell bank (WCB) containing cells that, on information and belief, produce a circular plasmid DNA encoding the mRNA component in the Accused Products. *See* Exhibit 40 (March 11, 2021, EMA Spikevax[®] (original monovalent) Assessment Report) at 18. On information and belief, Moderna harvests that circular plasmid DNA and linearizes it by cutting the circular plasmid DNA at a predetermined site with a restriction endonuclease enzyme to create a linear DNA template for *in vitro* transcription. Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 11 (“A unique linearised DNA plasmid template specific for CX-031302 mRNA was manufactured at ModernaTX, Inc. (Norwood, MA, USA).”).

70. On information and belief, following linearization of the circular plasmid DNA, Moderna purifies the linearization reaction mixture to remove enzymes, nucleotides, buffer components, and any other impurities that might interfere with the subsequent *in vitro* transcription

reaction to produce the mRNA. Exhibit 40 (March 11, 2021, EMA Spikevax[®] (original monovalent) Assessment Report) at 18 (“The linearised plasmid DNA is considered as the starting material. ... [T]he linearised plasmid DNA is in principle thoroughly tested.”). On information and belief, for commercial-scale production, Moderna subjects the linearization reaction mixture to TFF using membrane cassettes to purify the linearized DNA template.

71. On information and belief, following purification, the linearized DNA (template) is *in vitro* transcribed (IVT) to produce the (uncapped) mRNA. Exhibit 40 at 17 (“The uncapped mRNA is transcribed from linear DNA utilising an *in vitro* transcription (IVT) reaction”); Exhibit 39 (Moderna BLA § 3.2.S.2.5 Process Validation and/or Evaluation {CX-024414, Lonza Portsmouth}) at 5 (reporting “*In Vitro* Transcription Process Performance Qualification Results”). The IVT reaction mixture includes the linearized DNA template, an RNA polymerase enzyme, nucleoside triphosphates (the building blocks of RNA), a transcription buffer that, on information and belief, includes spermidine, and optionally an RNase inhibitor to prevent degradation of the transcribed mRNA by any ribonucleases that may also be present in the mixture. *See* Exhibit 39 at 5 (reporting the use of several nucleoside triphosphates, adenosine triphosphate, cytidine triphosphate, guanosine triphosphate, N1-methylpseudouridine triphosphate, as well as ethylenediaminetetraacetic acid (EDTA) and pyrophosphatase).

72. On information and belief, the RNA polymerase enzyme in the IVT reaction mixture is a T7 RNA polymerase. Following the IVT reaction, the linearized DNA (template) in the IVT reaction mixture is degraded by the introduction of DNase I enzyme. Exhibit 41 (Recommendation for an Emergency Use Listing of Covid-19 mRNA Vaccine (nucleoside modified) Submitted by Moderna Biotech Spain) at 5 (noting the transcription of the linearized

DNA template is done by “using T7 RNA polymerase” and the linearized DNA “template is then degraded by DNase I.”).

73. On information and belief, the transcribed (uncapped) mRNA is collected from the IVT reaction mixture and purified by a process that includes one or more TFF steps. *See* Exhibit 39 at 5 (“TFF = tangential flow filtration”), 6 (“In Vitro Transcription Tangential Flow Filtration Process Performance Qualification Results”).

74. On information and belief, Moderna uses TFF membrane cassettes in its filtration step to obtain purified transcribed mRNA. *See* Exhibit 41 at 5 (“First tangential flow filtration (TFF) step is performed for buffer exchange and to concentrate the transcribed [mRNA].”).

75. On information and belief, following the TFF step, Moderna subjects the transcribed mRNA to an (oligo dT) chromatography step to further purify the transcribed mRNA by binding to its poly(A) tail. *See* Exhibit 39 at 7 (referring to a “First Oligo dT Chromatography”); Exhibit 41 at 5 (“Full-length, polyA tail-containing RNA is subsequently purified by chromatography.”). Then, Moderna subjects the chromatographically pure transcribed mRNA to another TFF step. Exhibit 39 at 8 (referring to and offering performance characterization results for a “dT Tangential Flow Filtration Process”); Exhibit 41 at 5 (“A second TFF is performed to adjust the concentration and prepare the RNA for capping.”).

76. On information and belief, following the TFF and chromatography steps, Moderna “caps” the purified mRNA. *See* Exhibit 39 at 9 (referring to and offering performance characterization results for a “Capping”). On information and belief, Moderna then purifies the capped mRNA from the capping reaction mixture by another TFF step using membrane cassettes. *Id.* at 10 (referring to and offering performance characterization results for a “Cap Tangential Flow

Filtration Process”); Exhibit 41 at 5 (“A third TFF is performed for buffer exchange and concentration adjustment.”).

77. On information and belief, after this TFF step, Moderna subjects the purified capped mRNA to an (oligo dT) chromatography step to further purify the capped mRNA. Exhibit 39 at 11 (referring to a “Second Oligo dT Chromatography Process Parameters”); Exhibit 41 at 6 (“Capped mRNA is subsequently purified by a second chromatography step.”). Moderna then subjects the mRNA to another TFF step to produce the mRNA component used in the Accused Products. Exhibit 39 at 12 (referring to “Final Tangential Flow Filtration Process Parameters”); Exhibit 41 at 6 (“A final TFF is performed to concentrate the mRNA and to change the buffer.”).

78. On information and belief, Moderna encapsulates the purified, capped mRNA in a lipid nanoparticle (LNP) and combines it with a buffer and other preservatives (e.g., a cryoprotectant) in water to produce the finished drug product, *i.e.*, the Accused Products. Exhibit 41 at 7. To encapsulate the mRNA, Moderna mixes the mRNA with a lipid stock solution containing “SM-102” ((heptadecan-9-yl 8-{{(2-hydroxyethyl)[6-oxo-6-(undecyloxy) hexyl]amino}octanoate), an ionizable lipid that is protonated and therefore cationic in the acidic conditions in which the (negatively charged) mRNA is complexed and encapsulated by the formation of the LNP with the other lipid stock solution components such as phospholipids, pegylated lipids, and cholesterol. *Id.* at 6 (noting that in the manufacture of the LNP, the mRNA is mixed with SM-102, cholesterol, PEG2000-DMG (a pegylated lipid) and 1,2-distearoyl-sn-glycero-3-phosphatidylcholine or DSPC (phospholipids)); Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 9. The LNP encapsulation is similar to placing the mRNA component in a “package” that protects it and facilitates its delivery to a patient’s cells. The mRNA component has the same biological properties and function before and after it is

released from the LNP “package” in the patient’s body. That is, the protection that LNP encapsulation offers does not change—but rather preserves—the basic utility of the mRNA component.

79. Thus, on information and belief, Moderna produces the Accused Products by (i) manufacturing and maintaining a cell bank for the production of a circular plasmid DNA encoding the mRNA in the Accused Products, (ii) harvesting and linearizing the circular plasmid DNA in a reaction mixture to produce a linearized DNA template for in vitro transcription, (iii) purifying the linearization reaction mixture by tangential flow filtration (TFF) using membrane cassettes to obtain a purified linearized DNA, (iv) transcribing the linearized DNA in a transcription reaction mixture to produce an uncapped mRNA with a poly(A) tail, (v) purifying the transcribed mRNA from the transcription reaction mixture through two TFF steps that use membrane cassettes and a chromatography step, (vi) capping the purified mRNA, (vii) purifying the capped mRNA through two TFF steps, at least one of which uses a membrane cassette, and a chromatography step, and (viii) encapsulating the mRNA in a liquid nanoparticle and combining the LNP-encapsulated mRNA with pharmaceutical excipients (*e.g.*, buffers, preservatives, sucrose, and water). On information and belief, at least one of the TFF steps described above includes use of a TFF membrane cassette filter.

80. On information and belief, Moderna manufactures the mRNA(s) in each of the Accused Products by the same process and purification steps described above. Exhibit 15 at 10 (“The manufacturing process and process controls [for the imelasomeran in the Spikevax[®] bivalent vaccine] are the same as currently approved [by the EMA] for the manufacture of elasomeran” in Spikevax[®] (original monovalent)); *id.* at 11 (noting use of the same raw materials and starting materials for the mRNAs in the bivalent and monovalent vaccines and further noting the same

manufacturing method is used for both mRNAs); *id.* at 19 (noting “there are no changes in the manufacturing process” as it relates to encapsulation of the mRNAs for the bivalent vaccine relative to the monovalent vaccine).

81. When manufacturing an mRNA vaccine, it is critical to produce and purify the drug substance to pharmaceutical-grade quality at a scale that is large enough to meet market demand. With respect to the Accused Products, Moderna faced an even more critical production capacity issue because, particularly during the “lock-down” phase in 2020 and 2021, the global pandemic created an immediate, unprecedented demand for billions of doses of an mRNA vaccine.

82. The inventions described and claimed in CureVac’s TFF Patents provided and continue to provide high technical value and guidance to those in the field, including Moderna. On information and belief, Moderna would not have been able to meet the demand for billions of doses of its mRNA vaccine without the use of CureVac’s patented TFF methods.

COUNT I – INFRINGEMENT OF THE ’070 PATENT

83. CureVac incorporates by reference the allegations set forth in paragraphs 1–82 as though fully set forth here.

84. The ’070 Patent addressed an unmet need in the art as of May 29, 2015, for “a cost- and time-efficient” method of producing and “purify[ing] RNA at an industrial scale with high yield and pharmaceutical-grade purity, stability and/or shelf life.” Exhibit 1 (’070 Patent) at 2:32–36. The ’070 Patent describes and claims such a method, generally including the steps of providing DNA encoding the RNA, transcribing the DNA to produce RNA, and purifying the transcribed RNA by one or more steps of TFF using a membrane cassette. Separately, in providing the plasmid DNA, the method includes linearizing a plasmid DNA and purifying the linearized plasmid DNA by one or more TFF steps using a membrane cassette.

85. The ’070 Patent issued with 24 claims. Claim 1 recites:

1. A method for producing and purifying a RNA, comprising the steps of

A) providing a plasmid DNA encoding the RNA by

A1) linearizing the plasmid DNA in a linearization reaction;

A2) optionally terminating the linearization reaction; and

A3) diafiltering and/or concentrating and/or purifying the linearization reaction comprising linearized plasmid DNA by one or more steps of tangential flow filtration (TFF) using a TFF membrane cassette;

B) transcribing the linearized DNA to yield a solution comprising a transcribed RNA; and

C) diafiltering and/or concentrating and/or purifying the solution comprising the transcribed RNA by one or more steps of TFF, optionally a TFF membrane cassette.

86. On information and belief, the method Moderna uses to manufacture the mRNA in the Accused Products satisfies all of the limitations in at least Claim 1 of the '070 Patent, for the reasons described above.

87. Moderna has directly infringed and continues to directly infringe one or more claims of the '070 Patent, either literally or under the doctrine of equivalents, by making the mRNA in the Accused Products and/or making, using, selling, offering for sale, and/or importing the Accused Products in the United States in violation of 35 U.S.C. § 271(a).

88. Moderna has had knowledge of the TFF Patent Family since at least December 13, 2018, when Moderna was mailed an International Search Report from WIPO in connection with its International Patent Application No. PCT/US2018/046993 that identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. Moderna was later mailed an International

Search Report from WIPO on September 5, 2023 in connection with its International Patent Application No. PCT/US2023/067077 that again identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. WO2016/193206 is a publication of PCT/EP2016/062152, filed May 30, 2016. The '070 Patent is the patent that issued from the national phase application of PCT/EP2016/062152. The application that led to the '070 Patent was published as Patent Publication No. US2018/0298372, and is also identified on both International Search Reports as a family member in the same patent family as WO2016/193206.

89. Moderna has indirectly infringed and continues to indirectly infringe one or more claims of the '070 Patent in violation of 35 U.S.C. § 271(b). Moderna has actively induced and continues to actively induce third-party manufacturers to directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '070 Patent by making the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, during the term of the '070 Patent. For example, on information and belief, Moderna instructs and requires third-party manufacturers to use the purification process approved by the FDA that is described in Moderna's BLAs covering the Accused Products.

90. Moderna has infringed and/or will infringe one or more claims of the '070 Patent, either literally or under the doctrine of equivalents, by using, selling, offering for sale, and/or importing the mRNA used in the Accused Products, and/or the Accused Products themselves, made by the patented process claimed in the '070 Patent, in violation of 35 U.S.C. § 271(g).

91. Moderna's infringement of the claims of the '070 Patent has been and continues to be willful. On information and belief, Moderna acted with deliberate disregard for the '070 Patent

when it directly infringed, and encouraged direct infringement by others, with knowledge of the '070 Patent and knowledge that its actions and the actions it directed constituted infringement of the '070 Patent.

92. CureVac has suffered and continues to suffer damages as a result of Moderna's infringement of the claims of the '070 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the '070 Patent.

93. Moderna has engaged in egregious infringement behavior with respect to the '070 Patent, warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

94. Moderna's conduct with respect to the '070 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II – INFRINGEMENT OF THE '910 PATENT

95. CureVac incorporates by reference the allegations set forth in paragraphs 1–94 as though fully set forth here.

96. Like the '070 Patent, the '910 Patent also describes and claims a commercial-scale method of producing purified RNA. The method includes providing and linearizing plasmid DNA encoding an RNA having 500 to 10,000 nucleotides, transcribing the linearized DNA to produce the RNA, and purifying the transcribed RNA by one or more steps of tangential flow filtration (TFF) using a TFF membrane cassette. The method also includes at least one step of DNA or RNA purification using chromatography.

97. The '910 Patent issued with 26 claims. Claim 1 recites:

1. A method for producing purified RNA, comprising the steps of:

A1) providing plasmid DNA encoding a RNA of 500 to 10000 nucleotides in length;

A2) linearizing the DNA with a restriction endonuclease to produce linearized DNA;

B) transcribing the linearized DNA to yield transcribed RNA, wherein said transcribing is in a solution comprising: nucleoside triphosphates (NTPs); T7 polymerase, spermidine, salts and a HEPES or TRIS buffer; and

C) purifying the transcribed RNA by performing at least one step of tangential flow filtration (TFF) using a TFF membrane cassette, thereby producing purified RNA, wherein the method comprises at least one step of DNA or RNA purification using chromatography.

98. On information and belief, the method Moderna used and uses to manufacture the mRNA in the Accused Products satisfies all of the limitations in at least Claim 1 of the '910 Patent for all of the reasons described above.

99. Moderna has directly infringed and continues to directly infringe one or more claims of the '910 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, in violation of 35 U.S.C. § 271(a).

100. Moderna has had knowledge of the TFF Patent Family since at least December 13, 2018 when Moderna was mailed an International Search Report from WIPO in connection with its International Patent Application No. PCT/US2018/046993 that identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. Moderna was later mailed an International Search Report from WIPO on September 5, 2023 in connection with its International Patent Application No. PCT/US2023/067077 that again identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. WO2016/193206 is a publication of PCT/EP2016/062152, filed May 30,

2016. The '910 Patent is a continuation of U.S. Application No. 16/934,279, filed Jul. 21, 2020, which is a continuation of U.S. application Ser. No. 15/580,092, filed Dec. 6, 2017, now U.S. Pat. No. 10,760,070, which is a national phase application under 35 U.S.C. § 371 of International Application No. PCT/EP2016/062152. The application that led to the '910 Patent was published as Patent Publication No. US2022/0325273, and is identified on the September 5, 2023 International Search Reports as a family member in the same patent family as WO2016/193206.

101. Moderna has indirectly infringed and continues to indirectly infringe one or more claims of the '910 Patent in violation of 35 U.S.C. § 271(b). Moderna has actively induced and continues to actively induce third-party manufacturers to directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '910 Patent by making the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, during the term of the '910 Patent. For example, on information and belief, Moderna instructs and requires third party-manufacturers to use the purification process approved by the FDA that is described in Moderna's BLAs covering the Accused Products.

102. Moderna has infringed or will infringe one or more claims of the '910 Patent, either literally or under the doctrine of equivalents, by using, selling, offering for sale, and/or importing the mRNA used in the Accused Products, and/or the Accused Products themselves, made by the patented process claimed in the '910 Patent, in violation of 35 U.S.C. § 271(g).

103. Moderna's infringement of the claims of the '910 Patent has been and continues to be willful. On information and belief, Moderna acted with deliberate disregard for the '910 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '910 Patent and knowledge that its actions and the actions it directed constituted infringement of the '910 Patent.

104. CureVac has suffered and continues to suffer damages as a result of Moderna's infringement of the claims of the '910 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the '910 Patent.

105. Moderna has engaged in egregious infringement behavior with respect to the '910 Patent, warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

106. Moderna's conduct with respect to the '910 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III – INFRINGEMENT OF THE '992 PATENT

107. CureVac incorporates by reference the allegations set forth in paragraphs 1–106 as though fully set forth here.

108. The '992 Patent also describes and claims a commercial-scale method of producing purified RNA. The method generally includes the steps of providing and linearizing plasmid DNA encoding an RNA having 500 to 10,000 nucleotides, and purifying the linearized DNA by tangential flow filtration (TFF). The method also includes the steps of transcribing the purified linearized DNA to produce RNA, and purifying the transcribed RNA by one or more TFF steps using a TFF membrane cassette.

109. The '992 Patent issued with 30 claims. Claim 1 recites:

1. A method for producing purified RNA, comprising the steps of:

A1) providing a plasmid DNA encoding a RNA, wherein said RNA is 500 to 10000 nucleotides in length;

A2) linearizing the plasmid DNA to produce linearized DNA;

A3) ultrafiltering the linearized DNA by tangential flow filtration (TFF), to produce purified linearized DNA;

B1) transcribing the purified linearized DNA to produce transcribed RNA;

B2) treating the transcribed RNA with a DNase; and

C1) ultrafiltering the transcribed RNA by performing at least one step of TFF using a TFF membrane cassette having a molecular weight cutoff (MWCO) of less than or equal to 500 kDa, to produce the purified RNA.

110. Independent Claim 6 differs from Claim 1 insofar as it specifies transcribing the DNA in the presence of a cap to produce a transcribed capped RNA and includes a further TFF filtration step to further purify the RNA:

6. A method for producing purified RNA, comprising the steps of:

A1) providing a plasmid DNA encoding a RNA, wherein said RNA is 500 to 10000 nucleotides in length;

A2) linearizing the plasmid DNA to produce linearized DNA;

A3) ultrafiltering the linearized DNA by tangential flow filtration (TFF) to produce a purified linearized DNA;

B1) transcribing the purified linearized DNA in the presence of a cap analog to produce a transcribed capped RNA;

B2) treating the transcribed capped RNA with a DNase;

C1) ultrafiltering the transcribed capped RNA by at least one step of TFF with an aqueous salt solution using a TFF membrane cassette having a molecular weight cutoff (MWCO) of less than or equal to 500 kDa; and

C2) performing at least one further filtration using TFF, to obtain the purified RNA.

111. On information and belief, the method Moderna uses to manufacture the mRNA in the Accused Products satisfies all of the limitations in at least Claims 1 and 6 of the '992 Patent, for the reasons described above.

112. Moderna has directly infringed and continues to directly infringe one or more claims of the '992 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States in violation of 35 U.S.C. § 271(a).

113. Moderna has had knowledge of the TFF Patent Family since at least December 13, 2018 when Moderna was mailed an International Search Report from WIPO in connection with its International Patent Application No. PCT/US2018/046993 that identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. Moderna was later mailed an International Search Report from WIPO on September 5, 2023 in connection with its International Patent Application No. PCT/US2023/067077 that again identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. WO2016/193206 is a publication of PCT/EP2016/062152, filed May 30, 2016. The '992 Patent is a continuation of U.S. application Ser. No. 17/591,978, filed Feb. 3, 2022, which is a continuation of U.S. Application No. 16/934,279, filed Jul. 21, 2020, which is a continuation of U.S. Application No. 15/580, 092, filed Dec. 6, 2017, now U.S. Pat. No. 10,760,070, which is a national phase application under 35 U.S.C. § 371 of International Application No. PCT/EP2016/062152. The application that led to the '992 Patent was published as Patent Publication No. US2023/0151352, and is identified on the September 5, 2023 International Search Report as a family member in the same patent family as WO2016/193206.

114. Moderna has indirectly infringed and continues to indirectly infringe one or more claims of the '992 Patent in violation of 35 U.S.C. § 271(b). Moderna has actively induced third-party manufacturers to directly, either literally or under the doctrine of equivalents, infringe one or more claims of the '992 Patent by making the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, during the term of the '992 Patent. For example, on information and belief, Moderna instructs and requires third party-manufacturers to use the purification process approved by the FDA that is described in Moderna's BLAs covering the Accused Products.

115. Moderna has infringed or will infringe one or more claims of the '992 Patent, either literally or under the doctrine of equivalents, by using, selling, offering for sale, and/or importing the mRNA used in the Accused Products, and/or the Accused Products themselves, made by the patented process claimed in the '992 Patent, in violation of 35 U.S.C. § 271(g).

116. Moderna's infringement of the claims of the '992 Patent has been and continues to be willful. On information and belief, Moderna acted with deliberate disregard for the '992 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '992 Patent and knowledge that its actions and the actions it directed constituted infringement of the '992 Patent.

117. Moderna has caused (and CureVac has suffered and continues to suffer) damages as a result of Moderna's infringement of the claims of the '992 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the '992 Patent.

118. Moderna has engaged in egregious infringement behavior with respect to the '992 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

119. Moderna's conduct with respect to the '992 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV – INFRINGEMENT OF THE '651 PATENT

120. CureVac incorporates by reference the allegations set forth in paragraphs 1–119 as though fully set forth here.

121. The '651 Patent also describes and claims a commercial-scale method of producing purified RNA. The method generally includes the steps of providing and linearizing plasmid DNA encoding an RNA that is no greater than 15,000 nucleotides, and purifying the linearized DNA by tangential flow filtration (TFF). The method also includes the steps of transcribing the purified linearized DNA to produce RNA, purifying the transcribed RNA by one or more TFF steps using a TFF membrane cassette, and formulating the purified RNA.

122. The '651 Patent issued with 45 claims. Claim 1 recites:

1. A method for producing formulated purified RNA, comprising the steps of:

A1) providing a plasmid DNA encoding a RNA polymerase promoter sequence, a RNA coding sequence, and a restriction endonuclease cleavage site, wherein the coding sequence for said RNA is no greater than 15,000 nucleotides in length;

A2) linearizing the plasmid DNA with a restriction endonuclease to produce linearized DNA;

A3) ultrafiltering the linearized DNA by tangential flow filtration (TFF), to produce purified linearized DNA;

B1) transcribing the purified linearized DNA to produce transcribed RNA;

B2) treating the transcribed RNA with a DNase;

C1) ultrafiltering the transcribed RNA by performing at least one step of TFF using a TFF membrane cassette having a molecular weight cutoff (MWCO) of less than or equal to 500 kDa, to produce purified RNA; and

D) formulating the purified RNA to produce the formulated purified RNA.

123. Claim 31 recites:

31. A method for producing formulated purified RNA, comprising the steps of:

A1) providing a plasmid DNA encoding a RNA polymerase promoter sequence, a RNA coding sequence, and a restriction endonuclease cleavage site, wherein the coding sequence for said RNA is no greater than 15,000 nucleotides in length;

A2) linearizing the plasmid DNA with a restriction endonuclease to produce linearized DNA;

B1) transcribing the linearized DNA in the presence of nucleoside triphosphates (NTPs), T7 RNA polymerase, salts, and a buffer to produce a transcribed RNA;

B2) treating the transcribed RNA with a DNase;

C1) performing at least a first step of tangential flow filtration (TFF) on the transcribed RNA;

C2) performing at least a first step of chromatography on the transcribed RNA to obtain a purified RNA;

C3) performing at least a second step of TFF on the purified RNA; and

D) formulating the purified RNA by complexing the purified RNA with a cationic compound, to obtain the formulated purified RNA.

124. On information and belief, the method Moderna uses to manufacture the mRNA in the Accused Products satisfies all of the limitations in at least Claims 1 and 31 of the '651 Patent for the reasons described above.

125. Moderna has directly infringed and continues to directly infringe one or more claims of the '651 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States in violation of 35 U.S.C. § 271(a).

126. Moderna has had knowledge of the TFF Patent Family since at least December 13, 2018 when Moderna was mailed an International Search Report from WIPO in connection with its International Patent Application No. PCT/US2018/046993 that identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. Moderna was later mailed an International Search Report from WIPO on September 5, 2023 in connection with its International Patent Application No. PCT/US2023/067077 that again identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA, comprising at least one step of tangential flow filtration" as one of three documents deemed relevant to the patentability of Moderna's application. WO2016/193206 is a publication of PCT/EP2016/062152, filed May 30, 2016. The '651 Patent is a continuation of U.S. Application No. 17/820,242, filed August 16, 2022, which is a continuation of U.S. Application No. 17/591,978, filed February 3, 2022, which is a continuation of U.S. Application No. 16/934,279, filed July 21, 2020, now U.S. Patent No. 11,274,293, which is a continuation of U.S. Application No. 15/580,092, filed December 6, 2017, now U.S. Patent No. 10,760,070, which is a national phase application under 35 U.S.C. § 371 of International Application No. PCT/EP2016/062152.

127. Moderna has indirectly infringed and continues to indirectly infringe one or more claims of the '651 Patent in violation of 35 U.S.C. § 271(b). Moderna has actively induced and continues to actively induce third-party manufacturers to directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '651 Patent by making the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, during the term of the '651 Patent. For example, on information and belief, Moderna instructs and requires third

party-manufacturers to use the purification process approved by the FDA that is described in Moderna's BLAs covering the Accused Products.

128. Moderna has infringed or will infringe one or more claims of the '651 Patent, either literally or under the doctrine of equivalents, by using, selling, offering for sale, and/or importing the mRNA used in the Accused Products, and/or the Accused Products themselves, made by the patented process claimed in the '651 Patent, in violation of 35 U.S.C. § 271(g).

129. Moderna's infringement of the claims of the '651 Patent has been and continues to be willful. On information and belief, Moderna acted with deliberate disregard for the '651 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '651 Patent and knowledge that its actions and the actions it directed constituted infringement of the '651 Patent.

130. Moderna has caused (and CureVac has suffered and continues to suffer) damages as a result of Moderna's infringement of the claims of the '651 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the '651 Patent.

131. Moderna has engaged in egregious infringement behavior with respect to the '651 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

132. Moderna's conduct with respect to the '651 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT V – INFRINGEMENT OF THE '605 PATENT

133. CureVac incorporates by reference the allegations set forth in paragraphs 1–132 as though fully set forth here.

134. The '605 Patent also describes and claims a commercial-scale method of producing purified RNA. The method generally includes the steps of providing and linearizing plasmid DNA

encoding an RNA that is no greater than 15,000 nucleotides, and purifying the linearized DNA by tangential flow filtration (TFF). The method also includes the steps of transcribing the purified linearized DNA to produce RNA, purifying the transcribed RNA by (i) one or more TFF steps using a TFF membrane cassette (ii) chromatography, and (iii) and a further TFF step using a TFF membrane cassette, followed by a step of formulating the purified RNA.

135. The '605 Patent issued with 55 claims. Claim 1 recites:

1. A method for producing formulated purified RNA, comprising the steps of:

A1) providing a plasmid DNA comprising a RNA polymerase promoter sequence, a RNA coding sequence, and a restriction endonuclease cleavage site, wherein the coding sequence for said RNA is no greater than 15,000 nucleotides in length;

A2) linearizing the plasmid DNA with a restriction endonuclease to produce linearized DNA;

A3) ultrafiltering the linearized DNA by tangential flow filtration (TFF), to produce purified linearized DNA;

B1) transcribing the purified linearized DNA to produce transcribed RNA;

B2) treating the transcribed RNA with a DNase;

C1) performing at least one step of TFF using a TFF membrane cassette having a molecular weight cutoff (MWCO) of less than or equal to 500 kDa;

C2) further purifying the RNA by a step filtration or chromatography;

C3) performing at least one further step of TFF using a TFF membrane cassette to produce purified RNA; and

D) formulating the purified RNA to produce the formulated purified RNA.

136. Claim 28 recites:

28. A method for producing formulated purified RNA, comprising the steps of:

A1) providing a plasmid DNA comprising a RNA polymerase promoter sequence, a RNA coding sequence, and a restriction endonuclease cleavage site, wherein the coding sequence for said RNA is no greater than 15,000 nucleotides in length;

A2) linearizing the plasmid DNA with a restriction endonuclease to produce linearized DNA;

A3) ultrafiltering the linearized DNA by tangential flow filtration (TFF), to produce purified linearized DNA;

B1) transcribing the purified linearized DNA to produce transcribed RNA;

B2) treating the transcribed RNA with a DNase;

C1) performing at least one step of TFF using a TFF membrane cassette having a molecular weight cutoff (MWCO) of less than or equal to 500 kDa;

C2) further purifying the RNA by a step filtration or chromatography to produce purified RNA; and

D) formulating the purified RNA to produce the formulated purified RNA.

137. On information and belief, the method Moderna uses to manufacture the mRNA in the Accused Products satisfies all of the limitations in at least Claims 1 and 28 of the '605 Patent for all of the reasons described above.

138. Moderna has directly infringed and continues to directly infringe one or more claims of the '605 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, in violation of 35 U.S.C. § 271(a).

139. Moderna has had knowledge of the TFF Patent Family since at least December 13, 2018 when Moderna was mailed an International Search Report from WIPO in connection with its International Patent Application No. PCT/US2018/046993 that identified CureVac's International Publication WO2016/193206 titled "A method for producing and purifying RNA,

comprising at least one step of tangential flow filtration” as one of three documents deemed relevant to the patentability of Moderna’s application. Moderna was later mailed an International Search Report from WIPO on September 5, 2023 in connection with its International Patent Application No. PCT/US2023/067077 that again identified CureVac’s International Publication WO2016/193206 titled “A method for producing and purifying RNA, comprising at least one step of tangential flow filtration” as one of three documents deemed relevant to the patentability of Moderna’s application. WO2016/193206 is a publication of PCT/EP2016/062152, filed May 30, 2016. The ’605 Patent is a continuation of U.S. Application No. 18/198,258, filed May 16, 2023, which is a continuation of U.S. Application No. 17/820,242, filed August 16, 2022, now U.S. Patent No. 11,760,992, which is a continuation of U.S. Application No. 17/591,978, filed February 3, 2022, now U.S. Patent No. 11,667,910, which is a continuation of U.S. Application No. 16/934,279, filed July 21, 2020, now U.S. Patent No. 11,274,293, which is a continuation of U.S. Application No. 15/580,092, filed December 6, 2017, now U.S. Patent No. 10,760,070, which is a national phase application under 35 U.S.C. § 371 of International Application No. PCT/EP2016/062152.

140. Moderna has indirectly infringed and continues to indirectly infringe one or more claims of the ’605 Patent in violation of 35 U.S.C. § 271(b). Moderna has actively induced and continues to actively induce third-party manufacturers to directly infringe, either literally or under the doctrine of equivalents, one or more claims of the ’605 Patent by making the mRNA in the Accused Products, and/or the Accused Products themselves, in the United States, during the term of the ’605 Patent. For example, on information and belief, Moderna instructs and requires third party-manufacturers to use the purification process approved by the FDA that is described in Moderna’s BLAs covering the Accused Products.

141. Moderna has infringed or will infringe one or more claims of the '605 Patent, either literally or under the doctrine of equivalents, by using, selling, offering for sale, and/or importing the mRNA used in the Accused Products, and/or the Accused Products themselves, made by the patented process claimed in the '605 Patent, in violation of 35 U.S.C. § 271(g).

142. Moderna's infringement of the claims of the '605 Patent has been and continues to be willful. On information and belief, Moderna acted with deliberate disregard for the '605 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '605 Patent and knowledge that its actions and the actions it directed constituted infringement of the '605 Patent.

143. Moderna has caused (and CureVac has suffered and continues to suffer) damages as a result of Moderna's infringement of the claims of the '605 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the '605 Patent.

144. Moderna has engaged in egregious infringement behavior with respect to the '605 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

145. Moderna's conduct with respect to the '605 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VI – INFRINGEMENT OF THE '312 PATENT

146. CureVac incorporates each of the above Paragraphs 1–145 as though fully set forth here.

147. The '312 Patent is directed to methods for stabilizing mRNA molecules by altering their coding sequence. The inventors of the '312 Patent discovered that increasing the content of guanine and cytosine nucleotides (“the G/C content”) in the coding sequence of an mRNA

increases its stability and allows for increased production of protein (“polypeptide”) from the mRNA.

148. The ’312 Patent issued with sixteen claims. Claim 1 recites:

1. A method for producing a stabilized mRNA comprising 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, 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.

149. Claims 2 and 3 serially narrow Claim 1:

2. The method of claim 1, wherein the sequence encoding the polypeptide has a G/C content increased by at least 15 percentage points compared to the original nucleic acid sequence encoding the polypeptide.

3. The method of claim 2, wherein the sequence encoding the polypeptide has a G/C content increased by at least 20 percentage points compared to the original nucleic acid sequence encoding the polypeptide.

150. Claims 7–9 serially narrow Claim 1:

7. The method of claim 1, wherein synthesizing the stabilized mRNA comprises producing a DNA molecule encoding the stabilized mRNA.

8. The method of claim 7, wherein synthesizing the stabilized mRNA further comprises transcribing the stabilized mRNA from the DNA molecule.

9. The method of claim 8, wherein the transcription is in vitro transcription.

151. Claim 14 depends from Claim 1, and recites:

14. The method of claim 1, further comprising the formulating the stabilized mRNA into a pharmaceutically acceptable carrier.

152. Claim 15 depends from Claim 1, and recites:

15. The method of claim 1, further comprising synthesizing a stabilized mRNA comprising at least one nucleotide position replaced with a nucleotide analogue.

153. On information and belief, the method Moderna used to manufacture Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula) satisfies all of the limitations of at least Claims 1-3, 7-9, 14, and 15 of the '312 Patent. Moderna's actions with respect to these products have thus infringed at least these claims of the '312 Patent.

154. On information and belief, Moderna increased the G/C-content of the coding sequence of elasomeran/CX-024414, which was present in Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), and Spikevax[®] (bivalent BA.4/BA.5), relative to the original coding sequence. In fact, the coding sequence in elasomeran has a G/C-content greater than 62%, which is more than a 20% point increase over the original coding sequence. *See* Exhibit 20 (Proposed International Nonproprietary Names List 125 – COVID-19) at 3 (identifying GenBank ID MN908947.3 as the original coding sequence for elasomeran).

155. On information and belief, Moderna increased the G/C content of imelasomeran/CX-031302, which was present with elasomeran in Spikevax[®] (bivalent BA.1), and davesomeran/CX-034476, which was present with elasomeran in Spikevax[®] (bivalent BA.4/BA.5), relative to the original coding sequences. On information and belief, Moderna increased the G/C-content of these mRNAs relative to their original sequences in roughly the same amount that it increased G/C-content in elasomeran relative to its original sequence.

156. On information and belief, Moderna increased the G/C-content of the coding sequence of andusomeran/CX-038839, which was present in Spikevax[®] (2023-2024 Formula), relative to the original coding sequence. In fact, andusomeran has a G/C-content greater than 62%, which is more than a 20% point increase over the original coding sequence. *See* Exhibit 23 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2 (identifying GISAID: EPI_ISL_15948646 as the original coding sequence for andusomeran).

157. On information and belief, the method Moderna used to increase the G/C-content of the coding sequences in elasomeran, imelasomeran, davesomeran, and andusomeran relative to their original coding sequences resulted in each mRNA being more stable. Indeed, Moderna promoted the stability effects of increasing G/C content in its mRNAs in David M. Mauger et al., *mRNA Structure Regulates Protein Expression Through Changes in Functional Half-Life*, 116(48) Proc. Natl. Acad. Sci. U.S.A. 24075, 24075-83 (2019). Moderna developed the mRNA molecules in Spikevax[®] by, among other things, increasing the G/C content of their coding regions to increase the stability of the molecules and to increase the expression of protein from those molecules. In its 2020 annual report, Moderna explained that in addition to codon preferences, “the amount of protein produced is also determined by the secondary structure of mRNA, or the propensity of mRNA to fold on itself, with more structured mRNAs producing more protein.” Exhibit 25 (excerpts from February 26, 2021, Moderna, Inc. FY2020 Annual Report (Form 10-K)) at 13-14.

158. On information and belief, the method Moderna used to increase the G/C content of the coding sequences in elasomeran, imelasomeran, davesomeran, and andusomeran relative to their original coding sequences resulted in the elimination of at least one destabilizing sequence element in each coding sequence. On information and belief, Moderna’s increase in G/C content of the coding sequences of elasomeran, imelasomeran, davesomeran, and andusomeran relative to

their original coding sequences resulted in each accused mRNA exhibiting enhanced expression of spike protein compared to the original coding sequence. Moderna's manufacture of the Accused Products therefore infringed at least Claims 1-3 of the '312 Patent.

159. Moderna made each mRNA used in the manufacture of Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula) by producing a template DNA molecule encoding the mRNA, followed by the *in vitro* transcription of the template DNA molecule to produce the mRNA. Exhibit 25 (excerpts from February 26, 2021, Moderna, Inc. FY2020 Annual Report (Form 10-K)) at 16 (“Our platform creates mRNA using a cell-free approach called *in vitro* transcription in which an RNA polymerase enzyme binds to and transcribes a DNA template, adding the nucleotides encoded by the DNA to the growing RNA strand.”); Exhibits 26 at 12, 27 at 12, 28 at 10, 29 at 10, 30 at 10 (Annual Reports of Moderna Inc. for FY2021-25) (stating same). Moderna's manufacture of the Accused Products therefore infringed at least Claims 7-9 of the '312 Patent.

160. On information and belief, the accused Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula) were formulated with a pharmaceutically acceptable carrier. On information and belief, those vaccine products included the following excipients: (1) SM-102 (heptadecan-9-yl 8-{{2-hydroxyethyl}[6-oxo-6-(undecyloxy)hexyl]amino}octanoate); (2) cholesterol; (3) 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); (4) 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG); (5) tromethamine; (6) tromethamine hydrochloride; (7) acetic acid; (8) sodium acetate trihydrate, (9) sucrose; and (10) water for injection. Exhibit 42 (Spikevax[®] (original monovalent) Package Insert) at 11; Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 9; Exhibit 43 (Spikevax[®] (bivalent BA.4/BA.5) Package

insert) at 48; Exhibit 44 (Spikevax[®] (2023-2024 Formula) Package Insert) at 28. Moderna's manufacture of the Accused Products therefore infringed at least Claim 14 of the '312 Patent.

161. On information and belief, when each mRNA in the Accused Products was transcribed from its respective plasmid, a modified form of uridine, 1-methyl-3'-pseudouridylyl, was incorporated at the positions that would otherwise contain uridine residues. Exhibit 25 (excerpts from February 26, 2021, Moderna, Inc. FY2020 Annual Report (Form 10-K)) at 13; Exhibit 27 (excerpts from February 24, 2023, Moderna, Inc. FY2022 Annual Report (Form 10-K)) at 11 (stating same); Exhibit 29 (Moderna, Inc. FY2024 Annual Report (Form 10-K) dated February 21, 2025) at 9 (stating same); Exhibit 40 (March 11, 2021, EMA Spikevax[®] (original monovalent) Assessment Report) at 17; Exhibit 15 (December 16, 2022, EMA Spikevax[®] (bivalent BA.1) Assessment Report) at 10; Exhibit 16 (October 19, 2022, EMA Spikevax[®] (bivalent BA.4/BA.5) Assessment Report) at 8; Exhibit 45 (September 11, 2023, FDA Spikevax[®] (2023-2024 Formula) EUA Review Memo) at 17. Moderna's manufacture of the Accused Products therefore infringed at least Claim 15 of the '312 Patent.

162. Thus, on information and belief, Moderna has directly infringed at least Claims 1-3, 7-9, 14, and 15 of the '312 Patent, either literally or under the doctrine of equivalents, by manufacturing the mRNA in Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula) in the United States for use in the Accused Products sold in the United States and outside the United States, in violation of 35 U.S.C. § 271(a).

163. Moderna is a sophisticated competitor in this relatively small market. Moderna was aware of CureVac's role as a market leader in research and development of mRNA-based technologies. In fact, in November of 2022, Moderna jointly organized the 10th Annual mRNA

Health Conference with CureVac and others. Exhibit 46 (November 11, 2022, Moderna Blog Post). As described on Moderna's website, the mRNA Health Conference is "the only annual conference dedicated solely to mRNA-based science and medicine. The event brings together thought leaders from pharma, biotech and academic institutions to learn the latest on the rapidly expanding science, business, and regulatory landscape of mRNA medicine." *Id.* At least as early as 2014, Moderna has been aware of CureVac's patent family that includes the '312 Patent, as a result of licensing discussions that occurred between Moderna and CureVac related to several patent families, including the '312 Patent family. Additionally, on information and belief, Moderna has had knowledge of the '312 Patent because it was actively tracking the prosecution of the '312 Patent family. For example, in its U.S. Patent No. 9,572,897 ("the '897 Patent"), Moderna recites the priority chain for the '312 Patent and expressly incorporated the entirety of its contents by reference into the body of the '897 Patent. To the extent Moderna contends it was unaware of its infringement of the '312 Patent, it must have taken deliberate steps to avoid learning of the '312 Patent and confirming its infringement.

164. Moderna has indirectly infringed one or more claims of the '312 Patent in violation of 35 U.S.C. § 271(b), by actively inducing third-party manufacturers to directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '312 Patent by manufacturing the mRNA in, and/or making the accused Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula), in the United States, during the term of the '312 Patent. For example, on information and belief, Moderna instructed and required third party-manufacturers to manufacture the mRNA in the accused Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula) using the coding sequence that is described in

Moderna's BLAs covering the Accused Products with knowledge of the '312 Patent and with knowledge that it was encouraging the direct infringement of the '312 Patent.

165. Moderna has infringed one or more claims of the '312 Patent, either literally or under the doctrine of equivalents, by using, selling, offering for sale, and/or importing the mRNA used to manufacture Spikevax[®] (original monovalent), Spikevax[®] (bivalent BA.1), Spikevax[®] (bivalent BA.4/BA.5), and Spikevax[®] (2023-2024 Formula) made by the patented process claimed in the '312 Patent, in violation of 35 U.S.C. § 271(g).

166. Moderna's infringement of the claims of the '312 Patent was willful. On information and belief, Moderna acted with deliberate disregard for the '312 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '312 Patent and knowledge that its actions and the actions it directed constituted infringement of the '312 Patent.

167. CureVac has suffered damages as a result of Moderna's infringement of the claims of the '312 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the claims of the '312 Patent.

168. Moderna has engaged in egregious infringement behavior with respect to the '312 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

169. Moderna's conduct with respect to the '312 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VII – INFRINGEMENT OF THE '966 PATENT

170. CureVac incorporates each of the above paragraphs 1–169 as though fully set forth here.

171. The '966 Patent is directed to RNA-based vaccine compositions for treating coronavirus infections, in particular SARS-CoV-2 infections, containing an mRNA that encodes a pre-fusion stabilized form of the spike protein on the SARS-CoV-2 virus, also containing

additional mutations in the coding sequence. The '966 Patent also describes formulating such mRNAs in an LNP containing at least one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polymer conjugated lipid, preferably a polyethylene glycol-lipid. The '966 Patent also describes formulating such mRNAs in a pharmaceutically acceptable carrier.

172. The '966 Patent issued with 27 claims. Claim 1 recites:

1. A composition comprising a mRNA comprising:

(a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_{stab}) comprising K986P and V987P stabilizing mutations and H69del, V70del, S477N, T478K, E484A, N501Y, and D614G amino acid substitutions relative to SEQ ID NO: 10;

(b) at least one heterologous untranslated region (UTR); and

(c) at least one pharmaceutically acceptable carrier,

wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:

(i) at least one cationic lipid;

(ii) at least one neutral lipid;

(iii) at least one steroid or steroid analogue; and

(iv) at least one PEG-lipid,

wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-10% PEG-lipid.

173. On information and belief, davesomeran/CX-034476 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '966 Patent, contains the pre-fusion stabilizing K986P and V987P mutations, and has the following amino acid substitutions relative to SEQ ID NO: 10: H69del, V70del, S477N, T478K, E484A,

N501Y, and D614G . Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2.

174. On information and belief, davesomeran/CX-034476 comprises at least one heterologous untranslated region. Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2 (“... flanked by an artificial 5' untranslated region (UTR) and a 3' UTR derived from the human alpha globin gene (HBA1) modified to contain an identification and ratio (IDR) sequence to enable identification and relative ratio determination of individual RNA components in a multivalent mRNA vaccine, and terminated by a 3' poly(A) tail.”).

175. On information and belief, Spikevax[®] (bivalent BA.4/BA.5) is formulated with a pharmaceutically acceptable carrier. On information and belief, the Accused Product includes mRNA complexed or associated with lipid nanoparticles comprising: at least (1) one cationic lipid, SM-102 (heptadecan-9-yl 8-{{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate));(2) at least one neutral lipid, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); (3) at least one steroid or steroid analogue, cholesterol; and (4) at least one PEG-lipid, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG). Exhibit 43 (Spikevax[®] (bivalent BA.4/BA.5) Package insert) at 48. On information and belief, additional excipients in Spikevax[®] (bivalent BA.4/BA.5) include tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, and water for injection. *Id.*

176. On information and belief, the lipid nanoparticles in the accused Spikevax[®] (bivalent BA.4/BA.5) product includes the cationic, neutral, and PEG lipids and sterol in a molar ratio of about 48% cationic lipid, 11% neutral lipid, 39% sterol, and 1% PEG-lipid. Exhibit 41

(Recommendation for an Emergency Use Listing of Covid-19 mRNA Vaccine (nucleoside modified) Submitted by Moderna Biotech Spain) at 7.

177. On information and belief, the accused Spikevax[®] (bivalent BA.4/BA.5) satisfies all of the limitations of at least Claim 1 of the '966 Patent for the reasons described above.

178. On information and belief, Moderna has directly infringed at least Claim 1 of the '966 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Spikevax[®] (bivalent BA.4/BA.5) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

179. On information and belief, Moderna has induced infringement of at least Claim 1 of the '966 Patent by encouraging others, including but not limited to healthcare providers and patients, to use Spikevax[®] (bivalent BA.4/BA.5) in the United States in a manner that would directly infringe, either literally or under the doctrine of equivalents, the '966 Patent. Moderna has intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '966 Patent and with knowledge that its acts are encouraging infringement, in violation of 35 U.S.C. § 271(b). For example, Moderna provides an FDA-approved label with each of its products instructing such healthcare providers to administer the Accused Products to patients.

180. On information and belief, Moderna has induced infringement of at least Claim 1 of the '966 Patent by encouraging others to manufacture and/or make Spikevax[®] (bivalent BA.4/BA.5) in the United States, during the term of the '966 Patent, in a manner that would directly infringe, either literally or under the doctrine of equivalents, the '966 Patent. Moderna has intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, with knowledge of the '966 Patent and with knowledge that its acts are encouraging

infringement, in violation of 35 U.S.C. § 271(b). For example, Moderna instructs third-party manufacturers to manufacture the Accused Products pursuant to the process set forth in its BLA. That process results in the manufacture of the Accused Products.

181. On information and belief, the accused Spikevax[®] (bivalent BA.4/BA.5) constitutes a material part of the invention of at least Claim 1 of the '966 Patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use. Moderna has contributorily infringed and continues to contributorily infringe at least Claim 1 of the '966 Patent by promoting the use of Spikevax[®] (bivalent BA.4/BA.5) in accordance with their authorized uses in the United States by others, including but not limited to healthcare providers and patients, and knowing that the Accused Products are especially made or especially adapted for use to directly infringe, either literally or under the doctrine of equivalents, the '966 Patent, in violation of 35 U.S.C. § 271(c).

182. On information and belief, Moderna had knowledge of the '966 Patent and knowledge that its actions promoting the use of Spikevax[®] (bivalent BA.4/BA.5) in the United States induces infringement and contributorily infringes the '966 Patent.

183. Moderna's infringement of the claims of the '966 Patent has been and continues to be willful. On information and belief, Moderna acted with deliberate disregard for the '966 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '966 Patent and knowledge that its actions and the actions it directed constituted infringement of the '966 Patent.

184. CureVac has suffered damages as a result of Moderna's infringement of the claims of the '966 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the claims of the '966 Patent.

185. Moderna has engaged in egregious infringement behavior with respect to the '966 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

186. Moderna's conduct with respect to the '966 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VIII – INFRINGEMENT OF THE '686 PATENT

187. CureVac incorporates each of the above paragraphs 1–186 as though fully set forth here.

188. The '686 Patent is directed to purified mRNAs that encode a pre-fusion stabilized form of the spike protein on the SARS-CoV-2 virus, and that contain an additional "D614G" mutation in their coding sequence. The '686 Patent also describes formulating such mRNAs in a pharmaceutically acceptable carrier.

189. The '686 Patent issued with 30 claims. Claim 1 recites:

1. A purified mRNA comprising:

(a) a 5' cap structure;

(b) a heterologous 5' untranslated region (UTR);

(c) a coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_{stab}) comprising K986P and V987P stabilizing substitutions and further comprising a D614G amino acid substitution relative to SEQ ID NO: 10; and

(d) a heterologous 3' UTR,

wherein the mRNA optionally comprises a nucleotide substitution at one or more uracil position(s) selected from a 1-methylpseudouridine or a pseudouridine substitution.

190. On information and belief, Moderna's Spikevax[®] (bivalent BA.4/BA.5) contains the mRNA molecule davesomeran/CX-034476; Moderna's Spikevax[®] (2023-2024 Formula)

contains the mRNA molecule andusomeran/CX-038839; and Moderna's Spikevax[®] (2024-2025 Formula) contains the mRNA molecule CX-046684.

191. On information and belief, davesomeran/CX-034476 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '686 Patent, contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G substitution relative to SEQ ID NO: 10. Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2.

192. On information and belief, andusomeran/CX-038839 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '686 Patent, and contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G substitution relative to SEQ ID NO: 10. Exhibit 23 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2.

193. On information and belief, CX-046684 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 95% identical to SEQ ID NO: 10 in the '686 Patent, and contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G substitution relative to SEQ ID NO: 10.

194. On information and belief, davesomeran/CX-034476, andusomeran/CX-038839, and CX-046684 comprise a 5'-cap structure. Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2 ("5'-capped ..."); Exhibit 23 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2 ("5'-capped ...").

195. On information and belief, davesomeran/CX-034476, andusomeran/CX-038839, and CX-046684 comprise a heterologous 3' UTR, and a heterologous 5' UTR. Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2 ("flanked by an

artificial 5' untranslated region (UTR) and a 3' UTR derived from the human alpha globin gene (HBA1”); Exhibit 23 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2 (“flanked by an artificial 5' untranslated region (UTR) and a 3' UTR derived from the human alpha globin gene (HBA1”).

196. On information and belief, 100% of the uracil positions in the coding sequences of davesomeran/CX-034476, andusomeran/CX-038839, and CX-046684 are replaced with 1-methylpseudouridine, a nucleotide analog. Exhibit 22 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2 (“... contains N¹-methylpseudouridine instead of uridine (*all-U>m¹Ψ*)”); Exhibit 23 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2 (“... contains N¹-methylpseudouridine instead of uridine (*all-U>m¹Ψ*)”).

197. On information and belief, Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), and Spikevax[®] (2024-2025 Formula) satisfy all of the limitations of at least Claim 1 of the '686 Patent for the reasons described above.

198. On information and belief, Moderna has directly infringed at least Claim 1 of the '686 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), and Spikevax[®] (2024-2025 Formula) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

199. On information and belief, Moderna has induced infringement of at least Claim 1 of the '686 Patent by encouraging others, including but not limited to healthcare providers and patients, to use Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), and Spikevax[®] (2024-2025 Formula) in the United States in a manner that would directly infringe, either literally or under the doctrine of equivalents, the '686 Patent. Moderna has intentionally encouraged and

will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '686 Patent and with knowledge that its acts are encouraging infringement, in violation of 35 U.S.C. § 271(b). For example, Moderna provides an FDA-approved label with each of its products that instructs such healthcare providers to administer the Accused Products to patients.

200. On information and belief, Moderna has induced infringement of at least Claim 1 of the '686 Patent by encouraging others to manufacture and/or make Spikevax[®] (bivalent BA.4/BA.5) and Spikevax[®] (2023-2024 Formula) in the United States, during the term of the '686 Patent, in a manner that would directly infringe, either literally or under the doctrine of equivalents, the '686 Patent. Moderna has intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, with knowledge of the '686 Patent and with knowledge that its acts are encouraging infringement, in violation of 35 U.S.C. § 271(b). For example, Moderna instructs third-party manufacturers to manufacture the Accused Products pursuant to the process set forth in its BLA. That process results in the manufacture of the Accused Products.

201. On information and belief, Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), and Spikevax[®] (2024-2025 Formula) constitute a material part of the invention of at least Claim 1 of the '686 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Moderna has contributorily infringed and continues to contributorily infringe at least Claim 1 of the '686 Patent by promoting the use of Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), and Spikevax[®] (2024-2025 Formula) in accordance with their authorized uses in the United States by others, including but not limited to healthcare providers and patients, and knowing that those products are especially made or

especially adapted for use to directly infringe, either literally or under the doctrine of equivalents, the '686 Patent, in violation of 35 U.S.C. § 271(c).

202. On information and belief, Moderna had knowledge of the '686 Patent and knowledge that its actions promoting the use of Spikevax[®] (bivalent BA.4/BA.5), Spikevax[®] (2023-2024 Formula), and Spikevax[®] (2024-2025 Formula) in the United States induces infringement of and contributorily infringes the '686 Patent.

203. Moderna's infringement of the '686 Patent has been willful. On information and belief, Moderna acted with deliberate disregard for the '686 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '686 Patent and knowledge that its actions and the actions it directed constituted infringement of the '686 Patent.

204. CureVac has suffered damages as a result of Moderna's infringement of the claims of the '686 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the claims of the '686 Patent.

205. Moderna has engaged in egregious infringement behavior with respect to the '686 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

206. Moderna's conduct with respect to the '686 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IX – INFRINGEMENT OF THE '089 PATENT

207. CureVac incorporates each of the above paragraphs 1–206 as though fully set forth here.

208. The '089 Patent is directed to purified mRNAs that encode a pre-fusion stabilized form of the spike protein on the SARS-CoV-2 virus, and that contain additional "E484K" and "D614G" mutations in the coding sequence. The '089 Patent also describes formulating such mRNAs in a pharmaceutically acceptable carrier and in an LNP.

209. The '089 Patent issued with 52 claims. Claim 1 recites:

1. A composition comprising a mRNA comprising:

(a) at least one coding sequence encoding a SARS-COV-2 spike protein(S) comprising an amino acid sequence at least 90% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing substitutions and further comprising E484K and D614G amino acid substitutions relative to SEQ ID NO: 10;

(b) at least one heterologous untranslated region (UTR); and

(c) at least one pharmaceutically acceptable carrier,

wherein the mRNA is complexed or associated with a lipid nanoparticle (LNP).

210. On information and belief, Moderna's Spikevax[®] (2024-2025 Formula) contains the mRNA molecule CX-046684, and Spikevax[®] (2025-2026 Formula) contains the mRNA molecule CX-051869.

211. On information and belief, CX-046684 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 95% identical to SEQ ID NO: 10 in the '089 Patent, contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G and E484K amino-acid substitutions relative to SEQ ID NO: 10.

212. On information and belief, CX-051869 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 94% identical to SEQ ID NO: 10 in the '089 Patent, contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G and E484K amino-acid substitutions relative to SEQ ID NO: 10.

213. On information and belief, CX-046684 and CX-051869 comprise a heterologous 3' UTR and a heterologous 5' UTR.

214. On information and belief, Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) are formulated with a pharmaceutically acceptable carrier: Spikevax[®] (2024-2025

Formula) and Spikevax[®] (2025-2026 Formula) include mRNA complexed or associated with lipid nanoparticles comprising: at least (1) one cationic lipid, SM-102 (heptadecan-9-yl 8-{{2-hydroxyethyl}[6-oxo-6-(undecyloxy)hexyl]amino}octanoate));(2) at least one neutral lipid, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); (3) at least one steroid or steroid analogue, cholesterol; and (4) at least one PEG-lipid, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG). Exhibit 47 (Spikevax[®] (2024-2025 Formula) package insert) at 27; Exhibit 48 (Spikevax[®] (2025-2026 Formula) package insert) at 50. On information and belief, additional excipients in Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) include tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, and water for injection. *Id.*

215. On information and belief, 100% of the uracil positions in the coding sequences of CX-046684 and CX-051869 are replaced with 1-methylpseudouridine, a nucleotide analog.

216. On information and belief, Moderna's Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) satisfy all of the limitations of at least Claim 1 of the '089 Patent for the reasons described above.

217. On information and belief, Moderna has directly infringed at least Claim 1 of the '089 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

218. On information and belief, Moderna has induced infringement of at least Claim 1 of the '089 Patent by encouraging others, including but not limited to healthcare providers and patients, to use Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in the United States in a manner that would directly infringe, either literally or under the doctrine of

equivalents, the '089 Patent. Moderna has intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '089 Patent and with knowledge that its acts are encouraging infringement, in violation of 35 U.S.C. § 271(b). For example, Moderna provides an FDA- approved label with each of its products that instructs such healthcare providers to administer the Accused Products to patients.

219. On information and belief, Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) constitute a material part of the invention of at least Claim 1 of the '089 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Moderna has contributorily infringed and continues to contributorily infringe at least Claim 1 of the '089 Patent, by promoting the use of Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in accordance with their authorized uses in the United States by others, including but not limited to healthcare providers and patients, and knowing that those products are especially made or especially adapted for use to directly infringe, either literally or under the doctrine of equivalents, the '089 Patent, in violation of 35 U.S.C. § 271(c).

220. On information and belief, Moderna had knowledge of the '089 Patent and knowledge that its actions promoting the use of Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in the United States induces infringement of and contributorily infringes the '089 Patent.

221. Moderna's infringement of the '089 Patent has been willful. On information and belief, Moderna acted with deliberate disregard for the '089 Patent when it directly infringed, and encouraged direct infringement by others, with knowledge of the '089 Patent and knowledge that its actions and the actions it directed constituted infringement of the '089 Patent.

222. CureVac has suffered damages as a result of Moderna's infringement of the claims of the '089 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the claims of the '089 Patent.

223. Moderna has engaged in egregious infringement behavior with respect to the '089 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

224. Moderna's conduct with respect to the '089 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT X – INFRINGEMENT OF THE '523 PATENT

225. CureVac incorporates each of the above paragraphs 1–224 as though fully set forth here.

226. The '523 Patent is directed to purified mRNAs that encodes a pre-fusion stabilized form of the spike protein on the SARS-CoV-2 virus, also containing additional "E484K" and "D614G" mutations in the coding sequence. The '523 Patent also describes formulating such mRNAs in a pharmaceutically acceptable carrier.

227. The '523 Patent issued with 119 claims. Claim 1 recites:

1. A purified RNA comprising:

(a) a 5' cap structure;

(b) at least one coding sequence encoding a SARS-CoV-2 spike protein comprising an amino acid sequence at least 90% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_{stab}) comprising K986P and V987P stabilizing substitutions and further comprising E484K and D614G amino acid substitutions relative to SEQ ID NO: 10; and

(c) a 3' untranslated region (UTR) comprising at least one poly (A) sequence having 30 to 200 adenosine nucleotides.

228. On information and belief, Moderna's Spikevax[®] (2024-2025 Formula) contains the mRNA molecule CX-046684, and Spikevax[®] (2025-2026 Formula) contains the mRNA molecule CX-051869.

229. On information and belief, CX-046684 and CX-051869 comprise a 5'-cap structure.

230. On information and belief, CX-046684 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 95% identical to SEQ ID NO: 10 in the '523 Patent, and contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G and E484K amino acid substitutions relative to SEQ ID NO: 10.

231. On information and belief, CX-051869 has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 94% identical to SEQ ID NO: 10 in the '523 Patent, and contains the pre-fusion stabilizing K986P and V987P mutations, and has the D614G and E484K amino acid substitutions relative to SEQ ID NO: 10.

232. On information and belief, CX-046684 and CX-051869 comprise a heterologous 3' UTR, and a heterologous 5' UTR, and a terminal poly(A) sequence comprising 100 adenosine nucleotides.

233. On information and belief, Moderna's Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) satisfy all of the limitations of at least Claim 1 of the '523 Patent for the reasons described above.

234. On information and belief, Moderna has directly infringed at least Claim 1 of the '523 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

235. On information and belief, Moderna has induced infringement of at least Claim 1 of the '523 Patent by encouraging others, including but not limited to healthcare providers and patients, to use Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in the United States in a manner that would directly infringe, either literally or under the doctrine of equivalents, the '523 Patent. Moderna has intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '523 Patent and with knowledge that its acts are encouraging infringement, in violation of 35 U.S.C. § 271(b). For example, Moderna provides an FDA- approved label with each of its products instructing such healthcare providers to administer the Accused Products to patients.

236. On information and belief, Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) constitute a material part of the invention of at least Claim 1 of the '523 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Moderna has contributorily infringed and continues to contributorily infringe at least Claim 1 of the '523 Patent by promoting the use of Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in accordance with their authorized uses in the United States by others, including but not limited to healthcare providers and patients, and knowing that those products are especially made or especially adapted for use to directly infringe, either literally or under the doctrine of equivalents, the '523 Patent, in violation of 35 U.S.C. § 271(c).

237. On information and belief, Moderna had knowledge of the '523 Patent and knowledge that its actions promoting the use of Spikevax[®] (2024-2025 Formula) and Spikevax[®] (2025-2026 Formula) in the United States induces infringement of and contributorily infringes the '523 Patent.

238. Moderna's infringement of the '523 Patent has been willful. On information and belief, Moderna acted with deliberate disregard for the '523 Patent when it directly infringed, and encouraged the direct infringement by others, with knowledge of the '523 Patent and knowledge that its actions and the actions it directed constituted infringement of the '523 Patent.

239. CureVac has suffered damages as a result of Moderna's infringement of the claims of the '523 Patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Moderna's infringement of the claims of the '523 Patent.

240. Moderna has engaged in egregious infringement behavior with respect to the '523 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

241. Moderna's conduct with respect to the '523 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

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

- a. A judgment that Moderna has infringed one or more claims of the '070, '910, '992, '651, '605, '312, '966, '686, '089, and '523 Patents, induced infringement of one or more claims of the '070, '910, '992, '651, '605, '312, '966, '686, '089, and '523 Patents, and/or contributorily infringed one or more claims of the '070, '910, '992, '651, '605, '312, '966, '686, '089, and '523 Patents;
- b. A judgment that Moderna's infringement has been and is willful;
- c. An award to CureVac of monetary damages for Moderna's infringement, including reasonable royalties, together with interest, costs, expenses, disbursements, and an accounting and/or ongoing royalty for any post-judgment infringement;
- d. An award to CureVac of all other damages permitted by 35 U.S.C. § 284, including enhanced damages up to three times the amount of compensatory damages found;

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

f. Such other relief as this Court may deem just and proper, except CureVac does not seek injunctive relief against the Accused Products.

DEMAND FOR JURY TRIAL

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

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