IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIONTECH SE, Plaintiff, v. MODERNATX, INC., MODERNA, INC. and MODERNA US, INC., Defendants.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff BioNTech SE ("BioNTech"), by and through its undersigned counsel, and for its Complaint against Defendants ModernaTX, Inc. ("ModernaTX"), Moderna, Inc. ("Moderna Inc.") and Moderna US, Inc. ("Moderna US") (collectively, "Moderna"), alleges as follows:

INTRODUCTION

1. BioNTech is a household name for its central role in combating the COVID-19 pandemic. In partnership with Pfizer, BioNTech delivered the first-ever vaccine for COVID-19 – and the first mRNA vaccine ever approved by the FDA: COMIRNATY®. Since its launch, over five ***billion*** doses of COMIRNATY® have been distributed globally, saving ***millions*** of lives. In order to meet the critical and immediate demands of the pandemic, BioNTech prioritized COMIRNATY®'s development. But, even at the outset of its pandemic efforts, BioNTech conceived of alternative advanced technologies for fighting COVID-19 disease; indeed, it successfully tested that technology in early-stage clinical trials alongside COMIRNATY® and obtained a patent for it. This action is based on BioNTech's patented COVID-19 vaccine technology, which Moderna is using without permission in its mNEXSPIKE® vaccine.

2. Key to BioNTech's patented technology is the philosophy that less is more. COMIRNATY® presents to the body's immune system the complete "spike protein" of the SARS-CoV-2 virus that causes COVID-19, in order to protect against later infection by the virus. BioNTech discovered that a ***streamlined*** vaccine design, focusing on select ***domains*** of the spike protein, triggers an equally strong immune response to that of the complete spike protein. This ***streamlined***, ***domain-based*** vaccine includes mRNA for making the receptor binding domain ("RBD") of the spike protein, along with a "trimerization domain" and/or a "transmembrane domain," and a "secretory signal." This vaccine mimics features of the virus's full-length spike protein, bolstering a robust immune response and protection against later infection by the virus. Compared to vaccines that feature a full-length spike protein, BioNTech's innovative vaccine can be given to patients at a ***lower dose***, and is ***more stable*** during storage and transport.

3. Innovation is at the heart of BioNTech's mission. For decades, researchers overlooked the use of mRNA to treat disease – mRNA was considered too unstable for drug development. Starting in the mid-1990s, BioNTech's co-founders (Prof. Ugur Sahin, M.D. and Prof. Özlem Türeci, M.D.) bucked conventional approaches and focused their research on mRNA; over the next few decades, they discovered technological breakthroughs harnessing its potential to treat infectious disease and save lives. Today, BioNTech is recognized as a global leader in mRNA therapeutics, collaborating on cutting-edge technologies with companies like Pfizer, Genentech, Regeneron and others. And BioNTech continues to innovate, spending over $1 billion on mRNA research and development in 2024 alone. BioNTech's pipeline extends well beyond COVID-19 vaccines, seeking to transform the prevention of a wide range of infectious diseases, such as malaria, tuberculosis, and HIV, and treatment of myriad cancers, with a wide range of technologies in addition to mRNA.

4. BioNTech's intellectual property portfolio is critical to protecting and sustaining its current and future research and development. For BioNTech's breakthrough discovery of its streamlined, domain-based COVID-19 vaccine technology, BioNTech sought and obtained a patent protecting its invention: U.S. Patent No. 12,133,899 (the "'899 Patent") (attached hereto as Ex. 1).

5. Moderna's mNEXSPIKE® vaccine exploits BioNTech's streamlined, domain-based COVID-19 vaccine technology claimed and protected by the '899 Patent. Moderna specifically touts ***BioNTech's*** invention as mNEXSPIKE®'s major advancement over its prior vaccine, SPIKEVAX®: mNEXSPIKE® is a "***streamlined*** vaccine design aim[ed] to target key parts of the spike protein rather than the entire spike protein, and at a ***lower dose***." *See, e.g.*, Ex. 2 (Moderna June 3, 2025 Blog) at 2 (emphases added). Just as claimed in the '899 Patent, the domain-based mNEXSPIKE® vaccine contains the RBD (receptor binding domain) of the spike protein, a secretory signal peptide, and a transmembrane domain that mimics the presentation of a full-length spike protein to the immune system. Even though Moderna practices BioNTech's '899 Patent, Moderna has not sought a license from BioNTech. And even though Moderna refers to mNEXSPIKE® as its "Next Generation COVID-19 Vaccine" and touts its immune response at a low dose and improved stability, it has yet to compensate BioNTech for inventing the technology underlying that vaccine. *See* Ex. 3 (Stewart-Jones 2023) at 9 ("[mNEXSPIKE®] shows promise as a vaccine that can elicit robust immune responses at low doses and potentially can be stored considerably longer"); Ex. 4 (SPIKEVAX® label) at 78 ("After thawing, SPIKEVAX may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for ***up to 60 days*** . . . . After thawing, SPIKEVAX may be stored between 8ºC to 25ºC (46ºF to 77ºF) for ***up to 12 hours***.") (emphases added); Ex. 5 (mNEXSPIKE® label) at 33 ("After thawing, MNEXSPIKE may be stored

refrigerated between 2ºC to 8ºC (36ºF to 46ºF) for ***up to 90 days*** . . . . After thawing, MNEXSPIKE may be stored between 8ºC to 25ºC (46ºF to 77ºF) for ***up to 24 hours***.") (emphases added).

6. Moderna has already profited and will continue to profit from its unauthorized and unlicensed use of BioNTech's streamlined, domain-based COVID-19 vaccine technology. Moderna reports $1.168 billion in sales of its COVID-19 vaccines through the third quarter of 2025, with mNEXSPIKE® expected to account for 55% of COVID-19 vaccines sold by Moderna in the 2025-2026 respiratory virus season. Ex. 6 (Moderna Third Quarter 2025 10-Q) at 13, 34; Ex. 7 (Moderna Third Quarter 2025 Financial Results) at 13; *see also* Ex. 13 (Moderna February 13, 2026 Press Release) at 2 ("Total revenue for the full year 2025 was $1.9 billion . . . with the majority generated from COVID vaccine sales . . . .").

7. BioNTech brings this suit so that it can be compensated with monetary damages for Moderna's deliberate and willful infringement of the '899 Patent.

NATURE OF THIS 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 mNEXSPIKE® product.

9. On November 5, 2024, the United States Patent and Trademark Office duly and legally issued the '899 Patent, titled "Coronavirus Vaccine." The '899 Patent lists BioNTech as the assignee. The '899 Patent claims BioNTech's streamlined, domain-based vaccine technology for COVID-19.

10. As alleged herein, Moderna's manufacturing, use, sale, marketing, offer for sale, and/or importation of mNEXSPIKE® directly infringed and continues to directly infringe, actively induced and continues to actively induce infringement of, and contributorily infringed and continues to contributorily infringe, one or more claims of the '899 Patent. At all relevant times,

BioNTech has lawfully owned, and continues to lawfully own, all substantial rights, title, and interest in the ’899 Patent, including the right to sue and recover for past infringement.

THE PARTIES

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

12. Upon information and belief, Defendant ModernaTX is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Technology Square, Suite 300, Cambridge, MA 02139. ModernaTX is a wholly-owned subsidiary of Moderna Inc.

13. Upon information and belief, Defendant Moderna US is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Technology Square, Suite 300, Cambridge, MA 02139. Moderna US is a wholly-owned subsidiary of Moderna Inc.

14. Upon 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.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction in this case pursuant to 28 U.S.C. §§ 1331, 1338(a).

16. This Court has personal jurisdiction over ModernaTX because, *inter alia,* ModernaTX is a Delaware corporation.

17. This Court has personal jurisdiction over Moderna US because, *inter alia*, Moderna US is a Delaware corporation.

18. This Court has personal jurisdiction over Moderna Inc. because, *inter alia*, Moderna Inc. is a Delaware corporation.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400 because Defendants ModernaTX, Moderna US, and Moderna Inc. are entities organized and existing under the laws of the State of Delaware and therefore reside in Delaware for purposes of venue.

20. Defendants ModernaTX, Moderna US, and Moderna Inc. have consented to this Court as a proper venue, and have asserted counterclaims in this Court, in other litigations including in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 22-355-CFC and *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 23-580-CFC, and Defendants Moderna Inc. and ModernaTX have also consented to this Court as a proper venue, and have asserted counterclaims in this Court, in *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al*., C.A. No. 22-252-MSG.

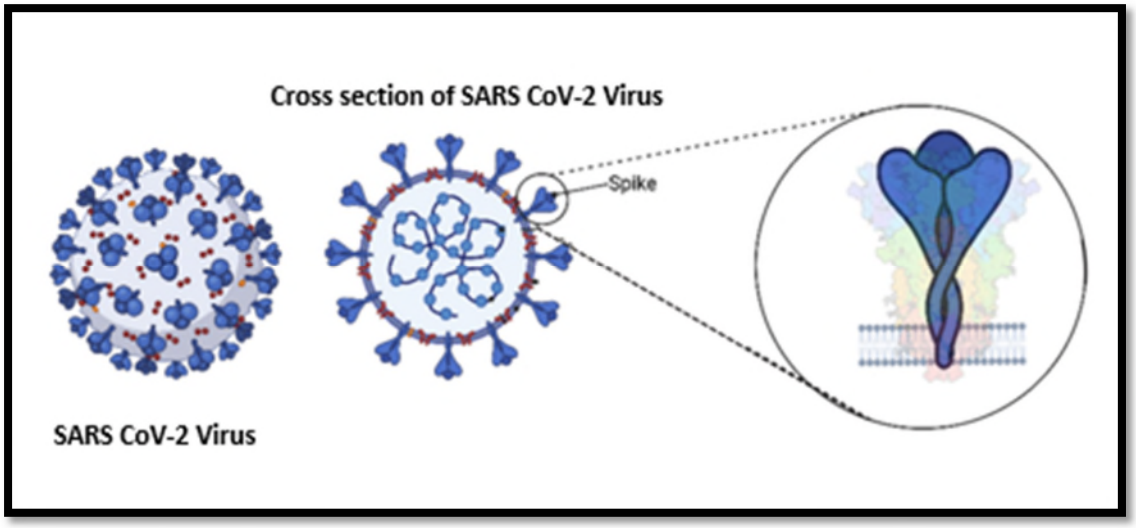
FACTUAL BACKGROUND

I. The SARS-CoV-2 Virus and COVID-19

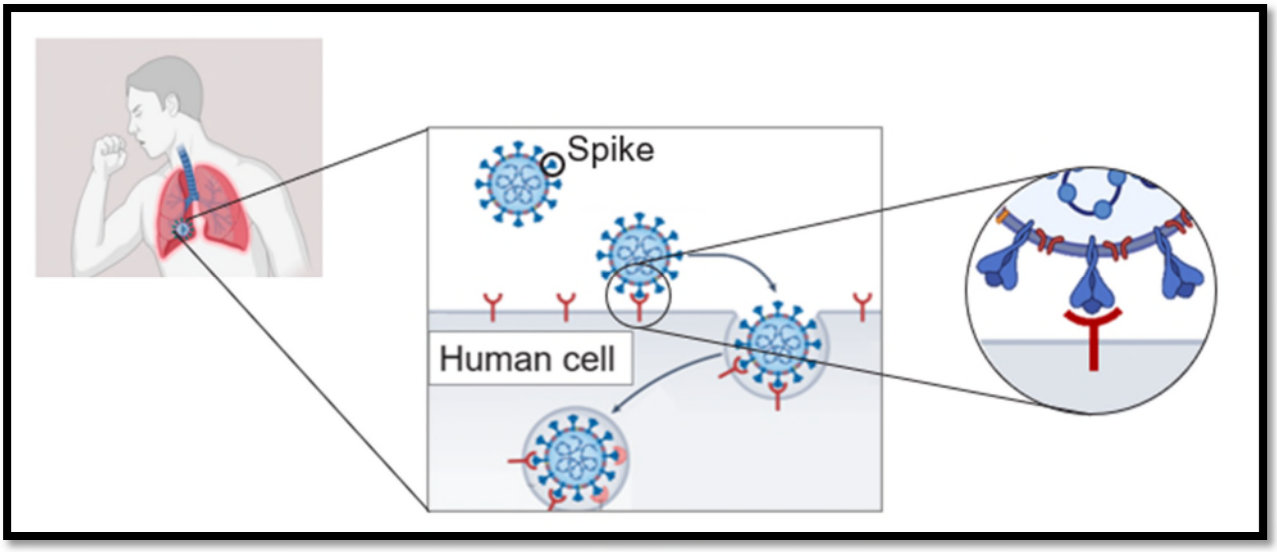
21. COVID-19 triggered an unprecedented global pandemic, causing the deaths of at least three million people globally by the end of 2020 alone.

22. COVID-19 is a disease marked by serious short- and long-term medical complications, and even death. Short-term symptoms include fever, chills, cough, shortness of breath, fatigue, headache, loss of taste and smell, and congestion. Long-term effects include extreme fatigue, "brain fog," fast or irregular heartbeat, sleep problems, and issues with taste or smell.

23. SARS-CoV-2 is the virus that causes COVID-19. Infection by SARS-CoV-2 is mediated by "spike proteins" – spike-like projections covering the surface of the virus.



24. The spike proteins bind to a person's cells, which leads to the virus entering into and infecting the cells.



II. mRNA Vaccines

25. Vaccines safely mimic aspects of an infection by a virus and train the body's immune system to recognize and attack the virus. In this way, the body is protected against subsequent infection by the virus.

26. Prior to the COVID-19 pandemic, approved vaccines included inactivated (killed) virus vaccines (e.g., polio vaccine), live attenuated (weakened) virus vaccines (e.g., chicken pox

vaccine) and protein vaccines (e.g., meningitis B and HPV vaccines). With the outbreak of COVID-19, many companies tried to use those conventional approaches to bring a COVID-19 vaccine to market, but the development was slow, challenging, and in most cases, unsuccessful.

27. mRNA vaccines work differently from conventional vaccines. The mRNA provides instructions for the patient's own cells to ***make*** virus protein that triggers the immune system. In this way, mRNA vaccines rely on the patient's own body to quickly and efficiently make virus protein and generate a strong immune response to protect against future infection. Notably, mRNA vaccines can also be manufactured quickly and at large scale compared to conventional vaccines. That was precisely what was needed to respond to the global COVID-19 pandemic. And yet, as of that time, no company had successfully brought any mRNA vaccine to market.

III. BioNTech's Pioneering Work That Led to COMIRNATY® - the First COVID-19 Vaccine

28. Developing an mRNA vaccine presents significant challenges. mRNA is extremely fragile—it degrades quickly both in the body and in a controlled laboratory setting. Given mRNA's fragility, researchers overlooked mRNA for decades—but not BioNTech's co-founders. Starting in the mid-1990s, Professor Ugur Sahin and Professor Özlem Türeci engaged in foundational research on mRNA technology and mRNA-based medicines. Their goal: creating cutting-edge mRNA technology to develop innovative vaccines and therapeutics to overcome emerging and existing infectious diseases, and to treat cancer. Founded in 2008, BioNTech has realized its founders' vision to translate their mRNA discoveries into life-saving pharmaceutical treatments.

29. The co-founders' foundational discoveries included structural improvements to components of mRNA (*i.e.*, cap, poly-A tail and untranslated regions), making mRNA potent

enough to be used in a pharmaceutical setting. That groundbreaking work culminated in the development of key mRNA platforms in use today at BioNTech.

30. By late 2019, when COVID-19 struck, BioNTech was uniquely situated to rapidly develop a COVID-19 vaccine based on its decades' worth of research and development and innovation in the field of mRNA technology.

31. In the race to secure a safe and effective vaccine against COVID-19, BioNTech scientists—along with their collaborator, Pfizer, in an initiative named "Project Lightspeed"—targeted the mRNA to make the complete, full-length spike protein of the SARS-CoV-2 virus. By fall 2020, BioNTech and Pfizer developed their full-length spike COVID-19 vaccine—the fastest vaccine development against a new pathogen in medical history, and proof of concept for mRNA as a new drug class in medicine.

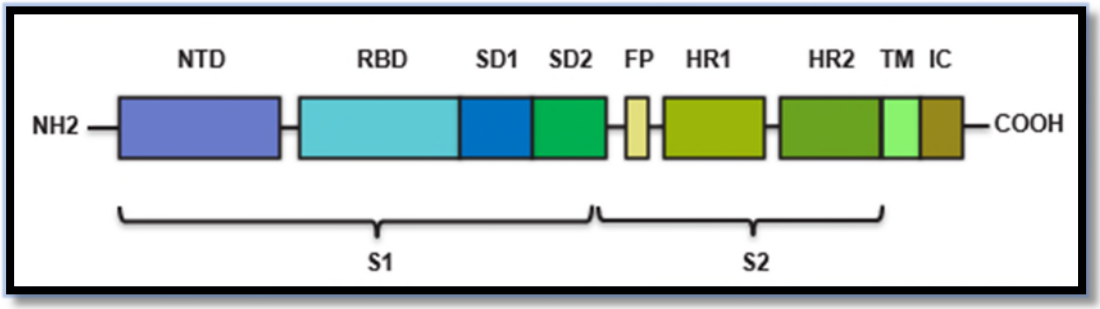
32. In December 2020, less than a year after the first reported case of COVID-19, FDA granted Emergency Use Authorization to BioNTech's and Pfizer's COVID-19 vaccine in the United States. BioNTech's and Pfizer's COMIRNATY® vaccine won the global race as the first COVID-19 vaccine to gain FDA approval.

33. An immediate global success, COMIRNATY® stemmed the tide of COVID-19 and changed the course of the pandemic. To date, more than five billion doses of COMIRNATY® have been distributed globally. It is estimated that COVID-19 vaccines, including COMIRNATY®, have saved at least 2.5 million lives – and that number grows with each passing year. BioNTech's achievements and innovation – past, present, and future – would not be possible without its dedicated investment in research and development. Since 2020, BioNTech has invested over $5 billion in mRNA research and development with over $1 billion of that budget directed to COVID-19 research alone.

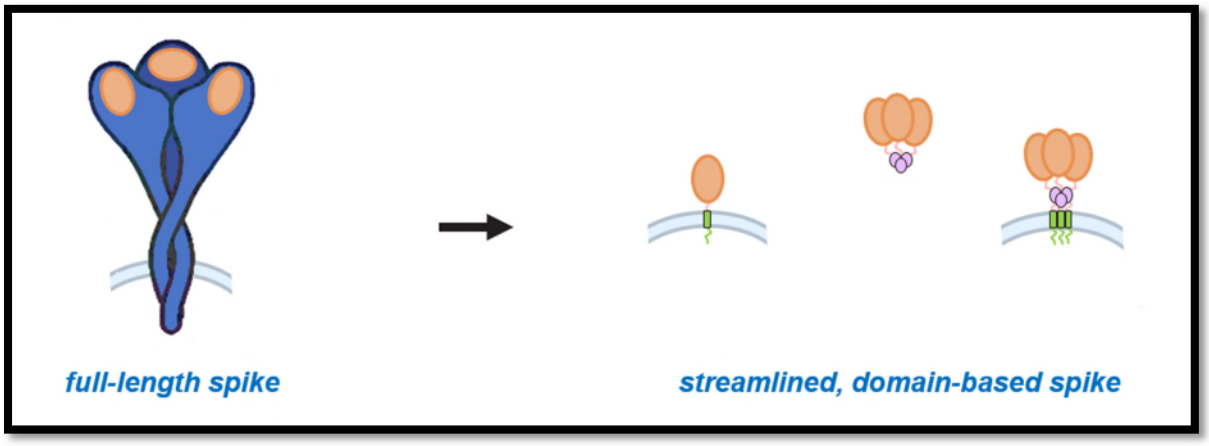
IV. The ’899 Patent: BioNTech’s Streamlined, Domain-Based COVID-19 Vaccine Technology

34. BioNTech prioritized the development of COMIRNATY® to combat the COVID-19 pandemic. But even at the outset of its pandemic efforts, BioNTech conceived of alternative advanced technologies.

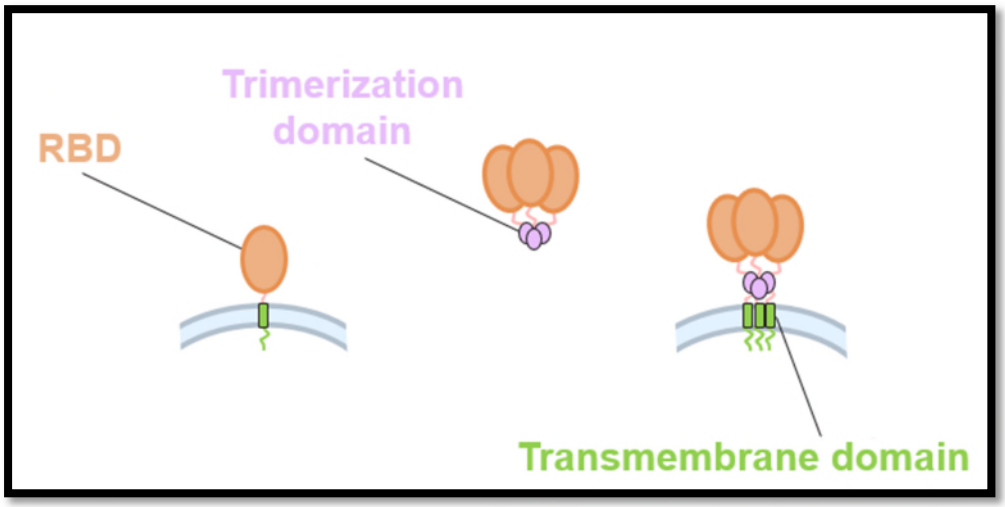
35. The full-length spike protein (made by a patient’s cells after vaccination with COMIRNATY®) is depicted below, with two distinct subunits (S1 and S2), and multiple distinct regions (domains) within each subunit.



36. BioNTech scientists surprisingly discovered that mRNA for a streamlined, domain-based vaccine triggers an equally strong immune response, as compared to mRNA for the full-length spike protein.



37. BioNTech's streamlined, domain-based vaccine includes mRNA to make the RBD of that spike protein (colored orange above), along with a secretory signal peptide to shuttle the RBD outside the cell for detection by the immune system. So that presentation of the streamlined spike protein to the immune system is similar to that of the full-length spike protein, it also includes mRNA to make a transmembrane domain and/or a trimerization domain. The transmembrane domain acts as the anchor for the RBD and holds the RBD on the cell surface; the trimerization domain acts as glue to bundle three RBDs together, similar to how the spike proteins bundle together on the virus. Taken together, the mRNA in BioNTech's domain-based vaccine is a fraction of the size required for making the full-length spike protein. As such, the domain-based vaccine can be given to patients at a ***lower dose*** and is ***more stable*** during storage and transport.



38. BioNTech was the first to demonstrate the promise of streamlined, domain-based COVID-19 vaccines. By way of example, the '899 Patent discloses that the "provided mRNA constructs that encode less than a full-length SARS-CoV-2 S protein, and particularly those that encode at least an RBD portion of such SARS-CoV-2 S protein may be particularly useful and/or effective for use as or in an immunogenic composition (e.g., a vaccine)[.]" Ex. 1 at 14:23-28.

39. The ’899 Patent provides *in vivo* mouse data reporting immunogenicity for an mRNA vaccine based on the full-length spike protein. *Id*. at Fig. 13. The ’899 Patent also provides data for exemplary streamlined, domain-based mRNA vaccines: BNT162b1 contains the RBD, as well as a signal peptide and a trimerization domain. BNT162b3 adds a transmembrane domain. *Id*. at Fig. 7, Fig. 32. The data in the ’899 Patent demonstrates that domain-based mRNA vaccines provide comparable immunogenicity to vaccines featuring full-length spike protein.

40. The ’899 Patent further provides data showing that the exemplary BNT162b1 streamlined, domain-based mRNA vaccine “is protective in non-human primates.” *Id*. at 368:56-59; *see also id*. at 396:18-22 (“We demonstrate that BNT162b1 . . . is highly immunogenic in mice and rhesus macaques and limits infection in rhesus macaques challenged with infectious SARS-CoV-2.”). And consistent with the prior findings in animal studies, “[r]obust immunogenicity was observed after vaccination with BNT162b1” in Phase 1/2 clinical trial in healthy adults. *Id*. at 372:44-45**.** “The data overall show similar neutralizing antibody responses post-dose 2 between BNT162b1 and BNT162b2 [mRNA for full-length spike protein].” *Id*. at 382:20-21; *see also id.* at 382:61-63 (“the immune response data are similar between the 2 candidates”).

41. Notably, the ’899 Patent acknowledges the potential pitfalls of a novel streamlined, domain-based mRNA vaccine, *e.g.*: “BNT162b1 encodes a relatively small RBD immunogen, which might induce a narrower spectrum of neutralizing antibodies that are less robust to potential antigenic drift of SARS-CoV-2, compared with BNT162b2, which encodes a full-length spike immunogen.” *Id*. at 499:66-500:4; *see also id*. at 381:29-31 (“A purely RBD-directed immunity might be considered prone to escape of the virus by single amino acid changes in this small domain.”). But BioNTech’s rigorous testing unexpectedly demonstrates otherwise—domain-based vaccines neutralized viruses. *Id*. at 381:31-35 (“However, neutralisation of 17 pseudo-typed

viruses, 16 of which enter cells using a spike with a different RBD variant found in circulating strains and one of which uses the dominant spike variant D614G, alleviates this potential concern.").

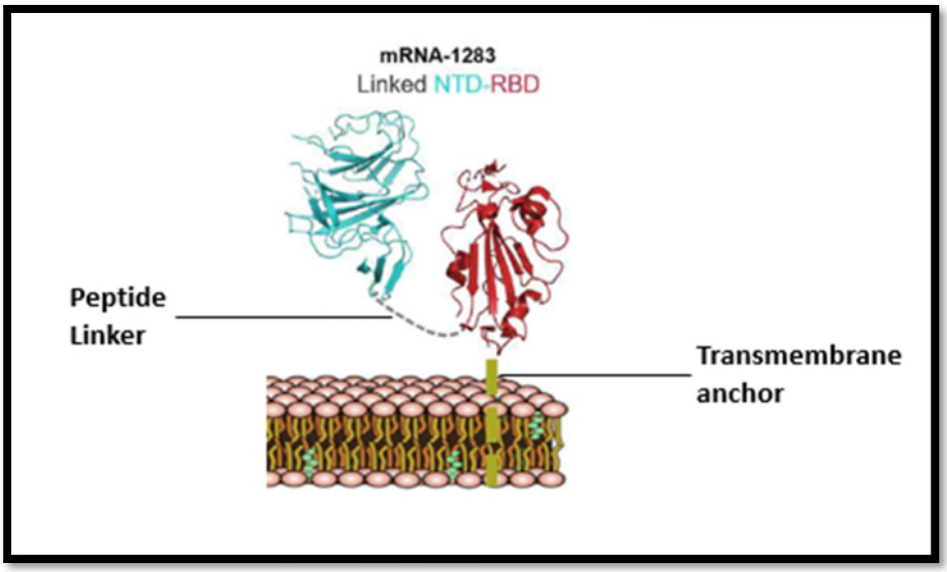
42. Sole independent claim 1 of the '899 Patent reflects BioNTech's streamlined, domain-based mRNA vaccine technology for COVID-19. It recites a pharmaceutical composition with RNA featuring an RBD, a secretory signal, and a transmembrane and/or trimerization domain:

> A pharmaceutical composition comprising a RNA that:
>
> (i) includes modified uridines in place of all uridines, and
>
> (ii) comprises a nucleotide sequence that encodes a polypeptide, wherein the polypeptide comprises:
>
> (a) one or more fragments of a SARS-CoV-2 Spike (S) protein, wherein ***one of the fragments comprise a receptor binding domain (RBD)***,
>
> (b) ***a secretory signal***; and
>
> (c) ***one or more additional domains selected from a trimerization domain, a transmembrane domain, and a combination thereof***;
>
> wherein the RBD is linked to one of the additional domains via a linker, and wherein the linker comprises a GS linker.

V. Moderna's mNEXSPIKE® (mRNA-1283) Vaccine Infringes the '899 Patent

43. On March 15, 2021, Moderna announced it was advancing a "Next Generation COVID-19 Vaccine" referred to as mRNA-1283. Ex. 8 (Moderna March 15, 2021 Press Release) at 1. On May 30, 2025, the FDA approved mRNA-1283 under the brand name mNEXSPIKE® for use in adults 65 years or older and individuals aged 12-64 years old with at least one comorbidity. Ex. 9 (FDA Approval Letter).

44. Upon information and belief, mNEXSPIKE®, depicted below, leverages BioNTech's claimed invention of the '899 Patent. Ex. 3 (Stewart-Jones 2023) at Fig. 1 (annotated).



45. mNEXSPIKE® is a "pharmaceutical composition comprising a RNA that . . . includes modified uridines in place of all uridines." *See* Ex. 5 (mNEXSPIKE® label) at 20 ("MNEXSPIKE (COVID-19 Vaccine, mRNA) . . . contains 10 mcg nucleoside-modified messenger RNA (mRNA) . . ."); Ex. 10 (May 30, 2025 Summary Basis for Regulatory Action) at 6 ("The mRNA is transcribed using N1-methyl-pseudoruridine instead of uridine nucleoside . . .").

46. mNEXSPIKE®'s "nucleotide sequence . . . encodes a polypeptide, wherein the polypeptide comprises: one or more fragments of a SARS-CoV-2 Spike (S) protein, wherein one of the fragments comprise a receptor binding domain (RBD)" and "secretory signal." In particular, mNEXSPIKE® contains mRNA encoding the RBD of the SARS-CoV-2 spike protein, as well as the N-terminal domain ("NTD") that contains a secretory signal peptide. *See* Ex. 5 (mNEXSPIKE® label) at 20 ("Each 0.2 mL dose of MNEXSPIKE (2025-2026 Formula) contains 10 mcg nucleoside-modified messenger RNA (mRNA) encoding the N-terminal domain (NTD)

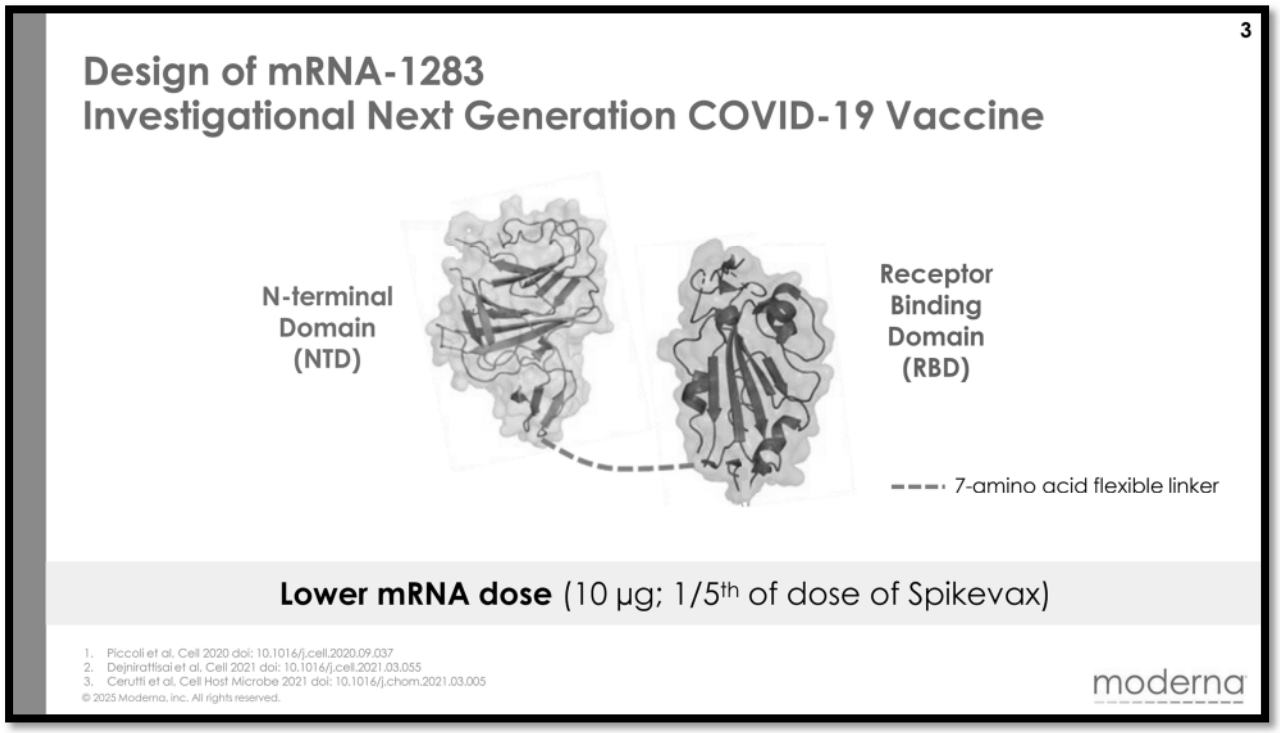
and receptor-binding domain (RBD) of the Spike glycoprotein of the SARS-CoV-2 Omicron variant sublineage LP.8.1."); Ex. 10 **(**May 30, 2025 Summary Basis for Regulatory Action) at 3 ("MNEXSPIKE . . . contains a nucleoside-modified *in vitro*-transcribed messenger RNA (mRNA) encoding the N-terminal domain (NTD) and receptor binding domain (RBD) of the S protein . . ."); *see, e.g.*, Ex. 11 (U.S. Patent App. No. 18/282,097) at [0029], [0527], Table 9A, Table 9B.

47. mNEXSPIKE® further contains "one or more additional domains"—*i.e.*, "a transmembrane domain"—and "the RBD is linked to one of the additional domains [*i.e.*, to the transmembrane domain] via a linker, and wherein the linker comprises a GS linker." *See* Ex. 10 (May 30, 2025 Summary Basis for Regulatory Action) at 6 ("The linked NTD-RBD polypeptide is attached via a [redacted in original] linker to a 23-aa influenza hemagglutinin transmembrane domain (HATM), which anchors the linked NTD-RBD antigen to the host cell membrane."); *see, e.g.*, Ex. 11 (U.S. Patent App. No. 18/282,097) at [0029], [0527], Table 9A, Table 9B.

48. In its marketing materials and its presentations to regulatory agencies, Moderna touts that mNEXSPIKE®'s "***streamlined*** vaccine design aims to target key parts of the spike protein rather than the entire spike protein, and at a lower dose." *See, e.g.*, Ex. 2 (Moderna June 3, 2025 Blog) at 2 (emphasis added).

49. Likewise, in a presentation to the Advisory Committee on Immunization Practices—who develop vaccine recommendations in the US—Moderna called mRNA-1283 (*i.e.*,

mNEXSPIKE®) a "Next Generation COVID-19 Vaccine" with a "Lower mRNA dose" that could be given at "1/5th" of the dose of its prior vaccine ("Spikevax"):



Ex. 12 (Moderna April 2025 presentation) at 3.

50. Moderna further stressed the comparable immunogenicity of mNEXSPIKE® compared to its prior vaccine:

Id. at 18.

51. On information and belief, Moderna has had knowledge of and specific notice of its infringement of the '899 Patent by the manufacture and sale of mNEXSPIKE® at least since November 5, 2024, the issuance date of the '899 Patent.

52. Moderna and BioNTech have an extensive history of engaging in patent disputes. *See, e.g., ModernaTX, Inc. et al. v. Pfizer Inc., et al.*, C.A. No. 22-11378 (D. Mass.); *BioNTech SE et al. v. ModernaTX, Inc.*, IPR2023-01358 (P.T.A.B. Aug. 28, 2023); *ModernaTX, Inc. et al., v. Pfizer Inc., et al.*, C.A. No. 23-00154 (E.D. Pa.); *ModernaTX, Inc. v. BioNTech SE*, C.A. No. 25-01757 (Fed. Cir.). On information and belief, Moderna routinely monitors BioNTech's patent applications on COVID-19 mRNA vaccines, including Application No. 17/988,742, which issued as the '899 Patent.

53. At no point did Moderna pursue or acquire a license from BioNTech to the '899 Patent.

54. Moderna stands to profit significantly from its infringement of the '899 Patent without permission. Moderna reports $1.168 billion in sales of its COVID-19 vaccines, through the third quarter of 2025, with mNEXSPIKE® accounting for 55% of COVID-19 vaccines sold by Moderna in the 2025-2026 respiratory virus season. Ex. 6 (Moderna Third Quarter 2025 10-Q) at 13, 34; Ex. 7 (Moderna Third Quarter 2025 Financial Results) at 13; *see also* Ex. 13 (Moderna February 13, 2026 Press Release) at 2 ("Total revenue for the full year 2025 was $1.9 billion . . . with the majority generated from COVID vaccine sales . . . .").

55. BioNTech filed this lawsuit to be compensated for Moderna's continued infringement of BioNTech's patented streamlined, domain-based COVID-19 vaccine technology. Such compensation will allow BioNTech to reinvest in its mRNA platform, so that it can continue to discover cutting-edge vaccines to combat infectious disease and save lives globally.

COUNT ONE: INFRINGEMENT OF THE '899 PATENT

56. BioNTech incorporates by reference the allegations set forth in paragraphs 1-55 as though fully set forth herein.

57. Upon information and belief, Moderna has directly infringed and continues to directly infringe one or more claims of the ’899 Patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing mNEXSPIKE® in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

58. Upon information and belief, Moderna has indirectly infringed and continues to indirectly infringe one or more claims of the ’899 Patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(b). Moderna has actively induced third-party manufacturers to directly infringe one or more claims of the ’899 Patent by making mNEXSPIKE® within the United States without authority or license to do so, during the term of the ’899 Patent.

59. In addition or in the alternative, Moderna has infringed, and continues to infringe, one or more claims of the ’899 Patent by actively inducing healthcare practitioners to directly infringe one or more claims of the ’899 Patent by administering mNEXSPIKE® to patients within the United States, in accordance with the instructions in Moderna’s labeling and prescribing information, and therefore with FDA authorized and/or approved uses, without authority or license to do so during the term of the ’899 Patent, in violation of 35 U.S.C. § 271(b). Ex. 5 (mNEXSPIKE® label) at 3 (“Administer mNEXSPIKE® intramuscularly.”).

60. Upon information and belief, Moderna has contributorily infringed, and continues to contributorily infringe, one or more claims of the ’899 Patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents, by offering to sell or selling within the United States, and/or importing into the United States, components of mNEXSPIKE® (including the mRNA and/or lipid particles), without any authority or license to do so, during the term of the ’899 Patent, knowing that each constitutes a material part of the inventions of, and are especially made or

adapted to infringe, at least one claim of the ’899 Patent, and knowing that such components are not staple articles or commodities of commerce suitable for substantial non-infringing use.

61. Upon information and belief, Moderna has infringed, and will continue to infringe, one or more claims of the ’899 Patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), including by supplying the global market for mNEXSPIKE® with components, such as mRNA, manufactured in the United States.

62. As explained *supra*, mNEXSPIKE® satisfies each and every element of one or more claims of the ’899 Patent, including at least independent claim 1. Moderna’s actions with respect to mNEXSPIKE® have infringed, induced infringement of, and/or contributorily infringed at least independent claim 1 of the ’899 Patent.

63. Moderna’s infringement of the ’899 Patent has been willful. On information and belief, Moderna chose to market and sell mNEXSPIKE® knowing that it practiced the technology disclosed and claimed in the ’899 Patent. On information and belief, Moderna has continued to use the invention claimed in the ’899 Patent in deliberate disregard for BioNTech’s patent rights.

64. BioNTech has suffered damages as a result of Moderna’s infringement of the ’899 Patent. BioNTech is entitled to an award of compensatory damages, including reasonable royalties and/or lost profits, for Moderna’s infringement of the ’899 Patent.

65. Moderna has engaged in egregious infringement behavior with respect to the ’899 Patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

66. Moderna’s conduct with respect to the ’899 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, BioNTech prays for judgment as follows:

A. That Moderna has directly infringed, either literally or under the doctrine of equivalents, at least one claim of the ’899 Patent;

B. That Moderna has induced infringement of, either literally or under the doctrine of equivalents, at least one claim of the ’899 Patent;

C. That Moderna has contributorily infringed, either literally or under the doctrine of equivalents, at least one claim of the ’899 Patent;

D. That Moderna’s infringement of at least one claim of the ’899 Patent has been willful;

E. That BioNTech be awarded all damages adequate to compensate it for Moderna’s infringement of the ’899 Patent, such damages to be determined by a jury, and if necessary to adequately compensate BioNTech for the infringement, an accounting, and that such damages be trebled and awarded to BioNTech with pre- and post-judgment interest;

F. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that BioNTech be awarded the attorneys’ fees, costs, and expenses incurred in connection with this action; and

G. That BioNTech be awarded such other and further relief at law or equity as this Court deems just and proper.

DEMAND FOR JURY TRIAL

BioNTech hereby demands a trial by jury on all issues so triable.

Dated: February 19, 2026

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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