Receipt number AUSFCC-10990503

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

MNG BIO, LLC, Plaintiff, vs. THE UNITED STATES OF AMERICA, Defendant.	26-12 C

COMPLAINT FOR PATENT INFRINGEMENT UNDER 28 U.S.C. § 1498(a)

Plaintiff, mNG Bio, LLC ("mNG Bio"), files this action under 28 U.S.C. § 1498(a), by and through its undersigned counsel, for reasonable and entire compensation unauthorized and unlicensed use of the claimed inventions disclosed in United States Patent No. 10,221,221 ("the '221 Patent") by and for the Defendant United States of America (the "United States," "Government" or "Defendant").

NATURE OF THE ACTION

1. This is an action under 28 U.S.C. § 1498(a) for the unlicensed use, by and for the United States, of inventions described in and covered by the '221 Patent owned by mNG Bio.

2. The Government, acting through the Department of Health and Human Services ("HHS") and its component, the Biomedical Advanced Research and Development Authority ("BARDA"), entered into contractual relationships and purchase orders with ModernaTX, Inc. ("Moderna") relating to the COVID vaccines, including without limit Contract No. 75A5012C000034 titled "Development of an mRNA Vaccine for SARS-CoV-2" (the "C-034 Contract").

3. Under the C-034 Contract, the Government directed, funded, and accepted the advanced development, clinical testing, scale-up, scale-out, validation, and domestic manufacture

of Moderna's mRNA-1273 mRNA vaccine for SARS-CoV-2 ("Spikevax"), including development of a manufacturing capacity of at least 100 million doses by 2021.

4. In performing and benefitting from the C-034 Contract, the Government has used and, on information and belief, claims it has caused its contractor and subcontractors to use inventions described in and covered by the claims of the '221 Patent without license or lawful right, thereby rendering the United States liable to Plaintiff for "reasonable and entire compensation" under 28 U.S.C. § 1498(a).

5. As further alleged herein, Defendant and/or Moderna made, and upon information and belief are continuing to make, pre-clinical, clinical, and post-clinical use of mNeonGreen in a neutralization assay, which included and includes use of mNeonGreen to (a) rapidly winnow an unmanageable number of Moderna vaccine candidates down to vaccine candidates; (b) select Moderna's mRNA-1273 COVID-19 vaccine candidate; (c) conduct preclinical and Phase I-III clinical trials of Moderna's vaccine; (d) secure rapid FDA authorization for distribution of Moderna's commercial vaccine; (e) validate Moderna's commercial vaccine; and (f) further test Moderna's commercial vaccine, for example, against new COVID-19 strains.

THE PARTIES

6. mNG Bio is the owner by assignment of the revolutionary mNeonGreen fluorescent protein technology, referred to also as "mNG", and all related inventions and patent rights, including the '221 Patent, as assignee of Allele Biotechnology and Pharmaceuticals, Inc. Hereinafter, mNG Bio, including mNG Bio's assignors and predecessors-in-interest, including Allele, are collectively referred to as "Plaintiff".

7. mNG Bio is a Texas Limited Liability Company, with its principal place of business being 6404 Nancy Ridge Drive, San Diego, California 92121.

8. mNG Bio's predecessor-in-interest, Allele, was founded in 1999 and is recognized as a leading developer of technologies for clinical and therapeutic use. These include research tools for inducing discoveries in a variety of spaces in the life-sciences, including but not limited to investigation, winnowing, and validation of drug and vaccine candidates, as in the ever-changing race to prevent, treat, and cure COVID-19.

9. Neither mNG Bio nor any predecessor-in-interest had more than 500 employees at any time during the 5-year period preceding the uses alleged herein and asserted herein, including any use or manufacture of its invention, as embodied in the Accused Products, by or for the United States

10. Defendant is the United States of America, acting through its various agencies, including by way of example, and not limitation, the U.S. Department of Health & Human Services ("HHS"), the Administration for Strategic Preparedness and Response ("ASPR"), the Biomedical Advanced Research and Development Authority ("BARDA"), the National Institute of Allergy and Infectious Diseases ("NIAID"), the National Institutes of Health ("NIH") and any other departments, agencies, and instrumentalities acting "for the Government" with its authorization and consent that used or benefited from the C-034 Contract or from products, data, or services supplied thereunder.

JURISDICTION AND VENUE

11. Moderna and the Government have both taken the position in other COVID-related litigation, including through a Statement of Interest filed by the United States in the *Arbutus v. Moderna* litigation (*Arbutus Biopharma Corp. v. Moderna, Inc.*, No. 1:22-cv-00252 (D. Del.) (D.I. 49)) ("*Arbutus* Statement of Interest"), that the United States authorized and consented to a wide range of infringing activities in connection with Moderna's COVID-19 vaccine activities and

Spikevax, and that Moderna's actions were for the United States. This Complaint is filed in the alternative to liability directly against Moderna, if and to the extent that this or any other court or tribunal determines that these assertions are correct, and to the extent these assertions are accepted or shown. To be clear, no Court has accepted these assertions, and they have been rejected to-date, and this suit is brought expressly reserving mNG Bio's primary contention that Moderna is liable for the acts of infringement concerning or relating to Spikevax or any Moderna-related COVID vaccine.

12. Hence, this lawsuit is brought in the alternative to liability against Moderna, and without waiving or admitting any lack of liability by Moderna directly for its infringing actions or the actions of others for whom Moderna would be liable but for the workings of Section 1498.

13. Plaintiff expressly reserves its position on which of Moderna and/or the United States are ultimately to be liable for each of the infringing acts, and each allegation as to the acts being for the United States and with its authorization and consent is intended and is to be understood as being made on information and belief based on Moderna and the Government's public positions, and made in the alternative subject to full discovery and resolution for or against either, for purposes of this Action only and without limit on a suit directly against Moderna based on its direct liability.

14. On information and belief, the jurisdiction and venue for this action in this Court arise under 28 U.S.C. § 1498(a) and 28 U.S.C. § 1491(a)(1). Section 1498(a) provides that whenever an invention covered by a United States patent "is used or manufactured by or for the United States without license of the owner thereof or lawful right," the owner's remedy shall be by action against the United States in this Court for reasonable and entire compensation.

15. Section 1498(a) further provides that the use or manufacture of a patented invention "by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."

16. On information and belief, based on the Government's Statement of Interest in *Arbutus v. Moderna* and related positions, the Government takes the position and assertion that its contractual arrangements with Moderna under the C-034 Contract, and the inclusion of the Federal Acquisition Regulation ("FAR") clause 52.227-1 ("Authorization and Consent") in that Contract, constitutes the Government's express authorization and consent for purposes of 28 U.S.C. § 1498(a).

17. Venue is proper in this Court for any action brought under 28 U.S.C. § 1498(a), including this Action.

PATENT IN SUIT

18. Nathan C. Shaner, Gerard G. Lambert, Yuhui Ni, and Jiwu Wang are joint inventors (collectively, "Inventors") of the '221 Patent, entitled "Monomeric yellow-green fluorescent protein from cephalochordate" and which issued on March 5, 2019. A true and correct copy of the '221 Patent is attached hereto as Exhibit A.

19. On April 28, 2014, the Inventors assigned the '221 Patent to Allele. A true and correct copy of the assignment is attached hereto as Exhibit B.

20. Prior to the filing of this Action, on January 6, 2026, Allele assigned the '221 Patent to mNG Bio. A true and correct copy of the assignment is attached hereto as Exhibit C.

21. mNG Bio is the owner by assignment of all right, title, and interest in and to the ’221 Patent, including the right to enforce the ’221 Patent and collect damages for all past and future infringement of the patent.

22. The ’221 Patent is valid, enforceable, and was in full force and effect at all relevant times.

23. The ’221 Patent will expire on or about December 8, 2033, if all maintenance fees are timely paid (*i.e.*, in approximately 8 years).

24. The ’221 Patent (and the mNeonGreen technology covered by it) is not a patented invention subject to review by the FDA or any Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. As a result, the ’221 Patent is also ineligible for patent term extension under 35 U.S.C. § 156.

25. Although the invention(s) set forth in the ’221 Patent are best described by its claims, the claims of the ’221 Patent are generally directed to isolated nucleic acid sequences encoding a monomeric green/yellow fluorescent proteins and fragments and derivatives thereof.

26. The claims of the ’221 Patent encompass Plaintiff’s mNeonGreen product, which is a fluorescent protein used as a biological tag in genetic engineering work. mNeonGreen is a monomeric protein that was derived from a tetrameric wild-type yellow-green fluorescent protein isolated from the cephalochordate Branchiostoma lanceolatum (a “lanYFP”). In nature, two lanYFP monomers form a dimer and two dimers form an “obligate” (mandatory) tetramer. When exposed to certain wavelengths of light, the lanYFP tetramer will brightly fluoresce. However, the tetramer is large and often unsuitable as a fluorescent tag. The engineered mNeonGreen monomer is among the brightest and most stable monomeric fluorescent reporter proteins currently known. As described in the patent, the mNeonGreen proteins “have exceptional utility as a biomarker

and/or protein fusion tag and have shown great usefulness as a FRET acceptor for the newest generation of cyan fluorescent proteins."

27. The resulting mNeonGreen, synthetic lanYFP fluorescent protein described and claimed in the '221 Patent is widely recognized as a breakthrough, is used throughout the industry, and has been called the "King of fluorescent proteins." Applications involving infectious viruses, such as COVID-19 vaccine work, are high concentration environments well suited for mNeonGreen, as broadly recognized. *See*, Xie, et al., An Infectious cDNA Clone of SARS-CoV-2, Cell Host & Microbe 27, 841-848 (May 13, 2020) and Muruato, et al., A High-throughput Neutralizing Antibody Assay for COVID-19 Diagnosis and Vaccine Evaluation, Nat Commun 2020; 11(1):4059 https://doi.org/10.1101/2020.05.21.109546 (May 22, 2020), true and correct copies of each attached hereto as Exhibit D (hereafter, "Cell Host Article") and Exhibit E (hereafter, "Muruato"), respectively.

28. The commercial protein of mNeonGreen corresponds to SEQ ID NO:1 of the patent (claims 1, 2, 3, 4 and 5). Plaintiff used the nucleic acid of SEQ ID NO:2 (claim 3) to express this protein.

29. Prior to the COVID-19 crisis, Plaintiff had already developed the revolutionary mNeonGreen. mNeonGreen belongs to mNG Bio, as does the '221 Patent covering the exclusive right to use mNeonGreen. mNeonGreen is an artificial fluorescent that Plaintiff painstakingly developed over many years through the genius of its inventors. It is the world's brightest monomeric fluorescent protein, dubbed by third-party industry veterans as the "King of fluorescent proteins." A prominent university used mNeonGreen to make the "gold standard" COVID-19 assay for effectively testing against vaccine candidates, which was used extensively for

unauthorized commercial testing and development in connection with Moderna's COVID vaccines, including Spikevax.

FACTUAL BACKGROUND

a. mNeonGreen Background

30. Plaintiff's mNeonGreen is a pioneering breakthrough in fluorescent protein technology, the latest in its history of innovation. mNeonGreen is a broad and flexible discovery-inducing innovation in biotechnology and medicine, allowing scientists and researchers to see biological subjects quickly, clearly, and with a new level of certainty—something of increased importance for therapeutics targeting COVID-19. mNeonGreen's versatility provides a wide array of uses, for example, high throughput studies in the tracking of proteins in a cell to research cell development in growing worms, a use with no relationship to veterinary or medical advancements.

31. mNeonGreen is a broad and flexible discovery-inducing innovation in biotechnology and medicine, allowing scientists and researchers to see what could not as clearly and quickly be seen before—something of increased importance for therapeutics targeting COVID-19.

32. In practice, mNeonGreen facilitates quick, targeted, and incredibly precise research in many different fields, including during investigation and winnowing of vaccine candidates to treat COVID-19, as well as post-authorization marketing and research for independent commercial purposes. The fluorescent-tagged therapeutic proteins associated with mNeonGreen are constructed to determine receptor expression and dynamics with therapeutic outcome for high-throughput systems, as was the case in the present global race for a vaccine to COVID-19. A key hurdle in developing a vaccine for infectious diseases, such as the novel coronavirus of COVID-19, is narrowing many candidates to a manageable amount by determining therapeutic outcome of

potential drug candidates against COVID-19 strains, something which mNeonGreen readily solves.

33. Where there is a race against time, fluorescent protein alternatives are simply a less desirable option, due to their inferior photophysical and biological properties. mNeonGreen proved critical to Moderna's COVID-19 vaccine development for narrowing many candidates to a manageable amount, its Phase I, II, and III trial success, authorization by the FDA (in addition to uses totally unrelated to and apart from the United States), and on information and belief, obtaining marketing data as to effectiveness against other strains of the COVID-19 virus. This research tool was even more critical in a global pandemic where the need for a vaccine to save lives is never more crucial. Neither the Government nor Moderna on its behalf never sought a license with Plaintiff or even contacted Plaintiff in connection with the infringing uses.

b. The C-034 Contract and the "urgent need to rapidly develop vaccines"

34. In March 2020, the United States declared a national emergency in response to the COVID-19 pandemic. Shortly thereafter, the Government initiated "Operation Warp Speed," a "whole of nation effort" to support development, manufacture, and deployment of vaccines and other countermeasures.

35. On April 16, 2020, the United States acting through Department of Health and Human Services ("HHS"), the Biomedical Advanced Research and Development Authority ("BARDA"), and the Administration for Strategic Preparedness and Response ("ASPR") awarded Contract No. 75A50120C00034 to ModernaTX, Inc. ("Moderna"), then titled "Development of an mRNA Vaccine for SARS-CoV-2" (the "C-034 Contract"). (Exhibit F).

36. The C-034 Contract was awarded on an "other than full and open competition" basis (Ex. F at 1, ¶13 identifying 41 U.S.C. 3304(a)) in view of the urgent national emergency posed by the COVID-19 pandemic.

37. The C-034 Contract identified a contract award ceiling of $430,298,520.00.

38. The C-034 Contract required that Moderna perform on an accelerated, emergency-driven schedule, "[t]he project shall be accomplished on an **accelerated timeline**, with parallel activity WBS, **aggressive** manufacturing scale-up, risk management, and **taking advantage of any regulatory flexibilities**." *Id*. at Part I, Sec. B1, p. 4 (emphasis added).

39. The C-034 Contract was expressly identified as an accelerated program: "B.4.8 Advanced Understanding: Milestone Review: the development of a COVID-19 vaccine is an accelerated program. Progress for vaccine development **will be continually assessed for go/no go decisions** so that funding is properly allocated across the MCM development effort to those candidates most likely to be available in time to impact the COVID-19 public health emergency. **Formal 'go/no go' assessments will be made at multiple points**…" *Id*. at Section B.4.8, p. 5-6 (emphasis added).

40. The C-034 Contract stated that the COVID- 19 outbreak created a "national emergency" (Section B.4.11, p. 6–7) and therefore there was "**an urgent need to rapidly develop vaccines** to prevent COVID-19 disease. Developing and delivering a vaccine for highly transmissible, emerging diseases such as the SAR-CoV-2 virus **requires breaking from traditional approaches. It requires parallel development activities, aggressive manufacturing scale-up, risk management and implementation of regulatory flexibilities.**" *Id.* at Sec. C.1, Background, p. 8–9 (emphasis added).

41. The C-034 Contract required Moderna to, *inter alia*, "develop a mRNA vaccine to licensure for the prevention of COVID-19. The project will entail pre-clinical and Phase 2 and Phase 3 clinical studies sufficient to demonstrate the safety and efficacy of the proposed vaccine(s); CMC development, scale-up, scale-out and validation of manufacturing capacities, including bulk drug substance and fill and finished drug product, with a capacity of 100 million doses by 2021 and all program management and regulatory activities necessary to achieve FDA licensure of the vaccine." *Id.* at 4.

42. The C-034 Contract required that Moderna "perform all work required to support the advanced development, scale-up manufacturing, and FDA licensure of their lead SARS-CoV-2 vaccine candidate(s). This work includes preclinical development of mRNA vaccines to demonstrate safety and efficacy against COVID-19, mRNA vaccine process and manufacturing scale-up development, product lot release assay development and process validation, production of clinical material and consistency lots clinical evaluation studies for safety, immunogenicity and efficacy; and fill/finish capacity evaluation, expansion, and validation." *Id*. at 9.

43. The C-034 Contract further required that Moderna "Establish a Surrogate of Protection (WBS 1.3.3.2) ***The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay***. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay." *Id*. at 11 (emphasis added).

c. Government's Relationship to the Vaccine Product

44. The C-034 states: "ownership and applicable usage rights of all materials/product (e.g., vaccines, validated lots) manufactured and/or acquired with Government funds, throughout

the Contract's entire period of performance, shall be retained by the USG." Ex. F at Sec. B.4.6, p. 6.

45. The C-034 Contract further states that the Government "reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System." *Id*. at Sec. B.4.2, p. 6.

46. The Government also imposes and enforces extensive program-management, reporting, and Earned Value Management requirements to plan, monitor, and approve Moderna's performance, *see id.* at Program Management (WBS 1.1), p. 9-10; Reporting & oversight obligations, *see* Summary of Contract Deliverables Table 5, p. 18-20; Technical Reporting, *see id.* at p. 21-27, 29; Risk management plan & incident reporting, *see id.* at p. 24-25, 31.

d. The Government and Moderna's Positions as to Authorization and Consent "by and for the Government"

47. The C-034 Contract expressly purports to incorporate Federal Acquisition Regulation ("FAR") clause 52.227-1 (48 C.F.R. §52.227-1, "Authorization and Consent"), which provides:

> (a) The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent
>
> (1) Embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract; or
>
> (2) Used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or a subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance. The entire liability to the Government for infringement of a United States patent shall be determined

> solely by the provisions of the indemnity clause, if any, included in this contract or any subcontract hereunder (including any lower-tier subcontract), and the Government assumes liability for all other infringement to the extent of the authorization and consent hereinabove granted.

(Ex. F at p. 50).

48. On information and belief, based on *inter alia* the Government's *Arbutus* Statement of Interest discussed *infra*, the Government takes the position that by incorporating FAR clause 52.227-1 it has, granted its express "authorization and consent" for Moderna's unauthorized and unlicensed use of patented inventions in performance of the C-034 Contract.

49. The Government has previously asserted in its *Arbutus* Statement of Interest, that incorporation of such a FAR clause in a government contract, such as the C-034 Contract, "constitutes the Government's express authorization and consent. Section 1498(a), therefore, provides the exclusive remedy for any infringement occurring in the course of" performance of the contract.

50. Thus, on information and belief, the Government's position is that Moderna's use of patented inventions, including the '221 Patent, in connection with the development, testing, manufacturing and other activity relating to Spikevax was "for the United States" under 28 U.S.C. § 1498(a).

51. The Government takes the position that the Moderna contracts, which on information and belief include the C-034 Contract, are the type of direct procurement contract by which the United States obtains the benefit.

e. Government Benefit and Public-Health/Economic Impact

52. Consistent with the Government position in its *Arbutus* Statement of Interest, and on information and belief, the Government takes the position that it "has received the benefit of its

contract, namely, procuring the vaccine that it then offered for free public distribution in an effort to thwart the COVID-19 pandemic" from the C-034 Contract.

ACCUSED PRODUCTS

53. Moderna has used and continues to use a fluorescent "FRNTmNG" assay, based on Plaintiff's mNeonGreen, without Plaintiff's permission. This is a key test for neutralizing antibodies against COVID-19 infection and uses the University of Texas Medical Branch ("UTMB") SARS-CoV-2-mNG reporter virus, a critical part of the COVID-19 vaccine development and governmental approval process.

54. Defendant or Moderna made, and upon information and belief are continuing to make, pre-clinical, clinical, and post-clinical use of mNeonGreen in a neutralization assay, which included and includes use of mNeonGreen to (a) rapidly winnow an unmanageable number of Moderna vaccine candidates down; (b) select Moderna's mRNA-1273 COVID-19 vaccine candidate; (c) conduct preclinical and Phase I-III clinical trials; (d) secure rapid FDA authorization for distribution of a commercial vaccine; (e) validate the commercial vaccine; and (f) further test the commercial vaccine, for example, against new COVID-19 strains.

55. Moderna's approach to a COVID-19 vaccine relied on an unproven, gene-based biotechnology using messenger ribonucleic acid (mRNA).

56. Moderna had been trying for years to create a marketable mRNA-based therapeutic, with products for example targeting the flu, slowly working through their pipeline, but had not launched a single commercial product in that timeframe.

57. Through its use of mNeonGreen, Moderna was able to research, develop, and test their SARS-CoV-2 vaccine candidates at lightspeed, and be first to market. On information and belief, Plaintiff's mNeonGreen was an instrumental driver in selecting the most potent vaccine

candidate, which has saved precious time and lives as a result. mNeonGreen was used to facilitate the rapid proof of concept of Moderna's vaccine during the discovery, research and further development of products, entry into clinical trials, regulatory approval, and sales.

58. Consistent with the C-034 Contract, Moderna developed and brought to market a COVID-19 vaccine, both within and outside the United States.

59. Moderna needed a way to safely, reliably, and rapidly evaluate a large number of vaccine candidates and therefore used mNeonGreen in a reporter assay to narrow those candidates down to a manageable number in a period of approximately 60 days.

60. On or about March 16, 2020, Moderna initiated Phase I of their COVID-19 vaccine trial, in part to further evaluate and narrow COVID-19 vaccine candidates, with one such Phase I trial being NCT04283461 (aka Study 20-0003). Phase II of their COVID-19 trial initiated on or about May 20, 2020, to further evaluate vaccine candidates with an expanded cohort, and Phase 3 initiated on or about July 20, 2020, with one such trial being NCT04470427. Throughout each of Phases I and II of their COVID-19 vaccine trial, Moderna analyzed patient samples using an mNeonGreen neutralization assay to evaluate COVID-19 neutralizing antibody levels.

61. mNeonGreen was not, and is not, regulated by the FDA or any government agency or federal law, particularly those involving drugs, biologics, or medical devices or implicated by 35 U.S.C. § 271(e)(1). Plaintiff's '221 Patent covering mNeonGreen was not, and is not, eligible for patent term extension under 35 U.S.C. § 156. The FDA also did not require that Moderna use the mNeonGreen Neutralization Assay in their vaccine work.

62. Under Clinical Trial No. NCT04283461, first posted to clinicaltrials.gov on February 25, 2020, Moderna and the National Institute of Allergy and Infectious Diseases

("NIAID") conducted a Phase I study "to assess the safety, reactogenicity and immunogenicity of mRNA-1273 manufactured by ModernaTX, Inc."[1]

63. Clinical trial No. NCT04283461, and others, employ Plaintiff's patented mNeonGreen in an immunogenicity assay based on the SARS-CoV-2-mNG reporter virus obtained from UTMB.

64. On information and belief, Clinical Trial No. NCT04283461 concluded on or around April 26, 2022. The cited references include Anderson et al., Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. N. Engl. J. Med. 2020 Dec 17;383(25):2427-2438 (published 9/29/2020 and updated 11/6/2020) ("Anderson 2020") (Exhibit G). It states:

> Three live-virus neutralization methods were used, [including] the focus reduction neutralization test mNeonGreen (FRNTmNG), which uses recombinant SARS-CoV-2 expressing the fluorescent reporter gene mNeon-Green [11].

Ex. G at 2429.

65. Further, Muruato demonstrated that the FRNTmNG assay generated "values comparable to the convention PRNT assay: and comparatively the FRNTmNG assay "has shortened turnaround time by several days and increased the testing capacity to high throughput." Ex. E at 3. Furthermore, Muruato indicated that FRNTmNG was being utilized to evaluate COVID-19 vaccine candidates in clinical trials at the time of the publication. It states:

> Despite the BSL-3 limitation, the mNG reporter assay offers a rapid, high-throughput platform to test COVID-19 patient sera not previously available. Indeed, the mNG SARS-CoV-2 assay is currently being used to support clinical trials for COVID-19 vaccine candidates.

[1] https://www.clinicaltrials.gov/ct2/show/NCT04283461?term=NCT04283461&draw=2&rank=1 (first posted 2/25/2020, last update posted 2/11/2022)

Id.

66. The NIAID and Moderna collaborated and participated in, and are each directly responsible for, the study described in Muruato. *Id.* at 12.

67. In addition to Anderson 2020 and Muruato, the FRNTmNG assay was also described in Vanderheiden, Development of a Rapid Focus Reduction Neutralization Test Assay for Measuring SARS-CoV-2 Neutralizing Antibodies, Curr Protoc Immunol 2021; 131(1) (doi: 10.1002/cpim.116) (published on 12/01/2020) (Exhibit H). Therein, the protocols of the FRNTmNG assay and the traditional FRNT assay, which requires immunostaining, were compared. It was observed that the fluorescence-based approach, enabled by mNeonGreen as a reporter, allowed developers to omit time-intensive steps, thereby substantially reducing assay time. *Id.* at 8.

68. Likewise, the European Medicines Agency issued an Assessment Report on the Moderna COVID-19 vaccine describing development and clinical outcomes for Study 20-003 (*i.e.*, NCT04283461), depicting FRNTmNG assay data and further confirming its use for the study. Exhibit I at 68.

69. Similarly, the mRNA-1273 vaccine in study NCT04283461 "encodes for a full-length, prefusion stabilized spike (S) protein of SARS-CoV-2." A branch of this study, initiated in March 2021 under Clinical Trial No. NCT04785144, evaluated the mRNA-1273.351 vaccine, in addition to mRNA-1237, which "encodes for a full-length, prefusion stabilized S protein of the SARS-CoV-2 B.1.351 variant." Interim results of the trial published as a preprint by Anderson et al., on May 3, 2022, in "Safety and Immunogenicity of a Third Dose of SARS-CoV-2 mRNA Vaccine- An Interim Analysis, Res Sq [Preprint] 2022; 3 (doi: 10.21203/rs.3.rs-1222037/v1) (published 5/3/2022) ("Anderson 2022") (Exhibit J).

70. Anderson 2022 lists the use of FRNTmNG to evaluate neutralizing antibody responses to the vaccinees. Ex. J at 7, 12. Accordingly, Moderna is using the same protocols, including the FRNTmNG assay, to test (and seek approval) for at least one vaccine targeting a COVID-19 variant, in addition to the original vaccine.

71. In other words, Moderna, through for example Anderson, Muruato, and Vanderheiden, used in Phases I, II and III of their COVID-19 vaccine trial the FRNTmNG assay, which contains and is fundamentally based on the mNeonGreen research and validation tool, to research its SARS-CoV-2 vaccine candidates, including Spikevax.

72. Moderna has not used mNeonGreen in order to enter the market with a product that competes with mNeonGreen. mNeonGreen is not a patented drug with a soon-to-expire patent term and Moderna did not need to establish bioequivalence of a generic substitute of mNeonGreen to enter the market with their vaccine. Moderna has not conducted appropriately limited safe harbor testing so that their vaccine could be pre-approved and ready to launch as soon as the '221 Patent expires.

73. On the contrary, Moderna has FDA authorization for their own product, have launched, did infringe, and on information and belief continue to infringe, openly and intentionally, many years before the '221 Patent will expire, in total disregard for Plaintiff's rights and Plaintiff's crucial contribution to the success of Moderna's vaccine.

74. Using the data premised on Moderna's use of mNeonGreen, Moderna has successfully received commercial authorizations for their COVID-19 vaccine outside the United States, and on information and belief, foreign sales to date, comprise the majority of Moderna's total COVID-19 vaccine sales. For example, and without limitation, Moderna's Spikevax has been authorized for use or approved in over 70 countries and an active commercial footprint in Europe

and the Asia-Pacific region.[2] Moderna has misused Plaintiff's '221 Patent and mNeonGreen without authorization to develop a patented product of their own.

75. Moderna's Spikevax has generated over $47 billion in revenue for Moderna and has saved the Government substantial sums in reduced costs of care.

76. On information and belief, while not required by the FDA and instead for marketing purposes, Moderna has continued to use the mNeonGreen neutralization assay as a research tool to evaluate their commercially authorized COVID-19 vaccine against a variety of new COVID-19 strains, including without limit the beta and omicron variants.

UNLICENSED USE OF THE '221 PATENT BY OR FOR THE GOVERNMENT

77. mNG Bio incorporates all paragraphs in this Complaint as if fully set forth herein.

78. Scientists from UTMB, who provided the mNeonGreen-SARS-CoV-2 DNA construct to Defendants, reported an "urgently needed ... fluorescent-based SARS-CoV-2 neutralization assay" with "gold standard" results. *See* Ex. E at 1 (Summary), 2. The assay of Muruato "was built on a stable mNeonGreen SARS-CoV-2" reporter virus (*id*. at 2) (citing the Cell Host Article) and is "superior ... because it measures functional SARS-CoV-2 neutralizing activity.... [T]he mNeonGreen reporter assay [aka mNeonGreen neutralization assay] offers a rapid, high throughput platform to test COVID-19 patient sera not previously available." *Id*. at 3-4. The Cell Host Article (Ex. D) also evidences that UTMB made a "reverse genetics system" for SARS-CoV-2 by assembling seven cDNA fragments into a full-genome cDNA of the virus. The recombinant virus has been distinguished from wild-type SARS-CoV-2. *See* Ex. D at 3 (842, Fig.

[2] https://www.sec.gov/ix?doc=/Archives/edgar/data/0001682852/000168285224000015/mrna-20231231.htm

2E). RNA transcribed from this cDNA produced a highly infectious virus that, according to UTMB, "recapitulates the replication kinetics of the original clinical isolate." *Id*. at 2.

> mNeonGreen was incorporated into this cDNA to make a reporter virus:
> **We generated a stable mNeonGreen SARS-CoV-2 (icSARS-CoV-2-mNG)** by introducing this reporter gene into ORF7 of the viral genome. icSARS-CoV-2-mNG was successfully used to evaluate the antiviral activities of interferon (IFN). Collectively, the reverse genetic system and reporter virus provide key reagents to study SARS-CoV-2 and develop countermeasures.

Id. at 2 (841 (Summary)), 4 (843, Fig. 3A).

79. While the Cell Host Article describes an mNeonGreen neutralization assay, for SARS-CoV-2, it emphasizes the robustness of using mNeonGreen as a gold standard tool for rapid characterization and development of "countermeasures" for a variety of emerging infections. As a representative example of such emerging viruses, the authors of the Cell Host Article developed a SARS-CoV-2 reporter tool, the aforementioned mNeonGreen neutralization assay, with the "mNeonGreen virus [] be[ing] reliably used to study viral replication and pathogenesis as well as to develop vaccines and antiviral drugs." *Id*. at 3 (842). The authors further describe the mNeonGreen reporter virus as "a reliable surrogate for high-throughput drug discovery" that "represents a major tool for the research community and significantly advances opportunities for countermeasure development for COVID-19." *Id*. at 8 (847).

80. The Key Resources Table of the Cell Host Article lists "synthesized mNeonGreen gene (sequence optimized)" and refers to a publication from 2013 by the Inventors which corresponds to the '221 Patent. *See*, Ex. D at 10 (e1).

81. mNeonGreen in UTMB's construct is identical to SEQ ID NO:1 of the '221 patent.

82. While not required by the FDA, Moderna, on information and belief, continued using the mNeonGreen neutralization assay or variant thereof, which includes mNeonGreen, to research SARS-CoV-2-neutralizing antibody levels against a host of new COVID-19 strains, including beta, delta, gamma, omicron, BA.1, and omicron BA.4/BA.5. The purpose of this infringing use is to compete in the marketplace against other COVID-19 vaccines, by highlighting to potential purchasers and users of the vaccine added benefits of using Moderna's Spikevax vaccine instead of other vaccines. These uses are referred to herein as "Post-Approval Marketing Use."

83. A protein made using the DNA construct used by Moderna has "at least one" of the mutations in claim 1, at least three of the mutations in claim 3, at least three of the mutations in claim 4, at least 95% sequence identity according to claims 1, 2, and 4; has at least 90% sequence identity according to claim 3, has at least 97% sequence identity according to claim 5, and has a monomer according to claim 2.

84. Therefore, the mNeonGreen protein used by Moderna, including in mNeonGreen neutralization assays, directly infringes at least claims 1-5 of the '221 Patent.

85. At no time has Plaintiff granted Defendant nor Moderna authorization, license, or permission to practice the inventions claimed in the '221 Patent in connection with Moderna's Spikevax or any other Moderna COVID vaccine candidate.

86. Because of this continued infringement, Moderna was able to identify their COVID-19 vaccine candidate, Spikevax, as the most promising candidate to commercialize and race through preclinical and clinical trials to release the vaccine for use by members of the public in the United States and worldwide.

CLAIM FOR RELIEF: PATENT INFRINGEMENT
UNDER 28 U.S.C. § 1498(a)

87. mNG Bio incorporates by reference all paragraphs in this Complaint as if fully set forth herein.

88. The ’221 Patent is a valid and enforceable patent of the United States, and mNG Bio owns all rights to enforce it and to recover compensation for past and future infringement.

89. Without license or lawful right, the United States, Moderna, and its subcontractors, used the inventions described in and covered by one or more claims of the ’221 Patent, in connection with the development, manufacture, and use of Moderna’s mRNA SARS-CoV-2 vaccine (including Spikevax).

90. Such use occurred and continued to occur by the United States within the meaning of 28 U.S.C. § 1498(a) by direct use of Government agencies and instrumentalities, such as NIAID.

91. Further, on information and belief, the Government takes the position that use by Moderna and its subcontractors was “for the United States” within the meaning of 28 U.S.C. § 1498(a), including the Government on information and belief asserts it provided express authorization and consent under FAR 52.227-1.

92. The United States’ use of the patented inventions, and the use by Moderna and its subcontractors, infringes one or more claims of the ’221 Patent.

93. As a direct and proximate result of these unlicensed uses of the patented inventions, mNG Bio has suffered and will continue to suffer damages in the form of lost license fees, lost royalties, and other measures of “reasonable and entire compensation” within the meaning of 28 U.S.C. § 1498(a).

94. mNG Bio is entitled to recover from the United States reasonable and entire compensation for all past and future use by or for the United States of the inventions described in

and covered by the ’221 Patent in connection with the C-034 Contract, including any extensions, modifications, or additional procurements of the same or functionally equivalent vaccine products or manufacturing processes.

95. Plaintiff is further entitled to interest and costs as allowed by law, and for attorney’s fees and expert fees.

PRAYER FOR RELIEF

WHEREFORE, mNG Bio respectfully requests that the Court enter judgment in its favor and against the United States and award the following relief:

a. A judgment that the United States is liable under 28 U.S.C. § 1498(a) for uses of the inventions described in and covered by one or more claims of the ’221 Patent in connection with Moderna’s COVID vaccine (including Spikevax), without license or lawful right;

b. An award to mNG Bio of “reasonable and entire compensation” under 28 U.S.C. § 1498(a) for all such past and ongoing use, including, without limitation, a reasonable royalty or other appropriate measure of compensation for the unlicensed use of the ’221 Patent;

c. An award of pre-judgment and post-judgment interest as allowed by law;

d. An award of attorneys’ fees and expert fees;

e. An award of mNG Bio’s allowable costs of suit, both taxable and non-taxable; and

f. Such other and further relief as the Court deems just and proper.

Dated: January 7, 2026

Respectfully submitted,

By: /s/ *Ben L. Wagner*

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Exhibit List	
Exhibit A	United States Patent No. 10,221,221
Exhibit B	Assignment to Allele Biotechnology and Pharmaceuticals, Inc. (April 28, 2014)
Exhibit C	Allele Assignment to mNG Bio, LLC (January 6, 2026)
Exhibit D	Xie, et al., An Infectious cDNA Clone of SARS-CoV-2, Cell Host & Microbe 27, 841-848 (May 13, 2020) ("Cell Host Article")
Exhibit E	Muruato, et al., A High-throughput Neutralizing Antibody Assay for COVID-19 Diagnosis and Vaccine Evaluation, Nat Commun 2020; 11(1):4059 (doi: 10.1038/s41467-020-17892-0) (August 13, 2020) ("Muruato")
Exhibit F	HHS-Moderna Contract No. 75A50120C00034 "Development of an mRNA Vaccine for SARS-CoV-2" ("C-034 Contract")
Exhibit G	Anderson et al., Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. N. Engl. J. Med. 2020 Dec 17;383(25):2427-2438 (published 9/29/2020 and updated 11/6/2020) ("Anderson 2020")
Exhibit H	Vanderheiden, Development of a Rapid Focus Reduction Neutralization Test Assay for Measuring SARS-CoV-2 Neutralizing Antibodies, Curr Protoc Immunol 2021; 131(1) (doi: 10.1002/cpim.116) (published on 12/01/2020)
Exhibit I	European Medicines Agency Assessment Report: COVID-19 Vaccine Moderna
Exhibit J	Anderson et al. "Safety and Immunogenicity of a Third Dose of SARS-CoV-2 mRNA Vaccine- An Interim Analysis, Res Sq [Preprint] 2022; 3 (doi: 10.21203/rs.3.rs-1222037/v1) (published 5/3/2022) ("Anderson 2022")