IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

MNG BIO, LLC,

Plaintiff,

vs.

MODERNA INC., MODERNATX, INC., and DOES 1-30,

Defendants.

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, mNG Bio, LLC ("mNG Bio"), brings this Complaint for monetary relief against Defendants Moderna, Inc., ModernaTX, Inc. and DOES 1-30 (collectively, "Moderna" or "Defendants"), to address Defendants' infringement of mNG Bio's patent related to Defendants' COVID-19 vaccine, mRNA-1273 vaccine ("Spikevax").

This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., based on Defendants' infringement of United States Patent No. 10,221,221 ("the '221 Patent"). mNG Bio does not seek to impede the COVID-19 response or ongoing vaccinations and simply seeks reasonable compensation for Defendants' unauthorized use of its patented mNeonGreen technology.

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271.

2. The revolutionary mNeonGreen was already developed years prior to the COVID-19 crisis. 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.

3. 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.

4. 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, 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. Moderna never sought a license with Plaintiff or even contacted Plaintiff in connection with the infringing uses.

5. As further alleged herein, Moderna has used and continues to use a fluorescent "FRNTmNG" assay, based on Plaintiff's mNeonGreen, without Plaintiff's permission. This key test for neutralizing antibodies against COVID-19 infection uses the University of Texas Medical Branch ("UTMB") SARS-CoV-2-mNG reporter virus and has been an important part of the COVID-19 vaccine development, release and distribution worldwide.

6. As further alleged herein, Moderna made, and upon information and belief, is 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 a manageable number; (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.

7. Moderna's approach to a COVID-19 vaccine relied on a previously unproven, gene-based biotechnology using messenger ribonucleic acid (mRNA). More specifically, 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 commercially-available mRNA-based therapeutic product in that timeframe.

8. Through its use of mNeonGreen, Moderna was able to research, develop, and test their SARS-CoV-2 vaccine candidates at lightspeed, and be quick 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.

9. More specifically, Moderna needed a way to safely, reliably, and rapidly evaluate a large number of vaccine candidates and therefore used mNeonGreen to narrow those candidates down to a manageable number in a period of approximately 60 days (that 60-day period being within the statute of limitations, and before any U.S. government contract), for the purpose of winning the race to a vaccine for worldwide distribution and commercialization.

10. Through its unauthorized and unlicensed use of Plaintiff's patented mNeonGreen technology, Moderna developed and brought to market a COVID-19 vaccine, both within and outside the United States.

THE PARTIES

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

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

13. 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.

14. Upon information and belief, Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. Moderna, Inc., itself and through its subsidiary ModernaTX, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells vaccines and other medicines in the Commonwealth of Massachusetts and throughout the United States, for use in the State of Massachusetts and throughout the United States.

15. Upon information and belief, ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc. (collectively, "Moderna"). ModernaTX, Inc. is also a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. ModernaTX, Inc. develops, manufactures, imports, markets, distributes, offers to sell, and/or sells vaccines and other medicines in the Commonwealth of Massachusetts and throughout the United States, for use in Massachusetts and throughout the United States.

16. The true names and capacities, whether individual, corporate, associate, or otherwise, of defendants DOES 1 through 30, inclusive, engaging in the acts of infringement with or for Defendants are unknown to mNG Bio, who therefore sues said defendants by such fictitious names. mNG Bio will amend this Complaint to state their true names and capacities when the same is ascertained. mNG Bio is informed and believes that at all times herein mentioned, each defendant named herein was the agent of each of the remaining defendants and, in doing the things herein alleged, was acting within the course and scope of said agency. Any reference in this Complaint to the actions or inactions of any defendant, whether such reference is made to such

defendant by specific name or otherwise, is also a reference to the actions or inactions of DOES 1 through 30, inclusive.

JURISDICTION AND VENUE

17. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et. seq.

18. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1332 and 1338(a).

19. This Court has personal jurisdiction over Defendants because of their systematic and continuous contacts with Massachusetts, have their principal place of business in Massachusetts and are at home in Massachusetts and this District such that the maintenance of this suit does not offend traditional notions of fair play and substantial justice. Further, Defendants regularly conduct business within, and specifically direct their business activities to, the District of Massachusetts ("this District"). Defendants have purposefully availed themselves of the opportunity to conduct business in this state through systematic and continuous dealings in this state. Defendants' actions that give rise to personal jurisdiction also include, but are not limited to, the following: making and using infringing products in this State and in this District, knowing and intending that the infringing products would be used in this District, deriving substantial revenue from the use of infringing products within this District, and expecting their infringing actions to have consequences in this District.

20. For example, on December 18, 2020, Moderna received Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") for its COVID-19 vaccine to be distributed and administered to people throughout the United States, including in Massachusetts and, on January 31, 2022, the FDA approved Moderna's Biologics

License Application ("BLA") for its COVID-19 vaccine. Therefore, each of Moderna, Inc. and ModernaTX, Inc. transacts business within Massachusetts relating to Plaintiff's claims and has engaged in systematic and continuous business contacts here.

21. Moderna, Inc. and ModernaTX, Inc. have also purposefully availed themselves to the benefits and protections of the courts in Massachusetts, including by initiating litigation relating to Spikevax before this Court. *See ModernaTX, Inc. et al. v. Pfizer Inc. et al.*, Case No. 1-22-cv-11378 (D. Mass) (filed August 26, 2022).

22. Venue is proper in this District under 28 U.S.C. §§ 1391(c)(2) and 1400(b) because both Moderna, Inc. and ModernaTX, Inc. have regular and established places of business in this District, including having their principal places of business as 200 Technology Square, Cambridge, Massachusetts, 02139. Defendants have committed acts of infringement, induced others to commit, or contributed to others committing, acts of infringement in this District and, upon information and belief, will commit further acts of infringement in Massachusetts.

PATENT IN SUIT

23. 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.

24. 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.

25. 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.

26. 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.

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

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

29. 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.

30. 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.

31. 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. The tetramer, however, 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 ’221 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."

32. 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 (May 22, 2020)[1], true and correct copies of each attached hereto as Exhibit D (hereafter, "Cell Host Article") and Exhibit E (hereafter, "Muruato"), respectively.

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

ACCUSED PRODUCTS

34. Moderna has used and continues to use a fluorescent "FRNTmNG" assay, based on Plaintiff's mNeonGreen, without Plaintiff's permission. This key test for neutralizing antibodies against COVID-19 infection uses UTMB SARS-CoV-2-mNG reporter virus, a critical part of the COVID-19 vaccine development, FDA approval process, and distribution worldwide.

35. Moderna made, and upon information and belief, is 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) the

[1] https://doi.org/10.1101/2020.05.21.109546

conduct of preclinical and Phase I-III clinical trials of and for 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, all of which above acts of infringement Moderna is legally responsible for.

36. 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 Moderna's COVID-19 trial initiated on or about May 20, 2020, to further evaluate vaccine candidates with an expanded cohort, and Phase III was initiated on or about July 20, 2020, with one such trial being NCT04470427. Throughout each clinical trial Phase of its COVID-19 vaccine trials, Moderna analyzed patient samples using an mNeonGreen neutralization assay to evaluate COVID-19 neutralizing antibody levels.

37. 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.

38. 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."[2]

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

39. 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.

40. On information and belief, Clinical Trial No. NCT04283461 concluded by 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 F). Anderson 2020 states:

> Three live-virus neutralization methods were used, [including] the focus reduction neutralization test mNeonGreen (FRNT-mNG), which uses recombinant SARS-CoV-2 expressing the fluorescent reporter gene mNeonGreen [citing Cell Host Article].

Id. at 2429.

41. 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.

Id. at 3[3].

42. In addition to Anderson 2020 and Muruato, the FRNTmNG assay was also described in Vanderheiden et al., Development of a Rapid Focus Reduction Neutralization Test

[3] citing Mulligan, M. J. et al., Phase 1/2 study of a COVID-19 RNA vaccine candidate (BNT162b1) in adults. *Nature* (2020).

Assay for Measuring SARS-CoV-2 Neutralizing Antibodies, *Curr Protoc Immunol* 2021; 131(1) (published 12/01/2020)[4] (Exhibit G). 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.

43. 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 H at 68.

44. 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 I).

45. Anderson 2022 lists the use of FRNTmNG to evaluate neutralizing antibody responses to the vaccines. Ex. I at 7, 12 citing Anderson 2020 and Vanderheiden. Accordingly, Moderna has used and 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.

[4] doi: 10.1002/cpim.116

46. 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.

47. Moderna developed its vaccines to directly benefit the American public and worldwide public by providing the public with an immunological defense against the COVID-19 pandemic.

48. Upon information and belief, at least 98% of Moderna's vaccine doses were distributed to the public.

49. Upon information and belief, most of these doses were allocated and distributed by non-federal entities, such as state and local governments, pharmacies, and private dialysis clinics.

50. Upon information and belief, once Moderna, or others working on behalf of Moderna, allocated doses to these channels (like pharmacies and local governments), Moderna decided how the doses would be distributed within those channels.

51. Upon information and belief, the direct beneficiaries of the Moderna vaccine were the individuals who received the vaccine because they would be less likely to develop asymptomatic infection, symptomatic infection, and severe infection.

52. 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 limited safe harbor testing so that their vaccine could be pre-approved and ready to launch as soon as the '221 Patent expires.

53. 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.

54. 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 has an active commercial footprint in Europe and the Asia-Pacific region.[5] Moderna has misused Plaintiff's '221 Patent and mNeonGreen without authorization to develop a patented product of their own.

55. Moderna's Spikevax alone has generated over $47 billion in revenues for Moderna, all or at least the vast and overwhelming majority of which could not and are not in any way even remotely sales to or for the United States.

56. Moderna made the decision to use and did use mNeonGreen to winnow vaccine candidates and for preclinical testing, as well as made the choice to design further testing for its COVID-19 vaccine candidates, on information and belief, without the requirement, authorization or approval of any state, federal, or foreign governmental authority.

57. 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

[5] *See e.g.*, https://www.sec.gov/ix?doc=/Archives/edgar/data/0001682852/000168285224000015/mrna-20231231.htm

to evaluate their commercially authorized COVID-19 vaccine against a variety of new COVID-19 strains, including without limit the beta and omicron variants.

DEFENDANTS' USE OF THE MNEONGREEN NEUTRALIZATION ASSAY AT ALL TIMES

58. 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 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. 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 29.

> 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.

Ex. D at 2 (841 (Summary)) and 4 (843, Fig. 3A).

59. 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." Ex. D 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).

60. 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).

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

62. 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."

63. 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.

64. Therefore, the mNeonGreen protein used by Moderna, including in mNeonGreen neutralization assays, directly infringes one or more claims of the ’221 Patent.

65. At no time has Plaintiff granted 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.

66. 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.

67. Discovery is still ongoing, and mNG Bio intends to and does assert all unauthorized uses by or for Moderna in connection with any of Moderna’s COVID-19 vaccines pursuant to this Complaint, and Moderna’s infringement extends to all unauthorized uses of the ’221 Patent in connection with COVID-19 vaccines or COVID-19 vaccine variants in SARS-CoV-2-mNG (FRNT-mNG), or otherwise.

DEFENDANTS’ WILLFUL INFRINGEMENT

68. The ’221 Patent was issued by the United States Patent and Trademark Office. As an issued patent, the ’221 Patent has a presumption of validity per 35 U.S.C. § 282. One or more claims of the ’221 Patent have all of their limitations met by the Accused Product, which thus infringes the ’221 Patent.

69. Upon information and belief, as early as May 2013, Defendants have been aware of Plaintiff’s novel monomeric yellow-green fluorescent protein, mNeonGreen as discussed and

disclosed in Shaner N., et al., A Bright Monomeric Green Fluorescent Protein Derived From *Branchiostoma lanceolatum*. *Nat Methods* 2013 May;10(5):407-9 ("Shaner 2013") (Exhibit J). Shaner 2013 has been cited in over 750 separate publications. Additionally, Shaner 2013 discloses that Allele, mNG Bio's predecessor-in-interest, "has filed for patent protection of mNeonGreen," and on information and belief Defendants were aware of the '221 Patent and its applicability to use of mNeonGreen prior to their use of it in connection with developing a COVID-19 vaccine, including Spikevax.

70. Since at least the start of the preclinical and Phase 1 testing in early 2020 using mNeonGreen in the reporter virus, Defendants have been aware of the '221 Patent and have had actual knowledge of the '221 Patent and the obvious risk of infringement by continued use of mNeonGreen throughout their development of their COVID-19 vaccine candidate in the United States. Further, on information and belief, Moderna was aware early in its usage that other companies had been sued over their unauthorized use of FRNT-mNG specifically because its use in connection with vaccine development infringes the '221 Patent and utilized the patented invention's mNeonGreen. Nevertheless, Defendants continued to use mNeonGreen in connection with the development of its vaccine.

71. Despite their knowledge of the obvious risk of infringement of the '221 Patent, on information and belief, Defendants since at least as early as early 2020 continued using mNG Bio's mNeonGreen throughout their COVID-19 vaccine trials and, on information and belief, after their post-FDA authorization of commercial use of their COVID-19 vaccine.

72. Defendants' continued infringement was and is subjectively reckless and intentional. Defendants have infringed the '221 Patent in a willful and egregious manner, in wanton disregard of the '221 Patent.

CLAIM FOR RELIEF
(Infringement of the ’221 Patent Against All Defendants)

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

74. This is a claim for patent infringement and arises under the Patent Laws of the United States and, in particular, under 35 U.S.C. §§ 271, et seq.

75. 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.

76. Defendants have in the past infringed and continue to infringe the ’221 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, and/or selling, in the United States, or importing into the United States, mNeonGreen with its SARS-CoV-2 neutralization assay and DNA construct that infringes at least one or more claims of the ’221 Patent.

77. mNG Bio is informed and believes that Defendants have infringed, and continue to infringe, the ’221 Patent by making, using, selling, offering for sale and/or licensing products covered by one or more claims of the ’221 Patent without mNG Bio’s authorization or consent.

78. Defendants have in the past infringed and continue to infringe the ’221 Patent in violation of 35 U.S.C. § 271(f) because Defendants supplied or caused to be supplied from the United States all or a substantial portion of the patented invention for combination outside the United States, including use of mNeonGreen with its SARS-CoV-2 neutralization assay and DNA construct throughout their COVID-19 vaccine trial in the United States and outside the United States, in a manner that would infringe one or more claims of the ’221 Patent, if such combination occurred within the United States.

79. Upon information and belief, Defendants have induced infringement and continue to induce infringement of one or more of the claims of the ’221 Patent by encouraging others,

including but not limited to third parties that assisted or were directed by Defendants in at least its pre-clinical and clinical studies and activities related to the same, to use mNeonGreen in the United States and in this District in a manner that would directly infringe the ’221 Patent. Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to third parties that assisted Defendants in at least its pre-clinical and clinical studies and activities related to the same, with knowledge of the ’221 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

80. Upon information and belief, Defendants’ use of mNeonGreen constitutes a material part of one or more claims of the ’221 Patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants have contributorily infringed and continue to contributorily infringe one or more of the claims of the ’221 patent by knowingly promoting the making and use of mNeonGreen in the United States and in this District by others, including but not limited to any third parties that assisted Defendants or were directed by Defendants in at least its pre-clinical and clinical studies and activities related to the same, with knowledge of the ’221 patent and and knowing that the use of mNeonGreen to infringe the ’221 Patent, in violation of 35 U.S.C. § 271(c).

81. Section 287 of Chapter 35 of the U.S.C. has been satisfied.

82. These acts of infringement were, and continue to be, knowing, willful and intentional on the part of Defendants.

83. mNG Bio is entitled to an award of damages adequate to compensate mNG Bio for patent infringement, as well as prejudgment interest from the date the infringement began, but in no event less than a reasonable royalty as permitted by 35 U.S.C. § 284.

84. mNG Bio is entitled to an award of treble damages pursuant to 35 U.S.C. § 284, including without limit for the period of any willful infringement.

85. mNG Bio is entitled to a finding that this case is exceptional and an award of interest, costs and attorneys' fees incurred by mNG Bio in prosecuting this action as provided by 35 U.S.C. § 285.

86. mNG Bio is entitled to an award of pre-judgment and post-judgment interest as provided by law.

87. mNG Bio is entitled to such other and further relief as this Court or a jury may deem just and proper.

PRAYER FOR RELIEF

WHEREFORE, in consideration of the foregoing, mNG Bio respectfully prays for a judgment against Defendants:

A. Finding that Defendants have infringement one or more of the claims of the '221 Patent, induced infringement of one or more claims of the '221 Patent, and/or contributorily infringed one or more claims of the '221 Patent in violation of 35 U.S.C. §271;

B. Finding that Defendants' infringement of the '221 Patent is willful;

C. An award of damages adequate to compensate mNG Bio for patent infringement, as well as pre-judgment interest from the date the infringement began, but in no event less than a reasonable royalty as permitted by 35 U.S.C. § 284;

D. An award of treble damages, including without limit for the period of any willful infringement pursuant to 35 U.S.C. § 284;

E. A finding that this case is exceptional and an award of interest, costs and attorneys' fees incurred by mNG Bio in prosecuting this action as provided by 35 U.S.C. § 285;

F. For an award of pre-judgment and post-judgment interest as provided by law; and

G. For such other and further relief as this Court or a jury may deem just and proper.

Dated: January 8, 2026

Respectfully Submitted,

/s/ L. Andrew Tseng

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DEMAND FOR JURY TRIAL

Plaintiff respectfully requests a trial by jury on all issues and claims so triable in this action and in accordance with Rule 38 of the Federal Rules of Civil Procedure.

Dated: January 8, 2026

Respectfully Submitted,

/s/ L. Andrew Tseng

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Exhibit List	
Exhibit A	United States Patent No. 10,221,221
Exhibit B	Assignment to Allele Biotechnology and Pharmaceuticals, Inc. (dated April 28, 2014)
Exhibit C	Assignment to mNG Bio, LLC (dated 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	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	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	European Medicines Agency Assessment Report: COVID-19 Vaccine Moderna
Exhibit I	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")
Exhibit J	Shaner N., et al., A Bright Monomeric Green Fluorescent Protein Derived From *Branchiostoma lanceolatum*. *Nat Methods* 2013 May;10(5):407-9 ("Shaner 2013")