IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER CROPSCIENCE LLC, MONSANTO COMPANY, and MONSANTO TECHNOLOGY, LLC, Plaintiffs, v. MODERNA, INC., MODERNA US, INC., and MODERNATX, INC, Defendants.	C.A. No. _____ JURY TRIAL DEMANDED

PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bayer CropScience LLC, Monsanto Company, and Monsanto Technology, LLC (collectively "Plaintiffs" or "Bayer") file this Complaint for Patent Infringement against Defendants Moderna, Inc., Moderna US, Inc. ("Moderna US"), and ModernaTX, Inc. ("ModernaTX," and collectively with Moderna, Inc. and Moderna US, "Moderna" or "Defendants") and allege as follows:

Introduction

1. The COVID-19 pandemic resulted in more than 7 million deaths worldwide, including 1.2 million in the United States, and triggered a severe economic crisis that caused more than 20 million U.S. job losses at its peak. The Trump Administration's Operation Warp Speed, a landmark venture by the federal government and leading vaccine manufacturers to safely and swiftly bring COVID-19 vaccines to market, was a major achievement that hastened the end of the global pandemic and saved millions of lives.

2. The success of Moderna's vaccine was made possible in part by the company's infringement of Plaintiffs' intellectual property ("IP"), developed in the 1980s and for which patent

protection was filed in 1989, to eliminate "problem" coding sequences in the building blocks of cells to improve mRNA stability and the amount or quality of protein produced. Two federal courts (including this one) and the U.S Patent Office have confirmed Plaintiffs' critical technology was the first of its kind to be developed, with the patent ultimately being issued by the United States Patent and Trademark Office in 2010. Across U.S. industries, cutting-edge solutions to complex challenges are grounded in innovation from the world's top researchers and scientists. Taking legal steps to safeguard those innovations is a common business practice for many technology-based companies like Plaintiffs, as protecting IP rights is critical to continued scientific advancements that solve longstanding problems, especially given the significant cost and time required. Without IP protection, innovation would diminish, leaving fewer options to address today's constantly-evolving global challenges and improve life for Americans and people around the world.

3. Plaintiffs' innovation was originally used to make plants resistant to insect pests, improving agricultural output and reducing need for pesticide sprays through the increased expression of an insect-resistant protein in crop plants. As Moderna has noted, mRNA instability leading to poor protein expression was the main roadblock they faced in developing an effective COVID vaccine. Moderna used Plaintiffs' patented method to enhance its vaccines' mRNA stability and thus the vaccines' ability to confer immunity to the virus. Moderna used Plaintiffs' discovery to make its COVID-19 vaccines without Plaintiffs' permission; Plaintiffs did not have any affiliation with the vaccines' manufacturer regarding the vaccines or any involvement in the development of the vaccines.

4. Plaintiffs do not seek to interfere with Moderna's ongoing efforts with respect to COVID or Moderna's creation of vaccines for myriad other illnesses. By the same token, Moderna has profited handsomely from infringing vaccine sales worldwide. The patent system provides an

important, predictable framework for advancing scientific knowledge by allowing companies a limited period to recover at least a reasonable royalty for the unauthorized use of their patented inventions. Indeed, over the past several years, many companies and research institutions alleging that their technologies were used in the development of the vaccine have sued Moderna, asking to obtain fair compensation for the use of their IP. Now, Plaintiffs are alleging the same and are asking for the basic compensation afforded to a patent holder under the patent statute.

Nature of the Action

5. This patent infringement action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, seeking damages for Moderna's infringement of Plaintiffs' U.S. Patent 7,741,118 (the "'118 Patent"), a copy of which is attached as **Exhibit A**. As stated in the Abstract, the '118 Patent discloses "method[s] for modifying structural gene sequences to enhance the expression of the protein product."

6. In the 1980s, researchers for Plaintiffs, Dr. David Fischhoff ("Fischhoff") and Dr. Fred Perlak ("Perlak") (collectively, "Plaintiffs' Scientists"), dedicated significant efforts towards advancements in making plants resistant to insects and viruses, increasing crop yields, and reducing need for pesticide sprays. While working to express proteins of bacterial and viral origin in plants to confer insect and virus resistance, Drs. Fischhoff and Perlak discovered that certain genes from bacteria and viruses were replete with specified problem sequences that they conceived contributed to mRNA instability, leading to poor protein expression in higher organisms. Fischhoff and Perlak linked these problem sequences to mRNA instability in animal and plant cells alike, and discovered that making genes that encode a desired protein with fewer (or none) of the problem sequences dramatically increased protein expression and related bioactivity. The '118 Patent includes a teaching that its basic method may be used "to express [a] viral coat protein at an

effective level" and thereby "achieve virus resistance" in eukaryotic cells and includes an illustrative example of such use.[1]

7. Based upon this research, the '118 Patent claims the inventions of Drs. Fischhoff and Perlak of methods for making a structural gene by reducing specified destabilizing sequences and substituting sense codons in their place. The '118 Patent identifies the destabilizing sequences as including, for example, putative plant and animal polyadenylation signal sequences listed in Table II ("Table II Sequences"), ATTTA sequences, and regions with over five consecutive A and/or T nucleotides (collectively, "Problem Sequences"). While Drs. Fischhoff and Perlak were not working on these gene modifications specifically for use in mRNA vaccines, their methods to improve protein production and mRNA stability represented an important discovery that benefits applications in other industries beyond agriculture, including pharmaceuticals.

8. Moderna used the claimed method of the '118 Patent in the development of its mRNA vaccines for COVID-19 that Moderna markets under the name Spikevax®. Moderna's Spikevax® vaccines deliver instructions to cells to make a new "spike" protein, which activates the body's immune response to the virus. To make their Spikevax® vaccines work, Moderna leveraged the inventions claimed in the '118 Patent to increase mRNA stability and thus the effectiveness of their vaccines. For example, in its original Spikevax® vaccine, Moderna used Plaintiffs' patented method to remove approximately 100 identified Problem Sequences found in the COVID-19 spike protein gene to enhance the stability its mRNA and its ability to confer immunity to the virus. Upon information and belief, Moderna has continued to use the claimed method of the '118 Patent in connection with other mRNA vaccine embodiments, including its subsequent Spikevax®

[1] '118 Patent at 38:25-39:25.

vaccines and its vaccine to treat respiratory syncitial virus (RSV), called mRESVIA®, as well as vaccines in its product pipeline, including its mRNA 1010 flu vaccine.

9. While Moderna chose to utilize Dr. Fischhoff and Perlak's invention(s) to improve its COVID-19 vaccines, Plaintiffs did not have any involvement in the development of the vaccines, and Moderna used their patented method without Plaintiffs' permission. Moderna has earned substantial benefit, including tens of billions of dollars in revenue from this unauthorized use, to develop, produce, and deliver its mRNA vaccines. Moderna has acknowledged that mRNA instability was a quintessential problem it faced in its development of an effective vaccine:

> The problems that Moderna faced started with the mRNA itself. mRNA is an unstable molecule that is quickly destroyed inside the body. Moderna scientists had to develop novel ways to stabilize mRNA by modifying its chemical structure so that it could be used in vaccines and therapeutics.[2]

10. Moderna's mRNA stability work began within the last 10-15 years. In comparison, as confirmed by this District,[3] the Federal Circuit,[4] and the Patent Office[5] in awarding priority to Fischhoff and Perlak, their groundbreaking work began more than 35 years ago. The '118 Patent is a pre-GATT patent, claiming priority to February 24, 1989, and (because of the time required for prosecution, including an 8-year interference proceeding) issued on June 22, 2010. Thus, the '118 Patent covers the entire duration of Moderna's mRNA vaccine work. The '118 patent is assigned to Monsanto Technology, LLC and is exclusively licensed to Bayer CropScience LLC.

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[2] *ModernaTX, Inc. v. Pfizer Inc.*, No. 1:22-cv-11378-RGS (D. Mass. Aug. 26, 2022), ECF No. 1 ("Moderna Compl.") ¶43.

[3] *Mycogen Plant Science, Inc. v. Monsanto Co*., 61 F. Supp. 2d 199 (D. Del. 1999).

[4] *Mycogen Plant Science, Inc. v. Monsanto Co*., 243 F.3d 1316 (Fed. Cir. 2001).

[5] *Barton or Fischhoff v. Adang*, 2003 WL 23280019 (BPAI Jan. 29, 2004).

11. The patent system provides an important, predictable framework for advancing scientific knowledge by allowing companies for a limited period to recover not less than a reasonable royalty for the use of their patented inventions. Plaintiffs thus seek compensation to which they are entitled by law "for the use made of the[ir] invention," which is "in no event less than a reasonable royalty." 35 U.S.C. § 284.

Parties

12. Plaintiff Bayer CropScience LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 800 N. Lindbergh Blvd., Creve Coeur, Missouri 63141.

13. Plaintiff Monsanto Company is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 800 N. Lindbergh Blvd., Creve Coeur, Missouri 63141.

14. Plaintiff Monsanto Technology LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 800 N. Lindbergh Blvd., Creve Coeur, Missouri 63141.

15. Upon information and belief, Defendant Moderna, Inc. is a publicly traded corporation organized and existing under the laws of the State of Delaware with a principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. Upon information and belief, Moderna, Inc., is the parent company of the other defendants and recognizes the revenue from sales of Moderna's COVID-19 vaccine, including Spikevax®, and its mResvia® vaccine.

16. 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 325 Binney Street, Cambridge, Massachusetts 02142. ModernaTX is a wholly-owned subsidiary of

Moderna, Inc. The FDA granted the Biologic License Approval ("BLA") for Spikevax® to ModernaTX.

17. Upon information and belief, Moderna US is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. Moderna US is a wholly-owned subsidiary of Moderna, Inc. and sells Spikevax® in the United States.

18. Upon information and belief, Defendants Moderna, Inc., ModernaTX, and Moderna US are agents of each other and/or work in concert with each other with respect to the development and regulatory approval, marketing, manufacturing, sales, offers for sale, and distribution of Moderna's infringing mRNA vaccines.

Jurisdiction & Venue

19. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*

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

21. Venue is proper in this judicial District under 28 U.S.C. § 1400(b) with respect to Moderna, Inc., ModernaTX, and Moderna US, because each is organized and existing under the laws of Delaware and therefore reside in Delaware for purposes of venue.

22. Defendants Moderna, Inc., ModernaTX, and Moderna US have consented to this Court as a proper venue and its exercise of personal jurisdiction in other litigations involving their mRNA vaccines, including in *Alynylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 22-cv-335-CFC, and *Alynlyam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 23-cv-580-CFC.

Background
Scientific Background

23. The U.S. Court of Appeals for the Federal Circuit addressed much of the scientific background to certain embodiments of Fischhoff and Perlak's invention in its decision awarding them priority. *Mycogen Plant Science v. Monsanto Company*, 243 F.3d 1316, 1322-24 (Fed. Cir. 2001).[6] Eukaryotic organisms like plants and animals, though incredibly diverse in appearance, have much in common at the molecular level. They are made up of vast quantities of cells with distinct nuclei that contain chromosomes. Chromosomes carry deoxyribonucleic acid, or DNA, which contains coded genetic information that cells use to make, or "express," proteins.

24. DNA molecules consist of two strands running antiparallel to each other in the familiar "double helix," or twisted-ladder shape, as first described in 1953 by Doctors James Watson and Francis Crick. The strands are connected to each other, like rungs on a twisted ladder, by pairs of chemically joined molecules called nucleotides. There are four possible nucleotides: adenine (A), thymine (T), cytosine (C), and guanine (G). Each nucleotide pairs naturally with only one other nucleotide: A pairs with T; and C pairs with G. These A/T and C/G nucleotide pairs constitute the genetic code of the cell.

25. Cells use DNA to express proteins through a two-step process known as transcription and translation. At the transcription phase, the code from an existing strand of DNA is copied to a newly created strand of RNA, or ribonucleic acid called mRNA, or messenger RNA. The mRNA is then translated into the encoded protein by a process which the Federal Circuit has described as follows:

[6] Additional relevant scientific background can be found in *In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988), and *Association for Molecular Pathology v. Myriad*, 569 U.S. 576, 580-82 (2013).

In the second step, translation, the nucleotide sequence of the mRNA is translated into the amino acid sequence of the corresponding protein. For this translation to work, a complex structure known as a ribosome reads the mRNA nucleotide sequence and generates amino acids. These amino acids are then assembled into proteins. In this way, ribosomes carry out protein synthesis.

Ribosomes read a nucleotide sequence in sets of three nucleotides, known as codons. Each codon directs the ribosome to select a certain amino acid. For example, GCT is a codon directing the ribosome to select the amino acid alanine. Just as nucleotides are the basic units of DNA, amino acids are the basic units of proteins. Thus, a given series of codons specifies a sequence of amino acids comprising a particular protein. A protein can contain few or many amino acids. For example, some Bt pesticidal proteins contain more than 600 amino acids.

While there are 61 possible codons, there are only 20 amino acids. Some amino acids can be specified by more than one codon. In other words, one codon can be substituted for another in the gene without changing the amino acid and resulting protein. For instance, the amino acid alanine is specified by four different codons: GCT, GCG, GCC and GCA. Two very different series of codons could produce the exact same series of amino acids. In fact, most amino acids are specified or coded by more than one codon.[7]

[7] *Mycogen*, 243 F.3d at 1322-24.

26. Each potential codon triplet used to express each of the 20 amino acids were known and described in Table I of the '118 Patent.[8]

27. As the Federal Circuit has explained, the foregoing molecular processes of protein expression are common to all organisms:

> Man, other animals, plants, protozoa, and yeast are *eucaryotic* (or eukaryotic) organisms: their DNA is packaged in chromosomes in a special compartment of the cell, the nucleus. Bacteria (*procaryotic* or prokaryotic organisms) have a different organization. Their DNA, usually a circular loop, is not contained in any specialized compartment. Despite the incredible differences between them, all organisms, whether eucaryote or procaryote, whether man or mouse or lowly bacterium, use the same molecular rules to make proteins under the control of genes. In all organisms, codons in DNA are transcribed into codons in RNA which is translated on ribosomes into polypeptides according to the same genetic code.[9]

28. An unstable mRNA molecule can therefore hinder the ability of a coding sequence to express a particular protein, as it can result in poor translation and poor accumulation of the encoded protein.

[8] '118 Patent at 11:30-12:28.

[9] *O'Farrell*, 853 F.2d at 898.

Plaintiffs' Scientists Discovered and Patented a Method That Resulted in Improved mRNA Stability and Protein Expression.

29. The '118 Patent is the result of groundbreaking research done by Fischhoff and Perlak. In the mid-1980s (decades before Moderna was even founded), Fischhoff and Perlak worked on a problem later faced by Moderna in Moderna's mRNA vaccine work—namely, how to get a genetic coding sequence from a microorganism (including bacteria and viruses) to adequately express in a eukaryotic organism (a class of higher organisms that includes plants and animals).

30. The '118 Patent includes illustrative examples of Fischhoff and Perlak's method, including methods that expressed coding sequences from the bacterium *Bacillus thuringiensis* ("B.t.")[10] and a Potato Leaf Roll Virus Coat Protein Gene.[11] A goal of the B.t. work was to express a protein naturally made by *Bacillus thuringiensis* soil bacteria that is toxic to insects, but harmless to animals, to impart insect resistance in plants. A goal of the potato leaf roll virus coat protein work was to express the coat protein to make plants resistant to the potato leaf roll virus.[12]

31. Plaintiffs' Scientists' early efforts in 1983-1986 to express naturally occurring coding sequences resulted in low levels of expression. They set out to solve the expression problem, and like Moderna, their solution "started with the mRNA itself."[13] As the '118 patent explains:

> Several potential factors could be responsible in varying degrees for the level of protein expression from a particular coding sequence. The level of a particular mRNA in the cell is certainly a critical factor.
>
> . . .

[10] *See* '118 Patent at Examples 1, 4, 5, 6, and 8.

[11] *See* '118 Patent at Examples 1 and 9.

[12] '118 Patent at 38:25-30.

[13] Moderna Compl. ¶43.

> In the cytoplasm, mRNAs have distinct halflives that are determined by their sequences and by the cell type in which they are expressed. Some RNAs are very short-lived and some are much more long-lived. In addition, there is an effect, whose magnitude is uncertain, of translational efficiency on mRNA half-life. In addition, every RNA molecule folds into a particular structure, or perhaps family of structures, which is determined by its sequence.[14]

32. In 1986, Fischhoff and Perlak conceived a solution[15] revolving around certain sequences prevalent in certain bacterial and viral origin coding sequences that had contributed to mRNA instability in higher organisms. Fischhoff and Perlak theorized that these sequences were likely destabilizing for expression in plants and animals alike:

> Some particular sequences have been identified in RNAs that have the potential for having a specific effect on RNA stability. This section summarizes what is known about these sequences and signals. These identified sequences often are A+T rich, and thus are more likely to occur in an A+T rich coding sequence such as a B.t. gene. The sequence motif ATTTA (or AUUUA as it appears in RNA) has been implicated as a destabilizing sequence in mammalian cell mRNA 60 (Shaw and Kamen, 1986). No analysis of the function of this sequence in plants has been done.[16]

. . .

[14] '118 Patent at 1:21-25, 36-49.

[15] *Barton or Fischhoff v. Adang*, 2003 WL 23280019 at *1, 25-26.

[16] '118 Patent at 1:53-62.

Some studies on mRNA degradation in animal cells also indicate that RNA degradation may begin in some cases with nucleotlytic attack in A+T rich regions. It is not clear if these cleavages occur at ATTTA sequences. There are also examples of mRNAs that have differential stability depending on the cell type in which they are expressed or on the stage within the cell cycle at which they are expressed.[17]

. . .

The addition of a polyadenylate string to the 3' end is common to most eucaryotic mRNAs, both plant and animal. The currently accepted view of poly A addition is that the nascent transcript extends beyond the mature 3' terminus. Contained within this transcript are signals for polyadenylation and proper 3' end formation. This processing at the 3' end involves cleavage of the mRNA and addition of poly A to the mature 3' end. By searching for consensus sequences near the polyA tract in both plant and animal mRNAs, it has been possible to identify consensus sequences that apparently are involved in poly A addition and 3' end cleavage. The same consensus sequences seem to be important to both of these processes. These signals are typically a variation on the sequence AATAAA. In animal cells, some variants of this sequence that are functional have been identified; in plant cells there seems to be an extended range of functional sequences (Wickens and Stephenson, 1984; Dean et al., 1986). Because all of these consensus sequences are variations on AATAAA, they all are A+ T rich sequences. This sequence is typically found 15 to 10 bp before

[17] '118 Patent at 2:21-27

> the ply A tract in a mature mRNA. Experiments in animal cells indicate that this sequence is involved in both polyA addition and 3' maturation.[18]
>
> . . .
>
> From these examples, it is clear that in natural mRNAs proper polyadenylation is important in mRNA accumulation, and that disruption of this process can effect mRNA levels significantly. However, insufficient knowledge exists to predict the effect of changes in a normal gene. In a heterologous gene, where we do not know if the putative polyA sites (consensus sequences) are functional, it is even harder to predict the consequences. However, it is possible that the putative sites identified are disfunctional. That is, these sites may not act as proper polyA sites, but instead function as aberrant sites that give rise to unstable mRNAs.[19]

33. In addition to the ATTTA sequence, Fischhoff and Perlak identified 16 AT-rich "Potential Polyadenylation Signals" in Table II of the '118 Patent that they believed contributed to mRNA instability in plant and animal cells ("Table II Sequences"):

[18] '118 Patent at 2:51-3:6.

[19] '118 Patent at 3:53-63.

Figure 1

'118 Patent, Table II (15:50-64)

TABLE II

List of Sequences of the Potential Polyadenylation Signals	
AATAAA*	AAGCAT
AATAAT*	ATTAAT
AACCAA	ATACAT
ATATAA	AAAATA
AATCAA	ATTAAA**
ATACTA	AATTAA**
ATAAAA	AATACA**
ATGAAA	CATAAA**

*indicates a potential major plant polyadenylation site.
**indicates a potential minor animal polyadenylation site.
All others are potential minor plant polyadenylation sites.

34. Plaintiffs' Scientists conceived replacing of Table II Sequences and "ATTTA" sequences found in native mRNA with "sense" codons encoding for the same amino acid would increase mRNA stability, resulting in better protein expression.

35. The '118 Patent describes that "[i]t is also preferred that regions comprising many consecutive A+T bases … are disrupted since these regions are predicted to have a higher likelihood to form hairpin structure due to self-complementarity."[20] The '118 Patent explains that "[i]n most cases, the adverse effects may be minimized by using sequences which do not contain

[20] '118 Patent at 10:60-65.

more than five consecutive A+T or G+C."[21] Elsewhere, the '118 patent explains "Of course, due to the A+T content of B.t. genes, they are rich in runs of A or T that could act as terminators."[22]

36. The '118 Patent discloses that utilizing Fischhoff and Perlak's method to reduce Problem Sequences in the gene's coding region resulted in a dramatic increase in protein expression. Plaintiffs' Scientists utilized their novel method with well-known genetic engineering techniques like site-directed mutagenesis and *de novo* synthesis. In one example, Plaintiffs' Scientists observed a 500-fold increase in the expression of B.t.k. protein with a coding sequence modified to remove nearly all of the Problem Sequences, and a 100-fold increase in plants with a coding sequence modified to remove nearly half of those sequences.[23] These increases in protein expression resulted in corresponding increases in bioactivity: Whereas plants with the native coding sequence received "only minimal protection" against insect damage, plants with half-modified coding sequence showed "almost complete protection" and plants with fully-modified coding sequence were "totally protected."[24] Plaintiffs' Scientists concluded that these results were caused by increases in mRNA levels and translation efficiency attributable to their method of reducing Problem Sequences.[25]

[21] '118 Patent at 10:68-11:2.

[22] '118 Patent at 5:65-66.

[23] '118 Patent at 16:65-17:1, 21:1-2, 24:25-40.

[24] '118 Patent at 24:40-67.

[25] '118 Patent at 30:36-47.

37. Plaintiffs' Scientists also disclosed that their method could be used "to express [a] viral coat protein at an effective level" and thereby "achieve virus resistance."[26] In one example, they designed a coding sequence that removed Problem Sequences from the native sequence of "the coat protein gene from potato leaf roll virus" to make a "synthetic gene [] designed to improve plant expression of the [viral] coat protein" while encoding the same protein as the naturally occurring gene.[27] The '118 Patent states that plants with the modified coding sequence "express the [viral] coat protein at higher levels than achieved with the naturally occurring gene" and "exhibit increased resistance to infection" by the virus.[28]

38. After discovering their novel method, Plaintiffs' Scientists timely sought legal protection for their invention, filing patent application No. 07/315,355 on February 24, 1989. Following a lengthy examination period that included an eight-year interference proceeding that confirmed their earlier invention date, the '118 Patent issued on June 22, 2010.

39. While the '118 Patent includes claims reciting methods of making structural genes encoding insecticidal proteins, Plaintiffs' Scientists did not limit their claims and disclosure to a particular gene, cell, or expression level. Instead, Plaintiffs' Scientists claimed and described method steps for reducing the specific Problem Sequences they found contributed to unstable mRNAs.[29] They described the "most rigorous application" of this "present invention" as modification of a coding sequence "by removal of ATTTA sequences and putative polyadenylation signals" (*i.e.*, Table II Sequences).[30] They further described that "if a synthetic gene is prepared

[26] '118 Patent at 38:25-29.

[27] '118 Patent at 38:30-39:19.

[28] '118 Patent at 39:23-25.

[29] '118 Patent at 3:61-63.

[30] '118 Patent at 10:14-17.

which codes for the expression of the subject protein, codons are selected to avoid the [Problem Sequences]."[31] Claim 59, for example, recites "[a] method for making a structural gene that encodes a protein" comprising three steps: "(a) starting with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II; (b) reducing the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence; and (c) making a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein." Claims 60 and 73 recite additionally reducing ATTTA sequences, and Claims 79 and 80 recite additionally reducing regions with greater than five consecutive adenine and thymine (A+T) nucleotides.

40. The '118 Patent was filed before implementation of the General Agreement on Tariffs and Trade (GATT). As a pre-GATT patent, the '118 Patent's term extends 17 years from the date of issuance—through June 22, 2027.

Moderna Developed mRNA Products Using Plaintiffs' Patented Method.

41. Moderna was founded in 2010. Its name comes from a combination of the words "modified" and "RNA."[32] Since its founding, Moderna has focused on what it calls "messenger RNA Therapeutics™," or the use of modified mRNA to "stimulat[e] the body's natural ability to

[31] '118 Patent at 10:17-20.

[32] Moderna Website, *Our Story*, https://perma.cc/SBA2-XG9U.

produce therapeutic proteins."[33] Moderna's "mRNA medicines use a specific nucleotide sequence to encode instructions to make the exact protein needed for a particular disease."[34]

42. Upon information and belief, Moderna has designed and manufactured its mRNA products in the United States, including its infringing mRNA vaccine products. In 2014, Moderna opened its headquarters and labs in Cambridge, Massachusetts.[35] In 2016, Moderna signed a lease to build a 200,000 square foot mRNA clinical manufacturing facility in Norwood, Massachusetts.[36] Moderna has credited its ability to move quickly in creating its infringing COVID-19 mRNA vaccine in part to its "decision in 2016 to build a manufacturing plant in Massachusetts."[37] This "integrated plant capable of full-scale development production" was "operational by summer 2018."[38]

43. According to the Center for Disease Control ("CDC"), Moderna's Spikevax® COVID-19 vaccine works on the basic premise illustrated below.

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[33] Moderna Press Release, *Moderna Announces $40 Million In Financing To Advance Development Of New Biotherapeutic Modality: Messenger RNA Therapeutics™* (Dec. 6, 2012), https://perma.cc/VC48-AC7J.

[34] Moderna Compl. ¶42.

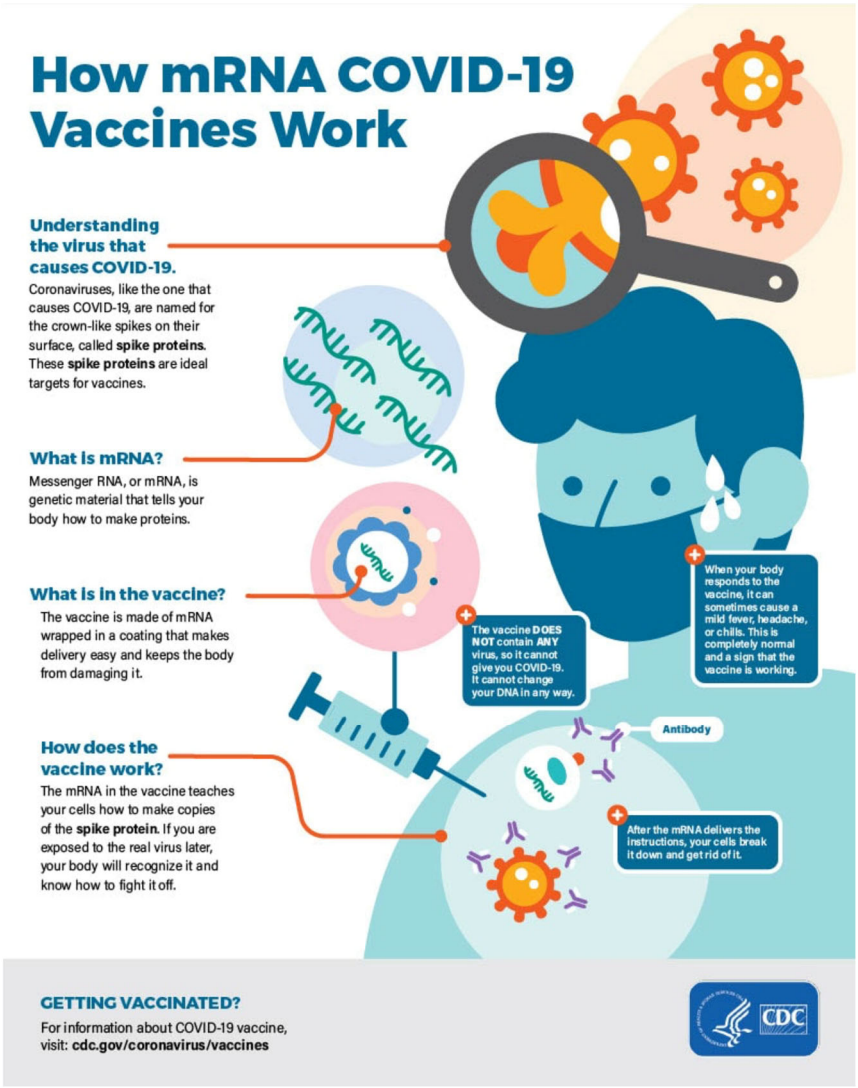
[35] Moderna Website, *Our Story*, https://perma.cc/SBA2-XG9U.

[36] Moderna Website, *Our Story*, https://perma.cc/SBA2-XG9U.

[37] *Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the Covid Vaccine?: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 118th Cong. 6 (2023) (testimony of Stéphane Bancel, Chief Executive Officer and Director, Moderna, Inc.), https://perma.cc/ASM6-2M2U.

[38] *Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the Covid Vaccine?: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 118th Cong. 9 (2023) (testimony of Stéphane Bancel, Chief Executive Officer and Director, Moderna, Inc.), https://perma.cc/ASM6-2M2U.

Figure 2
mRNA Vaccines CDC Publication[39]



44. Briefly, modified mRNA coding for a protein based on the SARS-CoV-2 spike protein is generated and introduced into the human body. Ribosomes in the body then translate the mRNA into the spike protein so that the body generates antibodies capable of binding to the spike protein. If a vaccinated person later encounters the SARS-CoV-2 virus, these antibodies may bind to the

[39] CDC, *COVID-19 Vaccine Basics*, https://perma.cc/24YT-FQUT.

virus's spike proteins to help stop its spread. Thus, these vaccines will not be effective if the mRNA is unstable and unable to adequately express the spike protein.

45. To develop effective mRNA medicines, Moderna needed to stabilize the mRNA molecule and optimize its protein expression. Moderna has recognized that this required optimizing the mRNA molecule itself:

> The problems that Moderna faced started with the mRNA itself. mRNA is an unstable molecule that is quickly destroyed inside the body. Moderna scientists had to develop novel ways to stabilize mRNA by modifying its chemical structure so that it could be used in vaccines and therapeutics. Moderna also optimized its mRNA platform to make it more effective at producing the proteins needed to fight and prevent disease.[40]

46. Moderna's mRNA platform used "sequence engineering" to "[m]aximiz[e] protein expression" and "optimize the amount of protein produced per mRNA."[41] This included "design[ing] the nucleotide sequence of the coding region to maximize its successful translation into protein."[42]

47. Moderna's website claims "we maximize the utility of mRNA in our proprietary, web-based mRNA Design Studio."[43] Under the caption "mRNA tailoring," Moderna asserts that its "in-house digital application suite contains a Sequence Designer module to tailor an entire mRNA."[44] According to the posted video on Moderna's "Research Engine," its "algorithms consider

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[40] Moderna Compl. ¶43.

[41] Moderna 2022 Form 10-K, p.12 (Feb. 24, 2023), https://perma.cc/7S6Q-UGG2.

[42] Moderna 2022 Form 10-K, p.12 (Feb. 24, 2023), https://perma.cc/7S6Q-UGG2.

[43] Moderna Website, *The power of mRNA*, https://perma.cc/G9EJ-NL5P.

[44] Moderna Website, *The power of mRNA*, https://perma.cc/G9EJ-NL5P.

sequence, structure, and other factors to identify mRNA sequences that are predicted to confer desired pharmacologic properties."[45]

48. In early 2020, when reports of COVID-19 first began to emerge, Moderna "was able to respond rapidly" by developing an mRNA vaccine "specifically targeting COVID-19."[46] Unlike "traditional vaccine development" that used "a dead or weakened version of the novel coronavirus or one of its components," Moderna's mRNA vaccine development "use[d] the information from the virus to teach the cells in a patient's body how to make the virus's Spike protein, which itself provokes a protective immune response."[47] "[T]his … approach" enabled Moderna to "progress[] from genetic sequencing to a vaccine ready for human testing in just 63 days."[48]

49. The native genetic sequence for the original SARS-CoV-2 spike protein became public on January 11, 2020.[49] "Within a matter of days," Moderna "took that information to create an mRNA sequence encoding for the virus's spike protein" for its original monovalent Spikevax® vaccine.[50] That sequence is called mRNA-1273.[51] Moderna was "able to research and develop

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[45] Moderna Website, *The power of mRNA*, available at https://www.modernatx.com/en-US/power-of-mrna/modernas-mrna-platform#our-research-engine (last accessed Dec. 11, 2025); *see also* YouTube, *Moderna's Research Engine*, available at https://youtu.be/3fvuFkmQmxQ (last accessed Dec. 11, 2025).

[46] Moderna Compl. ¶46.

[47] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 4-5 (2021) (Testimony of Dr. Stephen Hoge, President, Moderna, Inc.), https://perma.cc/AG86-C64K.

[48] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 5 (2021) (Testimony of Dr. Stephen Hoge, President, Moderna, Inc.), https://perma.cc/AG86-C64K.

[49] Moderna Compl. ¶48.

[50] Moderna Compl. ¶48.

[51] *Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the Covid Vaccine?: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 118th Cong.

mRNA-1273 so quickly because [Moderna] leveraged [its] prior research on vaccines and other mRNA-based medicines."[52] It "began to develop mRNA-1273 by reviewing the genetic sequence for the Spike protein" and "design[ing] a[nd] synthesiz[ing] a corresponding mRNA sequence."[53] As detailed below, part of that design process included eliminating all or substantially all of the Problem Sequences that were present in the native sequence. Moderna made the mRNA in its mRNA-1273 vaccines by creating a DNA template which was transcribed in vitro.[54]

50. Upon information and belief, Moderna's ability to quickly and effectively design and synthesize mRNA-1273 was enabled in part by its use of Plaintiffs' patented method for removing the Problem Sequences identified in the '118 Patent by substituting sense codons.

51. Moderna proved the effectiveness of mRNA-1273 in clinical trials. Less than a month after designing the coding sequence for mRNA-1273, Moderna used its DNA template to manufacture its first clinical samples of mRNA-1273.[55] The Phase I trial of Moderna's resulting mRNA vaccine, branded as Spikevax®, began in March 2020; Phase II began in May 2020, and

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6 (2023) (testimony of Stéphane Bancel, Chief Executive Officer and Director, Moderna, Inc.), https://perma.cc/ASM6-2M2U.

[52] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 4 (2021) (Testimony of Dr. Stephen Hoge, President, Moderna, Inc.), https://perma.cc/AG86-C64K.

[53] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 4 (2021) (Testimony of Dr. Stephen Hoge, President, Moderna, Inc.), https://perma.cc/AG86-C64K.

[54] Kizzmekia S. Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, 586 NATURE 567, 568 (2020).

[55] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 5 (2021) (Testimony of Dr. Stephen Hoge, President, Moderna, Inc.), https://perma.cc/AG86-C64K.

Phase III began in July 2020.[56] These trials demonstrated mRNA-1273's significant (94%) effectiveness in preventing infection from the original coronavirus strain after a two-dose regimen.[57]

52. The successful clinical results of Moderna's mRNA vaccine led to a series of regulatory approvals in the United States market. The FDA first approved Spikevax® for adults under an emergency use authorization in December 2020,[58] followed by a number of other approvals. For example, the FDA provided an emergency-use authorization for a "booster" dose of mRNA-1273 in November 2021.[59] Moderna eventually received full commercial approval for mRNA-1273 and a second booster dose of same.[60]

53. Moderna has since developed booster vaccines and monovalent and bivalent boosters for variants of COVID-19. Moderna has developed additional mRNA sequences targeting SARS-CoV-2 spike protein variants, including mRNA-1273.214[61] for the BA.1 variant, mRNA-1273.222

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[56] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 5 (2021) (Testimony of Dr. Stephen Hoge, President, Moderna, Inc.), https://perma.cc/AG86-C64K.

[57] Moderna Compl. ¶50.

[58] Moderna Compl. ¶51.

[59] Moderna Press Release, *Moderna Announces FDA Authorization of Booster Dose of COVID-19 Vaccine in the U.S. for Adults 18 Years and Older* (Nov. 19, 2021), https://perma.cc/7WJW-LWNE.

[60] Moderna Press Release, *Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax* (Jan. 31, 2022), https://perma.cc/J3ZC-ZJMV; Moderna Press Release, *Moderna Receives FDA Approval for Emergency Use Authorization of 2nd Booster Dose of Its COVID-19 Vaccine, mRNA-1273* (Mar. 29, 2022), https://perma.cc/D2LS-5QAZ.

[61] Moderna Press Release, *Moderna Announces Omicron-Containing Bivalent Booster Candidate mRNA-1273.214 Demonstrates Superior Antibody Response Against Omicron* (June 8, 2022), https://perma.cc/2YAH-8UR5; Moderna 2022 Form 10-K, p.97 (Feb. 24, 2023), https://perma.cc/8NZ7-9YKL.

for the BA.4/5 variant,[62] mRNA-1273.815 for the XBB.1.5 variant,[63] and mRNA-1273.712 for the KP.2 variant.[64]

54. Upon information and belief, Moderna used similar coding sequence design protocols for its mRNA sequences targeting SARS-CoV-2 spike protein variants, including designing their coding sequences to have none or substantially none of the Problem Sequences present in the respective spike protein starting sequences by substituting sense codons, as illustrated below:

Reductions of Table II Sequences				
Variant mRNAs	mRNA-1273	mRNA-1273.214	mRNA-1273.222	mRNA-1273.815
Starting Sequence	30	27	28	29
Vaccine Sequence	1	0	1	1

Reductions of ATTTA Sequences				
Variant mRNAs	mRNA-1273	mRNA-1273.214	mRNA-1273.222	mRNA-1273.815
Starting Sequence	7	6	7	7
Vaccine Sequence	0	0	0	0

Reductions of Regions with >5 A+T				
Variant mRNAs	mRNA-1273	mRNA-1273.214	mRNA-1273.222	mRNA-1273.815
Starting Sequence	68	70	71	70
Vaccine Sequence	0	0	0	0

[62] Moderna Press Release, *Moderna Receives FDA Authorization for Emergency Use of Omicron-Targeting Bivalent COVID-19 Booster Vaccine for Adults 18 Years and Older* (Aug. 31, 2022), https://perma.cc/6U67-22LN; Moderna 2022 Form 10-K, p.97 (Feb. 24, 2023), https://perma.cc/8NZ7-9YKL.

[63] Moderna Press Release, *Moderna Expands the Field of mRNA Medicine with Positive Clinical Results Across Cancer, Rare Disease, and Infectious Disease* (Sept. 13, 2023), https://perma.cc/RV8L-6B6S.

[64] FDA, Emergency Use Authorization (EUA), p.17 (Aug. 22, 2024), https://perma.cc/G8WM-2G3F.

55. Upon information and belief, Moderna also received regulatory approvals in more than 70 foreign markets for its bivalent and monovalent COVID-19 mRNA vaccines.[65] Upon information and belief, the coding sequence for all such vaccines sold in the United States and internationally was originally designed and made by Moderna in the United States.

56. Moderna has generated tens of billions of dollars in revenue from the sale of its COVID-19 mRNA vaccines. In 2020, Moderna reported $200 million in revenue from global sales of its COVID-19 vaccine, virtually all of which was in the United States.[66] In 2021, Moderna reported $17.7 billion in revenue from global sales of its COVID-19 vaccine, including $5.4 billion in the United States.[67] In 2022, Moderna reported $18.4 billion in revenue from global sales of its COVID-19 vaccine, including $4.4 billion in the United States.[68] In 2023, Moderna reported $6.7 billion in revenue from global sales of its COVID-19 vaccine, including $1.7 billion in the United States.[69] In 2024, Moderna reported $3.1 billion in revenue from global sales of its COVID-19 vaccine, including $1.7 billion in the United States.[70] Through Q3 of 2025, Moderna reported $1.2 billion in revenue from global sales of its COVID-19 vaccine, including $897 million in the United States.[71] Upon information and belief, Moderna has generated over $47 billion in global sales revenue attributable to its mRNA COVID-19 vaccines, including over $14 billion in the United

[65] Moderna 2023 Form 10-K, p.14 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5.
[66] Moderna 2022 Form 10-K, p.127 (Feb. 24, 2023), https://perma.cc/8NZ7-9YKL.
[67] Moderna 2023 Form 10-K, p.119 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5.
[68] Moderna 2023 Form 10-K, p.119 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5.
[69] Moderna 2023 Form 10-K, p.119 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5.
[70] Moderna 2024 Form 10-K, p.115 (Feb. 21, 2025), https://perma.cc/X7SS-D58B.
[71] Moderna 2025 Q3 Form 10-Q, p.13 (Nov. 6, 2025), https://perma.cc/EJ5S-98UK.

States. Upon information and belief, all of these sales resulted from Moderna's activities infringing the '118 patent in the United States.

57. Moderna has also received substantial grant revenue attributable to its development of mRNA-1273. For example, in April 2020, Moderna entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA) for an award of up to $483 million to accelerate development of mRNA-1273.[72] Upon information and belief, this agreement has been amended to increase Moderna's maximum award attributable to mRNA-1273's development efforts to $1.8 billion.[73] In 2020, 2021, 2022, and 2023, Moderna reported grant revenue from the BARDA agreement of $522 million, $713 million, $372 million, and $88 million, respectively.[74]

58. Moderna continues to generate revenue from its COVID-19 mRNA vaccines. In 2023, Moderna announced a 400% price increase for its COVID-19 mRNA vaccine.[75] As of March 2024, Moderna estimated a roughly $10 billion market for all COVID-19 vaccines.[76]

59. Moderna has also developed a vaccine for lower respiratory tract disease caused by respiratory syncytial virus (RSV), which it markets under the name mRESVIA®.[77] mRESVIA® "is an mRNA vaccine encoding a stabilized prefusion F glycoprotein from RSV A strain

[72] Moderna 2023 Form 10-K, p.29 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5.

[73] Moderna 2023 Form 10-K, p.29 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5.

[74] Moderna 2023 Form 10-K, p.120 (Feb. 23, 2024), https://perma.cc/YT2W-UBP5; Moderna 2022 Form 10-K, p.128 (Feb. 24, 2023), https://perma.cc/8NZ7-9YKL.

[75] *Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the Covid Vaccine?: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 118th Cong. 43 (2023) (testimony of Stéphane Bancel, Chief Executive Officer and Director, Moderna, Inc.), https://perma.cc/ASM6-2M2U.

[76] Moderna Vaccine & Business Updates PPT, p.108 (Mar. 27, 2024), https://perma.cc/749X-VCV2.

[77] FDA, *Summary Basis for Regulatory Action*, p.1 (May 31, 2024), https://perma.cc/W3N8-EJ93; Moderna Website, mRESVIA® Product Information, https://perma.cc/6RYH-RALN.

formulated in lipid nanoparticles."[78] Moderna also refers to mRESVIA® as "mRNA-1345,"[79] and the modified RNA sequence in mRESVIA® is known as "RNA-100-AR02."[80] Moderna makes mRESVIA® with the "same manufacturing process" as its COVID-19 vaccines, including the use of "the same equipment, people, and raw material."[81] "RNA-100-AR02 is manufactured and tested at the site ModernaTX, Inc. (ModernaTX Norwood) One Moderna Way Norwood, MA 02062 USA."[82] Shown in the table below is a comparison of the coding sequence for the stabilized prefusion F glycoprotein and Moderna's mRESVIA® sequence. Upon information and belief, mRNA-1345 and RNA-100-AR02 were made by a method which resulted in a reduced number of Problem Sequences compared to the starting sequence by substituting sense codons.

mRESVIA®			
	Reductions of Table II Sequences	**Reductions of ATTTA Sequences**	**Reductions of Regions with >5 A+T**
Starting Sequence	22	3	34
Vaccine Sequence	0	0	0

[78] FDA, *BLA Clinical Review Memorandum*, p.3 (May 29, 2024), https://perma.cc/YM6G-9G38. *See also* Moderna Press Release, *Moderna Receives U.S. FDA Approval for RSV Vaccine mRESVIA(R)* (May 31, 2024), https://perma.cc/Q8WN-X2TR.

[79] Moderna Press Release, *Moderna Receives U.S. FDA Approval for RSV Vaccine mRESVIA(R)* (May 31, 2024), https://perma.cc/Q8WN-X2TR.

[80] European Medicines Agency, mRESVIA® Assessment Report, p.11 (June 27, 2024), https://perma.cc/SZ6G-GW5E.

[81] CNBC Television, "Moderna CEO: We're preparing our FDA filing for our RSV vaccine," at 2:21 (Jan. 18, 2023), https://perma.cc/FK4Y-ADPP.

[82] European Medicines Agency, mRESVIA® Assessment Report, p.11 (June 27, 2024), https://perma.cc/SZ6G-GW5E.

60. Upon information and belief, Moderna continues to use the same design protocol with respect to its other mRNA vaccine products currently in its product pipeline, including its mRNA1010 flu vaccine.[83]

Count 1: Infringement of the '118 Patent

61. Plaintiffs repeat and re-allege the allegations in the preceding paragraphs as if fully set forth herein.

62. On June 22, 2010, the United States Patent and Trademark Office issued the '118 Patent. A true and correct copy of the '118 Patent is attached as **Exhibit A**.

63. Plaintiffs collectively own all rights, titles, and interests in the '118 Patent, including the right to assert all causes of action under the '118 Patent and the right to remedies obtained on the '118 Patent.

64. Each claim of the '118 Patent is in effect, valid, and enforceable.

65. Moderna has directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '118 Patent, in violation of 35 U.S.C. § 271(a) and (g). For example, Moderna performed and/or directed the performance of the infringing method by its agents in the United States to make the SARS-CoV-2 spike protein coding sequences and/or DNA template and RSV F glycoprotein coding sequences and/or DNA template

[83] Moderna 2022 Form 10-K, p.12 (Feb. 24, 2023), https://perma.cc/7S6Q-UGG2 (Moderna's "platform" includes "mRNA sequence engineering," that includes "design[ing] the nucleotide sequence of the coding region to maximize its successful translation into protein"); *id.* at p.121 (disclosing that Moderna's "platform" provides it "the capability to pursue in parallel a robust pipeline of new development candidates"); Moderna Website, *The power of mRNA*, https://perma.cc/G9EJ-NL5P (Moderna's "mRNA DESIGN STUDIO enables rapid design of multiple mRNAs," and includes steps where a "protein target is automatically converted to an initial optimized mRNA sequence" and refined with Moderna's "Sequence Designer module to tailor an entire mRNA").

used to make all of its COVID-19 and RSV vaccine products sold worldwide. Accordingly, Moderna's worldwide sales of the Accused Products are enabled by and causally connected to Moderna's acts of infringement in the United States. Moderna makes, uses, offers for sale, sells, and/or imports certain products made by the claimed method, including but not limited to Moderna's COVID-19 vaccines incorporating mRNA-1273, mRNA-1273.214, mRNA-1273.222, mRNA-1273.815, and/or mRNA-1273.712, Moderna's mRESVIA® vaccine (including foreign or domestic variants or equivalents thereof sold under different commercial names), as well as other mRNA vaccine products currently in its product pipeline, including its mRNA 1010 flu vaccine, which were developed using the infringing method to reduce Problem Sequences (the "Accused Products").

66. For purposes of illustration and example, Claim 59 of the '118 Patent recites:

> A method of making a structural gene that encodes a protein, the method comprising:
>
> (a) starting with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II;
>
> (b) reducing the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence; and
>
> (c) making a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein.

67. Upon information and belief, the method performed by Moderna in making the Accused Products satisfies all elements of Claim 59 of the ’118 Patent.

68. Moderna “start[ed] with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II.” For example, upon information and belief, the viral coding sequences for the SARS-CoV-2 spike proteins and RSV F glycoprotein (including their respective subunit proteins) encoded by the mRNA in the Accused Products contain Table II Sequences.

69. Moderna “reduc[ed] the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence.” For example, upon information and belief, Moderna designed the SARS-CoV-2 spike protein and RSV F glycoprotein coding sequences and/or DNA templates for the Accused Products to have a reduced number of Table II Sequences by substituting sense codons.

70. Moderna “ma[de] a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein.” For example, upon information and belief, the Accused Products were made using and additionally include a structural gene that comprises a coding sequence with codons that were substituted according to paragraph 69 and that encodes a SARS-CoV-2 spike protein and RSV F glycoprotein, respectively (including any subunit proteins).

71. For purposes of additional illustration and example, Claim 60 of the ’118 Patent recites:

> The method of claim 59, wherein the starting coding sequence of step (a) contains ATTTA sequences, and wherein step (b) further comprises reducing the

number of said ATTTA sequences in the coding sequence by substituting sense codons for codons in the coding sequence.

72. Upon information and belief, the method performed by Moderna in making the Accused Products satisfies all elements of Claim 60 of the ’118 Patent.

73. Moderna started with a “coding sequence … contain[ing] ATTTA sequences.” For example, upon information and belief, the viral coding sequences for the SARS-CoV-2 spike proteins and RSV F glycoproteins (including their respective subunit proteins) encoded by the mRNA in the accused products contained ATTTA Sequences.

74. Moderna “reduc[ed] the number of said ATTTA sequences in the coding sequence by substituting sense codons for codons in the coding sequence.” For example, Moderna designed the SARS-CoV-2 spike protein and RSV F glycoprotein coding sequences for the Accused Products to have a reduced number of ATTTA sequences by substituting sense codons.

75. For purposes of further illustration and example, Claim 73 of the ’118 Patent recites:

The method according to any one of claims 51-54, and 56-68, wherein the structural gene made according to the method contains no ATTTA sequences.

76. Upon information and belief, the method performed by Moderna in making the Accused Products satisfies all elements of Claim 73 of the ’118 Patent.

77. Moderna “ma[de] a structural gene … contain[ing] no ATTTA sequences.” For example, upon information and belief, the Accused Products include structural genes made according to the method described in paragraphs 66-70 that contain no ATTTA sequences.

78. For purposes of further illustration and example, Claim 79 of the ’118 Patent recites:

> The method according to any one of claims 51, 58-64, and 66, further comprising reducing the number of regions in the coding sequence(s) with greater than five consecutive adenine and thymine (A+T) nucleotides by substituting sense codons for codons in the coding sequence(s).

79. Upon information and belief, the method performed by Moderna in making the Accused Products satisfies all elements of Claim 79 of the ’118 Patent.

80. Moderna “reduc[ed] the number of regions in the coding sequence(s) with greater than five consecutive adenine and thymine (A+T) nucleotides by substituting sense codons for codons in the coding sequence(s).” For example, upon information and belief, the Accused Products made according to the methods described in paragraphs 66-70 include coding sequences with the number of regions with greater than five consecutive adenine and thymine (A+T) nucleotides reduced by substituting sense codons.

81. Upon information and belief, Moderna has imported, used, sold, and/or offered for sale in the United States a product made by the methods of at least Claims 59, 60, 73, and 79 of the ’118 Patent, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. §271(g). Upon information and belief, Moderna performs the infringing method to make the coding sequences used in and to make the Accused Products in the United States. Moderna makes, uses, offers for sale, sells, and/or imports the Accused Products.

82. Plaintiffs are entitled to damages as a result of Moderna’s infringement of the ’118 Patent in an amount yet to be determined and adequate to compensate Plaintiffs for Moderna’s infringement, but in no event less than a reasonable royalty for the use made of the patented invention by Moderna, together with interest and costs as fixed by the Court, except that Plaintiffs do not seek damages for acts of infringement, if any, covered by 28 U.S.C. § 1498.

Demand for Jury Trial

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs hereby demand a trial by jury on all issues so triable.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request that the Court:

1. Enter judgment that Moderna has infringed and continues to infringe the ’118 Patent literally and/or under the doctrine of equivalents;
2. Award Plaintiffs damages to be paid by Moderna in an amount adequate to compensate Plaintiffs for Moderna’s infringement of the ’118 Patent, together with pre-judgment and post-judgment interest;
3. Award Plaintiffs a compulsory ongoing royalty through expiration of the ’118 Patent;
4. Award Plaintiffs their costs; and
5. Grant any further relief that the Court deems just and proper.

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