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**Pro hac vice application forthcoming*

Attorneys for Plaintiff Promosome LLC

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

PROMOSOME LLC,

Plaintiff,

vs.

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

Defendants.

Case No. **'23CV1047 JES DDL**

PROMOSOME COMPLAINT FOR PATENT INFRINGEMENT

DEMAND FOR JURY TRIAL

Plaintiff Promosome LLC ("Promosome"), by and through its attorneys, files 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") and alleges as follows:

Introduction & Nature of the Action

1. Promosome is a biotechnology firm created to develop and commercialize the scientific advancements of Nobel laureate Gerald Edelman[1] and Vincent Mauro, both of whom researched at The Scripps Research Institute ("Scripps"). Dr. Edelman was and Dr. Mauro is a pioneer in the field of biochemistry, discovering numerous concepts underlying ribonucleic acid ("RNA") therapeutics and vaccines, including those behind the messenger RNA ("mRNA") vaccines recently developed to combat the COVID-19 pandemic. One of their most significant contributions is a patented method for increasing mRNA protein expression, which is protected by U.S. Patent No. 8,853,179 (the "'179 Patent"). Promosome, the exclusive licensee of the '179 Patent, disclosed and taught its method of increasing protein expression to Moderna, but Moderna declined to license it. Years later, Moderna developed a COVID-19 vaccine generating tens-of-billions in revenue for the company. And when the sequence used in its mRNA was revealed, it became clear that Moderna had simply taken Promosome's patented method. This Complaint arises from Moderna's willful and unlawful infringement of the '179 Patent.

2. mRNA is genetic material that instructs the body how to produce proteins. It has numerous applications, one of which is mRNA vaccines. The virus causing COVID-19, Severe Acute Respiratory Syndrome Coronavirus 2, or SARS-CoV-2, is a novel coronavirus, which is a type of virus known for its distinctive, crown-like spike proteins. Its genome is composed of RNA instead of DNA. Coronaviruses are ideal candidates for mRNA vaccines because cells in the body can

[1] https://www.nobelprize.org/prizes/medicine/1972/edelman/biographical/ (last visited June 5, 2023). Dr. Edelman passed away in 2014.

be instructed to create the coronavirus's unique spike protein, which itself contains no virus. The body's natural immune system will then recognize the newly minted spike protein as foreign and attack it. That learned defense will prepare the immune system to fight the actual virus in the future.

3. One challenge facing mRNA vaccines is enabling cells to produce enough of the desired protein while administering acceptably small dosages of mRNA. To do that, the amount of protein generated per unit of mRNA must be increased. In and around 2009, Dr. Edelman, Dr. Mauro, and two colleagues named Stephen A. Chappell and Wei Zhou (collectively, the "Promosome Scientists") discovered a method for increasing protein expression by making small changes to the mRNA that could affect the amount of protein produced without altering the amino acid sequence encoded by the mRNA. (Amino acids are the building blocks of proteins.) This is possible because different mRNA sequences can encode the same amino acids while having different secondary effects.

4. Underlying their innovation, the Promosome Scientists developed a novel understanding of how ribosomes—components of a cell that translate mRNA into the amino acid sequences that make up proteins—select a start site along the mRNA to begin their work. Start sites are typically denoted by certain sequences within the mRNA, most commonly the AUG codon. The scientists posited that ribosomes, instead of simply scanning along mRNA to find the first start sequence, used tethering or clustering mechanisms to find start sites based on other criteria, including relative accessibility. These mechanisms would cause ribosomes to sometimes start downstream of the actual, authentic start site, which would not only cause the ribosomes to fail to produce the desired protein, but potentially also to create novel and dangerous cryptic peptides.

5. To solve this problem, the Promosome Scientists discovered a method for modifying mRNA to remove alternative or secondary start sites, and thus avoid competition between potential start sites, effectively directing more ribosomes to the

authentic start site by reducing the unproductive diversion of ribosomes by alternative start sites. Doing so accomplishes numerous goals, including reducing the number of potentially toxic peptides generated by the modified mRNA and, most significantly, increasing the expression of the desired protein encoded by the mRNA. As described above, sufficient expression of the desired protein is necessary for creating safe and beneficial mRNA vaccines.

6. On February 24, 2009, the Promosome Scientists filed provisional patent application No. 61/155,049, entitled "Re-engineering mRNA primary structure for enhanced protein production." Shortly thereafter, the Promosome Scientists assigned the application to Scripps, and Scripps granted an exclusive, worldwide license to Promosome for all patents deriving from the February 2009 application, including the '179 Patent, which issued in 2014.

7. Promosome then brought the method described in the '179 Patent to market, engaging in both primary research and development activities and pursuing partnerships with others in the field. Promosome marketed the practice of the '179 Patent under the trade name RESCUE™. Promosome recognized that Moderna was a significant potential licensing or business partner with respect to its RESCUE™ technology and the '179 Patent. Between 2013 and 2016, Promosome engaged with Moderna about a potential licensing and business partnership. To facilitate these discussions, Promosome and Moderna entered into a Confidential Disclosure and Non-Use Agreement ("CDA") as of July 5, 2013.

8. With that agreement in place, Dr. Stephen Hoge—currently the President of Moderna and described as "le[ading] Moderna's science for nearly 10 years, including the creation of our platform and therapeutic areas"[2]—visited Promosome's facilities at Scripps in La Jolla, California on July 29, 2013. While there, Dr. Hoge engaged with Promosome's leadership and scientists regarding its

[2] https://www.modernatx.com/about-us/leadership#stephen-hoge-md (last visited June 5, 2023).

RESCUE™ technology. Within its presentations, Promosome specifically disclosed and discussed its intellectual property, including Patent Cooperation Treaty application No. PCT/US10/00567, describing the patent family for "Reengineering mRNA Primary Structure for Enhanced Protein Production" and noting that patents had been filed in the United States. This patent family includes the '179 Patent, which issued in 2014. Dr. Hoge also attended a scientific presentation during which Drs. Edelman and Mauro described the science underlying the '179 Patent and RESCUE™, the theory for why the patented method is beneficial, and research and data demonstrating its efficacy. Indeed, all four inventors of the '179 Patent attended this meeting.

9. Dr. Hoge and other Moderna scientists reengaged with Promosome in 2015, at which time Promosome shared an updated slide deck describing RESCUE™ and the method of the '179 Patent. At that time, Promosome specifically informed Moderna of the existence of the patent family including the by-then-issued '179 Patent. After explaining the methodology in more detail, Promosome showed specifically how RESCUE™ could be applied to a modified mRNA disclosed in one of Moderna's patents. In other words, Promosome demonstrated how its patented method could be integrated into Moderna's existing mRNA approach to increase protein expression and otherwise improve mRNA performance by eliminating novel cryptic peptides that were introduced as a result of Moderna's codon changes.

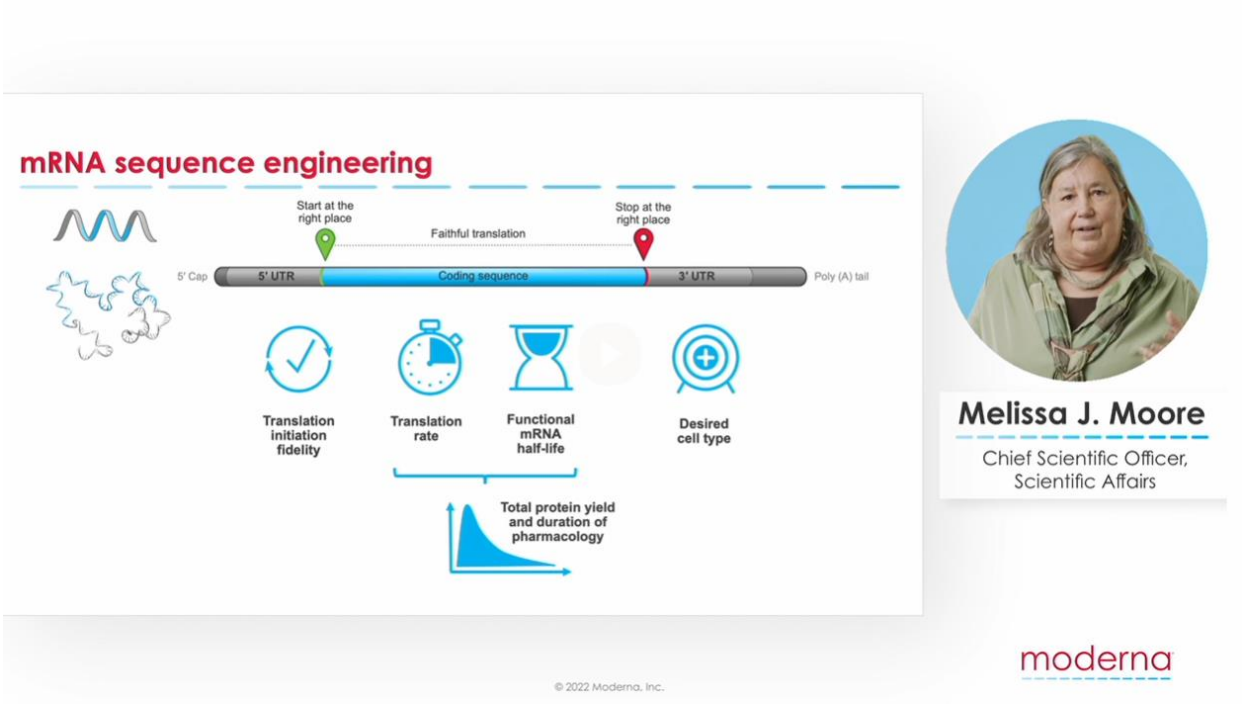
10. Upon information and belief, in 2016, Promosome sent a copy of the '179 Patent to Moderna's now-Head of Business Development, who said that Moderna's Head of IP would review it. Further, Promosome's then-CEO Chris LeMasters emailed Moderna CEO Stéphane Bancel to discuss potential uses of Promosome's intellectual property in the mRNA space. Mr. Bancel connected Mr. LeMasters with Dr. Hoge, who reemphasized over email that he had "some familiarity with your approach" after "visit[ing] Vince [Mauro] et al at Scripps in the summer of 2013." Moderna's President recalled that "the focus at the time" he visited

Promosome included "engineering out alternative/non-canonical start codons"—*i.e.*, the method of the '179 Patent.

11. Despite these many disclosures and interactions over a period of years, Moderna never reengaged Promosome to license its intellectual property, including the rights to practice the method of the '179 Patent. That did not stop Moderna, however, from doing so. Upon information and belief, Moderna has incorporated the method of the '179 Patent into its mRNA development platform, including the development of the COVID-19 vaccine that it now markets under the name Spikevax®.

12. In 2022, Moderna's then-Chief Scientific Officer, Melissa J. Moore, highlighted what she viewed as the key elements of its mRNA sequence engineering platform:

Figure 1
Moderna mRNA Sequence Engineering Slide



13. Moderna clearly identified "[t]ranslation initiation fidelity" as central to its platform. In other words, that initiation starts at the "right place" (the primary initiation codon). Indeed, Moderna's then-Chief Scientific Officer explained how

navigating this problem addressed by the'179 Patent is critical to Moderna's mRNA sequence engineering[3]:

> Let's talk about mRNA sequence engineering. So one of the things that we've put a lot of effort into at Moderna over the last 10 years is learning the engineering principles of how to make a therapeutic RNA that has the properties that we want. And so what are those properties? ***Well of course we would, we always want the ribosome to start at the right place. It turns out that in nature on endogenous mRNAs the ribosome, the small subunit of the ribosome, often misses that first incidence of AUG and starts down somewhere downstream. We don't want that to happen, so we've really learned the rules of how to get the ribosome to always start at the right place.***

14. Upon information and belief, Moderna learned those rules from Promosome and the '179 Patent.

15. Upon information and belief, Moderna initially did not publicly disclose the mRNA sequence used by its COVID-19 vaccine, but in March 2021, scientists at Stanford published the results of their sequencing of Moderna's COVID-19 vaccine. *See* Jeong et al., *Assemblies of Putative SARS-CoV2-Spike-Encoding mRNA Sequences for Vaccines BNT-162b2 and mRNA*-1273, available at https://virological.org/t/assemblies-of-putative-sars-cov2-spike-encoding-mrna-sequences-for-vaccines-bnt-162b2-and-mrna-1273/663 (last visited June 5, 2023). Moderna's previously hidden mRNA sequence starkly revealed that it had modified its mRNA sequence to alter secondary initiation codons without changing the underlying amino acid sequence encoded by the mRNA—the method of the '179 Patent.

16. Promosome applauds Moderna's efforts to develop and sell a COVID-19 vaccine. Those efforts have saved innumerable lives. And the COVID-19 vaccines have accelerated and demonstrated the promise of mRNA therapeutics and vaccines unlocked by Promosome's patented method. But it is now clear that Moderna

[3] Moderna Seminar Series, Chapter 3: mRNA Anatomy (February 8, 2022), quote starting around 12:30 (emphasis added), *available at* https://mrna-access.modernatx.com/resources (last visited June 5, 2023).

incorporated the method of the '179 Patent—which it knew about years before the advent of COVID-19—into the mRNA platform used to develop its COVID-19 vaccine. That vaccine alone has now generated for Moderna more than $35 billion in revenues. And Moderna's own efforts to enforce its intellectual property in this space tout "a pipeline of several dozen mRNA vaccines and therapeutic medicines for a wide range of diseases"[4] with unknown sequences that likely also infringe Promosome's patented method. Promosome files this complaint to receive its rightful share of the tens-of-billions in revenues Moderna already has earned and countless billions it will earn by willfully infringing the '179 Patent.

Parties

17. Plaintiff Promosome LLC is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 48 Gurley Road, Stamford, CT 06902. Promosome is the exclusive licensee holding all substantial rights to the '179 Patent.

18. Upon information and belief, Defendant Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant Moderna, Inc. was previously known as Moderna Therapeutics, Inc. Upon information and belief, Defendant Moderna, Inc., is the parent company of the other defendants and recognizes the revenue from sales of Moderna's COVID-19 vaccine, named Spikevax®.

19. Upon information and belief, Defendant ModernaTX is a corporation organized and existing under the laws of Delaware, having its principal place of business at 200 Technology Square, Cambridge, MA 02139. Upon information and belief, ModernaTX is a wholly owned subsidiary of Moderna, Inc. The FDA granted the Biologic License Approval ("BLA") for Spikevax® to ModernaTX.

[4] Quoting *ModernaTX, Inc. et al. v. Pfizer Inc. et al.*, Case No. 22-cv-11378, Complaint at ¶ 31 (D. Mass. Aug. 26, 2022).

Additionally, ModernaTX is listed as the contact in the prescribing information for Spikevax® and is described as owning the trademark for the same product.

20. Upon information and belief, Moderna US is a corporation organized and existing under the laws of Delaware, having its principal place of business at 200 Technology Square, Cambridge, MA 02139. Moderna US is a wholly owned subsidiary of Moderna, Inc. and sells Spikevax® in the United States.

21. 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 COVID-19 vaccine.

Jurisdiction & Venue

22. 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*.

23. This Court has personal jurisdiction over Moderna, Inc., ModernaTX, and Moderna US. The defendants, collectively and individually, entered into a contract with Promosome, which was based in San Diego County; Moderna's now-President, Stephen Hoge, visited San Diego County under the terms of that contract and disclosures of the method underlying the '179 Patent were made to Dr. Hoge in this District; Moderna knew that the technology it took was developed in this District; and multiple Moderna employees engaged in correspondence and conference calls with persons in this District under the terms of the contract. Furthermore, the Defendants, collectively and individually, directly and through others, make, use, induce others to use, offer for sale, and/or sell their COVID-19 vaccine developed using the '179 Patent, including in this District. To wit, San Diego County estimates that more than 2.7 million residents of this County have completed a primary

vaccination series,[5] many of whom have received doses of Moderna's COVID-19 vaccine. Moderna sold vaccines knowing and indenting their use in this District. Furthermore, upon information and belief, Moderna employs or retains persons residing in this District in conjunction with sales, development, and/or education relating to the COVID-19 vaccine and other products/projects that relate to the '179 Patent. Further, Moderna has engaged in clinical trials of the Accused Products in this District.

24. Therefore, Moderna has sufficient contacts with this District related to this suit. And it is not unfair to sue Moderna here.

25. Venue is proper in this District under 28 U.S.C. § 1400(b) because Moderna, Inc., ModernaTX, and Moderna US have a regular and established place or places of business in this District and have committed acts of infringement in this District.

26. Upon information and belief, Moderna employs at least the following persons who are believed to reside in this District: an Associate Director, Data Catalog & Governance; a Medical Science Liaison for California, Nevada, and Hawaii; a Director, U.S. National Accounts; a Senior Scientist; a Director, Biostatistics, Infectious Diseases. Moderna further solicits persons to work for Moderna in this District with job postings relating to work in this District, including a regional account manager. The places of work within this District of those employees, including any locations they use for work, are regular and established places of business of Moderna.

27. Further, upon information and belief, Moderna hires agents residing in this District, including an Associate Professor at the J. Craig Venter Institute; a Talent

[5] *See* San Diego County, Summary of COVID-19 Vaccination Among San Diego County Residents, available at https://www.sandiegocounty.gov/content/sdc/hhsa/programs/phs/community_epidemiology/dc/2019-nCoV/status/COVID19_Vaccines_Administered_Dashboard.html (last visited June 5, 2023).

Acquisition Recruiter for Moderna via Pharmalogics Recruiting; and a strategist with Sciencia Consulting. Moderna further uses repeat and regular agents in this District for clinical testing, including but not limited to Acclaim Clinical Research, Velocity Clinical Research, Rady Children's Hospital, University of California—San Diego, and Medical Center for Clinical Research – M3 Wake Research. The places of work of these agents of Moderna are regular and established places of business of Moderna.

28. As further described below, Moderna engages in acts of infringement in this District, including but not limited to selling, using, and offering to sell its COVID-19 vaccines, which are products made by the patented process, within this District in violation of 35 U.S.C. § 271(g). Further, Moderna actively induces others to use its COVID-19 vaccines in this District, in violation of 35 U.S.C. § 271(b).

Background

A. mRNA Vaccines

29. This lawsuit centers on Moderna's vaccine meant to prevent and lessen the severity of COVID-19, the disease caused by the SARS-CoV-2 virus. SARS-CoV-2 is a coronavirus, which is a group of RNA viruses known for their distinctive, crown-like surface projections called spike proteins. Viruses like SARS-CoV-2 appropriate a host cell's cellular machinery and instruct the host cell to create additional copies of the virus, which can then spread the infection. In the process, the host cells can be damaged or destroyed, harming and possibly even killing the host organism.

30. Vaccines targeting viruses train the human body to recognize and attack viruses before the virus infects the vaccine recipient. Historically, vaccines consisted of weakened or inactive virus that was unlikely to cause infection yet sufficient to provoke an immune response. mRNA vaccines, however, generally function differently. These vaccines prompt the body to express proteins with sufficient similarity to certain features of the virus to provoke a natural immune response that would also be effective in recognizing and attacking the virus itself. In the case of

SARS-CoV-2, mRNA vaccines like Moderna's cause the body to create a protein like the virus's distinctive spike protein, which itself contains no virus. The body's efforts to attack the mimicked spike proteins train the body to recognize the spike protein of the SARS-CoV-2 virus and thus provoke an immune response to the virus itself.

31. mRNA vaccines historically held great promise but had not yet been commercialized until the COVID-19 pandemic. In part, this traced to various technological challenges facing mRNA vaccines. One significant challenge was creating synthetic mRNA that would cause the body to express enough of the desired protein per unit of mRNA. The amount of protein expressed per mRNA is known as efficiency. Efficient protein synthesis allows sufficient therapeutic benefit with tolerable dosages of mRNA. Otherwise, such a large amount of mRNA would have to be administered that, among other things, there would be a potentially dangerous level of unwanted cryptic peptides produced and cells could be overwhelmed by the surge of mRNA. The patented method underlying this suit increases protein expression by affecting the process of protein synthesis.

B. Protein Expression and mRNA Translation

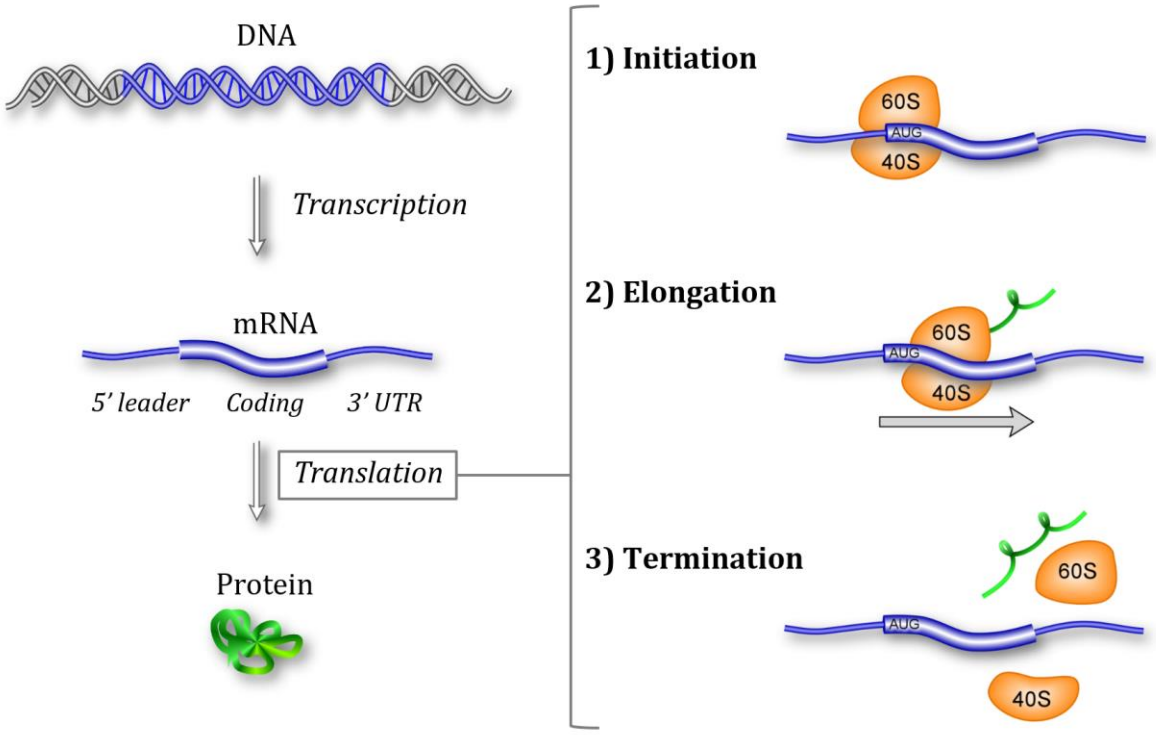
32. Proteins perform most of the functions in the human body and are necessary to human existence. Protein synthesis is the cellular process for expressing proteins. Humans retain instructions for certain proteins through nucleic acids, which are molecules that encode genetic information. Deoxyribonucleic acid, or DNA, is a type of nucleic acid found in human chromosomes. Protein synthesis generally begins when the cell creates mRNA from DNA through a process called transcription. A similar process can be used outside of the body to manufacture mRNA with desired properties.

33. The process of producing proteins from mRNA is called translation, which is the focus of the '179 Patent. mRNA is a linear template composed of 4 nucleosides: guanosine (G), uridine (U), adenosine (A), and cytidine (C), each of

which has a nitrogen-containing ring structure linked to a ribose sugar. Individual nucleosides are linked together by phosphate bonds between the ribose sugars (nucleosides with a phosphate group are called nucleotides). Phosphate bonds join the 5' carbon of one ribose sugar to the 3' carbon of another. By convention, 5' to 3' is used to indicate the directionality of mRNA (indicated schematically as left to right). Relevant to this discussion are a few mRNA components, including the 5′ untranslated region ("UTR")—often called the 5′ leader because it comes near the start (5' end) of the mRNA—followed by the coding sequence, and then the 3′ UTR. The coding sequence describes various amino acids, ordered in the 5′ to 3′ direction, that form the encoded protein. Each amino acid is encoded by 3 nucleotides called a trinucleotide codon. There are 64 (4^3) different trinucleotide codons, which collectively encode for the 20 amino acids in human proteins. For instance, the codon GCU—that is, a triplet of guanosine, cytidine, and uridine in that order—encodes the amino acid alanine. While two amino acids are encoded by only a single codon, the other 18 are encoded by 2, 3, 4, or 6 synonymous codons. As a result, an effectively infinite variety of mRNA sequences could encode any given amino acid sequence.

34. Ribosomes translate an mRNA's coding sequence into amino acid chains called polypeptides that form proteins. As shown below, translation has three steps: initiation, elongation, and termination.

Figure 2
Translation within Protein Synthesis



35. The first step, initiation, is the focus of the Promosome's patented method and involves the processes that lead to the formation of a eukaryotic ribosome at the translation start site. These processes include (i) recruitment of a eukaryotic small ribosomal subunit (the "40S ribosomal subunit") to the mRNA and (ii) start site selection, where the 40S ribosomal subunit moves to an initiation codon and joins with the eukaryotic large ribosomal subunit (the "60S ribosomal subunit") to form a eukaryotic ribosome, called an 80S ribosome.[6] Start sites are denoted by certain codons called initiation codons. The most common initiation codon is AUG, but there are other noncanonical initiation codons including CUG, ACG, GUG, UUG, AUA, AUC, and AUU. The initiation codon at the start of the coding sequence is called the primary initiation codon. The primary initiation codon is the authentic start site for

[6] 80S ribosomes, as it happens, seem less than the sum of their parts simply because of a complex and non-additive naming convention.

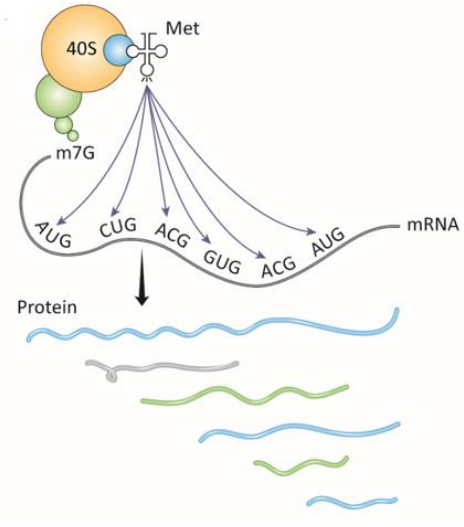
translation.

36. Potential start sites downstream of the primary initiation codon (*i.e.*, within the coding sequence) are called secondary initiation codons. These alternate start sites can either be in the same reading frame as the coding sequence (in-frame) or in a different reading frame that groups nucleotides in different sets of three (out-of-frame). An in-frame codon encodes an amino acid as part of the intended reading frame of the coding sequence—in other words, the grouping of nucleotides into triplets that occurs when translation begins with the primary initiation codon. Because all start codons also encode an amino acid, these codons can be mistaken for a start site when existing simply to encode an amino acid somewhere downstream of the authentic start site. For instance, AUG is the most prevalent start site but also the only codon for the amino acid methionine, so can serve as a secondary initiation codon when encoding methionine.

37. An out-of-frame initiation codon, by contrast, is a codon formed by reading parts of consecutive codons within the authentic reading frame. Consider, for example, a short mRNA sequence for the amino acid histidine followed by valine, which could be encoded by a CAU codon (in bold) followed by a GUU codon (in italics): **C A U** *G U U*. This sequence would create an out-of-frame initiation codon AUG by reading the middle adenosine (A) and final uridine (U) in the CAU codon along with the initial guanosine (G) in the GUU codon, as underlined here: **C A U** *G U U*.

38. To express the desired protein, the authentic, primary initiation codon must be used as the ribosomal start site. As shown below, however, the 40S ribosomal subunit can instead be attracted to downstream in-frame or out-of-frame secondary initiation codons. This is known as ribosomal diversion. Ribosomal diversion prevents the affected ribosome from creating the desired protein and potentially causes the creation of novel or dangerous polypeptides.

Figure 3
An Illustration of Start Site Selection



39. The second and third steps of the translation process follow naturally from initiation. In the second step, elongation, the 80S ribosome travels along the mRNA translating one codon at a time and linking the encoded amino acids into polypeptides as it goes. The elongation process continues as the 80S ribosome travels towards the 3′ UTR until the third step, termination. Termination is the conclusion of the translation process and occurs when the 80S ribosome reaches a stop codon. The three stop codons—UAA, UAG, and UGA—do not encode any amino acid. During translation, co-translational processes, including folding, may occur. Upon termination, the polypeptide chain may undergo other post-translational modifications to form a protein and complete protein synthesis.

C. Promosome Scientists Discover a Method for Improving Protein Expression Efficiency

40. As described above, mRNA vaccines take advantage of the translation process by introducing synthetic mRNA into the body so that human cells produce the desired protein. For mRNA vaccines to provide sufficient therapeutic benefits at reasonable dosages, the constituent mRNA must be highly efficient at protein

synthesis. In other words, it must prompt the body to maximize the production of the desired protein per unit of mRNA introduced into the body.

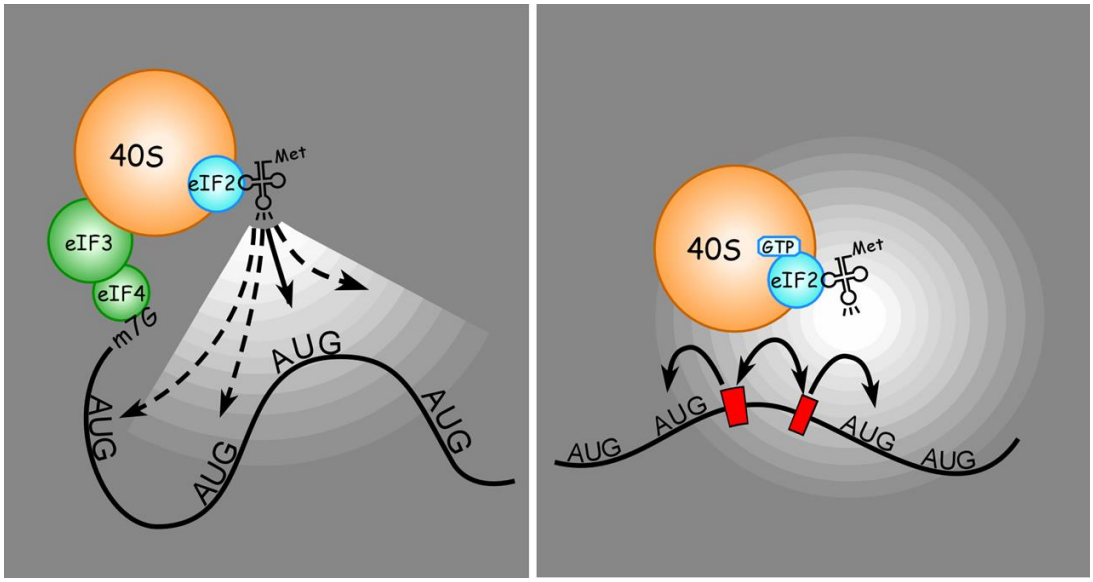
41. Protein expression efficiency relates to the sequence of the underlying mRNA. As described above, because most amino acids can be encoded by one of several synonymous codons, a near infinite variety of mRNA sequences can cause the body to create the same polypeptide chain needed for a given protein. But the different mRNA sequences will present varying levels of protein expression efficiency and other secondary characteristics. Early efforts to increase efficiency focused on codon optimization, which typically posits that 80S ribosomes translate certain synonymous codons more quickly than others. Codon optimization, then, often involves modifying mRNA by replacing certain codons with synonymous codons that encode the same amino acid—thus not changing the amino acid sequence in the resultant polypeptide—but that theoretically cause quicker translation. Similarly, optimization can attempt to reduce the amount of uridine (U) and cytidine (C) in the mRNA sequence to increase stability and reduce immune response against the mRNA itself.

42. Scientists at The Scripps Research Institute were long on the forefront of mRNA discovery. These scientists included: Gerald Edelman, who shared the 1972 Nobel Prize for Physiology or Medicine for his pioneering work studying the chemical structure of antibodies, and who worked as Scripps's Chairman of Neurobiology; Vincent Mauro, a global thought leader in mRNA translation who served at Scripps as an Associate Professor of Cell and Molecular Biology; and Wei Zhou & Stephen Chappell, Scientists at Scripps and eventually Promosome. Each of these scientists, referred to as the Promosome Scientists, was affiliated with Promosome.

43. The Promosome Scientists developed an advanced understanding of the translation process and, in particular, the recruitment and start site selection processes involved in initiation. Prior to their discovery, scientists and prior art generally

followed a scanning model of translation initiation, where the 40S ribosomal subunit scanned across the mRNA from the 5′ leader in the direction of the 3′ UTR until an initiation codon was identified. The Promosome Scientists discovered and hypothesized that that 40S ribosomal subunits likely used other mechanisms for start-site selection, including tethering or clustering mechanisms. At a high level, ribosomal tethering describes a mechanism in which ribosomal subunits reach the initiation codon while bound to a fixed point in the mRNA. With tethering, the intervening sequences are not scanned, but are bypassed when the ribosomal subunit pairs to the initiation codon. Ribosomal clustering, by contrast, is a dynamic process that involves reversible binding of the ribosomal subunit to and detachment from various sites in the mRNA and that does not require that the ribosomal subunit be tethered to the mRNA for it to reach the initiation codon.

Figure 4
Illustrations of Ribosomal Tethering (left) and Ribosomal Clustering (right)



44. The particulars of these mechanisms are beyond the scope of this Complaint, but the thrust of these alternate mechanisms then-hypothesized by the Promosome Scientists is that there would be a likelihood that translation would initiate at secondary initiation codons, including out-of-frame secondary initiation

codons, rather than the authentic or primary initiation codon. In other words, the secondary initiation codons effectively competed with the primary initiation codon in the ribosomal recruitment process, increasing ribosomal diversion and reducing the number of ribosomes starting at the authentic start site. 80S ribosomes initiating translations at secondary initiation codons would nonetheless work from the wrong starting place to translate incorrect (*i.e.*, out of sync with the proper reading frames) or incomplete (*i.e.*, starting mid-sequence) polypeptides that cannot result in the desired protein. The consequences of binding to a secondary initiation codon, then, would include reduced expression of the full-length protein and the potential creation of dangerous cryptic peptides. The latter consequence would be exacerbated by codon optimization, because while substituting synonymous codons preserves the intended codon sequence of the primary reading frame, it completely changes out-of-frame codons read when elongation begins at out-of-frame secondary initiation codons. This means that codon optimization can cause the body to produce novel cryptic peptides.

45. Building from their fundamental insights regarding the translation process, the Promosome Scientists discovered a method for increasing full-length protein expression efficiency that would help unlock the promise of mRNA therapeutics and vaccines. In particular, they discovered that mRNA or other polynucleotides could be modified to reduce the impact of one or more secondary initiation codons or to eliminate one or more such codons altogether. Like codon optimization, one embodiment of this novel method took advantage of synonymous codons that could replace existing codons to disrupt secondary initiation sites without altering the corresponding amino acid sequence.

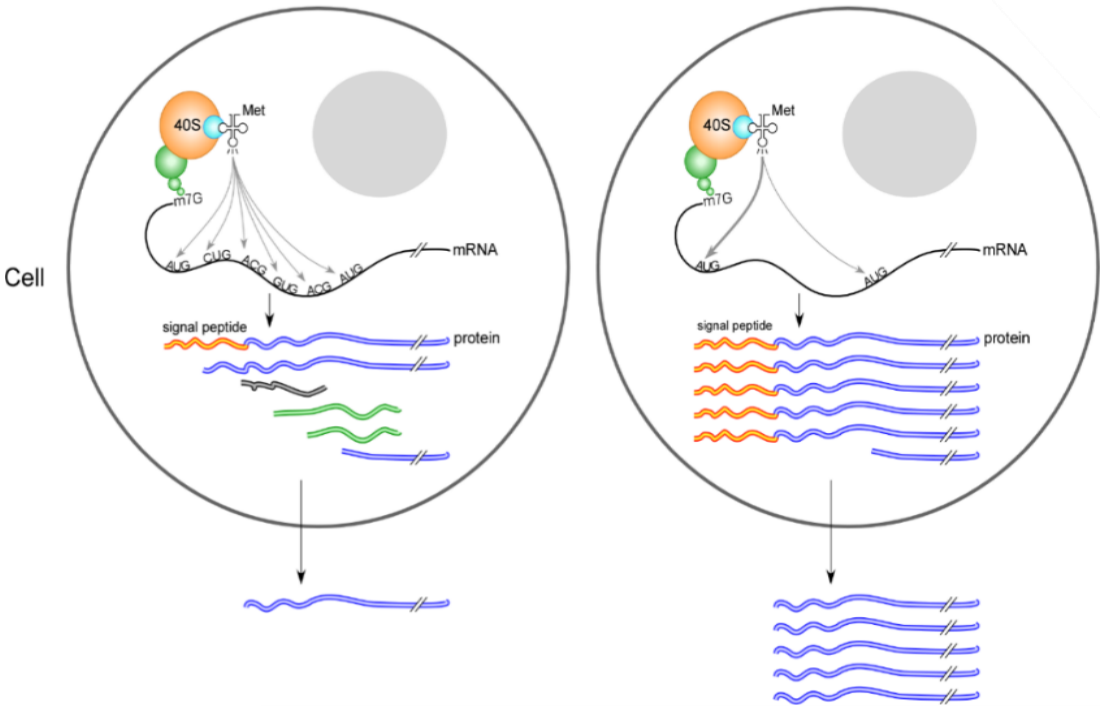
46. To illustrate, recall from above the short mRNA sequence encoding the amino acids histidine then valine with a CAU codon (in bold) followed by a GUU codon (in italics), but which presents an out-of-frame initiation codon AUG (underlined): **C <u>A U</u>** ***G U U***. Under the Promosome Scientists' innovative method,

for example, the first CAU codon could be modified to CAC by replacing the uridine (U) with cytidine (C) to eliminate the out-of-frame initiation codon AUG and replace it with the comparatively weak, noncanonical initiation codon ACG: **C A C** *G U U*. Such a modification would not alter the resultant amino acid sequence in the intended polypeptide because CAU and CAC both encode the amino acid histidine. But it would be likely to reduce ribosomal diversion and thus cause more ribosomes to translate the desired amino acid sequence by starting at the primary initiation codon. Other codons permit complete elimination of the secondary initiation site even for in-frame initiation codons. For instance, the secondary initiation codon CUG, which encodes Leucine, can be mutated to CUA, CUC, CUU, or UUA, all of which also encode Leucine but are not known initiation codons.[7]

47. The below illustration shows how removing secondary initiation codons via modification—here, eliminating CUG, ACG, GUG, and ACG codons—can cause more ribosomes to initiate translation at the primary initiation codon and thus create more of the desired protein:

[7] CUG can also be mutated to UUG, but UUG is a possible initiation codon.

Figure 5
Illustrations of Protein Expression Efficiency with Promosome IP
Pre-Modification (left) and Post-Modification (right)



48. In Figure 5, above, the blue proteins with an orange signal peptide represent the desired result of translation starting at the primary initiation codon. (A signal peptide is the amino acid chain encoded by the first portion of the coding sequence that labels a protein for secretion from the cell; it is cleaved off the mature protein.) Gray and green lines represent undesirable peptides generated from out-of-frame secondary initiation codons, and mis-sized blue lines represent undesirable peptides generated from in-frame secondary initiation codons. The illustration on the right shows how removing secondary initiation codons results in a greater protein expression efficiency of the desired protein as more ribosomes start at the primary initiation codon and thus translate the desired amino acid sequence. The same method can be applied to DNA to cause mRNA transcribed from the DNA to have the desired modifications.

49. The Promosome Scientists engaged in testing, described in the '179 Patent and elsewhere, that confirmed the validity and usefulness of their method for

increasing protein expression. In some instances, the method caused protein expression to increase by significant multiples. And time has only underscored the importance of their innovative approach to increasing protein expression efficiency, as (among other things) mRNA vaccines have now demonstrated their efficacy against COVID-19. Indeed, one of the key insights of the Promosome Scientists—that initiation often mistakenly occurs at downstream secondary initiation codons—is now widely accepted and even admitted by Moderna's then-Chief Scientific Officer: "It turns out that in nature on endogenous mRNAs the ribosome, the small subunit of the ribosome, often misses that first incidence of AUG and starts down somewhere downstream."[8] To be sure, the method of the '179 Patent remains agnostic to the precise mechanism(s) used for translation initiation, and there remains significant scientific debate over the appropriate mechanism. But further study has only strengthened the critique of the linear scanning model questioned by the Promosome Scientists.

50. Increased protein expression is essential to, among other things, the prospect of modern mRNA therapeutics and vaccines. mRNA vaccines like the COVID-19 vaccines, for instance, must cause sufficiently efficient protein synthesis so that they can be dosed safely. Otherwise, generating a sufficient immune response would require a much larger dose of mRNA. Larger doses would lead to increased production of cryptic peptides, which may negatively affect both overall expression levels and cell physiology (and, ultimately, human health).[9] In addition, too large of

[8] Moderna Seminar Series, Chapter 3: mRNA Anatomy, quote starting around 12:57, *available at* https://mrna-access.modernatx.com/resources (last visited June 5, 2023).

[9] Not to mention, practicing the method discovered by the Promosome Scientists reduces the generation of cryptic peptides on a per-unit of mRNA basis by minimizing translation that starts at secondary initiation codons, in addition to reducing the overall production of cryptic peptides by reducing the number of units of mRNA required to achieve therapeutic benefit.

doses of mRNA may in fact limit protein production, which would negatively affect other processes in the cells.

D. Promosome Scientists Protect Their Discovery with the '179 Patent

51. Shortly after discovering their novel method for increasing protein expression, the Promosome Scientists timely sought legal protections for their discovery.

52. On, February 24, 2009, they filed U.S. Provisional Patent Application No. 61/155,049. Exactly one year later, they filed a Patent Cooperation Treaty application No. PCT/US2010/000567. The U.S. Application resulted in publication of application No. 2012/005333 A1 on March 1, 2012. And an extensive catalogue of foreign patents also were obtained under the PCT application.[10]

53. Relevant here, on October 7, 2014, the United States Patent and Trademark Office duly and legally issued the '179 Patent entitled "Reengineering mRNA Primary Structure for Enhanced Protein Production." A true and correct copy of the '179 Patent is attached as Exhibit 1 to this Complaint.

54. Claim 1 of the '179 Patent—the only claim in the patent—recites:

> 1. A method of improving full-length protein expression efficiency comprising:
>
> a) providing a polynucleotide comprising:
>
> i) a coding sequence for the full-length protein;
>
> ii) a primary initiation codon that is upstream of the coding sequence of the full-length protein, said primary initiation codon encoding the first amino acid of the coding sequence of the full-length protein; and
>
> iii) one or more secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon; and
>
> b) mutating the one or more secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary

[10] Foreign patents in the same patent family include JP 5,735,927 B2; CA 2,753,362 C; AU 2,010,218,388 B2; and EP 2,401,365 B1.

initiation codon, wherein the mutation results in a decrease in initiation of protein synthesis at the one or more secondary initiation codons,

thereby increasing expression efficiency of the full-length protein initiated at the primary initiation codon,

wherein mutating the one or more secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon comprises mutating one or more nucleotides such that the amino acid sequence of the protein remains unaltered.

E. Promosome Licenses the '179 Patent as Part of its Technology Suite

55. Promosome is a Delaware limited liability company that was incorporated in 2001 to develop and commercialize inventions from Nobel laureate Gerald Edelman and Vincent Mauro at Scripps, among others. Promosome worked closely with numerous scientists from Scripps. Promosome engaged in a series of two-year Research Funding & Option (RFO) agreements with Scripps specific to the laboratory operated by Drs. Edelman and Mauro. Their fundamental research on mechanisms of mRNA translation had clear applications for optimizing protein expression and purity in the burgeoning field of protein biotherapeutics. Promosome experienced significant growth. Indeed, Dr. Mauro left Scripps in 2014 to join Promosome as its Senior Vice President and Chief Scientific Officer.

56. On June 25, 2009, shortly after the Promosome Scientists filed the provisional patent application related to the '179 Patent on February 24, 2009, Promosome obtained an exclusive, worldwide license to patents arising out of or resulting from that application, including the to-be-issued '179 Patent.

57. Under its licensing agreement and amendments thereto, Promosome owns all substantial rights to the '179 Patent, including the right to assert all causes of action under the '179 Patent and the right to remedies obtained on the '179 Patent.

58. Promosome has standing to bring this cause of action in its own name.

59. Promosome sought to bring the method of the '179 Patent, along with expertise in its implementation, to market under the trade name RESCUE™. RESCUE™ was part of a robust and then-growing technology suite, including

numerous patents and other technologies such as Positive Feedback Selection, Translation Enhancing Elements, and Landing Pad. Promosome actively sought to monetize its intellectual property through partnerships in fields like mammalian cell line development, mRNA therapeutics, and Coagulation Factors, as well as internal programs aimed at creating hard-to-express proteins and biosimilars.

60. In 2013, for example, the company had locations in New York City, New York and La Jolla, California. It had obtained between $10–12 million in research grants and raised $17 million in funding series A, B, and C. Around that time, it grew to about 15 employees led on the technical side by Drs. Edelman and Mauro and obtained ~10,000 square feet of class-A lab and office space in La Jolla. By late 2016, however, funding became scarce and Promosome was forced to reduce the scope of its operations, including by closing its wet lab. This reduction was caused by a financial shortfall, which, in part, traced to the inability to develop a partnership in the mRNA therapeutics realm in which Moderna operates. Despite these reductions in scope, Promosome continues to pursue partnerships to develop and advance its intellectual property.

F. Promosome Teaches Moderna the ’179 Patent

61. In its efforts to bring the method of the ’179 Patent to market, Promosome engaged Moderna about a license or business partnership multiple times between 2013 through 2016. These interactions involved Moderna’s highest levels of management—including its current CEO Stéphane Bancel and current President Stephen Hoge—and its senior research scientists. And they involved detailed disclosures of Promosome’s groundbreaking method protected by the ’179 patent and of the patent protections for that method.

62. By 2013, Promosome recognized that Moderna was a significant potential licensing partner with respect to its RESCUE™ technology and the method of the ’179 Patent. To facilitate these discussions, Promosome and Moderna’s predecessor Moderna Therapeutics, Inc., entered into a Confidential Disclosure and

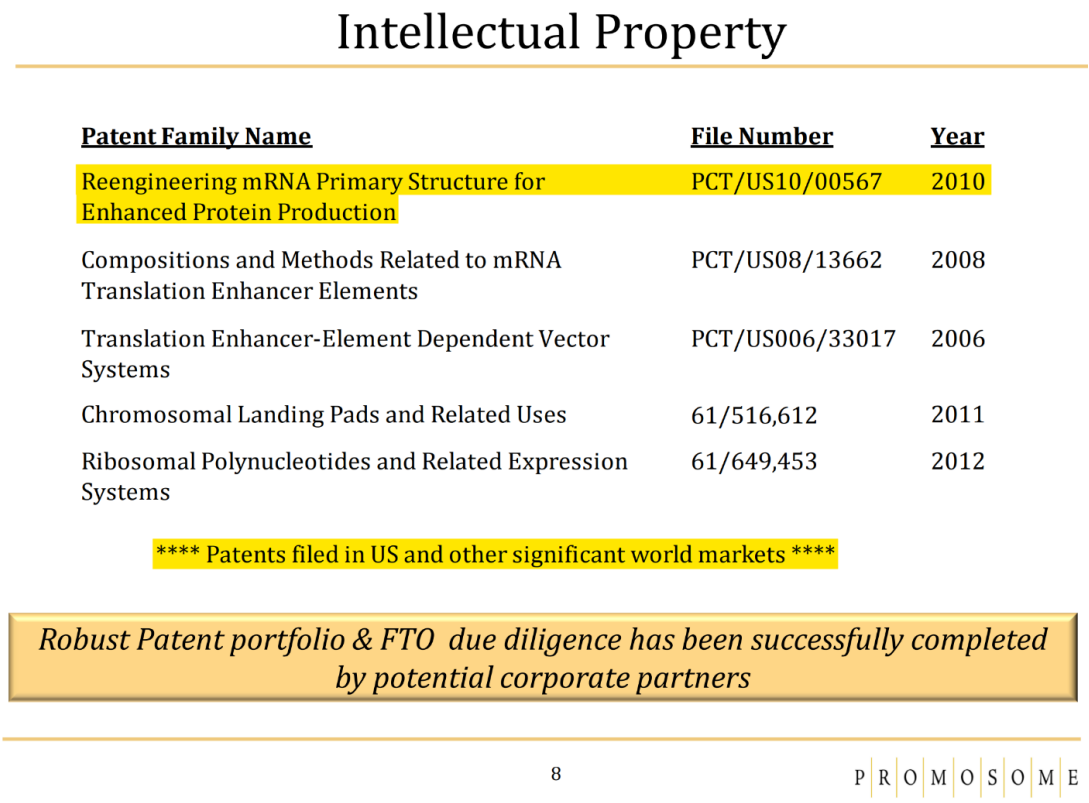
Non-Use Agreement ("CDA") as of July 5, 2013. The CDA was executed for Moderna by Dr. Stephen Hoge—then the Senior Vice President for Corporate Development and New Drug Concepts and now the President of Moderna who is described on its website as "le[ading] Moderna's science for nearly 10 years, including the creation of our platform and therapeutic areas."[11] The CDA included reciprocal nondisclosure and nonuse obligations meant to facilitate open disclosure of confidential information.

63. With that agreement in place, Promosome invited Dr. Hoge to visit its facilities at Scripps in La Jolla, California, which he in fact did on July 29, 2013. While there, Dr. Hoge attended in-person presentations regarding Promosome's corporate operations and technology suite. With additional Moderna personnel (including, upon information and belief, Antonin de Fougerolles) on speakerphone, Dr. Hoge engaged with Promosome's leadership and scientists regarding its RESCUE™ technology. This meeting included Vincent Mauro, Gerald Edelman, Wei Zhou, and Stephen Chappell, the four listed inventors on the '179 Patent. Dr. Hoge and his team were given slide decks to facilitate these discussions, including a corporate introduction and a scientific presentation.

64. Promosome's then-President John Manzello delivered the corporate presentation. This presentation specifically disclosed and discussed Promosome's intellectual property, including Patent Cooperation Treaty Application No. PCT/US10/00567, describing the patent family for "Reengineering mRNA Primary Structure for Enhanced Protein Production" and noting that patents had been filed in the United States. This patent family includes the '179 Patent, which was a pending application as of the time of this meeting and issued about a year after it.

[11] https://www.modernatx.com/about-us/leadership#stephen-hoge-md (last visited June 5, 2023).

Figure 6
Excerpt from 2013 Corporate Introduction (highlighted for emphasis)



Intellectual Property

Patent Family Name	File Number	Year
Reengineering mRNA Primary Structure for Enhanced Protein Production	PCT/US10/00567	2010
Compositions and Methods Related to mRNA Translation Enhancer Elements	PCT/US08/13662	2008
Translation Enhancer-Element Dependent Vector Systems	PCT/US006/33017	2006
Chromosomal Landing Pads and Related Uses	61/516,612	2011
Ribosomal Polynucleotides and Related Expression Systems	61/649,453	2012

**** Patents filed in US and other significant world markets ****

Robust Patent portfolio & FTO due diligence has been successfully completed by potential corporate partners

8 PROMOSOME

65. Dr. Hoge also attended a scientific presentation given by Dr. Mauro, then working with Promosome through Scripps. Dr. Mauro described his team's view of translation, including their hypothesized clustering and tethering mechanisms for start site selection. He then described RESCUE™, including the method later claimed by the '179 Patent. Dr. Mauro told Dr. Hoge and his colleagues that RESCUE™ involved eliminating or mitigating alternate start sites to decrease competition between various mRNA start sites, which would increase protein production. He further illustrated the mechanism for increased protein production and presented research and data demonstrating the effectiveness of this methodology.

66. At that time, Moderna did not express interest in a partnership with Promosome and talks fell apart. Upon information and belief, Moderna did not believe that Promosome's approach was compatible with its approach to codon

optimization, which at that time it viewed as essential to developing its mRNA platform. In particular, Promosome's scientists studied and described specific dangers of codon optimization, including the introduction of novel cryptic peptides via secondary initiation sites. This danger would be significantly more problematic if Dr. Mauro's understanding of translation and secondary initiation sites proved true. Further, one benefit of Promosome's approach was that it offered an alternative that required far less codon optimization to achieve sufficient protein expression efficiency (and, moreover, offers the ability to significantly increase efficiency whether the mRNA is codon optimized or not).

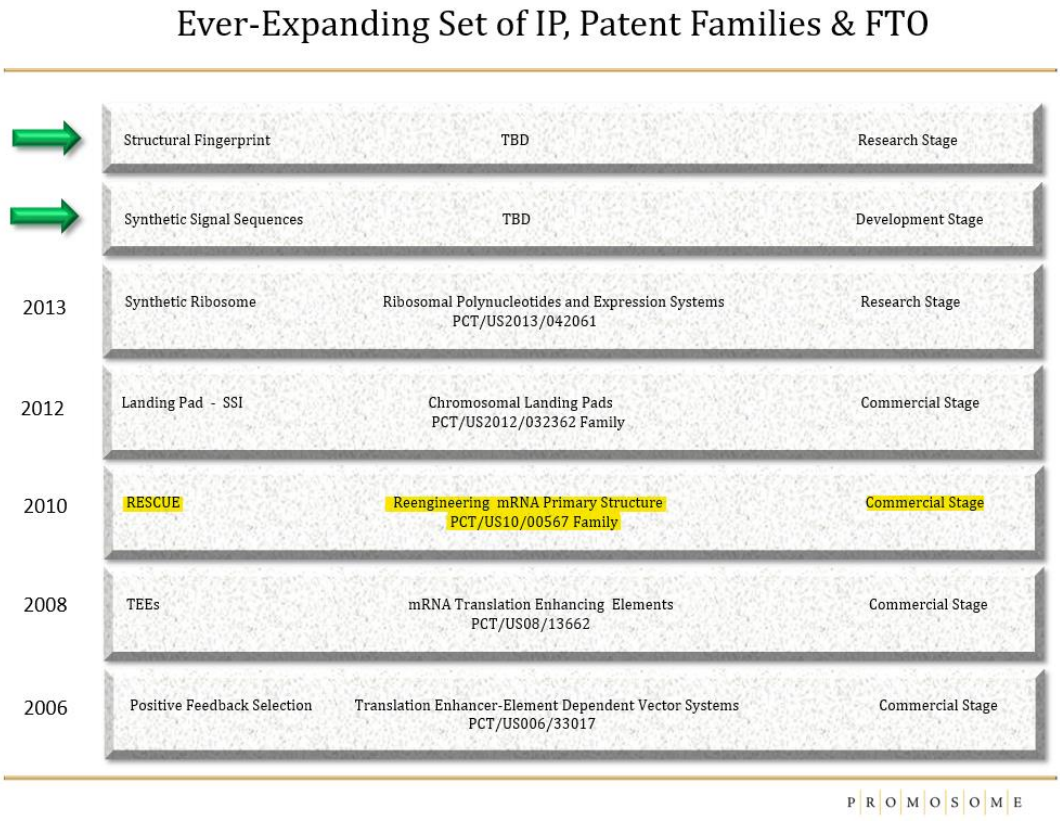
67. But in 2015 Promosome made a second effort to engage Moderna in licensing talks. The relevant connection came through Avak Kahvejian, a partner at Flagship Pioneering. Moderna has described that "Moderna was founded in 2010 by Flagship Pioneering."[12] In or around March 2015, Mr. Kahvejian spoke with Promosome's then-President John Manzello and volunteered to re-introduce Promosome to Moderna because the RESCUE™ method could be meaningful to Moderna. ***Mr. Kahvejian—who, again, worked for the fund that founded Moderna—questioned Promosome's President about the '179 Patent and how Promosome would defend its position against infringement of the method of modifying mRNA to increase protein expression efficiency***. Shortly thereafter, upon information and belief, Mr. Kahvejian spoke with Dr. Hoge at Moderna, who gave permission for Mr. Manzello to reach out to Moderna again.

68. Mr. Manzello did so and explained to Dr. Hoge how RESCUE™, a method practicing the '179 Patent, could benefit Moderna's existing IP and operations. On June 19, 2015, Promosome scientists and executives again presented to Moderna employees, including at least Tirtha Chakraborty and Matthias John,

[12] Moderna Form 424(b)(4) (Dec. 6, 2018), at 6, available at https://www.sec.gov/Archives/edgar/data/1682852/000119312518344982/d611137d424b4.htm (last visited June 5, 2023).

scientists working on mRNA at Moderna. This presentation included a refined and tailored scientific presentation as well as another corporate presentation. The scientific presentation again explained the RESCUE™ method, how it works, and evidence of its efficacy. The corporate presentation specifically described that RESCUE™ was protected by patent family PCT/US10/00567, which by that time included the issued '179 Patent.

Figure 7
Excerpt From 2015 Corporate Introduction (highlighted for emphasis)



69. Promosome speculated that one reason 2013 discussions fell apart was because Moderna, which upon information and belief then engaged in extensive codon optimization, felt that the RESCUE™ method was not compatible with mRNA that was extensively codon optimized. Therefore, Promosome rebutted this narrative in its scientific presentation. It explained, for example, how to eliminate potentially dangerous novel cryptic peptides that were introduced by Moderna's then-existing

approach. It also disclosed how RESCUE™ could significantly increase protein expression of Moderna's codon optimized mRNA. Following this meeting, Mr. Manzello sent the presentations by email to the Moderna scientists, who replied that they would seek "all relevant input from [M]oderna scientists & officials."

70. On September 21, 2015, Promosome's then-CEO Chris LeMasters emailed Moderna CEO Stéphane Bancel about the possibility of a partnership. Mr. Bancel directed Mr. LeMasters to Said Francis, currently the Head of Business Development & Corporate Strategy at Moderna. On or around October 1, 2015, Mr. Francis, along with Iain McFadyen, who was then involved in computational sciences at Moderna, spoke with Mr. LeMasters and Mr. Manzello from Promosome. This led to a mid-October call between Dr. Mauro, Mr. McFadyen, and Vladimir Presnyak, who worked in Moderna in bioinformatics. Dr. Mauro once again sent the slide deck from the earlier meeting. Following this technical meeting, Promosome and Moderna corresponded until Mr. Francis relayed that he had "talk[ed] to [a] few stakeholders internally about possible collaboration opportunities," and that Moderna "had a lot of respect to [Promosome's] science" but that personnel changes had left Moderna "short on resources to allocate to explore the possibility of combining your technology with [Moderna's] platform."

71. But conversations between Promosome and Mr. Francis continued. On information and belief, on March 30, 2016, Mr. LeMasters specifically followed up another call to Mr. Francis by sending him a copy of the '179 Patent (and three others not at issue in this lawsuit). Mr. Francis—now the Head of Business Development—responded that he had "asked" Moderna's "head of IP" to "help [him] in the review of the patents," including the '179 Patent. Upon information and belief, Moderna never followed up to relay the view from Moderna's Head of IP's review of the '179 Patent.

72. Also, around this time Moderna attempted to hire away from Promosome one of the listed inventors on the '179 Patent, Stephen Chappell. On

February 23, 2016, Carina Clingman, a consultant for Moderna, emailed Dr. Chappell asking if he was interested in the position of Head of Molecular Biology and External Technology Development. (Upon information and belief, Dr. Chappell did not pursue the position.) Further, in March 2016, Mr. Manzello emailed Mr. Bancel to propose that Dr. Mauro present RESCUE™ at the 2016 mRNA conference in Boston hosted by Moderna. This email again described the RESCUE™ approach protected by the '179 Patent.

73. Later in 2016, Promosome made one final push to engage Moderna in a business partnership involving RESCUE™ and the '179 Patent. Mr. LeMasters again emailed Moderna CEO Stéphane Bancel to discuss potential uses of Promosome's intellectual property in the mRNA space. This time, Mr. Bancel connected Mr. LeMasters to Dr. Hoge, who he described as leading "amongst other things the platform and all our technology decisions." Dr. Hoge subsequently confirmed that he had "some familiarity with [Promosome's] approach" after "visit[ing] Vince [Mauro] et al at Scripps in the summer of 2013." He recalled that "the focus at the time" included "engineering out alternative/non-canonical start codons"—*i.e.*, the method of the '179 Patent. Upon information and belief, Promosome spoke with Dr. Hoge again on August 15, 2016.

74. Talks in 2016 fizzled out, however, when Mr. LeMasters left Promosome, and the company soon thereafter reduced its wet lab operations due to an impending financial shortfall. But Promosome remained active in attempting to license and develop its intellectual property, including RESCUE™ and the '179 Patent, after that time. To that end, upon information and belief, Mr. LeMasters introduced Mr. Francis to other persons representing Promosome, including COO Leo Kim and Board Member David Horn Solomon. But Moderna never requested to license RESCUE™ or the '179 Patent.

75. In addition to these extensive interactions and disclosures, Moderna was fully aware of the '179 Patent because many of its own patents cited to that patent

family, including the '179 Patent and the related, published U.S. Patent Application No. 2012/005333 A1 (the "'179 App."). More than two dozen of Moderna's patents citing the'179 Patent family are described below. Inventors whose names are in bold are those who were involved in the licensing talks with Promosome discussed above, including Moderna's President Dr. Hoge and its CEO Mr. Bancel:

U.S. Patent No.	**Inventors**	**Initial Assignee**	**Pub. Date**	**Citing**[13]
8,664,194	**Antonin de Fougerolles** et al.	Moderna Therapeutics[14]	3/4/14	'179 App.
8,710,200	Jason P. Schrum et al.	Moderna Therapeutics	4/29/14	'179 App.
8,822,663	Jason P. Schrum **Stéphane Bancel** et al.	Moderna Therapeutics	9/2/14	'179 App.
8,980,864	**Stephen G. Hoge** et al.	Moderna Therapeutics	3/17/15	'179 App.
8,999,380	**Stéphane Bancel** **Tirtha Chakraborty** et al.	Moderna Therapeutics	4/7/15	'179 App.
9,095,552	**Tirtha Chakraborty** **Antonin de Fougerolles**	Moderna Therapeutics	8/4/15	'179 Patent
9,107,886	**Tirtha Chakraborty** **Antonin de Fougerolles**	Moderna Therapeutics	8/18/15	'179 Patent
9,181,319	Jason P. Schrum **Stéphane Bancel** Noubar B. Afeyan	Moderna Therapeutics	11/10/15	'179 Patent
9,186,372	**Antonin de Fougerolles** Sayda M. Elbashir	Moderna Therapeutics	11/17/15	'179 Patent
9,283,287	**Tirtha Chakraborty** **Antonin de Fougerolles** Ron Weiss	Moderna Therapeutics	3/15/16	'179 Patent

[13] Duplicative citations—for example a citation to the '179 Patent and the '179 App.—are omitted.

[14] Upon information and belief, Defendant Moderna, Inc. was previously known as Moderna Therapeutics, Inc. ("Moderna Therapeutics")

9,334,328	Jason P. Schrum et al.	Moderna Therapeutics	5/10/16	'179 App.
9,428,535	**Antonin de Fougerolles** **Stéphane Bancel** et al.	Moderna Therapeutics	8/30/16	'179 App.
9,464,124	**Stéphane Bancel** et al.	Moderna Therapeutics	10/11/16	'179 App.
9,512,456	Yuxun Wang **Antonin de Fougerolles** et al.	ModernaTX	12/6/16	'179 Patent
9,533,047	**Antonin de Fougerolles** Sayda M. Elbashir	ModernaTX	1/3/17	'179 Patent
9,572,897	**Stéphane Bancel** **Tirtha Chakraborty** et al.	ModernaTX	2/21/17	'179 Patent
9,597,380	**Tirtha Chakraborty** **Stéphane Bancel** **Stephen G. Hoge** et al.	ModernaTX	3/21/17	'179 Patent
9,701,965	Jason P. Schrum et al.	ModernaTX	7/11/17	'179 Patent
9,872,900	Giuseppe Ciaramella et al.	ModernaTX	1/23/18	'179 App.
10,023,626	Joseph Beene Bolen Joshua P. Frederick	ModernaTX	7/17/18	'179 Patent
10,258,698	**Stephen G. Hoge** et al.	ModernaTX	4/16/19	'179 Patent
10,323,076	Jeff Lynn Ellsworth et al.	ModernaTX	6/18/19	'179 App.
10,428,106	Gabor Butora et al.	ModernaTX	10/1/19	'179 App.
10,849,920	**Stephen G. Hoge** **Tirtha Chakraborty** et al.	ModernaTX	12/1/20	'179 Patent
11,603,399	**Stephen G. Hoge** **Tirtha Chakraborty** et al.	ModernaTX	3/14/23	'179 Patent

76. As can be seen above, Moderna began publishing patents citing the '179 Patent family as prior art shortly after its first interactions with Promosome, and it

continued to do so throughout its interactions and for many years leading up to and after the development of the infringing COVID-19 vaccine.

G. Moderna Develops a Platform for mRNA Development

77. Upon information and belief, in the years leading up to the COVID-19 pandemic, Moderna developed its mRNA platform, which among other things can rapidly generate mRNA sequences that have been modified to meet Moderna's therapeutic goals while encoding the amino acid sequence for a desired protein. This platform development took place during and after the occasions where Promosome disclosed and taught Moderna the method of the '179 Patent.

78. Upon information and belief, the platform was implemented around the time of Moderna's first meetings with Promosome in 2013 and has been updated over time following those interactions. For example, in 2014, Moderna created a division focused on developing mRNA vaccines for infectious diseases. In 2015, again during Promosome's period of interactions and disclosures to Moderna, Moderna developed an mRNA vaccine for the Middle East Respiratory Syndrome ("MERS") Coronavirus.[15]

79. Upon information and belief, in the years that followed the MERS vaccine and leading up to the advent of the COVID-19 pandemic, Moderna studied many potential mRNA subjects that allowed it to continue to refine its engineering algorithms and approach. Further, in the two years prior to the COVID-19 pandemic, Moderna used the platform to produce more than 100 batches of mRNA for use in human clinical trials.

80. Upon information and belief, Moderna's mRNA platform is described as a research engine. The research engine includes mRNA design tools that permit Moderna to design mRNA, among other things, from known sequences. The engine can convert known protein sequences to mRNA sequences that consider sequence,

[15] *See ModernaTX, Inc. et al. v. Pfizer Inc. et al.*, Case No. 22-cv-11378, Complaint at ¶ 7 (D. Mass. Aug. 26, 2022).

structure, and other factors that Moderna predicts will produce the desired therapeutic or vaccination effects. The platform, and the possibility of further tweaks from Moderna scientists, engages in mRNA sequence engineering. For instance, Moderna's 2021 10-K describes how "[w]e additionally design the nucleotide sequence of the coding region to maximize its successful translation into protein."[16] And it further describes how it is "developing AI tools to predict mRNA sequences that can enhance protein expression."[17] Further still, it describes: "Our proprietary in-house digital application suite contains a Sequence Designer module to tailor an entire mRNA, with ever-improving rule sets that contain our accumulated learning about mRNA design. Drug Design Studio utilizes cloud-based computational capacity to run various algorithms we have developed to design each mRNA sequence."[18] Indeed, these technologies were in development prior to the COVID-19 pandemic. In Moderna's 2019 10-k, for example, it describes: "***By optimizing translation initiation*** and efficiency, ***we have further increased the average number of full-length desired proteins per molecule mRNA***. This permits us to reduce the mRNA doses required to achieve the same therapeutic benefit."[19] As described above, optimizing translation initiation is a defining feature of the '179 Patent.

81. Moderna's then-Chief Scientific Officer for Scientific Affairs, Melissa J. Moore, recently explained how navigating the problem solved by the method of the '179 Patent is critical to Moderna's mRNA sequence engineering[20]:

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[16] Moderna 2021 Form 10-K, at 11, available at https://www.sec.gov/Archives/edgar/data/1682852/000168285222000012/mrna-20211231.htm (last visited June 5, 2023).

[17] *Id.* at 37.

[18] *Id.* at 36.

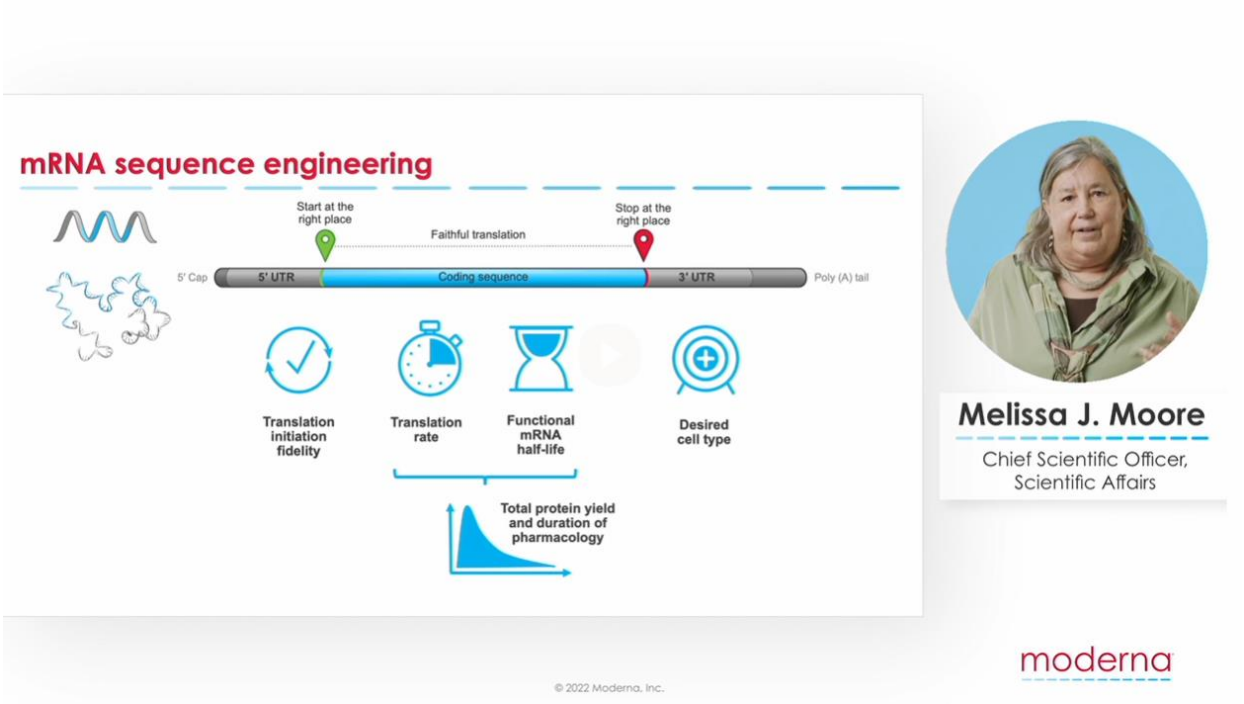
[19] Moderna 2019 Form 10-k, at 13 (emphasis added), available at: https://www.sec.gov/Archives/edgar/data/1682852/000168285220000006/moderna10-k12312019.htm (last visited June 5, 2023); see also id. at 13, 25, 130 (containing language similar to above quotes from 2021 Form 10-K).

[20] Moderna Seminar Series, Chapter 3: mRNA Anatomy (February 8, 2022),

> Let's talk about mRNA sequence engineering. So one of the things that we've put a lot of effort into at Moderna over the last 10 years is learning the engineering principles of how to make a therapeutic RNA that has the properties that we want. And so what are those properties? ***Well of course we would, we always want the ribosome to start at the right place. It turns out that in nature on endogenous mRNAs the ribosome, the small subunit of the ribosome, often misses that first incidence of AUG and starts down somewhere downstream. We don't want that to happen, so we've really learned the rules of how to get the ribosome to always start at the right place.***

82. Those words were spoken while the following graphic was on the screen, which illustrated Moderna's take on the key aspects of mRNA sequence engineering.

Figure 8
Moderna mRNA Sequence Engineering Slide



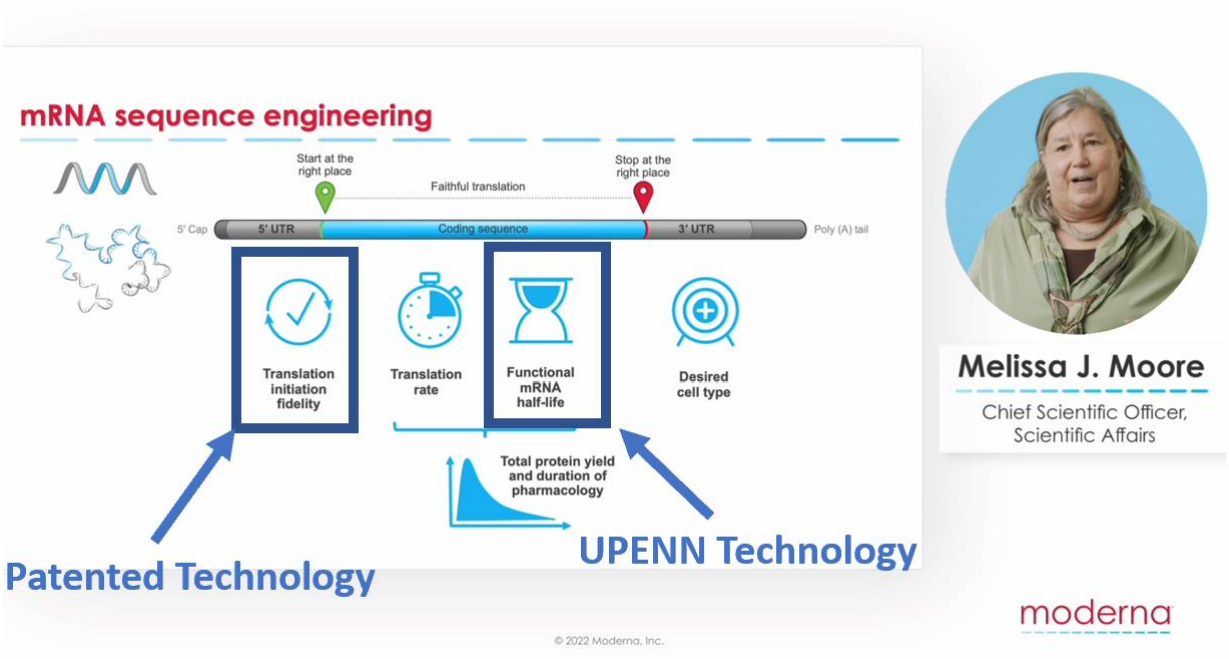
83. The '179 Patent teaches how to achieve what Moderna terms "[t]ranslation initiation fidelity." In other words, that initiation starts at the "right

quote starting around 12:30 (emphasis added), *available at* https://mrna-access.modernatx.com/resources (last visited June 5, 2023).

place" (the primary initiation codon). Upon information and belief, these different aspects of mRNA engineering are of critical value to Moderna's ability to produce a COVID-19 vaccine.

84. Upon information and belief, Moderna has licensed at least one patent implemented in another of the key aspects of mRNA sequence engineering—that is "[f]unctional mRNA half-life." By way of analogy, Moderna has licensed U.S. Patent No. 8,691,966, which relates generally to the substitution of substances like pseudouridine (Ψ) or N1-methylpseudouridine ($m^1\Psi$) for uridine (U) in mRNA. This patent derives from the research of Dr. Katalin Karikó and Dr. Drew Weissman while at the University of Pennsylvania ("UPenn"), and UPenn retains a financial interest in the patent. Moderna has paid more than $1 billion on a license with Cellscript, LLC that relates to U.S. Patent No. 8,691,966. The following graphic shows how the UPenn technology and the method of the '179 Patent—the "Patented Technology"—play into Moderna's description of the core tenants of mRNA sequence engineering.

Figure 9
Moderna mRNA Sequence Engineering Slide (Annotated)



85. Upon information and belief, Moderna incorporated into its platform the method of the '179 Patent—*i.e.*, modifying mRNA to eliminate or mitigate secondary initiation codons. Moderna knowingly incorporated this infringing method into its mRNA platform despite refusing to license from Promosome the right to practice the method of the '179 Patent.

H. Moderna Develops and Markets its Infringing COVID-19 Vaccine

86. Upon information and belief, the genomic sequence for SARS-CoV-2 was first published by January 11, 2020. Just two days later, Moderna had used its preexisting mRNA platform to generate an mRNA sequence encoding the SARS-CoV-2 spike protein with the desired clinical properties. That sequence is called mRNA-1273. Indeed, Dr. Hoge has described: "We were able to research and develop mRNA-1273 so quickly because we leveraged our prior research on vaccines and other mRNA-based medicines."[21]

87. Upon information and belief, the first clinical batch of mRNA-1273 was ready by February 7, 2020. The company worked with the National Institutes of Health to accelerate clinical testing of the vaccine candidate. Moderna's resulting COVID-19 vaccine, branded as Spikevax®, blazed through clinical trials, with a Phase I trial beginning in March 2020, a Phase II trial in May 2020, and a Phase III trial in July 2020. These trials demonstrated significant clinical effectiveness against the original SARS-CoV-2 strain.

88. Upon information and belief, the FDA authorized Spikevax® for individuals 18 and older under an emergency use authorization on December 18, 2020, and fully approved Spikevax® for those adults on January 31, 2022. There have been a medley of other authorizations and approvals. For example, on October

[21] Quoting Testimony of Dr. Stephen Hoge, President, Moderna, Inc. to House Energy and Commerce Committee, Subcommittee on Oversight & Investigations, at 4 (Feb. 23, 2021), available at https://www.congress.gov/117/meeting/house/111226/witnesses/HHRG-117-IF02-Wstate-HogeS-20210223.pdf (last visited June 5, 2023).

20, 2021, the FDA expanded its emergency use authorization for Moderna's COVID-19 vaccine to permit a booster dose for in certain vaccinated individuals, which was further expanded on November 19, 2021 to all individuals 18 or older. On March 29, 2022, the FDA expanded Moderna's emergency use authorization to permit the administration of a second booster dose to individuals 50 years of age and older and to immunocompromised individuals 18 years of age and older. On June 17, 2022, the FDA expanded Moderna's emergency use authorization to permit the use of Moderna's COVID-19 vaccine in children six months and older. On April 18, 2023, the FDA announced that it was limiting the authorized use of the monovalent version of Spikevax® in favor of the bivalent vaccine described below.

89. Upon information and belief, Moderna also developed a bivalent vaccine/booster including both mRNA found in the original Spikevax® vaccine and additional mRNA targeting the spike protein of the BA.4/.5 Omicron SARS-CoV-2 variant. The FDA gave emergency use authorization to the bivalent booster, for example, for ages 18+ on August 31, 2022, for ages 6–17 on October 12, 2022, and for ages 6 months–5 years on December 8, 2022. The bivalent vaccine now is also authorized for use as a primary vaccine dosage in lieu of the monovalent vaccine.

90. Upon information and belief, Moderna has also received a variety of regulatory approvals in foreign markets for the vaccines described above as well as mRNA-1273.214, a bivalent booster designed around the Omicron BA.1 spike protein. mRNA-1273.214 incorporates some of the original mRNA found in Spikevax®.

91. Upon information and belief, Moderna has sold its COVID-19 vaccines within the United States. It has also designed and manufactured COVID-19 vaccines in the United States for sales abroad.

92. Upon information and belief, Moderna recognized approximately $200 million in revenue in 2020 from sales of its COVID-19 vaccines.

93. Upon information and belief, Moderna recognized approximately $17.7 billion in revenue in 2021 from sales of its COVID-19 vaccines. Moderna breaks down these revenues by region as follows: United States, $5.393 Billion; Europe, $6.834 Billion; Rest of World, $5.448 Billion.

94. Upon information and belief, Moderna recognized approximately $18.4 billion in revenue in 2022 from sales of its COVID-19 vaccines. Moderna breaks down these revenues by region as follows: United States, $4.405 billion; Europe, $6.732 billion; Rest of World, $7.298 billion.

95. Upon information and belief, Moderna generated about $1.8 billion in COVID-19 vaccine revenues in the first quarter of 2023 and anticipates billions more in sales of its COVID-19 vaccines in the rest of 2023 and beyond.

96. Upon information and belief, the development of mRNA-1273, including design of its sequence and creation of complementary DNA ("cDNA") or plasmid DNA ("pDNA") for that sequence, took place in the United States. Moderna has manufactured or caused to be manufactured in the United States doses of its COVID-19 vaccines, including at its own facility in Norwood, Massachusetts and a partner's facility in Portsmouth, New Hampshire. Moderna has shipped those doses to other countries, including but not limited to Canada. Moderna has sent from the United States mRNA-1273, an equivalent, or an analogous DNA sequence (*e.g.*, cDNA or pDNA) to enable the completion of its vaccines in other countries, including by third parties such as Lonza Ltd. and ROVI.

97. Upon information and belief, on August 11, 2020, Moderna executed Contract No. W911QY-20-C-0100 with the United States relating to doses of its COVID-19 vaccines. Moderna's vaccine doses made in the United States and administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. All of the manufacturing and sales of vaccines distributed in the United States were for the benefit of the American public. Moderna's President, Dr. Hoge,

has said the same thing to Congress: "In August, we signed a contract with the U.S. government to provide millions of doses of our prospective vaccine ***to the American people***." (emphasis added).[22]

98. Upon information and belief, on July 28, 2022, Moderna executed Contract No. W58P05-22-C-0017 with the United States relating to COVID-19 vaccine doses. Contract No. W58P05-22-C-0017 expressly disclaimed any authorization or consent of the United States for the use of patented inventions.

99. Upon information and belief, Moderna has "a pipeline of several dozen mRNA vaccines and therapeutic medicines for a wide range of diseases"[23] with unknown sequences. These vaccines and therapeutics were likely developed using the same platform that practices the method of the '179 Patent in engineering mRNA sequences.

100. For avoidance of doubt, and based on the extensive interactions with Moderna, specific disclosures of the '179 Patent family to Moderna, and Moderna's extensive citations to '179 Patent, Moderna and each individual defendant had knowledge of the '179 Patent prior to engaging in any of the Infringing Activities.

A. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2014.

B. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2015.

C. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2016.

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[22] Quoting Testimony of Dr. Stephen Hoge, President, Moderna, Inc. to House Energy and Commerce Committee, Subcommittee on Oversight & Investigations, at 3 (Feb. 23, 2021), available at https://www.congress.gov/117/meeting/house/111226/witnesses/HHRG-117-IF02-Wstate-HogeS-20210223.pdf (last visited June 5, 2023).

[23] Quoting *ModernaTX, Inc. et al. v. Pfizer Inc. et al.*, Case No. 22-cv-11378, Complaint at ¶ 31 (D. Mass. Aug. 26, 2022).

D. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2017.

E. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2018.

F. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2019.

G. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2020.

H. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2021.

I. Upon information and belief, Moderna knew of the '179 Patent on or before December 31, 2022.

101. On February 8, 2023, Promosome's Chairman, William J. Gedale, sent a letter to Moderna's Chief Legal Officer, Shannon Thyme Klinger, describing Promosome's "patent-protected RESCUE technology," and offering to have licensing discussions with Moderna.

102. On March 3, 2023, Scripps contacted Moderna again requesting that Moderna engage in licensing discussions with Promosome. Mr. Gedale subsequently emailed with Moderna employees Jimmy Cao and Felipe Heiderich, including further descriptions of Promosome's past interactions with Moderna and an offer to Mr. Cao "to discuss a potential sublicense of our patent-protected technology for your COVID-19 vaccines and other products." Moderna never responded to that offer.

103. Moderna has never requested from Promosome a license for the '179 Patent.

104. Upon information and belief, Moderna and each individual defendant knew and should have known that it infringed the '179 Patent prior to engaging in any of the Infringing Activities, and at the time of all revenues generated by any

COVID-19 vaccines. Moreover, Moderna and each individual defendant acted deliberately and intentionally in infringing the '179 Patent.

105. In willfully infringing the '179 Patent, and for the reasons described above, Moderna engaged in wanton, egregious, and outrageous conduct warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

106. Moderna's conduct with respect to the '179 Patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

CLAIM 1

(Infringement of the '179 Patent)

107. Promosome repeats and re-alleges the allegations in the preceding paragraphs as if fully set forth herein.

108. On October 7, 2014, the United States Patent and Trademark Office duly and legally issued the '179 Patent entitled "Reengineering mRNA Primary Structure for Enhanced Protein Production." A true and correct copy of the '179 Patent is attached as Exhibit 1 to this Complaint.

109. Promosome owns all substantial rights to the '179 Patent, including the right to assert all causes of action under the '179 Patent and the right to remedies obtained on the '179 Patent. The ''179 Patent is fully maintained and is valid and enforceable.

110. Claim 1 of the '179 Patent recites:

> 1. A method of improving full-length protein expression efficiency comprising:
>
> a) providing a polynucleotide comprising:
>
> i) a coding sequence for the full-length protein;
>
> ii) a primary initiation codon that is upstream of the coding sequence of the full-length protein, said primary initiation codon encoding the first amino acid of the coding sequence of the full-length protein; and

iii) one or more secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon; and

b) mutating the one or more secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon, wherein the mutation results in a decrease in initiation of protein synthesis at the one or more secondary initiation codons,

thereby increasing expression efficiency of the full-length protein initiated at the primary initiation codon,

wherein mutating the one or more secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon comprises mutating one or more nucleotides such that the amino acid sequence of the protein remains unaltered.

111. Moderna has used and continues to use Promosome's intellectual property without authority or license to do so and is willfully infringing the '179 Patent.

112. Moderna has directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, Claim 1 of the '179 Patent, in violation of 35 U.S.C. § 271(a). For example, Moderna performs the infringing method to produce cDNA or pDNA which in turn is used to produce the mRNA product that it incorporates into its vaccines. Moderna makes, uses, offers for sale, sells, and/or imports certain products made by the patented method, including but not limited to Moderna's mRNA-1273/Spikevax®, Omicron variant + wild-type mRNA-1273.214, Omicron (BA.4/5) variant + wild-type mRNA-1273.222, mRNA-1273/TeenCove, and mRNA-1273/KidCove, and any foreign or domestic variants or equivalents thereof (the "Accused Products").

113. Moderna's infringing development of the Accused Products includes its internal use, testing, and production of the Accused Products including but not limited to the cDNA or pDNA construct used to produce the Accused Products.

114. The method performed by Moderna in the production of the Accused Products satisfy all claim limitations of Claim 1 of the '179 Patent.

115. Briefly, the Accused Products comprise an mRNA a polynucleotide that contains the coding sequence for the Covid-19 spike protein and also are derived from cDNA or pDNA, which are also polynucleotides. The native protein contains a primary initiation codon at the start of the coding sequence of the full-length protein. The primary initiation codon encodes the first amino acid of the coding sequence of the full-length protein. The native protein also contains numerous secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon. In order to create the Accused Products, Moderna mutated numerous secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon without altering the amnio acid sequence of the spike protein.[24] By mutating these secondary initiation codons there is a decrease in initiation of protein synthesis at the one or more secondary initiation codons. As described above, these mutations increase expression efficiency of the full-length protein initiated at the primary initiation codon.

116. Moderna has received notice and has had actual or constructive knowledge of the ’179 Patent since 2015 and at least from the date of pre-filing licensing offers, and from service of this Complaint. Moderna has received notice and has had actual or constructive knowledge of the infringing nature of its activities with respect to the Accused Products since it engaged in those activities or, at least, since pre-filing communications with Mr. Gedale.

117. Since 2020, through its actions, Moderna has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, the ’179 Patent in violation of 35 U.S.C. § 271(b). Moderna has actively induced contract

[24] Indeed, the vaccine and native proteins include exactly the same amino acid sequence save for two amino acids that were modified to achieve additional stability for reasons separate from the ’179 Patent. These modifications do not affect infringement of Claim 1.

vaccine manufacturers to directly infringe the '179 Patent throughout the United States. Further, Moderna has actively induced third parties to use products made by the patented method throughout the United States, including by and through its advertising, education, and sales efforts, with the goal of actively encouraging directly infringing use of the vaccine.

118. Moderna does so knowing and intending that its contract manufacturers and other third parties will commit these infringing acts. Moderna also continues to make, use, offer for sale, sell, and/or import the Accused Products, despite its knowledge of the '179 Patent, thereby specifically intending for and inducing its contract manufacturers and other third parties to infringe the '179 Patent.

119. Upon information and belief, Moderna's COVID-19 vaccines constitute a material part of the invention of Claim 1 of the '179 Patent and are not staple articles or commodities of commerce suitable for substantial non-infringing use. Moderna has contributorily infringed and will continue to contributorily infringe Claim 1 of the '179 Patent, literally and/or under the doctrine of equivalents, by promoting the making and use of its COVID-19 vaccines in the United States, including by healthcare providers and patients, and knowing that its COVID-19 vaccines are especially made or especially adapted for use to infringe the '179 Patent, in violation of 35 U.S.C. § 271(c).

120. Upon information and belief, Defendants' have imported, used, sold, and/or offered for sale in the United States a product made by the method of Claim 1 of the '179 Patent, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(g). Moderna performs the infringing method to produce cDNA or pDNA, which is used to produce mRNA incorporated into its vaccines, and to produce mRNA, which it incorporates into its vaccines. Moderna makes, uses, offers for sale, sells, and/or imports the Accused Products.

121. Promosome has suffered and continues to suffer damages because of Moderna' infringement of the '179 Patent in an amount yet to be determined and

adequate to compensate for Moderna' infringement, but in no event less than a reasonable royalty for the use made of the invention by Moderna, together with interest and costs as fixed by the Court, as well as other relief prayed for below.

122. Moderna has known of the '179 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna further was aware of Promosome's intellectual property more generally, and that it had engaged with Moderna about potential licensing of RESCUE™ and the '179 Patent. And Moderna was aware that its conduct infringed the '179 Patent. Despite that knowledge, Moderna nonetheless has engaged in infringing activities with the United States in violation of Promosome's patent rights.

123. Moderna has undertaken its infringing actions despite knowing that such actions infringed Claim 1 of the '179 Patent. Accordingly, Defendants have willfully infringed and continue to willfully infringe Claim 1 of the '179 Patent.

Prayer for Relief

WHEREFORE, Promosome requests that the Court:

(a) enter judgment that Moderna has infringed and continues to infringe Claim 1 of the '179 Patent literally and/or under the doctrine of equivalents;

(b) enter judgment that Moderna has induced infringement and continues to induce infringement of Claim 1 of the '179 Patent literally and/or under the doctrine of equivalents;

(c) enter judgment that Moderna has contributorily infringed and continues to contributorily infringe Claim 1 of the '179 Patent literally and/or under the doctrine of equivalents;

(d) enter judgment that Moderna has imported, used, sold, and/or offered for sale in the United States a product made by the method of Claim 1 of the '179 Patent, in violation of 35 U.S.C. § 271(g), literally and/or under the doctrine of equivalents, and continues to do so;

(e) award Promosome damages, to be paid by Moderna in an amount

adequate to compensate Promosome for such damages, together with pre-judgment and post-judgment interest for the infringement by Moderna of Claim 1 of the '179 Patent, except that Promosome does not seek damages for acts of infringement, if any, covered by 28 U.S.C. § 1498;

(f) enter judgment that the infringement has been willful and enhance damages accordingly up to three times the amount of compensatory damages found under 35 U.S.C. § 284;

(g) declare this case exceptional pursuant to 35 U.S.C. § 285; and

(h) award Promosome its costs, disbursements, attorneys' fees, and such further and additional relief as is deemed appropriate by this Court, except that Promosome does not seek any form of injunctive relief against any COVID-19 vaccine.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Promosome hereby demands a jury trial as to all issues so triable.

Dated: June 6, 2023

SUSMAN GODFREY L.L.P.

By: */s/ Amanda K. Bonn*

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**Pro hac vice application forthcoming*
Attorneys for Plaintiff Promosome LLC

JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Promosome LLC

(b) County of Residence of First Listed Plaintiff Fairfield County, CT
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

(see attachment)

DEFENDANTS

Moderna, Inc., Moderna US, Inc. and ModernaTX, Inc

County of Residence of First Listed Defendant Middlesex County, MA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
35 U.S.C. §§ 271, 281 et seq

Brief description of cause:
Patent Infringement

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
June 6, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/Amanda K. Bonn

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Attachment

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**Pro hac vice application forthcoming*
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