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**Pro hac vice application forthcoming*
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

PROMOSOME LLC, Plaintiff, vs. PFIZER INC., BIONTECH SE, and BIONTECH MANUFACTURING GMBH Defendants.	Case No. **'23CV1048 CAB BLM** **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 Pfizer Inc. ("Pfizer"), BioNTech SE, and BioNTech Manufacturing GmbH (collectively with BioNTech SE "BioNTech," and BioNTech collectively with Pfizer, "Defendants") 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"). Dr. Mauro and his colleagues at Promosome—the exclusive licensee of the '179 Patent—disclosed the patented technology to Dr. Katalin Karikó, at that time one of BioNTech's leading mRNA scientists and its Senior Vice President.[2] But BioNTech and Pfizer never attempted to obtain a license. Years later, Defendants developed a COVID-19 vaccine generating tens-of-billions in revenues for the companies. And the sequence underlying Defendants' COVID-19 vaccine tells a clear story: Defendants used the method of the '179 Patent in their COVID-19 vaccine. This Complaint arises from Defendants' willful and unlawful infringement of the '179 Patent.

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

[2] Upon information and belief, Dr. Karikó recently concluded her employment with BioNTech.

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 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. And 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 the 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 BioNTech was a significant potential licensing or business partner with respect to its RESCUE™ technology and the '179 Patent. In 2015, upon information and belief, Promosome's President John Manzello spoke with Dr. Katalin Karikó and provided her with a slide deck describing RESCUE™. Soon thereafter, on December 21, 2015, Dr. Mauro spoke with Dr. Karikó on the phone. Dr. Karikó told Dr. Mauro that she had already reviewed the slides prior to the meeting. She particularly told Dr. Mauro that she had

spent all weekend considering a publication highlighted on one of the slides supporting the danger of a common approach to mRNA called codon optimization. The method of the '179 Patent could help mitigate that problem.

8. Months later, in April 2016, Dr. Karikó inquired further of Dr. Mauro, specifically asking whether the RESCUE™ approach of the '179 Patent could be employed to increase protein expression in human T-cells. After Dr. Mauro responded, Dr. Karikó informed Promosome that she was waiting to see whether partners in the human T-cell area were interested in RESCUE™. Upon information and belief, BioNTech never again followed up with Promosome.

9. Upon information and belief, BioNTech never reengaged Promosome to license its intellectual property, including as relevant here the rights to practice the method of the '179 Patent. That did not stop Defendants, however, from doing so. Defendants have described how they "developed their vaccine by utilizing innovation from their respective scientists and ***relying upon decades of research conducted by others before the pandemic began***."[3] Upon information and belief, the unnamed "others" include Drs. Edelman and Mauro and the research underlying the method of the of the '179 Patent. Indeed, Defendants have incorporated the method of the '179 Patent into the COVID-19 vaccine that they now market under the name Comirnaty®, which includes an mRNA sequence termed BNT162b2.

10. Defendants' vaccine sequence is now public. For example, in March 2021, scientists at Stanford published the results of their sequencing of Defendants' 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). Defendants' mRNA sequence starkly reveals they have modified their mRNA

[3] Answer ¶ 4, *ModernaTX, Inc. et al. v. Pfizer Inc. et al.*, No. 22-cv-11378, D.I. 45 (D. Mass. Dec. 5, 2022) (emphasis added).

sequence to alter secondary initiation codons without changing the underlying amino acid sequence encoded by the mRNA—the method of the '179 Patent.

11. Promosome applauds Defendants' 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 Defendants incorporated the method of the '179 Patent into their COVID-19 vaccine without appropriately compensating Promosome for the right to do so. Promosome is and was a small biotech innovator. And Pfizer's CEO Dr. Albert Bourla has made clear that patents are crucial to "small biotech innovators that are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected."[4] Upon information and belief, that vaccine alone has now generated for Defendants more than $75 billion in revenues. Promosome files this Complaint to receive its rightful share of the tens-of-billions in revenues Defendants already have earned and countless billions they will continue to earn by willfully infringing the '179 Patent.

Parties

12. Plaintiff Promosome 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.

13. Upon information and belief, Pfizer is a corporation organized and existing under the laws of Delaware, with its principal place of business at 235 East 42nd Street, New York, NY 10017.

[4] Albert Bourla, An Open Letter from Pfizer Chairman and CEO to Colleagues (May 7, 2021), https://www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines (last visited June 5, 2023).

14. Upon information and belief, BioNTech SE is a company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

15. Upon information and belief, BioNTech Manufacturing GmbH, a wholly-owned subsidiary of BioNTech SE, is a company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany. BioNTech Manufacturing GmbH is the Biologics License Application ("BLA") holder for Comirnaty® in the United States.

16. Upon information and belief, Pfizer and BioNTech together developed and commercialize Comirnaty®. In particular, Pfizer and BioNTech are and have been operating jointly and as agents of one another as to Defendants' vaccine, including by sharing the profits from the vaccine. For example:

- In a March 17, 2020, Collaboration Agreement Pfizer and BioNTech agree to undertake "collaborative research and development" to develop and launch a Covid-19 vaccine "in all countries of the Territory," where they "wish that Pfizer Commercialize[] the Product in all countries of the Territory," where (i) "Commercialize" is defined as "market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product," and (ii) "Territory" is defined to include the United States and the rest of the World except the People's Republic of China (including Hong Kong SAR and Macau SAR) and Taiwan.
- In a July 25, 2022, Complaint, Pfizer and BioNTech alleged that they "partnered together, and continue to work together" on the vaccine; "partnered together to develop, manufacture, and secure regulatory approval" of the vaccine, including as to "clinical testing [and] distribution"; and "agreed to share the costs of developing" the vaccine.[5]

[5] Complaint, *BioNTech SE, BioNTech Manufacturing GmbH, and Pfizer Inc. v. Curevac AG*, Case No. 1:22-cv-11202 (D. Mass. July 25, 2022) at ⁋⁋ 1, 2, 48, 49.

Jurisdiction & Venue

17. 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*.

18. This Court has personal jurisdiction over Defendants. Defendants regularly conduct business within this District. Pfizer has a significant business presence in this District and employs many persons in it. On information and belief, those employees contribute to vaccine development, including Comirnaty® and its bivalent versions. Pfizer and each BioNTech defendant have specifically directed their business activities to selling and inducing persons to use Comirnaty® and its bivalent versions in this District, knowing and intending Comirnaty® and its bivalent versions would be used in this District and expecting their infringing actions to have consequences in this District, and have derived substantial revenue from the sale and use of Comirnaty® and its bivalent versions in this District. Pfizer and each BioNTech defendant have purposefully availed themselves of the benefits and protections of this District. There is nothing unfair about haling Pfizer and BioNTech into courts in this District.

19. Venue is proper in this District against Pfizer under 28 U.S.C. § 1400(b) because it has regular and established places of business herein and has committed acts of infringement herein. For example, on information and belief, Pfizer has a La Jolla Campus with multiple buildings in this District from which it engages in regular and established business, including but not limited to "CB1" located at 10777 Science Center Drive, San Diego, CA 92121 and other buildings that are part of the La Jolla Campus, including others on Science Center Drive.

20. Pfizer also has committed 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, Pfizer actively induces others to use its COVID-19 vaccines

in this District, in violation of 35 U.S.C. § 271(b), including through advertising and promotion of its COVID-19 vaccines to persons and medical providers in this District.

21. Venue is proper in this District against BioNTech SE and BioNTech Manufacturing GmbH, *inter alia*, under 28 U.S.C. § 1391(c)(3) because they are foreign entities.

Background

A. mRNA Vaccines

22. This lawsuit centers on Defendants' 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.

23. 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 Defendants' 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.

24. 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

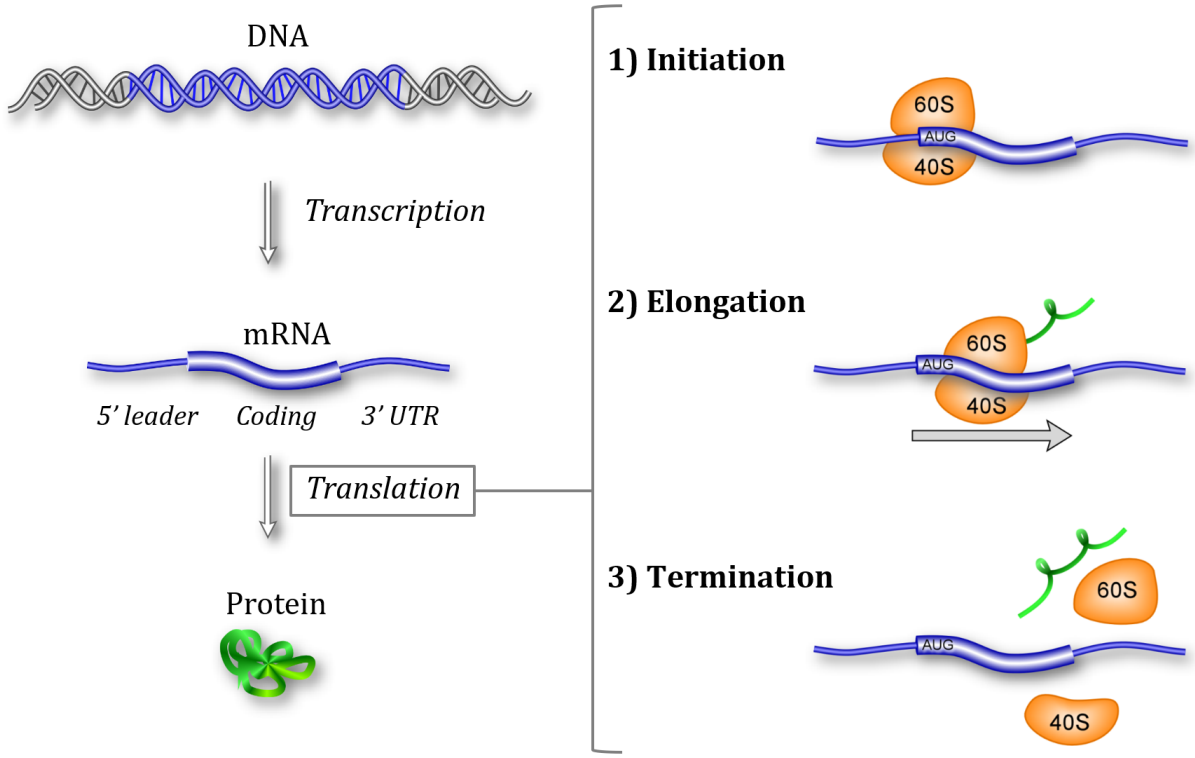
25. Proteins perform most of the functions in the human body and are necessary to human existence. Protein synthesis is the cellular process for expressing proteins. Humans retain instructions for certain proteins through nucleic acids, which are molecules that encode genetic information. Deoxyribonucleic 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.

26. 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.

27. 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 1
Translation within Protein Synthesis



28. 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 translation of the desired amino acid sequence.

29. 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.

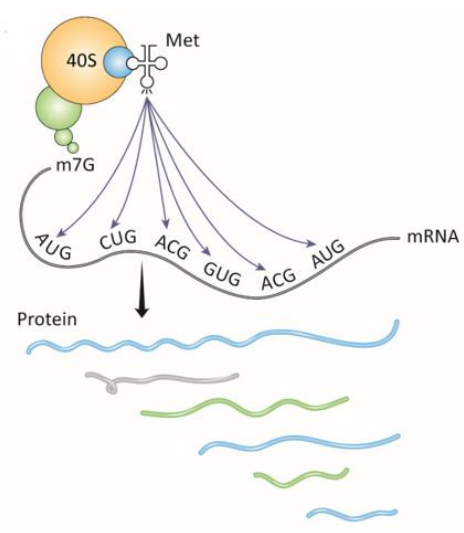
30. An out-of-frame initiation codon, by contrast, is a codon formed by reading parts of consecutive codons within the authentic reading frame. Consider, for

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

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*.

31. 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 2
An Illustration of Start Site Selection



32. 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

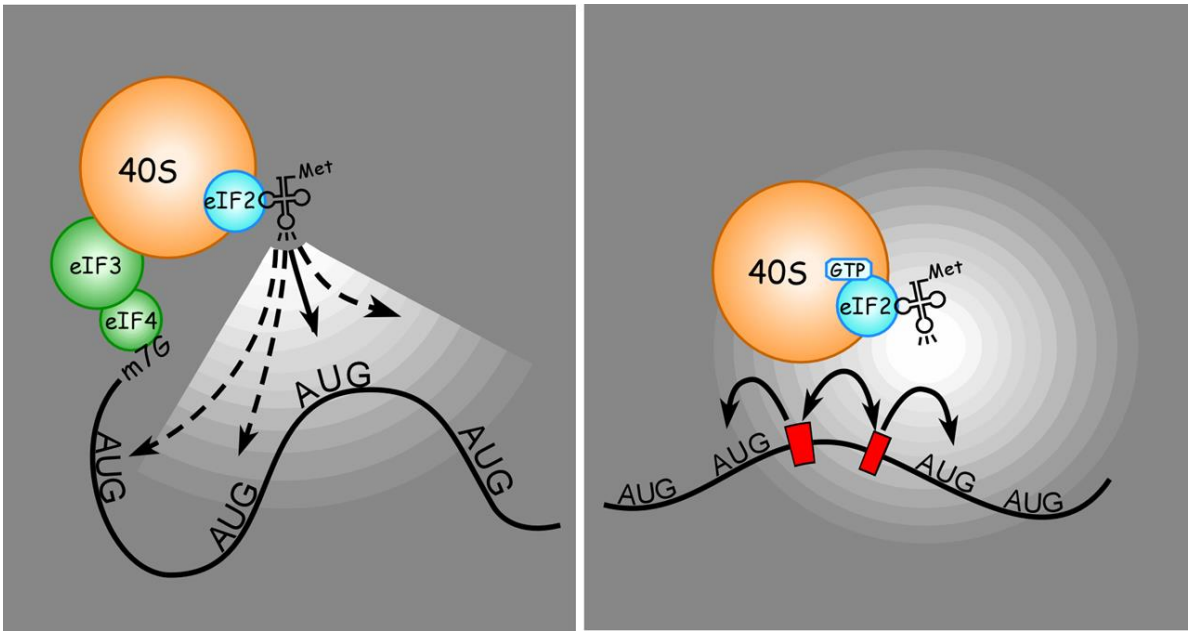
33. As described above, mRNA vaccines take advantage of the translation process by introducing synthetic mRNA into the body so that human cells produce the desired protein. For mRNA vaccines to provide sufficient therapeutic benefits at reasonable dosages, the constituent mRNA must be highly efficient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

34. 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.

35. 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.

36. 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 3
Illustrations of Ribosomal Tethering (left) and Ribosomal Clustering (right)



37. 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 translation 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.

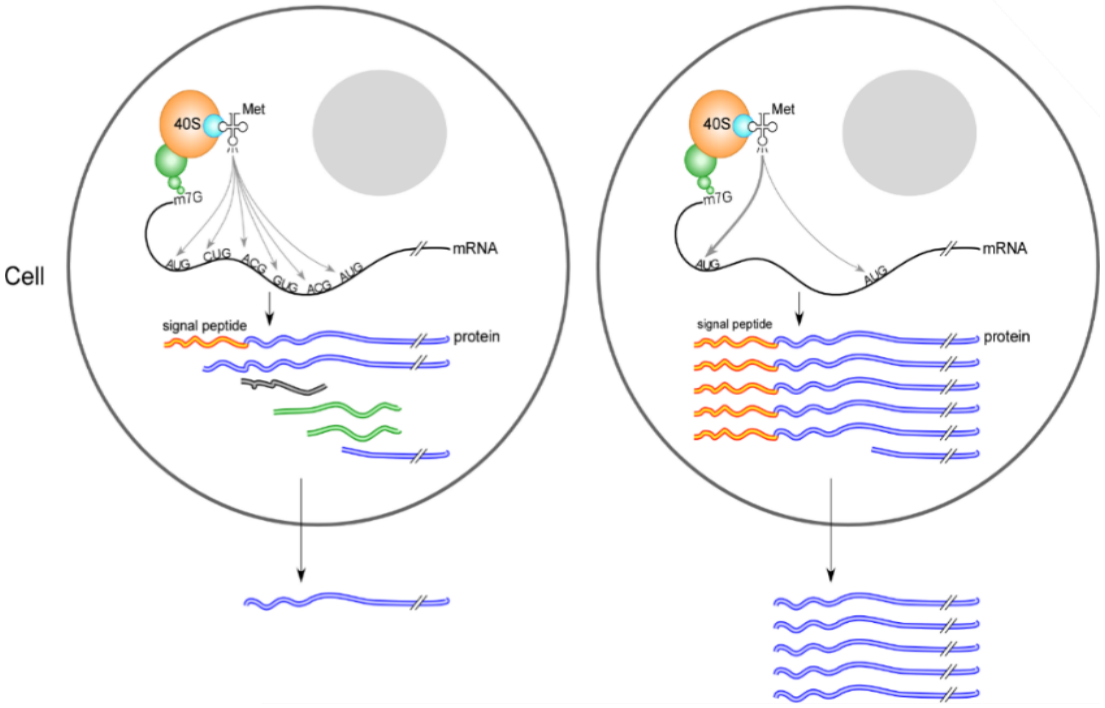
38. Building from their fundamental insights regarding the translation process, the Promosome Scientists discovered a method for increasing full-length protein expression efficiency that would help unlock the promise of mRNA therapeutics and vaccines. In particular, they discovered that mRNA or other 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.

39. 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 A 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]

40. 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:

Figure 4
Illustrations of Protein Expression Efficiency with Promosome IP Pre-Modification (left) and Post-Modification (right)



41. In Figure 4, 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

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

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.

42. 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. 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.

43. 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).[8] In addition, too large of

[8] 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

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

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

45. 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.[9]

46. 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.

47. 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

reducing the overall production of cryptic peptides by reducing the number of units of mRNA required to achieve therapeutic benefit.

[9] 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.

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.

E. Promosome Attempts to Commercialize the '179 Patent, Including to BioNTech

48. 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.

49. 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.

50. 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.

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

52. 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.

53. 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.

54. During this time period, Promosome recognized that BioNTech was a significant potential licensing or business partner with respect to its RESCUE™ technology and the '179 Patent. On information and belief, in 2015, Promosome's President John Manzello spoke with Dr. Katalin Karikó, then a Senior Vice President and leading scientist at BioNTech, and provided her with a slide deck that described RESCUE™. Dr. Karikó said that she was "very familiar with the outstanding work of Vincent Mauro" and that she had "studied the documents" given to her by Mr. Manzello. Soon thereafter, on December 21, 2015, Dr. Mauro spoke with Dr. Karikó on the phone. Dr. Karikó again told Dr. Mauro that she had already reviewed the slides prior to the meeting. She particularly told Dr. Mauro that she had spent all weekend considering a slide describing dangers of a common approach to mRNA

called codon optimization. RESCUE™, the slide deck explained, could help mitigate that problem.

55. Months later, in April 2016, Dr. Karikó inquired further of Dr. Mauro, specifically asking whether the RESCUE™ approach of the '179 Patent could be employed to increase protein expression in human T-cells. After Dr. Mauro responded, Dr. Karikó informed Promosome that she was waiting to see whether partners in the human T-cell area were interested in RESCUE™. Upon information and belief, BioNTech never again followed up with Promosome.

56. Around this time, Promosome also had interactions with Pfizer, including in connection with Pfizer's partnership with non-party Spark Therapeutics for a different treatment. For example, upon information and belief, Mr. Manzello met with Paul Young, Executive Director and Head of Technologies for Pfizer's External Research & Development Innovation (ERDI) Group, at the 2015 Biotechnology Industry Organization International Convention. Upon information and belief, Mr. Manzello had follow-up communications with Dr. Young after this meeting.

57. 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 Defendants operate. Despite these reductions in scope, Promosome continues to pursue partnerships to develop and advance its intellectual property.

F. Defendants Develop and Market an Infringing COVID-19 Vaccine

58. Upon information and belief, the genomic sequence for SARS-CoV-2 was published online by January 11, 2020. Shortly thereafter, BioNTech began working on an mRNA vaccine to combat the COVID-19 pandemic, which eventually took the name "Project Lightspeed." This development effort began with a number of potential vaccine candidates in the BNT162 family of mRNA sequences, of which

the ultimate sequence BNT162b2 was a part.

59. Upon information and belief, Pfizer and BioNTech executed a Material Transfer and Collaboration Agreement to co-develop a COVID-19 vaccine on or before March 17, 2020. Under that agreement, BioNTech's mRNA vaccine technology and expertise would be paired with Pfizer's development, regulatory, and commercial capabilities to develop and commercialize a COVID-19 vaccine.

60. Upon information and belief, Defendants imported into the United States complementary DNA ("cDNA") or plasmid DNA ("pDNA") encoding BNT162b2 created using the patented method in Germany. Pfizer then used that cDNA or pDNA as a seed for subsequent production of additional cDNA or pDNA and, ultimately, the manufacture of the mRNA used in Comirnaty®. In the alternative, Pfizer itself practiced the patented method to create cDNA or pDNA. The importation of BNT162b2 cDNA or pDNA and its replication occurred before any contract was signed for sales of BNT162b2 with the United States Government.

61. cDNA or pDNA can be replicated. Upon information and belief, all cDNA or pDNA used for worldwide production of Comirnaty® is manufactured at a Pfizer plant in Chesterfield, Missouri or elsewhere in the United States. This is the first step in manufacturing the mRNA used in Comirnaty®. In the alternative, certain cDNA or pDNA used for worldwide production of Comirnaty® is manufactured in the United States and shipped to foreign countries.

62. Upon information and belief, Defendants use the cDNA or pDNA to manufacture mRNA drug substance in at least Andover, Massachusetts, Mainz, Germany, and Laupheim, Germany. Certain cDNA or pDNA manufactured in the United States is shipped internationally for further production of drug substance (*i.e.*, mRNA) in foreign countries.

63. Upon information and belief, drug substance is finished into drug product in Kalamazoo, Michigan or in locations in Europe, including Puurs, Belgium.

64. Upon information and belief, Defendants ship drug substance and drug

product from the United States to other countries around the world, including Canada, Mexico, and Australia.

65. Upon information and belief, Defendants import drug product from Europe into the United States.

66. Upon information and belief, on November 18, 2020, Pfizer and BioNTech announced that BNT162b2 showed 95% efficacy against the original coronavirus strain in study participants who had no prior SARS-CoV-2 infection. On December 11, 2020, the FDA granted emergency use authorization for the use of BNT162b2 in persons over 16 years of age. On August 23, 2021, the FDA approved the BLA for Comirnaty® (BNT162b2) for use in persons over 16 years of age. On July 8, 2022, the FDA approved the BLA for Comirnaty® (BNT162b2) for use in persons ages 12–15. Upon information and belief, BioNTech Manufacturing GmbH is the BLA holder for Comirnaty®.

67. Upon information and belief, on October 29, 2021, the FDA authorized the use of BNT162b2 in children between 5 and 11 years of age pursuant to an emergency use authorization. On June 17, 2022, that emergency use authorization was expanded to include the use of the vaccine in children between six months and 4 years of age.

68. Upon information and belief, on September 22, 2021, the FDA amended its emergency use authorization for Comirnaty® to permit administration of a booster dose in some persons six months after completing their primary two-dose series of Comirnaty®. On November 19, 2021, the FDA expanded its emergency use authorization to permit a booster dose of Comirnaty® for all persons at least 18 years old who completed a primary vaccination series with any FDA-authorized or approved COVID-19 vaccine, which was further expanded to 16- and 17-year-olds on December 9, 2021, and all persons 12 or older on January 3, 2022. On January 3, 2022, the FDA also shortened the time period for administration of the third booster dose of Comirnaty® to five months after competition of the primary vaccination

series. On March 29, 2022, the FDA authorized persons over the age of 50 or immunocompromised persons 12 or older to receive a second booster dose four months after the first. On April 18, 2023, the FDA announced that it was limiting the authorized use of the monovalent version of the COVID-19 vaccine in favor of its bivalent equivalent described below.

69. Upon information and belief, Defendants have also designed and received regulatory authorization for a bivalent vaccine dose that incorporates both BNT162b2 and additional drug substance tailored for the Omicron BA.4/BA.5 subvariants. On August 31, 2022, for instance, the FDA granted emergency use authorization for the bivalent vaccine in persons 12 and older. On October 12, 2022, the FDA granted emergency use authorization for the bivalent vaccine for children 5–11 years old. On December 8, 2022, the FDA granted emergency use authorization for children between six months and four years of age.

70. Upon information and belief, Pfizer has received analogous regulatory approval and/or authorization for Comirnaty®, bivalent versions of Comirnaty®, and similar COVID-19 vaccines in countries around the world.

71. Upon information and belief, Pfizer shares profits from Comirnaty® (here and below including all versions of Defendants' COVID-19 vaccines) with BioNTech.

72. Upon information and belief, Pfizer recognized approximately $154 million in revenues in 2020 from sales of Comirnaty®. All sales occurred in the United States.

73. Upon information and belief, Pfizer recognized approximately $36.8 billion in revenues in 2021 from sales of Comirnaty®. Approximately $7.8 billion in revenues traced to domestic sales. Approximately $29.0 billion in revenues traced to international sales.

74. Upon information and belief, Pfizer recognized approximately $37.8 billion in revenues in 2022 from sales of Comirnaty®. Approximately $8.8 billion in

revenues traced to domestic sales. Approximately $29.0 billion in revenues traced to international sales.

75. Upon information and belief, Pfizer recognized about $3.1 billion in revenues in the first quarter of 2023 from sales of Comirnaty®. Defendants anticipate billions an annual revenue from sales of Comirnaty® going forward.

76. Upon information and belief, Pfizer has entered into various contracts to sell COVID-19 vaccines to the United States government. Defendants' 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.

77. Upon information and belief, Defendants knew of the existence of the '179 Patent at the time of all acts of infringement alleged herein.

78. On February 8, 2023, Promosome's Chairman, William J. Gedale, sent a letter to Pfizer's General Counsel, Douglas M. Lankler, describing Promosome's "patent-protected RESCUE technology," and offering to have licensing discussions with Pfizer.

79. On March 3, 2023, Scripps contacted Pfizer to encourage it to engage in licensing discussions with Promosome.

80. Mr. Gedale subsequently sent multiple emails to Pfizer employees Jake Wasserman, Yin Yin, and John Androsavich offering to discuss a license to the '179 Patent. In one of those emails on March 10, 2023, Mr. Gedale attached the '179 Patent to his email. In a follow-up email on March 22, Mr. Gedale made clear that "[w]e believe that Promosome's patented method is employed in the COVID-19 vaccines you jointly developed with BioNTech" and that Promosome "remain[ed] open to licensing [its] technology to you on commercially reasonable terms." Pfizer never responded to this email.

81. On April 18, 2023, an Assistant General Counsel at Pfizer, Michael P. Bauer, responded to Mr. Gedale's February 8 letter suggesting that "BioNTech is the appropriate party" with whom to discuss "Promosome's patent-protected RESCUE technology" with respect to Comirnaty®. Mr. Gedale responded with April 21 letters to Pfizer and BioNTech's domestic affiliate, with the latter specifically stating that Promosome's approach is "protected by U.S. Patent No. 8,853,179." These letters have received no response.

82. Defendants have never requested from Promosome a license for the '179 Patent.

83. Upon information and belief, each defendant knew and should have known that its COVID-19 vaccines infringed the '179 Patent prior to engaging in any of the Infringing Activities, and at the time of all revenues generated by any Accused Product. In the alternative, Defendants were aware of the '179 Patent prior to the filing of this lawsuit based on pre-filing licensing communications. Moreover, Defendants acted deliberately and intentionally in infringing the '179 Patent.

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

85. Defendants' 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)

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

87. 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.

88. 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.

89. 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.

90. Defendants have used and continue to use Promosome's intellectual property without authority or license to do so and are willfully infringing the '179

Patent jointly and/or as agents of one another.

91. Defendants have directly infringed and continue 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). Defendants make, use, offer for sale, sell, and/or import certain products made by the patented method, including but not limited to Defendants' BNT162b2/Comirnaty® Vaccine, the Comirnaty Original/Omicron BA.1 Vaccine, and Comirnaty Original/Omicron BA.4/BA.5 Vaccine, and all foreign or domestic equivalents, variations, or dosages thereof (the "Accused Products").

92. Defendants' 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.

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

94. 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 as described above. In order to create the Accused Products, Defendants mutated numerous secondary initiation codons located within the coding sequence of the full-length protein downstream of the primary initiation codon without altering the amino acid sequence of the spike protein.[10] By mutating these secondary initiation codons there is a decrease in

[10] 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.

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.

95. Defendants have received notice and have had actual or constructive knowledge of the '179 Patent since 2015 and at least from the date of pre-filing communications with Mr. Gedale. Defendants have received notice and have had actual or constructive knowledge of the infringing nature of their activities with respect to the Accused Products since they engaged in those activities or, at least, since pre-filing communications with Mr. Gedale.

96. Since 2020, through its actions, Defendants indirectly infringed and continue to indirectly infringe the '179 Patent, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(b). Defendants have actively induced contract vaccine manufacturers to directly infringe the '179 Patent throughout the United States. Further, Defendants have actively induced third parties to use products made by the patented method throughout the United States, including by through sales, education, and advertising efforts, with the goal of actively encouraging directly infringing use of the vaccine.

97. Defendants do so knowing and intending that contract manufacturers and other third parties will commit these infringing acts. Defendants also continue 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 to infringe the '179 Patent.

98. Upon information and belief, the Accused Products 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. Defendants have 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 their 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).

99. 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). Defendants perform the infringing method to produce cDNA or pDNA, which is used to produce mRNA incorporated into their vaccines, and to produce mRNA, which is incorporated into their vaccines. Defendants make, use, offer for sale, sell, and/or import the Accused Products, which are made by the patented method.

100. Promosome has suffered and continues to suffer damages because of Defendants' infringement of the '179 Patent in an amount yet to be determined and adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, as well as other relief prayed for below.

101. Defendants have known of the '179 Patent or have been willfully blind to its existence and contents since before they commenced the infringing conduct, or in the alternative since before the filing of this lawsuit. Defendants were further aware of Promosome's intellectual property prior to the infringing activity and prior to the filing of this lawsuit. And Defendants were aware that their conduct infringed the '179 Patent. Defendants have nonetheless engaged in infringing conduct as described above and continued to do so in violation of Promosome's patent rights.

102. Defendants have undertaken their 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 Defendants have infringed and continue to infringe Claim 1 of the '179 Patent literally and/or under the doctrine of equivalents;

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

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

(d) enter judgment that 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, in violation of 35 U.S.C. § 271(g), literally and/or under the doctrine of equivalents, and continue to do so;

(e) award Promosome damages, to be paid by Defendants in an amount adequate to compensate Promosome for such damages, together with pre-judgment and post-judgment interest for the infringement by Defendants of Claim 1 of the '179 Patent;

(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

Pfizer Inc., BioNTech SE, and BioNTech Manufacturing GmbH

County of Residence of First Listed Defendant New York County, NY
(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

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

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

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

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

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): *Promosome LLC V. Moderna, Inc. et al.* (Filed 06/06/2023 in S.D. Cal.)

JUDGE Judge Not Yet Assigned DOCKET NUMBER Case Number Not Yet Assigned

DATE June 6, 2023

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

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Attachment

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**Pro hac vice application forthcoming*
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