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

20 **UNITED STATES DISTRICT COURT**
21 **SOUTHERN DISTRICT OF CALIFORNIA**

22 PROMOSOME LLC,

23 Plaintiff,

24 vs.

25 PFIZER INC., BIONTECH SE, and
26 BIONTECH MANUFACTURING
27 GMBH

28 Defendants.

Case No. '23CV1048 CAB BLM

**PROMOSOME COMPLAINT
FOR PATENT INFRINGEMENT**

DEMAND FOR JURY TRIAL

1 Plaintiff Promosome LLC (“Promosome”), by and through its attorneys, files
2 this Complaint for Patent Infringement against Defendants Pfizer Inc. (“Pfizer”),
3 BioNTech SE, and BioNTech Manufacturing GmbH (collectively with BioNTech
4 SE “BioNTech,” and BioNTech collectively with Pfizer, “Defendants”) and alleges
5 as follows:

6 **Introduction & Nature of the Action**

7 1. Promosome is a biotechnology firm created to develop and
8 commercialize the scientific advancements of Nobel laureate Gerald Edelman¹ and
9 Vincent Mauro, both of whom researched at The Scripps Research Institute
10 (“Scripps”). Dr. Edelman was and Dr. Mauro is a pioneer in the field of biochemistry,
11 discovering numerous concepts underlying ribonucleic acid (“RNA”) therapeutics
12 and vaccines, including those behind the messenger RNA (“mRNA”) vaccines
13 recently developed to combat the COVID-19 pandemic. One of their most significant
14 contributions is a patented method for increasing mRNA protein expression, which
15 is protected by U.S. Patent No. 8,853,179 (the “’179 Patent”). Dr. Mauro and his
16 colleagues at Promosome—the exclusive licensee of the ’179 Patent—disclosed the
17 patented technology to Dr. Katalin Karikó, at that time one of BioNTech’s leading
18 mRNA scientists and its Senior Vice President.² But BioNTech and Pfizer never
19 attempted to obtain a license. Years later, Defendants developed a COVID-19
20 vaccine generating tens-of-billions in revenues for the companies. And the sequence
21 underlying Defendants’ COVID-19 vaccine tells a clear story: Defendants used the
22 method of the ’179 Patent in their COVID-19 vaccine. This Complaint arises from
23 Defendants’ willful and unlawful infringement of the ’179 Patent.

24
25
26 ¹ <https://www.nobelprize.org/prizes/medicine/1972/edelman/biographical/> (last
27 visited June 5, 2023). Dr. Edelman passed away in 2014.

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

1 2. mRNA is genetic material that instructs the body how to produce
2 proteins. It has numerous applications, one of which is mRNA vaccines. The virus
3 causing COVID-19, Severe Acute Respiratory Syndrome Coronavirus 2, or SARS-
4 CoV-2, is a novel coronavirus, which is a type of virus known for its distinctive,
5 crown-like spike proteins. Its genome is composed of RNA instead of DNA.
6 Coronaviruses are ideal candidates for mRNA vaccines because cells in the body can
7 be instructed to create the coronavirus's unique spike protein, which itself contains
8 no virus. The body's natural immune system will then recognize the newly minted
9 spike protein as foreign and attack it. And that learned defense will prepare the
10 immune system to fight the actual virus in the future.

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

21 4. Underlying their innovation, the Promosome Scientists developed a
22 novel understanding of how ribosomes—components of a cell that translate mRNA
23 into the amino acid sequences that make up proteins—select a start site along the
24 mRNA to begin their work. Start sites are typically denoted by certain sequences
25 within the mRNA, most commonly the AUG codon. The scientists posited that
26 ribosomes, instead of simply scanning along mRNA to find the first start sequence,
27 used tethering or clustering mechanisms to find start sites based on other criteria,
28 including relative accessibility. These mechanisms would cause ribosomes to

1 sometimes start downstream of the actual, authentic start site, which would not only
2 cause the ribosomes to fail to produce the desired protein, but potentially also to
3 create novel and dangerous cryptic peptides.

4 5. To solve this problem, the Promosome Scientists discovered a method
5 for modifying mRNA to remove alternative or secondary start sites, and thus avoid
6 competition between potential start sites, effectively directing more ribosomes to the
7 authentic start site by reducing the unproductive diversion of ribosomes by the
8 alternative start sites. Doing so accomplishes numerous goals, including reducing the
9 number of potentially toxic peptides generated by the modified mRNA and, most
10 significantly, increasing the expression of the desired protein encoded by the mRNA.
11 As described above, sufficient expression of the desired protein is necessary for
12 creating safe and beneficial mRNA vaccines.

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

19 7. Promosome then brought the method described in the ’179 Patent to
20 market, engaging in both primary research and development activities and pursuing
21 partnerships with others in the field. Promosome marketed the practice of the ’179
22 Patent under the trade name RESCUE™. Promosome recognized that BioNTech was
23 a significant potential licensing or business partner with respect to its RESCUE™
24 technology and the ’179 Patent. In 2015, upon information and belief, Promosome’s
25 President John Manzello spoke with Dr. Katalin Karikó and provided her with a slide
26 deck describing RESCUE™. Soon thereafter, on December 21, 2015, Dr. Mauro
27 spoke with Dr. Karikó on the phone. Dr. Karikó told Dr. Mauro that she had already
28 reviewed the slides prior to the meeting. She particularly told Dr. Mauro that she had

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

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

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

20 10. Defendants’ vaccine sequence is now public. For example, in March
21 2021, scientists at Stanford published the results of their sequencing of Defendants’
22 COVID-19 vaccine. See Jeong et al., *Assemblies of Putative SARS-CoV2-Spike-*
23 *Encoding mRNA Sequences for Vaccines BNT-162b2 and mRNA-1273*, available at
24 [https://virological.org/t/assemblies-of-putative-sars-cov2-spike-encoding-mrna-](https://virological.org/t/assemblies-of-putative-sars-cov2-spike-encoding-mrna-sequences-for-vaccines-bnt-162b2-and-mrna-1273/663)
25 [sequences-for-vaccines-bnt-162b2-and-mrna-1273/663](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).
26 Defendants’ mRNA sequence starkly reveals they have modified their mRNA

27 ³ Answer ¶ 4, *ModernaTX, Inc. et al. v. Pfizer Inc. et al.*, No. 22-cv-11378, D.I.
28 45 (D. Mass. Dec. 5, 2022) (emphasis added).

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

3 11. Promosome applauds Defendants' efforts to develop and sell a COVID-
4 19 vaccine. Those efforts have saved innumerable lives. And the COVID-19 vaccines
5 have accelerated and demonstrated the promise of mRNA therapeutics and vaccines
6 unlocked by Promosome's patented method. But it is now clear that Defendants
7 incorporated the method of the '179 Patent into their COVID-19 vaccine without
8 appropriately compensating Promosome for the right to do so. Promosome is and was
9 a small biotech innovator. And Pfizer's CEO Dr. Albert Bourla has made clear that
10 patents are crucial to "small biotech innovators that are totally dependent on
11 accessing capital from investors who invest only on the premise that their intellectual
12 property will be protected."⁴ Upon information and belief, that vaccine alone has now
13 generated for Defendants more than \$75 billion in revenues. Promosome files this
14 Complaint to receive its rightful share of the tens-of-billions in revenues Defendants
15 already have earned and countless billions they will continue to earn by willfully
16 infringing the '179 Patent.

17 **Parties**

18 12. Plaintiff Promosome is a limited liability company organized and
19 existing under the laws of the State of Delaware with a principal place of business at
20 48 Gurley Road, Stamford, CT 06902. Promosome is the exclusive licensee holding
21 all substantial rights to the '179 Patent.

22 13. Upon information and belief, Pfizer is a corporation organized and
23 existing under the laws of Delaware, with its principal place of business at 235 East
24 42nd Street, New York, NY 10017.

25
26 _____
27 ⁴ Albert Bourla, An Open Letter from Pfizer Chairman and CEO to Colleagues
28 ([https://www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_p
ropery_waiver_for_covid_19_vaccines](https://www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines) (last visited June 5, 2023)).

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

4 15. Upon information and belief, BioNTech Manufacturing GmbH, a
5 wholly-owned subsidiary of BioNTech SE, is a company organized and existing
6 under the laws of Germany, with its principal place of business at An der Goldgrube
7 12, Mainz, 55131 Germany. BioNTech Manufacturing GmbH is the Biologics
8 License Application (“BLA”) holder for Comirnaty® in the United States.

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

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

27
28 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.

1 **Jurisdiction & Venue**

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

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

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

25 20. Pfizer also has committed acts of infringement in this District, including
26 but not limited to selling, using, and offering to sell its COVID-19 vaccines, which
27 are products made by the patented process, within this District in violation of 35
28 U.S.C. § 271(g). Further, Pfizer actively induces others to use its COVID-19 vaccines

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

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

7 **Background**

8 **A. mRNA Vaccines**

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

17 23. Vaccines targeting viruses train the human body to recognize and attack
18 viruses before the virus infects the vaccine recipient. Historically, vaccines consisted
19 of weakened or inactive virus that was unlikely to cause infection yet sufficient to
20 provoke an immune response. mRNA vaccines, however, generally function
21 differently. These vaccines prompt the body to express proteins with sufficient
22 similarity to certain features of the virus to provoke a natural immune response that
23 would also be effective in recognizing and attacking the virus itself. In the case of
24 SARS-CoV-2, mRNA vaccines like Defendants' cause the body to create a protein
25 like the virus's distinctive spike protein, which itself contains no virus. The body's
26 efforts to attack the mimicked spike proteins train the body to recognize the spike
27 protein of the SARS-CoV-2 virus and thus provoke an immune response to the virus
28 itself.

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

12 **B. Protein Expression and mRNA Translation**

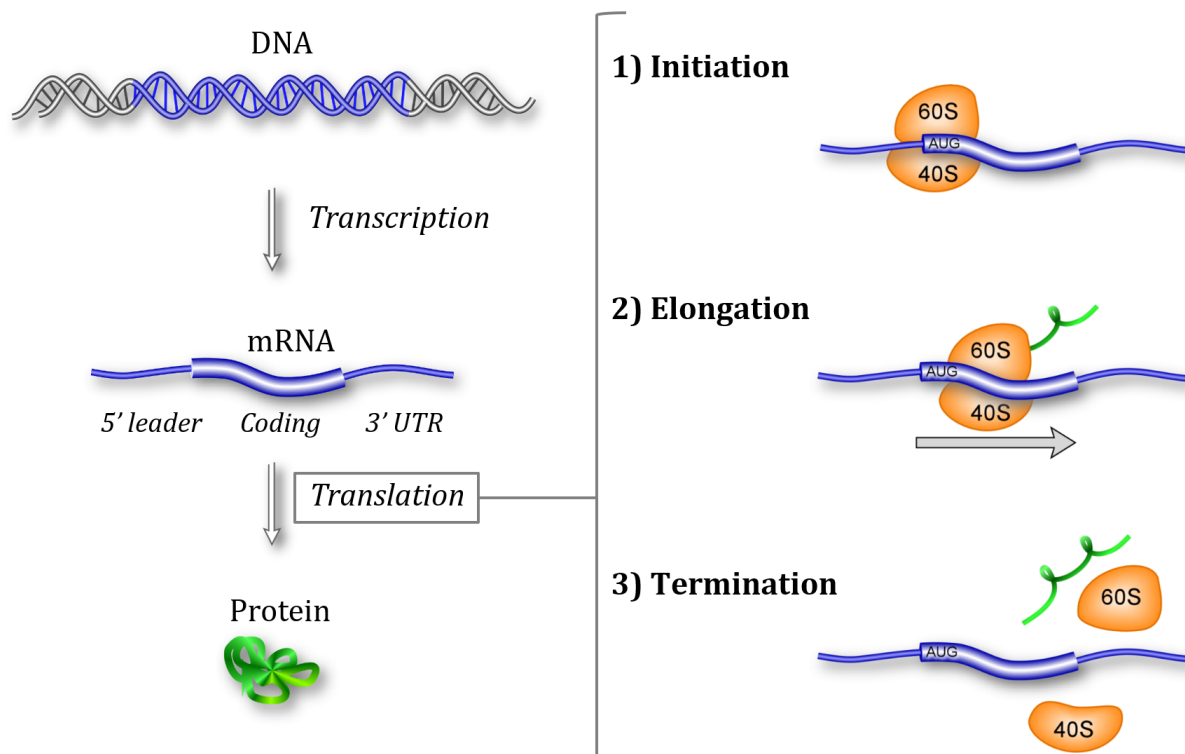
13 25. Proteins perform most of the functions in the human body and are
14 necessary to human existence. Protein synthesis is the cellular process for expressing
15 proteins. Humans retain instructions for certain proteins through nucleic acids, which
16 are molecules that encode genetic information.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

21 26. The process of producing proteins from mRNA is called translation,
22 which is the focus of the '179 Patent. mRNA is a linear template composed of 4
23 nucleosides: guanosine (G), uridine (U), adenosine (A), and cytidine (C), each of
24 which has a nitrogen-containing ring structure linked to a ribose sugar. Individual
25 nucleosides are linked together by phosphate bonds between the ribose sugars
26 (nucleosides with a phosphate group are called nucleotides). Phosphate bonds join
27 the 5' carbon of one ribose sugar to the 3' carbon of another. By convention, 5' to 3'
28 is used to indicate the directionality of mRNA (indicated schematically as left to

1 right). Relevant to this discussion are a few mRNA components, including the 5'
 2 untranslated region (“UTR”)—often called the 5' leader because it comes near the
 3 start (5' end) of the mRNA—followed by the coding sequence, and then the 3' UTR.
 4 The coding sequence describes various amino acids, ordered in the 5' to 3' direction,
 5 that form the encoded protein. Each amino acid is encoded by 3 nucleotides called a
 6 trinucleotide codon. There are 64 (4^3) different trinucleotide codons, which
 7 collectively encode for the 20 amino acids in human proteins. For instance, the codon
 8 GCU—that is, a triplet of guanosine, cytidine, and uridine in that order—encodes the
 9 amino acid alanine. While two amino acids are encoded by only a single codon, the
 10 other 18 are encoded by 2, 3, 4, or 6 synonymous codons. As a result, an effectively
 11 infinite variety of mRNA sequences could encode any given amino acid sequence.

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

15 **Figure 1**
 16 **Translation within Protein Synthesis**



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

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

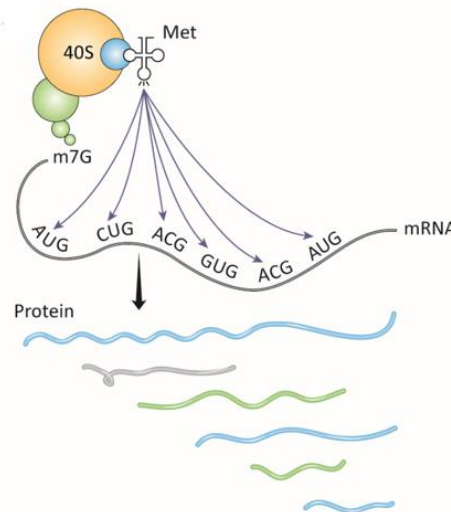
25 30. An out-of-frame initiation codon, by contrast, is a codon formed by
26 reading parts of consecutive codons within the authentic reading frame. Consider, for

27 _____
28 ⁶ 80S ribosomes, as it happens, seem less than the sum of their parts simply
because of a complex and non-additive naming convention.

1 example, a short mRNA sequence for the amino acid histidine followed by valine,
2 which could be encoded by a CAU codon (in bold) followed by a GUU codon (in
3 italics): **CAU** *GUU*. This sequence would create an out-of-frame initiation codon
4 AUG by reading the middle adenosine (A) and final uridine (U) in the CAU codon
5 along with the initial guanosine (G) in the GUU codon, as underlined here:
6 **CAUGUU**.

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

13 **Figure 2**
14 **An Illustration of Start Site Selection**



23
24 32. The second and third steps of the translation process follow naturally
25 from initiation. In the second step, elongation, the 80S ribosome travels along the
26 mRNA translating one codon at a time and linking the encoded amino acids into
27 polypeptides as it goes. The elongation process continues as the 80S ribosome travels
28 towards the 3' UTR until the third step, termination. Termination is the conclusion of

1 the translation process and occurs when the 80S ribosome reaches a stop codon. The
2 three stop codons—UAA, UAG, and UGA—do not encode any amino acid. During
3 translation, co-translational processes, including folding, may occur. Upon
4 termination, the polypeptide chain may undergo other post-translational
5 modifications to form a protein and complete protein synthesis.

6 **C. Promosome Scientists Discover a Method for Improving Protein** 7 **Expression Efficiency**

8 33. As described above, mRNA vaccines take advantage of the translation
9 process by introducing synthetic mRNA into the body so that human cells produce
10 the desired protein. For mRNA vaccines to provide sufficient therapeutic benefits at
11 reasonable dosages, the constituent mRNA must be highly efficient at protein
12 synthesis. In other words, it must prompt the body to maximize the production of the
13 desired protein per unit of mRNA introduced into the body.

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

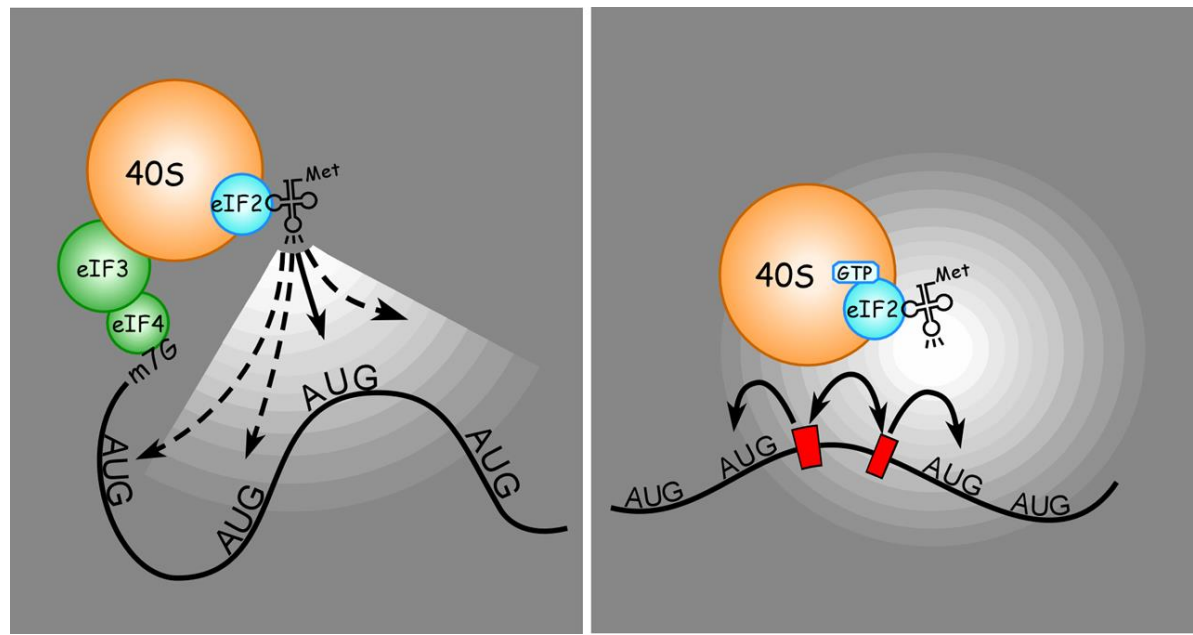
28

1 35. Scientists at The Scripps Research Institute were long on the forefront
2 of mRNA discovery. These scientists included: Gerald Edelman, who shared the
3 1972 Nobel Prize for Physiology or Medicine for his pioneering work studying the
4 chemical structure of antibodies, and who worked as Scripps's Chairman of
5 Neurobiology; Vincent Mauro, a global thought leader in mRNA translation who
6 served at Scripps as an Associate Professor of Cell and Molecular Biology; and Wei
7 Zhou & Stephen Chappell, Scientists at Scripps and eventually Promosome. Each of
8 these scientists, referred to as the Promosome Scientists, was affiliated with
9 Promosome.

10 36. The Promosome Scientists developed an advanced understanding of the
11 translation process and, in particular, the recruitment and start site selection processes
12 involved in initiation. Prior to their discovery, scientists and prior art generally
13 followed a scanning model of translation initiation, where the 40S ribosomal subunit
14 scanned across the mRNA from the 5' leader in the direction of the 3' UTR until an
15 initiation codon was identified. The Promosome Scientists discovered and
16 hypothesized that that 40S ribosomal subunits likely used other mechanisms for start-
17 site selection, including tethering or clustering mechanisms. At a high level,
18 ribosomal tethering describes a mechanism in which ribosomal subunits reach the
19 initiation codon while bound to a fixed point in the mRNA. With tethering, the
20 intervening sequences are not scanned, but are bypassed when the ribosomal subunit
21 pairs to the initiation codon. Ribosomal clustering, by contrast, is a dynamic process
22 that involves reversible binding of the ribosomal subunit to and detachment from
23 various sites in the mRNA and that does not require that the ribosomal subunit be
24 tethered to the mRNA for it to reach the initiation codon.

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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

1 intended codon sequence of the primary reading frame, it completely changes out-
2 of-frame codons read when elongation begins at out-of-frame secondary initiation
3 codons. This means that codon optimization can cause the body to produce novel
4 cryptic peptides.

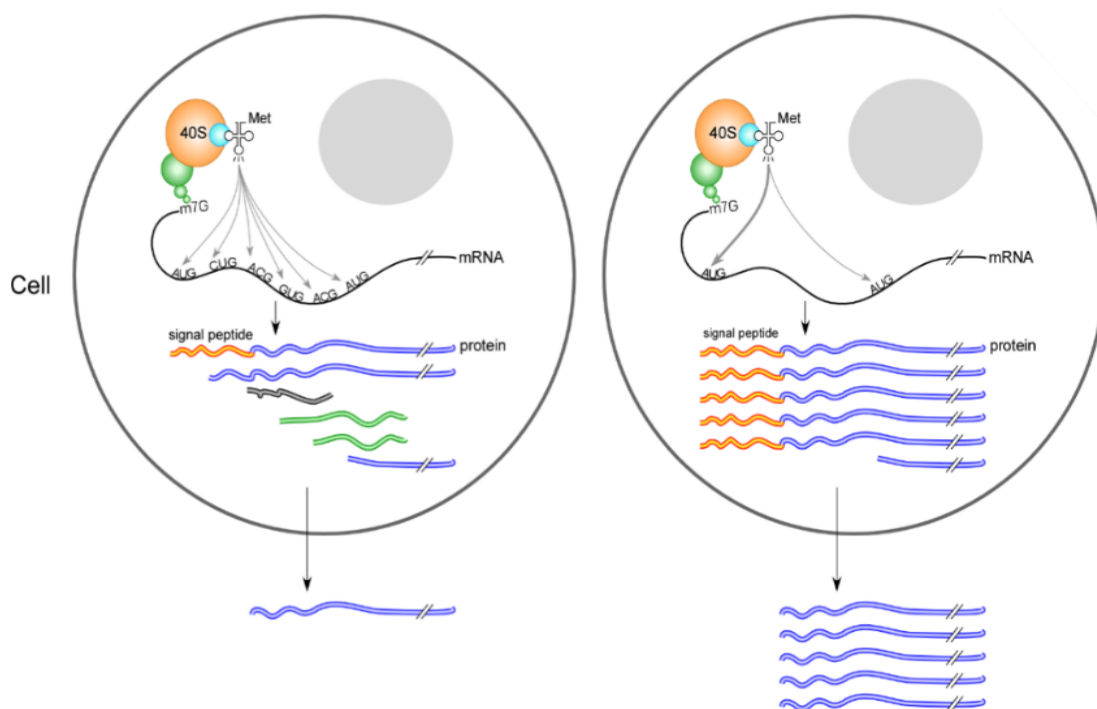
5 38. Building from their fundamental insights regarding the translation
6 process, the Promosome Scientists discovered a method for increasing full-length
7 protein expression efficiency that would help unlock the promise of mRNA
8 therapeutics and vaccines. In particular, they discovered that mRNA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

14 39. To illustrate, recall from above the short mRNA sequence encoding the
15 amino acids histidine then valine with a CAU codon (in bold) followed by a GUU
16 codon (in italics), but which presents an out-of-frame initiation codon AUG
17 (underlined): **C A U** *G U U*. Under the Promosome Scientists' innovative method,
18 for example, the first CAU codon could be modified to CAC by replacing the uridine
19 (U) with cytidine (C) to eliminate the out-of-frame initiation codon AUG and replace
20 it with the comparatively weak, noncanonical initiation codon ACG: **C A C** *G U U*.
21 Such a modification would not alter the resultant amino acid sequence in the intended
22 polypeptide because CAU and CAC both encode the amino acid histidine. But it
23 would be likely to reduce ribosomal diversion and thus cause more ribosomes to
24 translate the desired amino acid sequence by starting at the primary initiation codon.
25 Other codons permit complete elimination of the secondary initiation site even for
26 in-frame initiation codons. For instance, the secondary initiation codon CUG, which
27 encodes Leucine, can be mutated to CUA, CUC, CUU, or UUA, all of which also
28

1 encode Leucine but are not known initiation codons.⁷

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

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



21 41. In Figure 4, above, the blue proteins with an orange signal peptide
22 represent the desired result of translation starting at the primary initiation codon. (A
23 signal peptide is the amino acid chain encoded by the first portion of the coding
24 sequence that labels a protein for secretion from the cell; it is cleaved off the mature
25 protein.) Gray and green lines represent undesirable peptides generated from out-of-
26 frame secondary initiation codons, and mis-sized blue lines represent undesirable
27 peptides generated from in-frame secondary initiation codons. The illustration on the

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

1 right shows how removing secondary initiation codons results in a greater protein
2 expression efficiency of the desired protein as more ribosomes start at the primary
3 initiation codon and thus translate the desired amino acid sequence. The same method
4 can be applied to DNA to cause mRNA transcribed from the DNA to have the desired
5 modifications.

6 42. The Promosome Scientists engaged in testing, described in the '179
7 Patent and elsewhere, that confirmed the validity and usefulness of their method for
8 increasing protein expression. In some instances, the method caused protein
9 expression to increase by significant multiples. And time has only underscored the
10 importance of their innovative approach to increasing protein expression efficiency,
11 as (among other things) mRNA vaccines have now demonstrated their efficacy
12 against COVID-19. Indeed, one of the key insights of the Promosome Scientists—
13 that initiation often mistakenly occurs at downstream secondary initiation codons—
14 is now widely accepted. To be sure, the method of the '179 Patent remains agnostic
15 to the precise mechanism(s) used for translation initiation, and there remains
16 significant scientific debate over the appropriate mechanism. But further study has
17 only strengthened the critique of the linear scanning model questioned by the
18 Promosome Scientists.

19 43. Increased protein expression is essential to, among other things, the
20 prospect of modern mRNA therapeutics and vaccines. mRNA vaccines like the
21 COVID-19 vaccines, for instance, must cause sufficiently efficient protein synthesis
22 so that they can be dosed safely. Otherwise, generating a sufficient immune response
23 would require a much larger dose of mRNA. Larger doses would lead to increased
24 production of cryptic peptides, which may negatively affect both overall expression
25 levels and cell physiology (and, ultimately, human health).⁸ In addition, too large of
26

27 ⁸ Not to mention, practicing the method discovered by the Promosome Scientists
28 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

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

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

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

7 45. On, February 24, 2009, they filed U.S. Provisional Patent Application
8 No. 61/155,049. Exactly one year later, they filed a Patent Cooperation Treaty
9 application No. PCT/US2010/000567. The U.S. Application resulted in publication
10 of application No. 2012/005333 A1 on March 1, 2012. And an extensive catalogue
11 of foreign patents also were obtained under the PCT application.⁹

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

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

17 1. A method of improving full-length protein expression efficiency
18 comprising:

19 a) providing a polynucleotide comprising:

20 i) a coding sequence for the full-length protein;

21 ii) a primary initiation codon that is upstream of the coding
22 sequence of the full-length protein, said primary initiation
23 codon encoding the first amino acid of the coding sequence
24 of the full-length protein; and

25 iii) one or more secondary initiation codons located within the

26 _____
27 reducing the overall production of cryptic peptides by reducing the number of units
28 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.

1 coding sequence of the full-length protein downstream of
2 the primary initiation codon; and

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

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

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

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

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

27 49. On June 25, 2009, shortly after the Promosome Scientists filed the
28 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.

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

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

5 52. Promosome sought to bring the method of the '179 Patent, along with
6 expertise in its implementation, to market under the trade name RESCUE™.
7 RESCUE™ was part of a robust and then-growing technology suite, including
8 numerous patents and other technologies such as Positive Feedback Selection,
9 Translation Enhancing Elements, and Landing Pad. Promosome actively sought to
10 monetize its intellectual property through partnerships in fields like mammalian cell
11 line development, mRNA therapeutics, and Coagulation Factors, as well as internal
12 programs aimed at creating hard-to-express proteins and biosimilars.

13 53. In 2013, for example, the company had locations in New York City,
14 New York and La Jolla, California. It had obtained between \$10–12 million in
15 research grants and raised \$17 million in funding series A, B, and C. Around that
16 time, it grew to about 15 employees led on the technical side by Drs. Edelman and
17 Mauro and obtained ~10,000 square feet of class-A lab and office space in La Jolla.

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

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

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

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

17 57. By late 2016, however, funding became scarce and Promosome was
18 forced to reduce the scope of its operations, including by closing its wet lab. This
19 reduction was caused by a financial shortfall, which, in part, traced to the inability to
20 develop a partnership in the mRNA therapeutics realm in which Defendants operate.
21 Despite these reductions in scope, Promosome continues to pursue partnerships to
22 develop and advance its intellectual property.

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

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

1 the ultimate sequence BNT162b2 was a part.

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

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

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

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

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

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

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

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

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

14 67. Upon information and belief, on October 29, 2021, the FDA authorized
15 the use of BNT162b2 in children between 5 and 11 years of age pursuant to an
16 emergency use authorization. On June 17, 2022, that emergency use authorization
17 was expanded to include the use of the vaccine in children between six months and
18 4 years of age.

19 68. Upon information and belief, on September 22, 2021, the FDA amended
20 its emergency use authorization for Comirnaty® to permit administration of a booster
21 dose in some persons six months after completing their primary two-dose series of
22 Comirnaty®. On November 19, 2021, the FDA expanded its emergency use
23 authorization to permit a booster dose of Comirnaty® for all persons at least 18 years
24 old who completed a primary vaccination series with any FDA-authorized or
25 approved COVID-19 vaccine, which was further expanded to 16- and 17-year-olds
26 on December 9, 2021, and all persons 12 or older on January 3, 2022. On January 3,
27 2022, the FDA also shortened the time period for administration of the third booster
28 dose of Comirnaty® to five months after completion of the primary vaccination

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

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

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

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

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

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

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

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

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

6 76. Upon information and belief, Pfizer has entered into various contracts
7 to sell COVID-19 vaccines to the United States government. Defendants' vaccine
8 doses made in the United States and administered in the United States were
9 distributed to hospitals, pharmacies, clinics, and numerous other entities for the
10 benefit of individual vaccine recipients in the United States. All of the manufacturing
11 and sales of vaccines distributed in the United States were for the benefit of the
12 American public.

13 77. Upon information and belief, Defendants knew of the existence of the
14 '179 Patent at the time of all acts of infringement alleged herein.

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

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

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

1 attached as Exhibit 1 to this Complaint.

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

6 89. Claim 1 of the '179 Patent recites:

7 1. A method of improving full-length protein expression efficiency
8 comprising:

9 a) providing a polynucleotide comprising:

10 i) a coding sequence for the full-length protein;

11 ii) a primary initiation codon that is upstream of the coding
12 sequence of the full-length protein, said primary initiation
13 codon encoding the first amino acid of the coding sequence
14 of the full-length protein; and

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

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

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

25 wherein mutating the one or more secondary initiation codons
26 located within the coding sequence of the full-length protein
27 downstream of the primary initiation codon comprises mutating
28 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

1 Patent jointly and/or as agents of one another.

2 91. Defendants have directly infringed and continue to directly infringe,
3 literally and/or under the doctrine of equivalents, Claim 1 of the '179 Patent, in
4 violation of 35 U.S.C. § 271(a). Defendants make, use, offer for sale, sell, and/or
5 import certain products made by the patented method, including but not limited to
6 Defendants' BNT162b2/Comirnaty® Vaccine, the Comirnaty Original/Omicron
7 BA.1 Vaccine, and Comirnaty Original/Omicron BA.4/BA.5 Vaccine, and all foreign
8 or domestic equivalents, variations, or dosages thereof (the "Accused Products").

9 92. Defendants' infringing development of the Accused Products includes
10 its internal use, testing, and production of the Accused Products including but not
11 limited to the cDNA or pDNA construct used to produce the Accused Products.

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

14 94. Briefly, the Accused Products comprise an mRNA a polynucleotide that
15 contains the coding sequence for the Covid-19 spike protein and also are derived
16 from cDNA or pDNA, which are also polynucleotides. The native protein contains a
17 primary initiation codon at the start of the coding sequence of the full-length protein.
18 The primary initiation codon encodes the first amino acid of the coding sequence of
19 the full-length protein. The native protein also contains numerous secondary
20 initiation codons located within the coding sequence of the full-length protein
21 downstream of the primary initiation codon as described above. In order to create the
22 Accused Products, Defendants mutated numerous secondary initiation codons
23 located within the coding sequence of the full-length protein downstream of the
24 primary initiation codon without altering the amino acid sequence of the spike
25 protein.¹⁰ By mutating these secondary initiation codons there is a decrease in

26 _____
27 ¹⁰ Indeed, the vaccine and native proteins include exactly the same amino acid
28 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.

1 initiation of protein synthesis at the one or more secondary initiation codons. As
2 described above, these mutations increase expression efficiency of the full-length
3 protein initiated at the primary initiation codon.

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

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

18 97. Defendants do so knowing and intending that contract manufacturers
19 and other third parties will commit these infringing acts. Defendants also continue to
20 make, use, offer for sale, sell, and/or import the Accused Products, despite its
21 knowledge of the '179 Patent, thereby specifically intending for and inducing its
22 contract manufacturers to infringe the '179 Patent.

23 98. Upon information and belief, the Accused Products constitute a material
24 part of the invention of Claim 1 of the '179 Patent and are not staple articles or
25 commodities of commerce suitable for substantial non-infringing use. Defendants
26 have contributorily infringed and will continue to contributorily infringe Claim 1 of
27 the '179 Patent, literally and/or under the doctrine of equivalents, by promoting the
28 making and use of their COVID-19 vaccines in the United States, including by

1 healthcare providers and patients, and knowing that its COVID-19 vaccines are
2 especially made or especially adapted for use to infringe the '179 Patent, in violation
3 of 35 U.S.C. § 271(c).

4 99. Upon information and belief, Defendants' have imported, used, sold,
5 and/or offered for sale in the United States a product made by the method of Claim 1
6 of the '179 Patent, literally and/or under the doctrine of equivalents, in violation of
7 35 U.S.C. § 271(g). Defendants perform the infringing method to produce cDNA or
8 pDNA, which is used to produce mRNA incorporated into their vaccines, and to
9 produce mRNA, which is incorporated into their vaccines. Defendants make, use,
10 offer for sale, sell, and/or import the Accused Products, which are made by the
11 patented method.

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

17 101. Defendants have known of the '179 Patent or have been willfully blind
18 to its existence and contents since before they commenced the infringing conduct, or
19 in the alternative since before the filing of this lawsuit. Defendants were further aware
20 of Promosome's intellectual property prior to the infringing activity and prior to the
21 filing of this lawsuit. And Defendants were aware that their conduct infringed the
22 '179 Patent. Defendants have nonetheless engaged in infringing conduct as described
23 above and continued to do so in violation of Promosome's patent rights.

24 102. Defendants have undertaken their infringing actions despite knowing
25 that such actions infringed Claim 1 of the '179 Patent. Accordingly, Defendants have
26 willfully infringed and continue to willfully infringe Claim 1 of the '179 Patent.

27 **Prayer for Relief**

28 WHEREFORE, Promosome requests that the Court:

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

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

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

9 (d) enter judgment that Defendants have imported, used, sold, and/or
10 offered for sale in the United States a product made by the method of Claim 1 of the
11 '179 Patent, in violation of 35 U.S.C. § 271(g), literally and/or under the doctrine of
12 equivalents, and continue to do so;

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

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

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

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

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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

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)

- | | | | | | |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS			
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 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

Promosome LLC v. Moderna, Inc. et al. (Filed 06/06/2023 in S.D. Cal.)
(See instructions): 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

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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