IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER CROPSCIENCE LLC, MONSANTO COMPANY, and MONSANTO TECHNOLOGY, LLC, Plaintiffs, v. PFIZER INC., BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC., Defendants.	C.A. No. _____ JURY TRIAL DEMANDED

PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bayer CropScience LLC, Monsanto Company, and Monsanto Technology, LLC (collectively "Plaintiffs" or "Bayer") file this Complaint for Patent Infringement against Defendants Pfizer, Inc. ("Pfizer"), BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US, Inc. (collectively "BioNTech") (together with Pfizer, "Defendants") and allege as follows:

Introduction

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

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

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

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

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

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

Nature of the Action

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

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

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

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

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

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

9. While Defendants chose to utilize Dr. Fischhoff and Perlak's invention(s) to improve their COVID-19 vaccines, Plaintiffs did not have any involvement in the development of the vaccines, and Defendants used their patented method without Plaintiffs' permission. Defendants have earned substantial benefit, including tens of billions of dollars in revenue from this unauthorized use, to develop, produce, and deliver their mRNA vaccines. BioNTech has acknowledged that it utilizes codon optimization in its mRNA products:

> We have also invented a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein.[2]

BioNTech states that its BNT162b2 vaccine consists of "nucleoside modified RNA, which has blunted innate immune sensor activating capacity and thus augmented antigen expression."[3]

10. Defendants' mRNA stability work began within the last 10-15 years. In comparison, as confirmed by this District,[4] the Federal Circuit,[5] and the Patent Office[6] in awarding priority to Fischhoff and Perlak, their groundbreaking work began more than 35 years ago. The '118 Patent is a pre-GATT patent, claiming priority to February 24, 1989, and (because of the time required for prosecution, including an 8-year interference proceeding) issued on June 22, 2010. Thus, the

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[2] BioNTech SE 2020 Form 20-F, p.108 (Mar. 30, 2021), https://perma.cc/CY9G-9JY3.

[3] BioNTech SE 2022 Form 20-F, p.112 (Mar. 27, 2023), https://perma.cc/A4N9-PK4Z.

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

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

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

'118 Patent covers the entire duration of Defendants' mRNA vaccine work. The '118 patent is assigned to Monsanto Technology, LLC and exclusively licensed to Bayer CropScience LLC.

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

Parties

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

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

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

15. Upon information and belief, Defendant Pfizer Inc. is a publicly traded corporation organized and existing under the laws of the State of Delaware with a principal place of business at 235 East 42nd Street, New York, NY 10017.

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

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

18. Upon information and belief, Defendant BioNTech US, a wholly-owned subsidiary of BioNTech SE, is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 40 Erie St., Suite 110, Cambridge, MA 02139. BioNTech US's office in Cambridge, MA serves as BioNTech's North American headquarters.[7] BioNTech US is BioNTech's agent for service of process in the United States.

19. Upon information and belief, Defendants Pfizer Inc., BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US are agents of each other and/or work in concert with each other with respect to the development and regulatory approval, marketing, manufacturing, sales, offers for sale, and distribution of Defendants' infringing COVID-19 vaccine Comirnaty®.

Jurisdiction & Venue

20. 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.*

21. This Court has personal jurisdiction over Pfizer Inc. and BioNTech US, because each is organized under the laws of Delaware.

[7] BioNTech Website, *A transatlantic leader in individualized neoantigen-targeted T cell therapies*, https://perma.cc/3KGW-YQGL.

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

23. Venue is proper in this District with respect to BioNTech SE and BioNTech Manufacturing GmbH under 28 U.S.C. § 1391(c)(3) because BioNTech SE and BioNTech Manufacturing GmbH are not residents of the United States.

24. Defendants Pfizer Inc., BioNTech SE, and BioNTech Manufacturing GmbH have consented to this Court as a proper venue and its exercise of personal jurisdiction in other litigations involving the accused Comirnaty® vaccine, including in *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, C.A. No. 22-cv-336-CFC; *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, C.A. No. 23-cv-578-CFC; and *GlaxoSmithKline Biologicals SA, et al v. Pfizer Inc. et al*, C.A. No. 24-cv-512-GBW.

Background

Scientific Background

25. The U.S. Court of Appeals for the Federal Circuit addressed much of the scientific background to certain embodiments of Fischhoff and Perlak's invention in its decision awarding them priority. *Mycogen Plant Science v. Monsanto Company*, 243 F.3d 1316, 1322-24 (Fed. Cir. 2001).[8] Eukaryotic organisms like plants and animals, though incredibly diverse in appearance, have much in common at the molecular level. They are made up of vast quantities of cells with distinct nuclei that contain chromosomes. Chromosomes carry deoxyribonucleic acid, or DNA, which contains coded genetic information that cells use to make, or "express," proteins.

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

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

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

> In the second step, translation, the nucleotide sequence of the mRNA is translated into the amino acid sequence of the corresponding protein. For this translation to work, a complex structure known as a ribosome reads the mRNA nucleotide sequence and generates amino acids. These amino acids are then assembled into proteins. In this way, ribosomes carry out protein synthesis.
>
> Ribosomes read a nucleotide sequence in sets of three nucleotides, known as codons. Each codon directs the ribosome to select a certain amino acid. For example, GCT is a codon directing the ribosome to select the amino acid alanine. Just as nucleotides are the basic units of DNA, amino acids are the basic units of proteins. Thus, a given series of codons specifies a sequence of amino acids

> comprising a particular protein. A protein can contain few or many amino acids. For example, some Bt pesticidal proteins contain more than 600 amino acids.
>
> While there are 61 possible codons, there are only 20 amino acids. Some amino acids can be specified by more than one codon. In other words, one codon can be substituted for another in the gene without changing the amino acid and resulting protein. For instance, the amino acid alanine is specified by four different codons: GCT, GCG, GCC and GCA. Two very different series of codons could produce the exact same series of amino acids. In fact, most amino acids are specified or coded by more than one codon.[9]

28. Each potential codon triplet used to express each of the 20 amino acids were known and described in Table I of the '118 Patent.[10]

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

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

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

[10] '118 Patent at 11:30-12:28.

> genes. In all organisms, codons in DNA are transcribed into codons in RNA which is translated on ribosomes into polypeptides according to the same genetic code.[11]

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

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

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

32. The '118 Patent includes illustrative examples of Fischhoff and Perlak's method, including methods that expressed coding sequences from the bacterium *Bacillus thuringiensis* ("B.t.")[12] and a Potato Leaf Roll Virus Coat Protein Gene.[13] A goal of the B.t. work was to express a protein naturally made by *Bacillus thuringiensis* soil bacteria that is toxic to insects, but harmless to animals, to impart insect resistance in plants. A goal of the potato leaf roll virus coat protein work was to express the coat protein to make plants resistant to the potato leaf roll virus.[14]

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

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

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

[14] '118 Patent at 38:25-30.

33. Plaintiffs' Scientists' early efforts in 1983-1986 to express naturally occurring coding sequences resulted in low levels of expression. They set out to solve the expression problem, and like Defendants, their solution started with the mRNA itself:

> Several potential factors could be responsible in varying degrees for the level of protein expression from a particular coding sequence. The level of a particular mRNA in the cell is certainly a critical factor.
>
> . . .
>
> In the cytoplasm, mRNAs have distinct halflives that are determined by their sequences and by the cell type in which they are expressed. Some RNAs are very short-lived and some are much more long-lived. In addition, there is an effect, whose magnitude is uncertain, of translational efficiency on mRNA half-life. In addition, every RNA molecule folds into a particular structure, or perhaps family of structures, which is determined by its sequence.[15]

34. In 1986, Fischhoff and Perlak conceived a solution[16] revolving around certain sequences prevalent in certain bacterial and viral origin coding sequences that had contributed to mRNA instability in higher organisms. Fischhoff and Perlak theorized that these sequences were likely destabilizing for expression in plants and animals alike:

> Some particular sequences have been identified in RNAs that have the potential for having a specific effect on RNA stability. This section summarizes what is

[15] '118 Patent at 1:21-25, 36-49.

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

known about these sequences and signals. These identified sequences often are A+T rich, and thus are more likely to occur in an A+T rich coding sequence such as a B.t. gene. The sequence motif ATTTA (or AUUUA as it appears in RNA) has been implicated as a destabilizing sequence in mammalian cell mRNA 60 (Shaw and Kamen, 1986). No analysis of the function of this sequence in plants has been done.[17]

. . .

Some studies on mRNA degradation in animal cells also indicate that RNA degradation may begin in some cases with nucleotlytic attack in A+T rich regions. It is not clear if these cleavages occur at ATTTA sequences. There are also examples of mRNAs that have differential stability depending on the cell type in which they are expressed or on the stage within the cell cycle at which they are expressed.[18]

. . .

The addition of a polyadenylate string to the 3' end is common to most eucaryotic mRNAs, both plant and animal. The currently accepted view of poly A addition is that the nascent transcript extends beyond the mature 3' terminus. Contained within this transcript are signals for polyadenylation and proper 3' end formation. This processing at the 3' end involves cleavage of the mRNA and

[17] '118 Patent at 1:53-62.

[18] '118 Patent at 2:21-27

addition of poly A to the mature 3' end. By searching for consensus sequences near the polyA tract in both plant and animal mRNAs, it has been possible to identify consensus sequences that apparently are involved in poly A addition and 3' end cleavage. The same consensus sequences seem to be important to both of these processes. These signals are typically a variation on the sequence AATAAA. In animal cells, some variants of this sequence that are functional have been identified; in plant cells there seems to be an extended range of functional sequences (Wickens and Stephenson, 1984; Dean et al., 1986). Because all of these consensus sequences are variations on AATAAA, they all are A+ T rich sequences. This sequence is typically found 15 to 10 bp before the ply A tract in a mature mRNA. Experiments in animal cells indicate that this sequence is involved in both polyA addition and 3' maturation.[19]

. . .

From these examples, it is clear that in natural mRNAs proper polyadenylation is important in mRNA accumulation, and that disruption of this process can effect mRNA levels significantly. However, insufficient knowledge exists to predict the effect of changes in a normal gene. In a heterologous gene, where we do not know if the putative polyA sites (consensus sequences) are functional, it is even harder to predict the consequences. However, it is possible that the putative sites identified are disfunctional. That is, these sites may not act as

[19] '118 Patent at 2:51-3:6.

proper polyA sites, but instead function as aberrant sites that give rise to unstable mRNAs.[20]

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

Figure 1
'118 Patent, Table II (15:50-64)

TABLE II

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

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

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

37. The '118 Patent describes that "[i]t is also preferred that regions comprising many consecutive A+T bases … are disrupted since these regions are predicted to have a higher likelihood to form hairpin structure due to self-complementarity."[21] The '118 Patent explains that "[i]n most cases, the adverse effects may be minimized by using sequences which do not contain

[20] '118 Patent at 3:53-63.

[21] '118 Patent at 10:60-65.

more than five consecutive A+T or G+C."[22] Elsewhere, the '118 patent explains "Of course, due to the A+T content of B.t. genes, they are rich in runs of A or T that could act as terminators."[23]

38. The '118 Patent discloses that utilizing Fischhoff and Perlak's method to reduce Problem Sequences in the gene's coding region resulted in a dramatic increase in protein expression. Plaintiffs' Scientists utilized their novel method with well-known genetic engineering techniques like site-directed mutagenesis and *de novo* synthesis. In one example, Plaintiffs' Scientists observed a 500-fold increase in the expression of B.t.k. protein with a coding sequence modified to remove nearly all of the Problem Sequences, and a 100-fold increase in plants with a coding sequence modified to remove nearly half of those sequences.[24] These increases in protein expression resulted in corresponding increases in bioactivity: Whereas plants with the native coding sequence received "only minimal protection" against insect damage, plants with half-modified coding sequence showed "almost complete protection" and plants with fully-modified coding sequence were "totally protected."[25] Plaintiffs' Scientists concluded that these results were caused by increases in mRNA levels and translation efficiency attributable to their method of reducing Problem Sequences.[26]

39. Plaintiffs' Scientists also disclosed that their method could be used "to express [a] viral coat protein at an effective level" and thereby "achieve virus resistance."[27] In one example, they designed a coding sequence that removed Problem Sequences from the native sequence of "the

[22] '118 Patent at 10:68-11:2.

[23] '118 Patent at 5:65-66.

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

[25] '118 Patent at 24:40-67.

[26] '118 Patent at 30:36-47.

[27] '118 Patent at 38:25-29.

coat protein gene from potato leaf roll virus" to make a "synthetic gene [] designed to improve plant expression of the [viral] coat protein" while encoding the same protein as the naturally occurring gene.[28] The '118 Patent states that plants with the modified coding sequence "express the [viral] coat protein at higher levels than achieved with the naturally occurring gene" and "exhibit increased resistance to infection" by the virus.[29]

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

41. While the '118 Patent includes claims reciting methods of making structural genes encoding insecticidal proteins, Plaintiffs' Scientists did not limit their claims and disclosure to a particular gene, cell, or expression level. Instead, Plaintiffs' Scientists claimed and described method steps for reducing the specific Problem Sequences they found contributed to unstable mRNAs.[30] They described the "most rigorous application" of this "present invention" as modification of a coding sequence "by removal of ATTTA sequences and putative polyadenylation signals" (*i.e.*, Table II Sequences).[31] They further described that "if a synthetic gene is prepared which codes for the expression of the subject protein, codons are selected to avoid the [Problem Sequences]."[32] Claim 59, for example, recites "[a] method for making a structural gene that encodes a protein" comprising three steps: "(a) starting with a coding sequence that encodes a

[28] '118 Patent at 38:30-39:19.

[29] '118 Patent at 39:23-25.

[30] '118 Patent at 3:61-63.

[31] '118 Patent at 10:14-17.

[32] '118 Patent at 10:17-20.

protein and that contains polyadenylation signal sequences listed in Table II; (b) reducing the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence; and (c) making a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein." Claims 60 and 73 recite additionally reducing ATTTA sequences, and Claims 79 and 80 recite additionally reducing regions with greater than five consecutive adenine and thymine (A+T) nucleotides.

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

Defendants Developed mRNA Products Using Plaintiffs' Patented Method.

43. Pfizer Inc. was founded in New York in 1849 as a chemical manufacturing company.[33] It has since expanded to pharmaceuticals. BioNTech SE was founded in Germany in 2008 to develop and produce treatments for individualized cancer immunotherapy.[34] BioNTech first began working on mRNA vaccine candidates "in the early- to mid-2010s," and "partnered with several companies and research institutes to develop mRNA-based clinical vaccines."[35] BioNTech US originated in 2015 as Neon Therapeutics, which was acquired by BioNTech SE in 2020.[36]

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[33] Pfizer Website, *Company Timeline: a Legacy of Innovation*, https://perma.cc/D8KW-NF55.

[34] BioNTech Website, *Our History*, https://perma.cc/9ZLH-VQ2D.

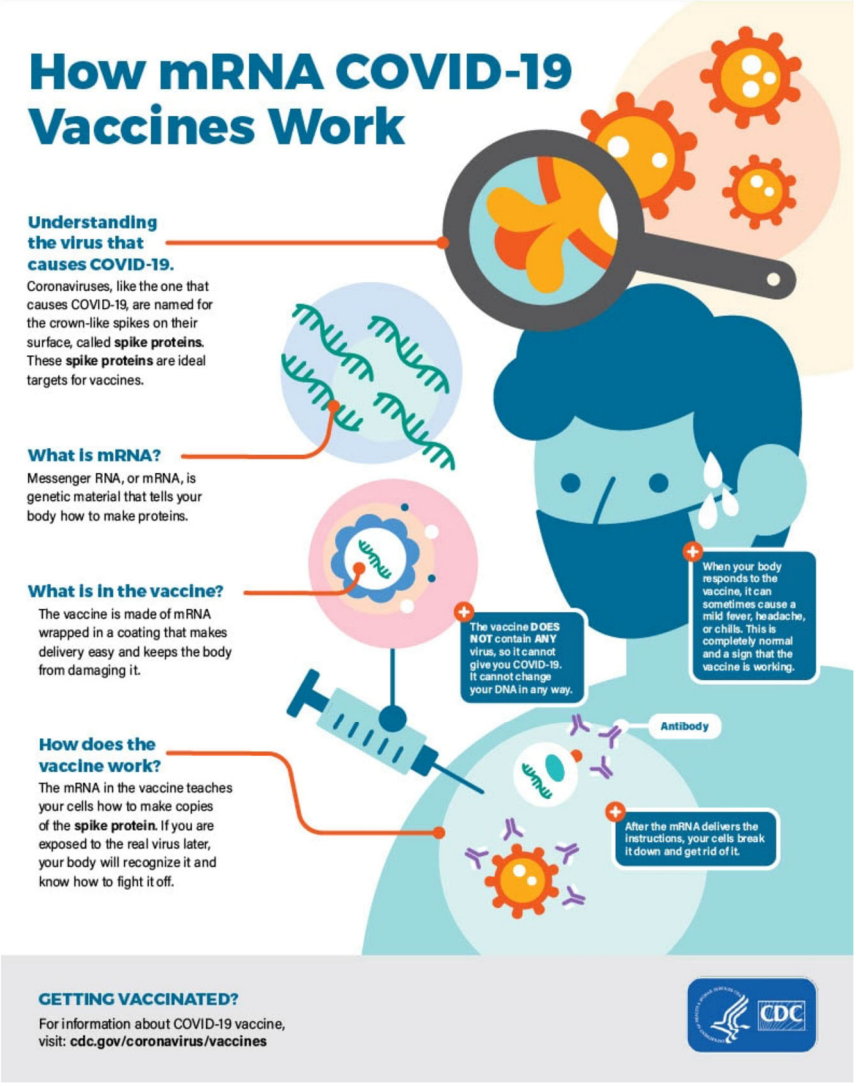
[35] Defs.' Answer and Counterclaims, *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, No. 1:22-cv-00336-CFC, Dkt. 13 at p.26 (May 27, 2022).

[36] BioNTech Website, *A transatlantic leader in individualized neoantigen-targeted T cell therapies*, https://perma.cc/YR8F-XAPH.

44. According to the Center for Disease Control ("CDC"), Defendants' Comirnaty® COVID-19 vaccine works on the basic premise illustrated below.

Figure 2

mRNA Vaccines CDC Publication[37]



45. Briefly, modified mRNA coding for a protein based on the SARS-CoV-2 spike protein is generated and introduced into the human body. Ribosomes in the body then translate the mRNA

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

into the spike protein so that the body generates antibodies capable of binding to the spike protein. If a vaccinated person later encounters the SARS-CoV-2 virus, these antibodies may bind to the virus's spike proteins to help stop its spread. Thus, these vaccines will not be effective if the mRNA is unstable and unable to adequately express the spike protein.

46. To develop effective mRNA medicines, Defendants needed to stabilize the mRNA molecule and optimize its protein expression. Defendants recognized that this required optimizing the native mRNA molecule itself. For example, BioNTech identifies "unwanted immune reactions prolonging the duration of protein production" as "two major challenges in the development of safe and effective mRNA vaccines."[38]

47. BioNTech has acknowledged that it utilizes codon optimization in its mRNA products:

> We have also invented a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein.[39]

48. Pfizer has also acknowledged that "our spike has also some unique features among that being code and optimize for efficient expression in humans."[40]

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[38] BioNTech Website, *Our mRNA Platforms – revolutionizing vaccine technology*, https://perma.cc/8ZD7-9UWJ.

[39] BioNTech SE 2020 Form 20-F, p.108 (Mar. 30, 2021), https://perma.cc/CY9G-9JY3.

[40] Thomson Reuters Streetevents, *PFE - Pfizer Inc To Discuss Data From An Ongoing Phase 1/2 Study Of mRNA-Based Vaccine Candidate Against SARS-CoV-2 Call*, p.14 (July 1, 2020), https://perma.cc/5BS7-GY45.

49. Upon information and belief, Defendants have optimized and manufactured their infringing mRNA vaccine products starting with a DNA template in the United States. For example, Defendants' "manufacturing and testing process…takes 60 days and involves Pfizer facilities in three [U.S.] states."[41] BioNTech states:

> To produce mRNA, a DNA template is required. The biopharmaceutical industry uses plasmids for this purpose. A part of the plasmid DNA encodes for the relevant protein of interest, e.g. the spike protein of SARS-CoV-2. The majority of the plasmid is used to shape the DNA into the required ring form….
>
> In [the Oligosynthesis] process, the blueprint for the desired protein of interest is created. For this purpose, nucleotides are lined up as building blocks to form a code. Two complementary single DNA strands are produced chemically, forming the familiar double helix structure. This DNA fragment is inserted into a plasmid that serves as a carrier….
>
> Plasmids are transferred into bacteria. During their cell division, the plasmids are also replicated. The relevant DNA fragments are isolated from the plasmids and cells. They form the template for mRNA transcription….
>
> To produce mRNA, the DNA template is transcribed into mRNA in a bioreactor. This enzyme-based process is known as in-vitro transcription (IVT). More than

[41] Emma Cott et al., *How Pfizer Makes its COVID-19 Vaccine*, N.Y. TIMES, (Apr. 28, 2021), https://perma.cc/EH8Q-2J5E.

> 500 mRNA strands can be produced with a single DNA template obtained from a plasmid.[42]

Pfizer's "Chesterfield [Missouri] facility is Pfizer's only source of [DNA] plasmids for its Covid-19 vaccine."[43] Pfizer's plant in Andover, Massachusetts, "process[es] the DNA into messenger RNA, or mRNA, the active ingredient of the Pfizer-BioNTech vaccine."[44] In the Andover plant, "enzymes pry open the DNA templates and transcribe them into strands of mRNA."[45] After filtering, containers of mRNA "are shipped to a Pfizer facility in Kalamazoo, Mich., where they [are] processed into the finished vaccine and packaged in vials."[46] John Young, Chief Business Officer at Pfizer, testified to Congress that "Pfizer facilities in St. Lous, Missouri; Andover, Massachusetts; and Kalamazoo, Michigan, will be the sites in our U.S. supply chain."[47] Mr. Young later testified that increased COVID-19 mRNA vaccine production was "possible because Pfizer has made *significant* investments in [its] U.S. manufacturing sites including Saint Louis, MO; Andover, MA; Kalamazoo, MI; and Pleasant Prairie, WI," and that Pfizer "added new lines at [its]

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[42] BioNTech Website, *What is plasmid DNA?*, https://perma.cc/EUZ8-AQQC.

[43] Cott et al., *supra* note 41.

[44] *Id. See also* FDA, BLA Approval letter, p.1 (Aug. 23, 2021), https://perma.cc/5KR6-AE72 ("Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts.").

[45] Cott et al., *supra* note 41.

[46] *Id. See also* FDA, BLA Approval letter, p.1 (Aug. 23, 2021), https://perma.cc/5KR6-AE72 ("The final formulated product will be manufactured, filled, labeled and packaged at . . . Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan.").

[47] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. 6 (2020) (Testimony of John Young, Chief Business Officer, Pfizer), https://perma.cc/2TV4-ASM3.

site in McPherson, KS, started lipid production at our site in Groton, CT; and added two contract manufacturers."[48]

50. In early 2020, when reports of COVID-19 first began to emerge, BioNTech claimed it had "personalized mRNA technology" enabling it to "design very fast vaccines, genetically engineered vaccines."[49] BioNTech "realized [it] could be among the first companies" to create vaccine candidates if they acted quickly, and as a result begin to "shift resources from the cancer research to the vaccine development."[50] BioNTech relied on "processes in place allowing [it] to… generate new vaccines within a few weeks," and "rel[ied] on this process in developing a vaccine in an extremely short time."[51] Unlike traditional vaccines, for the mRNA vaccine BioNTech "convey[ed] genetic instructions (the mRNA) to human cells that then use their cellular machinery to 'translate' or make the spike protein antigen specific for the COVID-19 virus that is displayed on the surface of the cell."[52]

51. The native genetic sequence for the original SARS-CoV-2 spike protein became public on January 11, 2020.[53] BioNTech began developing candidate mRNA-based vaccine candidates

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[48] *Hearing on "Pathway to Protection: Expanding Availability of COVID-19 Vaccines" Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 117th Cong. 1 (2021) (Written Testimony of John Young, Chief Business Officer, Pfizer), https://perma.cc/XV36-ZCMW.

[49] Ugur Sahin interview, CNBC, https://www.youtube.com/watch?v=K7SXqkCb1k4 (at 15:09-32).

[50] *Id.*

[51] Ugur Sahin interview, stars – for Leaders of the Next Generation, https://www.youtube.com/watch?v=eMtRv5FYVOE (at 1:29-50).

[52] *Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. 4 (2020) (Testimony of John Young, Chief Business Officer, Pfizer), https://perma.cc/U2K9-B5BF.

[53] Def.'s Answer and Counterclaims, *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, No. 1:22-cv-00336-CFC, Dkt. 13 at p.27 (May 27, 2022).

soon thereafter, including a product candidate known as BNT162.[54] BioNTech developed "more than twenty candidates for a vaccine," including the spike protein and selected domains of the spike protein.[55] In March 2020, Pfizer and BioNTech began a collaborative effort focused on bringing a COVID-19 vaccine to market.[56] As part of that agreement, BioNTech would provide the clinical supply of selected BNT162 candidate vaccines, and the companies would work together to scale-up manufacturing capacity to produce a worldwide supply of vaccines.[57] In July 2021, Pfizer and BioNTech selected candidate BNT162b2 for Phase III clinical testing.[58]

52. BioNTech called its COVID-19 vaccine development project "Project Lightspeed."[59] BioNTech and Pfizer announced approval to start the first in-human clinical trials on four vaccine candidates in April 2020,[60] and on December 11, 2020, the U.S. FDA authorized the Defendants' BNT162b2 vaccine for emergency use, the first vaccine to receive such authorization.[61]

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[54] *Id.*

[55] Atlantic Council, *If the pandemic hit a year earlier, 'we might not have been in the position to respond this fast,' say BioNTech co-founders. Here's why.*, NEW ATLANTICIST (Nov. 8, 2021), https://perma.cc/AUH5-XKDT.

[56] Defs.' Answer and Counterclaims, *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, No. 1:22-cv-00336-CFC, Dkt. 13 at p.27 (May 27, 2022).

[57] Pfizer Press Release, *Pfizer and BioNTech Announce Further Details on Collaboration to Accelerate Global COVID-19 Vaccine Development* (Apr. 9, 2020) https://perma.cc/J7YM-JZ2J.

[58] Atlantic Council, *supra* note 55.

[59] BioNTech Press Release, *BioNTech reports rapid progress on COVID-19 vaccine program to address global public health threat* (Mar. 16, 2020), https://perma.cc/QS3W-LPQH.

[60] BioNTech Press Release, *BioNTech and Pfizer announce regulatory approval from German authority Paul-Ehrlich-Institut to commence first clinical trial of COVID-19 vaccine candidates* (Apr. 22, 2020), https://perma.cc/2RKJ-LTGK.

[61] BioNTech Press Release, *Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19* (Dec. 11, 2020), https://perma.cc/B967-CHHN.

53. Upon information and belief, Defendants' ability to quickly and effectively design and synthesize BNT162b2 was enabled in part by their use of Plaintiffs' patented method for removing the Problem Sequences identified in the '118 Patent by substituting sense codons.

54. Defendants proved the effectiveness of the BNT162b2 mRNA coding sequence in clinical trials. The Phase I/II trials of Defendants' resulting mRNA vaccine, later branded as Comirnaty®, began in May 2020[62] and Phase III began in July 2020.[63] These trials demonstrated BNT162b2's significant (95%) effectiveness in preventing infection from the original coronavirus strain after a two-dose regimen.[64]

55. The successful clinical results of Defendants' mRNA vaccine led to a series of regulatory approvals in the United States market. The FDA first approved Comirnaty® for adults under an emergency use authorization in December 2020,[65] followed by a number of other approvals. For example, the FDA provided an emergency-use authorization for a "booster" dose of BNT162b2 in November 2021.[66] Defendants eventually received full commercial approval for BNT162b2 and a second booster dose of same.[67]

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[62] Pfizer Press Release, *BioNTech and Pfizer announce completion of dosing for first cohort of Phase 1/2 trial of COVID-19 vaccine candidates in Germany* (Apr. 29, 2020), https://perma.cc/FP4V-9CFG.

[63] Pfizer Website, *About Our Landmark Trial*, https://perma.cc/8FPG-N73R.

[64] Pfizer Press Release, *Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints* (Nov. 18, 2020), https://perma.cc/FCB5-EG2L.

[65] BioNTech Press Release, *Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19* (December 11, 2020), https://perma.cc/B967-CHHN.

[66] Pfizer Press Release, *Pfizer and BioNTech Receive Expanded U.S. FDA Emergency Use Authorization of COVID-19 Vaccine Booster to Include Individuals 18 and Older* (Nov. 19, 2021), https://perma.cc/E674-PSV4.

[67] Pfizer Press Release, *Pfizer and BioNTech Receive Expanded U.S. Emergency Use Authorization for an Additional COVID-19 Vaccine Booster in Individuals Aged 50 Years and Older* (Mar. 29, 2022), https://perma.cc/JUJ7-GGGG; Pfizer Press Release, *Pfizer-BioNTech COVID-19 Vaccine*

56. Defendants have since developed booster vaccines and monovalent and bivalent boosters for variants of COVID-19. Defendants have developed additional mRNA sequences targeting SARS-CoV-2 spike protein variants, including BNT162b2 (B.1.1.529)/BNT162b2 Bivalent (WT/OMI BA.1)/Riltozinameran for the BA.1 variant,[68] BNT162b2 Bivalent (WT/OMI BA.4/BA.5)/Famtozinameran for the BA.4/5 variant,[69] BNT162b2 XBB.1.5/Raxtozinameran for the XBB.1.5 variant,[70] Comirnaty KP.2 for the KP.2 variant,[71] and Comirnaty JN.1/Bretovameran for the JN.1 variant.[72]

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

COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older (Aug. 23, 2021), https://perma.cc/T6MF-CQ32.

[68] BioNTech Press Release, *Pfizer and BioNTech Receive Positive CHMP Opinion for Conversion of COMIRNATY® Conditional Marketing Authorization to Full Marketing Authorization in the European Union* (Sept. 16, 2022), https://perma.cc/ADL9-A5SW.

[69] Pfizer Press Release, *Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older* (Aug. 31, 2022), https://perma.cc/K2KD-Z862.

[70] Pfizer Press Release, *Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron XBB.1.5-adapted COVID-19 Vaccine in the European Union* (Aug. 30, 2023), https://perma.cc/SV3K-KPUH.

[71] Pfizer Press Release, *Pfizer and BioNTech Receive U.S. FDA Approval & Authorization for Omicron KP.2-adapted COVID-19 Vaccine* (Aug. 22, 2024), https://perma.cc/3FQ4-YP6L.

[72] BioNTech Press Release, *Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron JN.1-adapted COVID-19 Vaccine in the European Union* (July, 27, 2024), https://perma.cc/B2Q3-RSLS.

Reductions of Table II Sequences				
Variant mRNAs	BNT162b2	BNT162b2 BA.1	BNT162b2 BA.4/5	BNT162b2 XBB.1.5
Starting Sequence	30	27	28	29
Vaccine Sequence	1	1	1	1

Reductions of ATTTA Sequences				
Variant mRNAs	BNT162b2	BNT162b2 BA.1	BNT162b2 BA.4/5	BNT162b2 XBB.1.5
Starting Sequence	7	6	7	7
Vaccine Sequence	0	0	0	0

Reductions of Regions with >5 A+T				
Variant mRNAs	BNT162b2	BNT162b2 BA.1	BNT162b2 BA.4/5	BNT162b2 XBB.1.5
Starting Sequence	68	70	71	70
Vaccine Sequence	0	0	0	0

58. Upon information and belief, Defendants also received regulatory approvals in more than 100 foreign markets for its bivalent and monovalent mRNA vaccines.[73] For example, Pfizer claims that it is "supplying vaccines to more than 165 countries."[74] Upon information and belief, the coding sequence for all such vaccines sold in the United States and internationally was originally designed and made by Defendants in the United States.

[73] COVID19 Vaccine Tracker, *Pfizer/BioNTech: Comirnaty* (last updated Dec. 2, 2022), https://perma.cc/4SXD-AF5Z.

[74] Pfizer Website, *Manufacturing and Distributing the COVID-19 Vaccine*, https://perma.cc/7UF5-QRTX.

59. Defendants have generated tens of billions of dollars in revenue from the sale of their COVID-19 mRNA vaccines. In 2020, Pfizer reported $154 million[75] and BioNTech reported €21 million[76] in revenue from global sales of their COVID-19 vaccine, with all of Pfizer's revenues occurring in the United States. In 2021, Pfizer reported $36.8 billion in revenue from global sales of their COVID-19 vaccine, including $7.8 billion in the United States,[77] and BioNTech reported €3 billion in revenue from global sales. In 2022, Pfizer reported $37.8 billion in revenue from global sales of their COVID-19 vaccine, including $8.8 billion in the United States,[78] and BioNTech reported €3.2 billion in revenue from global sales.[79] In 2023, Pfizer reported $11.2 billion in revenue from global sales of their COVID-19 vaccine, including $2.4 billion in the United States,[80] and BioNTech reported €473 million in revenue from global sales.[81] In 2024, Pfizer reported $5.3 billion in revenue from global sales of their COVID-19 vaccine, including $2.0 billion in the United States,[82] and BioNTech reported €701 million in revenue from global sales.[83] Through Q3 of 2025, Pfizer reported $2.1 billion in revenue from global sales of their COVID-19 vaccine, including $1.3 billion in the United States.[84] Upon information and belief, Defendants have generated over $93 billion in global sales revenue attributable to its mRNA

[75] Pfizer 2021 Form 10-K, p.35 (Feb. 24, 2022), https://perma.cc/XK9G-M27K.

[76] BioNTech 2021 Form 20-F, p.192 (Mar. 30, 2022), https://perma.cc/VL43-JFU6.

[77] Pfizer 2021 Form 10-K, p.35 (Feb. 24, 2022), https://perma.cc/XK9G-M27K.

[78] Pfizer 2023 Form 10-K, p.38 (Feb. 22, 2024), https://perma.cc/Z8VX-46EB.

[79] BioNTech 2023 Form 20-F, p.165 (Mar. 20, 2024), https://perma.cc/6W5B-FTCC.

[80] Pfizer 2023 Form 10-K, p.38 (Feb. 22, 2024), https://perma.cc/Z8VX-46EB.

[81] BioNTech 2023 Form 20-F, p.165 (Mar. 20, 2024), https://perma.cc/6W5B-FTCC.

[82] Pfizer 2024 Form 10-K, p.36 (Feb. 27, 2025), https://perma.cc/GKU2-PYAC.

[83] BioNTech 2024 Form 20-F, p.F-34 (Mar. 10, 2025), https://perma.cc/Z8FP-EYP5.

[84] Pfizer 2025 Q3 Form 10-Q, p.42 (Nov. 4, 2025), https://perma.cc/6E4K-Y56Y.

COVID-19 vaccines, including over $22 billion in the United States. Upon information and belief, all of these sales resulted from Defendants' activities infringing the '118 patent in the United States

60. BioNTech has also received substantial grant revenue attributable to its development of BNT162b2. For example, in September 2020, BioNTech received a grant of up to €375 million from the German Federal Ministry of Education and Research (BMBF) to support the accelerated development of SARS-CoV-2 vaccines such as BNT162b2.[85]

61. Defendants continue to generate revenue from their COVID-19 mRNA vaccines. In 2023, Pfizer announced a 500% increase for its COVID-19 mRNA vaccine, from $19.50 per dose to $120 per dose.[86] As of March 2024, BioNTech expected that "there will be continued demand for vaccine boosting and primary vaccinations of immunologically naïve individuals, especially amongst older and immunocompromised populations."[87]

62. Upon information and belief, Defendants continue to use the same design protocol with respect to their other mRNA vaccine products currently in their product pipelines.

Count 1: Infringement of the '118 Patent

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

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

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[85] BioNTech Press Release, *BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162* (Sept. 15, 2020), https://perma.cc/XF2Q-GK8Q.

[86] Jon Miltimore, *Understanding the 500% Price Increase of Pfizer's COVID Vaccine*, FOUNDATION FOR ECONOMIC FREEDOM (Oct. 22, 2023), https://perma.cc/K72P-BRDW; *COVID vaccine manufacturers set list price between $120-$130 per dose*, REUTERS (Sept. 12, 2023), https://perma.cc/4D9D-2WZ6.

[87] BioNTech 2023 Form 20-F, p.87 (Mar. 20, 2024), https://perma.cc/6W5B-FTCC.

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

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

67. Defendants have directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '118 Patent, in violation of 35 U.S.C. § 271(a) and (g). For example, Defendants performed and/or directed the performance of the infringing method by their agents in the United States to make SARS-CoV-2 spike protein coding sequences and/or DNA template used to make all of their COVID-19 vaccine products sold worldwide. Accordingly, Defendants' worldwide sales of the Accused Products are enabled by and causally connected to Defendants' acts of infringement in the United States. Defendants make, use, offer for sale, sell, and/or import certain products made by the claimed method, including but not limited to Defendants' BNT162b2, BNT162b2 (B.1.1.529)/BNT162b2 Bivalent (WT/OMI BA.1)/Riltozinameran for the BA.1 variant, BNT162b2 Bivalent (WT/OMI BA.4/BA.5)/Famtozinameran for the BA.4/5 variant, BNT162b2 XBB.1.5/Raxtozinameran for the XBB.1.5 variant, and any foreign or domestic variants or equivalents thereof as well as other vaccine products that are commercial or currently in their product pipeline which were developed using the infringing method to reduce Problem Sequences (the "Accused Products").

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

> A method of making a structural gene that encodes a protein, the method comprising:
>
> (a) starting with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II;

(b) reducing the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence; and

(c) making a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein.

69. Upon information and belief, the method performed by Defendants in making the Accused Products satisfies all elements of Claim 59 of the '118 Patent.

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

71. Defendants "reduc[ed] the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence." For example, upon information and belief, Defendants designed the SARS-CoV-2 spike protein coding sequence for the Accused Products to have a reduced number of Table II Sequences by substituting sense codons.

72. Defendants "ma[de] a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein." For example, upon information and belief, the Accused Products were made using and additionally include a structural gene that comprises a coding sequence with codons that were substituted according to paragraph 71 and that encodes a SARS-CoV-2 spike protein (including any subunit proteins).

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

> The method of claim 59, wherein the starting coding sequence of step (a) contains ATTTA sequences, and wherein step (b) further comprises reducing the number of said ATTTA sequences in the coding sequence by substituting sense codons for codons in the coding sequence.

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

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

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

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

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

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

79. Defendants "ma[de] a structural gene … contain[ing] no ATTTA sequences." For example, upon information and belief, the Accused Products include structural genes made according to the method described in paragraphs 68-72 that contain no ATTTA sequences.

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

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

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

82. Defendants "reduc[ed] the number of regions in the coding sequence(s) with greater than five consecutive adenine and thymine (A+T) nucleotides by substituting sense codons for codons in the coding sequence(s)." For example, upon information and belief, the Accused Products made according to the methods described in paragraphs 68-72 include coding sequences with the number of regions with greater than five consecutive adenine and thymine (A+T) nucleotides reduced by substituting sense codons.

83. 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 at least Claims 59, 60, 73, and 79 of the '118 Patent, literally and/or under the doctrine of equivalents, in violations of 35 U.S.C. §271(g). Upon information and belief, Defendants perform the infringing method to make the coding sequences used in and to make the Accused Products in the United States. Defendants make, use, offer for sale, sell, and/or import the Accused Products.

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

Demand for Jury Trial

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

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request that the Court:

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

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7700
farnan@rlf.com

OF COUNSEL:

Michael C. Wilson
Jared M. Hoggan
Chase A. Cobern
Jordan C. Strauss
Alexander D. Jablonski
Lucas R. Dombroski
MUNCK WILSON MANDALA LLP
2000 McKinney Avenue, Suite 1900
Dallas, Texas 75201
(972) 628-3600

Steven G. Spears
Merritt D. Westcott
MUNCK WILSON MANDALA LLP
1330 Post Oak Boulevard, Suite 2850
Houston, Texas 77056
(832) 615-2744

Dated: January 6, 2026