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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAYER CROPSCIENCE LLC, MONSANTO COMPANY, and MONSANTO TECHNOLOGY, LLC, *Plaintiffs*, v. JOHNSON & JOHNSON, INC.; JANSSEN PHARMACEUTICA NV; JANSSEN PHARMACEUTICALS, INC.; JANSSEN BIOTECH, INC. AND JANSSEN VACCINES & PREVENTION NV, *Defendants*.	Honorable Civil Action No. **COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL**

Plaintiffs Bayer CropScience LLC, Monsanto Company, and Monsanto Technology, LLC (collectively "Plaintiffs" or "Bayer") file this Complaint for Patent Infringement against Defendants Johnson and Johnson, Inc., ("J&J Inc."), and against Janssen Pharmaceutica NV ("Janssen NV"), Janssen Pharmaceuticals, Inc., ("Janssen Pharma"), Janssen Biotech, Inc., ("Janssen Biotech"), and Janssen Vaccines & Prevention NV ("Janssen Vacc"), (collectively, "Janssen") (the Janssen and J&J Defendants are collectively referred to as "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 the company's infringement of Plaintiffs' intellectual property ("IP"), developed in the 1980s and for which patent protection was filed in 1989, to eliminate "problem" coding sequences in the building blocks of cells to improve mRNA stability and the amount or quality of protein produced. Two federal courts 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, enhancing expression of the spike protein was a roadblock they faced in developing an effective COVID

vaccine.[1] Defendants used Plaintiffs' patented method to enhance their vaccine's mRNA stability, protein expression, and thus the vaccine's 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. Plaintiffs seek this 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 Defendants' 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

[1] *See*, Janssen Pharmaceuticals, Inc.'s United States Patent No. 11,384,122 at column 44, lines 28-34 ("To optimize expression and/or in vitro transcription, it may be necessary to…eliminate extra, potential inappropriate alternative translation initiation codons or other sequences that may interfere with or reduce expression, either at the level of transcription or translation.")

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.[2]

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 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 its vaccines for COVID-19 that Defendants marketed under the name Jcvoden or Ad26.COV2.S ("Jcvoden").

[2] '118 Patent at 38:25-39:25.

Jcvoden is a recombinant vector vaccine that uses a human adenovirus to express a codon-modified coding sequence for the SARS-CoV-2 spike protein to achieve virus resistance in patients.[3] Defendants' Jcvoden vaccine encodes the S protein of the Wuhan-Hu-1 SARS-CoV-2 strain.[4] To make their Jcovden vaccine work, Defendants leveraged the inventions claimed in the '118 Patent to increase mRNA stability, protein expression, and thus the effectiveness of their vaccine. For example, in their Jcvoden vaccine, Defendants used Platintiffs' 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. On information and belief, Defendants would also need to use Plaintiffs' patented method on any pipleline products under development in which the native DNA sequence was replete with problem sequences.

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 accused vaccine.

10. As confirmed by the Federal District Court in Delaware,[5] the Federal Circuit,[6] and the Board of Patent Appeals and Interferences[7] in awarding priority to Fischhoff and Perlak, their groundbreaking work began more than 35 years ago. The '118 Patent is a pre-GATT patent,

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[3] World Health Organization, *Background document on the Janssen Ad26.COV2.S (COVID-19) vaccine*, p.3 (March 17,2021), [https://iris.who.int/server/api/core/bitstreams/2620706d-e8ff-41cc-887a-c30d10637c88/content]

[4] *Id*.

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

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

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

claiming priority to February 24, 1989, and (because of the time required for prosecution, including an 8-year interference proceeding) issued on June 22, 2010. Thus, the '118 Patent covers the entire duration of Defendants' COVID 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, J&J is a limited liability company organized and existing under the laws of New Jersey and having its principal place of business at 1 Johnson and Johnson Plaza, New Brunswick, New Jersey. Upon information and belief, J&J is the parent company of the other defendants and recognizes the revenue from sales of Defendants' COVID-19 vaccine.

Furthermore, J&J repeatedly represented to the public that the COVID-19 vaccine developed by its subsidiary, Janssen Pharma, was the "Johnson & Johnson" COVID-19 vaccine.[8]

16. Upon information and belief, Janssen NV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

17. Upon information and belief, Janssen Pharma is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Upon information and belief, Janssen Pharma is a wholly owned corporate subsidiary of Johnson & Johnson, and was involved in the development of Defendants' COVID-19 vaccine.

18. Upon information and belief, Janssen Biotech is a corporation organized and existing under the laws of Pennsylvania, with a place of business at 920 Route 202, Raritan, New Jersey 08869. The FDA granted the Biologic License Approval ("BLA") for the Janssen COVID-19 vaccine to Janssen Biotech. Correspondence from the FDA to Janssen Biotech regarding the Janssen COVID-19 vaccine was sent to the above referenced New Jersey address.[9] Upon information and belief, Janssen Biotech. is a wholly-owned subsidiary of J&J, and was involved in the development of Defendants' COVID-19 vaccine.

19. Upon information and belief, Janssen Vacc is a corporation organized under the existing laws of Belgium, with a principal place of business at Archimedesweg 4–6, 2333 CN Leiden,

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[8] *See, for example*: Johnson & Johnson press release, *Johnson & Johnson Updates U.S. COVID-19 Vaccine Fact Sheet*, https://perma.cc/JX4C-GG52 ("the Johnson & Johnson COVID-19 vaccine"); Johnson & Johnson press release, *Johnson & Johnon Announces Real-World Evidence of Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S.*, https://perma.cc/7WBS-PJQ2 ("the single-shot Johnson & Johnon vaccine").

[9] *See, for example,* FDA letters to Janssen Biotech, Inc. regarding COVID-19 vaccine, https://www.fda.gov/media/150567/download and https://www.fda.gov/media/169003/download.

Netherlands. Upon information and belief, Janssen Vacc is a wholly-owned subsidiary of J&J.

20. Upon information and belief, one or more of the Janssen entities may have been rebranded under the name Johnson & Johnson Innovative Medicines.

21. Upon information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, manufacturing, importation into the United States, sales, offers for sale, and distribution of Defendants' infringing COVID-19 vaccine.

Jurisdiction & Venue

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

23. Venue is proper in this District for J&J, Janssen Pharma, and Janssen Biotech under 35 U.S.C. § 1400(b) because these Defendants are either incorporated in New Jersey or have a regular and established place of business in this District and have committed acts of infringement here.

24. This Court has personal jurisdiction over J&J, Inc., Janssen Pharma, and Janssen Biotech because, among other things, they have committed, aided, abetted, contributed to, and/or participated in the commission of patent infringement in this judicial district through their manufacture, importation, use, sale, offer to sell within the United States of Defendants' COVID-19 vaccine product.

25. This Court also has personal jurisdiction over J&J, Inc., Janssen Pharma, and Janssen Biotech because, among other reasons, they have are either incorporated in the forum, have established business addresses in the forum, or have established minimum contacts within the forum such that the exercise of jurisdiction over these Defendants will not offend traditional notions of fair play and substantial justice. For example, these Defendants placed infringing

product into the stream of commerce with reasonable expectations and/or knowledge that purchasers and users of such products were located within this District. They have also sold, advertised, marketed and distributed infringing product in this District.

26. Venue is proper in this District for Janssen NV and Janssen Vacc under 28 U.S.C. § 1391(c)(3).

27. This court has personal jurisdiction over Janssen NV and Janssen Vacc under Fed. R. Civ. P. 4(k)(2), because on information and belief these Defendants are not subject to jurisdiction in any particular state's courts of general jurisdiction, because they extensive contacts with the United States, and exercising jurisdiction over them is consistent with the laws of the United States and the Constitution. Among other things, Janssen NV and Janssen Vacc are subsidiaries of J&J, and have commercial relationship and business dealings with J&J, Janssen Pharma, and Janssen Biotech in this District.

Background

Scientific Background

28. 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).[10] 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.

[10] 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).

29. 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.

30. 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.[11]

31. Each potential codon triplet used to express each of the 20 amino acids were known and described in Table I of the '118 Patent.[12]

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

> Man, other animals, plants, protozoa, and yeast are *eucaryotic* (or eukaryotic) organisms: their DNA is packaged in chromosomes in a special compartment of the cell, the nucleus. Bacteria (*procaryotic* or prokaryotic organisms) have a different organization. Their DNA, usually a circular loop, is not contained in any specialized compartment. Despite the incredible differences between them, all organisms, whether eucaryote or procaryote, whether man or mouse or lowly bacterium, use the same molecular rules to make proteins under the control of genes. In all organisms, codons in DNA are transcribed into codons in RNA which is translated on ribosomes into polypeptides according to the same genetic code.[13]

33. An excessively unstable mRNA molecule can thus 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.

34. The '118 Patent is the result of groundbreaking research done by Fischhoff and Perlak. In the mid-1980s, Fischhoff and Perlak worked on a problem later faced by Defendants in their 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).

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

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

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

35. 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.")[14] and a Potato Leaf Roll Virus Coat Protein Gene.[15] 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.[16]

36. 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, focusing on 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.[17]

37. In 1986, Fischhoff and Perlak conceived a solution[18] 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

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

[15] *See id.* at Examples 1 and 9.

[16] '118 Patent at 38:25-30.

[17] '118 Patent at 1:21-25, 36-49.

[18] *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.[19]

. . .

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.[20]

. . .

The addition of a polyadenylate string to the 3' end is common to most eucaryotic mRNAs, both plant and animal. The currently accepted view of poly A addition is that the nascent transcript extends beyond the mature 3' terminus. Contained within this transcript are signals for polyadenylation and proper 3' end formation. This processing at the 3' end involves cleavage of the mRNA and addition of poly A to the mature 3' end. By searching for consensus sequences near the polyA tract in both plant and animal mRNAs, it has been possible to identify consensus sequences that apparently are involved in poly A addition and 3' end cleavage. The same consensus sequences seem to be important to both of these processes. These signals are typically a variation on the sequence AATAAA. In animal cells, some variants of this sequence that are functional have been identified; in plant cells there seems to be an extended range of functional sequences (Wickens and Stephenson, 1984; Dean et al., 1986). Because all of these consensus sequences are variations on AATAAA, they all are A+ T rich sequences. This sequence is typically found 15 to 10 bp before the poly A tract in a mature mRNA. Experiments in animal cells indicate that this sequence is involved in both polyA addition and 3' maturation.[21]

. . .

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

[19] '118 Patent at 1:53-62.

[20] *Id.* at 2:21-27

[21] *Id.* at 2:51-3:6.

> is even harder to predict the consequences. However, it is possible that the putative sites identified are disfunctional. That is, these sites may not act as proper polyA sites, but instead function as aberrant sites that give rise to unstable mRNAs.[22]

38. 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.

39. 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.

40. 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."[23] The '118 Patent explains that "[i]n most cases, the adverse effects may be minimized by using sequences which do not contain

[22] *Id.* at 3:53-63.

[23] *Id.* at 10:60-65.

more than five consecutive A+T or G+C."[24] 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."[25]

41. 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.[26] 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."[27] Plaintiffs' Scientists concluded that these results were caused by increases in mRNA levels and translation efficiency attributable to their method of reducing Problem Sequences.[28]

42. 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."[29] In one example, they designed a coding sequence that removed Problem Sequences from the native sequence of "the coat protein gene from potato leaf roll virus" to make a "synthetic gene [] designed to improve plant expression of the [viral] coat protein" while encoding the same protein as the naturally

[24] *Id.* at 10:68-11:2.

[25] *Id.* at 5:65-66.

[26] *Id.* at 16:65-17:1, 21:1-2, 24:25-40.

[27] *Id.* at 24:40-67.

[28] *Id.* at 30:36-47.

[29] *Id.* at 38:25-29.

occurring gene.[30] 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.[31]

43. 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.

44. 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.[32] 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).[33] 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]."[34] Claim 59, for example, recites "[a] method for making a structural gene that encodes a protein" comprising three steps: "(a) starting with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II; (b) reducing the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence; and (c) making a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein."

[30] *Id.* at 38:30-39:19.

[31] *Id.* at 39:23-25.

[32] *Id.* at 3:61-63.

[33] *Id.* at 10:14-17.

[34] *Id.* at 10:17-20.

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.

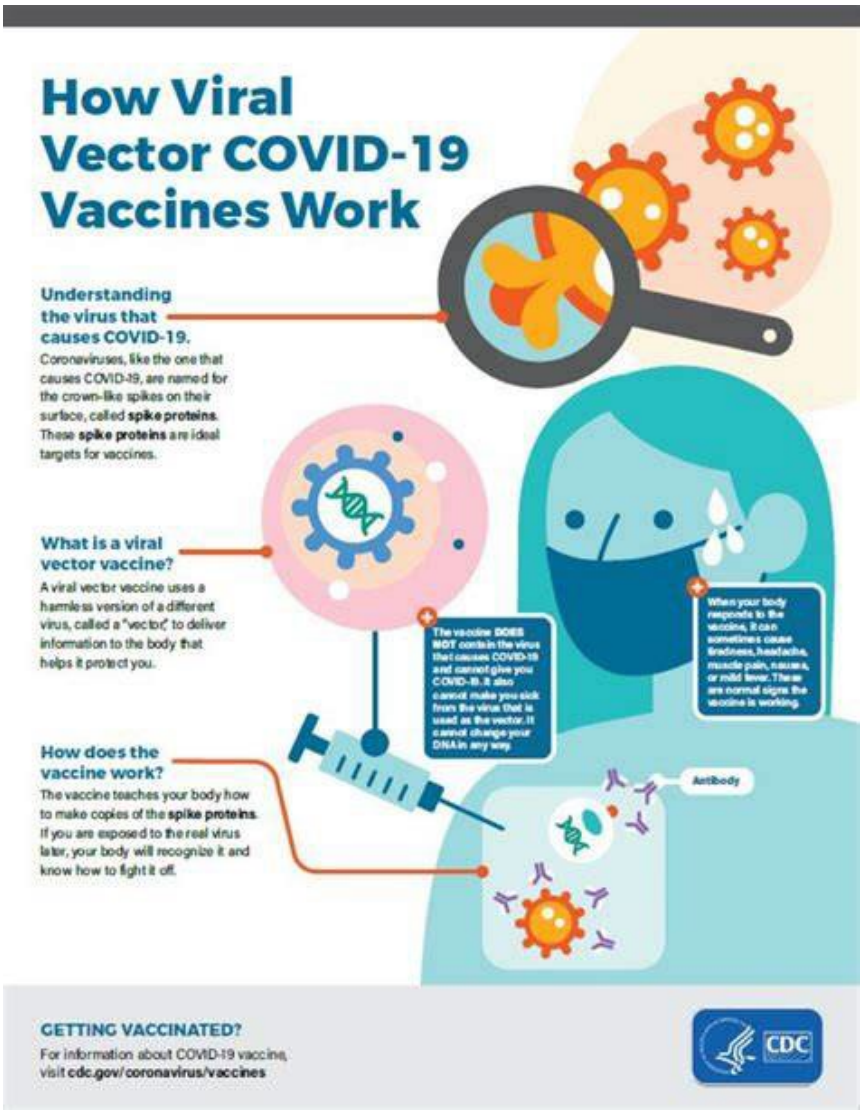
45. The '118 Patent was filed before implementation of the General Agreement on Tariffs and Trade (GATT). As a pre-GATT patent, the '118 Patent's term extends 17 years from the date of issuance—through June 22, 2027.

Defendants' Developed a COVID Vaccine Using Plaintiffs' Patented Method

46. According to the CDC, Defendants' Jcvoden vaccine works on the basic premise described and illustrated below.

Figure 2
Viral Vector Vaccines CDC Publication[35]

[35] https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/downloads/vaccines/How-Viral-Vector-COVID-19-Vaccines-Work.pdf



47. Briefly, the codon-modified nucleotide sequence encoding the spike protein is inserted into a viral vector that is replication-deficient (meaning it cannot reproduce in the patient's cells). The vector thus acts solely as a delivery vehicle for the spike protein nucleotide sequence. When the vaccine is administered, the viral vector enters the host cells and the vector delivers the spike protein nucleotide sequence in the patient's cell nucleus, where it is transcribed into mRNA. The mRNA is then transported to the cell cytoplasm for translation into the spike protein. These spike protein fragments cause the patient to make antibodies to the SARS-COV2 spike protein, protecting the patient from future exposure to the live SARS-COV2 virus. Thus, the Jcvoden

vaccine would not be effective if the spike protein sequence were not adequately expressed by the patient's cells.

48. The native genetic sequence for the original SARS-CoV-2 spike protein became public at least by January 11, 2020.[36] By March 2020, Defendants had announced the selection of a lead vaccine candidate for its COVID-19 vaccine.[37] And by July 2020, Defendants had entered Phase 1 clinical trials with the lead candidate (termed AD26.COV2.S), which contained the genetic sequence of the original spike protein that had been "codon-optimized" for expression in human cells.[38,39] As detailed below, part of that design process included eliminating all or substantially all of the Problem Sequences identified in the '118 Patent that were present in the native Wuhan spike protein sequence, as illustrated below:

	Table II Sequences	**ATTTA Sequences**	**Over 5 Consecutive A and T nucleotides**
Starting Sequence	30	7	68
Jcvoden Vaccine Sequence	2	0	1

49. Upon information and belief, Defendants' ability to quickly develop AD26.COV2.S, which ultimately became the commercial vaccine called Jcvoden, was enabled in part by its use of

[36] https://pmc.ncbi.nlm.nih.gov/articles/PMC10129129

[37] https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use

[38] *Ad26 vector-based COVID-19 vaccine encoding a prefusion-stabilized SARS-CoV-2 Spike immunogen induces potent humoral and cellular immune responses*, NPJ Vaccines. 2020 Sep 28;5:91 ("The S protein of SARS-CoV-2 corresponding to positions 21,536–25,384 in SARS-CoV-2 isolate Wuhan-Hu-1 (GenBank accession number: MN908947) was codon-optimized for expression in human cell lines.")

[39] Study Details | NCT04436276 | A Study of Ad26.COV2.S in Adults (COVID-19) | ClinicalTrials.gov

Plaintiffs' patented method for removing the Problem Sequences identified in the '118 Patent by substituting sense codons.

50. Defendants demonstrated the effectiveness of AD26.COV2.S in clinical trials, showing 52.9% protection against moderate to severe-critical COVID-19 infection.[40]

51. These clinical results led to regulatory approval in the United States market. The FDA first approved Jcvoden for adults under an emergency use authorization in February 2021.[41] Such authorization was in effect until June 1, 2023, after Defendants requested the withdrawal of Emergency Use Authorization.[42]

52. Upon information and belief, Defendants also received regulatory approvals in more than 100 foreign markets for its COVID-19 vaccine.[43]

53. Defendants have generated billions of dollars in revenue from the sale of its COVID-19 vaccine. In 2021, J&J reported $2.3 billion in sales of its COVID-19 vaccine, $634 million of which was in the in the United States.[44] In 2022, J&J reported $2.17 billion in global sales of its COVID-19 vaccine, including $120 million in the United States.[45] In 2023, J&J reported $1.1

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[40] *Final Analysis of Efficacy and Safety of Single-Dose Ad26.COV2*.S, N Engl J Med. 2022 Mar 3;386(9):847-860.

[41] Federal Register: Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability.

[42] Janssen COVID-19 Vaccine | FDA

[43] Janssen (Johnson & Johnson): Jcovden – COVID19 Vaccine Tracker.

[44] Johnson & Johnson 2021 Form 10-K, pp. 24, 78 (Feb. 17, 2022), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000200406/95a96a32-2c0b-46cb-b73f-5c7cae6b4de4.pdf

[45] Johnson & Johnson 2022 Form 10-K, pp. 24, 76 (Feb. 16, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000200406/2d8bead4-a89a-4802-8c63-1266ad78e6a2.pdf

billion in global sales of its COVID-19 vaccine.[46] In 2024, J&J reported $198 million from global sales of its COVID-19 vaccine.[47] To the extent that the coding sequence for the Jcovden vaccine was designed and/or made in the United States by Defendants or their agents, and/or vaccines sold overseas were made in the United States by Defendants or their agents, then all of these sales resulted from Defendants' activities infringing the '118 patent in the United States.

54. Defendants also received substantial grant revenue attributable to the development its COVID-19 vaccine. For example, in March 2020, J&J announced that it had entered into a partnership in the Biomedical Advanced Research and Development Authority (BARDA), and had jointly committed more than $1 billion of investment to "co-fund vaccine research, development, and clinical testing."[48]

Count 1: Infringement of the '118 Patent

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

56. 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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[46] Johnson & Johnson 2023 Form 10-K, p. 25 (Feb. 26, 2024), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000200406/0fbb5a91-be1e-4de7-90ec-36ac966b88e7.pdf

[47] Johnson & Johnson 2024 Form 10-K, p. 25 (Feb. 13, 2025); https://s203.q4cdn.com/636242992/files/doc_financials/2024/q4/Form-10-K-2024-as-filed-13Feb2025.pdf

[48] https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use

57. 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.

58. Each claim of the ’118 Patent is in effect, valid, and enforceable.

59. Defendants have directly infringed and continue 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 its agents in the United States to make the modified SARS-CoV-2 spike protein coding sequence and/or DNA template used to make its COVID-19 vaccine product sold worldwide. To the extent that the modified spike protein sequence was designed and/or made in the United States, Defendants’ worldwide sales of the Accused Product is enabled by, and causally connected to, Defendants’ acts of infringement in the United States. Alternatively, Defendants make, use, offer for sale, sell, and/or import the Accused Product made by the claimed method.

60. 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.

61. Upon information and belief, the method performed by Defendants in making the Accused Product satisfies all elements of Claim 59 of the ’118 Patent.

62. 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 its respective subunit proteins) encoded by the nucleotide sequence in the Accused Products contain Table II Sequences.

63. 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 sequences for the Accused Product to have a reduced number of Table II Sequences by substituting sense codons.

64. 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 Product was made using and additionally include a structural gene that comprises a coding sequence with codons that were substituted according to paragraph 63 and that encodes a SARS-CoV-2 spike protein (including its subunit proteins).

65. 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.

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

67. 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 its respective subunit proteins) encoded by the mRNA in the accused products contained ATTTA Sequences.

68. 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 sequence for the Accused Product to have a reduced number of ATTTA sequences by substituting sense codons.

69. 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.

70. Upon information and belief, the method performed by Defendants in making the Accused Product satisfies all elements of Claim 73 of the '118 Patent.

71. Defendants "ma[de] a structural gene … contain[ing] no ATTTA sequences." For example, upon information and belief, the Accused Product includes structural genes made according to the method described in paragraphs 60-64 that contain no ATTTA sequences.

72. 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).

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

74. 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 Product is made according to the methods described in paragraphs 60-64 and includes coding sequences with the number of regions with greater than five consecutive adenine and thymine (A+T) nucleotides reduced by substituting sense codons.

75. Upon information and belief, Defendants have imported, used, sold, and/or offered for sale in the United States a product made by the methods of at least Claims 59, 60, 73, and 79 of the '118 Patent, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. §271(g). Defendants make, use, offer for sale, sell, and/or import the Accused Product. Further, Defendants may have performed the infringing method of modifying the spike protein coding sequences in the United States.

76. 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 continue 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.

MIDLIGE RICHTER LLC
Attorneys for Plaintiffs,
Bayer CropScience LLC,
Monsanto Company, and
Monsanto Technology, LLC

By: *s/ James S. Richter*
James S. Richter

Dated: January 6, 2025

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CERTIFICATION PURUSANT TO L. CIV. R. 201.1

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that to my knowledge, Plaintiffs' Complaint seeks damages that exceed the sum of $150,000, exclusive of interest and costs and any claim for punitive damages and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: January 6, 2026

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in the above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ James S. Richter
James S. Richter

Dated: January 6, 2026