

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAYER CROPSCIENCE LLC, )  
MONSANTO COMPANY, and )  
MONSANTO TECHNOLOGY, LLC, )

Plaintiffs, )

v. )

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

Defendants. )

C.A. No. 26-cv-12-CFC

**MODERNA’S OPENING BRIEF IN SUPPORT OF ITS MOTION TO  
DISMISS THE COMPLAINT FOR FAILURE TO STATE A CLAIM**

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## I. INTRODUCTION

The patent-in-suit, “Synthetic Plant Genes and Method for Preparation,” dates back to 1989 and relates to genetically engineering plants to express proteins that could reduce the need to apply insecticides. Just shy of six years after the first sales of Moderna’s COVID-19 human mRNA vaccine, Plaintiffs Bayer and Monsanto assert that Moderna infringed those methods in making its groundbreaking vaccines. Plaintiffs’ overreach is plain on the face of the Complaint; any assertions that Moderna infringes the claims directed to plants or insecticidal genes are not plausibly alleged. The remaining handful of claims that are not limited on their face to insecticidal or plant-specific genes sweep so broadly as to claim no more than a general law of nature, and must be dismissed as ineligible under 35 U.S.C. § 101. As all of the potentially asserted claims are either not plausibly alleged or facially ineligible under § 101, the complaint should be dismissed in its entirety.

As the patent states, while scientists had made strides in introducing foreign genes (segments of DNA) into organisms, they faced a problem: sometimes the organism expressed the foreign gene as protein at undesirably low levels. In the late 1980s, Monsanto scientists Fischhoff and Perlak set out to address that problem in plants. Certain genetic sequences and signals had already been shown to reduce gene expression in animal cells. However, according to the patent, whether those “problematic” sequences functioned the same way in *plant* cells was still unknown.

The inventors predicted that the types of sequences identified in animal DNA might have a similar effect in plants, and sought to test that prediction by modifying “problematic” DNA sequences in plant cells to determine whether changing those sequences increased protein expression. The USPTO ultimately issued U.S. Patent No. 7,741,118.

More than thirty years after the claimed invention date, the global COVID pandemic began. Moderna’s response was revolutionary. Having invested years of work designing therapeutic messenger RNA (mRNA) sequences and advancing modified mRNA technology, Moderna generated the sequence for its groundbreaking mRNA vaccine within days of the first identification of the SARS-CoV-2 spike protein. Thirty years of advances in genetic engineering, including nearly a decade of Moderna’s work on modified mRNA, rendered obsolete any insight claimed in the patent. Moderna manufactured hundreds of millions of doses of its vaccines *in vitro*—avoiding the concerns and considerations of making mRNAs from DNA in live organisms that purportedly motivated the inventors. Six years later, Plaintiffs sued Moderna, accusing it of infringing the ’118 “[s]ynthetic [p]lant [g]enes” patent in making a human mRNA vaccine.

The complaint should be dismissed. Moderna’s vaccines are not genetically engineered for plants and Plaintiffs do not suggest otherwise. Consistent with the ’118 patent’s disclosure, 103 of its 113 claims are expressly limited to modifying

insecticidal genes or to expression in plants. It is not clear Plaintiffs even assert these claims, but to the extent they do, the claims of infringement are not plausibly alleged and must be dismissed.

The only exemplary claims in the Complaint which do not explicitly reference insecticidal genes or expression in plants are facially broader claims 59, 63, and their dependent claims. These broad “Generic Claims” fail to claim patentable subject matter. The Generic Claims are directed to a law of nature—the relationship between certain nucleotide sequence motifs and reduced mRNA stability and protein expression. The Generic Claims require only “reducing” the number of those DNA sequences by modifying them with any other sequences and thereby making a gene “characterized” by having fewer of those problem sequences. The Generic Claims do not specify on their face the method to reduce these sequences, for what purpose, in what cells, to what extent, or even whether the reduction must be intentional rather than inadvertent or naturally occurring. Instead, they arguably claim *any* method of reducing the number of these “Problem Sequences” for any reason with any result. Even if the Court were to determine that the patent reflects a discovery as to the scope of a law of nature (*i.e.*, that this relationship extends to plants, not just animals), a claim to simply generally apply such a discovery is invalid under § 101.

## II. SUMMARY OF THE ARGUMENT

1. To the extent Plaintiffs' infringement claim relates to the 103 claims of the '118 patent directed to genes encoding insecticidal proteins and plant-specific sequences, the claim must be dismissed. Plaintiffs do not—and cannot—plead facts supporting a plausible inference that Moderna's human mRNA vaccines infringe these claims.

2. To the extent Plaintiffs' infringement claim relates to the remaining ten Generic Claims, the claim must be dismissed because those Generic Claims are invalid under § 101. The claims are directed toward a law of nature: that reducing the number of potentially “problematic” sequences in genes may lessen the “problem” associated with those sequences. Claim 59 is illustrative. The method of claim 59 lists three steps: (a) “starting with” a gene that contains certain enumerated sequences, (b) “reducing the number of said” sequences, and (c) producing a gene characterized by a “reduced number” of those sequences. That is not patentable—it is a “manifestation of nature, free to all men and reserved exclusively to none.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (internal quotations and alterations omitted). One may not patent the natural relationship by reciting it and adding the instruction to “apply it.” *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72 (2012). But that is, at most, what the Generic Claims do.

Whatever may be new about these claims arises not from the tools or techniques used and is limited to the inventors' decision to see whether known *animal* problem sequences proved destabilizing in *plants*. While this Court need not decide if that is sufficient to save some claims of the '118 patent from ineligibility, it cannot save the Generic Claims.

### III. BACKGROUND

#### A. Molecular Biology

The scientific principles at issue are well-accepted. *See* D.I. 1 (“Complaint”) ¶ 23. Plaintiffs’ complaint notes that the Federal Circuit has explained the science at issue. Complaint ¶ 25 (quoting *Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1323-24 (Fed. Cir. 2001)). As explained in *Mycogen*, living things store information in molecules known as nucleic acids. Deoxyribonucleic acid (“DNA”) and ribonucleic acid (“RNA”) consist of long chains of building blocks called “nucleotides.” Each of the four nucleotides is represented by a letter: adenine (“A”), guanine (“G”), cytosine (“C”) and thymine (“T”) in DNA. *Mycogen*, 243 F.3d at 1323. In RNA, the thymine is replaced with uridine (“U”). “DNA directs cells to make proteins through a two-step process of transcription and translation.” *Id.* In the first step, transcription, information is “transcribed” from DNA to produce a “messenger” RNA (mRNA) molecule with nucleotides that replicate the DNA instructions. In the second step, translation, the nucleotide code of the mRNA is

“translated” to produce the encoded protein. Cellular machinery “read[s] a nucleotide sequence in sets of three nucleotides, known as codons.” *Id.* Each codon directs the addition of an amino acid building block in a protein. But there is redundancy in the genetic code: there are 64 possible sets of 3-nucleotide codons, but only 20 amino acids. This means that “[s]ome 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.” *Id.*

### **B. mRNA Stability and Optimization**

The specification acknowledges that the field of genetic engineering was not new when the inventors filed for patent protection. *See* D.I. 1-1 (“118 patent”) at 1:17-25. The specification refers to genetic engineering applications involving expression of heterologous (*i.e.*, foreign) genes. *Id.* at 1:14-16. Most prominent in the specification is a DNA sequence for the bacteria *Bacillus thuringiensis* B.t.k. HD-1 gene, which produces an insecticidal toxin (*B.t.* toxin). *Id.* at 6:27-33.

Expressing a foreign protein in a cell starts with DNA and requires mRNA that encodes that protein. Skilled artisans already understood the role that mRNA played in protein synthesis, and earlier work had investigated why some mRNAs

were more stable than others. *Id.* at 1:17-52. At the time, it was believed that greater mRNA stability could enhance the level of protein synthesis (because the mRNA survived longer to produce more protein). *Id.* at 1:22-23. As the specification acknowledges, at the time of the claimed invention, scientists had already identified “[s]ome particular sequences and signals ... in RNAs that have the potential for having a specific effect on RNA stability.” *Id.* 1:53-55. In particular, the specification acknowledged that “[t]he sequence motif ATTTA ... has been implicated as a destabilizing sequence in mammalian cell mRNA.” *Id.* at 1:58-61 (citing prior art).

Skilled artisans also understood that certain DNA sequences known as “poly-A” signals could contribute to mRNA instability. When transcription happens *in vivo* in the nuclei of cells (as contemplated in the patent), native cellular machinery synthesizes mRNA from DNA by copying the DNA nucleotide sequence. Complaint ¶ 25; ’118 patent at 1:28-35. Once transcription is complete, a string of adenine nucleotides is added to the end of the mRNA. *See* ’118 patent at 2:51-52. This string of adenines is called the polyadenylate string (or “poly-A tail”). *Id.* Poly-A “signals”—certain sequences in the mRNA—serve as triggers for the machinery in the cell nucleus to end transcription of the mRNA and add a poly-A tail. *Id.* at 2:51-56. Scientists at the time of the invention understood that removing poly-A

signals could also impact stability of the mRNA made through transcription in the cell. *Id.* at 3:19-52.

The inventors tested these principles in plants by removing poly-A signals and other known instability-inducing motifs in the B.t.k. HD-1 gene before expressing it in plant cells. The specification states that this led to improved production of *B.t.* toxin encoded by that gene. *See* Complaint ¶ 36 (citing specification). The specific problem DNA sequences referenced in the patent include: (1) sixteen sequences identified in Table II of the specification; (2) the previously identified ATTTA motif; and (3) DNA sequences containing over five consecutive A and/or T nucleotides, which the specification also states were known to be associated with destabilizing effects on animal protein expression. '118 patent at 1:65-2:20, 15:50-65; Complaint ¶ 7. The sequences in Table II of the specification are characterized as previously known “potential” poly-A signal sequences for the wild-type (*i.e.*, predominantly naturally occurring) B.t.k. HD-1 gene. '118 patent at 15:43-64, 16:49-51.

### **C. The Claims-in-Suit**

The '118 patent contains 113 claims. The vast majority of the '118 patent's claims are directed to making certain changes to genes encoding *Bacillus thuringiensis* insecticidal proteins.

Despite the '118 patent's focus on expressing insecticidal genes in plants, the complaint alleges that “Plaintiffs’ Scientists did not limit their claims and disclosure

to a particular gene, cell, or expression level.” Complaint ¶ 39. For “illustration,” Plaintiffs allege that the process of making Moderna’s vaccines infringe independent claim 59, *id.* ¶ 66, which recites:

59. 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.

In addition to claim 59, Plaintiffs specifically allege Moderna infringes claims 60, 73, and 79. Complaint ¶ 81.

#### **IV. ARGUMENT**

##### **A. Plaintiffs have failed to plausibly plead that Moderna infringes the insecticidal and plant-specific gene claims**

To state a claim for patent infringement, a plaintiff must plead facts “that plausibly indicate that the accused products contain each of the limitations found in the claim.” *Kamal v. Femtosense, Inc.*, 2025 WL 2676733, at \*2 (D. Del. Sept. 18, 2025). The complaint must explain how the “accused product[s] satisfy each and every claim limitation of the asserted claims.” *Swirlate IP LLC v. Keep Truckin*,

*Inc.*, 2021 WL 3187571, at \*2 (D. Del. July 28, 2021). Where a patentee fails to allege facts sufficient to make infringement plausible, dismissal is appropriate. *Id.*

The complaint accuses the method of making Moderna’s human mRNA vaccines of infringement. There is no plausible allegation, nor could there be, that the accused products infringe the claims requiring genes that encode insecticidal proteins or plant-specific sequences. Consistent with its title (“Synthetic Plant Genes and Method for Preparation”), most of the claims of the ’118 patent are expressly directed to genetic engineering of plants. All of the independent claims except claims 59 and 63 explicitly require encoding an insecticidal protein,<sup>1</sup> using *Bacillus thuringiensis* genes (which encode insecticidal proteins),<sup>2</sup> or expressing sequences through “plant promoter” gene sequences.<sup>3</sup> Making Moderna’s human mRNA vaccines cannot infringe these claims, and the Complaint fails to allege any facts to make infringement plausible. A complaint for infringement “must show how the defendant plausibly infringes by alleging some facts connecting the allegedly infringing product to the claim elements.” *Uniloc 2017 LLC v. Zenpayroll, Inc.*, 2020 WL 4260616, at \*3 (D. Del. July 23, 2020), *adopted*, 2020 WL 5077416 (D. Del. Aug. 27, 2020). Plaintiffs have made no allegations that the accused

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<sup>1</sup> Claims 1, 4, 10, 14, 18, 51, 52, 56, 58, 67, 83, 84, 87, 103.

<sup>2</sup> Claims 1, 4, 7, 10, 14, 18, 51, 52, 56, 58, 67, 83, 84, 87, 103.

<sup>3</sup> Claims 61, 65, 83, 85.

products infringe the non-Generic Claims. Therefore, to the extent Plaintiffs' infringement action is based on those claims, it must be dismissed. *See id.*

## **B. The Generic Claims are not patent eligible under § 101**

The ten Generic Claims—claims 59, 60, 63-64, 73-74, 77-79, and 81 are ineligible for patenting under § 101 of the Patent Act. Each claims only a law of nature, *i.e.*, the implicit recognition that reducing certain DNA sequences associated with mRNA instability might result in improved mRNA stability.<sup>4</sup> To the extent Plaintiffs' Complaint rests on the Generic Claims, the Complaint must be dismissed.

### **1. Legal Standard**

“Eligibility is ultimately a question of law that may be based on underlying factual findings. And it may be resolved on a Rule 12(b)(6) motion where the undisputed facts, considered under the standards required by that Rule, require a holding of ineligibility under the substantive standards of law.” *AI Visualize, Inc. v. Nuance Commc'ns, Inc.*, 97 F.4th 1371, 1377 (Fed. Cir. 2024) (internal quotation omitted). In ruling on a 12(b)(6) motion, the Court may accept facts “based on intrinsic evidence from the specification.” *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017).

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<sup>4</sup> The Complaint implicitly gives the Generic Claims an exceptionally broad reading that divorces the claims from what is described in the specification. While no claim construction is required to resolve this motion, if this Court denies the motion, Moderna reserves the right to propose constructions of the Generic Claims.

For method claims,<sup>5</sup> the court assesses whether claims are ineligible under § 101 using the two-step *Alice/Mayo* framework. *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH*, 933 F.3d 1302, 1315 (Fed. Cir. 2019). That test requires that the court first determine if the claim “is directed to a patent-ineligible concept, *i.e.*, a law of nature, natural phenomenon, or abstract idea, and (2), if so, [whether] the particular elements of the claim, considered both individually and as an ordered combination, do not add enough to transform the nature of the claim into a patent-eligible application.” *Id.*

**2. The Generic Claims are directed to patent-ineligible subject matter at *Alice/Mayo* step one because they are directed to a law of nature**

The Generic Claims of the '118 patent claim a law of nature: that reducing certain nucleic acid motifs reduces mRNA instability. The Generic Claims on their face do not purport to require any particular starting material, method of reduction, or result. They do not require a certain type of gene or sequence. They do not apply new or specific techniques for reducing the identified sequences. Instead, the Generic Claims monopolize any use of the observed natural correlation between

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<sup>5</sup> As the Federal Circuit recently explained in *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, composition claims may be evaluated by asking whether the claimed compound has “markedly different characteristics” from what exists in nature. 167 F.4th 1206, 1212-13 (Fed. Cir. 2026) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)). The Generic Claims are method claims, not composition claims.

known DNA sequences and their destabilizing effects on mRNA. Section 101 precludes monopolizing natural laws to preempt their use in other advances.

Independent Generic Claim 59 is representative. Indeed, Plaintiffs selected claim 59, reproduced above, as illustrative of their infringement allegations. And the other Generic Claims are substantially similar and directed to the same law of nature: reducing mRNA-destabilizing sequences enhances mRNA stability. The remaining Generic Claims merely add additional Problem Sequences (such as ATTTA) or refine the degree of motif reduction to one or more genes. None introduces a new technological mechanism, a novel laboratory technique, or a structural limitation that alters the focus of the claimed advance. “Where, as here, the claims are substantially similar and linked to the same law of nature, analyzing representative claims is proper” at the motion to dismiss stage. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017).

**a. The Generic Claims are directed to a patent-ineligible law of nature**

“[C]laims [are] directed to a patent-ineligible concept when they amount[] to nothing more than observing or identifying [an] ineligible concept itself.” *Genetic Veterinary Scis.*, 933 F.3d at 1316 (quotation marks omitted). The presence of physical steps or laboratory terminology does not alter this inquiry. Rather, at step one, courts must determine the “focus of the claims, their character as a whole.” *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). The

Federal Circuit has sometimes referred to this inquiry as identifying the “claimed advance.” *E.g.*, *Genetic Techs. Ltd. v. Meril L.L.C.*, 818 F.3d 1369, 1375-76 (Fed. Cir. 2016).

The claimed advance here is a natural law: reducing sequences associated with mRNA instability can enhance mRNA stability. *Cf. Genetic Veterinary*, 933 F.3d at 1316-17 (claims directed to observing natural correlation ineligible). The patent explains that certain A+T-rich sequences—most prominently poly-A signal sequences and ATTTA motifs—are associated with mRNA instability and reduced protein expression in mammals. ’118 patent at 1:58-61. The specification presents the asserted discovery as recognizing that this previously identified relationship in mammals also operates in plants and, allegedly, more broadly. *See Complaint* ¶¶ 34-35. The Generic Claims do no more than observe that this natural correlation—certain A+T motifs in DNA are associated with instability in the later-formed mRNA—may be useful. The claims do not require a novel method or certain results. They are fundamentally directed to the natural correlation itself: A+T-rich motifs are correlated with instability. That is the “focus” of the Generic Claims.

The only step the Generic Claims require is reducing the presence of known problematic motifs by “substituting sense codons.” As noted above, a “codon” is a sequence of three nucleotides that encodes an amino acid and a “nonsense” codon is a codon that causes translation to stop. ’118 patent at 6:11-12. The recitation of this

generic step does not alter the § 101 analysis. Modifying genes to desired ends, including by substituting certain codons with other codons that encode amino acids, was a conventional, generic concept in the enterprise of genetic modification. ’118 patent at 1:53-55, 15:33-36. “[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.” *Mayo*, 566 U.S. at 82.

An examination of other claims that have previously been held ineligible at step one confirms that the “substitution” step of the Generic Claims does not rise to the level of patentability. In *CareDx, Inc. v. Natera, Inc.*, the claims were directed to a correlation between the presence of certain cell-free DNA and the likelihood of organ transplant rejection, and recited specific laboratory steps such as multiplex sequencing and sensitivity thresholds. 40 F.4th 1371, 1372-73, 1379 (Fed. Cir. 2022). Both this Court and the Federal Circuit held the claims ineligible because they merely applied conventional techniques to observe a natural correlation. *Id.* at 1379-80. Where a patentee “does not actually claim any improvement in laboratory techniques,” but instead invokes routine methods to exploit a correlation, the claims remain directed to a law of nature. *Id.*; see also *Genetic Veterinary*, 933 F.3d at 1317-18 (claims reciting collecting DNA sample, genotyping, and detecting a specific genetic change ineligible because they did no more than name the naturally occurring mutation and recite standard methods for “observing or identifying” it).

The Generic Claims here do materially less with the relevant law of nature than the claims in *Mayo*, *CareDx*, or *Genetic Veterinary*. The Generic Claims do not recite a mechanical structure, physical configuration, or operational constraints. Nor do they specify how to choose the codons to substitute, how many substitutions must be made, or any concrete technical method for accomplishing those substitutions. Given their breadth, the claims could even cover naturally occurring mutations that reduce a problematic motif, because as written they require only “reducing the number” of such sequences.

This Court and the Federal Circuit’s decision in *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, is instructive. 967 F.3d 1285 (Fed. Cir. 2020). There, the claims recited physical components, structural relationships, and operational constraints in a method for manufacturing mechanical devices. But these limitations amounted to nothing more than a direction to the reader to apply a natural law at an unacceptable level of generality. *Id.* at 1292. Ineligible claim 22 was directed to “controlling the mass and ... stiffness” of a metal “liner” of a propeller shaft to reduce unwanted vibrations in the shaft. *Id.* at 1292-1294. The claim required “providing a hollow shaft member,” “controlling the mass and stiffness of at least one liner to configure the liner to match the relevant frequency or frequencies,” and “inserting the at least one liner into the shaft member.” *Id.* at 1290-94. The claims imposed placement and configuration requirements on the liner

and required tuning specifically for certain vibrational modes. *Id.* The court concluded that, despite the structural language, the claims were nonetheless directed to Hooke’s law, a mathematical formula that governs vibrations, and merely instructed the artisan to achieve the desired result—attenuation of vibrations—without specifying the means of doing so. *Id.* at 1295-98. The claims thus “simply require[d] the application of” a natural law. *Id.* at 1292. Just so here.

Other cases explaining what *does* qualify as patentable subject matter reinforce the point. In *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, for example, the accused infringer argued that the claims were patent-ineligible because they attempted to claim the discovery that cells called hepatocytes could be frozen multiple times. 827 F.3d 1042, 1045-48 (Fed. Cir. 2016). But the claims required performing specific, defined physical interventions—density gradient fractionation, recovery of viable cells, and refreezing—to achieve an improved preservation method. *Id.* at 1045-46. The court emphasized that the claims thus recited a “new and useful process” that “achieve[d] a better way of preserving hepatocytes” than “conventional methods.” *Id.* at 1048-49. The claims were thus limited to a narrow and specific application of the discovery, not the broad discovery itself, and hence were patent-eligible. *Id.* at 1050-51. Likewise, in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, the claims applied the natural law that “cell-free fetal DNA tends to be shorter than cell-free maternal DNA.” 967 F.3d 1319, 1325-26 (Fed. Cir.

2020). But the claims were patent-eligible because they recited “specific process steps—size discriminating and selectively removing DNA fragments that are above a specified size threshold” and thus did more than merely claim the law of nature generally. *Id.* at 1326.

Plaintiffs cannot point to any similar process step in the claims here that makes them at all analogous to the claims in either *CellzDirect* or *Illumina*. Those claims recited new, specific, concrete, and structured steps with defined parameters that altered the physical inputs in improved and specified ways. Here, by contrast, the inventors never claimed to have invented a new way of modifying genes, nor are the Generic Claims directed to specific genetic modifications. Instead, the Generic Claims attempt to encompass *any* application of the natural law that certain sequences destabilize mRNA. Thus, like in *American Axle*, the claims instruct the reader to achieve a desired result, without specifying a particular (much less improved) technical pathway for doing so. That is not a patent-eligible application, but simply a directive for the reader to apply the natural law. *See Mayo*, 566 U.S. at 72 (claims that “simply state the law of nature while adding the words ‘apply it’” are ineligible). The Generic Claims include, at most, one general step: simply “reducing” the number of “Problem Sequences.” But that is not a novel *solution* to a problem; it is an observation of a naturally occurring problem and a direction to those in the art to solve the problem for themselves.

Plaintiffs’ attempt to capture Moderna’s work through the ’118 patent claims demonstrates the importance of the judicial exception to § 101. “Laws of nature, natural phenomena, and abstract ideas are the basic tools of scientific and technological work. Monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,” thereby “thwarting the primary object of the patent laws.” *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014). The motifs identified in the ’118 patent are ubiquitous features of genes. A patent that purports to cover any change—natural or man-made, intentional or not—that results in reducing such motifs would preempt a broad swath of scientific advancements, contrary to the goals of § 101.

**3. At *Alice/Mayo* step two, the Generic Claims do not recite an inventive concept**

In the second step of the *Alice/Mayo* analysis, the court “examine[s] the elements of the claim to determine whether the claim contains an inventive concept sufficient to ‘transform’ the claimed naturally occurring phenomenon into a patent-eligible application.” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015). “[T]ransformation into a patent-eligible application requires ‘more than simply stat[ing] the law of nature while adding the words “apply it.””” *Id.* (quoting *Mayo*, 566 U.S. at 72). In particular, where a claim purports to recite a method but the “method steps were well-understood, conventional and routine,”

those steps fail to transform a patent-ineligible law of nature into a patent-eligible method. *Ariosa*, 788 F.3d at 1377.

The generic claims recite no specific steps that limit the law of nature to which the claims are directed. They recite no techniques for sequencing genes, substituting nucleotides within genes, or making genes. *See* '118 patent at 10:24-37. Instead, claim 59 generally claims reducing the problematic sequences by replacing them with other sequences, without regard to the means used to accomplish the task. Accordingly, as discussed above, claim 59 is merely directed to a law of nature (the alleged discovery that certain sequences lead to instability) and then adds the words “apply it” by creating a structural gene with fewer of these sequences. This is not enough to make claim 59 patent-eligible. *Ariosa*, 788 F.3d at 1377.

As in *Ariosa*, the '118 patent itself confirms that its methods are merely routine and conventional applications of a law of nature. The specification of the '118 patent concedes that certain sequences, such as ATTTA and poly-adenylation sequences, were already known to negatively impact mRNA stability in the prior art. *Supra* § III.B. Thus, as in *Ariosa*, even if Fischhoff and Perlak’s “discovery” regarding the effect of Table II sequences “may have been a significant contribution to the ... field, that alone does not make it patentable.” 788 F.3d at 1379-80. Indeed, the Complaint does not suggest the '118 patent pertains to any discovery other than the naturally destabilizing effects of certain sequences. *See* Complaint ¶¶ 32-35

(describing invention as discovering the destabilizing properties of sequences disclosed in Table II). A *discovery* of this law of nature is not a new technique that can satisfy *Alice* step two, and thus, the '118 patent's Generic Claims are invalid under § 101. *Genetic Techs.*, 818 F.3d at 1376 (“The inventive concept necessary at step two of the *Mayo/Alice* analysis cannot be furnished by the unpatentable law of nature ... itself.”); *Genetic Veterinary*, 933 F.3d at 1319-20 (identifying correlation between nucleotide and undesirable result is patent-ineligible).

The claimed step of “substituting sense codons” fares no better. The specification of the '118 patent never discloses any method of substituting such codons. Instead, the patent assumes that a skilled artisan would be able to substitute sense codons using well-understood techniques in the art. This lack of disclosure makes sense; at the time of filing “great progress ha[d] been made ... with respect to transgenic plants,” but more was known about the effect of destabilizing sequences on mRNA in animals than in plants. *See* '118 patent, 1:14-2:20. Indeed, the Complaint acknowledges that “Plaintiffs’ Scientists utilized their novel method with well-known genetic engineering techniques like site-directed mutagenesis and de novo synthesis.” Complaint ¶ 36. Thus, as with the “amplifying” step in the claims found ineligible in *Ariosa*, because the skilled artisan would already understand the molecular biology techniques used in the claim, the “substituting”

step in the '118 patent's claims does not transform the law of nature to which these claims are directed at *Alice/Mayo* step two. *See* 788 F.3d at 1374.

## V. CONCLUSION

For the foregoing reasons, Plaintiffs' complaint should be dismissed.

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Respectfully submitted,

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**CERTIFICATION OF COMPLIANCE**

The foregoing document complies with the type-volume limitation of this Court's November 10, 2022 Standing Order regarding Briefing in All Cases. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 4,999 words, excluding the case caption, signature block, table of contents and table of authorities.

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