

Civil Procedure, arguing (1) that Bayer failed to adequately plead that Monsanto infringes the asserted claims of the '118 patent, and (2) that the '118 patent is invalid under 35 U.S.C. § 101. No. 26-12, D.I. 22, 23. Bayer has filed a response, No. 26-12, D.I. 27, and Moderna has filed a reply, No. 26-12, D.I. 28. For the reasons set forth below, Moderna's motion is denied.

On the same day that the plaintiffs filed the Moderna case, they filed a second patent infringement action against Pfizer, Inc.; BioNTech SE; BioNTech Manufacturing GmbH; and BioNTech US, Inc. (collectively, "Pfizer"), in Civil Action No. 26-13, alleging that those defendants have also infringed the '118 patent. No. 26-13, D.I. 1. Pfizer has moved to dismiss Bayer's complaint under Rule 12(b)(6) on three grounds. No. 26-13, D.I. 30, 31. First, Pfizer argues that Bayer has failed to plausibly plead performance of the claimed method steps. Second, Pfizer argues that Bayer's claim under section 271(a) of the Patent Act, 35 U.S.C. § 271(a), should be dismissed because Bayer has failed to plead that the claimed method was practiced in the United States. Second, Pfizer argues that Bayer's claims under section 271(g) of the Patent Act, 35 U.S.C. § 271(g), should be dismissed because (1) the product Bayer accused of infringement is not a "product . . . made by" a patented process, (2) Bayer failed to provide the notice of infringement required by section 287(b)(2) of the Patent Act, 35 U.S.C. § 287(b)(2), and (3) Bayer failed to plausibly allege infringement. Bayer has filed a response, No. 26-13, D.I. 37, and Pfizer has filed a reply, No. 26-13, D.I. 38. At Pfizer's request, I held oral argument on Pfizer's motion to dismiss. For the reasons set forth below, Pfizer's motion is denied.

I. Background

On a motion to dismiss under Rule 12(b)(6), the court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009). The court must "determine whether the facts alleged in the

complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The facts set forth in this order are based on the allegations in the two complaints and the ’118 patent, which was attached as an exhibit to both complaints.

The ’118 patent, which is directed to methods of making structural genes, has a long prosecution history. Although it was issued in 2010, the patent claims priority to an original application filed in 1989. The patent will expire on June 22, 2027.

The principal focus of the ’118 patent is on gene editing designed to cause plants to produce insecticidal proteins so as to provide the plants with improved pest resistance. Not all the claims, however, contain limitations that are directed to that specific goal. Several are more general; four of those more general claims—claims 59, 60, 73, and 79—are at issue in this case.

The basic scientific principles underlying cellular protein expression are well understood. The Federal Circuit has explained that basic process as follows:

Organisms, like plants and animals, are made up of cells. Genes are comprised of DNA (deoxyribonucleic acid), which encodes the necessary information for cells to reproduce and to produce specific proteins.

DNA consists of two long chains or strands that wrap around each other in a shape known as a double-stranded spiral helix. Visually, a molecule of DNA resembles a twisted ladder. The sides of the ladder are connected by rungs made up of pairs of molecules called nucleotides. Four different nucleotides, each containing one of the bases adenine (“A”), guanine (“G”), cytosine (“C”) and thymine (“T”), form the particular DNA make-up of genes. A particular DNA molecule can be graphically represented by listing the nucleotide sequences making up that DNA molecule.

Because of the nucleotides’ chemical make-up, A will only pair with T, and C will only pair with G. This strict complementary pairing means that the order of the nucleotides on one side of a DNA rung determines the order on the other side of the rung. Therefore, each rung of the ladder is composed of one pair consisting of A and T, or C and G. Each rung is called a nucleotide pair, and the order in which these nucleotide pairs appear on the DNA ladder constitutes the genetic code for the cell.

DNA directs cells to make proteins through a two-step process of transcription and translation. In the first step, transcription, information is transferred from DNA to an RNA, or ribonucleic acid, molecule. RNA that codes for a protein is called messenger RNA (“mRNA”).

RNA is a long single strand of linked nucleotides similar to DNA. However, one of the differences between DNA and RNA is that RNA contains the base uracil (“U”) in place of thymine. In transcription, specific nucleotide sequences on the DNA determine where the RNA copy begins and ends.

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 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.

Mycogen Plant Science v. Monsanto Co., 243 F.3d 1316, 1322–23 (Fed. Cir. 2001) (footnotes omitted).

The techniques described and claimed in the ’118 patent were principally designed to modify certain plant genes so as to increase the amount of insecticidal protein that the plant produced. As described by the specification, plant cells that were modified to produce insecticidal proteins were widely observed to produce those proteins, but at much lower levels than was expected. ’118 patent, col. 7, line 60, through col. 8, line 63. One identified reason for that

shortfall was that certain nucleotide sequences were observed to have an adverse effect on the stability of mRNA sequences. *Id.* at col. 1, ll. 53–55.

The complaints in both cases allege that in the mid-1980s, two of the plaintiffs’ scientists who were working on the problem conceived a solution.¹ They noted that certain coding sequences contributed to mRNA instability in higher organisms, and that those sequences were often rich in A + T nucleotides. No. 26-12, D.I. 1 at ¶¶ 29–32; No. 26-13, D.I. 1 at ¶¶ 31–34. The scientists identified 16 sequences rich in A + T nucleotides that they believed contributed to mRNA instability in plant and animal cells and thus reduced the expression of the desired proteins. No. 26-12, D.I. 1 at ¶ 33; No. 26-13, D.I. 1 at ¶ 35. They also determined that genes containing a coding sequence of ATTTA nucleotides, as well as genes containing more than five consecutive A + T nucleotides were associated with low expression of the desired proteins. The scientists conceived of replacing those “problem sequences” with “sense” codons that would code for the same amino acids but without destabilizing the mRNA, thereby resulting in better protein expression. No. 26-12, D.I. 1 at ¶ 34; No. 26-13, D.I. 1 at ¶ 36.

According to the complaint, using the method of editing mRNA in that manner resulted in a dramatic increase in protein expression, including increases as large as 500-fold, which in turn resulted in corresponding increases in bioactivity, such as protecting plants from insect damage. No. 26-12, D.I. 1 at ¶ 36; No. 26-13, D.I. 1 at ¶ 38. The scientists discovered that their method could be used to make a synthetic gene that allowed for plant expression of a viral coat protein at an effective level and thereby achieve viral resistance, while encoding the same protein as the naturally occurring gene. No. 26-12, D.I. 1 at ¶ 37; No. 26-13, D.I. 1 at ¶ 39.

¹ The two scientists, David A. Fischhoff and Frederick J. Perlak, became the named inventors on the ’118 patent.

The claims of the patent that was filed based on the scientists' work were not limited to the specific genes that were the principal focus of the scientists' studies, but included claims that more generally recited method steps for eliminating the problematic sequences that contributed to unstable mRNAs. In particular, the claims that Bayer asserts in this case are directed to methods that require (1) starting with a DNA sequence that encodes a protein and that contains at least some of the identified destabilizing sequences, and then (2) reducing the number of destabilizing sequences by replacing the identified sequences with alternative sense codons. No. 26-12, D.I. 1 at ¶¶ 39–40; No. 26-13, D.I. 1 at ¶¶ 41–42.

Representative independent claim 59 of the '118 patent recites as follows:

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.

Table II in the specification of the '118 patent, referred to in claim 59, lists the following sequences of potential polyadenylation signals:

AATAAA*	AAGCAT
ATAAAT*	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.

'118 patent, col. 15, ll. 50–64.²

In addition, the complaint alleges that the sequence motif ATTTA (or AUUUA as it appears in RNA) was implicated as a destabilizing sequence in mRNA, as were coding sequences containing more than five consecutive adenine and thymine (A + T) nucleotides. Asserted claim 60 of the '118 patent, which depends from claim 59, is likewise directed to making a structural gene in the same manner, but substituting sense codons for ATTTA sequences in the coding sequence of the starting gene. Asserted claim 73 is directed replacing all the ATTTA sequences in the starting gene. And asserted claim 79 is directed to “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).”

Bayer brought suit against the defendants in both the Moderna case, No. 26-12, and the Pfizer/BioNTech case, No. 26-13. Bayer alleged that the defendants in both cases used the methods claimed in the '118 patent to produce the mRNA that coded for the spike protein in the COVID-19 coronavirus and was thus essential to the development of mRNA COVID-19 vaccines. No. 26-12, D.I. 1 at ¶ 8; No. 26-13, D.I. 1 at ¶ 8.

II. Discussion: The Moderna Case

a. The Insecticidal and Plant-Specific Gene Claims

Moderna begins by arguing that all the independent claims of the '118 patent except for claims 59 and 63 “explicitly require encoding an insecticidal protein, using *Bacillus thuringiensis* genes[,] . . . or expressing sequences through ‘plant promoter’ gene sequences.” No. 26-12, D.I.

² The term “polyadenylation” refers to the addition of a series of adenine nucleotides to the 3’ end of an RNA transcript (referred to as a “poly(A) tail”). The poly(A) tail serves various roles in the translation process, including providing protection for mRNA from being broken down by enzymes.

23 at 10 (footnotes omitted). Moderna argues that Bayer has made no allegations that Moderna's product infringes any of those claims.

In response, Bayer asserts that its complaint asserts infringement of only claims 59, 60, 73, and 79, which do not contain requirements relating to insecticidal genes, and that Moderna's arguments about the claims directed to insecticidal genes are therefore irrelevant. No. 26-12, D.I. 27 at 22.

Given Bayer's representation that it does not assert the insecticidal claims with which Moderna takes issue, Moderna's motion, as applied to those claims, is denied as moot.

b. Patent Eligibility Under Section 101

Moderna next argues that claims 59, 60, 63, 64, 73, 74, 77–79, and 81 of the '118 patent, which are the claims that are not related to an insecticidal protein (and which include Bayer's asserted claims 59, 60, 73, and 79) are patent ineligible under 35 U.S.C. § 101 for being directed to a law of nature. No. 26-12, D.I. 23 at 11. Specifically, Moderna argues that the claims are directed to the natural law of "reducing [DNA] sequences associated with mRNA instability [in order to] enhance mRNA stability." *Id.* at 14. Moderna argues that the claims do little more than direct the observation of a natural phenomenon and the use of a generic process to reduce problematic sequences. *Id.* at 14–16.

In response, Bayer argues that the four claims it asserts are not directed to a law of nature, but rather are directed to methods covering "synthetically created DNA," which is patent-eligible subject matter. No. 26-12, D.I. 27 at 9 (citation omitted). Bayer argues that Moderna does not dispute that a man-made structural gene is eligible for patenting, and that there is no meaningful difference for patentability purposes between a method claim for making such a gene and a composition claim directed to the structure of the gene itself.

Moderna replies that Bayer’s asserted claims are unpatentable because they contain “only one operative instruction: Reduce, *by any amount*, Problem Sequences through codon substitution.” No. 26-12, D.I. 28 at 4. Viewed in that manner, Moderna argues, Bayer’s asserted method claims are not directed to a patentable invention, but are merely directed to a natural law and therefore are not eligible for patenting under section 101.

The Supreme Court has made clear that synthetic genes may be patentable. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (holding that bacteria modified by humans to serve a particular purpose, and having “markedly different characteristics from any found in nature” are patent-eligible, even if the structure of the human-made item was dictated or controlled in large part by the natural structure from which it was derived); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594–95 (2013) (finding synthetically created cDNA to be patent eligible under section 101).³

Recent decisions from the Federal Circuit have likewise recognized that engineered alterations in the natural genetic code of an organism that provide a novel utility constitute patentable subject matter. For example, in *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, 167 F.4th 1206, 1216 (Fed. Cir. 2026), the court held that claims to genetically engineered cells with utility for gene therapy are patent eligible. The court noted that it was uncontested that the claimed cells in *REGENXBIO* “include a recombinant nucleic acid molecule that does not and cannot exist in nature.” *Id.* at 1213. The claimed nucleic acid molecules, the court found, were “not nature’s handiwork”; the “‘lab technician unquestionably creates something new’ when she splices together

³ In *Myriad*, the Supreme Court held that the act of locating genes and isolating them from the human genome does not render those genes patent eligible, 569 U.S. at 593, but that the act of creating a new gene that is not found in nature is eligible for patenting, *id.* at 596.

the claimed recombinant nucleic acid molecule that encodes [a new protein] and inserts said molecule into a host cell.” *Id.* at 1213–14 (quoting *Myriad*, 569 U.S. at 595); *see also id.* at 1216 (“Accordingly, the claimed host cells here contain a recombinant nucleic acid molecule that, by definition, is markedly different from anything occurring in nature. The claimed host cells are, therefore, not patent-ineligible claims to naturally occurring subject matter.”).

The Federal Circuit’s decisions in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319 (Fed. Cir. 2020), and *Rapid Litigation Management LTD v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016), have employed similar analysis to reach the same conclusion. In *Illumina*, the claims at issue were directed to methods for preparing a fraction of a pregnant woman’s cell-free DNA that is enriched in fetal DNA for the purpose of genetic testing. The method involved physical processing steps that altered the composition of the mixture of fetal and cell-free DNA from the naturally occurring composition in the mother’s blood. *Illumina*, 967 F.3d at 1326. The court concluded that the claims were patent eligible because they were directed to more than just determining the correlation between a DNA fragment’s size and the likelihood that the fragment would be fetal rather than maternal. Instead, the claims were directed to methods for removing enough of the non-fetal DNA to facilitate testing of the mixture, which involved the application of human-designed techniques. *Id.* at 1328.

Likewise, in *Rapid Litigation Management*, the patent in suit was directed to producing a desired preparation of multi-cryopreserved hepatocyte that are capable of surviving multiple freeze-thaw cycles. The district court in that case identified in the claims a “natural law” that hepatic cells were capable of surviving multiple freeze-thaw cycles. The Federal Circuit disagreed, however, and held that the claims were directed to a new and useful laboratory technique for preserving hepatocytes, which the court characterized as a “type of constructive process, carried

out by an artisan to achieve ‘a new and useful end,’ [which] is precisely the type of claim that is eligible for patenting.” *Rapid Litigation Management*, 827 F.3d at 1048 (citation omitted).

Moderna attempts to distinguish *Rapid Litigation Management* from this case. However, the claims that the court found to be patentable in *Rapid Litigation Management* required, according to Moderna’s own characterization, the performance of “specific, defined physical interventions.” No. 26-12, D.I. 23 at 17 (citing *Rapid Litigation Management*, 827 F.3d at 1045–48). The asserted claims of the ’118 patent likewise specifically require direct physical intervention in the form of substituting certain codons with alternative codons in order to reduce the number of problematic sequences. While the intervention described by the ’118 patent may not be as complex or require as many steps as the inventions at issue in *Rapid Litigation Management*, the intervention in this case requires more than simply reciting or relying on an abstract concept or a law of nature.

Moderna argues that because the claims at issue in this case are method claims, the analysis of section 101 arguments is different than it would be for composition claims, such as those at issue in *Chakrabarty* and *Myriad*. It is true that in addressing the patentability of method claims under section 101, the Supreme Court has employed a two-part test that asks (1) “whether the claims at issue are directed to . . . patent-ineligible concepts,” including “laws of nature, natural phenomena, and abstract ideas,” and then, if they are, (2) whether there is an additional element of the claim that serves to “‘transform the nature of the claim’ into a patent-eligible application.” *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014) (quoting *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 78 (2012)).

It is also true that the Federal Circuit has at times analyzed composition-of-matter claims under *Myriad* and *Chakrabarty*, and has analyzed method claims under the *Alice* and *Mayo*

framework. See *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280, 1285–86 n.5 (Fed. Cir. 2023) (citing *In re BRCA1 and BRCA2*, 774 F.3d 755, 759–61 (Fed. Cir. 2014)). In this case, however, the asserted claims have aspects of both method and composition claims. The claims recite methods for making a structural gene, and they define the structural gene that is made as one that includes codons substituted for naturally occurring codons in a manner that encodes a protein, in circumstances in which the structural gene is not found in nature. In that setting, it is appropriate to look to both the *Myriad-Chakrabarty* standard and the *Alice-Mayo* test to assess whether the claims are directed to patent-eligible subject matter.

Claim 59, like the other asserted claims of the '118 patent, is directed to making a structural gene that does not appear in nature, but is the product of a human engineered alteration in its coding sequence. That alteration results in a gene that performs quite differently from its naturally occurring predecessor. In that respect, claim 59 cannot be disqualified from patent eligibility on the ground that it is a natural product. To the contrary, the gene that is the product of the method recited in claim 59 is what the Supreme Court in *Chakrabarty* characterized as “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Chakrabarty*, 447 U.S. at 309–10 (alteration in original) (citing *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

The same principle applies here. Claim 59 directs that a structural gene be created from a coding sequence that includes certain identified signals and substituting sense codons for those signal sequences. As explained by the patent, those changes have the effect of greatly increasing the encoding of the desired coding sequence for the altered genetic material, resulting in a potential for substantial enhancement to the utility of the product.

Although claim 59, like the other asserted claims, is a method claim in form, it incorporates the requirement of modifying a naturally occurring gene to create a new man-made gene that performs a desired function much better than its naturally occurring predecessor. As such, the patent-eligibility of the claim can be analyzed under the *Chakrabarty-Myriad* test that applies to composition claims. And under that test the asserted claims plainly survive Moderna's motion to dismiss predicated on the assertion that the claims are directed to unpatentable subject matter.

Applying the *Mayo-Alice* analysis to the method claims at issue in this case leads to the same conclusion. The first step under the two-step analysis of section 101 claims dictated by *Mayo* and *Alice* is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts" such as laws of nature, natural phenomena, and abstract ideas. *Alice*, 573 U.S. at 217. Upon review of the claims asserted in this case, I find that they are not directed to a law of nature or any other patent-ineligible concept.

Although the asserted claims make use of the "relationship between certain nucleotide sequence motifs and reduced mRNA stability and protein expression" to accomplish their end goals, it is inaccurate to characterize the claims as being "directed to" that relationship, as Moderna argues. No. 26-12, D.I. 23 at 3. While knowledge of the natural laws of genetics may guide the choice of which specific codon replacements are made and how the replacement is performed, the asserted claims employ that knowledge to create a technique using specific codon replacements to achieve a concrete result. As the Supreme Court has noted, "[a]t some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Alice*, 573 U.S. at 217 (cleaned up). For that reason, the Court cautioned that "an invention is not rendered ineligible for patent simply because it involves an abstract concept." *Id.* This case is one in which the asserted claims plainly make use of laws of nature, but they make use of those laws to lay claim

to a concrete technological advancement. The claims are therefore not rendered patent ineligible simply because the invention ultimately relies on the inventors' knowledge of the science underlying the invention.

To the extent that Moderna's argument is premised on the contention that Bayer's claims are unpatentable because they are not directed to a novel method of substituting sense codons for the problematic sequences in the native genes, that argument misses the point. The inventors' contribution did not consist of proposing a new technique for inserting foreign material into a native gene, such as a new method of gene splicing. Instead, what the inventors claim to have invented is based on the selection of the particular genetic structures to be removed from the native gene and replaced with particular codons that would not adversely impact the mRNA generated by the genes. The inventive aspect of the method turns on the selection of the material to be replaced, not the manner in which the replacement is performed.

Since the claims are not directed to a natural law under the first step of the *Alice-Mayo* test for patentability, it is not necessary to address the second step of that test, which asks whether the claim contains an inventive concept. In any event, the claims contain an additional element that transforms the nature of the claim into a patent-eligible application, i.e., the substitution of sense codons for the problem sequences in the coding sequence.

The cases on which Moderna relies to support its section 101 theory involve patents directed to measuring, observing, or amplifying natural phenomena or characteristics. *E.g.*, *Genetic Veterinary Scis., Inc. v. LABOLIN GmbH*, 933 F.3d 1302, 1315 (Fed. Cir. 2019) (quoting *Rapid Litigation Management*, 827 F.3d at 1048) ("claims [are] 'directed to a patent-ineligible concept when they amount[] to nothing more than observing or identifying [an] ineligible concept itself'"); *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371, 1379 (Fed. Cir. 2022) ("[T]he claims boil

down to collecting a bodily sample, analyzing the cfDNA using conventional techniques, including PCR, identifying naturally occurring DNA from the donor organ, and then using the natural correlation between heightened cfDNA levels and transplant health to identify a potential rejection, none of which was inventive.”).

Moderna also relies on *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020), but that case has little in common with this one. In that case, the Federal Circuit noted that not only was the invention based entirely on a natural law, but the “claimed advance” was “simply the concept of achieving [the claimed] result, by whatever structures or steps happen to work.” *Id.* at 1295. In this case, by contrast, the asserted claims are based on the substitution of sense codons for particular codons that the inventors determined to be the source of mRNA instability. While based on scientific principles, that process is directed to a concrete method of harnessing those scientific principles to achieve a useful result.

For the reasons set forth above, and accepting the facts set forth in the complaint as true, I conclude that the asserted claims of the ’118 patent are not directed to ineligible subject matter and therefore will not be dismissed on the grounds Moderna has urged.⁴

III. Discussion: The Pfizer/BioNTech Case

a. Plausible Pleading of the Claimed Method Steps

In support of its motion to dismiss, Pfizer argues that Bayer has failed to allege that the defendants in the Pfizer/BioNTech case engaged in activities satisfying each element of the asserted claims. Instead, Pfizer asserts that the complaint recites elements or offers allegations

⁴ Of course, the questions whether the claims are invalid in view of the prior art or on other grounds, or whether the claims have actually been infringed are not at issue in the section 101 inquiry. Any such challenges will need to await further proceedings in these cases.

that are “‘merely consistent with’ infringement.” No. 26-13, D.I. 31 at 9 (citation omitted). Pfizer also argues that Bayer’s complaint does not allege “which claim steps either Defendant purportedly performed.” *Id.*

In response, Bayer argues that the complaint includes “ten pages of factual allegations” to support Bayer’s infringement allegations. No. 26-13, D.I. 37 at 8 (citing No. 26-13, D.I. 1 at ¶¶ 43–62). Bayer argues that its allegations “not only provide ample notice of products and processes Plaintiffs accuse of infringement,” but that they also “lay out a well-supported narrative that Defendants worked together in the United States to generate modified spike protein DNA plasmids and the resulting mRNA vaccines using the ’118 Patent’s codon substitution method.” *Id.* at 9. Bayer further argues that many of the details of how and where the method steps were performed are particularly within the defendants’ knowledge or control and that it is therefore legitimate to plead those facts based on information and belief. *Id.* at 10.

In reply, Pfizer argues that Bayer failed to take reasonable steps to investigate the facts before filing its complaint, and that Bayer’s “information and belief” allegations are insufficient to survive a motion to dismiss. No. 26-13, D.I. 38 at 10–12.

I find that Bayer’s allegations in its complaint are sufficient to withstand Pfizer’s Rule 12(b)(6) challenge. Bayer’s complaint alleges that Pfizer and BioNTech have engaged in activity that could plausibly constitute infringement of the method claims. No. 26-13, D.I. 37 at 8–9 (citing No. 26-13, D.I. 1). Bayer’s factual allegations are not speculative, as Pfizer contends, but are sufficiently supported and detailed to give the defendants “fair notice of what the . . . claim is and the grounds upon which it rests.” *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1353 (Fed. Cir. 2021) (omission in original) (citation omitted). Those allegations include references to (1) filings that describe BioNTech’s activities “optimiz[ing] the DNA template through a [] codon

optimization process;” (2) Pfizer’s admissions discussing the spike protein sequence for its COVID-19 vaccine, and (3) BioNTech’s discussion about what work was performed at what physical locations. No. 26-13, D.I. 37 at 8 (alterations in original) (citing No. 26-13, D.I. 1). Those references, among other allegations, provide sufficient information to place Pfizer and BioNTech on notice of the claims against them and to provide a plausible basis for inferring infringement.

While some details of the defendants’ actions are pleaded on information and belief, many of the allegations in the complaint cite public filings and admissions made by, or websites controlled by, one or more of the defendants. The Third Circuit has noted that “pleading upon information and belief is permissible ‘[w]here it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control.’” *McDermott v. Clondalkin Grp., Inc.*, 649 F. App’x 263, 267–68 (3d Cir. 2016) (alteration in original) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002)). Many of the alleged facts involve non-public actions and research undertaken by the defendants. Because that information is peculiarly within the defendants’ knowledge, it is permissible for Bayer to base those allegations on information and belief.

b. Section 271(a) Claim

Pfizer next argues that the claims of direct infringement asserted under section 271(a) should be dismissed because Bayer has failed to plausibly allege that all steps of the claimed method were performed by the same entity within the United States, as is required for infringement under section 271(a). *See NTP, Inc. v. Rsch. In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005). Specifically, Pfizer argues that “the only entity that Plaintiffs specifically accuse of performing the claimed optimization method is BioNTech,” and that BioNTech is located in and operates only in

Germany. No. 26-13, D.I. 31 at 11–13. In light of that assertion, Pfizer argues that “some (or all) steps occurred outside of the U.S.” *Id.* at 13.⁵

In response, Bayer argues that its complaint alleges that the infringing method was performed domestically, specifically in the Pfizer facility located in Chesterfield, Missouri. No. 26-13, D.I. 37 at 13 (citing No. 26-13, D.I. 1 at ¶ 49). Bayer points to news articles cited in its complaint for support, and it relies on the proposition that all pleaded facts must be accepted as true at this stage of the litigation. *Id.* at 13–14. Bayer highlights the language in its complaint alleging that BioNTech collaborated with Pfizer. Bayer also argues that, even if the original plasmids were made in Germany, the evidence is sufficient to support an inference that later plasmid copies or variants were made or copied within the United States. *Id.* at 15.

In reply, Pfizer argues that the complaint identifies BioNTech as the entity that performed codon optimization, even if later development and manufacturing was performed with Pfizer’s assistance. No. 26-13, D.I. 38 at 3, 5 (citing No. 26-13, D.I. 1 at ¶ 47). Pfizer also argues that Bayer’s complaint shows that Pfizer did not become involved with BioNTech in the vaccine development process until after the plasmid had already been designed, and that Pfizer’s role was solely related to manufacturing. *Id.* at 5. Pfizer argues that it is irrelevant that Pfizer may have made later copies or variants of the DNA template in the United States, since the complaint does not allege that each step of the claimed method was performed for any of those variants.

⁵ As in the *Moderna* case, the defendants in the *Pfizer* case complain that the plaintiffs “fail[] to plausibly allege infringement of the vast majority of the ’118 Patent’s claims.” No. 26-13, D.I. 31 at 10. That observation is pointless, since the plaintiffs have asserted infringement of only four claims from the ’118 patent. It is irrelevant that most of the other claims do not apply to the technology at issue in this case.

Bayer alleges that all the steps of the claimed method were performed within the United States. No. 26-13, D.I. 1 ¶ 49 (reciting, on information and belief, that the defendants “have optimized and manufactured their infringing mRNA vaccine products starting with a DNA template in the United States,” and that the steps leading to the production of the vaccine were performed in Chesterfield, Missouri; Andover, Massachusetts; and Kalamazoo, Michigan). And even if BioNTech did exploratory work on the codon optimization process in Germany, Bayer asserts that the evidence is sufficient to support an inference that Pfizer replicated that work as part of its process of “optimiz[ing] and manufactur[ing] their infringing mRNA vaccine products starting with a DNA template in the United States.”⁶ *Id.*

In the alternative, Bayer argues that Pfizer’s collaboration with BioNTech constitutes a joint enterprise such that the defendants are subject to liability on a theory of joint (or divided) infringement. No. 26-13, D.I. 37, at 11; *see Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc). The defendants respond that Bayer has not pleaded joint infringement and that even if the defendants’ relationship can be characterized as a joint enterprise, that does not solve the “territoriality” problem. No. 26-13, D.I. 38 at 6.

Those arguments are unconvincing. Bayer’s assertion that Pfizer and BioNTech engaged in “a collaborative effort focused on bringing a COVID-19 vaccine to market,” No. 26-13, D.I. 1

⁶ Pfizer seeks to buttress its section 271(a) argument by contending that the complaint “pleads design work as *BioNTech*’s and synthesis as *Pfizer*’s, with the collaboration beginning only after BioNTech had developed ‘more than twenty candidates for a vaccine.’” No. 26-13, D.I. 38 at 5–6 (citation omitted). But that is not an accurate characterization of what the asserted claims cover. Claim 59, as a representative example, recites starting with a coding sequence that includes certain problematic signal sequences and then substituting sense codons for those problematic sequences. Even if BioNTech did all the design work leading to the synthesis performed by Pfizer, that does not mean that Pfizer did not optimize and manufacture manufacturing the mRNA vaccine products, including substituting sense codons for the problematic sequences, as alleged by Bayer.

at ¶ 51, is sufficient to plead joint infringement. And to the extent that the issue of joint infringement becomes relevant, it turns on factual issues and cannot be the subject of dismissal at this juncture.

Pfizer objects that Bayer’s critical allegations relating to this issue are based only on information and belief. Once again, however, because the details of the defendants’ internal product development and manufacturing constitute information that is uniquely within the defendants’ knowledge and control, Bayer’s choice of pleading on information and belief is permissible. *See British Telecomms. PLC v. IAC/InterActiveCorp.*, 381 F. Supp. 3d 293, 299–300 (D. Del. 2019); *DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 468–69 (D. Del. 2016) (“In the context of patent litigation, it is logical to presume that a defendant has greater access to and, therefore, more information [than the plaintiff] about its accused method.” (footnotes omitted)). Treating Bayer’s allegations as true, they are sufficient to support Bayer’s contention that all steps of the accused method were performed in this country. The ultimate question whether the steps of the claimed method were all actually performed within the United States raises a factual dispute that cannot be resolved at this early stage of the case on a Rule 12(b)(6) motion.

c. Section 271(g) Claim

In addition to alleging infringement under section 271(a), Bayer alleges that Pfizer and BioNTech have infringed the asserted claims under section 271(g) by importing, offering to sell, selling, or using within the United States a product made by a patented process. Pfizer contends that Bayer’s section 271(g) claim must be dismissed for several reasons.

i. First, Pfizer argues that the complaint “never commits to a coherent § 271(g) theory . . . and alternately suggests that the ‘product’ of the asserted method is either the finished vaccine or an upstream DNA template.” No. 26-13, D.I. 31 at 14.

Although Pfizer criticizes Bayer for asserting 271(a) and 271(g) as alternative grounds of infringement, there is nothing wrong with pleading both theories: (1) infringement under section 271(a) based on Bayer’s allegations that the infringing products were made in the United States, and (2) infringement under section 271(g) in the event that the finder of fact determines that some steps of the infringing process were performed only in Germany. With respect to its section 271(a) claim, Bayer relies on the theory that Pfizer’s vaccine was made by a process that infringed the ’118 patent, because all the steps of the process were ultimately performed in the United States, even if the initial research was conducted in Germany. With respect to the section 271(g) claim, Bayer principally relies on its allegations that BioNTech and Pfizer have imported the DNA template that was produced abroad through the use of the claimed methods. The two theories of liability can be reconciled. Bayer alleges that BioNTech used the claimed methods to generate the optimized DNA in Germany and later imported into the United States; Bayer also alleges that Pfizer subsequently employed all the steps of the claimed methods to produce the optimized DNA in this country and then used the optimized DNA to make the COVID-19 vaccine.⁷

ii. Second, Pfizer argues that the patent claims a DNA-modification method, and the accused products are lipid-based mRNA vaccines, which are plainly not DNA. No. 26-13, D.I. 31 at 15–16. With respect to Bayer’s 271(g) claim, Pfizer therefore contends that the products Pfizer makes and sells are not a “product . . . made by” the claimed process. It makes no difference, however, if the imported product is not the product Pfizer ultimately sells; it is enough that the

⁷ In the oral argument on the motion to dismiss, counsel for Bayer contended that the product that was the subject of the section 271(g) claim could also include the mRNA used in the vaccine and the finished vaccine itself. In response to questioning, counsel also contended that Bayer’s section 271(g) claim is not limited to the importation of products made by a patented process, but includes the finished vaccine as well. It is unnecessary to address those contentions for purposes of the motions to dismiss.

product that is imported is a product that is made by the claimed process, which is within the scope of Bayer's allegations.

iii. Third, Pfizer argues that if the allegedly imported product is the synthetic DNA template, there is another flaw in Bayer's theory of liability under section 271(g). Pfizer submits that to the extent Bayer contends that the finished vaccine is the product "made by" the claimed process practiced outside the United States, within the meaning of section 271(g), several manufacturing steps separate the structural gene made pursuant to the claimed process and the finished vaccine. No. 26-13, D.I. 31 at 16–17. For that reason, Pfizer argues that there is a material change between the mRNA and the vaccine.

In arguing that there is a material change between the imported DNA and the mRNA-based vaccine, which is produced from the imported DNA, Pfizer invokes the language from section 271(g) stating that the statute "does not apply if the product made by the patented process is 'materially changed by subsequent processes' before it is imported." *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1571 (Fed. Cir. 1996) (quoting 35 U.S.C. § 271(g)(1)). For that reason, Pfizer argues that Bayer's section 271(g) claim fails to plausibly support liability.

Pfizer's theory, however, misreads section 271(g). As the *Eli Lilly* case made clear, the "material change" referred to in section 271(g)(1) refers to a material change *before* the product is imported, not afterwards. *See also Amgen Inc v. F. Hoffman-LaRoche Ltd.*, 580 F.3d 1340, 1377 (Fed. Cir. 2009) (no infringement if product is materially changed "prior to importation"); *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1560 (Fed. Cir. 1996) (to be "materially changed" there must be "a real difference between the *product imported* . . . and the *product produced by the patented process*" (emphases added)). Thus, the phrase "materially changed by

subsequent processes” in section 271(g)(1) refers to changes subsequent to the making of the product but before its importation, not changes made after its importation.

iv. Fourth, Pfizer makes the curious argument that because the vaccine could be made by a method other than the patented method, Pfizer’s process cannot violate section 271(g). No. 26-13, D.I. 31 at 19.

This argument is based on language from the Federal Circuit’s decision in the previously cited *Eli Lilly* and *Bio-Technology* cases. Those cases, however, do not stand for the proposition for which Pfizer cites them.

As explained earlier, *Eli Lilly* addresses the situation in which a product made overseas by a process patented in this country is imported. If the product is materially changed by processes following its manufacture, but before its importation, the importation does not violate section 271(g). It was in that context that the court in *Eli Lilly* explained that the product would not be deemed materially changed prior to its importation if, but only if, “regardless of any subsequent changes [to the product prior to its importation], . . . it would not be possible or commercially viable to make that product but for the use of the patented process.” 82 F.3d at 1575 (quoting H.R. Rep No. 60, 100th Cong. 1st Sess. 13–14 (1987)). Put another way, if any change was dictated by circumstances, the change would not be “material” for purposes of section 271(g) liability. The *Bio-Technology General* case quotes similar language from the Senate Report of the same year and stands for the same proposition.

That analysis has no application to the situation in which a change is made *after* the importation of the product made by an infringing method. In that setting, there is still infringement, based on the importation of the product made by the infringing process. Any downstream change in the product made by the importer or others does nothing to alter the fact that infringement

occurred at the time of importation. Nor can such an infringer escape liability because it could have used an alternative process to make a product, but chose an infringing process instead.

v. Pfizer next contends that Bayer has failed to allege that it gave the defendants notice of infringement under the notice provision in section 287(b)(2). That provision states that no remedies for infringement under section 271(g) “shall be available with respect to any product in the possession of, or in transit to, the person subject to liability under such section before that person had notice of infringement with respect to that product.” 35 U.S.C. § 287(b)(2). For that reason, Pfizer argues, Bayer should be barred from collecting damages, at least against Pfizer.

Bayer responds that its failure to plead that it complied with the required notice under section 287(b)(2) is not fatal at the motion to dismiss stage of the case, for two reasons. First, Bayer argues that there is no requirement to plead compliance with the notice requirement in a complaint alleging a violation of section 271(g). *See Ocean Semiconductor LLC v. Analog Devices, Inc.*, 698 F. Supp. 3d 204, 212 (D. Mass. 2023); *Everlight Elecs. Co. v. Bridgelux, Inc.*, No. C 17-03363, 2017 WL 10447905, at *2 (N.D. Cal. Oct. 11, 2017); *Compound Photonics, Ltd. v. Sony Corp.*, No. 6:11-552, 2013 WL 12090660, at *3 (E.D. Tex. Mar. 7, 2013), *report and recommendation adopted*, 2013 WL 12091673 (E.D. Tex. Mar. 26, 2013); *Sorenson v. Dorman Prods., Inc.*, No. 09-1579, 2009 WL 4261189, at *2 (S.D. Cal. Nov. 24, 2009). I agree with those authorities that a complaint under section 271(g) is not required to plead compliance with the notice requirement, which is a defense against liability for damages in appropriate circumstances.⁸

⁸ The parties do not cite any of those authorities. Instead, Pfizer relies on *Arctic Cat Inc. v. Bombardier Recreational Products, Inc.*, 876 F.3d 1350 (Fed. Cir. 2017), which addressed the marking statute, 35 U.S.C. § 287(a). Pfizer characterizes the marking statute as analogous to section 287(b) and argues that *Arctic Cat* stands for the proposition that “the patentee bears the

In addition, Bayer asserts that section 287(b)(1) excuses any requirement for Bayer to plead pre-suit notice. No. 26-13, D.I. 37 at 23–24. Sections 287(b)(1) and 287(b)(2) together provide that remedies for infringement under section 271(g) are normally unavailable to entities that are not given notice of infringement. Section 287(b)(1)(A), however, states that such relief is not applicable to certain parties, including any party that has “practiced the patented process.” Because Bayer has alleged that the defendants collectively, and Pfizer individually, practiced the ’118 patent, the defendants cannot obtain dismissal of any award of damages based on the absence of notice of alleged infringement.

vi. Finally, in a brief section at the end of its brief, Pfizer argues that Bayer has failed to plausibly allege infringement of section 271(g) for the same reasons that Pfizer earlier argued that Bayer has failed to plausibly allege infringement of section 271(a). No. 26-13, D.I. 31 at 22. For the same reasons that I rejected that argument under section 271(a), I reject it in the repackaged form under section 271(g).

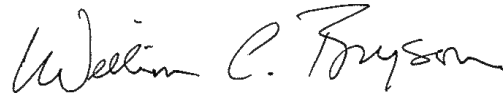
V. Conclusion

For the reasons set forth above, the defendants’ motions to dismiss the complaint are denied in both cases.

burden to plead and prove notice.” No. 26-13, D.I. 31 at 20 (citing *Arctic Cat*, 876 F.3d at 1366). But Pfizer’s characterization of *Arctic Cat* is incomplete. The court in *Arctic Cat* added that “an alleged infringer who challenges the patentee’s compliance with § 287 bears an initial burden of production to articulate the products it believes are unmarked ‘patented articles’ subject to § 287.” 876 F.3d at 1368; *see also Lubby Holdings LLC v. Chung*, 11 F.4th 1355, 1359 (Fed. Cir. 2021); *Guidance Endodontics, LLC v. Dentsply Sirona, Inc.*, No. 25-1123, 2026 WL 2287895, at *11 (D. Del. Aug. 10, 2026) (citing cases). *Arctic Cat* therefore does not support Pfizer’s argument.

IT IS SO ORDERED.

SIGNED this 28th day of September, 2026.

A handwritten signature in black ink, reading "William C. Bryson". The signature is written in a cursive style with a horizontal line underneath it.

WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE