

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

Plaintiffs,)

v.)

PFIZER INC., BIONTECH SE,)
BIONTECH MANUFACTURING)
GMBH, and BIONTECH US INC.,)

Defendants.)

C.A. No. 26-13-CFC

**DEFENDANTS PFIZER INC., BIONTECH SE, BIONTECH
MANUFACTURING GMBH, AND BIONTECH US INC.’S OPENING
BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS
PURSUANT TO RULE 12(b)(6)**

CONNOLLY GALLAGHER LLP

Arthur G. Connolly, III (#2667)
Allen R. Silverstein (#5066)
1201 North Market Street, 20th Floor
Wilmington, DE 19801
(302) 757-7300
aconnolly@connollygallagher.com
asilverstein@connollygallagher.com

FISH & RICHARDSON P.C.

Martina Tyreus Hufnal (#4771)
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
(302) 652-5070
TyreusHufnal@fr.com

Jonathan E. Singer
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
(858) 678-5634
singer@fr.com

Sara Tonnies Horton
**WILLKIE FARR &
GALLAGHER LLP**
300 North LaSalle Drive
Chicago, IL 60654-3406
(312) 728-9000
SHorton@willkie.com

Matthew Freimuth
Dan Constantinescu
**WILLKIE FARR &
GALLAGHER LLP**
787 Seventh Avenue
New York, NY 10019
(212) 728-8000
MFreimuth@willkie.com
DConstantinescu@willkie.com

Attorneys For Defendant Pfizer Inc.

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Andria R. Crisler
FISH & RICHARDSON P.C.
1717 Main Street, Suite 5000
Dallas, TX 75201
(214) 760-6138
crisler@fr.com

Dexter J.S. Whitley
FISH & RICHARDSON P.C.
1180 Peachtree Street NE, 21st Floor
Atlanta, GA 30309
(404) 724-2808
whitley@fr.com

Shelby Farrand
FISH & RICHARDSON P.C.
909 Fannin Street, Suite 2100
Houston, TX 77010
(713) 654-5313
sfarrand@fr.com

*Attorneys For Defendants BioNTech SE,
BioNTech Manufacturing GmbH, and
BioNTech US Inc.*

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I. INTRODUCTION

In 2020, Defendants Pfizer and BioNTech began producing the COVID-19 mRNA vaccine, COMIRNATY[®]. Now, almost six years later, Plaintiffs accuse COMIRNATY[®] of infringing a 2010 patent originally filed in 1989 entitled “*Synthetic Plant Genes and Method for Preparation.*” The claims identify a method of engineering plant DNA, which Plaintiffs assert reach modern mRNA vaccines.

Despite having nearly six years to investigate their purported claims, Plaintiffs do not plausibly plead infringement of a method claim in their Complaint. Instead, Plaintiffs’ conclusory, “upon information and belief” assertions improperly merge disparate conduct by different entities in different countries into undifferentiated claims of infringement. Even if accepted as true, the allegations are so lacking in substance that they do not permit a reasonable inference that Defendants performed the asserted method. The remaining claims—which are the vast majority of claims in the patent—are directed on their face to plant and/or insecticidal applications, and Plaintiffs make no effort to plead infringement of those claims. Those defects are fatal under *Twombly* and *Iqbal*.

Plaintiffs’ pleading failures are dispositive under 35 U.S.C. § 271(a). Method infringement requires domestic performance of all claim steps. Yet on the Complaint’s own allegations, at least some activities Plaintiffs rely on occurred outside the United States. A complaint does not plausibly state a claim for direct

infringement of a method under § 271(a) when it alleges a multinational process in which some asserted steps occurred abroad.

Compounding the problem, the Complaint never commits to a coherent § 271(g) theory. Plaintiffs alternately suggest that the “product” of the asserted method is either the finished vaccine or an upstream DNA template but plead facts sufficient to support neither. If the vaccine is the product, taking Plaintiff’s allegations as true, an mRNA vaccine cannot be the product of a method that, by its own terms, yields DNA. If the DNA template is the product, Plaintiffs still do not allege performance of the claim’s specific steps—or compliance with the § 271(g) notice requirements that would permit pre-suit damages for mere use.

Plaintiffs ultimately present a patchwork of assertions against different defendants in different countries and ask the Court to supply the missing legal link. The pleading rules do not permit that. Because any attempt to address the Complaint’s deficiencies would be futile, Defendants respectfully request the Court dismiss Plaintiffs’ Complaint with prejudice.

II. STATEMENT OF FACTS

In January 2020, following the emergence of SARS-CoV-2, BioNTech rapidly mobilized its vaccine research, leveraging decades of foundational work on its existing mRNA platform. (D.I. 1 (“Compl.”) ¶ 9, n.2 (excerpted as Ex. 1, highlighted), p.78–79.) In April 2020, BioNTech partnered with Pfizer. Using

methods developed through mRNA cancer-immunotherapy research in Germany, BioNTech placed a DNA sequence coding for the SARS-CoV-2 spike-protein mRNA sequence into its platform DNA template. (Ex. 1, p.166.) This platform DNA template includes important non-coding regulatory and stability elements that enhance the resulting mRNA stability and translation in human cells. (*Id.*, p.107.) BioNTech then inserted this complete DNA template into a circular DNA plasmid. (Compl. ¶ 49.) Plaintiffs allege that Pfizer then replicated the DNA plasmid to generate copies, which were used by enzymes to manufacture the mRNA that was later packaged in a lipid carrier for delivery to a patient's cells via the COMIRNATY[®] vaccine. (*Id.* ¶¶ 24, 49.)

The DNA used in plasmids is fundamentally different from the mRNA used in Defendants' COVID-19 vaccines. DNA is a double-stranded molecule made from four nucleotides—adenine (A), thymine (T), cytosine (C), and guanine (G). (*Id.* ¶ 26.) RNA is single-stranded and uses the same nucleotides A, C, and G, but substitutes *U* (uracil) for *T* (thymine). *See Mycogen Plant Science, Inc. v. Monsanto Co.*, 61 F. Supp. 2d 199, 208 (D. Del. 1999) (*cited in* Compl. ¶ 10, n.4).

Cells use DNA to express proteins through transcription and translation. (Compl. ¶ 27.) During transcription, DNA code is copied to a new RNA molecule, called messenger RNA (mRNA). (*Id.*) During translation, ribosomes read the

mRNA nucleotide sequence and assemble the corresponding amino acids into the encoded protein. (*Id.*)

The Complaint acknowledges that mRNA—not DNA—is the molecule present in COMIRNATY[®]. (*Id.* ¶ 44.) By contrast, the patent in suit—U.S. Patent No. 7,741,118 (the “’118 Patent”)—addresses modifying DNA for use in plants. (*Id.* ¶ 3.) “The ***DNA construct of the present invention*** also contains a modified or fully-synthetic structural coding sequence which has been changed to enhance the performance of the [toxic viral protein] gene in plants.” (’118 Patent at 13:56–59 (emphasis added).) The ’118 Patent attributes enhanced performance to the removal of so-called “problem sequences” from the DNA sequence. (Compl. ¶ 6; *see also* ’118 Patent at 10:8–13.)

Examples of these problem sequences are listed in Table II of the ’118 Patent:

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.

(’118 Patent at 15:50–64.) Unsurprisingly, Table II reflects DNA sequences (*T*s instead of *U*s).

Plaintiffs allege the '118 Patent's claims capture the concept of removing Table II DNA problem sequences to enhance plant expression of insecticidal proteins. (*See* Compl. ¶ 3.) Claim 1, for example, recites “[a] method of making a structural gene that encodes an insecticidal protein” comprising “reducing the number of [sequences listed in Table II].” (*See also* '118 Patent at claims 4, 7, 10, 14, 18, 51–52, 56, 58, 67, 83, 84, 87, 103.) Other claims similarly focus on general methods for making DNA constructs incorporating plant DNA sequences. (*See id.* at claims 61, 65, 83, 85.) In every case, the claimed method produces DNA—not mRNA.

Plaintiffs nevertheless contend that Claim 59 applies to COMIRNATY®. Claim 59 recites a method for making a “structural gene” comprising DNA, 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.

Plaintiffs filed this action almost six years after Defendants first dosed COMIRNATY[®], without alleging any pre-suit notice. The Complaint fails because Plaintiffs do not plausibly allege infringement; the Complaint never alleges that either Pfizer or BioNTech perform the specific steps of the claim or that the method was practiced in the U.S. In fact, Plaintiffs have pled themselves out of most—if not all—potential damages by failing to give pre-suit notice. The Court therefore should dismiss the Complaint with prejudice.

III. LEGAL STANDARDS

Rule 12(b)(6) permits dismissal of a complaint for failure to state a claim upon which relief can be granted. *See* FED. R. CIV. P. 12(b)(6). When considering such a motion, courts must accept as true all well-pleaded factual allegations in the complaint and view them in the light most favorable to the plaintiff. *See Umland v. PLANCO Fin. Servs. Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). However, “‘court[s] need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit, such as the claims and the patent specification.’” *Diogenes Ltd. v. DraftKings, Inc.*, 623 F. Supp. 3d 423, 433 (D. Del. 2022) (quoting *Yu v. Apple Inc.*, 1 F.4th 1040, 1046 (Fed. Cir. 2021)).

To survive a motion under Rule 12(b)(6), a complaint must set forth sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v.*

Iqbal, 556 U.S. 662, 678 (2009). A claim is facially plausible when the factual allegations permit the reasonable inference that the defendant is liable for the misconduct alleged. *See Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555–56.

IV. ARGUMENT

A. Plaintiffs Do Not Plausibly Plead Performance of the Claimed Method Steps

At the heart of Plaintiffs’ infringement allegations, the Complaint alleges, “upon information and belief,” that Defendants’ activities satisfy each element of claims 59, 60, 73, and 79. (Compl. ¶¶ 69, 74, 78, 81.) Plaintiffs then parrot selected claim language, make conclusory statements that Defendants engaged in the activities described therein, and, again “upon information and belief,” paraphrase the claim language while inserting references to the SARS-CoV-2 spike protein and the Accused Products. (*See id.* ¶¶ 70–72, 75–76, 79, 82.)

Plaintiffs’ allegations regarding Claim 59 are representative. The table below compares those allegations to the language of the claim itself:

Claim 59	Complaint Allegations
A method of making a structural gene that encodes a protein, the method comprising:	Upon information and belief, the method performed by Defendants in making the Accused Products satisfies all elements of Claim 59 of the ’118 Patent. (Compl. ¶ 69)
(a) starting with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II;	Defendants “start[ed] with a coding sequence that encodes a protein and that contains polyadenylation signal sequences listed in Table II.” For

	<p>example, upon information and belief, the viral coding sequences for the SARS-CoV-2 spike protein (including their respective subunit proteins) encoded by the mRNA in the Accused Products contain Table II Sequences. (<i>Id.</i> ¶ 70)</p>
<p>(b) reducing the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence; and</p>	<p>Defendants “reduc[ed] the number of said polyadenylation signal sequences in the coding sequence by substituting sense codons for codons in the coding sequence.” For example, upon information and belief, Defendants designed the SARS-CoV-2 spike protein coding sequence for the Accused Products to have a reduced number of Table II Sequences by substituting sense codons. (<i>Id.</i> ¶ 71)</p>
<p>(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.</p>	<p>Defendants “ma[de] a structural gene that comprises a coding sequence that includes the codons substituted according to step (b) and is characterized by the reduced number of Table II polyadenylation signal sequences, and that encodes the protein.” For example, upon information and belief, the Accused Products were made using and additionally include a structural gene that comprises a coding sequence with codons that were substituted according to paragraph 71 and that encodes a SARS-CoV-2 spike protein (including any subunit proteins). (<i>Id.</i> ¶ 72)</p>

Such allegations are inadequate where, as here, the technology is not simple. *See Swirlate IP LLC v. Keep Truckin, Inc.*, No. 20-1283, 2021 WL 3187571, at *2 (D.

Del. July 28, 2021) (Connolly, J.) (dismissing for lack of non-conclusory facts connecting accused product to specific claim elements).

A patentee need not prove its case at the pleading stage, but it cannot survive by reciting elements or offering allegations “merely consistent with” infringement; it must plead some facts that make infringement plausible and not internally inconsistent with the claims. *See Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1353–54 (Fed. Cir. 2021). This Court has explained that generic product references are not a substitute for connecting specific claim elements to specific product features. *Boston Sci. Corp. v. Nevro Corp.*, 415 F. Supp. 3d 482, 489 (D. Del. 2019).

Plaintiffs’ tables in Paragraph 57 do not salvage the pleading. Although labeled as “Variant *mRNAs*” “Starting Sequence”/“Vaccine Sequence,” the tables actually reflect *DNA* sequences, including from Table II of the ’118 Patent, and are pled “upon information and belief.” But those tables do not allege which claim steps either Defendant purportedly performed. That gap is fatal under applicable pleading standards. *Bot M8*, 4 F.4th at 1354 (citing *Twombly*, 550 U.S. at 557).

The ’118 Patent concedes that alternative means of reducing problem DNA sequences exist beyond the method of Claim 59, confirming that Paragraph 57’s tables do not plausibly allege that Defendants practice the claimed method. For example, the same results can be achieved through different methods that never start with the claimed DNA coding sequence; they can start instead with an *amino acid*

sequence. (*See, e.g.*, '118 Patent at 12:39–43, claims 10, 14, 18, 65, 85 (referring to a method of reducing problem sequences by starting with an amino acid sequence, rather than a DNA coding sequence).) The Court need not choose among alternatives or resolve technical disputes at the motion to dismiss stage; it is enough that the Complaint fails to plead facts tying Defendants to the claimed steps rather than other methods. *Bot M8*, 4 F.4th at 1355.

The Complaint also fails to plausibly allege infringement of the vast majority of the '118 Patent's claims for an additional reason. With the exception of claims 59, 60, 63–64, 73–74, 77–79, and 81, every claim in the '118 Patent includes express language that requires using either *Bacillus thuringiensis* (B.t.) genes that encode insecticidal proteins,¹ or “plant promoter” and “plant virus promoter” gene sequences.² In contrast, COMIRNATY[®] is an mRNA vaccine for humans that cannot infringe these claims, and Plaintiffs make no effort to allege any facts making infringement plausible.

Accordingly, the Complaint should be dismissed for failure to state a claim for infringement.

¹ *See* '118 Patent, independent claims 1, 4, 7, 10, 14, 18, 51, 52, 56, 58, 67, 83, 84, 87, 103, and claims depending therefrom.

² *See id.*, independent claims 61, 65, 83, 85, and claims depending therefrom.

B. The § 271(a) Claims Should Be Dismissed with Prejudice Because Plaintiffs Do Not Plausibly Allege the Claimed Method Was Practiced in the United States

Plaintiffs' § 271(a) claim also fails because the Complaint does not plausibly allege that Defendants performed the patented method in the U.S. Infringement of a method claim under Section 271(a) requires a patentee to plead facts showing that each and every step of the claimed method was performed within the United States. *See NTP, Inc. v. Rsch. In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005). Courts in this district also apply this rule. *See F45 Training Pty Ltd. v. Body Fit Training USA Inc.*, No. 20-cv-1194, 2022 WL 17177621, at *16 (D. Del. Nov. 17, 2022) (Bryson, J.) (concluding that method claims were not infringed because two of the claimed steps were performed outside the United States).

Here, the only entity that Plaintiffs specifically accuse of performing the claimed optimization method is BioNTech. (*See* Compl. ¶¶ 9, 47 (“BioNTech has acknowledged that it utilizes codon optimization in its mRNA products.”); *see also id.* ¶ 46 (identifying purported activity by BioNTech in the context of “optimizing”); *id.* ¶ 51 (alleging that BioNTech developed mRNA-based vaccine candidates including “the spike protein and selected domains of the spike protein”).) BioNTech is in Germany. (*Id.* ¶¶ 16–17.)

The Complaint briefly references BioNTech’s U.S. entity, but the cited documents³ confirm that BioNTech SE (in Germany) did not acquire the U.S. entity until May 6, 2020, when it purchased Neon Therapeutics. (Ex. 1, p.166–67, 179.) By then, the first human dosing of BNT162 in the U.S. had already begun and the vaccine candidates had already been designed and selected. (*See id.*, p.79; *see also* BioNTech SE May 2020 Form 6-K (May 5, 2020), <https://perma.cc/6ZPM-VU9A> (Ex. 2, highlighted) (announcing that BioNTech and Pfizer dosed the first participants in the U.S. with the COVID-19 mRNA vaccine on May 5, 2020).) The Complaint confirms that in early 2020—when BioNTech developed the BNT162 vaccine candidates—BioNTech operated only in Germany. (Ex. 1, p.166.)

With respect to the later variants, Plaintiffs do not allege that BioNTech US developed or redesigned variant sequences from scratch by practicing the asserted method in the U.S.; rather the Complaint alleges variant vaccines “used similar coding sequence design protocols,” which does not plausibly allege new or domestic performance of the claimed method. (Compl. ¶ 57.) Taking those allegations and

³ The Court may take judicial notice of documents submitted to the Securities and Exchange Commission. *See, e.g., In re Delmarva Sec. Litig.*, 794 F. Supp. 1293, 1299 (D. Del. 1992). The Court may also rely on documents cited in the Complaint. *See Network Managing Sols., LLC v. AT&T Inc.*, No. CV 16-295-RGA-MPT, 2017 WL 5195863, at *4 (D. Del. Nov. 9, 2017), *report and recommendation adopted sub nom. Network Managing Sols., LLC v. AT&T Mobility, LLC*, No. CV 16-295-RGA, 2017 WL 11553316 (D. Del. Dec. 1, 2017).

the documents cited in the Complaint into account, Plaintiffs cannot legally assert infringement of § 271(a). *See NTP*, 418 F.3d at 1318.

Plaintiffs' conclusory and unfounded allegations based "[u]pon information and belief" that "Defendants have optimized and manufactured their infringing mRNA vaccine products starting with a DNA template in the United States" do not fix the problem. (Compl. ¶ 49; *see also id.* ¶ 58.) First, those allegations flatly contradict Plaintiffs' cited materials. Allegations that conflict with documents subject to judicial notice are not credited when a ruling on a 12(b)(6) motion. *See Realtime Data LLC v. Array Networks Inc.*, 556 F. Supp. 3d 424, 434 (D. Del. 2021) (Connolly, J.). Second, because of BioNTech's alleged role and its location in Germany, some (or all) of the claimed steps must have occurred outside of the U.S. That is dispositive: because some (or all) steps occurred outside of the U.S., there cannot be infringement under § 271(a) as a matter of law. *See F45 Training*, 2022 WL 17177621, at *16.

Plaintiffs thus fail to state a plausible claim for direct infringement under § 271(a). Because repleading would be futile in view of the materials cited in the Complaint, Plaintiffs' claims under § 271(a) should be dismissed with prejudice.

C. The § 271(g) Claims Also Fail in Their Entirety

Presumably aware of their § 271(a) problems, Plaintiffs also plead infringement under § 271(g). Section 271(g) imposes liability only on "[w]hoever

without authority imports into the United States or offers to sell, sells, or uses within the United States *a product which is made by* a process patented in the United States.” 35 U.S.C. § 271(g) (emphasis added). The Complaint never commits to a coherent § 271(g) theory, however, and alternately suggests that the “product” of the asserted method is either the finished vaccine or an upstream DNA template. Ultimately, that ambiguity makes no difference: Plaintiffs’ § 271(g) claims fail under both alternatives.

If the vaccine is the “product,” Plaintiffs cannot plausibly state a claim as to BioNTech because the Complaint does not plausibly allege that BioNTech imports the vaccine; and, as to both Defendants, the *mRNA* vaccine cannot plausibly be the output of the claimed method that results in a *DNA* construct. Moreover, Plaintiffs’ allegations describing the process to make the mRNA vaccine from a DNA template amount to a material change that also defeats § 271(g) liability for the vaccine as the “product.”

If the DNA template is the “product,” Plaintiff’s failure to allege 35 U.S.C. § 287(b)(2) notice bars § 271(g) pre-suit damages at least against Pfizer, and Plaintiffs still fail to plausibly tie the DNA template back to the claimed method.

1. *The Vaccine is Not the “Product . . . Made By” the Claimed Method*

Plaintiffs define the “Accused Products” as COVID-19 vaccines and boosters, (Compl. ¶ 67), but never clarify whether those are also the § 271(g) “product.”

Assuming that to be the case, however, Plaintiffs' § 271(g) claims fail against both Pfizer and BioNTech.

a. Plaintiffs Have Not Plausibly Pled Infringement Under § 271(g) with Respect to Defendants' COVID Vaccines

As to BioNTech, the Complaint never alleges BioNTech imported, sold, offered for sale, or used COMIRNATY®. (*See id.*, ¶ 49.) Whether BioNTech performed all activity in Germany or split steps with Pfizer in the U.S., (*id.*), BioNTech's only conceivable § 271(g) liability would be importation—and the Complaint pleads no facts that BioNTech imported vaccines. The bare assertion that BioNTech “import[ed] the Accused Product,” (*id.*, ¶ 83), contradicts the Complaint's own allegations, (*id.* ¶ 49 (alleging that “Defendants have optimized and manufactured their infringing mRNA vaccine products starting with a DNA template in the United States”)), and is not entitled to credit.

The § 271(g) theory fares no better against Pfizer. The patent claims a DNA-modification method; the Accused Products are lipid-based mRNA vaccines. Claim 59—the sole asserted independent claim—requires “starting with a coding sequence” containing the Table II motifs and then reducing those motifs to make a structural gene. ('118 Patent, cl. 59.) The listed motifs are DNA, as reflected by the inclusion of T, thymine. (Compl. ¶ 26.) RNA, including mRNA, uses uracil (U), not T. (*See id.*, ¶ 34 (citing '118 Patent at 1:53–62).) Thus, the claimed method produces DNA. The Accused Products—mRNA vaccines—are plainly not DNA.

(*See id.*, ¶ 44.) The mRNA vaccines that Pfizer makes and sells are therefore not a “product . . . made by” the claimed process, and the Complaint pleads nothing to the contrary.

Plaintiffs cannot correct these deficiencies by repleading their § 271(g) claims with respect to Defendants’ COVID vaccines. Consequently, those claims should be dismissed with prejudice.

b. Plaintiffs Do Not—and Cannot—Plead Around the Material-Change Bar

Even if Plaintiffs could plausibly allege a “product . . . made by” the claimed method, § 271(g) still fails because the allegations themselves establish a material change between any DNA intermediate and the finished mRNA vaccine. Section 271(g) “does not apply if the product made by the patented process is ‘materially changed by subsequent processes’” before the accused act. *Eli Lilly and Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1571 (Fed. Cir. 1996) (quoting 35 U.S.C. § 271(g)(1)). Here, based on Plaintiffs’ own allegations, any DNA intermediate requires material changes like downstream transcription and formulation steps to produce the accused vaccines. (*See, e.g.*, Compl. ¶ 49.) Taken as true, these facts do not plausibly support § 271(g) liability.

The Federal Circuit assesses “material change” by asking two questions: (a) whether the end product reflects a significant change in structure and properties from the product of the patented process and (b) whether, notwithstanding any intervening

steps, the end product could not be made without using the patented process. *Eli Lilly*, 82 F.3d at 1573, 1575.

Courts have not spoken with one voice on whether “material change” is always resolved as a matter of law or may, in closer cases, present a fact-intensive inquiry. *See, e.g., Kyowa Hakka Bio, Co., Ltd. v. Ajinomoto Co., Inc.*, No. 17-313, 2018 WL 834583, at *9 (D. Del. Feb. 12, 2018). The court need not consider that distinction here, however, because Plaintiffs’ own allegations plead downstream steps that effect a substantial change in structure and properties, (*see* Compl. ¶ 49), leaving no plausible basis to infer a product “made by” the patented process. As a result, Plaintiffs have pled themselves out of this § 271(g) claim. *See Bot M8*, 4 F.4th at 1354 (explaining that plaintiff “essentially pleaded itself out of court” by making factual allegations that contradicted infringement).

Taking Plaintiffs’ allegations as pled, the accused mRNA vaccine arises only after downstream steps that substantially change the structure and utility of any DNA intermediate, and Plaintiffs nowhere allege the asserted method is the only possible or commercially viable route to the vaccine. Under *Eli Lilly*, either defect is fatal.

i. Plaintiffs plead structural and functional changes that bar § 271(g) liability

At Rule 12(b)(6), the question is plausibility. On Plaintiffs’ allegations, any “coding sequences and/or DNA template” is transcribed into mRNA and then formulated into the finished, lipid-based vaccine through multiple downstream steps,

(Compl. ¶ 67)—precisely the kind of structural/functional transformation § 271(g) excludes. *See Eli Lilly*, 82 F.3d at 1573–77.

The Federal Circuit’s touchstone for “material change” is whether there is a “significant change in the [] structure and properties” between the process output and the end product; minor form changes (e.g., tablet vs. powder) or trivial conversions (salts/esters, protecting-group removal) are not “material,” but substantive transformations are. *Id.* Courts apply the same rule in biologics: downstream genetic/manufacturing steps yielding a new molecule with new properties create the “real difference” that breaks the requirements of § 271(g). *Genentech, Inc. v. Boehringer Mannheim GmbH*, 47 F. Supp. 2d 91, 106–07 (D. Mass. 1999).

Measured against that standard, Plaintiffs’ own narrative confirms the break. At most, the claimed method yields a portion of the DNA template that is “used to make” the vaccines. (Compl. ¶ 67.) Plaintiffs’ manufacturing story then describes a sophisticated, multi-step conversion process. (*Id.* ¶ 49.) According to the Complaint, Pfizer’s facility in Missouri provides DNA plasmids; in Massachusetts, Pfizer uses enzymes to pry open the DNA templates and transcribe them into mRNA; in Michigan, Pfizer formulates, finishes, and packages mRNA into the lipid-based vaccine. (*Id.*) These pleaded steps are textbook material changes, severing § 271(g) liability. *See Eli Lilly*, 82 F.3d at 1573–77.

ii. Plaintiffs plead no essential, but-for use of the claimed method

Plaintiffs’ § 271(g) theory that the vaccine is “made by” an upstream DNA method also fails because *Eli Lilly* requires that the accused product could not be made—or made commercially viably—*but for* use of the patented process. *See id.*, at 1575.

The Federal Circuit’s decision in *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996) (“*BTG*”), illustrates the narrow circumstances in which this requirement can be met. There, the court treated a downstream protein as “made by” an upstream plasmid-construction process because, on a preliminary injunction record, the patented method was the sole way to obtain the therapeutic protein. *BTG*, 80 F.3d at 1556, 1561–62 (noting that prior to the asserted patents, the imported therapeutic protein could only be obtained from human cadavers). That essential-use showing is wholly absent here.

Plaintiffs do not allege that Defendants needed the claimed method to produce a spike-protein sequence. To the contrary, Defendants could have used other non-infringing methods to reduce Table II motifs. (*See supra* § IV.A.) Where commercially viable alternatives exist, the required connection between the patented process and the final product is broken as a matter of law. *Eli Lilly*, 82 F.3d at 1575. This independently defeats Plaintiffs’ § 271(g) claim.

2. Claims Based on the DNA Template Should Be Dismissed for Lack of Notice (As to the Pre-Suit Claims) and Failure to Plausibly Allege Infringement (For All § 271(g) Claims)

Even if the accused “product” were the “DNA Template,” (1) pre-suit damages are barred at least against Pfizer for lack of § 287(b)(2) notice and (2) the “DNA-template” theory still does not plausibly tie back to the claimed method.

a. As to Pfizer’s alleged “use” of a DNA template, pre-suit damages are barred for lack of § 287(b)(2) notice

If the § 271(g) “product” is the DNA template, any pre-suit damages against Pfizer are barred because Plaintiffs plead no pre-suit notice as required by 35 U.S.C. § 287(b)(2). When the accused party did not *perform* the claimed steps and merely possessed/used the resulting product without notice, pre-suit damages are unavailable. 35 U.S.C. § 287(b)(2); *see Seoul Viosys Co., Ltd. v. P3 Int’l Corp.*, No. 16-cv-6276, 2018 WL 4759744, at *10 (S.D.N.Y. Sept. 30, 2018) (describing § 287(b) as a “safe harbor” for § 271(g) claims and denying remedies absent notice), *aff’d*, 810 F. App’x 903 (Fed. Cir. 2020).

While the Federal Circuit has not squarely decided pleading compliance with § 287(b), it has held for the parallel statute § 287(a) that the patentee bears the burden to plead and prove notice. *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017).

Plaintiffs do not allege any pre-suit notice to Pfizer (or BioNTech)—which is unsurprising because no pre-suit notice was given. Even accepting the fallback

premise that the “product” is a DNA template, Plaintiffs do not plead Pfizer performed the claimed steps. At most, after accounting for the materials cited in the Complaint regarding BioNTech’s role in codon optimization, Plaintiffs’ allegations state only that Pfizer used the imported DNA template downstream from any optimization steps. (*See supra*, § IV.B; Compl. ¶ 49.)

Plaintiffs’ variant allegations do not change the analysis. Plaintiffs allege only that variants “used similar coding sequence design protocols,” not that any Defendant newly performed all steps of the asserted method in the U.S. (Compl. ¶¶ 56–57.) Alleging reuse of “similar” design protocols does not plausibly allege fresh performance of the claimed method, let alone domestic performance of each required step.

Under § 287(b)(2), lack of notice means that pre-suit damages cannot be tied to Pfizer’s alleged use of an imported DNA template. *See Seoul Viosys*, 2018 WL 4759744, at *10–11 (no remedy “as a matter of law” where the defendant received no § 287(b) notice prior to acquiring inventories). The Court should dismiss with prejudice any claim to § 271(g) pre-suit damages against Pfizer premised on “use” of an imported DNA template.

b. Even Assuming the “DNA Template” as the “Product,” Plaintiffs Do Not Plausibly Plead Performance of the Claimed Steps

Plaintiffs’ erroneous suggestion that the “DNA template” is the § 271(g) product does not cure the pleading defects discussed *supra*, in § IV.A. The same conclusory allegations in the Complaint apply, regardless of whether the § 271(g) product is the COMIRNATY[®] vaccine or the DNA template. (*See* Compl. ¶¶ 69, 74, 78, 81.) These allegations fail to plausibly allege infringement of the identified method claims for the same reasons explained in Section A. Plaintiffs thus have not plausibly alleged performance of the claimed steps, and the § 271(g) claim based on the DNA template should be dismissed for failure to state a claim.

V. CONCLUSION

For the foregoing reasons, the Complaint fails on multiple, independent grounds. The Court therefore should dismiss the Complaint with prejudice.

CONNOLLY GALLAGHER LLP

/s/ Alan R. Silverstein

Arthur G. Connolly, III (#2667)
Alan R. Silverstein (#5066)
1201 North Market Street, 20th Floor
Wilmington, DE 19801
(302) 757-7300
aconnolly@connollygallagher.com
asilverstein@connollygallagher.com

Sara Tonnies Horton
**WILLKIE FARR &
GALLAGHER LLP**
300 North LaSalle Drive
Chicago, IL 60654-3406
(312) 728-9000
shorton@willkie.com

Matthew Freimuth
Dan Constantinescu
**WILLKIE FARR &
GALLAGHER LLP**
787 Seventh Avenue
New York, NY 10019
(212) 728-8000
mfreimuth@willkie.com
dconstantinescu@willkie.com

Attorneys for Defendant Pfizer Inc.

Dated: March 30, 2026

FISH & RICHARDSON P.C.

/s/ Martina Tyreus Hufnal

Martina Tyreus Hufnal (#4771)
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
(302) 652-5070
tyreushufnal@fr.com

Jonathan E. Singer
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
(858) 678-5634
singer@fr.com

Andria R. Crisler
FISH & RICHARDSON P.C.
1717 Main Street, Suite 5000
Dallas, TX 75201
(214) 760-6138
crisler@fr.com

Dexter J.S. Whitley
FISH & RICHARDSON P.C.
1180 Peachtree Street NE, 21st Floor
Atlanta, GA 30309
(404) 724-2808
whitley@fr.com

Shelby Farrand
FISH & RICHARDSON P.C.
909 Fannin Street, Suite 2100
Houston, TX 77010
(713) 654-5313
sfarrand@fr.com

*Attorneys for Defendants BioNTech SE,
BioNTech Manufacturing GmbH, And
BioNTech US Inc.*

EXHIBIT 1

UNITED STATES
 SECURITIES AND EXCHANGE COMMISSION
 Washington, D.C. 20549

FORM 20-F

- (Mark One)
- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
 OR
- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
 For the fiscal year ended December 31, 2020
 OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
 OR
- SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
 Commission file number: 001-39081

BioNTech SE

(Exact name of Registrant as specified in its charter)

Federal Republic of Germany
 (Jurisdiction of incorporation or organization)

An der Goldgrube 12
 D-55131 Mainz
 Germany
 (Address of principal executive offices)

Prof. Ugur Sahin, M.D.,
 c/o BioNTech SE
 An der Goldgrube 12
 D-55131 Mainz
 Germany

+49 6131-9084-0 (Tel), +49 6131 9084-390 (Fax), info@biontech.de (E-mail)
 (Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered, pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each Representing one ordinary share Ordinary shares, no par value, with a notional amount attributable to each ordinary share of €1*	BNTX —	The Nasdaq Stock Market LLC The Nasdaq Stock Market LLC*

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report.

Ordinary shares, no par value, with a notional amount attributable to each share of €1 outstanding as of March 30, 2021, no par value: 241,521,065

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards † provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued
by the International Accounting Standards Board

Other

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

* Listed not for trading or quotation purposes, but only in connection with the registration of American Depositary Shares representing such ordinary shares pursuant to the requirements of the Securities and Exchange Commission. The American Depositary Shares are registered under the Securities Act of 1933, as amended, pursuant to a separate registration statement on Form F-6 (File No. 333-233898).

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II. Our Products and Pipeline of Product Candidates

We are advancing a deep and broad portfolio of product candidates derived from our four drug classes focused on the treatment of cancer, infectious and rare diseases to complement our commercial product, our COVID-19 vaccine:

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator	Milestones
mRNA	FluVac (live combination of shared cancer antigens)	BNT111	advanced melanoma	█	█			fully-owed	FPD ¹ phase 2: 1H 2021
		BNT112	prostate cancer	█	█			fully-owed	
		BNT113	HPV16+ head and neck cancer ¹	█	█			fully-owed	FPD ¹ phase 2: 1H 2021
		BNT114	triple negative breast cancer	█	█			fully-owed	
		BNT115	ovarian cancer ¹	█	█			fully-owed	
	iNOST (patient specific cancer antigen therapy)	autogene	IL melanoma	█	█			Genentech (global 50:50 profit/loss share)	Phase 2 trial planned in adjuvant CRC; FPD ¹ in 1H 2021
		onvovirna (BNT122)	solid tumors	█	█				
	Intratumoral Immunotherapy	SARA1006 (BNT131)	solid tumors (IL, IL2c, IL-13/na30, GM-CSF, IFN γ)	█	█				
		Ribo-Cytokines (mRNA-encoded Cytokines)	BNT151	solid tumors (optimal/IL-2)	█	█			fully-owed
	Antibodies	Near-Gen CP ² Immunomodulators	GEN1046 (BNT311)	solid tumors (PD-L1+/-JBB)	█	█			Genentech (global 50:50 profit/loss share)
GEN1042 (BNT312)			solid tumors (CD19+/-JBB)	█	█			Genentech (global 50:50 profit/loss share)	Data update 2H 2021
Largatec Cancer Antibodies		BNT321 (SMT-3875)	pancreatic cancer (L5a)	█	█			fully-owed	
SMDM ³ T cell Like Receptor Binding		BNT411	solid tumors (TLR7)	█	█			fully-owed	Data update 2H 2021
Cell Therapies	CAR-T Cells	BNT211	solid tumors (CD19)	█	█			fully-owed	Data update 2H 2021

¹BNT111 and BNT115 are currently being studied in investigator-initiated Phase 1 trials.
²Checkpoint inhibitor.
³Small Molecule Immunomodulator.
⁴FPD – First Patient Dosed

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator	Milestones
mRNA	FluVac	BNT116	NSCLC	█	█			fully-owed	
		BNT141	solid tumors	█	█			fully-owed	Phase 1 start in 2H 2021
	Ribo-MAbs (mRNA-encoded antibodies)	BNT142	solid tumors (CD3+CD28 ^{hi})	█	█			fully-owed	Phase 1 start in 2H 2021
Cell Therapies	CAR-T Cells	BNT152, BNT153	solid tumors (IL-7, IL-2)	█	█			fully-owed	Phase 1 start in 1H 2021
		BNT212	pancreatic, other cancers (CD19R, IL-2)	█	█			fully-owed	
Cell Therapies	Neonatal-based T cell therapy	BNT221 (NEO-PTC-41)	solid tumors	█	█			fully-owed	Phase 1 start in 1H 2021
		TCRs	to be selected	█	█			fully-owed	

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights Collaborator
mRNA Vaccine	COMENATY	COVID-19	█	█	█	█	█	Pfizer/Novartis
	BNT162b2 (mRNA)	COVID-19	█	█	█	█	█	Pfizer/Novartis
	BNT182b3 (modRNA)	COVID-19	█	█	█	█	█	Pfizer/Novartis
	BNT161	Seasonal Influenza	█	█				Pfizer
	Un named program	Tuberculosis	█	█				BMGF*
	Un named program	HIV	█	█				BMGF*
Antibodies	5 un named programs	Undisclosed indications	█	█				Fully-owed
	Undisclosed program	COVID-19	█	█				Fully-owed

*BMGF – Bill & Melinda Gates Foundation

Our mRNA COVID-19 vaccine product has been authorized or approved for emergency or temporary use or granted conditional marketing authorizations in over 69 countries worldwide.

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program, BNT162, in late January 2020, leveraging our proprietary mRNA platform, and assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China). In April 2020, we initiated a first-in-human clinical trial of BNT162b2 following preclinical studies. In July 2020, we initiated, along with our partner Pfizer, a phase 3 clinical trial of BNT162b2 and published the clinical results in November 2020. Subsequently, our COVID-19 vaccine has been authorized or approved for emergency use or temporary use or granted conditional marketing authorization in over 65 countries around the world, including the United States, the United Kingdom, and Canada and has received CMA following rolling submissions with the EMA.

We seek to drive long-term sustainable revenues from our COVID-19 vaccine program by increasing patient access through enhancing manufacturing and supply capabilities, broadening distribution geographies, expanding the label, and optimizing the formulation.

Clinical Research and Development

We and Pfizer have jointly conducted clinical trials for COVID-19 vaccine candidates across approximately 150 clinical trial sites globally. In late April 2020, we and Pfizer announced that the German regulatory authority, the Paul-Ehrlich-Institut, approved the Phase 1/2 clinical trial and the first patients in the first cohort of the Phase 1/2 clinical trial were dosed shortly thereafter. In early May 2020, we and Pfizer initiated a clinical trial for BNT162 in the U.S. and the first participants were dosed shortly thereafter.

Based on preclinical and clinical data observed, we and Pfizer progressed our BNT162 program into a Phase 2b/3 trial which commenced in late July 2020. For the initial Phase 2b/3 trial, we selected our nucleoside-modified mRNA (modRNA) vaccine candidate variant targeting the 2P-mutated full spike protein, BNT162b2. Both BNT162b2 and our BNT162b1 vaccine candidate, which uses modRNA and encodes the receptor binding domain antigen, received Fast Track status from the FDA. On the basis of data collected and analyzed for BNT162b1 and BNT162b2, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, along with input from the FDA, we selected BNT162b2 as our lead candidate to take into a Phase 2b/3 trial.

The Phase 3 clinical trial of BNT162b2 began in July 2020 and enrolled more than 44,000 participants from approximately 150 clinical trials sites in the United States, Germany, Turkey, South Africa, Brazil and Argentina. The Phase 3 trial is designed as a 1:1 vaccine candidate to placebo, randomized, observer-blinded study to obtain safety, immune response, and efficacy data needed for regulatory review.

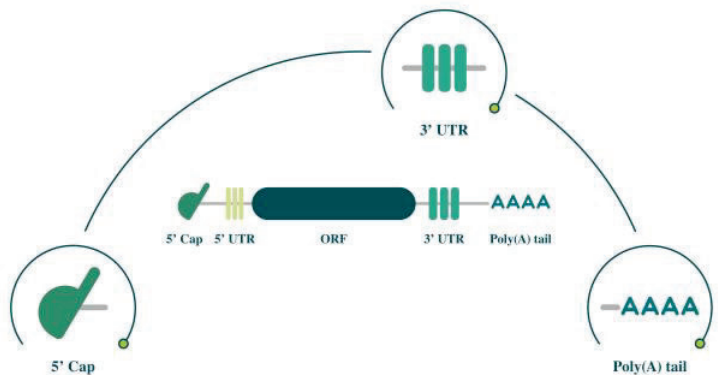
In August 2020, we and Fosun initiated a Phase 1 study to evaluate safety and immunogenicity in Chinese participants. In November 2020, we initiated a Phase 2 clinical trial of vaccine candidate BNT162b2 in Jiangsu Province, China to assess the safety and immunogenicity of the vaccine candidate and to support future Biologic License Application (BLA) in China.

On October 6, 2020, we announced the initiation of a rolling submission to the European Medicines Agency (EMA) for BNT162b2. The EMA's decision to start a rolling review follows the encouraging preliminary results from pre-clinical and early clinical studies in adults, which suggest that BNT162b2 triggers the production of neutralizing antibodies and TH-1 dominant CD4+ and CD8+ T cells that target SARS-CoV-2. A combination of an antibody and T cell response is believed to be important in eliciting protection against viral infection and disease.

On October 21, 2020 we and Pfizer announced initiation of a Phase 1/2 clinical trial in Japan to evaluate safety, tolerability and immunogenicity of two doses separated by 21 days and a single dose of BNT162b2.

On November 18, 2020, we and Pfizer announced that, after conducting the final efficacy analysis in our ongoing Phase 3 study, BNT162b2 met all of the study's primary efficacy endpoints. In this pivotal Phase 3 trial of BNT162b2, there were over 44,000 participants who were 16 years and older, 21,720 of whom received the two-dose regimen of 30 µg BNT162b2, which was given 21 days apart, and 21,728 of whom received the placebo. Among 36,523 participants who had no evidence of existing or prior SARS-CoV-2 infection at the time of the immunizations, there were 170 cases of COVID-19 observed at least seven days after the second dose. Of these 170 cases of COVID-19, 162 cases occurred among placebo

B. Our mRNA Backbone consists of the following:
Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the poly(A) tail, in addition to a coding sequence, that are all encoded by our DNA template.



- The cap is added to the 5' end of the mRNA during its synthesis. Our studies have demonstrated that incorporation of a unique cap analogue into the mRNA helps to achieve superior translational performance by stabilizing the mRNA molecule and directing the immune response. This unique cap analogue is extremely useful for our immunotherapy approaches.
- The composition and structure of the 5' and 3' untranslated regions of the mRNA molecule are important determinants of the intracellular stability of mRNA. As a result of rigorous screening of different mRNA sequences, we identified specific UTRs that promote increased protein translation for long duration.
- We have performed extensive research on the structure of the poly(A) tail and the translational performance of mRNA and customized our template design accordingly.

See Item 18.

D. Property, Plant and Equipment

Our headquarters are located in Mainz, Germany, where we occupy:

- Approximately 9,416 square meters (equivalent to approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space under a lease for the entire building located at An der Goldgrube 12, 55131 Mainz under a lease that has an initial term that expires on October 31, 2027, but which we have the option to extend until October, 2042.
- Approximately 1,069 square meters (equivalent to approximately 11,507 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 17019, 44116 Mainz under a lease that expires in March 31, 2022.
- Approximately 4,882 square meters (equivalent to approximately 52,549 square feet) of flexible use space intended for laboratory and office use located at Adam-Opel-Straße 10, 55129 Mainz, which is owned by us.
- Approximately 210,639 square meters (equivalent to approximately 22,673 square feet) of office and storage space under a lease for part of the building located at Robert-Koch- Straße 50, 55129 Mainz under a lease that expires in November 15, 2025.
- Approximately 82,881 square meters (equivalent to approximately 892,124 square feet) of office space and a further area of land associated with this office space of approximately 12,600 square meters (equivalent to approximately 135,625 square feet), which is owned by BioNTech.
- Approximately 360 square meters (equivalent to approximately 3,875 square feet) of office space under a lease for part of the building located at Heiligkreuzweg 90, 55130 Mainz under a lease that expires in December 31, 2022.
- We also own a plot of land of approximately 8,753 square meters (equivalent to 94,216 square feet) at Hechtsheimer Straße, 55131 Mainz, where construction for a GMP manufacturing facility has commenced early this year.

In addition, our BioNTech IMFS facility in Idar-Oberstein, Germany, occupies approximately 2,800 square meters (equivalent to approximately 30,140 square feet). This includes 650 square meters (approximately 7,000 square feet) of clean room area, and 700 square meters (approximately 7,500 square feet) of development and quality control laboratories. We occupy approximately 575 square meters (equivalent to approximately 6,200 square feet) of this space, which is used primarily for storage, under a lease that has an initial expiry date of October 1, 2021, but which we have the right to extend by an additional five years. We occupy approximately 100 square meters (equivalent to approximately 1,075 square feet) of this space, which is used primarily for storage, under a lease that can be terminated by either party on six months' written notice (but not earlier than May 1, 2020). We occupy approximately 80 square meters (equivalent to approximately 860 square feet) of this space, which is used as office space, under a lease that can be terminated by either party on three months' written notice. The rest of this facility, including the GMP-certified manufacturing suites, is owned by BioNTech. We also recently purchased a building of approximately 802 square meters (equivalent to 8,632 square feet) near our IMFS facility in Idar-Oberstein, which will be used as office space.

We have completed construction of two new buildings at our BioNTech IMFS facility in Idar-Oberstein, Germany, occupy an additional 780 square meters (equivalent to approximately 8,395 square feet) of clean room space and 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing and 650 square meters (equivalent to approximately 7,000 square feet) of office space.

At our manufacturing facility in Marburg, Germany, we occupy approximately 10,240 square meters (equivalent to approximately 110,220 square feet), including 4,589 square meters (equivalent to approximately 49,400 square feet) of GMP space, 2,422 square meters (equivalent to approximately 26,070 square feet) of technical and storage facilities, 540 square meters (equivalent to approximately 5,810 square feet) of laboratory space and 2,690 square meters (equivalent to approximately 28,960 square feet) of offices. That lease will expire December 31, 2034.

At our JPT facility in Berlin, Germany, we occupy approximately 1,794 square meters (equivalent to approximately 19,297 square feet) of laboratory and office space (equivalent to approximately 2,690 square feet) is occupied under a lease, which has an expiry date of June 20, 2020 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. Approximately 1,523 square meters (equivalent to approximately 16,199 square feet) are occupied under a lease on an indeterminate period but which may be terminated by either party on 12 months' prior written notice. The remaining approximately 20 square meters (equivalent to approximately 215 square feet) of storage space is occupied under a lease on a monthly basis and can be terminated by either party giving two weeks' written notice.

In Martinsried, Germany, outside Munich, Germany, we occupy approximately 1,681 square meters (equivalent to approximately 18,100 square feet) under a lease that had an initial term which expired on December 31, 2020, but which we exercised the option to extend until December 31, 2024.

In Neuried, Germany, outside Munich, Germany, we occupy approximately 725 square meters (equivalent to approximately 7,800 square feet) of laboratory and office space under a lease that expires on December 31, 2021, but which we have the option to extend until December 31, 2026. If the lease is not terminated before December 31, 2021 (where the option is not exercised) or December 31, 2026 (where the option is exercised) the lease will renew automatically for an additional one-year period until terminated by either party on 12 months' prior written notice.

In Halle (Saale), Germany, we have since the beginning of 2020 occupied approximately 415 square meters (equivalent to approximately 4,467 square feet) of office and other space under a lease that expires on February 28, 2022. We further occupy 90 square meters (equivalent to approximately 968 square feet) of laboratory space under a lease that also expires on February 28, 2022. Each lease will renew automatically for an additional one-year period until terminated by either party on six months' prior written notice to expire at the end of the lease period (or any extension thereof).

In Cambridge, Massachusetts we occupy approximately 2,490 square meters (equivalent to approximately 26,802 square feet) of laboratory and office space under a lease that has an initial term that expires on September 30, 2024, but which we have the option to extend until December 31, 2024.

We intend to expand our capacity as follows:

- In the second quarter of 2021, we will commence construction of a four-story building at our BioNTech Campus at An der Goldgrube 12 in Mainz, Germany, which we will own. We have planned laboratory space for research and development, offices, storage facilities, a conference center and cafeteria. As a result, we will occupy an additional 24,000 square meters (equivalent to approximately 258,300 square feet) of laboratory space and office space.
- We anticipate purchasing property and the construction of a new office building adjacent to the planned iNeST GMP manufacturing facility. Upon completion of the construction project, we will occupy up to approximately 6100 additional square meters (equivalent to approximately 65,650 square feet) of useable floor space for offices, storage, meeting areas and cafeteria.
- We anticipate completing the construction of a new building complex for our JPT business in Berlin, Germany, possibly as early as 2023. Upon completion of the construction project, we will occupy up to approximately 5,000 additional square meters (equivalent to approximately 53,820 square feet) of useable floor space split between laboratories, offices and storage.

We are committed to the continued development of world-class laboratory and manufacturing operations to support our research and development and clinical manufacturing needs, to prepare for commercial scale manufacturing of our product candidates, and to realize external commercial opportunities. Our planned laboratory and manufacturing investments include:

- two new buildings at our BioNTech IMFS facility, including three floors each of clean rooms and additional development and quality control laboratories;
- our planned commercial scale facility in Mainz, which will occupy more than 100,000 square feet and will house cleanrooms, laboratories and offices;
- an expansion of our JPT facility, which is designed to more than double our capacity; and
- an expansion of our laboratory space for research and development on our Mainz campus.

Other Operating Income / Expenses

During the year ended December 31, 2019, our other operating income amounted to €2.7 million, €1.5 million of which constituted government grants. In the year ended December 31, 2018, our other operating income amounted to €5.4 million, €4.2 million of which constituted government grants.

Finance Income / Expenses

During the year ended December 31, 2019, our finance income amounted to €4.1 million, €2.3 million of which was attributable to unrealized foreign exchange gains. During the year ended December 31, 2018, our finance income amounted to €8.0 million, €6.1 million of which was attributable to unrealized foreign exchange gains.

During the year ended December 31, 2019, our finance expense amounted to €0.3 million. During the year ended December 31, 2018, our finance expense amounted to €48 thousand. In both years, no foreign exchange losses were reported under finance expense.

During the years ended December 31, 2019 and December 31, 2018, interest expenses related to lease liabilities amounted to €1.7 million, for each year.

Tax Losses

As of December 31, 2019, we had accumulated tax losses of €356.0 million with respect to corporate tax and €352.3 million with respect to trade tax as of December 31, 2019.

Deferred tax assets on tax losses had not been capitalized in previous years, as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized. The accumulated tax losses as at December 31, 2019 relate to Germany and the United States (as at December 31, 2018: Germany). There is no expiration date for any of the accumulated tax losses under German tax law. The tax losses generated in the United States prior to December 31, 2017 begin to expire in 2033. Any tax losses generated after that date have no expiration date and can be carried forward indefinitely. The tax credits incurred in the United States are expected to expire at various dates beginning in 2035.

Information about our operating segments

Historically we reported four segments: Clinical, Technology Platform, Manufacturing and Product Sales & External Services. In the course of the year ended December 31, 2020, we leveraged the breadth of our immunotherapy technologies and used our expertise to mobilize these rapidly to address the COVID-19 pandemic. In December 2020, our COVID-19 vaccine was authorized or approved for emergency or temporary use or granted conditional marketing authorization in over 65 countries worldwide. Beginning in the fourth quarter, given the financial and operational significance of the activities to develop and then market, produce and transport the COVID-19 vaccine, our Management Board, as the chief operating decision maker (CODM), reviewed financial information presented on a consolidated basis. Decisions with respect to business operations and resource allocations are made by the CODM based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

Related Party Transactions

Related party transactions that occurred during the years ended December 31, 2020 and December 31, 2019 are explained in Item 7 of this Annual Report as well as in Note 21 of our consolidated financial statements included elsewhere in this Annual Report.

Merger Agreement with BioNTech US Inc. (formerly Neon Therapeutics, Inc.)

On May 6, 2020, we acquired Neon Therapeutics, Inc. (formerly Nasdaq: NTGN), or Neon, a biotechnology company developing novel neoantigen-based T-cell therapies, through a stock transaction and including de minimis cash consideration, or the Merger. The Merger was announced on January 16, 2020. Neon, now BioNTech US Inc., or BioNTech US, is operated as a wholly-owned subsidiary of BioNTech SE. The new subsidiary is based in Cambridge, Massachusetts and serves as our U.S. headquarters.

EXHIBIT 2

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE
SECURITIES EXCHANGE ACT OF 1934**

**FOR THE MONTH OF MAY 2020
COMMISSION FILE NUMBER 001-39081**

BioNTech SE

(Translation of registrant's name into English)

**An der Goldgrube 12 D-
55131 Mainz Germany
+49 6131-9084-0**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

On May 5, 2020, BioNTech SE (the “Company”) issued a press release, announcing that the Company and Pfizer Inc. dosed first participants in the U.S. as part of global COVID-19 mRNA vaccine development program. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Financial Officer

Date: May 5, 2020

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Press Release dated May 5, 2020 - Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program.



Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program

- *First participants dosed at NYU Grossman School of Medicine and University of Maryland School of Medicine*
- *Pfizer and BioNTech ramping up manufacturing capabilities to further increase production capacity in 2020/2021*

NEW YORK, USA, and MAINZ, Germany, May 5, 2020 (GLOBE NEWSWIRE) – Pfizer Inc. (NYSE:PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. This U.S. trial is part of a global development program, and the dosing of the first cohort in Germany was completed last week.

The Phase 1/2 study is designed to determine the safety, immunogenicity and optimal dose level of four mRNA vaccine candidates, and is to be evaluated in a single, continuous study. The dose level escalation portion (Stage 1) of the Phase 1/2 trial in the U.S. will enroll up to 360 healthy subjects into two age cohorts (18-55 and 65-85 years of age). The first subjects immunized in Stage 1 of the study will be healthy adults 18-55 years of age. Older adults will only be immunized with a given dose level of a vaccine candidate once testing of that candidate and dose level in younger adults has provided initial evidence of safety and immunogenicity. Sites currently dosing participants include NYU Grossman School of Medicine and the University of Maryland School of Medicine. The University of Rochester Medical Center/Rochester Regional Health and Cincinnati Children's Hospital Medical Center will begin enrollment shortly.

"With our unique and robust clinical study program underway, starting in Europe and now the U.S., we look forward to advancing quickly and collaboratively with our partners at BioNTech and regulatory authorities to bring a safe and efficacious vaccine to the patients who need it most. The short, less than four-month timeframe in which we've been able to move from pre-clinical studies to human testing is extraordinary and further demonstrates our commitment to dedicating our best-in-class resources, from the lab to manufacturing and beyond, in the battle against COVID-19," said **Albert Bourla, Chairman and CEO, Pfizer**.

Pfizer's and BioNTech's development program includes four vaccine candidates, each representing a different combination of mRNA format and target antigen. The novel design of the trial allows for the evaluation of the various mRNA candidates simultaneously in order to identify the safest and potentially most efficacious candidate to be evaluated in a greater number of volunteers in a manner that will facilitate the sharing of data with regulatory authorities in real time.

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"It is encouraging that we have been able to leverage more than a decade of experience in developing our mRNA platforms to initiate a global clinical trial in multiple regions for our vaccine program in such a short period. We are optimistic that advancing multiple vaccine candidates into human trials will allow us to identify the safest, most effective vaccination options against COVID-19," said **CEO and Co-founder of BioNTech, Ugur Sahin**.

During the clinical development stage, BioNTech will provide clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe.

In anticipation of a successful clinical development program, Pfizer and BioNTech are working to scale up production for global supply. Pfizer plans to activate its extensive manufacturing network and invest at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible for those most in need around the world. The breadth of this program should allow production of millions of vaccine doses in 2020, increasing to hundreds of millions in 2021. Pfizer-owned sites in three U.S. states (Massachusetts, Michigan and Missouri) and Puurs, Belgium, have been identified as manufacturing centers for COVID-19 vaccine production, with more sites to be selected. Through its existing mRNA production sites in Mainz and Idar-Oberstein, Germany, BioNTech plans to ramp up its production capacity to provide further capacities for a global supply of the potential vaccine.

BioNTech and Pfizer will work jointly to commercialize the vaccine worldwide upon regulatory approval (excluding China, where BioNTech has a collaboration with Fosun Pharma for BNT162 for both clinical development and commercialization).

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/channel/UCv31111111111111111111) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

Pfizer Disclosure Notice

The information contained in this release is as of May 5, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, BioNTech's mRNA vaccine program, BNT162, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine and manufacturing capacity, including their potential benefits, and the expected timing of clinical trials and potential supply, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or

implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for any potential vaccine candidates under the collaboration; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such vaccine candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such vaccine candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.Pfizer.com.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

BioNTech Forward-looking Statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the timing to initiate clinical trials of BNT162; collaborations between BioNTech and Pfizer, and

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BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: competition to create a vaccine for COVID-19 and potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which has been filed with the SEC and is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

BioNTech Media Relations

Jasmina Alatovic
Senior Manager Global External Communications
Tel: +49 (0)6131 9084 7640 or +49 (0)151 1978 1385
E-mail: media@biontech.de

BioNTech Investor Relations

Sylke Maas, Ph.D.
VP Investor Relations & Business Strategy
Tel: +49 (0)6131 9084 1074
E-mail: Investors@biontech.de

Pfizer Media Relations

Amy Rose (U.S.)
+1 (212) 733-7410
amy.rose@pfizer.com

Lisa O'Neill (UK)

+44 7929339560
lisa.o'neill@pfizer.com

Pfizer Investor Relations

Ryan Crowe
+1 (212) 733-8160
ryan.crowe@pfizer.com