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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Allele Biotechnology and Pharmaceuticals, Inc., a California corporation

Plaintiff,

v.

Pfizer, Inc., a Delaware corporation; BioNTech SE, a German company; BioNTech US, Inc., a Delaware corporation; and DOES 1-30

Defendants.

Case No. '20CV1958 GPC AHG

**COMPLAINT FOR PATENT INFRINGEMENT**

**JURY TRIAL DEMAND**

Plaintiff Allele Biotechnology and Pharmaceuticals, Inc. (hereafter "Allele") brings this Complaint for monetary and declaratory relief against Defendants Pfizer, Inc., a Delaware corporation ("Pfizer"), BioNTech SE, a German company, and BioNTech US, Inc., a Delaware company (collectively "BioNTech") (and each

Defendant collectively "Defendants") to address Defendants' infringement of Allele's patent related to Defendants' COVID-19 vaccine, BNT162.

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, based on Defendants' infringement of United States Patent No. 10,221,221 ("the '221 Patent").

## INTRODUCTION

2. Prior to the current COVID-19 crisis, Allele had already developed the revolutionary mNeonGreen. mNeonGreen belongs to Allele, as does the '221 Patent covering the exclusive right to use mNeonGreen. mNeonGreen is an artificial fluorescent that Allele painstakingly developed over many years through the genius of its inventors. It is the world's brightest monomeric fluorescent protein, dubbed by third party industry veterans as the "King of fluorescent proteins." A prominent university used mNeonGreen to make the "gold standard" COVID-19 assay for effectively testing against vaccine candidates, which Pfizer and BioNTech readily took for their own unauthorized commercial testing and development.

3. The results included selection of their BNT162 MRNA-based COVID-19 vaccine candidate currently in a Phase 3 trial. What's more, mNeonGreen has been used throughout Defendants' COVID-19 vaccine trials, right up to the present. Only through use of mNeonGreen were Defendants able to develop and test the BNT162 vaccine candidate at lightspeed making them first to market, earning them an immediate $445 million in grants and over $4 billion in sales of the vaccine to-date. All of this was simply the downstream benefit that Defendants enjoyed (and presumably the world will enjoy from the vaccine) from their choice to use Allele's mNeonGreen.

4. Allele's breakthrough in fluorescent protein technology is mNeonGreen, the latest in its history of innovation. Since 1999, Allele has been a leader in developing technology and research tools for clinical and therapeutic uses. Among other achievements, Allele's advancements have been directed to RNA

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interference, Fluorescent Proteins, Induced Pluripotent Stem Cells (iPSCs), Genome Editing, and camelid derived Single Domain Antibodies. More recently since January of 2020, Allele has been actively engaged in combating COVID-19, initiating impactful diagnostic and therapeutic platforms premised on speed, accuracy, and sensitivity.

5. This lawsuit follows because Defendants made the deliberate and calculated decision to infringe, rather than even so much as pick up the phone and seek to obtain the rights to use Allele's valuable intellectual property.

## JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271.

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1332 and 1338(a).

8. This Court has personal jurisdiction over Defendants because Defendants regularly conduct business within, and specifically direct their business activities to, the State of California and the Southern District of California ("this District"). Defendants have purposefully availed themselves of the opportunity to conduct business in this state through systematic and continuous dealings in this state. Defendants' actions that give rise to personal jurisdiction include, but are not limited to the following: making and using infringing products in this State and in this District, knowing and intending that the infringing products would be used in this District, deriving substantial revenue from the use of infringing products within this District, and expecting their infringing actions to have consequences in this District.

9. Venue is proper as to BioNTech SE in this judicial district pursuant to, *inter alia*, 28 U.S.C. § 1391(c)(3).

10. Venue also is proper as to Defendants under 28 U.S.C. § 1400(b). Each Defendant has committed, induced others to commit, or contributed to others committing, acts of infringement in this District, including by conducting an

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international trial of the vaccine utilizing mNeonGreen with over 30,000 participants and study sites including in San Diego County, Clinical Study Identifier NCT04368728. Pfizer has a regular and established place of business in La Jolla, California which on information and belief is a 25-acre campus with over half a million square feet of buildings and "one of the largest concentrations of academic and biotechnology institutions in the world." BioNTech has a regular and established place of business at 11535 Sorrento Valley Rd #400, San Diego CA, namely its 15,000 square foot US laboratory, research and development facility, which it identified as of January 2020 as its U.S. research and development hub.

**THE PARTIES**

11. Allele is a California corporation with its principal place of business being, 6404 Nancy Ridge Drive, San Diego, California 92121.

12. Allele was founded in 1999 and is recognized as a leading developer of technology for clinical and therapeutic use, such as research tools for drug candidates in vaccine trials as in the current race for the cure to COVID-19.

13. Defendant Pfizer is a company organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, NY 10017.

14. Defendant BioNTech SE, is a company organized and existing under the laws of Germany, traded in the United States on NASDAQ, with its principal place of business located in An der Goldgrube 12 Mainz, 55131 Germany. Defendant BioNTech US, Inc. is a company organized and existing under the laws of the State of Delaware with on information and belief its principal place of business located in Cambridge, Massachusetts.

15. The true names and capacities, whether individual, corporate, associate, or otherwise, of defendants DOES 1 through 30, inclusive, are unknown to Allele, who therefore sues said defendants by such fictitious names. Allele will amend this Complaint to state their true names and capacities when the same is ascertained.

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Allele is informed and believes that at all times herein mentioned, each defendant named herein was the agent of each of the remaining defendants and, in doing the things herein alleged, was acting within the course and scope of said agency. Any reference in this Complaint to the actions or inactions of any defendant, whether such reference is made to such defendant by specific name or otherwise, is also a reference to the actions or inactions of DOES 1 through 30, inclusive.

16. Defendant Pfizer is, among other things, engaged with BioNTech in the development of their BNT162 MRNA-based vaccine candidate, which was developed using Allele's mNeonGreen. The vaccine candidate is currently part of an ongoing Phase 3 trial that, on information and belief, has already surpassed enrollment of 30,000 participants as of September 2020. Based on promising results (premised on Defendants' use of mNeonGreen, which itself does not require government approval for clinical use), the U.S. government and U.S. Department of Health and Human Services have ordered up to 600,000,000 doses of their vaccine candidate.

17. At all times mentioned herein, defendants, and each of them, were the agents, servants, co-conspirators, or employees of one another, and the acts and omissions herein alleged were done or suffered by them, acting individually and through or by their alleged capacity, within the scope of their authority. Each of the defendants aided and abetted and rendered substantial assistance in the accomplishment of the acts complained of herein. In taking the actions, as particularized herein, to aid and abet and substantially assist in the commission of the misconduct complained of, each defendant acted with an awareness of his, her or its primary wrongdoing and realized that his, her or its conduct would substantially assist in the accomplishment of that misconduct and was aware of his, her or its overall contribution to, and furtherance of the conspiracy, common enterprise, and common course of conduct. Defendants' acts of aiding and abetting included, inter alia, all of the acts each defendant is alleged to have committed in furtherance of the

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conspiracy, common enterprise, and common course of conduct complained of herein.

## FACTS

### Background

18. Messrs. Nathan C. Shaner, Gerard G. Lambert, Yuhui Ni, and Jiwu Wang are joint inventors (collectively "Inventors") of the '221 Patent, entitled "Monomeric yellow-green fluorescent protein from cephalochordate" and which issued on March 5, 2019. A true and correct copy of the '221 Patent is attached hereto as Exhibit 1.

19. Although the invention(s) set forth in the '221 Patent are best described by its claims, the '221 Patent is generally directed to isolated nucleic acid sequences encoding a monomeric green/yellow fluorescent proteins, and fragments and derivatives thereof.

20. On April 28, 2014, the Inventors assigned the yet-to-be-issued '221 Patent to Allele. A true and correct copy of the assignment is attached hereto as Exhibit 2.

21. The claims of the '221 Patent encompass Allele's mNeonGreen product, which is a fluorescent protein used as a biological tag in genetic engineering work. mNeonGreen is a monomeric protein that was derived from a tetrameric wild-type yellow-green fluorescent protein isolated from the cephalochordate *Branchiostoma lanceolatum* (a "lanYFP"). In nature, two lanYFP monomers form a dimer and two dimers form an "obligate" (mandatory) tetramer. When exposed to certain wavelengths of light, the lanYFP tetramer will brightly fluoresce. However, the tetramer is large and often unsuitable as a fluorescent tag. The engineered mNeonGreen monomer is among the brightest and most stable monomeric fluorescent reporter proteins currently known.

22. The resulting mNeonGreen, synthetic lanYFP fluorescent protein described and claimed in the '221 Patent is widely recognized as a breakthrough, is

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used throughout the industry, and has been called the "King of fluorescent proteins" by Professor Amy Palmer, at the University of Colorado Boulder. Applications involving infectious viruses, such as COVID-19 vaccine work, are high concentration environments perfectly suited for mNeonGreen, as broadly recognized. *See*, Xie, et al, *Cell Host & Microbe 27, 841-848* (May 13, 2020) and Muruato, et al., bioRxiv preprint: https://doi.org/10.1101/2020.05.21.109546 (May 22, 2020), true and correct copies of each attached hereto as Exhibit 3 (hereafter "Cell Host Article") and Exhibit 4, respectively.

23. The commercial protein of mNeonGreen corresponds to SEQ ID NO:1 of the patent (claims 1, 3, 4 and 5). Allele used the nucleic acid of SEQ ID NO:2 (claim 3) to express this protein.

24. In practice, mNeonGreen facilitates quick, targeted, and precise receptor research, including for potential therapeutics to treat COVID-19. The fluorescent-tagged therapeutic proteins associated with mNeonGreen are constructed to determine receptor expression and dynamics with therapeutic outcome for high-throughput systems, as in the present global race for a vaccine to COVID-19. A key hurdle in developing a vaccine for infectious diseases, such as the novel coronavirus of COVID-19, is determining therapeutic outcome of potential drug candidates, something which mNeonGreen readily solves.

25. Where there is a race against time, weaker fluorescent alternatives are simply no option. mNeonGreen was the critical link in Defendants' COVID-19 vaccine development and its continued trial success. This research tool is even more critical in a global pandemic where the need for a vaccine to save lives has never been more crucial. While Defendants were required to obtain a commercial license from Allele, Defendants never sought a license with Allele or even contacted them.

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**Accused Products**

26. BioNTech adopted the technology protected by the '221 Patent in its COVID-19 vaccine trial. *See*, SEC Form 6K, a true and correct copy attached hereto as Exhibit 5.

27. At page 21 of Form 6K shown in Exhibit 5 Page 73, BioNTech states, "[t]he SARS-CoV-2 neutralization assay used a previously described strain of SARS-CoV-2 (USA_WA1/2020) that had been rescued by reverse genetics and engineered by the **insertion of an mNeonGreen (mNG) gene** into open reading frame 7 of the viral genome." Stated differently, the COVID-19 vaccine of Defendants' COVID-19 vaccine trial was developed by Defendants using a DNA construct with a monomeric mNeonGreen protein inserted into the recombinant and infectious SARS-COV2-19 virus.

28. Form 6K includes a copy of Mulligan et al., Phase 1/2 Study to Describe the Safety and Immunogenicity of a COVID-19 RNA Vaccine Candidate (BNT162b1) in Adults 18 to 55 Years of Age: Interim Report ("Mulligan"), a medRxiv preprint made available on July 1, 2020 at https://doi.org/10.1101/2020.06.30.20142570.

29. Mulligan contains additional information about BioNTech's work. *See* Exhibit 5 Page 62 (Exhibit 99.2, Mulligan p.1). For example, Mulligan reported dose-dependent titers of neutralizing antibodies in human subjects with safe (mild to moderate) adverse reactions:

> The SARS-CoV-2 neutralization assay used a previously described strain of SARS-CoV-2 (USA_WA1/2020) that had been rescued by reverse genetics and engineered by the **insertion of an mNeonGreen (mNG) gene** into open reading frame 7 of the viral genome.[20] This reporter virus generates similar plaque morphologies and indistinguishable growth curves from wild-type virus. Viral master stocks used for the neutralization assay were grown in Vero E6 cells as previously described.[20]

Exhibit 5 Page 73 (at Exhibit 99.2, page 12).

30. In other words, BioNTech admits in Exhibit 5 that it used (and continues using in its trials) the DNA construct described in the Cell Host Article to develop and test its SARS-CoV2 vaccine.

31. Defendants have used and continue using the infringing DNA construct described in the Cell Host Article.

32. In addition, scientists from the University of Texas Medical Branch (UTMB), who provides the DNA construct to Defendants, reported an "urgently needed ... fluorescent-based SARS-CoV-2 neutralization assay" with "gold standard" results. *See* Exhibit 4 Page 40). The assay of Exhibit 4 "was built on a stable mNeonGreen SARS-CoV-2" reporter virus (*Id.*, at 41) (citing the Cell Host Article) and is "superior ... because it measures functional SARSCoV-2 neutralizing activity. Notably, the mNeonGreen reporter assay offers a rapid, high throughput platform to test COVID-19 patient sera not previously available." *Id.*, at 43-44.

33. Defendants have used and continue using this infringing assay.

34. The Cell Host Article also evidences that UTMB made a "reverse genetics system" for SARS-CoV2 by assembling seven cDNA fragments into a full-genome cDNA of the virus. Three silent mutations were made to the genome as biological markers (A7486T, T7489A, and T18060C), to distinguish the recombinant virus from wild-type SARS-CoV2. *See* Cell Host Article at Exhibit 3 at 29, 31 (842, Fig. 2E). RNA transcribed from this cDNA produced a highly infectious virus that, according to UTMB, "recapitulates the replication kinetics of the original clinical isolate." *Id.*, at 29.

35. mNeonGreen was incorporated into this cDNA to make a reporter virus:

> **We generated a stable mNeonGreen SARS-CoV-2 (icSARS-CoV-2-mNG)** by introducing this reporter gene into ORF7 of the viral genome. icSARS-CoV-2-mNG was successfully used to evaluate the antiviral activities of interferon (IFN). Collectively, the reverse genetic system and reporter virus provide key reagents to study SARS-CoV-2 and develop countermeasures.

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Cell Host Article at Exhibit 3 at 28 (841 (Summary)), Exhibit 3 at 30, 32 (843, Fig. 3A).

36. The "countermeasures" referenced in the Cell Host Article by UTMB include "generation of live-attenuated vaccine candidates to respond to emerging virus outbreaks", including "**mNeonGreen virus [] be[ing] reliably used** to study viral replication and pathogenesis as well as to develop vaccines and antiviral drugs." *Id.* at 29, 30.

37. The Key Resources Table of the Cell Host Article lists "**synthesized mNeonGreen gene (sequence optimized)**" and refers to a publication from 2013 by the Inventors which corresponds to the '221 Patent. See, Cell Host Article at e1, e2.

38. mNeonGreen in UTMB's construct is identical to SEQ ID NO:1 of the '221 patent.

39. Mulligan of Exhibit 5 also states, "BioNTech is the Sponsor of the study" and that "Pfizer was responsible for the design, data collection, data analysis, data interpretation, and writing of the report," confirming Defendants' intimate involvement in every aspect of the study. *See* Exhibits 6, 7, and 8 with true and correct copies of each attached hereto which confirm mNeonGreen's continued use by Defendants in their development of a COVID-19 vaccine. Defendants directly used the invention patented in the '221 Patent, and for which Defendants have since obtained hefty government grants and sales. Exhibit 5 Page 66 (at Exhibit 99.2 p. 5).

40. A protein made using the DNA construct used by Defendants has "at least one" of the mutations in claim 1, at least three of the mutations in claim 4, at least 95% sequence identity according to claims 1, 2, and 4; has at least 97% sequence identity according to claim 5, and has a monomer according to claim 2.

41. Therefore, the mNeonGreen protein used by Defendants throughout their COVID-19 vaccine trial literally infringes at least claims 1, 2, 4 and 5 of the '221 Patent.

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42. At no time has Allele granted Defendants authorization, license, or permission to practice the inventions claimed in the '221 Patent.

43. Because of this continued infringement, Defendants were able to identify their COVID-19 vaccine candidate, BNT162, as the most promising candidate to commercialize.

**Defendants' Willful Infringement**

44. The '221 Patent was issued by the United States Patent and Trademark Office. As an issued patent, the '221 Patent has a presumption of validity per 35 U.S.C. § 282.

45. At least claims 1, 2, 4 and 5 of the '221 Patent have all of their limitations met by the Accused Product, which thus infringes the '221 Patent.

46. Since at least as early as May 2020, Defendants have been aware of the '221 Patent, and have had actual knowledge of the '221 Patent and the obvious risk of infringement by continued use of mNeonGreen throughout their development of their COVID-19 vaccine candidate in the United States.

47. Despite their knowledge of the obvious risk of infringement of the '221 Patent, Defendants since at least as early as May of 2020 continued using Allele's mNeonGreen throughout their ongoing COVID-19 trial.

48. Defendants' continued infringement was and is subjectively reckless and intentional. Defendants have infringed the '221 Patent in a willful and egregious manner, in wanton disregard of the '221 Patent.

**FIRST CLAIM FOR RELIEF**

(Infringement of the '221 Patent Against All Defendants)

49. Allele realleges and incorporates by reference all paragraphs in this Complaint above as if fully set forth herein.

50. This is a claim for patent infringement and arises under the Patent Laws of the United States and, in particular, under 35 U.S.C. §§ 271, *et seq.*

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51. Defendants have in the past infringed and continue to infringe the '221 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, and/or selling, in the United States, or importing into the United States, mNeonGreen with its SARS-CoV-2 neutralization assay and DNA construct that infringes at least claims 1, 2, 4, and 5, of the '221 Patent.

52. Allele is informed and believes that Defendants have infringed, and continue to infringe, the '221 patent by making, using, selling, offering for sale and/or licensing products covered by at least claims 1, 2, 4, and 5 of the '221 Patent without Allele's authorization or consent.

53. Defendants have in the past infringed and continue to infringe the '221 Patent in violation of 35 U.S.C. § 271(f) because Defendants supply or cause to be supplied from the United States all or a substantial portion of the patented invention for combination outside the United States, including use of mNeonGreen with its SARS-CoV-2 neutralization assay and DNA construct throughout their COVID-19 vaccine trial in the United States and Europe, in a manner that would infringe at least claims 1, 2, 4, and 5 of the '221 Patent, if such combination occurred within the United States.

54. Section 287 of Chapter 35 of the U.S.C. has been satisfied.

55. Defendants' infringing conduct will continue unless enjoined by this Court.

56. Defendants' acts of direct infringement have been, and continue to be, willful and deliberate and Defendants' acts of indirect infringement were, and continue to be, knowing and intentional.

57. Allele is entitled to an award of damages adequate to compensate Allele for patent infringement, as well as prejudgment interest from the date the infringement began, but in no event less than a reasonable royalty as permitted by 35 U.S.C. § 284.

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58. Allele is entitled to an award of treble damages for the period of any willful infringement pursuant to 35 U.S.C. § 284.

59. Allele is entitled to a finding that this case is exceptional and an award of interest, costs and attorneys' fees incurred by Allele in prosecuting this action as provided by 35 U.S.C. § 285.

60. Allele is entitled to an award of pre-judgment and post-judgment interest as provided by law.

61. Allele is entitled to such other and further relief as this Court or a jury may deem just and proper.

**PRAYER FOR RELIEF**

WHEREFORE, in consideration of the foregoing, Allele respectfully prays for a judgment against Defendants:

A. Finding that the '221 Patent has been infringed by Defendants in violation of 35 U.S.C. §271;

B. Finding that Defendants' infringement of the '221 Patent is willful;

C. An award of damages adequate to compensate Allele for patent infringement, as well as prejudgment interest from the date the infringement began, but in no event less than a reasonable royalty as permitted by 35 U.S.C. § 284;

D. An award of treble damages for the period of any willful infringement pursuant to 35 U.S.C. § 284;

E. A finding that this case is exceptional and an award of interest, costs and attorneys' fees incurred by Allele in prosecuting this action as provided by 35 U.S.C. § 285;

F. For an award of pre-judgment and post-judgment interest as provided by law; and

G. For such other and further relief as this Court or a jury may deem just and proper.

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Dated: October 5, 2020

Respectfully Submitted,

TROUTMAN PEPPER HAMILTON SANDERS LLP

*/s/ Ben Lewis Wagner*
Ben Lewis Wagner

Attorneys for Plaintiff
Allele Biotechnology and Pharmaceuticals, Inc.

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## DEMAND FOR JURY TRIAL

Plaintiff Allele Biotechnology and Pharmaceuticals, Inc. hereby demands a trial by the jury on its claims herein and all issues and claims so triable in this action.

Dated: October 5, 2020

Respectfully Submitted,

TROUTMAN PEPPER HAMILTON SANDERS LLP

*/s/ Ben Lewis Wagner*
Ben Lewis Wagner

Attorneys for Plaintiff
Allele Biotechnology and
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| **7** | Press Release: "Pfizer and BioNTech Granted FDA Fast Track Designation for Two Investigational mRNA-based Vaccine Candidates Against SARS-CoV2" | **85** |
| **8** | "RNA-Based COVID-19 Vaccine BNT162b2 Selected for a Pivotal Efficacy Study," Walsh, et al. medRxiv preprint | **90** |

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