

1 David J. Noonan, Esq. (SBN 55966)
2 dnoonan@noonanlance.com
3 Genevieve M. Ruch, Esq. (SBN 285722)
4 gruch@noonanlance.com
5 NOONAN LANCE BOYER &
6 BANACH LLP
7 701 Island Avenue, Suite 400
8 San Diego, California 92101
9 Telephone: (619) 780-0880
10 Facsimile: (619) 780-0877

11 *Attorneys for Defendants PFIZER, INC.,*
12 *a Delaware corporation*

13 Elizabeth L. Brann (SBN 222873)
14 elizabethbrann@paulhastings.com
15 PAUL HASTINGS LLP
16 4747 Executive Drive, 12th Floor
17 San Diego, CA 92121
18 Telephone: 858-458-3000
19 Facsimile : 858-458-3005

20 *Attorneys for Defendants BioNTech SE*
21 *and BioNTech US, Inc.*

22 **IN THE UNITED STATES DISTRICT COURT**
23 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

24 Allele Biotechnology and
25 Pharmaceuticals, Inc.,

26 Plaintiff,

27 v.

28 Pfizer Inc.; BioNTech SE;
BioNTech US, Inc.; and DOES 1-
30

Defendants.

Case No. 3:20-cv-01958-H (AHG)

**MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT OF
MOTION TO DISMISS
COMPLAINT PURSUANT TO
RULE 12(B)(6)**

Date: March 15, 2021
Time: 10:30 AM
Courtroom: 15A
Judge: Hon. Marilyn L. Huff
Magistrate: Hon. Allison H. Goddard

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INTRODUCTION

1
2 Since it first emerged in late 2019, COVID-19 has rapidly become a global
3 pandemic that has ended millions of lives and affected countless others. Faced with
4 this historic threat, scientists at Defendants Pfizer Inc. (“Pfizer”) and BioNTech SE
5 and BioNTech US, Inc. (collectively, “BioNTech”) have worked tirelessly to create,
6 test, and obtain emergency FDA regulatory approval for a vaccine against SARS-
7 CoV-2, the virus that causes COVID-19. Plaintiff Allele Biotechnology and
8 Pharmaceuticals, Inc. (“Allele”) filed this patent suit against Pfizer and BioNTech
9 alleging patent infringement arising from Defendants’ efforts to advance the COVID-
10 19 vaccine through the FDA approval process. For the reasons discussed below, the
11 allegations of the Complaint bring this case squarely within the safe harbor of 35
12 U.S.C. § 271(e)(1), and this suit should therefore be dismissed.

13 Allele’s complaint alleges that, in testing their COVID-19 vaccine, Pfizer and
14 BioNTech used Allele’s patented fluorescent protein, which Allele calls
15 “mNeonGreen.” Allele alleges that “mNeonGreen has been used throughout
16 Defendants’ COVID-19 vaccine trials” and seeks damages as a result of this alleged
17 infringement. D.I. 1, ¶ 3. Notably, Allele is not accusing Pfizer or BioNTech of
18 selling mNeonGreen, incorporating mNeonGreen into the vaccine itself, or using
19 mNeonGreen in the process of making the vaccine.

20 The allegations of the complaint do not (and cannot) state a cognizable claim
21 under established law. The alleged patent infringement—asserted uses by Pfizer and
22 BioNTech of the patented invention to generate data from clinical trials in support of
23 seeking FDA approval—are precisely the type of activity that is protected by the
24 “safe harbor” from patent infringement claims under 35 U.S.C. § 271(e)(1). That
25 provision, enacted as part of the Drug Price Competition and Patent Term Restoration
26 Act of 1984 (“the Hatch-Waxman Act”), immunizes parties from allegations of
27 patent infringement when, as here, the accused actions are undertaken in order to
28 develop information for submission to the FDA pursuant to a federal law regulating

1 the manufacture, use or sale of drugs. This immunity is broad and, in the words of
2 the Supreme Court, “extends to all uses of patent inventions that are reasonably
3 related to the development and submission of any information” to the FDA for
4 products like the Pfizer/BioNTech vaccine. *Merck KGaA v. Integra Lifesciences I,*
5 *Ltd.*, 545 U.S. 193, 202 (2005) (emphasis omitted).

6 Thus, even taking the allegations in the complaint as true for this motion, the
7 purported use of mNeonGreen here to obtain data for submission to the FDA does not
8 constitute infringement as a matter of law. This Court should dismiss Allele’s
9 complaint under Rule 12(b)(6) before this lawsuit becomes another burden on Pfizer
10 and BioNTech as they continue their work on this vital vaccine.¹

11 **BACKGROUND**

12 **I. Defendants Allegedly Used Testing Data In Support of FDA Approval for** 13 **Their Vaccine**

14 Early last year, scientists at Pfizer and BioNTech began working to develop a
15 vaccine against SARS-CoV-2, the virus that causes COVID-19. D.I. 1-2, Ex. 8, at
16 92. The vaccine, designated BNT162b2, utilizes a composition in which messenger
17 RNA (“mRNA”) is encapsulated in lipid nanoparticles and injected into the body. *Id.*
18 When administered, the mRNA prompts the body’s cells to make a protein that is
19 part of the SARS-CoV-2 virus. *Id.* This protein, in turn, elicits the body’s own
20 immune system to produce neutralizing antibodies against the virus. *Id.* Once
21 antibodies are present, the body can fight off, or “neutralize,” the real virus.

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23
24 ¹ For purposes of this motion, Pfizer and BioNTech cite and rely upon the statements
25 in the complaint as alleged. Nothing in this motion should be construed as agreement
26 that Pfizer, BioNTech US, Inc., or BioNTech SE in fact engaged in the activities
27 alleged in the complaint or that mNeonGreen is an invention entitled to patent
28 protection. Also, because Allele makes collective allegations against both BioNTech
entities, BioNTech is referred to collectively in this motion. None of the collective
references should be understood as agreement that Pfizer or particular BioNTech
entities, individually or collectively, engaged in the specific acts discussed herein.

1 On November 20, 2020, Pfizer and BioNTech requested Emergency Use
2 Authorization (“EUA”) from the FDA to allow use of the Pfizer/BioNTech vaccine in
3 individuals 16 years of age and older, which the FDA granted on December 11,
4 2020.² EUA is the first step on the regulatory pathway for the vaccine: Pfizer and
5 BioNTech also intend to submit a Biologics License Application (“BLA”) to obtain
6 full regulatory approval of the COVID-19 vaccine from the FDA. As of the date of
7 this submission, the Pfizer/BioNTech vaccine is administered under the FDA
8 regulatory authorization provided by the EUA, and the clinical use during this period
9 will be considered by the FDA in reviewing the full BLA when it is eventually
10 submitted.

11 As noted above, both the EUA and the eventual full regulatory approval require
12 Pfizer and BioNTech to show that their vaccine is safe and effective against SARS-
13 CoV-2 infection. *See* 42 U.S.C. § 262(a) (describing FDA regulation and license of
14 new biological drug products); 21 U.S.C. § 360bbb-3 (describing FDA regulation of
15 drug products for use in emergencies based on review of scientific evidence, including
16 clinical trial data). To meet the FDA’s requirements, Pfizer and BioNTech have been
17 and continue to be engaged in large scale clinical trials to evaluate, among other
18 things, whether individuals who receive the vaccine are less susceptible to COVID-19
19 infection. D.I. 1-2, Ex. 8, at 97. As part of these trials, the results of laboratory tests
20 on blood samples drawn from patients in the clinical trials who received the vaccine
21 are evaluated. D.I. 1-2, Ex. 8, at 93, 95. According to the complaint, one of these
22 tests is a “neutralization assay,” which as explained further below is a laboratory
23 procedure to detect the presence of antibodies in the blood of a patient after receiving
24 a vaccination capable of neutralizing the SARS-CoV-2 virus. D.I. 1-2, Ex. 4, at 40–
25

26 ² FDA, *Coronavirus (COVID-19) Update: FDA Announces Advisory Committee*
27 *Meeting to Discuss COVID-19 Vaccine Candidate* (Nov. 20, 2020),
28 <https://tinyurl.com/1120update>; FDA, *Pfizer-BioNTech COVID-19 Vaccine* (Dec. 11,
2020), <https://tinyurl.com/1211EUA>.

1 42, Ex. 8, at 93. Pfizer and BioNTech submitted the results of this neutralization
2 assay, along with numerous other assay results and data, in support of their application
3 for EUA, and will also submit these results as part of the full BLA. *Id.*, Ex. 5, at 62–
4 65, Ex. 8, at 91.

5 **II. Allele’s Infringement Allegations Are Directed to Testing Related to**
6 **Clinical Trials For Defendants’ Vaccine**

7 In October 2020, prior to the FDA’s emergency authorization of the
8 Pfizer/BioNTech vaccine, and with no prior notice to Pfizer or BioNTech, Allele filed
9 this suit asserting infringement of U.S. Patent No. 10,221,221 (“the ’221 patent”).
10 The ’221 patent is directed to a fluorescent protein, which Allele calls “mNeonGreen,”
11 that glows when exposed to certain wavelengths of light. D.I. 1, ¶ 21.

12 Allele’s complaint asserts that in the course of their clinical trials Pfizer and
13 BioNTech generated data using a neutralization assay that included the patented
14 mNeonGreen protein. *Id.* ¶¶ 26–27, 29, 30, 32, 33, 39, 41, 47, 53. The alleged
15 process of performing a neutralization assay (as it relates to the fluorescing protein
16 aspect) is outlined in the complaint and exhibits attached to the complaint. Allele
17 alleges that a non-party to this suit, the University of Texas Medical Branch
18 (“UTMB”), created a new, man-made version of the SARS-CoV-2 virus called
19 “icSARS-CoV-2-mNG.” *Id.* ¶¶ 32, 34–35. Allele alleges that UTMB’s icSARS-
20 CoV-2-mNG is a “reporter virus” that behaved the same way as the naturally
21 occurring SARS-CoV-2 virus, except that it also caused infected cells to produce a
22 glowing protein (in this case, mNeonGreen) when the virus is present. *Id.* ¶ 27. In the
23 neutralization assay, serum from a patient’s blood sample is mixed with the SARS-
24 CoV-2 reporter virus encoding the mNeonGreen protein. D.I. 1-2, Ex. 4, at 41-42, 46,
25 49-50. The infected serum is then introduced to test cells grown on a plate. *Id.* If the
26 patient’s serum does not contain antibodies, Allele alleges, the reporter virus causes
27 the test cells to produce the mNeonGreen protein and, in turn, glow green. *Id.*
28 However, if the patient’s serum contains antibodies generated by the vaccine, the

1 reporter virus is neutralized and unable to infect the test cell. Allele alleges that as a
2 result, the test cells do not produce the mNeonGreen protein. *Id.* Thus, the detection
3 of the glowing protein on the cell plate indicates the presence of the reporter virus, and
4 therefore the failure of the candidate vaccine to produce sufficient antibodies to
5 neutralize the virus. *Id.*

6 Allele asserts that Pfizer and BioNTech used UTMB’s SARS-CoV-2 reporter
7 virus (which in turn contained mNeonGreen) “to develop and test the BNT162
8 vaccine candidate.” D.I. 1, ¶ 3; *see also id.* ¶ 27 (vaccine clinically developed using
9 “neutralization assay”). Allele further alleges that “BioNTech adopted the technology
10 protected by the ’221 Patent in its COVID-19 vaccine trial,” *id.* ¶ 26, and that
11 BioNTech “used (and continues using in its trials) the DNA construct described in the
12 Cell Host Article to develop and test its SARS-CoV2 vaccine,” *id.* ¶ 30; *see also id.*
13 ¶ 3 (“mNeonGreen has been used throughout Defendants’ COVID-19 vaccine trials,
14 right up to the present”). The complaint cites and attaches exhibits, including Exhibits
15 6, 7, and 8, as purportedly showing the use of mNeonGreen in the context of the
16 ongoing clinical trials. *Id.* ¶ 39; D.I. 1-2, Exs. 6-8.

17 **III. Allele Does Not Assert that Defendants’ COVID-19 Vaccine or its**
18 **Manufacture, Infringes Allele’s Patent**

19 Allele does not and cannot assert that the BNT162b2 vaccine itself includes the
20 mNeonGreen protein, or that the manufacture or sale of that vaccine (which does not
21 contain mNeonGreen) infringes the ’221 patent. Nor does Allele assert that Pfizer or
22 BioNTech sell mNeonGreen to third parties. Instead, Allele’s complaint expressly
23 alleges infringement based on use of the reporter virus (allegedly containing the
24 mNeonGreen protein) in the testing of blood samples from patients who received the
25 vaccine in clinical trials to generate data useful for obtaining FDA regulatory
26 authorization for the Pfizer/BioNTech vaccine. *See, e.g.,* D.I. 1, ¶¶ 26, 30, 39, 41.

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LEGAL STANDARD

“A complaint is subject to dismissal for failure to state a claim if the allegations, taken as true, show the plaintiff is not entitled to relief.” *Jones v. Bock*, 549 U.S. 199, 215 (2007). Although the court must “assume the truth of all factual allegations . . . legal conclusions need not be taken as true merely because they are cast in the form of factual allegations.” *Toranto v. Jaffurs*, 297 F. Supp. 3d 1073, 1084 (S.D. Cal. 2018) (citations omitted).

“Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law.” *Neitzke v. Williams*, 490 U.S. 319, 326 (1989). Further, “the assertion of an affirmative defense may be considered properly on a motion to dismiss where the ‘allegations in the complaint suffice to establish’ the defense.” *Sams v. Yahoo! Inc.*, 713 F.3d 1175, 1179 (9th Cir. 2013); *see also Jablon v. Dean Witter & Co.*, 614 F.2d 677, 682 (9th Cir. 1980).

“When ruling on a motion to dismiss, the Court may consider the facts alleged in the complaint, documents attached to the complaint, documents relied upon but not attached to the complaint when authenticity is not contested, and matters of which the Court takes judicial notice.” *Toranto*, 297 F. Supp. 3d at 1084.

ARGUMENT

Allele’s complaint makes various assertions that Pfizer and BioNTech used mNeonGreen, the fluorescent protein allegedly claimed in the ’221 patent, in support of the ongoing clinical trials for their COVID-19 vaccine. Even accepting these allegations as true for purposes of this motion, Allele’s complaint fails to state a claim for infringement of the ’221 patent as a matter of law because the accused conduct is protected by the Hatch-Waxman Act’s statutory “safe harbor.” That provision, codified at 35 U.S.C. § 271(e)(1), states in relevant part:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably

1 *related to the development and submission of information*
2 *under a Federal law which regulates the manufacture, use,*
3 *or sale of drugs or veterinary biological products.*

4 (emphasis added). The safe harbor provision allows companies like Pfizer and
5 BioNTech “to engage in otherwise infringing activities necessary to obtain regulatory
6 approval.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). The statute
7 accomplishes this by immunizing the use of a “patented invention”—which the
8 Supreme Court has held “is defined to include all inventions,”—so long as the use of
9 that invention is “reasonably related” to development and submission of information
10 to the FDA. *Id.* at 665.

11 Allele’s allegations of infringement fall squarely within the statutory language
12 of the safe harbor provision. The alleged infringing use of that patented invention—
13 testing conducted on blood samples from clinical trial subjects in order to obtain data
14 for submission to the FDA as part of the approval process for the COVID-19
15 vaccine—is “reasonably related” to the development and submission of information
16 to the FDA in order to obtain regulatory approval. Because the allegations in the
17 complaint establish that Pfizer and BioNTech are entitled to the protection of the
18 § 271(e)(1) safe harbor, this Court should dismiss the complaint under Rule 12(b)(6).

19 **I. The Alleged Uses of mNeonGreen Are Reasonably Related to FDA**
20 **Submissions for the COVID-19 Vaccine**

21 Congress “exempted from infringement *all* uses of patented compounds
22 ‘reasonably related’ to the process of developing information for submission under
23 *any* federal law regulating the manufacture, use, or distribution of drugs.” *Merck*,
24 545 U.S. at 206. So long as the use of the patented invention is reasonably related to
25 developing information for FDA approval, the safe harbor applies regardless of “the
26 phase of research in which [the information] is developed or the particular
27 [regulatory] submission in which it could be included.” *Id.* at 202; *see also Classen*
28 *Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 897 (Fed. Cir. 2015)

1 (“[Accused infringer’s] clinical study and its FDA submissions clearly fall within the
2 scope of the safe harbor.”); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed.
3 Cir.), *opinion amended on reh’g*, 131 F.3d 1009 (Fed. Cir. 1997) (safe harbor “does
4 not look to the underlying purposes or attendant consequences of the activity (*e.g.*,
5 tests led to the sale of the patent), as long as the use is reasonably related to FDA
6 approval”); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, Nos. 09 Civ. 10112 (KBF), 10
7 Civ. 7246 (KBF), 2013 WL 3732867, at *6 (S.D.N.Y. July 16, 2013) (explaining that
8 the safe harbor “allows for the elective use of patented technology as long as it serves
9 to produce information required under a federal law”).

10 Because data showing, among other things, efficacy in clinical trials is required
11 for FDA approval of new drugs or biologics, *see* 42 U.S.C. § 262(a)(2); 21 U.S.C.
12 § 360bbb-3(c)(2), (e)(1), district courts have repeatedly dismissed patent
13 infringement complaints in which the alleged infringing activity occurs in connection
14 with clinical testing. For example, in *Galderma Labs., L.P. v. Medinter US, LLC*, the
15 district court dismissed a complaint because it could not conclude from the complaint
16 that the patented invention was used “for purposes unrelated to . . . clinical trials.”
17 No. 18-cv-1892-CFC-CJB, 2020 WL 871507, at *3 (D. Del. Feb. 14, 2020).
18 Similarly, in *Medical Diagnostic Laboratories, L.L.C. v. Protagonist Therapeutics,*
19 *Inc.*, the court dismissed a complaint wherein “the only specific examples alleged are
20 the sales . . . in connection with clinical trials.” 298 F. Supp. 3d 1241, 1248 (N.D.
21 Cal. 2018). The court explained that these allegations “d[id] not support a plausible
22 inference that [the accused infringer] used or sold [the] patented technology in a
23 manner not reasonably related to developing information for submission in
24 connection with the regulatory approval process.” *Id.* at 1249.

25 Here, the facts alleged in the Complaint themselves demonstrate that dismissal
26 is required. Allele’s complaint repeatedly alleges that the acts of infringement
27 against Pfizer and BioNTech relate to ongoing clinical trials to generate data and
28 information for regulatory approval for their vaccine candidate. Allele alleges that

1 “BioNTech adopted the technology protected by the ’221 Patent in its COVID-19
 2 *vaccine trial*,” D.I. 1, ¶ 26; that BioNTech “used (and continues using in its *trials*) the
 3 DNA construct described in the Cell Host Article to *develop and test* its SARS-CoV2
 4 vaccine,” *id.* ¶ 30; and that “the mNeonGreen protein used by Defendants throughout
 5 their COVID-19 *vaccine trial* literally infringes . . . the ’221 Patent.” *Id.* ¶ 41
 6 (emphases added). The complaint further asserts that Pfizer was responsible for the
 7 “design, data collection, data analysis, data interpretation, and writing” of a report
 8 that describes the phase 1 and 2 clinical trial of the COVID-19 vaccine candidate. *Id.*
 9 ¶ 39; D.I. 1-2, at 62. Each of the exhibits to the complaint cited as the purported
 10 evidence of infringement refers to the use of the data in connection with the FDA-
 11 mandated clinical trials. D.I. 1-2, at 27–109 (Exs. 3–8). Indeed, the lawsuit itself
 12 was filed as Defendants were *en route* to submitting their application to the FDA for
 13 emergency use authorization.

14 In short, throughout the complaint, the accused activity by Pfizer and
 15 BioNTech is alleged to be part and parcel of the ongoing clinical trials for the
 16 COVID-19 vaccine, which are reasonably related to the development and submission
 17 of information to the FDA. These activities are unquestionably within the ambit of
 18 the statutory safe harbor. *See Merck*, 545 U.S. at 202–06; *Galderma*, 2020 WL
 19 871507, at *3; *Medical Diagnostic*, 298 F. Supp. 3d at 1249.

20 **II. Allele’s “Research Tool” Allegations Do Not Avoid Application of the Safe** 21 **Harbor Statute**

22 The application of the plain language of the safe harbor provision is not upset
 23 by Allele’s allegations characterizing mNeonGreen as a “research tool” that “does
 24 not require government approval for clinical use.” D.I. 1, ¶¶ 16, 25. The § 271(e)(1)
 25 safe harbor by its terms covers the use of any “patented invention,” so long as the use
 26 is reasonably related to FDA submission. As Justice Scalia wrote for the Court, the
 27 term “patented invention” means just that—an invention that has been patented. *See*
 28 *Lilly*, 496 U.S. at 665 (“The phrase ‘patented invention’ in § 271(e)(1) is defined to

1 include *all* inventions” (emphasis added)); *see also* 35 U.S.C. § 271(e)(1)
2 (referring to “patented invention” without further qualification). Merely calling a
3 patented invention a “research tool” does not exempt it from this broad definition of a
4 patented invention.

5 Not surprisingly then, courts routinely hold that the use of an alleged “research
6 tool” by a party generating information about its drug product for submission to the
7 FDA is protected by the safe harbor. Take *Katz v. Avanir Pharms.*, No. 06-cv-0496
8 DMS (LSP), 2007 WL 9776599, at *6 (S.D. Cal. Aug. 21, 2007), in which Judge
9 Sabraw held that the use of a patented assay “to screen compounds as part of
10 [defendant’s] IgE drug development program” is protected by the § 271(e) safe
11 harbor. *Id.* at *6. Judge Sabraw directly rejected the argument that the patented
12 assay does not qualify for § 271(e)(1) because it was asserted to be “a research tool
13 rather than a patented compound.” *Id.* at *7. Rather, “the statute itself exempts the
14 use of ‘patented invention[s],’ and the Supreme Court has given the statute a broad
15 interpretation.” *Id.* (citing *Merck*, 545 U.S. at 193). More recently, Judge Forrest of
16 the Southern District of New York rejected the notion that characterizing a patented
17 invention as a research tool is sufficient to exempt it from being a “patented
18 invention” under the meaning of the statute. *Teva*, 2013 WL 3732867, at *1. The
19 court found that the safe harbor covers “polypeptide markers” used as an alleged
20 research tool to characterize the active ingredient in a drug to generate data for FDA
21 submission. *Id.*; *see also Classen*, 786 F.3d at 897 (safe harbor protects use of
22 patented method to analyze data on commercially available drugs); *Bristol-Myers*
23 *Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95 Civ. 8833 (RPP), 2001 WL
24 1512597, at *3 (S.D.N.Y. Nov. 28, 2001) (“‘patented invention’ means all patented
25 inventions or discoveries”).³

26 _____
27 ³ In a case involving different alleged facts, one district judge in Illinois made a broad
28 statement inconsistent with the statutory language and weight of authority that “only
‘patented inventions’ for which regulatory approval is required fall within the scope of

1 Of course, as with any other kind of patented invention, the use of a patented
2 invention alleged to be a “research tool” may not be protected by the safe harbor if,
3 unlike the allegations in the complaint discussed above, it is not reasonably related to
4 an FDA submission. For instance, in *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536
5 F.3d 1256 (Fed. Cir. 2008), the accused infringer made an optical spray analyzer
6 (“OSA”) which it then sold to customers, who then used it to “study and optimize the
7 delivery of various aerosol-based drugs.” *Id.* at 1258. The Federal Circuit found the
8 seller of the OSA was not exempt from patent infringement simply because they sold
9 a patented invention that their *customers* (who had not been accused of infringement)
10 might arguably use to generate information for the FDA. *Id.* at 1266; *see also*
11 *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619, 621 (Fed. Cir.
12 2015) (noting that research tools “may” not be covered while also recognizing that
13 preclinical research can be an activity that falls within the safe harbor). Likewise,
14 using a patented invention solely for basic research without relation to a specific drug
15 candidate or FDA submission may not be covered by the safe harbor. *See Isis*
16 *Pharms., Inc. v. Santaris Pharma A/S Corp.*, No. 11-cv-2214-GPC-KSC, 2014 WL
17 794811, at *1, *13 (S.D. Cal. Feb. 27, 2014) (factual issue as to whether the accused
18 infringer was merely providing basic research services on behalf of another company);
19 *PSN Ill.*, 2011 WL 4442825, at *1 (finding use was merely screening “thousands of
20 potential drug candidates for activity”).

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23 the safe harbor exemption.” *PSN Ill., LLC v. Abbott Labs.*, No. 09 C 5879, 2011 WL
24 4442825, at *5 (N.D. Ill. Sept. 20, 2011). Taken at face value, that statement
25 contradicts the language of the statute and the Supreme Court’s interpretation, *see*
26 *Lilly*, 496 U.S. at 665, and it is also inconsistent with how the Federal Circuit has
27 subsequently applied the safe harbor. *See, e.g., Classen*, 786 F.3d at 897 (involving
28 an alleged research tool and finding immunity). Indeed, the Southern District of New
York expressly declined to follow *PSN Illinois*, and characterized the decision as
“either wrong or irrelevant.” *Teva*, 2013 WL 3732867, at *8–9.

1 Unlike these cases, Allele’s complaint does not allege that Pfizer and BioNTech
2 sell mNeonGreen to third parties or that the acts of infringement are not related to the
3 COVID-19 vaccine drug product for which they are seeking FDA approval. To the
4 contrary, as discussed above, the complaint alleges that Defendants used mNeonGreen
5 “throughout Defendants’ COVID-19 vaccine trials,” D.I. 1, ¶ 3; *see also id.* ¶¶ 24, 25,
6 32, 34, 41, which is exactly the kind of conduct § 271(e)(1) immunizes. Thus,
7 regardless of whether Allele alleges that mNeonGreen is a “research tool,” the
8 invocation of that phrase does not negate the language and application of 35 U.S.C. §
9 271(e)(1). The alleged use of the patented invention to generate information for the
10 FDA in support of regulatory approval for the COVID-19 vaccine entitles Defendants
11 to the protection of the safe harbor.

12 **CONCLUSION**

13 Because the alleged infringing activity in Allele’s complaint is protected by the
14 statutory safe harbor, this Court should dismiss the complaint under Rule 12(b)(6).

15 Respectfully submitted,

16 Dated: February 8, 2021

NOONAN LANCE BOYER & BANACH LLP

17 By: /s/ David J. Noonan

18 David J. Noonan
19 Genevieve M. Ruch

20 Stanley Edward Fisher (*Pro Hac Vice*)
21 sfisher@wc.com

22 Thomas H.L. Selby (*Pro Hac Vice*)
23 tselby@wc.com

24 Charles L. McCloud (*Pro Hac Vice*)
25 lmcloud@wc.com

26 WILLIAMS & CONNOLLY LLP
27 725 – 12th Street NW
28 Washington, DC 20005
Telephone: (202) 434-5586

*Attorneys for Defendant
Pfizer, Inc.*

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Dated: February 8, 2021

PAUL HASTINGS LLP

By: */s/ Elizabeth L. Brann*

Elizabeth L. Brann

Bruce M. Wexler (*Pro Hac Vice*)

brucewexler@paulhastings.com

Merri C. Moken (*Pro Hac Vice*)

merrimoken@paulhastings.com

200 Park Avenue

New York, NY 10166

Telephone: 212-318-6000

Facsimile 212-319-4090

*Attorneys for Defendants BioNTech SE and
BioNTech US, Inc.*

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SIGNATURE CERTIFICATION

Pursuant to Section 2(f)(4) of the Electronic Case Filing Administrative Policies and Procedures Manual, I hereby certify that the content of this document is acceptable to Elizabeth L. Brann, counsel for Defendants BioNTech SE and BioNTech US, Inc., and that I have obtained Ms. Brann’s authorization to affix her electronic signature to this document.

Dated: February 8, 2021

NOONAN LANCE BOYER & BANACH LLP

By: */s/ David J. Noonan*

David J. Noonan
Genevieve M. Ruch
*Attorneys for Defendant
Pfizer, Inc.*