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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

Allele Biotechnology and Pharmaceuticals, Inc.,

Plaintiff,

v.

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

Defendants.

Case No. 20-cv-01958-H (AGS)

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

Date: May 3, 2021
Time: 10:30 AM
Courtroom: 15A
Judge: Hon. Marilyn L. Huff
Magistrate: Hon. Andrew G. Schopler

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INTRODUCTION

Since it first emerged in late 2019, COVID-19 has rapidly become a global pandemic that has ended millions of lives and affected countless others. Faced with this historic threat, scientists at Defendants Pfizer Inc. ("Pfizer") and BioNTech SE and BioNTech US, Inc. (collectively, "BioNTech") have worked tirelessly to create, test, and obtain emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for a vaccine against SARS-CoV-2, the virus that causes COVID-19. But Pfizer and BioNTech's work is not done. They continue to devote substantial time and resources to testing and studying their vaccine with the goal of obtaining final regulatory approval under a Biologics License Application ("BLA") from the FDA.

On the eve of Pfizer and BioNTech's submission of their EUA application to the FDA, and with no prior notice, Plaintiff Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed this patent suit alleging infringement arising from Defendants' efforts to advance their urgently needed COVID-19 vaccine through the FDA approval process. Allele's initial complaint did *not* accuse the COVID-19 vaccine itself of patent infringement. Nor did Allele's initial complaint allege that patients taking the COVID-19 vaccine were using any Allele invention. Instead, the basis of Allele's complaint was that Pfizer and BioNTech used a third-party's product containing Allele's patented fluorescent protein, which Allele calls "mNeonGreen," in *testing* their COVID-19 vaccine using blood drawn from clinical trial participants receiving the vaccine.

Pfizer and BioNTech moved to dismiss the complaint because it alleged activity that is plainly immune from patent infringement under 35 U.S.C. § 271(e)(1). Section 271(e)(1) immunizes parties from allegations of patent infringement when, as here, the accused actions are undertaken in order to develop information for submission to the FDA pursuant to a federal law regulating the manufacture, use, or sale of drugs. This immunity is broad, "extend[ing] to all uses of patented inventions

that are reasonably related to the development and submission of any information" to the FDA for products like the Pfizer/BioNTech vaccine. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis omitted).

Instead of responding to the motion, Allele filed an Amended Complaint that accuses the *same* immune activity of infringement but seeks to muddy the waters to obscure the fatal flaw in its initial complaint. Allele is still seeking damages by alleging that Pfizer and BioNTech have used mNeonGreen "by conducting Phase I, II, and III clinical trials of the vaccine." D.I. 29, ¶ 17. Allele is still *not* accusing Pfizer or BioNTech of selling a COVID-19 vaccine that infringes their patent, selling their alleged invention of mNeonGreen, incorporating mNeonGreen into the vaccine itself, or using mNeonGreen in the process of making the vaccine. Nonetheless, the Amended Complaint seeks to avoid dismissal by adding a grab bag of new and conclusory allegations, including assertions that Pfizer and BioNTech used mNeonGreen to "select" a vaccine candidate and disseminated clinical test data obtained from mNeonGreen for "commercial purposes." D.I. 29, ¶¶ 3, 33, 43, 44, 47.

This tactic cannot succeed because the purported new allegations in the Amended Complaint still do not change the critical fact that the *only* alleged use of mNeonGreen is in testing blood drawn from clinical study participants to generate data for the FDA. That use does not constitute infringement under Section 271(e)(1) as a matter of law. Even if Pfizer and BioNTech allegedly also made later uses of the data generated from the clinical testing, or if that clinical trial testing allegedly was involved in selecting the final vaccine to obtain EUA, that does not change the result. This Court should dismiss Allele's Amended Complaint under Rule 12(b)(6) before this lawsuit becomes another burden on Pfizer and BioNTech as they continue their work on this vital vaccine.[1]

[1] For purposes of this motion, Pfizer and BioNTech cite and rely upon the statements in the Amended Complaint as alleged. Nothing in this motion should be construed as agreement that Pfizer, BioNTech US, Inc., or BioNTech SE in fact engaged in the

BACKGROUND

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

Early last year, scientists at Pfizer began working with BioNTech to develop a vaccine against SARS-CoV-2, the virus that causes COVID-19. D.I. 29-5, at 12; D.I. 29-7, at 3. The vaccine, designated BNT162b2, utilizes a composition in which messenger RNA ("mRNA") is encapsulated in lipid nanoparticles and injected into the body. D.I. 29-5, at 12. When administered, the mRNA prompts the body's cells to make a protein that is part of the SARS-CoV-2 virus. *Id.* This protein, in turn, elicits the body's own immune system to produce neutralizing antibodies against the virus. *Id.* Once antibodies are present, the body can fight off, or "neutralize," the real virus.

On November 20, 2020, Pfizer and BioNTech requested Emergency Use Authorization ("EUA") from the FDA to allow use of the Pfizer/BioNTech vaccine in individuals 16 years of age and older, which the FDA granted on December 11, 2020. D.I. 29, ¶ 23. The EUA is not a full FDA approval of the vaccine. It is a temporary authorization by the FDA based on, *inter alia*, clinical trial safety and efficacy data to use the vaccine in a national emergency. *See* 21 U.S.C. § 360bbb-3(c)(2). To obtain full regulatory approval of the COVID-19 vaccine, Pfizer and BioNTech also will need to submit a Biologics License Application ("BLA"). *See* 42 U.S.C. § 262(a)(2)(C). As of the date of this submission, the Pfizer/BioNTech vaccine is administered solely under the FDA regulatory authorization provided by the EUA.

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activities alleged in the Amended Complaint or that mNeonGreen is an invention entitled to patent 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.

Both the EUA and the eventual full regulatory approval require Pfizer and BioNTech to show that their vaccine is safe and effective against SARS-CoV-2 infection. *See* 42 U.S.C. § 262(a) (describing FDA regulation and license of new biological drug products); 21 U.S.C. § 360bbb-3 (describing FDA regulation of drug products for use in emergencies based on review of scientific evidence, including clinical trial data). To meet the FDA's ongoing requirements during the pandemic, Pfizer and BioNTech are engaged in large scale clinical trials to evaluate, among other things, whether individuals who receive the vaccine are less susceptible to COVID-19 infection and whether the vaccine mitigates against individuals being susceptible to more serious outcomes. *See* D.I. 29, ¶ 23. The data generated by clinical use during this period will be considered by the FDA in reviewing the full BLA when it is submitted. *See* 42 U.S.C. § 262(a).

II. Allele's Infringement Allegations Are Directed to Testing Related to Clinical Trials for Defendants' Vaccine

In October 2020, after the clinical trials started but prior to the FDA's emergency authorization of the Pfizer/BioNTech vaccine, and with no notice to Pfizer or BioNTech, Allele filed this suit asserting infringement of U.S. Patent No. 10,221,221 ("the '221 patent"). The '221 patent purports to claim a fluorescent protein, which Allele calls "mNeonGreen," that glows when exposed to certain wavelengths of light. D.I. 29, ¶ 29.

The initial complaint asserted that Pfizer and BioNTech used mNeonGreen when performing one of many tests during their clinical trials. This alleged test, called a "neutralization assay," is a laboratory procedure to detect the presence of antibodies in a blood sample of a clinical trial patient after being given a vaccination capable of neutralizing the SARS-CoV-2 virus. D.I. 1, ¶¶ 26–27, 29–30, 32–33, 39, 41, 47, 53. According to the original complaint and the Amended Complaint, the purpose of the neutralization assay is to study whether a patient who received the

vaccine and submitted to a blood draw and testing of their sample has developed neutralizing antibodies against the SARS-CoV-2 virus. *Id.*, ¶ 32; D.I. 29 ¶ 37.

In the Amended Complaint, Allele does not allege that the COVID-19 vaccine includes mNeonGreen or that Pfizer or BioNTech have ever marketed mNeonGreen. Allele instead alleges that a non-party to this suit, the University of Texas Medical Branch ("UTMB"), supplied a product containing mNeonGreen that BioNTech and Pfizer allegedly used in testing the COVID-19 vaccine during clinical trials. In particular, Allele alleges UTMB created a new, man-made version of the SARS-CoV-2 virus called "icSARS-CoV-2-mNG." D.I. 29, ¶¶ 51–52. Allele alleges that UTMB's icSARS-CoV-2-mNG is a "reporter virus" that behaves the same way as the naturally occurring SARS-CoV-2 virus, except that it also causes infected cells to produce a glowing protein (allegedly mNeonGreen) when the virus is present. *Id.* Allele alleges that this reporter virus was used in a "neutralization assay." *Id.*

According to the Amended Complaint, the neutralization assay is performed by mixing serum drawn from a clinical trial participant with the UTMB reporter virus. D.I. 29-4, at 4–6; D.I. 29-5, at 22. The now-infected serum is then introduced to test cells grown on a plate. *Id.* If the serum of the clinical trial patient does not contain antibodies, the reporter virus allegedly causes the test cells to produce the mNeonGreen protein and, in turn, glow green. *Id.* But if the patient's serum contains antibodies generated by the vaccine, the reporter virus is neutralized and unable to infect the test cell, meaning the test cells allegedly do not produce the mNeonGreen protein. *Id.* Thus, as alleged, the detection of the glowing protein on the cell plate indicates the presence of the reporter virus, and therefore the failure of the vaccine to produce sufficient antibodies in that patient to neutralize the virus. *Id.*

Like the initial complaint, Allele's Amended Complaint asserts that "[t]hroughout each of Phases I and II of their COVID-19 vaccine trial, Defendants Pfizer and BioNTech analyzed patient samples using an mNeonGreen neutralization assay," D.I. 29, ¶ 37; *see also id.*, ¶ 65 ("Defendants since at least as early as May of

2020 continued using Allele's mNeonGreen throughout their COVID-19 vaccine trials"). The Amended Complaint cites and attaches exhibits (the same Exhibits as the original complaint), including Exhibits 5, 6, and 7, that purportedly show the use of mNeonGreen in the context of the ongoing clinical trials. D.I. 29-5, 29-6, 29-7. Allele alleges that Pfizer and BioNTech submitted the results of this neutralization assay, along with numerous other assay results and data, in support of their application for EUA, and that this information will also support the full approval sought by the BLA. D.I. 29, ¶¶ 23, 37–38, 41–44; D.I. 29-7, at 4.

III. Allele Amends Its Complaint But Does Not and Cannot Assert that Defendants' COVID-19 Vaccine or its Manufacture Infringe Allele's Patent

On February 8, 2021, Pfizer and BioNTech moved to dismiss the initial complaint based on the § 271(e)(1) safe harbor provision. D.I. 24. Defendants' motion noted that the gravamen of Allele's infringement allegations was the supposed use of the mNeonGreen protein in the neutralization assay during the COVID-19 clinical trials. Defendants explained that this alleged use fails to state a claim under well-established precedent, which holds that an accused infringer's "clinical study and its FDA submissions clearly fall within the scope of the safe harbor." *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 897 (Fed. Cir. 2015).

Rather than oppose the motion, Allele amended its complaint to make its prior allegations regarding use of mNeonGreen in clinical trials less clear. The Amended Complaint also seeks to characterize the use of the clinical trial data in other ways, such as conclusory assertions of Pfizer's and BioNTech's purported use of the neutralization assay for research and development purposes, and the use of data generated in the clinical trials for commercial purposes. D.I. 29, ¶¶ 3, 35–44, 47, 48. As with Allele's first complaint, however, the alleged *infringing act* is the use of mNeonGreen in the neutralization assay to test the blood drawn from clinical trial participants, which generated information for use in seeking FDA's emergency use

authorization for the COVID-19 vaccine and, ultimately, full regulatory approval under a BLA. Beyond conclusory assertions of commercial purpose, there is no allegation, nor could there be, that Pfizer and BioNTech engaged in commercial activities involving mNeonGreen such as making mNeonGreen and selling it to third parties. Nor does Allele assert that the BNT162b2 vaccine itself includes the mNeonGreen protein, or that the manufacture or sale of that vaccine (which does not contain mNeonGreen) infringes the '221 patent.

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). "While a plaintiff need not give 'detailed factual allegations,' he must plead sufficient facts that, if true, 'raise a right to relief above the speculative level.'" *Id.* at 1083 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007)).

"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) (quoting *Jones*, 549 U.S. at 215); *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.

Finally, a party asserting infringement cannot use lack of clarity in a complaint as to what the alleged infringing activities are in order to avoid a motion to dismiss. *See, e.g., Anza Technology, Inc. v. Novatel Wireless, Inc.*, No. 16-cv-585, 2016 WL 7555397, at *3–4 (S.D. Cal. Nov. 4, 2016). A deficient pleading also cannot be used as a tool to "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at *4 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009)).

ARGUMENT

The safe harbor provision excludes from infringement any use of a patented invention that is reasonably related to the development and submission of information to the FDA. *See* 35 U.S.C. § 271(e)(1). Allele's Amended Complaint alleges that Pfizer and BioNTech have used the "mNeonGreen" protein in ongoing clinical trials to generate data that will support final FDA approval for the Pfizer/BioNTech vaccine. Because the alleged use of the mNeonGreen protein is protected by the statutory safe harbor, this case should be dismissed.

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

(emphasis added). The safe harbor allows companies like Pfizer and BioNTech "to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). The statute accomplishes this by immunizing the use of a "patented invention"—which the Supreme Court has held "is defined to include all inventions"—so long as the use of

that invention is "reasonably related" to development and submission of information to the FDA. *Id.* at 665.

Congress "exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Merck*, 545 U.S. at 206. If the use of the patented invention is reasonably related to developing information for FDA approval, the safe harbor applies regardless of "the phase of research in which [the information] is developed or the particular [regulatory] submission in which it could be included." *Id.* at 202. Similarly, the safe harbor "does not look to the underlying purposes or attendant consequences of the activity . . . as long as the use is reasonably related to FDA approval." *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997), *opinion amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1524 (Fed. Cir. 1992) (finding no "unspoken requirement that the disclosure of information obtained during clinical trials to persons other than FDA officials, although not itself an act of infringement, somehow 'repeals' the exemption").

Under this black letter law, the claim alleged in the Amended Complaint cannot proceed. The alleged infringing act is the use of the mNeonGreen protein in a neutralization assay performed on blood samples drawn from patients involved in clinical trials of the COVID-19 vaccine. That assay allegedly generates data related to FDA submissions in support of regulatory authorization for a drug product (in this case, a lifesaving vaccine). Allele's recasting of its allegations to characterize this data as being for "research" or "development" or "commercial" purposes does nothing to change the fact that the alleged infringing act is the generation of clinical trial data reasonably related to FDA submissions. This is an immunized use under the safe harbor, and the Amended Complaint should be dismissed.

I. The Alleged Use of mNeonGreen in Clinical Trials is Reasonably Related to FDA Submissions for the COVID-19 Vaccine

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

Dismissal of Allele's Amended Complaint is required for the same reasons. Allele repeatedly acknowledges that the accused neutralization assay is used in clinical trials to generate data and information for regulatory approval for the Pfizer/BioNTech vaccine candidate. To take a few examples:

- Allele pleads that "[t]hrough continued unauthorized use of mNeonGreen, Defendants' vaccine candidate was further evaluated, and eventually authorized for use by the FDA on December 11, 2020 after, on information and belief, clinical trials involving at least about 40,000 participants," D.I. 29, ¶ 23.
- Allele alleges that "[t]hroughout each of Phases I and II of their COVID-19 vaccine trial, Defendants Pfizer and BioNTech analyzed patient samples using

an mNeonGreen neutralization assay to evaluate COVID-19 neutralizing antibody levels." *Id.*, ¶ 37.

- The Amended Complaint further states that BioNTech "used mNeonGreen technology in Phases I and II of its COVID-19 vaccine trial," *id.*, ¶ 38; and that "BioNTech admits in Exhibit 5 that it used in Phases I and II of their COVID-19 vaccine trial the DNA construct described in the Cell Host Article, which contains and is fundamentally based on the mNeonGreen research tool." *Id.*, ¶ 43.
- The Amended Complaint also asserts that Pfizer was responsible for the "design, data collection, data analysis, data interpretation, and writing" of a report that describes the phase I and II clinical trial of the COVID-19 vaccine candidate. *Id.*, ¶ 56; D.I. 29-5.
- Each of the exhibits to the complaint cited as the purported basis for the allegations of infringement refers to the use of the data in connection with the FDA-mandated clinical trials. D.I. 29-5, 29-6, 29-7.

All of these activities are reasonably related to obtaining FDA authorization for Defendants' vaccine. And all of them are therefore subject to the safe harbor. *See Medical Diagnostic Labs.*, 298 F. Supp. 3d at 1248.

2. Apparently recognizing that the safe harbor is fatal to their claim based on using mNeonGreen in connection with clinical trials, Allele tries three other gambits in the Amended Complaint, each of which is plainly contrary to law:

-- Allele makes conclusory references to Pfizer's and BioNTech's alleged use of the mNeonGreen neutralization assay in clinical studies to evaluate the effect of the vaccine against emerging COVID-19 variants. D.I. 29, ¶¶ 3, 49. Such an allegation still fails to state a claim. Where the results of an experiment "would be appropriate to include in a submission to the FDA, that use is" protected by the safe harbor. *Merck*, 545 U.S. at 207. The FDA has not yet granted full regulatory approval for Pfizer and BioNTech's COVID-19 vaccine, which is currently

distributed under the FDA's emergency use authorization. Clinical trial data collected in the course of determining whether BNT162b2 is also effective against emerging strains of COVID-19 is reasonably related to information for submission to the FDA in support of regulatory approval. *See* 42 U.S.C. § 262(a)(2); 21 U.S.C. § 360bbb-3(c)(2), (e)(1). Allele does not and cannot allege otherwise.

-- Allele repeatedly asserts that Pfizer was not *required* to use mNeonGreen (as opposed to some other laboratory test or reagent) in its clinical trials. *See* D.I. 29 ¶¶ 37, 40, 43, 45, 49, 57. But Allele's asserted belief that there were alternatives to mNeonGreen available for use in the COVID-19 vaccine trials is legally irrelevant under the safe harbor. *Momenta Pharms., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1353, 1359 (Fed. Cir. 2012) (rejecting argument that "testing is not protected because there are FDA endorsed non-infringing alternatives available" and holding that safe harbor "does not mandate the use of a noninfringing alternative when one exists"); *see also Teva Pharm. USA, Inc. v. Sandoz Inc.*, Nos. 09 Civ. 10112 (KBF), 10 Civ. 7246 (KBF), 2013 WL 3732867, at *6 (S.D.N.Y. July 16, 2013).

-- Allele alleges that Pfizer/BioNTech are not marketing a competing product to mNeonGreen and that the '221 patent is not about to expire. *See* D.I. 29, ¶ 45. But, again, such assertions do not avoid statutory immunity under 35 U.S.C. § 271(e)(1). *See Classen*, 786 F.3d at 897 ("Nor does the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product."); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1273 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993) (rejecting argument that safe harbor only protects use "which results in the alleged infringer entering the market place *after* the patent-in-issue has expired").

In sum, the allegations of the complaint demonstrate that the alleged use in clinical trials is related to seeking FDA approval. The safe harbor bars these claims.

II. Alleged Use of mNeonGreen in Development of the Vaccine is Reasonably Related to FDA Submissions for the COVID-19 Vaccine

1. In a further attempt to get around the safe harbor, Allele amended its complaint to make conclusory and self-contradictory assertions that Pfizer and BioNTech used mNeonGreen in a neutralization assay before conducting clinical trials on the COVID-19 vaccine. *See*, *e.g.*, D.I. 29, ¶¶ 3, 6, 7, 8, 12. Allele's proffered allegations fail to state a cognizable claim of infringement.

At the threshold, the Amended Complaint provides no specific factual allegations of infringing use of the '221 patent other than its alleged use in connection with analyzing blood drawn from clinical trials participants. Allele can state in a conclusory manner that the '221 patent was used to "research" and "develop" the vaccine, but these semantic allegations made without any further factual assertions add nothing to the analysis. *Alphamed Pharm. Corp. v. Arriva Pharm., Inc.*, 391 F. Supp. 2d 1148, 1159–60 (S.D. Fla. 2005) (dismissing infringement claim because the complaint failed to allege that "any of the activities [the defendant] has taken constitute research to identify new drugs . . . . [but] only contains allegations that Arriva has been conducting clinical trials."); *see also Med. Diagnostic*, 298 F. Supp. 3d at 1248.

In any event, nothing in Allele's conclusory allegation of "pre-clinical" use changes the safe harbor analysis. The Supreme Court held that the safe harbor applies regardless of "the phase of research in which [the information] is developed or the particular [regulatory] submission in which it could be included." *Merck*, 545 U.S. at 202. Pre-clinical research and development activities are protected by the safe harbor unless they constitute "[b]asic scientific research . . . performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce." *Merck*, 545 U.S. at 205–06. "[A]s long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an [FDA

submission]," the safe harbor applies, even if the results of those experiments are not ultimately submitted to FDA. *Id.* at 208 (internal quotation marks omitted); *see also Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 (Fed. Cir. 2007).

Allele's Amended Complaint falls squarely within this precedent. Allele pleads that "Defendants *did not* use mNeonGreen" in what they assert was "over a decade" of efforts to develop an mRNA-based therapeutic. D.I. 29., ¶ 5 (emphasis added). All of the alleged uses of mNeonGreen are related to evaluating or testing existing COVID-19 vaccine candidates whose anticipated effects—triggering the body to produce antibodies against the SARS-CoV-2 virus—were already known. *See, e.g., id.*, ¶ 33 ("determining therapeutic outcome of potential drug candidates"); ¶¶ 37–38 (evaluate and assess vaccine candidates); ¶57 (test the vaccine against new strains of COVID-19). Under *Merck* and *Integra*, such activities would be protected by the safe harbor even if Pfizer and BioNTech had never provided the results to FDA. *See Merck*, 545 U.S. at 207–08; *Integra Lifesciences I*, 496 F.3d at 1347. Allele's concessions that Defendants in fact allegedly used the results of their testing to support approval of their vaccine only underscores that the safe harbor applies here and that dismissal is necessary. *Teva*, 2013 WL 3732867, at *7 (dismissing where "complaints plead that in fact [defendants] used the [patented invention] to contribute to the generation of information relevant to their [FDA submissions]").[2]

[2] Paragraph 53 of the Amended Complaint cites Exhibit 3 for the proposition that the authors of that article "developed a SARS-CoV-2 reporter tool . . . , with the '*mNeonGreen virus[] be[ing] reliably used* to study viral replication and pathogenesis.'" (emphasis added). The authors in question were scientists affiliated with UTMB, who are not parties to this suit. And Plaintiffs misleadingly altered the actual quote from Exhibit 3, where the UTMB authors stated that "mNeonGreen virus *could be* reliably used to study viral replication and pathogenesis." D.I. 29-3 at 29. There is no allegation in the Amended Complaint, or citation of attached Exhibits, that the Defendants in this case, *Pfizer and BioNTech, actually used* mNeonGreen generally to "study viral replication and pathogenesis."

2. Allele further alleges in conclusory fashion that mNeonGreen was used to "winnow" down an "unmanageable" number of potential vaccine candidates. D.I. 29, ¶¶ 3, 19, 33. But these implausible allegations are similarly insufficient to state a claim on which relief can be granted.

Not surprisingly, Allele's allegations on this point lack any support. Allele's own complaint cites documents stating that Pfizer and BioNTech were purportedly evaluating *four* related candidates and were doing so *in the context of clinical trials*. D.I. 29-6, at 2 ("BioNTech and Pfizer are evaluating four vaccine constructs of BNT162 in an mRNA-based clinical program."); D.I. 29-5, at 6; D.I. 29-7, at 3. There is no factual allegation—in the Amended Complaint or the many exhibits attached thereto—that supports the assertion Pfizer or BioNTech used mNeonGreen with respect to any products that do not require FDA authorization, or even with respect to vaccine candidates beyond these four clinical candidates. The Court need not accept such conclusory assertions, especially when they are not even supported by the very exhibits attached to the Amended Complaint. *See, e.g.*, *DriveCam, Inc. v. SmartDrive Sys., Inc.*, No. 11-CV-0997-H (RBB), 2012 WL 13175930, at *7 (S.D. Cal. Mar. 26, 2012) (dismissing trade secret misappropriation claim where the complaint did "not allege factual content allowing a reasonable inference that a specific individual . . . misappropriated trade secrets.").

Further, the Court need not accept Allele's "winnowing" allegations because they are implausible. Even according to the Amended Complaint, the alleged neutralization assay is not an early-stage screening assay run on vast numbers of candidates. It is alleged that Pfizer and BioNTech purportedly infringed the '221 patent by testing the blood samples of patients who received the vaccine during clinical trials with a neutralization assay that involves mNeonGreen. D.I. 29, ¶¶ 37–38; D.I. 29-5, at 22. The Amended Complaint does not and cannot allege any factual support for the nonsensical claim that Pfizer and BioNTech performed this process of human clinical trial testing with an "unmanageable" number of untested vaccine

candidates. *See Ewing v. Integrity Cap. Sols., Inc.*, No. 16-CV-1469-JLS-MDD, 2017 WL 758402, at *2 (S.D. Cal. Feb. 27, 2017) (determining whether allegation is plausible is a "context-specific analysis involving the Court's 'judicial experience and common sense.'" (quoting *Iqbal*, 556 U.S. at 678). Just the opposite—as noted above, Allele's own exhibits discuss testing a limited number of vaccines during clinical trials.

Finally, Allele's bald and self-contradictory assertions of "winnowing" would fall within the safe harbor even if they did not suffer the defects discussed above. Once again, *Merck* and *Integra* are instructive. In *Merck*, the Supreme Court specifically held that using a patented invention to narrow the number of potential drug candidates is protected by the safe harbor. *See Merck*, 545 U.S. 203–07. "Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval." *Id.* at 207. Here, too, application of the safe harbor is not limited to experiments that occur "after there has been a final selection of the product that is proposed for clinical trials." *Integra Lifesciences I*, 496 F.3d at 1346.

III. The Alleged Use of Clinical Trial Data for Commercial Purposes is Not an Infringing Activity

Allele's Amended Complaint further alleges that Pfizer and BioNTech used data from clinical testing for a variety of alleged "commercial purposes," in addition to the submission of that data for FDA approval purposes. *See, e.g.*, D.I. 29, ¶ 44. But Allele again misunderstands the nature of what activities would constitute infringement and the legal scope of the safe harbor. The *use or disclosure of data* from clinical testing is not an act of infringement, regardless of safe harbor immunity. *See Telectronics*, 982 F.2d at 1524 ("[D]isclosure of clinical trial data cannot, in and of itself, constitute an infringing activity."); *see also Classen*, 786 F.3d at 898 ("[S]ubsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that

exemption of the clinical study . . . ."); *Abtox*, 122 F.3d at 1030 (safe harbor allows use of test data "for more than FDA approval").

To plead a legally cognizable claim of infringement, the alleged infringing act must relate to the *use of an invention*. *Edwards Lifesciences Corp. v. Meril Life Scis. PVT. Ltd.*, No. 19-CV-06593-HSG, 2020 WL 6118533, at *9 (N.D. Cal. Oct. 16, 2020). ("[T]he only relevant acts are those that would otherwise constitute patent infringement under Section 271."). If the alleged infringing use of the invention is reasonably related to obtaining FDA approval, then any "intent or alternative uses are irrelevant to [the defendant's] qualification to invoke the section 271(e)(1) shield." *Abtox*, 122 F.3d at 1030; *see also Intermedics*, 775 F. Supp. at 1284 (the safe harbor "is not concerned in this setting with motives, purposes, or ulterior designs. Instead, the law is concerned only with actual uses.").

Common sense dictates the same conclusion: as courts have recognized, *all* clinical testing by drug companies is performed with a commercial purpose of securing government approval to market a drug. *See Intermedics*, 775 F. Supp. at 1280. "If a party were to lose the exemption every time a business purpose was detectable in its otherwise infringing activities, the exemption would virtually never be available and thus would fail to achieve Congress' objective." *Id.*

This is a textbook case where allegations of commercialization do not undercut the safe harbor. Allele's "commercial use" allegations are not even directed to the use of mNeonGreen, but recite alleged commercial activities related to the COVID-19 vaccine itself (which is not and cannot be alleged to include mNeonGreen). Allele's asserted "commercial purposes" for the use of mNeonGreen include "receiv[ing] commercial authorizations for their COVID-19 vaccine outside the United States," D.I. 29, ¶ 47; "procur[ing] lucrative vaccine contracts," *id.*; and "compet[ing] in the marketplace against other COVID-19 vaccines, by highlighting to potential purchasers and users of the vaccine added benefits of using Defendant's BNT162 vaccine instead of other vaccines," *id.*, ¶ 57. Again, each of these allegations is based on actions

Pfizer and BioNTech purportedly took with respect to the COVID-19 *vaccine itself*. There is no, and can be no, allegation that the vaccine contains mNeonGreen, and its sale and manufacturing are not alleged to infringe the '221 patent. In other words, none of the alleged commercial activities with respect to the COVID-19 vaccine are purported to infringe the '221 patent. Instead, the allegedly infringing activities were the use of mNeonGreen in a neutralization assay performed on blood drawn from clinical trial participants to generate data for regulatory approval. As explained above, this testing alleged in the Amended Complaint was reasonably related to seeking FDA emergency use authorization for the vaccine and ultimately full regulatory approval. The alleged activities are protected by the safe harbor regardless of whether Defendants were also motivated by commercial purposes at the time they allegedly performed the testing.

It is equally irrelevant whether, as part of their alleged commercialization efforts, Defendants used data from the neutralization assay that was originally generated from clinical trials in support of FDA authorization. Communicating previously generated data is not an act of patent infringement. The "disclosure of clinical trial data cannot, in and of itself, constitute an infringing activity." *Telectronics*, 982 F.2d at 1524. The safe harbor therefore allows parties to use "derived test data for fund raising and other business purposes." *Id.* at 1525. Courts have accordingly extended safe harbor protection to activities such as "presenting clinical trial data at a [medical] conference, reporting clinical trial progress to investors, analysts and journalists, and describing clinical trial results in a private fund-raising memorandum." *Id.* at 1523–24; *see also Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F.Supp.2d 104, 107–08 (D. Mass. 1998) (safe harbor applies even when a party may have "ulterior motives or alternate purposes" in addition to obtaining FDA approval."). Pfizer's and BioNtech's purported use of mNeonGreen to generate data in clinical testing for FDA authorization does not then fall outside of the

safe harbor simply because Allele asserts that those data were later discussed for other purposes.

IV. Allele's "Research Tool" Allegations Do Not Avoid Application of the Safe Harbor Statute

The application of the plain language of the safe harbor provision is not upset by Allele's allegations characterizing mNeonGreen as a "research tool" that "does not require government approval for clinical use" and is not otherwise subject to FDA approval. D.I. 29, ¶¶ 23, 43, 49, 53. The § 271(e)(1) safe harbor covers the use of any "patented invention," so long as the use is reasonably related to FDA submission. As Justice Scalia wrote for the Supreme Court in *Lilly*, the term "patented invention" means just that—an invention that has been patented. *See Lilly*, 496 U.S. at 665 (the "phrase 'patented invention' in § 271(e)(1) is defined to include *all* inventions" (emphasis added)); *see also* 35 U.S.C. § 271(e)(1) (referring to "patented invention" without further qualification). Merely calling a patented invention a "research tool" does not exempt it from this broad definition.

Not surprisingly then, courts routinely hold that the use of an alleged "research tool" by a party generating information about its drug product for submission to the FDA is protected by the safe harbor. Take *Katz v. Avanir Pharms.*, No. 06-cv-0496-DMS (LSP), 2007 WL 9776599, at *6 (S.D. Cal. Aug. 21, 2007), in which Judge Sabraw held that the use of a patented assay "to screen compounds as part of [defendant's] IgE drug development program" is protected by the § 271(e) safe harbor. *Id.* at *6. Judge Sabraw directly rejected the argument that the patented assay does not qualify for § 271(e)(1) because it was asserted to be "a research tool rather than a patented compound." *Id.* at *7. Rather, "the statute itself exempts the use of 'patented invention[s],' and the Supreme Court has given the statute a broad interpretation." *Id.* (citing *Merck*, 545 U.S. at 193).

More recently, Judge Forrest of the Southern District of New York rejected the notion that characterizing a patented invention as a research tool is sufficient to

exempt it from being a "patented invention" under the meaning of the statute. *Teva*, 2013 WL 3732867, at *1, 7–9. The court found that the safe harbor covers "polypeptide markers" used as an alleged research tool to characterize the active ingredient in a drug to generate data for FDA submission. *Id.* at *7–9; *see also Classen*, 786 F.3d at 897 (safe harbor protects use of patented method to analyze data on commercially available drugs); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95-cv8833-RPP, 2001 WL 1512597, at *3 (S.D.N.Y. Nov. 28, 2001) ("'patented invention' means all patented inventions or discoveries").[3]

Of course, as with any other kind of patented invention, the use of a patented invention alleged to be a "research tool" may not be protected by the safe harbor if, unlike the allegations in the complaint discussed above, it is not reasonably related to an FDA submission. For instance, in *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008), the accused infringer made an optical spray analyzer ("OSA") device which it then sold to customers that were not parties to the suit. Those customers in turn used the device to "study and optimize the delivery of various aerosol-based drugs." *Id.* at 1258. The Federal Circuit found the seller of the OSA was not exempt from patent infringement simply because they sold a patented invention that their *customers* (who had not been accused of infringement) might arguably use to generate information for the FDA. *Id.* at 1265–66; *see also Momenta*

[3] In a case involving different alleged facts, one district judge in Illinois made a broad statement that "only 'patented inventions' for which regulatory approval is required fall within the scope of the safe harbor exemption." *PSN Ill., LLC v. Abbott Labs.*, No. 09 C 5879, 2011 WL 4442825, at *5 (N.D. Ill. Sept. 20, 2011). Taken at face value, that statement contradicts the language of the statute and the Supreme Court's interpretation, *see Lilly*, 496 U.S. at 665, and it is also inconsistent with how the Federal Circuit has subsequently applied the safe harbor. *See, e.g., Classen*, 786 F.3d at 897 (involving 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.

Pharms., Inc. v. Teva Pharms. USA Inc., 809 F.3d 610, 619, 621 (Fed. Cir. 2015) (noting that research tools "may" not be covered while also recognizing that preclinical research can be an activity that falls within the safe harbor). Likewise, as discussed above, *see supra* pp. 13–16, using a patented invention solely for basic research without relation to a specific drug candidate or FDA submission may not be covered by the safe harbor. *See Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, No. 11-cv-2214-GPC-KSC, 2014 WL 794811, at *1, *13 (S.D. Cal. Feb. 27, 2014) (factual issue as to whether the accused infringer was merely providing basic research services on behalf of another company); *PSN Ill.*, 2011 WL 4442825, at *1 (finding use was merely screening "thousands of potential drug candidates for activity").

Unlike in those cases, Allele does not allege that Pfizer and BioNTech sell mNeonGreen to third parties or that the acts of infringement are not related to clinical trial testing of COVID-19 vaccine drug products regulated by the FDA. To the contrary, the Amended Complaint alleges that Defendants obtained an assay containing mNeonGreen from a third party, UTMB, and then used that assay "[t]hroughout each of Phases I and II of their COVID-19 vaccine trial." D.I. 29, ¶ 37; *see also id.*, ¶¶ 3, 23, 38, 43, 56. This is exactly the kind of conduct the safe harbor immunizes. Thus, regardless of whether Allele alleges that mNeonGreen is a "research tool," the invocation of that phrase does not negate the plain language and application of § 271(e)(1). The alleged use of the patented invention to generate information for the FDA in support of regulatory approval for the COVID-19 vaccine entitles Defendants to the protection of the safe harbor.

CONCLUSION

Because the alleged infringing activity in Allele's Amended Complaint is protected by the statutory safe harbor, this Court should dismiss the Amended Complaint under Rule 12(b)(6).

Respectfully submitted,

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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: March 26, 2021

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