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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. 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

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 FDA regulatory approval for a vaccine against SARS-CoV-2, the virus that causes COVID-19. Plaintiff Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed this patent suit against Pfizer and BioNTech alleging patent infringement arising from Defendants' efforts to advance the COVID-19 vaccine through the FDA approval process. For the reasons discussed below, the allegations of the Complaint bring this case squarely within the safe harbor of 35 U.S.C. § 271(e)(1), and this suit should therefore be dismissed.

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

The allegations of the complaint do not (and cannot) state a cognizable claim under established law. The alleged patent infringement—asserted uses by Pfizer and BioNTech of the patented invention to generate data from clinical trials in support of seeking FDA approval—are precisely the type of activity that is protected by the "safe harbor" from patent infringement claims under 35 U.S.C. § 271(e)(1). That provision, enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), 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 and, in the words of the Supreme Court, "extends to all uses of patent 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).

Thus, even taking the allegations in the complaint as true for this motion, the purported use of mNeonGreen here to obtain data for submission to the FDA does not constitute infringement as a matter of law. This Court should dismiss Allele's 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]

BACKGROUND

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

Early last year, scientists at Pfizer and BioNTech began working to develop a vaccine against SARS-CoV-2, the virus that causes COVID-19. D.I. 1-2, Ex. 8, at 92. The vaccine, designated BNT162b2, utilizes a composition in which messenger RNA ("mRNA") is encapsulated in lipid nanoparticles and injected into the body. *Id.* 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.

[1] For purposes of this motion, Pfizer and BioNTech cite and rely upon the statements in the 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 activities alleged in the 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.

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.[2] EUA is the first stop on the regulatory pathway for the vaccine: Pfizer and BioNTech also intend to submit a Biologics License Application ("BLA") to obtain full regulatory approval of the COVID-19 vaccine from the FDA. As of the date of this submission, the Pfizer/BioNTech vaccine is administered under the FDA regulatory authorization provided by the EUA, and the clinical use during this period will be considered by the FDA in reviewing the full BLA when it is eventually submitted.

As noted above, 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 requirements, Pfizer and BioNTech have been and continue to be engaged in large scale clinical trials to evaluate, among other things, whether individuals who receive the vaccine are less susceptible to COVID-19 infection. D.I. 1-2, Ex. 8, at 97. As part of these trials, the results of laboratory tests on blood samples drawn from patients in the clinical trials who received the vaccine are evaluated. D.I. 1-2, Ex. 8, at 93, 95. According to the complaint, one of these tests is a "neutralization assay," which as explained further below is a laboratory procedure to detect the presence of antibodies in the blood of a patient after receiving a vaccination capable of neutralizing the SARS-CoV-2 virus. D.I. 1-2, Ex. 4, at 40–

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

42, Ex. 8, at 93. 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 will also submit these results as part of the full BLA. *Id.*, Ex. 5, at 62–65, Ex. 8, at 91.

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

In October 2020, prior to the FDA's emergency authorization of the Pfizer/BioNTech vaccine, and with no prior 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 is directed to a fluorescent protein, which Allele calls "mNeonGreen," that glows when exposed to certain wavelengths of light. D.I. 1, ¶ 21.

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

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

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

III. Allele Does Not Assert that Defendants' COVID-19 Vaccine or its Manufacture, Infringes Allele's Patent

Allele does not and cannot 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. Nor does Allele assert that Pfizer or BioNTech sell mNeonGreen to third parties. Instead, Allele's complaint expressly alleges infringement based on use of the reporter virus (allegedly containing the mNeonGreen protein) in the testing of blood samples from patients who received the vaccine in clinical trials to generate data useful for obtaining FDA regulatory authorization for the Pfizer/BioNTech vaccine. *See, e.g.*, D.I. 1, ¶¶ 26, 30, 39, 41.

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*

> *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 provision 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.

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

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

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. So long as 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; *see also Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 897 (Fed. Cir. 2015)

("[Accused infringer's] clinical study and its FDA submissions clearly fall within the scope of the safe harbor."); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir.), *opinion amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997) (safe harbor "does not look to the underlying purposes or attendant consequences of the activity (*e.g.*, tests led to the sale of the patent), as long as the use is reasonably related to FDA approval"); *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) (explaining that the safe harbor "allows for the elective use of patented technology as long as it serves to produce information required under a federal law").

Because data showing, among other things, efficacy in clinical trials is required for FDA approval of new drugs or biologics, *see* 42 U.S.C. § 262(a)(2); 21 U.S.C. § 360bbb-3(c)(2), (e)(1), district courts have repeatedly dismissed patent infringement complaints in which the alleged infringing activity occurs in connection with clinical testing. For example, 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). Similarly, in *Medical Diagnostic Laboratories, L.L.C. v. Protagonist Therapeutics, Inc.*, the court dismissed a complaint wherein "the only specific examples alleged are 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.

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

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

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

II. 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." D.I. 1, ¶¶ 16, 25. The § 271(e)(1) safe harbor by its terms covers the use of any "patented invention," so long as the use is reasonably related to FDA submission. As Justice Scalia wrote for the Court, 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 of a patented invention.

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. 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.*; *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 Civ. 8833 (RPP), 2001 WL 1512597, at *3 (S.D.N.Y. Nov. 28, 2001) ("'patented invention' means all patented inventions or discoveries").[3]

[3] In a case involving different alleged facts, one district judge in Illinois made a broad 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

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") which it then sold to customers, who then used it 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 1266; *see also Momenta 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, 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 Pharms., 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").

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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.

Unlike these cases, Allele's complaint does not allege that Pfizer and BioNTech sell mNeonGreen to third parties or that the acts of infringement are not related to the COVID-19 vaccine drug product for which they are seeking FDA approval. To the contrary, as discussed above, the complaint alleges that Defendants used mNeonGreen "throughout Defendants' COVID-19 vaccine trials," D.I. 1, ¶ 3; *see also id.* ¶¶ 24, 25, 32, 34, 41, which is exactly the kind of conduct § 271(e)(1) immunizes. Thus, regardless of whether Allele alleges that mNeonGreen is a "research tool," the invocation of that phrase does not negate the language and application of 35 U.S.C. § 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 complaint is protected by the statutory safe harbor, this Court should dismiss the complaint under Rule 12(b)(6).

Respectfully submitted,

Dated: February 8, 2021

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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

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