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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 (AHG)

REPLY 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. Allison H. Goddard

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Allele does not deny that the fundamental premise of its Amended Complaint is that Defendants allegedly used the mNeonGreen protein to test patient blood samples "[t]hroughout each of Phases I and II of their COVID-19 vaccine trial." D.I. 29, ¶ 37. This core alleged act of infringement, which was the sole basis for the original complaint, is repeated multiple times in various forms and with different glosses. *E.g.*, *id.* ¶¶ 36, 43–44, 47. Allele does not allege that the vaccine contains mNeonGreen. Nor can Allele dispute that clinical trial use of mNeonGreen is "reasonably related to the development and submission of information" to the FDA, as required for immunity under 35 U.S.C. § 271(e)(1).

So Allele pivots, asking the Court to recognize a *per se* exemption to the safe harbor for "research tools." That argument is wrong as a matter of law. Nothing in the statute carves out "research tools." Allele's reliance on comments in a *dissenting* opinion, legislative history, and inapposite cases cannot overrule the Supreme Court's clear pronouncement that the term "patented invention" in Section 271(e)(1) "include[s] all inventions," *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990), and Federal Circuit precedent following that holding.

Allele's remaining arguments are just as meritless. Allele's conclusory allegations about alleged "pre-clinical" testing of vaccine candidates retread arguments the Supreme Court has rejected. Its allegations of "post-approval" uses are implausible; Defendants have *not* yet received FDA approval for their vaccine, which is supplied under an FDA emergency use authorization. And even if the asserted uses had occurred "post-approval," they still would be protected because the only alleged infringing act—testing blood samples of patients in clinical trials—was itself protected. The Amended Complaint should be dismissed.

ARGUMENT

I. Safe Harbor Defenses Can Be Resolved on a Motion to Dismiss

Allele claims (Opp. 7) that the Court cannot decide safe harbor issues on a Rule 12 motion. Not so. Numerous authorities Defendants cited, *see* Mot. at 10, 12, prove

that the safe harbor "may properly be considered at the motion to dismiss stage, even if it is viewed as an affirmative defense." *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 575 (D. Md.), *aff'd*, 586 F. App'x 585 (Fed. Cir. 2014) (citing cases). Nothing stops the Court from deciding that the safe harbor applies here because "the applicability of the defense is apparent on the face of the complaint or documents incorporated by reference within the complaint." *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 2013 WL 3732867, at *3 (S.D.N.Y. July 16, 2013).[1]

II. Allele's "Research Tool" Arguments Do Not Negate the Safe Harbor

1. The only act of infringement Allele specifically alleges is the supposed use of mNeonGreen to test patient blood samples "[t]hroughout each of Phases I and II of [Defendants'] COVID-19 vaccine trial." D.I. 29, ¶ 37. This use lies at the very heart of the safe harbor. *See* Mot. 10 (collecting cases). Allele's amended complaint should be dismissed on this basis.

Unable to identify activities outside the safe harbor, Allele resorts to arguing that the safe harbor does not apply to mNeonGreen. According to Allele, the purported invention it patented is not a "patented invention" at all but a "research tool." In making this argument, Allele repeatedly asks the Court to adopt comments in Judge Rader's *dissenting* opinion in *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334 (Fed. Cir. 2007). But those comments are not law, and Judge Rader's policy concerns cannot change the broad language of Section 271(e)(1). *Cf. Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1678 (2017) (policy arguments "could not overcome the statute's plain language"). Section 271(e)(1) "exempt[s] from infringement *all* uses of patented compounds 'reasonably related' to the process of

[1] Neither *Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, 2020 WL 789559, at *3 (N.D. Cal. Feb. 18, 2020) nor *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1281 (S.D. Fla. 2005) (both cited Opp. 7) holds that safe harbor issues can never be resolved on a Rule 12 motion. That factual disputes may have precluded dismissal in those cases does not mean the same is true in this case.

developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005). The Supreme Court therefore "declin[ed]" to read the safe harbor's text "so narrowly as to render [its] stated protection of activities leading to FDA approval for all drugs illusory." *Id.* at 207. Judge Rader's dissent is not a basis to narrow the safe harbor in a way the Supreme Court deemed improper.

2. a. Allele also relies on *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008), but that case could not and did not hold that a "patented invention" must be eligible for a patent term extension ("PTE") to be eligible for the safe harbor. The Supreme Court held in *Lilly* that such equilibrium is not always achieved and does not trump the statute's plain language. *See* 496 U.S. at 671–72. The Federal Circuit has also rejected Allele's argument, noting in *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997) that "statutory symmetry" is "not required." The Federal Circuit went on to reiterate that the term "patented invention" covers *all* inventions—including class II medical devices not eligible for PTE. *Id.*

The Federal Circuit affirmed this understanding of *Lilly* even after *Proveris*. In *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, ("*Momenta I*"), Judge Rader, in dissent, again sought to limit the safe harbor, arguing that because the plaintiff could "not obtain the patent extension created in § 201," the safe harbor could not apply. 686 F.3d 1348, 1371 (Fed. Cir. 2012) (Rader, J., dissenting). The majority expressly rejected that position as "not correct," citing *Lilly* and *Abtox*. *Id.* at 1360; *see also id.* ("The Supreme Court in *Eli Lilly* noted that equilibrium was not always achieved . . . . We too have rejected this strict interpretation of the safe harbor . . . .").

Allele argues (Opp. 2) that *Momenta I* was overruled by the later decision in *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 614 (Fed. Cir. 2015) ("*Momenta II*"). But *Momenta II* held only that the safe harbor did not apply because the accused activity was not related to submissions for FDA authorization.

See 809 F.3d at 620. Nothing in that holding overruled the Federal Circuit's earlier explanation of the law relevant to the safe harbor. Regardless, *Momenta II* is consistent with Defendants' position; it does not hold that research tools are *never* covered by the safe harbor, only that they "*may* not be covered" if their use is disconnected from the regulatory process. *Id.* at 619 (emphasis added).

b. Allele also overstates *Proveris*'s holding. The accused infringer there made an otherwise infringing device and sold it to third parties who used it to identify drug candidates. The defendant was not involved in, and did not participate in, the development and submission of information to FDA. The Federal Circuit unsurprisingly held that the defendant was "not within the category of entities for whom the safe harbor provision was designed to provide relief." 536 F.3d at 1265.

Proveris said nothing about whether *customers* who used the allegedly infringing device for clinical testing to generate data for FDA submission—that is, the parties whose activities would be analogous to those alleged of Pfizer and BioNTech—would be ineligible for the safe harbor. When the Federal Circuit has considered the issue, it has confirmed the safe harbor protects use of a patented invention even if the invention itself is not subject to FDA approval. *See, e.g.*, *Classen Immunotherapies, Inc., v. Elan Pharm., Inc.*, 786 F.3d 892, 894 (Fed. Cir. 2015); *Momenta I*, 686 F.3d at 1359; *Abtox*, 122 F.3d at 1028–29.

c. Although virtually every district court to consider the question has followed the text of Section 271(e)(1) and declined to create an exemption for "research tools," *see* Mot. at 19–20, Defendants acknowledged an outlier in their opening brief, *see PSN Illinois, LLC v. Abbott Labs.*, 2011 WL 4442825, at *3 (N.D. Ill. Sept. 20, 2011). But *PSN Illinois* contradicts precedent holding that the term "patented invention" includes "all inventions." *Lilly*, 496 U.S. at 665. *PSN Illinois* is also inconsistent with the Federal Circuit's subsequent decision in *Classen*, which found that a general method of "accessing and analyzing data on a commercially available drug"—something that is not FDA approved and would clearly fall within

the category of "research tool"—qualifies as a "patented invention." 786 F.3d at 894. For these reasons, another district has rejected *PSN Illinois* as "either wrong or irrelevant." *Teva*, 2013 WL 3732867, at *8–9. This Court should do the same.

3. Lacking support in the case law or statute, Allele leans on legislative history. But reliance on legislative history is proper only to interpret ambiguities, and Allele points to none; the text of Section 271(e)(1) clearly reaches any "patented invention." There is "neither the need nor the occasion to refer to the legislative history." *Momenta I*, 686 F.3d at 1355.

Even if resort to legislative history were proper, it would not help Allele. Allele cites snippets suggesting that "Congress intended immunity for *de minimis* infringement, solely to obtain regulatory approval in time for prompt competition." Opp. 23 (citing H. Rep. No. 98-857, Part 2, 98th Cong., 2d Sess. (Aug. 1, 1984)). The Supreme Court has squarely rejected that cramped view, holding that the safe harbor is *not* "applicable only to the research relevant to filing an ANDA for approval of a generic drug." *Merck*, 545 U.S. at 206.

In any event, Allele's doomsday warnings are unwarranted.[2] Defendants do not contend that *every* use of every "research tool" is immune. As in *Proveris*, patentees may have recourse against parties who make a patented "research tool" or sell it to drug developers. (The Amended Complaint does not allege that Defendants created the allegedly infringing assay, but rather asserts that it came from the University of Texas Medical Branch. *See* D.I. 29, ¶¶ 51–52, 55; Mot. 5, 21.). What matters is whether Defendants' alleged activities were "carried out to 'satisfy the FDA's requirements.'" *Momenta I*, 686 F.3d at 1359. As explained below, that standard is plainly met.

[2] So are Allele's invocations of the Takings Clause. Allele cites no case holding that application of the safe harbor constitutes a taking.

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

1. Allele does not dispute that the bulk of its Amended Complaint alleges use during clinical trials. *See* D.I. 29, "Accused Products," ¶¶ 36, 37, 43, 44, 47. Allele instead suggests that some of Defendants' clinical trial uses—it does not say which ones—are not subject to the safe harbor because they had "sufficiently commercial purposes" or resulted in "commercial use overseas." Opp. 20, 22. But these allegations do not bring Defendants' conduct outside the safe harbor. As long as the allegedly infringing acts (here, clinical trial testing) are "reasonably related" to securing FDA approval, courts "do[] not look to the underlying purposes or attendant consequences of the activity." *Abtox*, 122 F.3d at 1030; *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 108 (D. Mass. 1998) ("ulterior motives or alternate purposes do not preclude application of the" safe harbor). Indeed, "inquiring into the motivation behind activities that are conducted under the auspices of FDA-approved clinical trials would be contrary to Congress's intent in enacting § 271(e)(1)." *Nexell Therapeutics, Inc. v. AmCell Corp.*, 199 F. Supp. 2d 197, 204 (D. Del. 2002). Whether Defendants hoped to earn a return from their investment in this lifesaving vaccine does not remove testing conducted during clinical trials from the safe harbor's scope.

The statute's inclusion of the word "solely" in the phrase "solely for uses reasonably related" does not change the analysis either. *Contra* Opp. 23–24. "Solely" simply "mandates that the making, using, or selling of the patented invention cannot be for uses that are *not* reasonably related to FDA approval." *Amgen*, 3. F. Supp. 2d at 107–08 & n.3. But if Defendants' uses were "reasonably related to the development and submission of *any* information" to the FDA, they are entitled to the safe harbor, even if the information is also used for some other purpose. *Merck*, 545 U.S. at 202.

2. For the same reasons, Allele's vague arguments (Opp. 22–23) about

(unspecified) patent applications are legally irrelevant. Section 271(e)(1) "does not identify dissemination of . . . information as a potentially infringing activity." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1524 (Fed. Cir. 1992). The Federal Circuit expressly rejected the "theory that the statute requires that the original [safe harbor] exemption . . . be revoked when the resulting data is later used for non-FDA reporting purposes." *Id.* Allele also alleges that Defendants used data "premised on . . . use of mNeonGreen" to "successfully receive[] commercial authorizations" outside the U.S. D.I. 29, ¶ 47. But reusing data originally generated for U.S. regulatory submissions in later foreign submissions does not nullify the safe harbor. *See Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1281 (N.D. Cal. 1991). Allele's cited cases do not change this law.[3]

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

Allele doubles down on its claim that Defendants used mNeonGreen to "winnow[] an unmanageable number of vaccine candidates." Opp. 18. Those allegations are as conclusory as they are implausible. *See* Mot. 15–16. And, in any case, the Supreme Court in *Merck* rejected the premise of Allele's "winnowing" allegations: that activities cannot be protected by the safe harbor if they occur early in the clinical development process. Even where the results of the allegedly infringing activity ultimately are not submitted to FDA, the safe harbor still applies "as long as there is a reasonable basis for believing that the experiments will produce

[3] *Chang v. Biosuccess Biotech Co., Ltd.* did not find that foreign patent applications were infringing; it concluded that infringing importation and manufacturing activities were still infringing *even if* performed to support foreign applications. 76 F. Supp. 3d 1022, 1037 (C.D. Cal. 2014). In *NeoRx Corp. v. Immunomedics, Inc.*, defendant "ma[de] the [infringing] Products in the United States then shipp[ed] them abroad to regulatory agencies." 877 F. Supp. 202, 207 (D.N.J. 1994). Allele makes no such allegations. And in *PSN Illinois*, discussed *supra* pp.4-5, the court incorrectly reasoned that the safe harbor did not apply because defendants were not trying to introduce a generic competitor to plaintiffs' invention. 2011 WL 4442825, at *5.

the types of information that are relevant to an [FDA submission]." 545 U.S. at 208 (internal quotations omitted). Here, Allele *concedes* that data from Defendants' development efforts *did* go to FDA in connection with the EUA, *see* D.I. 29, ¶ 23, and Defendants are unquestionably continuing to generate data for U.S. regulatory submissions, *see infra* Sec. V.

V. The Alleged "Post-Approval" Use of Clinical Trial Data Is Reasonably Related to FDA Submissions for the COVID-19 Vaccine

1. Allele further misapplies the safe harbor in discussing what it calls "Post-Approval Marketing Uses." Opp. 21. This category apparently refers to Defendants' alleged efforts "to probe 20 new COVID-19 strains," which Allele contends is "not for obtaining FDA approval of a vaccine already in . . . use." *Id.* But this argument by its nature is about sales of a hypothetical *future* product that would be based on clinical trial activity allegedly occurring now. It thus falls within the safe harbor. Moreover, Allele's assertion of "post" approval use is plainly implausible. As Defendants explained, Mot. 3–4, their COVID-19 vaccine is currently in use only under FDA's Emergency Use Authorization, *see* 21 U.S.C. § 360bbb-3(a)(2); *see also* https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19. Defendants have not yet applied for, and FDA has not granted, full regulatory approval. Obtaining that full regulatory approval will require additional data demonstrating the safety and efficacy of Defendants' COVID-19 vaccine, *see* 21 U.S.C. § 360bbb-3(c)(2), including its efficacy against emerging variants.[4]

[4] Allele relies on *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1340 (Fed. Cir. 2019), but the holding there was fact-specific; the safe harbor did not apply because the alleged infringer "was not required to manufacture additional batches" to obtain FDA approval. Here, Allele is not alleging that any batches of the COVID-19 vaccine infringe any patent. It alleges instead that Defendants used a protein construct containing mNeonGreen in testing of clinical trial samples for generating data for FDA authorization.

Incredibly, Allele asks the court to pretend that the legal-regulatory scheme ends at emergency authorization, *e.g.*, Opp. 5 (referring to unpled "full regulatory approval"). But Allele cannot evade the safe harbor through creative omission. Rule 12 does not mandate that courts blind themselves to obvious and easily verifiable information. *See Singh v. Ashcroft*, 393 F.3d 903, 905 (9th Cir. 2004); *Intri-Plex Techs., Inc. v. Crest Grp., Inc.*, 499 F.3d 1048, 1052 (9th Cir. 2007).[5] The Court can take judicial notice that the vaccine is supplied under an EUA. *Cf. Goico v. FDA*, 2020 WL 7078731, at *3–4 (D. Kan. Dec. 3, 2020) (taking judicial notice of "EUA for [hydroxychloroquine] for the treatment of COVID-19").

2. Allele's vague reference (Opp. 22) to infringing uses for post-EUA "quality control" is likewise unavailing. Simply saying that post-approval activities took place does not give rise to a plausible allegation of an infringing use that is not immune under the safe harbor. *See Classen*, 786 F.3d at 897 ("[T]he statutory language does not categorically exclude post-approval activities from the ambit of the safe harbor."). Allele must plead *facts* to support its allegation that Defendants' activities exceeded the safe harbor. Yet neither Allele's Amended Complaint nor its opposition explain what "quality control" Defendants supposedly performed, or even what it means by "quality control" in this context. Without such factual allegations—the who, what, when, and where of the supposed "quality control" testing—Allele cannot "support a plausible inference that [Defendants] ha[ve] engaged in activities outside the safe harbor." *Med. Diagnostic Labs., L.L.C. v. Protagonist Therapeutics,*

[5] Allele is wrong that *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988 (9th Cir. 2018) bars Defendants from "relying on third-party documents attached to the FAC to dispute or contradict" Allele's allegations. Opp. 6–7. *Khoja* involved documents that were *not* attached to the complaint, but that the defendant contended were implicitly "incorporated" into the complaint by reference. 899 F.3d at 1002–03; *see also In re Eventbrite, Inc. Sec. Litig.*, 2020 WL 2042078, at *7, *11-12, *16 (N.D. Cal. Apr. 28, 2020) (rejecting Allele's interpretation of *Khoja*).

Inc., 298 F. Supp. 3d 1241, 1248 (N.D. Cal. 2018) ("vague allegation of attempted sales" insufficient to survive dismissal).

VI. Allele's Request for Discovery Should Be Denied

Allele falls back to a request for discovery, theorizing that "[a]dditional facts are likely to exist" that may bear on its ability to overcome the safe harbor defense. Opp. 25. By seeking discovery to allege facts that bring its complaint out of the safe harbor, Allele tacitly concedes that the allegations in its current complaint *do* fall within the safe harbor and should be dismissed.

Allele also faults Defendants for its own problematic pleading, suggesting that relevant facts are "non-public" and "known in far more detail to [Defendants]." Opp. 25. Allele never reconciles its supposed need for more facts with its erroneous assertions that a legal "research tool" exception controls this motion. Regardless, Rule 12 does not countenance taking discovery to determine whether a lawsuit should have been brought. *See Ashcroft v. Iqbal*, 556 U.S. 662, 684–85 (2009) (motion to dismiss "does not turn on the controls placed upon the discovery process").

In sum, the only well-pleaded uses of mNeonGreen Allele alleges were in generating data in clinical trials relating to seeking FDA authorization to supply Defendants' COVID-19 vaccine—actions squarely within the safe harbor. Allele's request for a fishing expedition to shore up its other unsupported and speculative allegations only reinforces the inadequacy of its two complaints. Allele should not be given a third bite at the apple. *Ecological Rights Found. v. Pac. Gas & Elec. Co.*, 713 F.3d 502, 520 (9th Cir. 2013) (discretion to deny leave to amend "is 'particularly broad' where the plaintiff has previously amended its complaint").

CONCLUSION

For the reasons stated above and in Defendants' opening memorandum, 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: April 23, 2021

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