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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ALLELE BIOTECHNOLOGY AND PHARMACEUTICALS, INC.,

Plaintiff,

v.

PFIZER, INC., et al.,

Defendant.

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

OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT BASED ON A SAFE HARBOR AFFIRMATIVE DEFENSE

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

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In the words of Judge Rader, putting research tool patents inside Section 271(e)(1)'s Safe Harbor would be "devastating," "obliterate all value" in such patents, "shift control [] to the insular pharmaceutical industry," "amount to a charitable (but nondeductible) gift to the pharmaceutical industry," and "swallow" a small company's "reward for the lifetime of labor and investment that produced the research tool." Yet Defendants brazenly ask this Court to do just that.

I. INTRODUCTION

In their Motion to Dismiss ("Motion" or "Mot.") the First Amended Complaint ("FAC"), Defendants plead for perpetual immunity from patent infringement. They assert a fact-sensitive affirmative defense, for which they hold the burden, and show their willful disregard for Plaintiff Allele's undisputed patent rights. According to Defendants, even the highly-clarifying FAC and its many distinct acts of infringement should be dismissed – to relieve them of Allele's patent, a "burden" interfering with Defendants' efforts to make an estimated $4.35 billion in profit from the coronavirus pandemic. *See* Mot. 2:24. Allele's patented technology was instrumental to saving precious time and making Defendants first to market with a COVID-19 vaccine, protecting countless lives of those who received the vaccine, and shielding the surrounding community from further spread of SARS-Cov-2. Defendants hold a thicket of patents and are well aware that the Constitution provides for patent rights precisely for the type of infringement alleged in the FAC.

Defendants' reliance on a Safe Harbor research exception under 35 U.S.C. § 271(e)(1) is misplaced, would destroy established patent rights granted under the Constitution, and would violate the Constitution's Takings Clause. According to Defendants, "[t]he 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." Mot. 8:9–11 (emphasis added). Even a new and patented test-tube, microscope, computer program – indeed anything – could be co-opted,

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say Defendants. As former Chief Judge Rader of the Federal Circuit wrote, this argument incorrectly swallows the rule with the exception, and would have a "devastating impact on research tool inventions." *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1352, 1350 (Fed. Cir. 2007) (Rader, J., dissenting). Judge Rader explained the basic flaw behind Defendants' perverse rationale:

> A hypothetical example will help illustrate the importance of protecting research tool patent rights. Suppose a university professor or small independent research company invents and obtains a patent for a novel and extremely useful research tool. This invention represents the work of a lifetime for its inventors and perhaps most of the research budget for the university department or the small company – perhaps millions of dollars in investment. The only use of the invention tests other pharmaceutical compounds for effectiveness in fighting cancer. The invention does not itself fight cancer, but instead simply identifies the cancer fighting characteristics in other compounds. This patented invention would, of course, be of great use to the pharmaceutical industry. It would also benefit the public by identifying cancer treatments. The patent system of course would wish to protect this invention and give incentives for more investment in developing this kind of valuable research tool.

Id. at 1352. The Federal Circuit heeded this warning in *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265–66 (Fed. Cir. 2008) and in *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) ("*Momenta II*") (earlier ruling "would result in manifest injustice;" "research tools that are not themselves subject to FDA approval may not be covered.").

Defendants' overreaching attempt to exempt pharmaceutical companies from any infringement of research tool patents is unsupported. "The only activity which will be permitted by" the Safe Harbor "is a limited amount of testing," originally so that "generic manufacturers can establish the bioequivalency of a generic substitute." H. Rep. No. 98-857, Part 2, 98th Cong., 2d Sess. (Aug. 1, 1984).

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While Congress enacted the Safe Harbor to allow "interference with the rights of the patent holder [that] is not substantial," so a generic manufacturer could prepare for commercialization *after* a patent expires, *id.*, Defendants would turn the *de minimis* effect of the statute into a playground for willful infringers to eviscerate undisputed patent rights.

Binding precedent squarely rejects Defendants' argument. Patented "research tools" such as the '221 Patent are outside the scope of the Safe Harbor; their unauthorized use is not immunized from infringement. *Proveris*, 536 F.3d at 1265–66. Further, Defendants have the burden to demonstrate that each infringing use alleged in the FAC meets each element of the Safe Harbor. At a minimum, the parties' disputes concerning the Safe Harbor affirmative defense highlight that the issue is premature and unsuitable for a Rule 12(b)(6) motion, before discovery has even commenced, on these inherently factual issues. The Motion should be denied.

II. BACKGROUND

A. Relevant Allegations In The Complaint

The FAC alleges that Defendants extensively used and continue using Allele's patented mNeonGreen technology, infringing U.S. Patent number 10,221,221 (the "'221 Patent"). FAC ¶¶ 1–3. The '221 Patent claims nucleotide and amino acid sequences encompassing Allele's valuable artificial fluorescent probe technology known as mNeonGreen. FAC ¶¶ 2, 27, 29, 31. The scientific community has praised mNeonGreen as robust, *the* gold standard and go-to tool of its kind. It is a broad and flexible discovery-inducing innovation in biotechnology and medicine, with versatility beyond COVID-19 therapeutics and apart from drug research and development. FAC ¶¶ 7, 8, 34, 53. Moreover, the '221 Patent (and the mNeonGreen technology it covers) is not a patented invention subject to review by the FDA or any Federal law that regulates the manufacture, use, or sale of drugs or veterinary biological products. FAC ¶ 32.

Defendants began widespread use of mNeonGreen, which no regulatory

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agency required, without attempting to contact Allele for permission, as the key research tool in a reporter assay system to rapidly narrow and evaluate vaccine candidates. FAC ¶¶ 23, 34, 36–37, 45, 51, 52. Infringing the '221 Patent allowed Defendants to urgently research and develop their BNT162 mRNA-based COVID-19 vaccine, conduct pre-clinical, clinical and post-clinical studies, and gain Fast Track designation for expedited review and subsequent authorization for use in the U.S. and abroad. FAC ¶¶ 3, 6, 12, 23, 34, 44, 47–50. Defendants also used mNeonGreen to further efforts in developing their own patents, marketing and sales activity, and validation and quality control efforts. *Id*.

Despite downplaying its import, and given these benefits, Defendants' uses of mNeonGreen throughout the development process made them first to market with a COVID-19 vaccine and has led to billions in revenue and, most importantly, saved precious time and lives as a result. FAC ¶ 7. Despite viewing this case as all about clinical trials, Defendants in fact made distinct Preclinical Investigatory Uses, Clinical Trial Uses, and Post-Approval Uses. FAC ¶¶ 12, 3. And Defendants continue using mNeonGreen for commercial purposes such as validation, quality control, promotion, and marketing advantage. FAC ¶¶ 44, 34. Having received all the benefits, Defendants nevertheless want none of the burdens.

B. Defendants' Motion Relies On Attorney-Argument About Facts Outside The Pleadings

Defendants filed this pleadings challenge seeking to immunize their multiple uses of mNeonGreen and infringement of Allele's '221 Patent. An obvious fatal flaw is the Motion's reliance on purported facts outside the complaint.

For example, Defendants argue that "Allele is still *not* accusing Pfizer or BioNTech of . . . using mNeonGreen in the process of making the vaccine." Mot. 2:8–11. On the contrary, the FAC alleges that "[o]nly through use of mNeonGreen" were Defendants able to bring their SARS-CoV-2 vaccine to market, FAC ¶ 6, and Defendants used mNeonGreen at least in validation and quality

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control efforts during the manufacturing process, FAC ¶ 44.

Similarly, Defendants assert that their use of the '221 Patent is only "to generate data for the FDA," Mot. 2:16–19, and that Defendants' "goal" is to "obtain[] final regulatory approval under a Biologics License Application ('BLA') from the FDA," *id*. at 1:8–11. *See also id.* at 8:11–14 ("generate data that will support final FDA approval for the Pfizer/BioNTech vaccine") and 4:10–12 ("the full BLA when it is submitted"). The FAC is not so narrow, and the Motion fails to support Defendants' assertion, which is incorrect. Even beyond the research tool nature of the invention, the FAC alleges multiple distinct non-FDA uses by Defendants that are still not exempt from infringement.

Building upon unpled "facts" about Emergency Use Authorizations ("EUAs") and Biologic License Applications ("BLAs"), Defendants refer to unspecified testing activities and FDA requirements, uniquely within their knowledge, to argue that they are authorized to vaccinate the entire country, if not the world, at great profit, while openly infringing Plaintiff's patent, because they say a BLA is still to come. Mot. 3:13–21. These "facts" conflict with FAC ¶ 23's pleading that Defendants' vaccine has FDA authorization, and are used to argue that everything, including variant testing, is still related to the hypothetical, unpled future submission and approval. *Id.* at 11:22–28 ("The FDA has not yet granted full regulatory approval[.]"). An EUA in any case does not transform all exploitations of the '221 Patent into exempt uses; it is not a free pass for infringement; no authority or precedent would make it so.

The only suggestion in Defendants' Motion that their infringement was "solely for uses reasonably related to the development and submission of information" to the FDA, is from attorney argument in Defendants' Motion, which cannot serve as the basis for granting a motion to dismiss under Rule 12(b)(6) – especially before *any* discovery.

Defendants' Motion confirms this is not one of those rare opportunities

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where an affirmative defense may be posited as a pleadings-stage challenge.

III. LEGAL STANDARD

Disputed factual issues cannot be resolved on a motion to dismiss, rather "a district court must accept as true all facts alleged in the complaint, and draw all reasonable inferences in favor of the claimant." *Garot v. Cty. of San Diego*, No. 19-CV-01650-H-AGS, 2019 WL 5963641, at *2 (S.D. Cal. Nov. 13, 2019). "Dismissal under Rule 12(b)(6) on the basis of an affirmative defense is proper only if the defendant shows some obvious bar to securing relief on the face of the complaint." *ASARCO v. Union Pac. R.R.*, 765 F.3d 999, 1004 (9th Cir. 2014).

"[O]rdinarily, affirmative defenses . . . may not be raised on a motion to dismiss." *U.S. CFTC v. Monex Credit Co.*, 931 F.3d 966, 972 (9th Cir. 2019). Dismissal based on an affirmative defense is permitted only when the complaint conclusively establishes the defense. *Id*. at 973. Resolution of an affirmative defense on a motion to dismiss based on facts outside the complaint is improper. *See Garot*, 2019 WL 5963641, at *6 ("Defendant's arguments are better suited to a motion for summary judgment when the Court may consider evidence outside of the pleadings and the record is more fully developed.").

Defendants attempt to overcome this reality by improperly relying on third-party documents attached to the FAC to dispute or contradict the well-pled allegations, claiming broadly that "documents attached to the complaint" or "relied upon but not attached" may be considered on a motion to dismiss. Mot. 7:24–27, quoting *Toranto v. Jaffurs*, 297 F. Supp. 3d 1073, 1084 (S.D. Cal. 2018). But soon after *Toranto*, the Ninth Circuit strongly narrowed such practice to prevent the very misuse proposed here:

> We have stated [] a court may assume an incorporated document's contents are true for purposes of a motion to dismiss under Rule 12(b)(6). While this is generally true, it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts

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> stated in a well-pleaded complaint. This admonition is, of course, consistent with the prohibition against resolving factual disputes at the pleading stage.

Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988, 1003 (9th Cir. 2018) (quotation omitted). As Defendants had the standard wrong, their argument misses the mark by doing just what the Ninth Circuit prohibited – using attachments to contradict or dispute the well-pled allegations.

IV. THE SAFE HARBOR DOES NOT APPLY TO THE ASSERTED PATENT AS A MATTER OF LAW, AND EVEN IF IT COULD, WHETHER INFRINGEMENT IS IMMUNIZED UNDER THE SAFE HARBOR IS A FACT-SENSITIVE INQUIRY

Allele's FAC alleges that Defendants are infringing at least claims 1, 2, 4, and 5 of the '221 Patent by misappropriating mNeonGreen for their SARS-CoV-2 neutralization assay. *E.g.*, FAC ¶¶ 69, 71. Defendants do not challenge the sufficiency of these allegations to state a claim for patent infringement.

Instead, Defendants raise a defense based on a Safe Harbor exception to infringement provided in 35 U.S.C. § 271(e)(1). The Safe Harbor, however, is an affirmative defense such that a complaint need not plead around it. *See Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, No. 4:19-CV-06593-HSG, 2020 WL 789559, at *3 (N.D. Cal. Feb. 18, 2020) ("The procedural posture of these cases thus cautions against deciding the applicability of the section 271(e)(1) exemption on a motion to dismiss."); *Ventrassist Pty, Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1280–81 (S.D. Fla. 2005) (holding "the Section 271(e)(1) safe harbor is an affirmative defense" that a plaintiff is "not required to negate . . . in their complaint"). On this basis alone, Defendants' Motion should be denied.

Further, as set forth below, the Safe Harbor does not apply as a matter of law or deprive Allele's infringement claim of *Twombly* plausibility, and even if it could hypothetically apply, Defendants improperly exceed the pleadings to prematurely resolve disputed issues of fact on a Rule 12(b)(6) motion.

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A. The Safe Harbor Exception to Patent Infringement Liability

In 1984, Congress enacted the "Safe Harbor" as Section 202 of the broader Hatch-Waxman Act, 98 Stat. 1585, codified as 35 U.S.C. § 271(e)(1). Specifically, it shall not be an infringement to use 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. . . ." *Id.*

Congress understood the Safe Harbor as a "not substantial" impingement on a patent holder's rights because the only activity immunized would be "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute" for purposes of premarket approval by the FDA. H. Rep. No. 98-857, Part 2, 98th Cong., 2d Sess. (Aug. 1, 1984). This temporary Safe Harbor would not violate the Takings Clause, precisely because generic drug manufacturers would be unable to profit from *de minimis* infringement during the patent term, and instead, commercialization would wait until after patent expiration. *Id.* Appropriate use of the Safe Harbor, beyond generics, does not dismantle this foundation. *See below* at pp. 16–17.

In concert with the Safe Harbor, Congress extended the terms of patents for "products" subject to premarket delays by the FDA during drug application review. *Proveris*, 536 F.3d at 1261. "Section 202 of the 1984 Act added the infringement shield of 35 U.S.C. § 271(e). Of equal importance, Section 201 of the 1984 Act," at 35 U.S.C. § 156, "supplied a partial restoration of patent term when the lengthy regulatory approval process delays marketing of patented inventions." *AbTox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997); *Biogen v. Banner Life Scis,* 956 F.3d 1351, 1355 (Fed. Cir. 2020) (term extension for only one patent covering the approved product compensates for the FDA review period). The balance achieved by the Safe Harbor is grounded in fairness and respect for the bargain of granting a temporary monopoly over patent claims, in exchange for dedicating the disclosure to the public benefit at the end of the patent term.

On the one hand, the patentee may obtain an extension, at the back end of its patent term, when its ability to sell a regulated product is initially delayed. On the other hand, limited and appropriate premarket approval testing by a competitor within a Safe harbor, during the patent term, allows an alternative product, typically a generic, to be ready and waiting to be launched when the patent protection ends. But Congress also safeguarded the patentee's investment-backed expectations because other manufacturers are granted a limited window to infringe the patent with a "me too" product, solely to obtain FDA approval, and without profit until after the patent expires or its use is authorized.

Naturally then, "[e]xtensive precedent recites the purpose of §271(e)(1) to facilitate market entry upon patent expiration" and notably "to compete with patentees." *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1072 (Fed. Cir. 2011); *see also Proveris*, 536 F.3d at 1261; *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670–671 (1990).

B. The Asserted Patent Is Not A Patented Invention Within The Meaning Of The Safe Harbor

1. The Safe Harbor Does Not Apply To Research Tools, Which Are Not Extendable Under 35 USC § 156 And Not Subject To FDA Approval

Patented "research tools" are inventions "used in the development of FDA regulatory submissions, but [are] not [themselves] subject to the FDA premarket approval process". *Proveris*, 536 F.3d at 1265–66. As a matter of law, such research tools do not meet the "patented inventions" element of the Safe Harbor, and therefore their unauthorized infringement is not immunized. *Proveris*, 536 F.3d at 1265–66; *Momenta II*, 809 F.3d at 619 ("research tools or devices that are not themselves subject to FDA approval may not be covered."); *Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, No. 3:11-cv-2214-GPC-KSC, 2014 WL 794811, at *4 (S.D. Cal. Feb. 27, 2014) ("The Safe Harbor does not apply, however, when a biological compound is used…as a 'research tool.'"); *PSN Ill., LLC v. Abbot Labs.*,

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No. 09C5879, 2011 WL 4442825, at *5–6 (N.D. Ill. Sept. 20, 2011) (denying summary judgment based on the "clear holding" of the Federal Circuit in *Proveris* "exclud[ing] research tools from the purview of the safe harbor exemption").

Defendants assert that the Safe Harbor confers very broad and indiscriminate immunity, citing to *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), a case that preceded *Proveris* and expressly did not involve research tools:

> Respondents have never argued the RGD peptides were used … as research tools, and it is apparent from the record that they were not. … We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process.

Id. at 205 n.7. On remand the Federal Circuit similarly disclaimed that its holding decided whether the Safe Harbor includes research tools. Specifically, Judge Rader's dissent highlighted that expanding the "patented invention" element of the Safe Harbor in this way would "obliterate all value" of research tool patents and "amount only to a charitable (but nondeductible) gift to the pharmaceutical industry." *Integra Lifesciences I*, 496 F.3d at 1352. The majority rejected any notion that the opinion could be applied to research tools because "the parties emphatically confirmed that research tools were not at issue," and therefore "the issue [was] not present." *Id.* at 1348.

Proveris – decided the following year – was the Federal Circuit's opportunity to squarely and finally address whether the "patented invention" element of the Safe Harbor applies to research tool patents. The Court held it does not. Defendants attempt to distinguish *Proveris* as involving a "patented invention . . . not reasonably related to an FDA submission" because it was only "sold to customers" who "might arguably use [it] to generate information for the FDA." Mot. 20:9–19. But this diversion to the "reasonable relationship" element is not the basis for the court's holding. Instead, *Proveris* held a research tool that is not

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subject to FDA approval or patent term extension is outside the "*patented invention" element* of the Safe Harbor. *See Proveris*, 536 F.3d at 1264–66.

The patent in *Proveris* claimed a device that characterized aerosol sprays used in drug delivery devices. 536 F.3d at 1258. The defendant manufactured a device that infringed the patents and was used solely to obtain data to support FDA approval of aerosol products. *Id*. at 1259–60. The defendant argued that its infringing use was "'reasonably related' to the 'development and submission of information' pertinent to the FDA premarket approval required for inhaler-based drug delivery devices." *Id*. at 1266. The Federal Circuit found defendant's argument immaterial because they failed to carry their burden on the "patented invention" element, which it held was one of two "critical terms" in the Safe Harbor: "The problem with that argument is that it is premised on the proposition that the device claimed in the '400 patent is, for purposes of section 271(e)(1), a 'patented invention.' As we have just seen, it is not. We therefore reject the argument." *Id.* at 1266, 1262.

In reaching this holding, the Federal Circuit carefully reviewed the *Eli Lilly* decision, noting that "sections 156 and 271(e)(1) were enacted in order to eliminate two unintended distortions of the effective patent term resulting from premarket approval required of certain products pursuant to the FDCA." *Proveris*, 536 F.3d at 1265, citing *Eli Lilly*, 496 U.S. at 669–70. In *Eli Lilly*, the Supreme Court explained that "the first distortion was the reduction of effective patent life caused by the FDA premarket approval process," which was remedied by Section 156. *Eli Lilly*, 496 U.S. at 669. The "second distortion was the *de facto* extension of effective patent life at the end of the patent term – also caused by the FDA premarket approval process," which was remedied by Section 271(e)(1). *Id*.

The patented device in *Proveris* was neither subject to regulatory approval nor eligible for patent term extension under Section 156. Rather, it was a research tool and therefore "not…a 'patented invention'" within the Safe Harbor. *Proveris*,

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536 F.3d at 1265.

Defendants suggest that *Eli Lilly* somehow held a "patented invention" to include "all inventions" *period*. Mot. 8:25–9:2, 19:10–15. As the Supreme Court explained, and consistent with the legislative history, the "patented invention" element includes all products listed in Section 156(f), namely a drug product or medical device, food additive or color additive ***subject to regulation*** under the Federal Food, Drug, and Cosmetic Act. *See Eli Lilly*, 496 U.S. at 672; *Proveris*, 536 F.3d at 1265 (discussing *Eli Lilly*); 35 U.S.C. 156(f)(1). Absent from Section 156(f) and the Safe Harbor is a research tool that is not subject to FDA regulation. And even if it is not already apparent that research tools are outside the Safe Harbor, the Supreme Court held that "***unless the context otherwise indicates*** . . . the term 'invention' means invention or discovery." *Eli Lilly*, 496 U.S. at 665 quoting 35 U.S.C. § 100(a) (emphasis added). *Proveris* rejected an unjustifiably-broad interpretation of *Eli Lilly* and found such "context otherwise indicat[ing]" that research tools are outside the ambit of Section 271(e)(1). 536 F.3d at 1263.

Thus, *Proveris* is directly on point, squarely resolves the issue, is still the law of the land, and disposes of Defendants' Safe Harbor theory. *See Deckers Corp. v. United States*, 752 F.3d 949, 964 (Fed. Cir. 2014) (courts are "bound by the precedential decisions of prior panels unless and until overruled by an intervening Supreme Court or *en banc* decision").

Defendants fail to cite a single case to the contrary. Instead, Defendants' lead case involved a belated attempt at oral argument to introduce a new theory that the patent at issue claimed a research tool. *See Katz v. Avanir Pharm.*, No. 06CV0496 DMS (LSP), 2007 WL 9776599, at *7 (S.D. Cal. Aug. 21, 2007). Decided in 2007, the year *before Proveris*, the district court found no guiding authority on the relationship of the Safe Harbor to a research tool. *Id*. The Federal Circuit answered that question in *Proveris* the following year, meaning *Katz* is not good law on this point. Further, it is unsurprising there was a failure of evidence on

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summary judgment, since the argument only came orally, after briefing was closed. Finally, unlike the generally applicable research tool of the '271 Patent, the patent in *Katz* was specifically for IgE drug development, and led to a new drug application regarding IgE regulation. *Contrast id*. at *2 with FAC ¶ 53 (mNeonGreen is "a reliable surrogate for high-throughput drug discovery" that "represents a major tool for the research community . . . .").

Defendants' remaining cases are similarly inapt. In *Teva Pharm. USA, Inc. v. Sandoz Inc.*, the asserted patents were not found to be research tools, but rather they all "relate[d] to [Plaintiff Teva's] branded glatiramer acetate product marketed under the name Copaxone," and Teva's attempt to use its patents related to Copaxone to prevent the Defendant from obtaining ANDA approval for its competing generic. No. 09 CIV. 10112 KBF, 2013 WL 3732867, at *1, *7 (S.D.N.Y. July 16, 2013). In contrast, Defendants here are not seeking approval for a generic to compete with Allele, but are profiting on a high-demand product from their infringement of Plaintiff's crucial research tool. *See id*. at *2 ("defendants have used the patented products and methods claimed by Teva's patents-in-suit in preparing Mylan and Sandoz's ANDAs"). Finally, the *Sandoz* district court, at 2013 WL 3732867, *5, relied on *Momenta Pharms. v. Amphastar Pharms.*, 686 F.3d 1348 (Fed. Cir. 2012) ("*Momenta I*"), which was overruled by *Momenta II*, 809 F.3d at 619, as "manifestly unjust."

Defendants' remaining cases do not even address the Safe Harbor applied to research tools. *See* Mot. 20:4–8, citing *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, 786 F.3d 892, 897 (Fed. Cir. 2011) and *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95 Civ. 8833 (RPP), 2001 WL1512597, at *3 (S.D.N.Y. Nov. 28, 2001). Specifically, similar to the *Merck* case, whether the "patented invention" element of the Safe Harbor encompasses research tools was not at issue and instead the disputes primarily centered on whether the defendants' uses fell within the "reasonably related" element of the

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Safe Harbor. *See Classen*, 786 F.3d at 897; *Bristol-Myers Squibb Co.*, 2001 WL1512597, at *3–*4. No case can be stretched to convey that research tools are patentable, but nonetheless unenforceable, if used without permission to research, develop, and market a regulated drug. *See id.*

It is now black letter law that the Safe Harbor exception to infringement does not apply to research tools. In any event, even Defendants agree that there are circumstances where "use of a patented invention alleged to be a 'research tool' may not be protected by the safe harbor". Mot. 20:9–12. Defendants have not met their burden of proving they are "in" the Safe Harbor. Plaintiff does not have to prove they are "out," although its pleadings effectively do so. It would be manifestly improper to determine that the Safe Harbor categorically shields Defendants from all infringement, without the benefit of discovery, and without summary judgment briefing, should any party so move.

2. The '221 Patent Claims A Research Tool, Outside The Scope Of The "Patented Invention" Element Of The Safe Harbor

Defendants do not dispute that the '221 Patent claims a research tool. The Patent is commercialized by Plaintiff in an embodiment called mNeonGreen. Since research tools are outside the scope of the "patented invention" element of the Safe Harbor, then Defendants' use of mNeonGreen is not immunized from infringement.

Under the Federal Circuit's controlling precedent, research tools are inventions not subject to the FDA premarket approval process, but are used in development, *i.e.*, "tools that scientists use in the laboratory including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." *Integra Lifesciences I*, 496 F.3d at 1347 n.3, quoting The National Institutes of Health, 64 Fed.Reg. 72,090, 72092 n. 1 (Dec. 23, 1999); *Proveris*, 536 F.3d at 1265–66.

The '221 Patent is directed to specific nucleic and amino acid sequences that

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define a monomeric green/yellow fluorescent DNA and protein, including mNeonGreen. *See* FAC ¶ 27, 29, 31. mNeonGreen is an artificial fluorescent probe that Allele painstakingly developed over many years through the unique insight of its inventors. FAC ¶ 2.

The FAC alleges, which must be taken as true, that Defendants used Allele's patented mNeonGreen as a research tool. FAC ¶ 39, 43, 49. Specifically, Defendants used mNeonGreen in a reporter assay to rapidly evaluate and narrow vaccine candidates and vet the accused BNT162 vaccine. FAC ¶¶ 36–37.

The reporter assay used by Defendants comprises a genetic sequence encoding Allele's novel mNeonGreen protein, conjoined with a genetic sequence encoding SARS-Cov-2 proteins, so that fluorescence (from the mNeonGreen) above a threshold indicates replicating coronavirus, whereas fluorescence below the threshold indicates that viral replication has been inhibited. FAC ¶¶ 51, 52. Accordingly, in developing their COVID-19 vaccine, Defendants used a research tool that is fundamentally based on Allele's patented mNeonGreen. FAC ¶ 23.

The patented mNeonGreen is a uniquely powerful tool, and applications are not limited to SARS-Cov-2, or even viruses. As reported by Defendants' collaborators, the mNeonGreen reporter assay is a highly-valued alternative to standard plaque assay and quantification techniques:

> The icSARS-CoV-2-mNG reporter virus allows the use of fluorescence as a surrogate readout for viral replication. Compared with a standard plaque assay or median tissue culture infectious dose (TCID50) quantification, the fluorescent readout shortens the assay turnaround time by several days. In addition, the fluorescent readout offers a quantitative measure that is less labor-intensive than the traditional means of viral titer reduction. Furthermore, the mNG-virus-based assay could be automated in a high-throughput format to screen compounds against viral replication. FAC ¶ 7.

Other scientists have also observed that mNeonGreen is a robust, gold

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standard tool for rapid characterization and development of "countermeasures" for a variety of emerging infections. FAC ¶ 53; *see also id.* ¶¶ 8, 34. The patented invention is a broad and flexible discovery-inducing innovation in biotechnology and medicine, and its versatility provides a wide array of uses outside of COVID-19 therapeutics. FAC ¶ 9; *id.* ¶ 29 ("mNeonGreen proteins 'have exceptional utility as a biomarker and/or protein fusion tag, and have shown great usefulness as a FRET acceptor for the newest generation of cyan fluorescent proteins.'"). The mNeonGreen reporter virus used by Defendants was further described by scientists as "a reliable surrogate for high-throughput drug discovery" that "represents a major tool for the research community . . . ." FAC ¶ 53.

The '221 Patent and mNeonGreen is a research tool, plain and simple, which takes it outside the scope of "patented inventions" that are subject to the Safe Harbor. Indeed, for the very reason Defendants say they can infringe with impunity (its only use is for research) is a principle reason they cannot. The '221 Patent (and the mNeonGreen technology covered by it) is not subject to review by the FDA or any Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. As a result, the '221 Patent is ineligible for patent term extension under Section 156. FAC ¶ 32. Defendants also have not infringed the '221 Patent in order to manufacture a generic product or enter the market with a product that competes with mNeonGreen. FAC ¶ 45.

Defendants invite an untenable violation of the Constitution's Takings Clause. Defendants have willfully infringed, and proclaim they will continue indefinitely, without ever compensating Plaintiffs. FAC ¶¶ 12, 64–66; Mot. 1:23–2:3. Totally immunizing patent infringement and resulting monetary damages during a research tool's patent term, as Defendants suggest, would fatally imbalance the Safe Harbor, contradicting Congress' intent, and violating the Takings Clause. It is a long-established mandate that statutes must be interpreted so as to avoid such a Constitutional violation. *Jones v. U.S.*, 529 U.S. 848, 857

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(2000), quoting *U.S. v. Delaware & Hudson Co.*, 213 U.S. 366, 408 (1909) ("where a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter."). As Judge Rader observed, interpreting the Safe Harbor to immunize infringement of research tool patents as Defendants argue would "obliterate all value" in such patents.

Defendants claim it is immaterial that they are not marketing a competing product, the FDA does not require them to infringe, and the '221 Patent is not about to expire. Mot. 12:6–24. But these allegations demonstrate that, unlike a generic manufacturer who must incidentally infringe a patent covering a regulated product, in order to prepare to compete in the marketplace, the '221 Patent claims a research tool that Defendants are not required to use, nor is infringing the '221 Patent inherent in Defendants' vaccine itself. Their misappropriation of the patent is not incidental, reasonably *de minimis*, and balanced by statute, so as to place competing parties on even ground. Still, Defendants are seeking indefinite immunity, apparently for the entire term of the patent, in hopes of profiteering from the unique advantages they took from Allele's patented invention. Defendants plainly are "not within the category of entities for whom the safe harbor provision was designed to provide relief." *Proveris*, 536 F.3d at 1265.

As in *Proveris*, the patented product is a research tool not subject to FDA premarket approval, not subject to patent term extension under Section 156, and outside a Safe Harbor immunization from claims of infringement. 536 F.3d at 1265.

C. Even If The Asserted Patent Was Subject To The Safe Harbor, Defendants' Uses Of The Asserted Patent Are Not Protected

As a separate and independent basis for denying the Motion, Defendants have failed to demonstrate that the Safe Harbor applies to each category of use alleged in the FAC. "Each of the accused activities must be evaluated separately to determine whether the exemption applies." *Merck*, 545 U.S. at 200. At most,

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Defendants (incorrectly) assert that one of the infringing uses (vaguely, "clinical trials") is immunized under the Safe Harbor. Accordingly, it is undisputed on the current record that other infringing uses are not subject to Safe Harbor and therefore the Motion should be denied.

1. Each Of Defendants' Uses Is Not "Reasonably Related" To Information Required Under Federal Law

Defendants invoke the Safe Harbor based on a recasting of their infringement as a limited use and only "to generate data for the FDA." Mot. 2:16–19. But the FAC alleges numerous other uses that Defendants essentially ignore. Defendants have the burden to demonstrate that each of those uses is reasonably related to the development and submission of information to the FDA. *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1340 (Fed. Cir. 2019). "It is incorrect to 'assume[] that all otherwise infringing activities are exempt if conducted during the period before regulatory approval is granted.'" *Hospira*, 944 F.3d at 1339 n.2, quoting *Amgen. v. ITC*, 565 F.3d 846, 852 (Fed. Cir. 2009); *see also Edwards Lifesciences*, 2020 WL 789559, at *3 (denying motion to dismiss on Safe Harbor grounds where accused activity took place before FDA approval of infringing product).

The categories of Defendants' uses include Defendants' Preclinical Investigatory Uses (winnowing an unmanageable number of vaccine candidates down to four lead candidates), Clinical Trial Uses (Phases I, II and III), and Post-Approval Marketing Uses (*e.g.*, testing against new COVID-19 strains). FAC ¶¶ 12, 3. And from the time of the Clinical Trial Uses onward, Defendants were separately making uses "for commercial purposes such as validation, quality control, promotion, and marketing advantage." FAC ¶ 44.

First, as to the Preclinical Investigatory Uses, rapidly winnowing from an unmanageable number of candidates is not "reasonably related" to the development and submission of information required under federal law. Even Defendants are forced to concede that infringement for "screening 'thousands of potential drug

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candidates for activity'" is not "reasonably related to an FDA Submission." Mot. 20:11–12, 21:9–10, quoting *PSN Ill.*, 2011 WL 4442825, at *1, *6. Defendants baldly assert that allegations of use for research and development "add nothing to the analysis" and the allegations are "implausible." Mot. 13:10–13, 14:1–4. On the contrary, the FAC specifically alleges that Defendants used mNeonGreen to rapidly arrive at four (4) vaccine candidates, and ultimately select their BNT162 mRNA-based COVID-19 vaccine candidate. FAC ¶ 3.

That Defendants adopt a posture of incredulous disagreement is not grounds for dismissal, nor is a call for more "clarity" in the FAC about details known only to them. Mot. 8:1–7. If anything, it is Defendants who are "nonsensical" in suggesting (outside the pleadings) that winnowing did not occur or was manageable, or that the only way to winnow is by infringement using human subjects and is therefore exempt. Mot. 15:27–27. These are disputed factual contentions improperly injected into a motion to dismiss. To the extent Defendants are suggesting that it is implausible to use mNeonGreen at the preclinical stage at all, scientists praise the reporter virus with Allele's patented sequence for mNeonGreen for enabling "a rapid, high throughput platform to test COVID-19 patient sera," a potent research tool that is not limited to use at any particular stage of research as Defendants' attorney-argument suggests. *See* FAC ¶ 51; *id.* ¶ 53 ("a reliable surrogate for high-throughput discovery"). The FAC's allegations of such fact directly refute Defendants' argument that "Allele's 'winnowing' allegations … are implausible." Mot. 15:20–21.

As Defendants concede, "basic scientific research" is not protected by the safe harbor. Mot. 13:19–27, citing *Merck*, 545 U.S. at 205–06. And Allele did *not* concede that the results of the Pre-Clinical Investigatory Uses were used to support FDA approval, or go beyond basic scientific research, despite Defendants' assertion to the contrary. Mot. 14:15-17.

Second, even during the Clinical Testing period, distinct uses with

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sufficiently commercial purposes were not "reasonably related" to the development and submission of information required under federal law. *Hospira*, 944 F.3d at 1339–41 (affirming jury finding that drug batch manufacture during FDA approval fell outside the safe harbor because evidence showed it was not required and was intended for commercial inventory); *PSN Ill.*, 2011 WL 4442825, at *5–6 (safe harbor allows a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute).

Defendants assert that "use or disclosure of data from clinical testing is not an act of infringement." Mot. 16:23–25. But the law is not that broad. First, the clinical study must be deemed "exempt," and second, even if exempt, it must be established that the "subsequent disclosure or use is itself not an act of infringement of the asserted claims." *Classen*, 786 F.2d at 898, citing *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523-24 (Fed. Cir. 1992); *see also Edwards Lifesciences*, 2020 WL 789559, at *3 ("The Court is not convinced that *Telectronics* and its progeny establish a 'per se' rule that obviates the need for any further factual inquiry."). Defendants' reliance on the subsequent summary judgment ruling in *Edwards Lifesciences* is similarly unavailing because in that case the use at issue was importing the accused product for purposes of recruiting clinical investigators, a use that the Federal Circuit has previously held to fall within the Safe Harbor. *Edwards Lifesciences Corp. v. Meril Life Scis. PVT. Ltd.*, No. 19-CV-06593-HSG, 2020 WL 6118533, at *6–*7 (N.D. Cal. Oct. 16, 2020). Allele has not alleged that type of use here. Once again, Defendants' misplaced argument relies on its myopic effort to label all of its infringing uses as limited to clinical trials, which they deem "safe" by their own definition.[1]

[1] Defendants' remaining cases are similarly distinguishable as they involve use for clinical trials, but not other unprotected infringement activities. *See AbTox, Inc.*, 122 F.3d at 1027 (on appeal from grant of summary judgment, holding the infringing use was for obtaining FDA approval and no marketing or commercial activity of accused product had occurred); *Intermedics, Inc. v. Ventritex, Inc.*, 775

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Defendants' uses of mNeonGreen throughout the development process beyond clinical trials and for uses other than generating data for regulatory approval, for eventual distribution of a commercial vaccine and post-approval testing, has contributed to Defendants receiving billions in revenue. FAC ¶ 7; *see also id*. ¶ 44 ("commercial purposes such as validation, quality control, promotion, and marketing advantage").

Third, the testing in Post-Approval Marketing Uses – related as it is to activities to better compete in the marketplace – is not "reasonably related" to developing and submitting information required under federal law. *Edwards Lifesciences*, 2020 WL 789559, at *3 (safe harbor does not apply to marketing purposes). Defendants have continued their use of the patented invention to probe 20 new COVID-19 strains, not for obtaining FDA approval of a vaccine already marketed for widespread use, but to compete better by "highlighting to potential purchasers and users of the vaccine added benefits of using Defendant's BNT162 vaccine instead of other vaccines." FAC ¶ 57. Defendants repeat their conclusionary refrain that such use is "related to information for submission to the FDA in support of regulatory approval," and suggest more approvals are yet to come. Mot. 12:1–4. But this attempts to dispute and contradict the FAC, which is

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F. Supp. 1269, 1273 (N.D. Cal. 1991) (holding on summary judgment that defendants' infringement for clinical testing to obtain necessary data for FDA submission was exempt); *Alphamed Pharms. Corp. v. Arriva Pharms., Inc*., 391 F. Supp. 2d 1148, 1159 (S.D. Fla. 2005) ("the TAC only contains allegations that Arriva has been conducting clinical trials relating to AAT for use in ear infections"); *Med. Diagnostic Lab., L.L.C. v. Protagonist Therapeutics, Inc*., 298 F. Supp. 3d 1241, 1248 (N.D. Cal. 2018) ("the only specific examples alleged [we]re the sales . . . in connection with clinical trials"); *Galderma Labs., L.P. v. Medinter US, LLC*, No. 18-cv-1892-CFC-CJB, 2020 WL 871507, at *3 (D. Del. Feb. 14, 2020) (court could not conclude that the patented invention was used "for purposes unrelated to . . . clinical trials"). Further, "if there are any actual, non-*de minimis* uses that are not reasonably related to generating data for the FDA, the exemption will not protect" an infringer. *Intermedics*, 775 F. Supp. at 1280. As set forth herein, Allele alleges such non-*de minimis* uses.

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improper on this Motion. *See above* Section III at pp. 6–7.

Fourth, infringement for quality control uses is also not "reasonably related" because it is manufacturing the product to sell at market, not obtaining regulatory approval. *Momenta II*, 809 F.3d at 620 (Even if required to be routinely submitted to the FDA, "[t]he routine quality control testing of each batch of generic enoxaparin as part of the post-approval, commercial production process is therefore not 'reasonably related to the development and submission of information' to the FDA, and it was clearly erroneous to conclude otherwise.").[2] The FAC alleges that Defendants have used and continue to use mNeonGreen for quality control purposes related to commercialization of their vaccine. FAC ¶¶ 44, 34.

Fifth, infringing uses to advance international commercialization and patent applications are not immunized from infringement because they are not necessarily "reasonably related" to submissions under federal law. *Chang v. Biosuccess Biotech Co.*, 76 F. Supp. 3d 1022, 1037 (C.D. Cal. 2014) (denying summary judgment on Section 271(e)(1) where defendant submitted for foreign patents); *PSN Ill.*, 2011 WL 4442825, at *6 ("Defendants were not infringing on the S1P2 receptors in order to obtain FDA approval to introduce a generic receptor to compete in the marketplace when the patent on those receptors expired. They were using a patented invention to develop their own patentable product."). The FAC alleges that Defendants have enjoyed commercial use overseas with foreign sales anticipated to comprise the majority of Defendants' revenue, including through lucrative vaccine contracts, with revenue forecasts up to $26.44 billion. FAC ¶¶ 47, 48, 34. To protect their foreign interest, Defendants have also applied for patent coverage and forcefully opposed the World Health Organization's initiative to expand vaccine access to poor countries by granting compulsory patent rights or otherwise relaxing patent laws. FAC ¶¶ 47, 50. Defendants' infringing uses to

[2] *Momenta II's* holding rejected its contrary earlier preliminary injunction holding (which Defendants cite, Mot. 12:10–14) as clearly erroneous. *Id.* at 620.

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advance interests abroad fall outside the Safe Harbor immunity.

These numerous uses, ignored in Defendants' Motion, are not reasonably related to the development and submission of information to the FDA and are outside of any immunity under the Safe Harbor. *See, e.g. Classen*, 659 F.3d at 1070 ("The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained."). Defendants have not met their burden to demonstrate that each infringing use is immunized.

At a minimum, Defendants' various uses present disputed issues of fact to be decided after discovery. *Isis Pharm.*, 2014 WL 794811, at *12 ("disputes of material fact exist with regard to whether Santaris's collaboration agreements are 'reasonably related to the development and submission of information' to the FDA"); *see also Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 106 (D. Mass. 1998) (dismissal and summary judgment denied to allow for discovery). Accordingly, Defendants' motion should be denied.

2. Defendants' Use Is Not "Solely" To Obtain Information Required Under Federal Law

Even if, after discovery, Defendants could carry their burden to demonstrate some of their uses are reasonably related to the development and submission of information to the FDA, Defendants will further need to demonstrate that those infringing uses are "solely" to obtain information required by the FDA. *Chang*, 76 F. Supp. 3d at 1035 ("The Chang Parties have not presented evidence sufficient to establish that this importation of TPA was for the sole purpose of developing information to submit to the FDA.").

As set forth above, Defendants' numerous uses are far afield from solely uses reasonably related to required FDA submissions:

First, Defendants' infringement is not "solely for" obtaining information required by the FDA because it was to support patent applications. *See PSN Ill.*, 2011 WL 4442825, at *6 (holding Safe Harbor did not apply where defendants

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"were using a patented invention to develop their own patentable product.").

Second, Defendants' infringement is not "solely for" obtaining information required by the FDA because it was used for foreign regulatory approvals over which the FDA has no control or involvement. *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 207–8 (D.N.J. 1994) (after full factual development, finding certain uses of vials were for foreign regulatory approval and had a sufficiently unclear connection to FDA approval so as to fall outside of Section 271(e)(1) on summary judgment) citing *inter alia Telectronics Pacing Sys., Inc. v. Veritext*, 982 F.2d 152, 1524 (Fed. Cir. 1992).[3]

Third, Defendants' infringement is not "solely for" obtaining information required by the FDA because it was for current commercial and marketing efforts in the U.S. and abroad. *Hospira*, 944 F.3d at 1340 ("Hospira was not required to manufacture additional batches after it made its 2012 batches"); *Scripps Clinic & Rsch. Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1396 (N.D. Cal. 1987), rev'd on other grounds, 927 F.2d 1565 (Fed. Cir. 1991).

Defendants' infringing use to develop, commercialize, market, and patent their own product does not afford Safe Harbor protection – especially when Defendants' FDA-regulated vaccine product is not in competition with Plaintiffs' unregulated research tool. This makes sense because Congress intended immunity for *de minimis* infringement, solely to obtain regulatory approval in time for prompt competition. Otherwise, third parties must wait for permission, or patent expiration, before launch and commercialization. *See* H. Rep. No. 98-857, Part 2, 98th Cong., 2d Sess. (Aug. 1, 1984).

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[3] *Telectronics Pacing Sys., Inc. v. Veritext*, 982 F.2d 1520, 1524 (Fed. Cir. 1992) dealt with domestic acts to raise money and clinical-referral doctors in order to successfully get an FDA-approved product. It does not establish a "per se" rule, requires a heavily-factual inquiry, and is not appropriately resolved on a motion to dismiss. *Edwards Lifesciences*, 2020 WL 789559, *2–*4 (denying motion to dismiss where purpose of use was disputed).

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V. CONCLUSION AND NEXT STEPS

Based on the foregoing, Allele respectfully requests that the Court deny Defendants' Motion based on their Safe Harbor affirmative defense. The defense does not apply to Defendants' infringement of Allele's mNeonGreen '221 Patent, as a matter of law, and does not deprive Allele's patent infringement claim of *Twombly* plausibility, because Defendants used mNeonGreen as an unregulated research tool, meaning the Safe Harbor does not apply. Separately, Defendants fail to address, much less demonstrate, that each allegedly infringing use is immunized. The FAC alleges numerous infringing uses of mNeonGreen, which are neither "solely for uses" for submission of required information to the FDA nor "reasonably related" to submission of such information. At a minimum, whether Defendants infringed the '221 Patent "solely for uses reasonably related" to obtaining information for FDA submissions presents disputed issues of fact unsuitable for resolution on a Rule 12(b)(6) motion to dismiss.

Were the Court inclined to grant Defendants' Motion, in whole or in part, Allele requests leave to amend and to conduct discovery to more explicitly address the Safe Harbor affirmative defense. Leave is freely granted "when justice so requires," this "'mandate is to be heeded'" and the Ninth Circuit has "repeatedly held" leave must be granted whether requested or not "unless [the court] determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000) (error to dismiss without leave) quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962). Defendants demonstrated no such impossibility of cure. And Defendants' challenges involve many non-public details known in far more detail to them. Additional facts are likely to exist which would strongly impact analysis of the defense as to each multifaceted manner of use Defendants made. Allele should be given "some latitude" in pleading details and the "interests of justice" permit pre-amendment "limited discovery" to do so. *Menard v. CSX Transp., Inc.*, 698 F.3d 40, 45-46 (1st Cir. 2012).

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Dated: April 16, 2021

TROUTMAN PEPPER HAMILTON SANDERS LLP

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CERTIFICATE OF SERVICE

I, Ben Lewis Wagner, declare:

I hereby certify that on April 16, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all registered CM/ECF participants in this case.

I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made. Executed on April 16, 2021, at San Diego, California.

/s/ Ben Lewis Wagner
Ben Lewis Wagner

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