UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ALLELE BIOTECHNOLOGY AND PHARMACEUTICALS, INC., a California corporation,

Plaintiff,

v.

PFIZER, INC., a Delaware corporation; BIONTECH SE, a German company; BIONTECH US, INC., a Delaware corporation; and DOES 1-30,

Defendants.

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

ORDER DENYING DEFENDANTS' MOTION TO DISMISS

[Doc. No. 37.]

On March 26, 2021, Defendants Pfizer, Inc., BioNTech SE, and BioNTech US, Inc. filed a motion to dismiss Plaintiff Allele Biotechnology and Pharmaceuticals, Inc.'s first amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. (Doc. No. 37.) On April 16, 2021, Plaintiff filed a response in opposition to Defendants' motion to dismiss. (Doc. No. 38.) On April 23, 2021, Defendants filed their reply. (Doc. No. 39.)

The Court held a hearing on the matter on May 3, 2021. Ben L. Wagner and Robert Schaffer appeared for Plaintiff Allele. Charles L. McCloud, Thomas H.L. Selby, and David J. Noonan appeared for Defendant Pfizer. Bruce M. Wexler, Elizabeth L. Brann, and Merri

C. Moken appeared for Defendant BioNTech. For the reasons below, the Court denies Defendants' motion to dismiss.

Background

On October 5, 2020, Plaintiff Allele filed a complaint for patent infringement against Defendants Pfizer and BioNTech, alleging infringement of U.S. Patent No. 10,221,221. (Doc. No. 1, Compl.) Specifically, Plaintiff alleges that: "The claims of the '221 Patent encompass Allele's mNeonGreen product, which is a fluorescent protein used as a biological tag in genetic engineering work." (Doc. No. 29, FAC ¶ 29.) Plaintiff further alleges that Defendants have used and continue to use mNeonGreen to research, develop, and test their SARS-CoV-2 vaccine candidates. (Id. ¶¶ 2-3, 6, 23, 37-39, 41-44, 49, 51-57.) Plaintiff further alleges that Defendants' use of mNeonGreen directly infringes the '221 patent. (Id. ¶¶ 29-31, 58-61, 69-71.)

On February 8, 2021, Defendants filed a motion pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss Plaintiff's complaint for failure to state a claim. (Doc. No. 24.) On February 25, 2021, in lieu of filing an opposition to the motion to dismiss, Plaintiff filed a first amended complaint against Defendants. (Doc. No. 29, FAC.) On February 27, 2021, in light of the filing of the amended complaint, the Court denied Defendants' motion to dismiss the original complaint as moot. (Doc. No. 30 (citing Ramirez v. Cty. of San Bernardino, 806 F.3d 1002, 1008 (9th Cir. 2015)).) By the present motion, Defendants move pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss Plaintiff's first amended complaint for failure to state a claim. (Doc. No. 37-1 at 1-2, 21.)

Discussion

I. Legal Standards for a Rule 12(b)(6) Motion to Dismiss

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the pleadings and allows a court to dismiss a complaint if the plaintiff has failed to state a claim upon which relief can be granted. See Conservation Force v. Salazar, 646 F.3d 1240, 1241 (9th Cir. 2011). Federal Rule of Civil Procedure 8(a)(2) requires that a pleading stating a claim for relief contain "a short and plain statement of the claim

showing that the pleader is entitled to relief." The function of this pleading requirement is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint will survive a Rule 12(b)(6) motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Twombly, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id. (quoting Twombly, 550 U.S. at 557). Accordingly, dismissal for failure to state a claim is proper where the claim "lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." Mendiondo v. Centinela Hosp. Med. Ctr., 521 F.3d 1097, 1104 (9th Cir. 2008).

In reviewing a Rule 12(b)(6) motion to dismiss, a district court must accept as true all facts alleged in the complaint, and draw all reasonable inferences in favor of the claimant. See Retail Prop. Trust v. United Bhd. of Carpenters & Joiners of Am., 768 F.3d 938, 945 (9th Cir. 2014). But, a court need not accept "legal conclusions" as true. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Further, it is improper for a court to assume the claimant "can prove facts which it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged." Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983).

In addition, a court may consider documents incorporated into the complaint by reference and items that are proper subjects of judicial notice. See Coto Settlement v. Eisenberg, 593 F.3d 1031, 1038 (9th Cir. 2010). If the court dismisses a complaint for failure to state a claim, it must then determine whether to grant leave to amend. See Doe v. United States, 58 F.3d 494, 497 (9th Cir. 1995); see Telesaurus, 623 F.3d at 1003 (9th Cir. 2010).

II. Defendants' Motion to Dismiss

Defendants argue that Plaintiff's first amended complaint should be dismissed for failure to state a claim because Plaintiff's infringement allegations are barred by the safe harbor provision set forth in 35 U.S.C. § 271(e)(1). (Doc. No. 37-1 at 1, 8-21.) In response, Plaintiff argues that Defendants' motion should be denied because: (1) the safe harbor provision does not apply here as a matter of law; and (2) even if it could apply, the determination of whether the infringement at issue is covered by the safe harbor provision is fact-sensitive inquiry inappropriate for resolution at the motion to dismiss stage. (Doc. No. 38 at 7-9.)

A. Section 271(e)(1) Legal Standards

Section 271(e)(1) of the Patent Act provides:

> 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.

35 U.S.C. § 271(e)(1).

The purpose of this safe harbor provision set forth in section 271(e)(1) is "to facilitate market entry upon patent expiration." Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1072 (Fed. Cir. 2011) (citing Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1358 (Fed. Cir. 2003); Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265 (Fed. Cir. 2008)). In Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669–70 (1990), the Supreme Court explained that the section 271(e)(1) safe harbor provision was specifically designed to respond to the following unintended distortion:

> In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, see § 271(a), even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. See Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, cert. denied, 469 U.S. 856, 105 S. Ct. 183, 83 L.Ed.2d 117 (1984). Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the

> patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.

Id. at 670 (footnote omitted); see also Proveris, 536 F.3d at 1261 ("Prior to the Hatch–Waxman Act, competitors' activities involving a patented invention during the patent term constituted an act of infringement, even if undertaken for the sole purpose of obtaining FDA regulatory approval. Because such activities could not begin until patent expiration, patent owners enjoyed a de facto patent term extension while competitors spent time following patent expiration obtaining FDA premarket approval necessary for market entry." (citations omitted)). Section 271(e)(1) sought to eliminate this de facto patent term extension by "allow[ing] competitors to begin the regulatory approval process while the patent was still in force, followed by market entry immediately upon patent expiration." Proveris, 536 F.3d at 1262; see Eli Lilly, 496 U.S. at 671 (Section 271(e)(1) "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.").

Section 271(e)(1) accomplishes this purpose by "provid[ing] a wide berth for the use of patented drugs in activities related to the federal regulatory process." Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005). Section 271(e)(1) "exempt[s] 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." Id. at 206 (citing Eli Lilly, 496 U.S. at 674); see also id. at 202 ("[W]e think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA."). "This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process." Id. at 202; see also Med. Diagnostic Lab'ys, L.L.C. v. Protagonist Therapeutics, Inc., 298 F. Supp. 3d 1241, 1247 (N.D. Cal. 2018) ("The protection [set forth in section 271(e)(1)] extends both to preclinical studies and clinical

studies."). "Nor does the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product." Classen Immunotherapies, Inc. v. Elan Pharm., Inc., 786 F.3d 892, 897 (Fed. Cir. 2015) (citing Merck, 545 U.S. at 206).

"[T]he section 271(e)(1) safe harbor provision is an affirmative defense." Classen Immunotherapies Inc v. Somaxon Pharms., No. CV 12-06643-GAF-PLA, 2013 WL 9947386, at *2 (C.D. Cal. Apr. 11, 2013) (citing Amgen, Inc. v. F. Hoffman-LaRoche Ltd., 456 F. Supp. 2d 267, 273 (D. Mass. 2006)); see also Enteris Biopharma, Inc. v. Clinical Pharmacology of Miami, Inc., No. 1:14-CV-22770-UU, 2015 WL 12085848, at *7 (S.D. Fla. Mar. 20, 2015) ("Many courts have recognized that the Safe Harbor is an affirmative defense."). "Ordinarily, affirmative defenses . . . may not be raised on a motion to dismiss." Lusnak v. Bank of Am., N.A., 883 F.3d 1185, 1194 (9th Cir. 2018). A court only may "consider an affirmative defense on a motion to dismiss when there is 'some obvious bar to securing relief on the face of the complaint.'" U.S. Commodity Futures Trading Comm'n v. Monex Credit Co., 931 F.3d 966, 973 (9th Cir. 2019) (quoting ASARCO, LLC v. Union Pac. R.R. Co., 765 F.3d 999, 1004 (9th Cir. 2014)). "In other words, dismissal based on an affirmative defense is permitted when the complaint establishes the defense." Id.

B. Analysis

Defendants argue that Plaintiff's claim for patent infringement against them should be dismissed because the allegedly infringing conduct is activity that is immune from patent infringement under section 271(e)(1). (Doc. No. 37-1 at 1-2.) Defendants argue that all of the alleged acts of infringement were undertaken in order to develop information for submission to the FDA pursuant to federal law regulating the manufacture, use, or sale of drugs, and, thus, all of the infringement allegations are encompassed by the safe harbor provision in section 271(e)(1). (Id.) In response, Plaintiff argues that the safe harbor provision does not apply as a matter of law here because the safe harbor provision does not

apply to "research tools" that are used in the development of FDA regulatory submissions, but are not themselves subject to FDA premarket approval. (Doc. No. 38 at 9-17.)

Plaintiff's "research tools" argument is primarily based on the Federal Circuit's decision in Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008).[1] Proveris involved an accused device "known as the Optical Spray Analyzer ('OSA')." 536 F.3d 1259. The OSA was not itself "subject to FDA approval. It [wa]s, however, used in connection with FDA regulatory submissions. In that setting, the device measure[d] the physical parameters of aerosol sprays used in nasal spray drug delivery devices." Id. The plaintiff in Proveris alleged that the OSA infringed its patent, the '400 patent, which was "directed to a system and apparatus for characterizing aerosol sprays commonly used in various drug delivery devices, such as nasal spray pumps and inhalers." Id. at 1258. In response to those infringement allegations, the defendant in Proveris argued that its allegedly infringing activities were immunized by section 271(e)(1) because its OSA devices were used by third parties solely for the development and submission of information to the FDA. Id. at 1260.

The Proveris court framed the issue before it as follows: "whether section 271(e)(1) immunizes the manufacture, marketing, or sale of [defendant]'s OSA, which is used in the development of FDA regulatory submissions, but is not itself subject to the FDA premarket approval process." Id. at 1265. In resolving this issue, the Proveris court held that "the section 271(e)(1) safe harbor does not immunize the OSA from infringement."

The Proveris court provided two reasons for this holding that were both grounded the Supreme Court's description in Eli Lilly of the purposes behind section 271(e)(1) and section 156 of the Patent Act. See Proveris, 536 F.3d 1265–66. First, the Federal Circuit noted: "[Defendant]'s OSA device is not subject to FDA premarket approval. Rather, FDA premarket approval is required only in the case of the aerosol drug delivery product whose

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[1] Plaintiff also relies heavily on Judge Radar's dissent in part in Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334 (Fed. Cir. 2007). (Doc. No. 38 at 1-2, 10.) But the Court does not find Plaintiff's reliance on Integra persuasive as it is a dissenting opinion.

spray plume characteristics the OSA measures. In short, [defendant] is not a party seeking FDA approval for a product in order to enter the market to compete with patentees." Id. at 1265. The Federal Circuit explained that because the OSA device was not subject to premarket approval, the device was "not within the category of entities for whom the safe harbor provision was designed to provide relief." Id.

Second, the Federal Circuit noted that the invention claimed in the patent at issue, the '400 patent, also "[wa]s not subject to the premarket approval required by the FDCA." Id. The Federal Circuit explained that this fact was "significant" because the Supreme Court in Eli Lilly spoke of "interpreting the phrase 'patented invention' in section 271(e)(1) to include all products listed in section 156(f) as producing a 'perfect "product" fit' between the two provisions." Id. (quoting Eli Lilly, 496 U.S. at 672). The Federal Circuit explained that because the invention claimed in the patent at issue was not subject to a required FDA approval process, it was not a "patented invention" for the purposes of section 271(e)(1).[2] Id. at 1265–66.

Following Proveris, the Federal Circuit reiterated in Momenta Pharms., Inc. v. Teva Pharms. USA Inc. that "research tools or devices that are not themselves subject to FDA approval may not be covered" by section 271(e)(1). 809 F.3d 610, 619 (Fed. Cir. 2015) (citing Proveris, 536 F.3d at 1265–66). In addition, at least two district courts have recognized that under Proveris, research tools that are not themselves subject to FDA approval are excluded from the section 271(e)(1) safe harbor. See, e.g., Isis Pharms., Inc. v. Santaris Pharma A/S Corp., No. 11CV02214 BTM KSC, 2012 WL 4111157, at *4 (S.D.

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[2] Defendants attempt to impermissibly narrow the Federal Circuit's decision in Proveris. Defendants assert that in Proveris, the Federal Circuit found that the defendant was not exempt from patent infringement under section 271(e)(1) "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." (Doc. No. 37-1 at 20; see also Doc. No. 39 at 4.) The Court rejects this narrow reading of Proveris. This reading of Proveris fails to acknowledge the Proveris court's additional holding that section 271(e)(1) also did not apply because the invention claimed in the patent at issue was not subject to a required FDA approval process, and, thus, was not a "patented invention" for the purposes of section 271(e)(1). See Proveris, 536 F.3d at 1265–66.

Cal. Sept. 19, 2012) ("The Safe Harbor does not apply, however, when a biological compound is used to perform 'basic scientific research' or as a 'research tool.'"); Isis Pharms., Inc. v. Santaris Pharma A/S Corp., No. 3:11-CV-2214-GPC-KSC, 2014 WL 2212114, at *5 (S.D. Cal. May 28, 2014) ("'[R]esearch tools' do not qualify for protection under § 271(e)(1)."); PSN Illinois, LLC v. Abbott Lab'ys, No. 09 C 5879, 2011 WL 4442825, at *5 (N.D. Ill. Sept. 20, 2011) ("Proveris excluded research tools from the purview of the safe harbor exemption.").

In response, Defendants argue that research tools are not exempted from the section 271(e)(1) safe harbor. (Doc. No. 37-1 at 19-21.) To support this contention, Defendants primarily rely on the Supreme Court's decision in Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990). (Doc. No. 37-1 at 19.) Defendants argue that in Eli Lilly, the Supreme Court explained that the term "patented invention" in section 271(e)(1) covers all inventions. (Id. (citing Eli Lilly, 496 U.S. at 665 ("The phrase 'patented invention' in § 271(e)(1) is defined to include all inventions.")).) But the problem with this argument is that Proveris and Momenta were issued by the Federal Circuit subsequent to Eli Lilly. In particular, in Proveris, the Federal Circuit engaged in an extensive analysis of the Eli Lilly opinion and its discussion of the purposes behind section 271(e)(1). See 536 F.3d at 1260-63, 1265. Yet, in Proveris, the Federal Circuit held that the device claimed in the patent at issue was not a "patented invention" for purposes of section 271(e)(1) because it "[wa]s not subject to the premarket approval required by the FDCA." Id. at 1265–66. And the Proveris court explained that this holding was based on Eli Lilly's interpretation of "the phrase 'patented invention' in section 271(e)(1) to include all products listed in section 156(f) as producing a 'perfect "product" fit' between the two provisions." Id. at 1265 (quoting Eli Lilly, 496 U.S. at 672).

If, as Defendants contend, Eli Lilly stands for the proposition that research tools are not exempt from section 271(e)(1), Defendants fail to reconcile that argument with Proveris and Momenta. In particular, the Momenta court expressly stated that "research tools or

devices that are not themselves subject to FDA approval may not be covered."[3] 809 F.3d at 619 (citing Proveris, 536 F.3d at 1265–66). Defendants might contend that Proveris and Momenta were wrongly decided in light of the language in Eli Lilly, but as a district court, this Court is bound by those Federal Circuit decisions.[4] See Hart v. Massanari, 266 F.3d 1155, 1175 (9th Cir. 2001) ("A district court bound by circuit authority, for example, has no choice but to follow it, even if convinced that such authority was wrongly decided."); id. at 1171 ("Once a panel resolves an issue in a precedential opinion, the matter is deemed resolved, unless overruled by the court itself sitting en banc, or by the Supreme Court."); Deckers Corp. v. United States, 752 F.3d 949, 964 (Fed. Cir. 2014) (same).

To support its position, Defendants also rely on the Federal Circuit's decision in Classen Immunotherapies, Inc. v. Elan Pharms., Inc., 786 F.3d 892, 897 (Fed. Cir. 2015). (Doc. No. 37-1 at 20 n.3; Doc. No. 39 at 4-5.) Defendants' reliance on Classen is not persuasive. In Classen, the Federal Circuit described the patent at issue as "directed to a method for accessing and analyzing data on a commercially available drug to identify a new use of that drug, and then commercializing that new use." Classen, 786 F.3d at 894. Defendants suggest that Classen supports their position because the patented invention at issue in that case might have constituted a research tool that was not subject to FDA approval. (Doc. No. 39 at 4-5.) But the Classen decision contains no discussion or analysis

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[3] In reply, Defendants argue that in Eli Lilly, the Supreme Court explained that an equilibrium between section 156(f) and section 271(e)(1) is not always achieved. (Doc. No. 39 at 3.) This is not entirely accurate. In Eli Lilly, the Supreme Court stated: "Under respondent's interpretation, there may be some relatively rare situations in which a patentee will obtain the advantage of the § 201 extension but not suffer the disadvantage of the § 202 noninfringement provision, and others in which he will suffer the disadvantage without the benefit." 496 U.S. at 671–72. The Supreme Court further stated: "We cannot readily imagine such situations (and petitioner has not described any), except where there is good enough reason for the difference." Id. at 672 n.4. Thus, in Eli Lilly, the Supreme Court recognized that there might be situations where an equilibrium is not achieved, but the Supreme Court cautioned that such situations are rare and occur where there are good reasons for the differences.

[4] Moreover, even if the Court were to consider the correctness of Proveris – which the Court may not because it is binding precedent, see Hart, 266 F.3d at 1171, 1175 – the Court notes that it finds the analysis set forth in Proveris persuasive, particularly in light of Eli Lilly's discussion of the perfect product fit between section 271(e)(1) and section 156(f).

of whether the patent at issue constituted a research tool, and the decision contains no discussion or analysis of whether, in light of that, the patent at issue was a "patented invention" for the purposes of section 271(e)(1). Indeed, the Classen opinion does not contain a single citation to Proveris or Eli Lilly. Whether the patent at issue was a "patented invention" for the purposes of section 271(e)(1) was simply not at issue in Classen. Rather, the primary issue in Classen was whether "the district court erred in finding [the allegedly infringing] activities exempt under the safe harbor because, according to [plaintiff], those activities are merely routine post-approval reporting to the FDA." Classen, 786 F.3d at 896–97. Thus, Defendants' reliance on Classen is misplaced.

Defendants also attempt to rely on the Federal Circuit's decision in Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997). Abtox was issued prior to Proveris. Defendants contend that in Abtox, the Federal Circuit held "that 'statutory symmetry' is 'not required.'" (Doc. No. 39 at 3 (quoting Abtox, 122 F.3d at 1029).) Instead, the full sentence in Abtox reads: "the Supreme Court commands that statutory symmetry is preferable but not required." Abtox, 122 F.3d at 1029. Moreover, Abtox appears to be distinguishable from Proveris and the present case. Although the patented invention at issue in Abtox was not covered by section 156(f) because it was a Class II medical device, see id., as a Class II medical device, the patented invention in Abtox was still subject to a FDA "abbreviated approval process."[5] See id. at 1028 (citing 21 U.S.C. § 360(k)). In contrast, here, it is alleged that the patented invention is not "subject to review by the FDA or any Federal law which regulates the manufacture, use, or sale of drugs or veterinary

[5] The Supreme Court in Eli Lilly recognized that there may be rare situations where there is not an equilibrium between section 271(e)(1) and section 156(f), and, as an example of this, the Supreme Court expressly referenced certain drug products that are subject to "abbreviated regulatory approval procedures." 496 U.S. at 672 n.4.

biological products." (Doc. No. 29, FAC ¶ 32.) As such, the Court does not find Defendants' reliance on Abtox persuasive.[6]

In addition, the Court does not find persuasive Defendants' reliance on Teva Pharms. USA, Inc. v. Sandoz Inc., No. 09 CIV. 10112 KBF, 2013 WL 3732867, at *3 (S.D.N.Y. July 16, 2013). (See Doc. No. 37-1 at 19-20.) In Teva, the district court rejected the notion that the Federal Circuit's decision in Proveris held that "the phrase 'patented invention' limits the scope of the safe harbor." Teva, 2013 WL 3732867, at *7. In analyzing Proveris, the Teva court focused on Proveris's analysis of the accused device in that case. See Teva, 2013 WL 3732867, at *8. Proveris based its holding in part on the fact that the accused product was not subject to FDA premarket approval. But that was not the only basis for the Proveris court's holding. Teva never acknowledges the language in Proveris explaining that because the invention claimed in the patent at issue also was not subject to a required FDA approval process, it was not a "patented invention" for the purposes of section 271(e)(1). Teva also does not acknowledge the language in Proveris explaining that this holding was consistent with Supreme Court's language in Eli Lilly explaining the perfect product fit between section 271(e)(1) and section 156(f). As such, the Court does not find Teva's analysis of Proveris persuasive. Further, Teva is a non-binding district court case that at least one other district court has expressly declined to follow for similar reasons.[7] See, e.g., Isis Pharms., Inc. v. Santaris Pharma A/S Corp., No. 3:11-CV-2214-GPC-KSC, 2014 WL 794811, at *12 n.7 (S.D. Cal. Feb. 27, 2014) ("Having considered Teva, this

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[6] For these same reasons, the Court does not find persuasive Defendants' reliance on Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012), (Doc. No. 39 at 3), as Momenta I repeats Abtox's holding by stating: "We too have rejected this strict interpretation of the safe harbor, explaining that 'statutory symmetry is preferable but not required.'" Momenta I, 686 F.3d at 1361 (quoting Abtox, 122 F.3d 1019).

[7] The Court also does not find persuasive Defendants' reliance on the district court decisions in Katz v. Avanir Pharms., No. 06CV0496 DMS (LSP), 2007 WL 9776599, at *6–7 (S.D. Cal. Aug. 21, 2007), and 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), (see Doc. No. 37-1 at 19-20), as both of those decisions were issued prior to the Federal Circuit's decision in Proveris.

Court disagrees with its limited reading of Proveris and its complete rejection of PSN Illinois.").

With this dispute regarding the legal authorities resolved, the Court turns to the allegations in the first amended complaint. In the FAC, Plaintiff alleges: "The claims of the '221 Patent encompass Allele's mNeonGreen product, which is a fluorescent protein used as a biological tag in genetic engineering work." (Doc. No. 29, FAC ¶ 29.) Plaintiff alleges that Defendants use mNeonGreen as "a research tool."[8] (Id. ¶¶ 39, 43, 49; see also, e.g., id. ¶ 37 ("Defendants Pfizer and BioNTech analyzed patient samples using an mNeonGreen neutralization assay to evaluate COVID-19 neutralizing antibody levels.")) Plaintiff further alleges that "[t]he '221 Patent (and the mNeonGreen technology covered by it) is not a patented invention subject to review by the FDA or any Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." (Id. ¶ 32; accord id. ¶ 40.) At the 12(b)(6) stage, the Court must accept these factual allegations as true, and draw all reasonable inferences in favor of Plaintiff. See Retail Prop. Trust, 768 F.3d at 945. In light of these allegations, Defendants have failed to demonstrate that the invention claimed in the '221 Patent is a "patented invention" for the purposes of section 271(e)(1). See Proveris, 536 F.3d at 1265–66; Momenta, 809 F.3d at 619; Isis, 2012 WL 4111157, at *4; PSN Illinois, 2011 WL 4442825, at *5.

In sum, Defendants have failed to demonstrate that the facts alleged in the FAC establish that the allegedly infringing activity is exempted by section 271(e)(1)'s safe harbor provision. As such, the Court declines to dismiss Plaintiff's claims for patent infringement.[9]

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[8] "Research tools" are "'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, 496 F.3d at 1347 (quoting 64 Fed. Reg. 72,090, 72092 n.1 (Dec. 23, 1999)).

[9] Defendants may raise their Section 271(e)(1) safe harbor affirmative defense at a later stage in the proceedings when the record is more fully developed.

Conclusion

For the reasons above, the Court denies Defendants' motion to dismiss. Defendants must file their respective answers to Plaintiff's complaint within **thirty (30) days** from the date this order is filed.

IT IS SO ORDERED.

DATED: May 4, 2021

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT