IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Plaintiffs,

v.

SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC,

Defendants.

Civil Action No. 20-1226-RGA

MEMORANDUM

Before me is Defendants' Motion to Dismiss. (D.I. 12). I have reviewed the parties' briefing. (D.I. 13, 20, 22, 25). I heard oral argument on December 20, 2021. (References to the transcript of the oral argument are indicated by "Tr."). For the reasons that follow, I will DENY Defendants' motion.

I. BACKGROUND

On September 15, 2020, Plaintiffs REGENXBIO Inc. and The Trustees of the University of Pennsylvania filed a complaint for patent infringement against the Sarepta Defendants, alleging infringement of U.S. Patent No. 10,526,617 ("the '617 patent"). (D.I. 1).

The '617 patent claims a "cultured host cell containing a recombinant nucleic acid molecule encoding the capsid protein." (*Id.* at ¶ 18). The patented cultured host cells do not require FDA regulatory approval. (*Id.* at ¶ 34). Plaintiffs allege that Sarepta infringes the '617 patent by manufacturing and using the patented cultured host cells to make recombinant adeno-

associated virus ("rAAV") gene therapy products including "SRP-9001," which is used to treat Duchenne muscular dystrophy ("DMD"). (*Id.* at ¶¶ 1, 26).

II. LEGAL STANDARD

Rule 8 requires a complainant to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). Rule 12(b)(6) allows the accused party to bring a motion to dismiss the claim for failing to meet this standard. A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations "could not raise a claim of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." (internal quotation marks omitted)).

III. DISCUSSION

Sarepta argues that the complaint should be dismissed for failure to state a claim because the allegations in the complaint relate to activities that fall within the protections of 35 U.S.C. § 271(e)(1) ("the safe harbor"). In response REGENXBIO argues, the safe harbor does not apply here as a matter of law; and Sarepta's motion rests on factual disputes with regard to Sarepta's commercialization of SRP-9001 that cannot be resolved on a motion to dismiss.[1]

The safe harbor 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 safe harbor provision was enacted as part of the Hatch-Waxman Act. "Congress enacted the Hatch-Waxman Act in order to eliminate two unintended distortions of the effective patent term resulting from the premarket approval required for certain products by the [Food, Drug, and Cosmetic Act]." *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1260 (Fed. Cir. 2008).

The first distortion was the reduction of effective patent life. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). "Because patent applications were filed early in the regulatory process, but market entry was delayed pending regulatory review, the early years of the patent term were spent obtaining premarket approval for the patented invention rather than generating

[1] Plaintiff The Trustees of the University of Pennsylvania only joins in REGENXBIO's second argument. (*See* D.I. 22).

profits." *Proveris*, 536 F.3d at 1265 (citing *Eli Lilly*, 496 U.S. at 669). This distortion was remedied by the enactment of 35 U.S.C. § 156, which provides patent term extensions to make up for regulatory delays caused by the FDA's premarket approval process.

The second distortion was the de facto extension of effective patent life at the end of the patent term. *Eli Lilly*, 496 U.S. at 670. Before the Hatch-Waxman Act was enacted, any manufacture, use, or sale of a patented invention during the patent term was an act of infringement, even if it was for the sole purpose of obtaining FDA regulatory approval. *Id.* Because competitors could not commence these activities until the patent expired, the patentee's monopoly would continue until its competitors obtained regulatory approval, effectively extending the patent term. *Id.* This distortion was remedied by the enactment of § 271(e)(1).

Section 271(e)(1) is an affirmative defense. *Immunomedics, Inc. v. Roger Williams Med. Ctr.*, 2017 WL 58580, at *9 (D.N.J. Jan. 4, 2017); *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 273 (D. Mass. 2006). Generally, a court may not rely on an affirmative defense in dismissing a complaint under Rule 12(b)(6). *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *In re Tower Air*, 416 F.3d 229, 238 (3d Cir. 2005)). However, I may dismiss a complaint "under Rule 12(b)(6) where an unanswered affirmative defense appears on its face." *Id.*

Sarepta argues that its activities were solely related to the development and future submission of a Biologics License Application to the FDA under the Federal Public Health Service Act and are thus protected under the safe harbor. REGENXBIO argues that the safe harbor does not apply here as a matter of law because the patented products are not subject to FDA premarket approval.

REGENXBIO's argument is based on the Federal Circuit's decision in *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008). In *Proveris*, the patentee alleged that "Innova" infringed a patent directed to a system and apparatus for characterizing aerosol sprays used in drug delivery devices by making and selling its Optical Spray Analyzer ("OSA"). *Id.* at 1258–59. "The OSA itself is not subject to FDA approval. It is, however, used in connection with FDA regulatory submissions. In that setting, the device measures the physical parameters of aerosol sprays used in nasal spray drug delivery devices." *Id.* at 1259. Innova argued that its activities were protected under the safe harbor because it sold the OSA device to third parties who used it "solely for the development and submission of information to the FDA." *Id.* at 1260.

The Federal Circuit rejected Innova's argument. "[W]e hold that the section 271(e)(1) safe harbor does not immunize the OSA from infringement." *Id.* at 1265. In so holding, the Federal Circuit relied on the Supreme Court's discussion of the two distortions in *Eli Lilly*. First, the Federal Circuit found that Innova was "not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion." *Id.* The Court reasoned, "Innova'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 spray plume characteristics the OSA measures. In short, Innova is not a party seeking FDA approval for a product in order to enter the market to compete with patentees. . . . [and] faces no regulatory barriers to market entry upon patent expiration." *Id.*

Second, the Federal Circuit found that the patentee was "not a party who, prior to enactment of the Act, could be said to have been adversely affected by the first distortion"

because the patented device was not subject to a premarket approval process. *Id.* The Federal Circuit found this to be significant because, "[I]n *Eli Lilly* the [Supreme] Court spoke of its 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 concluded that because the patented product at issue was not subject to FDA premarket approval, it was not a "patented invention" for purposes of § 271(e)(1). *Id.* at 1265–66.

Following *Proveris*, several district courts have held that where the patented product is not subject to FDA premarket approval, the safe harbor does not apply. *See, e.g.*, *Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc.*, 2021 WL 1749903 (S.D. Cal. May 4, 2021) (Rule 12(b)(6) dismissal); *Isis Pharms., Inc. v. Santaris Pharma A/S Corp.*, 2014 WL 2212114 (S.D. Cal. May 28, 2014) (summary judgment); *PSN Illinois, LLC v. Abbott Lab'ys*, 2011 WL 4442825 (N.D. Ill. Sept. 20, 2011) (summary judgment).

For example, in *PSN Illinois*, the defendants used patented receptors to develop drug candidates that required FDA approval. *PSN Illinois*, 2011 WL 4442825, at *1. Relying on *Proveris*, the district court held that since the patented receptors were not subject to FDA approval, they were not a "patented invention" under § 271(e)(1). *Id.* at *6. The defendants were not adversely affected by the second distortion because they were not using the patented receptors "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." *Id.* Thus, the district court denied the defendants' motion for summary judgment that its activities were protected by the safe harbor. *Id.*

Sarepta responds that *PSN Illinois* and the cases adopting the same reasoning were wrongly decided. (D.I. 25 at 9 n.6; Tr. at 15:22–16:3). Sarepta argues that this Court should instead limit its reading of *Proveris* to the third-party supplier context. (D.I. 25 at 5). In *Proveris*, Innova was selling the OSA devices to third parties, who used the devices to submit information to the FDA. Sarepta argues that the Federal Circuit found that Innova was not within the category of entities affected by the second distortion because Innova sold the OSA device and was not directly involved in submitting any information to the FDA. (D.I. 25 at 5).

Sarepta cites *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 2013 WL 3732867 (S.D.N.Y. July 16, 2013) in support of its narrow reading of *Proveris*. In *Teva*, the district court rejected the plaintiffs' argument that *Proveris* "provide[s] that the phrase 'patented invention' limits the scope of the safe harbor." *Id.* at *7. The district court instead reasoned that the holding of *Proveris* should be limited to the facts of that case—i.e., where the defendant is actively commercializing the infringing product. *Id.* at *8. The Court thus dismissed the complaint. *Id.* at *10. I do not find the district court's reasoning in *Teva* persuasive.

The Federal Circuit in *Proveris* did not make any distinction between defendants who used the patented product to obtain information to submit to the FDA and defendants who sold the patented product to third parties who used it to submit information to the FDA. Instead, the *Proveris* Court focused on whether the patented product and accused device were subject to FDA premarket approval. Thus, I conclude that the *Teva* court's limited reading of *Proveris* is not supported by the language in the case, which the district court seems to acknowledge. *See Teva*, 2013 WL 3732867, at *8 ("[T]he Federal Circuit could just as easily, and perhaps it would have been clearer, to have referred to the language 'solely for uses' as it was those uses to which the

defendant was putting the patented devices that was objectionable (selling them to others and not itself actually developing any information for submission).").

Further, this distinction is not supported by the text of § 271(e)(1). The safe harbor states, "It shall not be an act of infringement to make, use, offer to sell, or *sell* . . . a patented invention . . . solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1) (emphasis added). This language makes clear that the safe harbor applies to both those who infringe by use and those who infringe by sale. *See PSN Illinois*, 2011 WL 4442825, at * 6 ("Defendants offer no reasoned explanation why the safe harbor exemption would apply more broadly to an alleged infringer who infringes only by use and more narrowly to an alleged infringer who infringes by manufacture and sale.").

Thus, I decline Sarepta's invitation to limit the holding of *Proveris* to the third-party supplier context. I instead agree with REGENXBIO that *Proveris* holds that a patented product that is not subject to FDA premarket approval is not a "patented invention" under § 271(e)(1). *See Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) ("[R]esearch tools or devices that are not themselves subject to FDA approval may not be covered" by the safe harbor. (citing *Proveris*, 536 F.3d at 1265–66)).

I now turn to the facts as alleged in this case. Sarepta uses the patented cultured host cells to develop their SRP-9001 gene therapy product. (D.I. 1 at ¶¶ 27–31). "Although SRP-9001 requires Food and Drug Administration approval for marketing, the cultured host cells claimed in the '617 Patent, and used by Sarepta to produce SRP- 9001, do not." (*Id.* at ¶ 34). "SRP-9001 is currently in clinical development in the United States." (*Id.* at ¶ 35). Under

Proveris, since the patented cultured host cells are not subject to FDA regulatory approval, they are not a "patented invention" under § 271(e)(1).

At oral argument, Sarepta argued that the safe harbor should apply because of the second distortion in *Eli Lilly*—i.e., the patentee will receive an effective patent term extension. (Tr. at 6:20–7:2). Sarepta argued that it is adversely affected by the second distortion because it will have to wait until the expiration of the '617 patent to work on SRP-9001. (*Id.* at 16:16–21). It may indeed be true that Sarepta will be adversely affected by not being able to use Plaintiffs' patented cells, but the argument that this gives Plaintiffs an effective patent term extension makes no sense. Sarepta is not using the patented cultured host cells to obtain FDA approval to introduce generic cultured host cells to compete in the marketplace when the '617 patent expires. Instead, Sarepta is using the patented cells to develop its own patentable product. Sarepta can begin using the patented host cells immediately upon expiration of the patent because the cells are not subject to any FDA regulatory approval process. Thus, Plaintiffs will not receive any effective patent term extension.

Sarepta has failed to demonstrate that the facts alleged in the complaint establish that the allegedly infringing activity is exempted by the § 271(e)(1) safe harbor. Thus, I deny Sarepta's motion to dismiss.

IV. CONCLUSION

An appropriate order will issue.

Entered this 4th day of January, 2022.

United States District Judge