IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WILSON WOLF MANUFACTURING CORPORATION,	)	
Plaintiff,	)	
v.	)	Civil Action No. 19-2316-RGA
SAREPTA THERAPEUTICS, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this patent infringement action filed by Plaintiff Wilson Wolf Manufacturing Corporation ("Plaintiff" or "Wilson Wolf") against Defendant Sarepta Therapeutics, Inc. ("Defendant" or "Sarepta"), pending is Sarepta's motion to dismiss Wilson Wolf's First Amended Complaint ("FAC"), filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 16) For the reasons set out below, the Court recommends that Sarepta's Motion be DENIED.

I. BACKGROUND

A. Factual Background

Growing cells in a laboratory environment ("culturing" cells) is critically important for the commercial production of medications, treatment of genetic disorders, and the production of cells which themselves can be used treat diseases. (D.I. 15 at ¶¶ 6-10) Cultured cells can be used to replicate specially engineered "viral vectors" in large quantities, which can be introduced into patients to treat genetic disorders ("gene therapy"). (*Id.* at ¶ 9) Wilson Wolf develops devices and methods for the process of culturing cells. (*Id.* at ¶¶ 6, 11) The asserted patents, United States Patent No. 9,441,192 (the "'192 patent") and United States Patent No. 8,697,443 (the "'443 patent" and together with the '192 patent, the "asserted patents") claim some of these

methods and devices. (*Id.* at ¶¶ 19-23)

Sarepta describes itself as a "commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases[.]" (D.I. 15, ex. F at 1) It is advancing a gene therapy program known as SRP-9001, which is designed to treat Duchenne Muscular Dystrophy. (*Id.* at ¶ 28; *id.*, ex. C at 15-17) SRP-9001 is currently undergoing testing in clinical trials. (*Id.*, ex. C at 15; *id.*, ex. D at 2-3; *see also* D.I. 17 at 4) The product has not yet been approved by the United States Food and Drug Administration ("FDA") and is not yet commercially available. (*Id.*; *see also* D.I. 18 at 4) It is not in dispute that before Sarepta can market and sell SRP-9001, Sarepta must obtain sufficient data from its clinical trials, must submit to the FDA a Biologics License Application ("BLA") and that the FDA must approve the BLA. (*See* D.I. 17 at 5)

In 2018, Sarepta entered into a "long-term strategic manufacturing partnership with Brammer Bio" under which Brammer Bio would design and build a commercial manufacturing facility for SRP-9001 (the "Brammer Agreement"). (D.I. 15, ex. F at 1-2; *see also id.* at ¶ 31) And in 2019, Sarepta entered into a license agreement with Roche for the commercialization of SRP-9001 outside of the United States, with Roche agreeing to pay over $1.1 billion up front for the commercial rights to SRP-9001 (the "Roche license"). (*Id.* at ¶ 32)

Wilson Wolf alleges that Sarepta has infringed the asserted patents through Sarepta's "use of cells and/or cell-derived products including viral vectors manufactured using the Corning HYPERStack cell culture device." (*Id.* at ¶ 24) According to the FAC, these cells and cell-derived products are products made by a process patented by Wilson Wolf in the United States within the meaning of 35 U.S.C. § 271(g). (*Id.*)

Further relevant facts related to resolution of the Motion will be set out as needed in Section III.

B. Procedural Background

Wilson Wolf initiated this lawsuit on December 20, 2019, (D.I. 1), and filed the operative FAC on April 23, 2020, (D.I. 15). The instant Motion was filed on May 14, 2020, (D.I. 16), and briefing was completed on June 12, 2020, (D.I. 20). United States District Judge Richard G. Andrews referred this Motion to the Court for resolution on July 14, 2020, (D.I. 23), and the Court heard argument on the Motion on December 15, 2020, (Transcript of December 15, 2020 Hearing (hereinafter, "Tr.")).

II. LEGAL STANDARD

When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting all of the complaint's well-pleaded facts as true, but disregarding any legal conclusions. *Id.* at 210-11. Second, the court determines whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "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." *Iqbal*, 556 U.S. at 678. In assessing the plausibility of a claim, the court must "'accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

III. DISCUSSION

With its Motion, Sarepta argues that Wilson Wolf has failed to state a claim because the FAC's allegations relate to activities that fall squarely within the protections of 35 U.S.C. § 271(e)(1) (the "Safe Harbor"). (D.I. 17 at 2-3)[1] The Safe Harbor reads as follows:

> 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 basic idea behind the Safe Harbor is to allow "competitors to begin the regulatory approval process while [a] patent [i]s still in force, followed by market entry immediately upon patent expiration." *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008). As a result of the provision, "a competitor who anticipates coming into the marketplace with a product that utilizes a currently patented invention may make, use, and sell that product so long as it is '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.* (certain internal quotation marks and citation omitted). Accordingly, the Safe Harbor applies "as long as there is a reasonable basis for believing that the use of the patented invention will produce the types of information that are relevant to an FDA submission." *Amgen*

[1] Thus, in making this argument, Sarepta is invoking an affirmative defense. *See Classen Immunotherapies Inc. v. Somaxon Pharms.*, No. CV 12-06643-GAF-PLA, 2013 WL 9947386, at *2 n.1 (C.D. Cal. Apr. 11, 2013) (noting that Section 271(e)(1) is considered an affirmative defense to patent infringement); *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 273 (D. Mass. 2006) (same). The Court may dismiss a claim pursuant to a Rule 12(b)(6) motion in light of an affirmative defense, but only where the well-pleaded factual allegations in the complaint, construed in the light most favorable to the plaintiff, clearly suffice to establish the defense. *See Jones v. Bock*, 549 U.S. 199, 215 (2007); *Kabbaj v. Google, Inc.*, Civ. No. 13-1522-RGA, 2014 WL 1369864, at *2 n.2 (D. Del. Apr. 7, 2014).

Inc. v. Hospira, Inc., 944 F.3d 1327, 1338 (Fed. Cir. 2019) (internal quotation marks and citation omitted). In determining whether the Safe Harbor applies, "'[e]ach of the accused activities must [ultimately] be evaluated separately[.]'" *Id.* (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005)).

Wilson Wolf responds by arguing that the FAC contains plausible allegations that at least some of Sarepta's infringement was "solely for non-FDA purposes" and that such use of Wilson Wolf's patented processes and methods is not immunized under the Safe Harbor. (D.I. 18 at 14 (internal quotation marks and citation omitted); *see also id*. at 1, 3, 5, 10-14) For the reasons discussed below, the Court agrees. That is, taken together, the FAC's allegations—assuming they are true and drawing all reasonable inferences in favor of Wilson Wolf—set out enough facts to allege a plausible claim that survives Sarepta's Motion.

The key allegations of the FAC with respect to this issue are as follows:

> 29. On information and belief, although some batches of SRP-9001 were manufactured for use by Sarepta in connection with submissions to the FDA, other batches of SRP-9001 were not manufactured for use by Sarepta for FDA purposes, and were instead used for other business purposes.
>
> 30. While some of Sarepta's infringement was strictly to generate information for the FDA, some of its infringement was for both FDA filings and other non-FDA purposes, and some of [its] infringement was solely for non-FDA purposes. For example, Sarepta had some batches of such products manufactured using Wilson Wolf's patented processes and methods for use to develop, improve, and optimize its manufacturing process for commercialization purposes. Sarepta also had some batches of such products manufactured using Wilson Wolf's patented process and methods for use in manufacturing capacity development and yield optimization for purposes of commercialization of the SRP-9001 product.
>
> 31. Even while conducting its clinical trials of SRP-9001, Sarepta moved forward in anticipation of commercialization of that product. For example, in 2018 Sarepta entered into a

> "manufacturing partnership" with Brammer Bio to build manufacturing capacity for the SRP-9001 product. *See* Exhibit F (Sarepta Press Release). The arrangement with Brammer Bio was designed to "integrate process development, clinical production and testing, and commercial manufacturing with the goal of bringing micro-dystrophin gene therapies to the patient community urgently and in sufficient supply." *Id.*
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> 32. In 2019, Sarepta entered into a license agreement with Roche for commercialization of the SRP-9001 product outside of the U.S. that has been described as the single biggest such license in biopharma history. Roche agreed to pay more than $1.1 billion up front for the commercial rights to SRP-9001 outside of the United States. The manufacture of Sarepta's SRP-9001 product using Wilson Wolf's patented processes and methods supported that commercialization agreement.
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> 33. The manufacture of some of Sarepta's SRP-9001 product using Wilson Wolf's patented processes and methods was done to assist in commercialization of the product, and was not done to create information for FDA submissions. Sarepta itself stated that it developed its program to "expedite development and commercialization" of its gene therapy products, including SRP-9001. *See* Exhibit G at 9.
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> 34. Because the manufacture of some of Sarepta's SRP-9001 product using Wilson Wolf's patented processes and methods was done to advance and support commercialization of the product, and was not done to create information for FDA submissions, Sarepta's use of that product falls outside of the Safe Harbor of 35 U.S.C. § 271(e)(1). . . .

(D.I. 15 at ¶¶ 29-34; *see also* D.I. 18 at 5) The parties are in agreement that "application of the Safe Harbor always turns on the statutory language and asks the question: are the allegedly infringing activities 'solely for uses reasonably related to the development and submission of information' to the FDA?" (D.I. 20 at 8; *see also* D.I. 18 at 13 (Wilson Wolf contending that "[t]he only question is whether [the batches at issue were] batches made in support of FDA approval or batches made for any other reason")) And in the above paragraphs, the FAC

expressly alleges that certain of Sarepta's infringing activities *were not done to create information for submission to the FDA.*

Despite this, Sarepta attacks the FAC's allegations in a couple of ways. With respect to the FAC's allegations in paragraph 30—i.e., that Sarepta had some batches of its drug manufactured "to develop, improve, and optimize its manufacturing process for commercialization purposes" and "for use in manufacturing capacity development and yield optimization for purposes of commercialization of the SRP-9001 product[,]" (D.I. 15 at ¶ 30)—Sarepta first asserted that these amount to "[b]ald [a]ssertions" that should not be accepted as true. (D.I. 17 at 17 (emphasis omitted); *see also id*. at 18-19; D.I. 20 at 9) Then, in its reply brief, Sarepta took another tack with respect to these allegations. There, it cited to the FDA's Guidance for Industry on *Human Gene Therapy for Rare Diseases* ("FDA Guidance"). (D.I. 20 at 10) In doing so, Sarepta asserted that: (1) pursuant to the FDA Guidance, drug companies are required to submit data demonstrating "'process control to ensure a consistent product'" by "'implementing manufacturing changes needed for commercial-scale production and demonstrating product comparability prior to the initiation of clinical trials intended to provide substantial evidence of effectiveness for a marketing application[,]'"; and (2) the Sarepta activities described in paragraph 30 were related to the submission of data to the FDA (pursuant to this FDA Guidance), such that they are not activities performed solely for non-FDA purposes. (*Id.* (quoting FDA Guidance at 2-3)) And lastly, with respect to paragraph 31 and 32's allegations relating to the Brammer Agreement and the Roche license, Sarepta asserted that these agreements address "*future possible* commercial manufacturing, not current commercial activities" and that they are therefore irrelevant to the question of whether Sarepta's alleged

infringing activities fall within the scope of the Safe Harbor. (D.I. 17 at 9 (emphasis in original); *see also id*. at 10-14)

At the outset, Sarepta's "bald assertion" argument can be easily discarded. In making its alternative argument about the FDA Guidance, Sarepta seems to be essentially acknowledging that paragraph 30's allegations are *not* merely bald assertions and instead are sufficiently fact-specific. In other words, Sarepta there seems to be conceding that paragraph 30 amounts to more than just a reference to labels or legal conclusions, and that instead, the paragraph describes specific, real-world acts that are asserted to have actually occurred in the past. Sarepta seems instead to be arguing that while these (fact-specific) acts did occur, the Court should infer that they were done for a *different purpose* than what Wilson Wolf alleges—i.e., to satisfy the FDA's request for data that demonstrates process control to ensure a consistent product. (D.I. 20 at 10; Tr. at 24) Indeed, during oral argument, Sarepta's counsel seemed to say just that. (Tr. at 23-24 ("There are reasonably detailed factual allegations in paragraph 30 [of the FAC] that describe activity. And they describe activity that but for the [S]afe [H]arbor, one could say that they would adequately plead patent infringement. For example 'Sarepta had some batches of such products manufactured using Wilson Wolf's patented processes and methods for use to develop, improve, and optimize its manufacturing process for commercialization purposes.' Your Honor, that is reasonably detailed. What's not reasonably detailed is any allegation that it's *for purposes other than* preparation of the BLA.") (emphasis added)) So the Court cannot grant the Motion on the ground that these are nothing more than "bald assertions."

As for Sarepta's FDA Guidance-argument, Sarepta's view is that the Motion should be granted because the FAC's allegations in paragraph 30 are "perfectly aligned" with activities undertaken for FDA purposes. (Tr. at 76) However, the question is not whether it is plausible

that these allegations are "aligned" with acts preformed for an FDA-related, non-infringing use (i.e., what Wilson Wolf is *not* alleging). The question is whether the allegations are plausibly "aligned" with acts performed *for a non-FDA-related, infringing use* (i.e., what Wilson Wolf *is* alleging). And even if the facts alleged would render *both* such conclusions plausible, then the claim would still survive.[2] Moreover, the Court has to also keep in mind that: (1) at the pleading stage, it is required to accept all of Wilson Wolf's well-pleaded facts as *true*, (D.I. 18 at 12-13); and (2) because an affirmative defense is being invoked here, it has to be *clear* on the face of the FAC that the defense is well-taken before a motion to dismiss is granted.

In light of these Rule 12(b)(6) standards, the Court concludes that Wilson Wolf has made out plausible claims of infringement—i.e., claims "aligned" with acts undertaken by Sarepta for non-FDA-related business purposes (at least as to certain of Sarepta's drug batches). The above-cited portion of the FDA Guidance does not "give Sarepta permission to make extra batches" that are solely for non-FDA commercial manufacturing or yield optimization purposes. (Wilson Wolf's Hearing Slides at Slide 13; *see also* Tr. at 40-41, 50)

The Court's conclusion is also bolstered by paragraph 31-32's allegations about the Brammer Agreement and Roche license. Wilson Wolf's point in including those allegations is that: (1) in light of the fact that Sarepta entered into a manufacturing partnership with Brammer Bio in 2018 to bring its gene therapies to patients "'urgently and in sufficient supply[,]'" (D.I. 15 at ¶ 31); and (2) that Sarepta also entered into a $1.1 billion license agreement with Roche in

[2] *See Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) ("A court ruling on [a Rule 12(b)(6) motion] may not properly dismiss a complaint that states a plausible version of the events merely because the court finds a different version more plausible."); *Deere & Co. v. AGCO Corp.*, Civil Action No. 18-827-CFC, 2019 WL 668492, at *5 (D. Del. Feb. 19, 2019) ("But the fact that an innocuous or even exculpatory inference can also plausibly be drawn from a complaint's alleged facts does not warrant dismissal").

2019 for international commercial distribution rights, (*id.* at ¶ 32); then (3) this all renders it more plausible that Sarepta "had some batches [of SRP-9001] manufactured . . . for use to develop, improve, and optimize its manufacturing process for commercialization purposes" and had some batches manufactured "for use in manufacturing capacity development and yield optimization for purposes" of commercializing its SRP-9001 product, (*id*. at ¶ 30). (D.I. 18 at 11-13; Tr. at 43-44, 46-48) Put differently, even though Sarepta has not yet received FDA approval for its drug product,[3] the Brammer Bio and Roche license allegations plausibly show that it has already been taking active steps to prepare for the commercialization of SRP-9001. (Tr. at 43-44, 46-48) And that, in turn, makes it more plausible that the above-referenced batches were in fact made for similar non-FDA "commercialization" purposes—and *not* made for a use reasonably related to the future submission of information to the FDA.[4]

[3] Sarepta suggests that because it is in the early stages of clinical development with respect to SRP-9001, it is just not plausible that it has previously or is currently engaged in commercial manufacturing activities outside of the scope of the Safe Harbor. (D.I. 17 at 12-14; Tr. at 33, 49) There is no *per se* rule, however, that if a company is in such a stage of clinical development, it cannot be simultaneously engaged in manufacturing activities that are not immunized under the Safe Harbor. *See, e.g.*, *Amgen, Inc.*, 944 F.3d at 1332, 1338-40 (affirming a jury verdict that certain batches of product manufactured after 2012 using plaintiff's patented method were not protected under the Safe Harbor exemption because the batches were not connected to use reasonably related to FDA approval, where the defendant submitted its BLA in 2014); *Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, Case No. 4:19-cv-06593-HSG, 2020 WL 789559, at *3 (N.D. Cal. Feb. 18, 2020) ("Not all activities performed prior to FDA approval, however, fall within the [Safe Harbor] exemption.").

[4] During oral argument, Sarepta's counsel argued that if the FAC's allegations were deemed sufficient to escape the reach of the Safe Harbor, that would mean that no similarly-situated defendant could rely upon the Safe Harbor. Counsel's argument was that: (1) since all such defendants have to engage in certain pre-FDA-approval manufacturing-related activities, so as to comply with the above-referenced FDA Guidance; then (2) any plaintiff could point to that very type of manufacturing, and then make the same allegations Wilson Wolf has here—thus turning what should be Safe Harbor-protected drug manufacturing activity into a plausible basis for an infringement claim. (Tr. at 27, 76; *see also* D.I. 20 at 10) The Court understands Sarepta's concern. But every case and every pleading will turn on its unique facts. And in light of the entirety of the allegations here, including those about the Brammer Agreement and the

Accordingly, the FAC plausibly alleges that Sarepta used the patented methods for the manufacture of certain drug batches unrelated to its FDA submissions, and such activity would not be immunized by the Safe Harbor. *Cf. Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, Case No. 4:19-cv-06593-HSG, 2020 WL 789559, at *2-4 (N.D. Cal. Feb. 18, 2020) (rejecting the defendants' argument that the complaint should be dismissed because the only act accused of infringement (exhibiting the accused device at a medical conference) was immunized by the Safe Harbor, where the complaint alleged that defendants displayed the accused device to promote commercial sales overseas and the parties' dispute constituted a "factual disagreement" not proper for resolution at the motion to dismiss-stage). As Wilson Wolf has viable claims of patent infringement as to both asserted patents, the Court recommends that the Motion be denied.[5]

IV. CONCLUSION

For the foregoing reasons, the Court recommends that Sarepta's Motion be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R.

Roche license, the Court concludes that this is not the type of "bare bones" complaint that might more credibly give rise to such concerns.

[5] Wilson Wolf also asserted a "separate and independent reason[]" for denial of Sarepta's motion. That is, the FAC alleges that Wilson Wolf's patented cell culturing methods constitute a general purpose "research tool," which brings Sarepta's infringement outside of the scope of the Safe Harbor. (D.I. 18 at 15; *see also id.* at 1, 2-3, 6-10; Tr. at 38) However, Wilson Wolf's view was that if the Court found its previously-referenced argument viable as to why it had stated a claim with regard to Count I, then the Court need not address this "research tool" issue at this time. (Tr. at 48-49 ("Your Honor, . . . if you agree with us that paragraphs 29 through 33 state a cause of action that's not covered by the [S]afe [H]arbor, you can stop your analysis there; you don't need to wade into the case law and address the research [tool] question.")) Sarepta did not assert a different view during oral argument, and it only addressed this "research tool" issue briefly during that argument. (*Id.* at 77-80) In light of all of this, and in light of the fact that the Court's conclusion above is that Wilson Wolf has otherwise pleaded a plausible claim of infringement as to both patents in the FAC's Count I, the Court exercises its discretion to not address the "research tool" issue here.

Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: December 30, 2020

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE