UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ENDO PAR INNOVATION COMPANY, LLC, **PAR PHARMACEUTICAL, INC.**, and **PAR STERILE PRODUCTS, LLC**,

Plaintiffs,

v. Case No. 8:23-cv-1953-WFJ-TGW

BPI LABS, LLC, and **BELCHER PHARMACEUTICALS, LLC**,

Defendants.
_____/

ORDER

Before the Court is BPI Labs, LLC ("BPI") and Belcher Pharmaceuticals, LLC's ("Belcher") (collectively, "Defendants") Motion to Dismiss or, in the alternative, Motion for a More Definite Statement (Dkt. 30). Endo Par Innovation Company, LLC ("Par Innovation"), Par Pharmaceutical, Inc. ("Par Pharmaceutical"), and Par Sterile Products, LLC ("Par Sterile") (collectively, "Plaintiffs") have responded in opposition (Dkt. 40). Defendants have replied (Dkt. 42). Upon careful consideration, the Court denies Defendants' Motion.

BACKGROUND

Plaintiffs and Defendants hold New Drug Applications ("NDAs") for epinephrine-based pharmaceutical products. Par Pharmaceutical is also the

assignee of two epinephrine-centric patents in which Par Innovation and Par Sterile own interests. In the instant case, Plaintiffs claim that, upon approval from the United States Food and Drug Administration (the "FDA"), Defendants' proposed epinephrine product will infringe their patents.[1]

I. Plaintiffs' NDAs, Products, and Patents

Par Sterile is the holder of NDA No. 204200 for epinephrine injection, Eq 1mg base/mL injectable solution ("Plaintiffs' 1 mL Adrenalin® Product") as well as NDA No. 204640 for epinephrine, Eq 30mg base/mL injectable solution ("Plaintiffs' 30 mL Adrenalin® Product") (collectively, "Adrenalin®"). Dkt. 1 at 4–5. "Adrenalin® is a clear, colorless, sterile parental solution containing the active ingredient L-epinephrine and is intended for intramuscular or subcutaneous administration." *Id.* at 5. It is primarily used for emergency treatment of anaphylactic reactions (hereafter, "Type 1 allergic reactions"). *Id.* at 5.

Notwithstanding the long history of clinical epinephrine use, in 2012, the FDA expressed a number of concerns regarding the epinephrine formulation in Adrenalin®. *Id.* This is largely because such epinephrine formulations can degrade "and can react with other ingredients to form epinephrine sulfonic acid ("ESA"), or can racemize in aqueous solution to form D-epinephrine, both of which cause a decrease in the effective concentration of the active ingredient L-epinephrine and

[1] The Court recounts the facts as alleged by Plaintiffs.

therefore decrease potency of the product." *Id.* at 6 (cleaned up). If this problem is left unaddressed, moreover, products like Adrenalin® might become "unacceptable to patients suffering from emergency anaphylaxis who need potent medication in a short period of time." *Id.*

In response to the FDA's concerns, Par Sterile undertook efforts to improve Adrenalin®. *Id.* These efforts resulted in a composition containing "epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges" which "reduced the formation of D-epinephrine and ESA without compromising pharmaceutical benefits." *Id.* at 7. In other words, Par Sterile created an epinephrine formulation for Adrenalin® that resulted in lower impurity levels and improved potency over a longer period of time or shelf life. *Id.*

Following this advancement, Par Sterile submitted supplemental NDAs for their reformulated Adrenalin® products. *Id.* The FDA approved Plaintiffs' 1 mL Adrenalin® Product in March 2015 and Plaintiffs' 30 mL Adrenalin® Product in September 2016. *Id.* In addition, Par Pharmaceutical obtained several patents, including U.S. Patent Nos. 9,119,876 (the "'876 Patent") and 9,295,657 (the "'657 patent") (collectively, the "Patents-in-Suit").

The Patents-in-Suit, both titled "Epinephrine Formulations," generally address "[p]harmaceutical compositions comprising epinephrine, methods of

administration, and methods of making the same." Dkt. 1-2 at 2; Dkt. 1-3 at 2. The '876 Patent specifically claims to cover the aforementioned epinephrine formulation which reduces impurities and boosts active-ingredient potency, while the '657 Patent claims to cover methods of using this inventive formulation to treat Type 1 allergic reactions. *See generally* Dkt. 1-2; Dkt. 1-3. Both are listed in "the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") with respect to Adrenalin® brand epinephrine injection." Dkt. 1 at 8.

II. Defendants' NDA and Proposed Product

BPI is the holder of NDA No. 205029 for epinephrine injection, 1 mg/mL, which the FDA approved on July 29, 2014. *Id.* BPI also recently submitted to the FDA a supplement to NDA No. 205029 "seeking to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a 30 mg/30mL vial presentation of Epinephrine Injection, USP, 1 mg/mL ("Defendants' Proposed Product")." *Id.* 9. At this point, Defendant BPI's Proposed Product is not approved.

On July 17, 2023, pursuant to 21 U.S.C. § 355(b)(3), BPI sent a notice letter to Plaintiffs seeking to explain why Plaintiffs' Patents were invalid and were not infringed by Defendants' Proposed Product (the "First Notice Letter"). *Id.* Plaintiffs claim that the First Notice letter was deficient for several reasons and did not include an offer of confidential access to NDA No. 205029. *Id.* Plaintiffs allegedly notified Defendants of these deficiencies on August 1, 2023. *Id.*

On August 9, 2023, BPI sent a second letter "purporting to cure the deficiencies of the First Notice Letter" and offering confidential access to NDA No. 205029 (the "Second Notice Letter"). *Id.* at 9–10. Plaintiffs maintain that the Second Notice Letter nevertheless "failed to provide, for each claim of the Patents-in-Suit, a full and detailed explanation of why the claim is not infringed or is invalid or unenforceable." *Id.* at 10. Plaintiffs further contend that Defendants "did not provide the entirety of NDA No. 205029 or the supplement thereto" and that "relevant parts" were redacted from NDA No. 205029. *Id.*

III. The Instant Suit

On December 15, 2023, Plaintiffs brought the instant suit to enjoin Defendants from "making, using, offering to sell, selling, and/or importing Defendants' Proposed Product into the United States." *Id.* at 13, 18. Plaintiffs assert two counts under 35 U.S.C. § 271(e)(2)(A): Count I—infringement of the '876 Patent; and Count II—infringement of the '657 Patent. *Id.* at 10–19. Defendants now move to dismiss Plaintiffs' Complaint or, in the alternative, force Plaintiffs to make a more definite statement of infringement. Dkt. 30 at 8–15.

LEGAL STANDARDS

I. Federal Rule of Civil Procedure 12(b)(6)

A complaint withstands dismissal under Federal Rule of Civil Procedure 12(b)(6) if the alleged facts state a claim for relief that is "plausible on its face."

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This standard does not require detailed factual allegations but demands more than an unadorned accusation. *Id.* All facts are accepted as true and viewed in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008).

At the dismissal stage, a court may consider matters judicially noticed, such as public records, without converting a defendant's motion to one for summary judgment. *See Universal Express, Inc. v. S.E.C.*, 177 F. App'x 52, 52 (11th Cir. 2006). Additionally, documents may be considered at the dismissal stage if they are central to, referenced in, or attached to the complaint. *LaGrasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004). Documents attached to a motion to dismiss may also be considered if the documents are (1) central to the plaintiff's claim, and (2) undisputed (if their authenticity is not challenged). *Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002).

II. Federal Rule of Civil Procedure 12(e)

Federal Rule of Civil Procedure 12(e) allows a party to "move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response." Such a motion "is proper only when the pleading to which it is addressed is so vague that it cannot be responded to and the information sought is

that which is necessary to frame a proper responsive pleading." *Parks v. Experian Credit Bureau*, No. 609-CV1284-ORL-19DAB, 2010 WL 457345, at *2 (M.D. Fla. Feb. 4, 2010) (internal quotations and citation omitted). "Most courts disfavor the use of Rule 12(e)[.]" *Royal Shell Vacations, Inc. v. Scheyndel*, 233 F.R.D. 629, 630 (M.D. Fla. 2005); *Dismuke v. Fla. Bd. of Governors*, No. 8:05-CV-340-T-17-TBM, 2005 WL 1668895, at *2 (M.D. Fla. July 8, 2005).

DISCUSSION

The Court will address Rule 12(b)(6) before turning to consider Rule 12(e).

I. Rule 12(b)(6)

In light of 35 U.S.C. § 271(e)(2), Plaintiffs have stated claims for infringement of the Patents-in-Suit. As the Federal Circuit has explained, § 271(e)(2) provides "patentees with a defined act of infringement sufficient to create a case or controversy" where a generic drug maker submits an NDA for a drug claimed in a patent with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the drug before the subject patent expires. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567–69 (Fed. Cir. 1997). "[A] plaintiff in receipt of a paragraph IV certification . . . relating to one of the plaintiff's Orange Book-listed patents may state a claim for infringement" by alleging four elements: (1) "its interest in the patent," (2) "its receipt of the paragraph IV certification," (3) "the filing of the ANDA or NDA," and (4) "its

contention that the defendant's proposed product will infringe." *Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331 (D. Del. 2019).

Plaintiffs have alleged each of these elements. First, Plaintiffs have a sufficient interest in the Patents-in-Suit because Par Pharmaceuticals is their assignee, Par Innovations is their exclusive licensee, and Par Sterile is the holder of NDA Nos. 204200 and 204640. Dkt. 1 at 4–5. Second, Plaintiffs have received paragraph IV certification in the form of the First and Second Notice Letters. *Id.* at 9. Third, BPI is the holder of NDA No. 205029 and submitted a supplement thereto seeking approval of Defendants' Proposed Product. *Id.* Finally, Plaintiffs have alleged that "Defendants' Proposed Product comprises epinephrine, a tonicity regulating agent, a pH raising agent, an antioxidant comprising sodium bisulfite and/or sodium metabisulfite, a pH lowering agent, and a transition metal complexing agent, in the ranges claimed in at least one claim, including at least claim 1 of the '876 patent" and "at least claim 1 of the '657 patent[.]" *Id.* at 12, 17. Nothing more is required under § 271(e)(2). *See Abraxis Bioscience, LLC v. HBT Labs, Inc.*, No. CV 18-2019-RGA, 2019 WL 2270440, at *5 (D. Del. May 28, 2019) (finding that a "[p]laintiff states a plausible claim for patent infringement under § 271(e)(2) by alleging that [d]efendant 1) made a [p]aragraph IV filing and 2) provided the required notice to [p]laintiff").

Plaintiffs have also plausibly alleged the aforementioned § 271(e)(2) elements under a Rule 12(b)(6) standard. As explained above, a complaint withstands dismissal under Rule 12(b)(6) if the alleged facts state a claim for relief that is "plausible on its face," *Ashcroft*, 556 U.S. at 678, with all facts accepted as true and viewed in the light most favorable to the plaintiff, *Pielage*, 516 F.3d at 1284. This being the case, the First and Second Notice letters do not render Plaintiffs' Complaint deficient at the motion to dismiss stage. Plaintiffs expressly allege, and the Court must accept as true, that the Notice Letters failed to provide, for each claim of the Patents-in-Suit, a "full and detailed explanation of why the claim is not infringed or is invalid or unenforceable." Dkt. 1 at 10. The Court may not ignore this allegation or engage in analysis akin to claim construction based on a seven-page letter. *See generally* Dkt. 30-2. This would be inappropriate. *See Cima Labs, Inc. v. Actavis Grp. HF*, No. 06-1970 (DRD), 2007 WL 1672229, at * (D.N.J. June 7, 2007) (collecting cases for the proposition that, "if a court is required to construe the meaning of claim terms and perform an infringement analysis in order to resolve a motion to dismiss or a motion for judgment on the pleadings, the motion should be denied, because this type of analysis is inappropriate at the pleading stage"). Defendants may raise these factual arguments following claim construction and discovery. The Court denies the Motion to Dismiss.

II. Rule 12(e)

The Court also denies Defendants' relief under Rule 12(e). As other Courts have explained, "[f]ederal courts disfavor motions for a more definite statement in view of the liberal pleading requirements set forth" in Federal Rule of Civil Procedure 8. *Parks*, 2010 WL 457345, at *2; *see also Royal Shell*, 233 F.R.D. at 630. Thereunder, if a complaint "indicates generally the type of litigation involved[,] it is sufficient to put the Defendants on notice." *Royal Shell*, 233 F.R.D. at 630; Fed. R. Civ. P. 8(a). Plaintiffs' Complaint achieves this by alleging that "Defendants' Proposed Product comprises epinephrine, a tonicity regulating agent, a pH raising agent, an antioxidant comprising sodium bisulfite and/or sodium metabisulfite, a pH lowering agent, and a transition metal complexing agent, in the ranges claimed in at least one claim, including at least claim 1 of the '876 patent" and "at least claim 1 of the '657 patent[.]" Dkt. 1 at 12, 17. This is sufficient to allow Defendants to prepare a responsive pleading.

CONCLUSION

Accordingly, it is hereby **ORDERED** and **ADJUDGED**:

(1) Defendants' Motion (Dkt. 30) is **DENIED.**

DONE AND ORDERED at Tampa, Florida, on February 22, 2024.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

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Counsel of Record