UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

VISION PHARMA, LLC,

Plaintiff,

v. Case No: 2:18-cv-500-FtM-99MRM

STERLING PHARMACEUTICAL SERVICES, LLC,

Defendant.
_____/

OPINION AND ORDER[1]

This matter comes before the Court on Defendant's Motion to Dismiss Second Amended Complaint (Doc. 39) filed on December 28, 2018. Plaintiff filed a Response in Opposition (Doc. 42) on January 18, 2019. For the reasons set forth below, the Motion is denied.

BACKGROUND

This lawsuit is the result of a business deal gone wrong between a pharmaceutical company (Plaintiff) and the company it outsourced the manufacture of some of its drugs to (Defendant). Plaintiff brings claims for breach of contract, breach of the implied covenant of good faith and fair dealing, breach of warranty, and promissory estoppel. (Doc. 38, ¶ 1). Vision Pharma, LLC (Vision) alleges that this Court has jurisdiction

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pursuant to 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds $75,000, exclusive of interests and costs, and the parties are diverse. (Doc. 38, ¶ 4).

The Court previously dismissed the Amended Complaint (Doc. 24) without prejudice for lack of subject-matter jurisdiction for failure to adequately allege that the amount in controversy exceeds $75,000. (Doc. 37). Vision filed a Second Amended Complaint (Doc. 38) on December 20, 2018. Defendant Sterling Pharmaceutical Services, LLC (Sterling) moves to dismiss the Second Amended Complaint for again failing to sufficiently allege the amount in controversy, as well as for failure to state a claim as to all counts. The Court recounts the factual background as pled in Plaintiff's Second Amended Complaint, which it must take as true to decide whether the Second Amended Complaint states a plausible claim. *See Chandler v. Sec'y Fla. Dep't of Transp.*, 695 F.3d 1194, 1198-99 (11th Cir. 2012).

Among other things, Vision develops, markets, and sells quality pharmaceutical products throughout the United States that follow FDA guidelines, rules, laws and regulations that include Current Good Manufacturing Practices. (Doc. 38, ¶ 6). It is common for pharmaceutical companies such as Vision to outsource to contract manufacturing organizations (CMOs) the development and manufacturing of the drugs that they market. (*Id.*, ¶ 7). Sterling served as Vision's CMO to develop and manufacture Nitroglycerin SL tablets and over-the-counter (OTC) Diphenhydramine Carbonated Liquid products. (*Id.*, ¶ 1).

A. The Product Supply Agreement

In May 2013, Vision and Sterling entered into a Product Supply Agreement (PSA)[2] in which Sterling would develop and manufacture various drugs for Vision as Vision's CMO. (Doc. 38, ¶¶ 9, 11). Under the PSA, Sterling agreed to use commercially reasonable efforts to manufacture each product according to various product specifications. (*Id.*, ¶ 12). In the PSA, Sterling represented and warranted to Vision, among other things, that (a) the products it manufactured would materially meet the agreed-to product specifications; (b) the products it manufactured would be manufactured in compliance with laws regarding good manufacturing practices and FDA regulations; and (c) if the FDA issued Sterling any Form 483 or warning letter, Sterling would, within three business days of receipt, report it to Vision and inform Vision of any follow-up responses to and from the FDA. (*Id.*, ¶ 14). Sterling agreed to indemnify Vision for any damages Vision suffered by reason of any material breach by Sterling of any of its representations, warranties, agreements, or covenants contained in the PSA. (*Id.*, ¶ 15).

The parties intended and understood that the PSA governed all projects that Sterling worked on for Vision. (Doc. 38, ¶ 20). Sterling's first project under the PSA was to manufacture Carisoprodol Tablets. (*Id.*, ¶ 17). Later, Sterling agreed to develop and manufacture OTC Diphenhydramine Carbonated Liquid products for Vision. (*Id.*, ¶ 18). While the Diphenhydramine project was ongoing, Sterling also agreed to develop and manufacture certain Nitroglycerin SL Tablets for Vision. (*Id.*, ¶ 19).

[2] Florida law governs the agreement. (Doc. 38, ¶ 10).

B. The FDA Approval Process

Approval by the Food and Drug Administration (FDA) is necessary to market the Nitroglycerin SL Tablets. (Doc. 38, ¶ 21). To obtain FDA approval to market the Nitroglycerin SL Tablets, Vision must submit an abbreviated new drug application (ANDA) to the FDA and that application must be approved. (*Id.*, ¶ 22). As part of these ANDAs, Vision must submit various documentation and data to the FDA, including, stability data. (*Id.*, ¶ 23). It is standard in the pharmaceutical industry that a CMO that is hired to develop and manufacture a drug will produce stability data and other data to the pharmaceutical company that hired it so the company can submit such documentation to the FDA. (*Id.*, ¶ 24).

Sterling understood that part of its obligations under the PSA included producing stability data and other data in time to meet FDA deadlines. Indeed, the purpose of developing and manufacturing a generic drug such as generic Nitroglycerin SL Tablets is to submit an ANDA, obtain an expedited approval process (which the FDA granted to Vision and which is important in becoming the first to market a generic drug), and become the first to market the generic drugs. Such an opportunity to be the first to market a generic drug is extremely valuable in the pharmaceutical industry and could provide Vision with tens of millions of dollars in profits. (Doc. 38, ¶ 25).

Sterling understood that Vision planned to submit an ANDA for the generic Nitroglycerin SL Tablets to the FDA and that its timely provision of stability data and other data was necessary to obtaining FDA approval. (Doc. 38, ¶ 26). OTC drugs, such as the Diphenhydramine Carbonated Liquid products that Vision utilized Sterling as its CMO to develop and manufacture, do not require FDA approval and would follow an "OTC

Monograph," but they are still subject to various federal regulations enforced by the FDA. (*Id.*, ¶ 27). In this context and as understood in the industry (and as understood by the parties), Sterling's agreement in the PSA to follow "good manufacturing practices" and to manufacture the products "in compliance with applicable law regarding good manufacturing practices and FDA regulations" necessarily was an agreement to provide stability and other data necessary for obtaining FDA approval and to do so timely to allow Vision the opportunity to obtain expedited approval and be the first to market the generic drugs. (*Id.*, ¶ 28).

C. Failure to Provide Stability Documents and Data

In addition to its agreements in the PSA, during the parties' course of dealing after Vision hired Sterling as its CMO, Sterling repeatedly agreed in various communications to provide stability documents and other documents and data necessary for the ANDAs on specific deadlines so Vision could timely submit the information to the FDA. (Doc. 38, ¶ 29). Sterling repeatedly failed to timely provide stability documents, updated formulas, and other data necessary for completing the ANDAs and to determine compliance with specifications as to the OTC drugs. (*Id.*, ¶ 30). Vision repeatedly stressed to Sterling that timeliness was critical for both the Nitroglycerin and Diphenhydramine projects. (*Id.*, ¶¶ 31-32).

Even though Vision made repeated requests for the documents and data, Sterling never provided much of the necessary documentation and the documents that were provided were incomplete, lacked necessary signatures, and contained figures that appeared incorrect. (Doc. 38, ¶¶ 33-34). Throughout the parties' business relationship, Sterling repeatedly represented that it would have documents ready, and failed to meet

deadlines and continued to make excuses. (*Id.*, ¶ 35). Sterling likewise represented to Vision that certain documents or tests were complete when they were not. (*Id.*, ¶¶ 36-38).

D. FDA Deadline Missed, Vision Damaged

Ultimately, due to Sterling's delays and false representations and promises, Vision missed an extended deadline with the FDA for its ANDAs and still has not been able to launch the OTC drugs that do not require FDA approval. (Doc. 38, ¶ 39). The fee to submit a new ANDA has significantly increased to $171,823 - a fact that Vision made Sterling aware of when repeatedly requesting the stability documents and other data, to no avail. (*Id.*, ¶¶ 40, 42). Submitting a new ANDA will entail additional fees and costs beyond those paid to the FDA. (*Id.*, ¶ 41).

As a result of Sterling's failure to provide stability documents and other data, Vision has been unable to develop and manufacture the Nitroglycerin SL Tablets and OTC Diphenhydramine Carbonated Liquid products, has been unable to obtain FDA approval for the Nitroglycerin SL Tablets (or determine approval with FDA regulations as to the OTC drugs), and has been unable to get the drugs to market. (Doc. 38, ¶ 43). As a result of Sterling's failure to timely provide stability documents and other data, Vision has lost the opportunity to be the first to market generic Nitroglycerin SL Tablets as several other generic competitors have obtained FDA approval and entered the market. (*Id.*, ¶ 44).

Vision spent millions of dollars on the generic Nitroglycerin SL Tablets alone, which is now a sunk cost due to Sterling's failure to provide stability documents and other data. Vision seeks recovery of all of its costs and expenses to develop and manufacture the generic Nitroglycerin SL Tablets and OTC Diphenhydramine Carbonated Liquid products.

(Doc. 38, ¶ 45). Because it did not have the promised stability documents and other data, Vision lost out on deals to sell the Nitroglycerin SL Tablets and OTC Diphenhydramine Carbonated Liquid products to other pharmaceutical companies, as such companies needed those documents and data before going forward with any deal. For the generic Nitroglycerin SL Tablets alone, negotiations with various pharmaceutical companies demonstrated that Vision stood to make millions of dollars had the deals gone through. Vision seeks recovery of its lost profits as a result of not being able to sell the Nitroglycerin SL Tablets and OTC Diphenhydramine Carbonated Liquid products. (*Id.*, ¶ 46).

Alternatively, had the ANDA been approved, Vision would have been the first to market generic Nitroglycerin SL Tablets pursuant to any ANDA and could have sold them itself (rather than sell those rights to another company to market the drugs). The opportunity to be the first to market the generic drugs after an expedited approval would have been extremely lucrative and made Vision tens of millions of dollars. But Vision lost this opportunity due to Sterling's failures. (Doc. 38, ¶ 47). Vision also values the stability documents and other data themselves at an amount much greater than $75,000 and seeks the documents and data themselves in this lawsuit as Vision cannot file a new ANDA (at the increased fee) unless and until Sterling provides the stability documents and data. (*Id.*, ¶¶ 48-49).

DISCUSSION

A. Subject-Matter Jurisdiction

Defendant's first basis for dismissal is that the Court lacks subject-matter jurisdiction because Plaintiff has failed to address the deficiencies identified by the Court

regarding the requisite amount in controversy as Plaintiff only pleads speculative and indeterminate damages.

Federal courts are courts of limited jurisdiction and are obligated to inquire about jurisdiction *sua sponte* whenever it may be lacking. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *Univ. of S. Ala. v. American Tobacco Co.*, 168 F.3d 405, 410 (11th Cir. 1999). "Without jurisdiction the court cannot proceed at all in any cause." *Univ. of S. Ala.*, 168 F.3d at 410. A district court has proper jurisdiction over a matter if diversity jurisdiction exists. *See* 28 U.S.C. § 1332. Diversity jurisdiction within the federal system requires complete diversity of citizenship and that the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs. *See* 28 U.S.C. § 1332(a): *Morrison*, 228 F.3d at 1261. In an action directly filed in federal court, a plaintiff bears the burden of adequately pleading, and ultimately proving jurisdiction. *See King v. Cessna Aircraft Co.*, 505 F.3d 1160, 1170 (11th Cir. 2007).

"When a claim is made for indeterminate damages . . . the party seeking to invoke federal jurisdiction bears the burden of proving by a preponderance of the evidence that the claim on which it is basing jurisdiction meets the jurisdictional minimum." *King v. Epstein*, 167 F. App'x. 121, 123 (11th Cir. 2006). "A conclusory allegation that the jurisdictional amount is satisfied, without setting forth the underlying facts supporting such an assertion, is insufficient to meet the plaintiff's burden." *Bradley v. Kelly Services*, 224 F. App'x. 893, 895 (11th Cir. 2007). *See also Federated Mut. Ins. Co. v. McKinnon Motors, LLC*, 329 F.3d 805, 809 (11th Cir. 2003) (noting that a party's mere speculation that the amount in controversy met the jurisdictional threshold did not satisfy its burden

of proving beyond a preponderance of the evidence the claim at issue exceeded $75,000).

The Court finds that Plaintiff has plausibly alleged that the amount in controversy exceeds $75,000 as the Second Amended Complaint does more than just allege conclusory allegations. Plaintiff alleges that Sterling's failure to provide stability documents and other data prevented Vision from being able to get any of the drugs to market, and most critically prevented Vision from being the first to market generic Nitroglycerin SL Tablets. As a result, Vision has lost out on millions of dollars in lost profits. Vision also was unable to conclude deals it was involved in negotiating with other pharmaceutical companies, and such negotiations demonstrated that Vision stood to make millions of dollars in profits if it had the necessary data for the deals to go through. Vision's millions of dollars in costs and expenses in pursuing the Diphenhydramine Carbonated Liquid and Nitroglycerin SL Tablets projects are also now sunk because it cannot get the drugs to market without such data (and in the case of the Nitroglycerin SL Tablets it cannot even submit a new ANDA until it has such data). Moreover, the stability documents and other data are Vision's property under the PSA, and Sterling's refusal to provide such property is in itself damage because Vision highly values that property in excess of $75,000. Finally, the fee to submit a new ADNA is $171,823, well beyond the requisite amount in controversy.

B. Failure to State a Claim

To survive a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss, a complaint must contain sufficient factual allegations that raise a right to relief above the speculative level. *Bell A. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In reviewing a

motion to dismiss, courts must accept all factual allegations as true and then determine whether the factual allegations plausibly give rise to a claim entitled to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While detailed factual allegations are not required, a complaint needs more than "unadorned, the-defendant-unlawfully-harmed-me accusation[s]." *Id*. And courts are under no obligation to accept legal conclusions as true. *Id*.

A complaint is also subject to dismissal under Rule 12(b)(6) if its allegations on their face show that an affirmative defense bars recovery on the claim. *See Cottone v. Jenne*, 326 F.3d 1352, 1357 (11th Cir. 2003). While a court is generally limited to reviewing the face of the complaint to determine the sufficiency of a plaintiff's claims, a court may consider documents attached to a motion to dismiss if the attached documents are (1) central to plaintiff's claims and (2) the authenticity of the documents are not challenged. *Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002). Defendant moves to dismiss all counts for failure to state a claim. The Court will address each in turn.

1. Breach of Contract (Count I)

Sterling submits that the Second Amended Complaint fails to allege essential facts regarding the subject transactions that are the basis of its breach of contract claim. Sterling argues that Plaintiff alleges that multiple agreements were breached, but there are too many conclusory statements to determine what those specific agreements were. Plaintiff responds that the breach of contract count is based on several breaches of specific terms of the PSA as well as breaches of each subsequent agreement created by Sterling's promises to meet certain deadlines.

In Florida, the elements for breach of contract are "(1) the existence of a contract; (2) a material breach of that contract; and (3) damages resulting from the breach." *Cordell Funding, LLLP v. Jenkins*, 722 F. App'x 890, 894-95 (11th Cir. 2018) (quoting *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1272 (11th Cir. 2009)). Here, the Second Amended Complaint alleges the existence of a contract between the parties (the PSA), breach of the PSA in Sterling's failure to provide stability data and other data necessary to file the ANDAs and develop and manufacture the OTCs (among other breaches), and damages. These allegations provide a plausible basis for relief. *See DiDomenico v. New York Life Ins. Co.*, 837 F. Supp. 1203, 1205 (M.D. Fla. 1993). Vision has adequately pled a claim for breach of contract.

2. Breach of Implied Covenant of Good Faith and Fair Dealing (Count II)

Vision alleges that Sterling's conduct breached Florida's implied covenant of good faith and fair dealing. All contracts in Florida carry an implied covenant of good faith and fair dealing. *Viridis Corp. v. TCA Global Credit Master Fund, LP*, 721 F. App'x 865, 877-78 (11th Cir. 2018). The covenant "is an interpreting, gap-filling tool of contract law." *Shibata v. Lim*, 133 F. Supp. 2d 1311, 1318 (M.D. Fla. 2000). It is "aimed at protecting the reasonable or justifiable expectations of the contracting parties in light of their express agreement." *Id.*

Establishing an actionable claim for breach of the covenant requires careful pleading. On one hand, a plaintiff must plead a breach of an express term of the contract. *Viridis Corp.*, 721 F. App'x at 878. On the other hand, courts dismiss a breach of the implied covenant if it duplicates a breach-of-contract claim. *Shibata*, 133 F. Supp. 2d at

1319. Here, Vision pleads a breach of an express term of the PSA and does distinguish Count II from Count I's breach of contract claim. Vision pleads the following:

> To the extent the PSA is found to not expressly require (including when considering industry standards and course of dealing) Sterling to timely provide necessary data and documentation to allow Vision to meet FDA deadlines, the duty of good faith and fair dealing required Sterling to timely provide necessary data and documentation to allow Vision to meet FDA deadlines as part of Sterling's performance of its express obligation to develop and manufacture products in compliance with good manufacturing practices and FDA regulations.

(Doc. 38, ¶ 69). The covenant of good faith and fair dealing is a gap-filling rule, and Vision has plausibly alleged that there is a gap to fill here. That is, if the provisions of the PSA are found insufficient to impose an obligation on Sterling to timely provide documents and data necessary for FDA approval or compliance such that the products could be marketed, Vision can rely on the implied covenant of good faith to show that this provision contained such a requirement. Therefore, the request to dismiss Count II is denied.

3. Breach of Warranty (Count III)

Sterling next argues that Count III, alleging breach of express warranty, must be dismissed because Plaintiff has failed to allege any essential terms to which the parties agreed either under the PSA or any other agreement for any work that falls under the PSA. Rather, Plaintiff relies on allegations that the parties "understood" various terms and responsibilities rather than any specifically agreed details related to particular projects. The Court disagrees.

To succeed on a breach of express warranty claim under Florida law, Plaintiffs must show: "(1) a covered defect existed in the product at the time of sale; (2) notice of the defect was given within a reasonable time after the defect was discovered; and (3) Defendant was unable to repair the defect." *Burns v. Winnebago Indus.*, No. 8:11–cv–

354-T-24TBM, 2012 WL 171088 (M.D. Fla. Jan. 20, 2012) (citing *Bailey v. Monaco Coach Corp.*, 350 F. Supp .2d 1036, 1043 (N.D. Ga. 2004)).

Here, the breach of express warranty claim alleges that the PSA includes an express warranty whereby Sterling warrants that the drugs it manufactures would meet certain agreed-to product specifications which Sterling breached. Specifically, Plaintiff alleges that:

> The PSA contains express warranties by Sterling to Vision that (a) the products it develops and manufactured would materially meet the agreed-to product specifications; (b) the products it developed and manufactured would be developed and manufactured in compliance with applicable laws regarding good manufacturing practices and FDA regulations; and (c) it would report, within three business days of its receipt, to Vision the receipt of any Form 483 or warning letter issued to Sterling by the FDA, as well as any follow-up responses to and from the FDA.

(Doc. 38, ¶ 73). Regarding the creation of express warranties, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." Fla. Stat. § 672.313(1)(a). The law of Florida is that to recover for the breach of a warranty, either express or implied, the plaintiff must be in privity of contract with the defendant. *Hill v. Hoover Co.*, 899 F. Supp. 2d 1259, 1266 (N.D. Fla. 2012).

The Court finds that Count III is plausibly alleged. The parties are in privity of contract and Sterling expressly warranted that the drugs it manufactured would conform to certain requirements as agreed to by the parties in the PSA.

4. Promissory Estoppel (Count IV)

In Count IV, Plaintiff pleads an alternative claim for promissory estoppel, alleging: "To the extent such promises are found to not be contracts, or the PSA is found not to

govern the parties' relationship as to the Diphenhydramine and Nitroglycerin projects, they are enforceable pursuant to the doctrine of promissory estoppel." (Doc. 38, ¶ 80). Sterling argues that Plaintiff fails to sufficiently allege a claim for promissory estoppel because Plaintiff only makes conclusory allegations and the claim is vague.

> Under Florida law, the basic elements of promissory estoppel are:
>
> > A promise which the promisor should reasonably expect to induce action or forbearance on the part of the promisee or a third person and which does induce such action or forbearance is binding if injustice can be avoided only by enforcement of the promise. The remedy granted for breach may be limited as justice requires.

Advanced Mktg. Sys. Corp. v. ZK Yacht Sales, 830 So. 2d 924, 927 (Fla. 4th DCA 2002); *see also Doe v. Univision Television Group, Inc.*, 717 So .2d 63, 65 (Fla. 3d DCA 1998) ("The doctrine of promissory estoppel comes into play where the requisites of contract are not met, yet the promise should be enforced to avoid injustice.").

The Court finds that Count IV has been adequately pled. Plaintiff alleges that Sterling repeatedly promised in multiple communications to Vision that it would provide stability data and other documentation and data necessary to complete the ANDAs and OTC drugs by specified deadlines so as to ensure that Vision would be able to comply with its deadlines to provide such information to the FDA and so Vision would be able to timely get the OTC drugs to market. (Doc. 38, ¶ 79). Sterling made such promises with the intent to induce Vision to keep Sterling as its CMO and to not find a substitute CMO or otherwise cancel its projects with Sterling, or Sterling reasonably should have expected that its promises would induce such action or forbearance. (*Id.*, ¶ 81). Vision detrimentally relied on Sterling's promises by retaining Sterling as its CMO and not cancelling its projects with Sterling. (*Id.*, ¶ 82). Plaintiff also alleges promissory estoppel

as alternative equitable relief if such promises are found to not be enforceable under the PSA. (*Id.*, ¶ 80). Based on these allegations, the Court finds that Plaintiff has plausibly alleged an alternative claim for promissory estoppel.

Accordingly, it is now

ORDERED:

Defendant's Motion to Dismiss Second Amended Complaint (Doc. 39) is **DENIED**.

DONE and **ORDERED** in Fort Myers, Florida this 9th day of April, 2019.



SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE

Copies: All Parties of Record