IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEL DRUG SOLUTIONS, LLC and EYE CARE NORTHWEST, PA,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-539 (MN)
IMPRIMIS PHARMACEUTICALS, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

Pilar G. Kraman, Esquire: YOUNG CONAWAY, STARGATT & TAYLOR, LLP, Wilmington, DE; Charles X. Gormally, Esquire, Paul M. Bishop, Esquire: BRACH EICHLER LLC, Roseland, NJ – attorneys for Plaintiffs Novel Drug Solutions, LLC and Eye Care Northwest, PA

Michael P. Kelly, Esquire, Daniel M. Silver, Esquire, Dawn Kurtz Crompton, Esquire: MCCARTER & ENGLISH, LLP, Wilmington, DE – attorneys for Defendant Imprimis Pharmaceuticals, Inc.

September 26, 2018

NOREIKA, U.S. DISTRICT JUDGE:

I. INTRODUCTION

On April 11, 2018, Novel Drug Solutions, LLC and Eye Care Northwest (jointly "Plaintiffs") commenced this action alleging that, pursuant to the Asset Purchase Agreement ("APA") entered by the parties, Imprimis Pharmaceuticals, Inc. ("Defendant" or "Imprimis") owes Plaintiffs royalty payments for, and financial information pertaining to, an injectable compounded pharmaceutical formulation called DropLess, as well as topical formulation called LessDrops." (D.I. 1; D.I. 23 at 1). On June 29, 2018, Imprimis, moved to dismiss Counts One and Three of the Complaint. (D.I. 9). Count One sought declaratory judgment that Imprimis owes royalties on the sales of LessDrops under the APA and Count Three alleged breach of the APA for failure to pay required royalties. (*Id.*).

On July 11, 2018, Plaintiffs filed their First Amended Complaint (D.I. 12) (the "Amended Complaint") adding "Factual Allegations" in support of the claims as well as Count Six for fraudulent inducement. The parties agreed that the filing of the Amended Complaint mooted the original motion to dismiss. (D.I. 15).

Before the Court is Defendant's motion to dismiss Counts One and Three of the Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (D.I. 17).

II. BACKGROUND

Imprimis entered the APA, dated August 8, 2013, with Plaintiffs. (D.I. 12 at ¶ 13; D.I. 18 at 3). Plaintiffs allege that Imprimis drafted the APA. (D.I. 12 at ¶ 13). By its terms, the APA is

governed by Delaware law. (D.I. 18, Ex. A at § 9.5).[1] Pursuant to the APA, Imprimis acquired certain assets, including technology and intellectual property, pertaining to a poloxamer technology. (D.I. 12 at ¶ 13). The acquired assets ("Assets") included, *inter alia*, the injectable DropLess formulation, as well as "all formulae, data, information, results of experimentation and testing, and other know-how," as well as "all intellectual property rights" relating thereto. (D.I. 18, Ex. A at § 1.2; D.I. 18 at 3). The APA also requires that Imprimis pay a royalty on any "Product". (D.I. 12 at ¶ 14, 15; D.I. 18, Ex. A at § 5.1). "Product" is defined as:

> any product, in any form or formulation, ***of an injectable ophthalmological pharmaceutical composition***, ***the composition comprising*** at least one therapeutically effective quantity of ***an anti-bacterial agent***, at least one therapeutically effective quantity of ***an anti-inflammatory agent***, at least one ***pharmaceutically acceptable excipient and*** at least one ***pharmaceutically acceptable carrier appropriate for intraocular or intravitreal injection***, in each case for use in the prevention or treatment of any ophthalmic disease . . . .

(D.I. 12 at ¶ 15; D.I. 18, Ex. A at § 1.16) (emphasis added). No definition or description of "an injectable ophthalmological pharmaceutical composition" is provided in the APA other than the language specifying that such a composition must comprise at least the above-referenced agents, excipient and carrier.

After execution of the APA, Imprimis began commercializing the DropLess formulation, which all parties agree is an injectable compounded eye medication. (D.I. 18 at 4; D.I. 12 at ¶ 18). Imprimis also produced a product line called "LessDrops," a "topical eye drop" (D.I. 12 at ¶ 19)

---

[1] Plaintiffs did not attach a copy of the APA to the Complaint or First Amended Complaint. Defendant submitted the APA in connection with its motion to dismiss. (D.I. 18, Exh. A). As noted by Defendant, it is appropriate for this Court to consider the APA, itself, as it is referenced throughout the Amended Complaint and incorporated therein by reference. (D.I. 18, n.1) (citing *Fletcher-Harlee v. Pote Concrete Contractors*, 482 F. 3d 247, 249, 251 (3d Cir. 2007) (citing Restatement (Second) of Contracts § 203(b)) (on a motion to dismiss it is appropriate to consider documents referenced in the complaint and to "interpret documents in accord with their plain language")).

which is "sold for non-injectable, topical use." (D.I. 12 at ¶ 24). Plaintiffs allege that "[b]oth DropLess and LessDrops are derived from Plaintiffs' invention" (D.I. 12 at ¶ 23), and that Plaintiffs have not received royalty payments for LessDrops "despite the fact that the LessDrops products are identical formulations to the DropLess products." (D.I. 12 at ¶ 25).

Plaintiffs also allege that LessDrops, while sold for topical use, "has been injected by doctors into patients" and "found to be curative and successful in improving medial difficulty." (D.I. 12 at ¶ 24). Plaintiffs further add that "[u]pon information and belief, numerous surgeons have inadvertently injected LessDrops into eye tissue without consequence and have been assured by Imprimis that the formulations are identical to DropLess." (*Id.*).[2] Thus, according to Plaintiffs, LessDrops is "appropriate for intraocular or intravitreal injection" and falls within the definition of Product in the APA.

III. LEGAL STANDARDS

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)). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1420

---

[2] Defendant disputes these allegations, but, in evaluating Defendant's motion to dismiss, the court must accept all well-pleaded factual allegations as true and view them in the light most favorable to the Plaintiffs. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997); *Apotex, Inc. v. Senju Pharm. Co.*, No. 12-196 (SLR), 2015 WL 1968493, at *1 (D. Del. May 1, 2015).

(internal quotations omitted). Thus, the court may grant a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to plaintiff, [the] plaintiff is not entitled to relief." *Id.*

In order to survive a motion to dismiss, however, "a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." "The complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotations omitted). The court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotations omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

IV. DISCUSSION

The issue underlying Defendant's motion to dismiss both Count One and Count Three is whether LessDrops is an "injectable ophthalmological pharmaceutical composition" pursuant to the APA.[3] In addressing issues of contract interpretation, the court must "give effect to the plain-

---

[3] Under Delaware law, "to survive a motion to dismiss for failure to state a breach of contract claim, [a] plaintiff must demonstrate: first, the existence of the contract, whether express or implied; second, the breach of an obligation imposed by that contract; and third, the resultant damage to the plaintiff." *VLIW Tech., LLC v. Hewlett–Packard Co.*, 840 A.2d 606, 612 (Del. 2003) (citations omitted). Here, there is no dispute, for purposes of the

meaning of [a] contract's terms and provisions." *LCY Chemical Corp. v. Kraton Performance Polymers, Inc.*, No. 14-1279 (GMS), 2015 WL 4486783, at *2 (D. Del. July 23, 2015) (quoting *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159-60) (Del. 2010). If contractual language "is plain and clear on its face, i.e., it[] . . . conveys an unmistakable meaning, the writing itself is the sole source for gaining an understanding of intent." *See Choupak v. Rivkin*, No. 7000 VCL, 2015 WL 1589610, at *18 (Del. Ch. Apr. 6, 2015) (quoting *City Investing Co. Liquid. Tr. v. Cont'l Cas. Co.*, 624 A.2d 1191, 1198 (Del. 1993)). If, however, the terms are ambiguous, extrinsic evidence may be considered to determine the parties' intentions. *See AT&T Corp. v. Lillis*, 953 A.2d 241, 253 (Del. 2008).

Ambiguity exists "when the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings." *Markow v. Synageva Biopharma Corp.*, No. N15C–06–152 WCC, 2016 WL 1613419, at *5 (Del. Super. Ct. Mar. 3, 2016) (unpublished) (internal quotations omitted). "At the motion to dismiss stage, the Court "cannot choose between two differing reasonable interpretations of ambiguous provisions." *Id. (quoting VLIW Technology,* 840 A.2d at 615). "Dismissal is proper only if the defendant['s] interpretation is the only reasonable construction as a matter of law." *Id. (quoting Vanderbilt Income & Growth Assocs., L.L.C. v. Arvida/JMB Managers, Inc.*, 691 A.2d 609, 613 (Del. 1996)). "When parties present differing – but reasonable – interpretations of a contract term, the Court turns to extrinsic evidence to understand the parties' agreement. Such an inquiry cannot proceed

---

present motion, as to the sufficiency of Plaintiffs' allegations with respect to the elements of an existing contract and, if proven, the damages that would flow from the breach. The dispute concerns the second requirement – breach of an obligation imposed by the contract – and whether the LessDrops product is a royalty bearing product.

on a motion to dismiss." *Id.* (quoting *Remo Grp., Inc. v. MacAndrews AMG Hldgs., LLC*, No. 7668 VCN, 2015 WL 394011, at *5 (Del. Ch. Jan. 29, 2015)).

Here, the parties offer competing interpretations of the meaning of the APA language defining a "Product" subject to a royalty payment. Defendant argues that the language imposes separate requirements on the "Product" that "(1) it must be 'of an injectable ophthalmological pharmaceutical composition;' and (2) it must be comprised of at least one pharmaceutically acceptable carrier appropriate for intraocular or intravitreal injection." (D.I. 18 at 6 (emphasis in original)).[4] It thus argues that its LessDrops product is a "topical formulation" that is not sold for injection and cannot be covered by the APA.

Plaintiffs, on the other hand, assert that LessDrops, while sold as a topical formulation, is an injectable ophthalmological pharmaceutical composition under the APA because it has been injected into patients and meets the "comprising" language that the product must be "appropriate for intraocular or intravitreal injection." (D.I. 23 at 2). They argue that taking their allegations as true, as the court must, they have asserted a claim that LessDrops is a royalty bearing Product because it is alleged, *inter alia*, to be an "identical formulation[] to the DropLess products" (D.I. 12 at ¶ 25) and it "has been injected by doctors into patients" and "found to be curative and successful in improving medial difficulty." (D.I. 12 at ¶ 24). It is, thus, according to Plaintiffs, "appropriate for intraocular or intravitreal injection" and a covered "Product." (*Id.*).

Ultimately, at this stage, the court cannot conclude that Plaintiffs are unreasonable in interpreting "Product" to include formulations "appropriate for intraocular or intravitreal

---

[4] In its Reply brief (D.I. 26 at 2 (emphasis in original)), Defendant refers to the "two criteria" as: "(l) the product must be an **injectable ophthalmological pharmaceutical composition**; and (2) such injectable ophthalmological pharmaceutical composition must meet the limitations of one or more claims of the Assigned Patent Rights."

injection" that contain the requisite ingredients and that have been alleged to have been injected. And the court cannot conclude that Defendant's interpretation is the only reasonable construction of the APA. Confronted with conflicting yet reasonable constructions, the court denies Defendant's motion to dismiss Counts One and Three of the Amended Complaint pursuant to Rule 12(b)(6).

V. CONCLUSION

For the foregoing reasons, the court denies Defendant's motion to dismiss Counts One and Three of the Amended Complaint. An appropriate order will follow.