#### Doc. 197

#### **NOT FOR PUBLICATION**

# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

VISION PHARMA, LLC,

Civil Action No. 13-04692

Plaintiff,

**OPINION** 

v.

SUNRISE PHARMACEUTICAL, INC.,

Defendant.

# **CECCHI**, District Judge.

This matter comes before the Court on the motion for summary judgment of Sunrise Pharmaceutical, Inc. ("Sunrise" or "Defendant"), seeking judgment in favor of Defendant on all counts of the Complaint (ECF No. 1) ("Compl.") filed by Vision Pharma, LLC ("Vision" or "Plaintiff"). ECF No. 139. The Court has considered the submissions made in support of and in opposition to the instant motion, *see* ECF Nos. 140 ("Def. Br."), 157 ("Pl. Br."), 170 ("Def. Reply"), the declarations and exhibits supporting those submissions, *see* ECF Nos. 142, 152, 159, 166, and heard oral argument, *see* ECF No. 187 ("Oral Arg. Tr."). For the reasons set forth below, Defendant's Motion is GRANTED in part and DENIED in part.

## I. BACKGROUND¹

This dispute arises from a contractual relationship between two pharmaceutical companies that called for the manufacture and sale of unapproved new prescription drug products that

<sup>&</sup>lt;sup>1</sup> Plaintiff's Response to Defendant's Local Rule 56.1 statement ("Pl. SMF Resp."), and Plaintiff's own Counter Local Rule 56.1 statement ("Pl. SMF"), are contained in the same document (ECF No. 158). As such, the Court will use the abbreviations stated above to differentiate them.

contained hyoscyamine and colchicine (the "Drug Products").<sup>2</sup>

The relationship at issue here began in 2006 and, though its exact nature is disputed, was based generally on various written instruments including certain term sheets (styled by the parties as the "Supply Agreements"), purchase orders, packing slips, as well as the parties' course of dealing and industry custom. Id. ¶¶ 6, 10-12, 15, 17, 25. It is undisputed that at the time the parties began to engage with one another, both parties were aware that the Drug Products had not yet been approved by the FDA. Id. ¶¶ 6-9; Oral Arg. Tr. at 48:2-5. One of the Supply Agreements for another substance, Methylene Blue, which the parties ultimately never developed or manufactured, included a notice provision ("Notice Term"), providing that Defendant was obligated to notify Plaintiff within five days if the FDA sent Defendant any Form 483s (forms used by the FDA to document concerns after an inspection, hereinafter "483s"), warning letters, or any of Defendant's responses thereto. ECF No. 158 ¶ 29 ("Pl. SMF Resp."). Whether the Notice Term was incorporated into each Supply Agreement or the overall contractual relationship for the other Drug Products is disputed. Pl. SMF Resp. ¶ 29; Def. SMF ¶ 29. Plaintiff also maintains that the two parties entered into a separate "verbal agreement" regarding the Notice Term, which Defendant strongly contests. Id. ¶¶ 31-46; Pl. SMF Resp. ¶¶ 31-46.

On January 14, 2010, Defendant received a warning letter from the FDA. Def. SMF ¶ 70; ECF No. 142-43, Ex. RR (the "Sunrise Warning Letter"). In the letter, the FDA stated the following: that the FDA's inspection of Defendant's facility "identified significant violations of the Current Good Manufacturing Practice regulations" ("CGMPs") in manufacturing the Drug

 $<sup>^2</sup>$  The specific drugs produced by Defendant and purchased by Plaintiff are: (1) Colchicine .6mg Tablets; (2) Hyoscyamine Sulfate Tablets .125mg; (3) Hyoscyamine Sulfate Orally Disintegrating Tablets .125mg; and (4) Hyoscyamine Sulfate Sublingual Tablets .125mg. Def. SMF ¶ 7. As explained further below, the parties also reached terms for the manufacture and sale of a fifth drug, Methylene Blue.

Products; that these violations caused the Drug Products to be deemed "adulterated" pursuant to 21 U.S.C. § 351(a)(2)(B); and that the Drug Products were "unapproved new drugs," and as such, they were in violation of the Federal Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. Def. SMF ¶ 72; Sunrise Warning Ltr. at 1. Defendant subsequently notified Plaintiff of the Sunrise Warning Letter on February 2, 2010. Id. ¶ 71. On April 29, 2010, Plaintiff also received its own warning letter from the FDA. Id. ¶ 75; ECF No. 142-45, Ex. TT ("Vision Warning Letter"). The Vision Warning Letter expressly referenced the Sunrise Warning Letter; it went on to state that because the Drug Products were new and lacked approval, they could not be introduced into interstate commerce. Vision Warning Ltr. at 1. It also stated that the Drug Products were adulterated another reason why they were prohibited from being sold. Id. The parties dispute whether the FDA's use of "adulterated" in the warning letter referred only to manufacturing processes or also suggested that the Drug Products themselves were not of proper quality. See Pl. Br. at 23-25, Def. Br. at 27-29. Although the details are contested, after receiving the Vision Warning Letter, it appears Plaintiff attempted to negotiate with the FDA to find a way to sell its inventory. Def. SMF ¶¶ 79-80. The FDA ultimately rejected this attempt on June 2, 2010. See ECF No. 142-47, Ex. VV. On June 23, 2010, Plaintiff emailed Defendant a letter demanding a refund for its inventory of adulterated Drug Products, which Defendant purportedly refused. Pl. SMF ¶ 126.

It was later revealed that in addition to the Sunrise Warning Letter, Defendant also received multiple 483s at the conclusion of four separate inspections of Defendant's facility by the FDA occurring in September 2006, January-February 2007, July-August 2007, and June-July 2009 (Defendant received a 483 after each inspection). Pl. SMF ¶ 96. Each 483 identifies multiple CGMP violations observed by the FDA during its inspections. Id. ¶ 97. There is no evidence that Defendant notified Plaintiff of the 483s. Id. ¶¶ 104-05. However, Defendant contends that the 483s were referenced in the Sunrise Warning Letter, so Plaintiff was constructively aware of them as of

February 2, 2010—the date Defendant notified Plaintiff of its warning letter. ECF No. 175 ¶¶ 104-05 ("Def. Reply SMF"). Defendant maintains that after it notified Plaintiff of the Sunrise Warning Letter, Plaintiff still tried to order more Drug Products knowing that the products were adulterated and unapproved. Def. SMF ¶ 89. Plaintiff acknowledges that it did do so, but only if Defendant "correctly manufactured [the Drug Products] according to CGMPs." Pl. SMF Resp. ¶ 89. Nevertheless, Defendant refused to manufacture and sell additional Drug Products to Plaintiff, thereby ending their contractual relationship. Def. SMF ¶ 90.

## II. PROCEDURAL HISTORY

This action was filed on August 5, 2013. See Compl. Plaintiff asserts the following causes of action: violation of the New Jersey Consumer Fraud Act ("NJCFA") (Count I), breach of contract (Count II), breach of the implied warranty of merchantability (Count III), breach of the implied warranty of fitness for a particular purpose (Count IV), breach of the implied covenant of good faith and fair dealing (Count V), unjust enrichment (Count VI), negligence (Count VII), deceptive trade practices (Count VIII), and fraud and deceit (Count IX). See Compl. ¶¶ 51-120. Although the relationship between the parties ended in 2010 at the latest, with no additional purchase orders after that point, Plaintiff seeks relief primarily in the form of lost profits it claims it could have captured from 2010 to 2017 had the parties continued working together to sell these Drug Products "but-for" Defendant's alleged wrongful acts. ECF No. 142-32, Ex. GG, Pl. Damages Exp. Rep. at 14-15; Def. SMF ¶ 23-24. On February 26, 2016, Defendant moved to dismiss Plaintiff's claims. See ECF No. 72. By Opinion and Order dated June 20, 2018, the Court granted Defendant's motion to dismiss as to the NJCFA claim (Count I) only. See ECF No. 117. Defendant moved for summary judgment as to all remaining claims on June 1, 2020. See ECF No. 139. Thereafter, this Court referred this matter to mediation, but mediation efforts were unsuccessful. The Motion is now before this Court. See ECF Nos. 178, 180.

## III. <u>LEGAL STANDARD</u>

Summary judgment is appropriate if the "depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials" demonstrate that there is no genuine issue as to any material fact, and, construing all facts and inferences in a light most favorable to the non-moving party, "the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986); *see also Pollock v. Am. Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986); Fed. R. Civ. P. 56(c).

The moving party has the initial burden of proving the absence of a genuine issue of material fact. *See Celotex*, 477 U.S. at 323. Once the moving party meets this burden, the non-moving party has the burden of identifying specific facts to show that, to the contrary, a genuine issue of material fact exists for trial. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). To meet its burden, the nonmoving party must "go beyond the pleadings and by [its] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex*, 477 U.S. at 324; *see also Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990) (stating that "[t]he object of [Rule 56(e)] is not to replace conclusory allegations of the complaint . . . with conclusory allegations of an affidavit"); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986); *Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992) ("To raise a genuine issue of material fact . . . [the opponent must] exceed[] the 'mere scintilla' threshold.").

An issue is "genuine" if it is supported by evidence such that a reasonable jury could return a verdict in the nonmoving party's favor. *Anderson*, 477 U.S. at 248. A fact is "material" if, under the governing substantive law, a dispute about the fact might affect the outcome of the suit. *Id.* In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's

evidence "is to be believed and all justifiable inferences are to be drawn in his favor." *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255).

#### IV. DISCUSSION

## A. Breach of Contract (Count II)

While the parties appear to agree that their "conduct establishes a contractual relationship that incorporates various agreements to manufacture various drugs products," there is a fundamental disagreement about the nature and scope of their contractual relationship. Pl. Br. at 11; Def. Reply at 12. Defendant argues that the parties entered into multiple discrete contracts for the purchase and delivery of the Drug Products, each consisting of a term sheet governing multiple purchases (the "Supply Agreements"), and then a specific purchase order and packing slip included with the Drug Products upon shipment.<sup>3</sup> Def. Br. at 14-16. Although the Supply Agreements supplied some essential terms, because they did not provide a specific quantity for the sale, each purported contract was only finalized once an individual purchase order was placed and Plaintiff subsequently accepted delivery of the shipment. Id. at 13 (explaining the Supply Agreements as "akin to product catalogs"). In Defendant's view, the parties' arrangement consisted entirely of the sale of the manufactured Drug Products from Defendant to Plaintiff. See generally id. at 12-20. Defendant contends that it is undisputed these contracts were valid, and Defendant performed its obligations under the contract. See id. at 22-26. Thus, Defendant argues it is entitled to summary judgment.

By contrast, Plaintiff argues that the parties entered into a complex business relationship, and as such, the operative contract spanned beyond any one supply agreement (i.e. term

<sup>&</sup>lt;sup>3</sup> Defendant also appears to recognize the additional possibility that "a contract may have been formed" at the moment Sunrise "signed and returned the Purchase Order to Vision" rather than upon shipment. Def. Br. at 15.

sheet/purchase order/packing slip combination). *See, e.g,* Oral Arg. Tr. at 34. Indeed, Plaintiff argues that the relationship included terms related to the development and manufacture of the Drug Products. Further, Plaintiff argues that Defendant breached this contractual relationship by failing to provide Vision notice of FDA oversight, and by selling Vision adulterated Drug Products.

Under New Jersey law, a breach of contract claim requires the plaintiff to show that "the parties entered into a valid contract, that the defendant failed to perform [its] obligations under the contract and that the plaintiff sustained damages as a result." Murphy v. Implicito, 392 N.J. Super. 245, 265 (App. Div. 2007). "Parties to a contract must 'agree on essential terms and manifest an intention to be bound by those terms." Shogen v. Glob. Aggressive Growth Fund, Ltd., No. 04-5695, 2007 WL 2264978, at \*3 (D.N.J. Aug. 3, 2007) (quoting Weichert Co. Realtors v. Ryan, 128 N.J. 427, 435 (1992)). While a contract "must be sufficiently definite so that the performance to be rendered by each party can be ascertained with reasonable certainty," Baer v. Chase, 392 F.3d 609, 618-19 (3d Cir. 2004) (citations and internal quotations omitted), properly formed express or implied-in-fact contracts may have missing essential terms. However, "[w]hether the parties acted in a manner sufficient to create implied contractual terms is a question of fact generally precluding summary judgment." Troy v. Rutgers, 774 A.2d 476, 483 (N.J. 2001) Moreover, "[w]hether a party's conduct constitutes a breach of contract and, if it does, whether the breach is material are ordinarily jury questions." Mango v. Pierce-Coombs, 851 A.2d 62, 73 (N.J. Super. App. Div. 2004).

The Court finds that multiple genuine issues of material fact exist regarding the formation, scope and terms of the contract, as well as whether Defendant ultimately breached. Beginning with formation of the contract, the parties' agreement that a contract existed in some form does not establish the formation of a contract under New Jersey law if there was not a "meeting of the minds" on its terms. For example, the term sheet for Hyoscyamine Sulfate Tablets 0.125mg

appears to include an agreement for Sunrise to *develop* the pills for \$11,950, separate and apart from any purchase order. *See* ECF No. 142-6 ("Development costs, plus tooling: \$11,950 (Vision will own tooling)"). Defendant rejects that this term sheet alone is a contract (because it lacks a quantity term for the number of cases of drugs) but does not fully address the possibility that the term sheet instead represents a contract for development. While neither party explains the contours of this potential development agreement, this provision at the very least belies Defendant's argument that the supply agreements were discrete arrangements for specific drug orders and nothing more, thus raising a dispute of fact. Moreover, if this indeed constitutes a development agreement—and not a contract to purchase the drugs—there would be an additional question of fact as to whether this is a common-law services contract, or a Uniform Commercial Code ("UCC") contract for goods. *See Conopco, Inc. v. McCreadie*, 826 F. Supp. 855, 867-68 (D.N.J. 1993), *aff'd* 40 F.3d 1239 (3d Cir. 1994) (noting that determining whether the UCC governs contracts covering both goods and services is a question of fact).

Further, the parties dispute whether the contract required Defendant to notify Plaintiff of any investigations, adverse inspections, or actions undertaken by the FDA. Defendant argues that the term sheets for the Drug Products include no such term, and thus, there is no dispute on this issue. Plaintiff counters that because the contract should be viewed as all the term sheets taken together, the notice provision found in the term sheet for the drug "Methylene Blue" applies to the totality of the parties' relationship, even though Methylene Blue itself was never shipped. Further, there is testimony from Vision's Chief Executive Officer Sander Busman and Sunrise employee Hasmukh Patel that suggests the parties understood the overall arrangement to include a notice provision. *See* ECF No. 159-2 ("Busman Dep.") at 264:8-272:5. ECF No. 159-7 ("Patel Dep.") at 65:13-66:10. Though parol evidence may not be examined when offered to contradict the terms of a fully integrated contract, the court may use parol evidence to interpret or supplement the terms

of a written instrument that lacks a merger clause. *See, e.g., Conway v. 287 Corp. Ctr. Associates*, 901 A.2d 341, 347 (N.J. 2006); *A. N. Airlines v. Schwimmer*, 96 A.2d 652, 656 (N.J. 1953). Additionally, the record includes testimony that trade usage and course of dealing might have supplied such a notice provision. *See id.* at 269 (explaining that New Jersey law "allow[s] a thorough examination of extrinsic evidence in the interpretation of contracts," including "custom" and "usage"); *see also* Patel Dep. at 106 (discussing Sunrise's and the industry's general practices regarding notice). Given the complex business relationship acknowledged by the parties, whether Defendant had an obligation to provide notice of all 438s to Plaintiff is another genuine dispute of material fact.<sup>4</sup>

Even if notice of the 483s was not a term of the contract, there still exists an issue of material fact as to whether the Drug Products sold to Plaintiff were "unsalable" under the terms of the contract, and if so, for what reason. *See* Def. Br. at 27-29; Pl. Br. at 23-25. On this point, Defendant argues that the drugs sold were of acceptable quality considering that the drugs at issue were still unapproved—that is, their "adulterated" label from the FDA stemmed from Defendant's facility and process, not of the quality of the drugs themselves. Plaintiff, on the other hand, argues

<sup>&</sup>lt;sup>4</sup> Defendant also raises a variation of its statute of limitations argument that was previously rejected in its motion to dismiss. *See* Def. Br. at 33 (arguing Plaintiff should be barred from claims arising before August 6, 2009); ECF Nos. 72, 118. However, in addition to the disputes about the terms of the contract and the purported breach, there is the consequent issue of fact of *when* the breach occurred. Accordingly, where "a material issue of fact remains in dispute concerning a potential statute of limitations bar," courts have held summary judgment "would be premature." *Craig v. Ewing Twp.*, 678 F. Supp. 1106, 1109 (D.N.J. 1988); *see also Albright v. Virtue*, 273 F.3d 564, 575 (3d Cir. 2001) (vacating grant of summary judgment where record did not definitively show "a date certain on which ... the statute of limitations began to run"); *Luongo v. Vill. Supermarket, Inc.*, 261 F. Supp. 3d 520, 528 (D.N.J. 2017).

that the drugs' adulterated status—due to faulty manufacturing processes impairing the quality of the Drug Products—renders Defendant in breach.<sup>5</sup>

Moreover, Plaintiff refutes that the drugs' unapproved status is what led to being prohibited from selling the drugs to consumers; rather, Plaintiff contends, supported by the expert report of former Chief Counsel for the FDA, that but for Defendant's violation of the CGMPs, Plaintiff would have been able to continue selling the drugs. See ECF No. 166-12, Expert Report of S. Bradshaw. Plaintiff's expert explained that "the mere fact that Sunrise was manufacturing (and Vision was marketing) unapproved drugs did not cause FDA to take action against the Drug Products." Id. at 14. In fact, he elaborated, "[i]t is clear from the 483s alone that FDA was well aware that Sunrise had been manufacturing a number of unapproved drugs for years," yet "[i]t was not until FDA had to take action against Sunrise due to the cGMP violations that it took any action to remove the Drug Products from the market." Id. at 13, 14. Accordingly, he concluded that "but for Sunrise's cGMP violations, Vision could still be marketing drug products containing hyoscyamine sulfate." Id. at 13. Therefore, on the record before the Court, regardless of whether the contract is viewed as individual purchase orders or the entirety of the business relationship, the agreed-upon terms with respect to quality and the reason for Plaintiff's inability to sell the drugs are additional disputes of fact. See Mango, 851 A.2d at 73.6

<sup>&</sup>lt;sup>5</sup> Plaintiff, in defending its position that the drugs were not inherently unsafe, also points to the fact that colchicine is now an approved drug product. *See* Pl. SMF Resp. ¶ 20; *but see* Def. SMF ¶¶ 61-62 (explaining that colchicine was approved by the FDA only after submission of a New Drug Application by a third party, which in turn led to the third-party filing suit against Plaintiff and others for marketing and selling colchicine without FDA approval).

<sup>&</sup>lt;sup>6</sup> The Court notes Defendant contends that, even assuming there was a breach of contract, Plaintiff waived any remedy under the UCC by failing to notify Defendant of the breach and failing to revoke acceptance within a reasonable time. Def. Br. (citing N.J.S.A. §§ 12A:2-607(3), 608(2). By contrast, Plaintiff responds that it did not discover the full implications of Defendant's conduct until June 2010, after the FDA rejected Plaintiff's request to sell its inventory after switching manufacturers. Pl. Br. at 28. Whether a party revoked, has lost its right to revoke, or revoked within

Finally, Defendant argues that even if the Court credits Plaintiff's contract arguments, summary judgment is still warranted because the parties have entered into an illegal and unenforceable contract to sell unapproved drugs in U.S. markets. The parties do not dispute that section 355 of the FDCA proscribes the sale of unapproved drugs in interstate commerce. And the parties also do not dispute that the drugs were ultimately not approved by the FDA nor subject to any exception. Defendant asserts that, at bottom, the parties understood the risks of forming a contract regarding pharmaceutical drugs that were not yet approved by the FDA, and thus the parties should be left where they are, without any assistance from a court of law. However, the Court finds, as explained further below, that issues of material fact exist regarding the circumstances surrounding the parties' arrangement that bear upon this defense.

Courts have chosen to refuse to enforce contracts in situations where doing so would violate public policy. Freedman Truck Ctr., Inc. v. Gen. Motors Corp., 784 F. Supp. 167, 178 (D.N.J. 1992) (citing Vasquez v. Glassboro Serv. Ass'n, Inc., 415 A.2d 1156 (N.J. 1980)). "An agreement is against public policy if it is injurious to the interest of the public, contravenes some established interest of society, violates some public statute, is against good morals, tends to interfere with the public welfare or safety, or, as it is sometimes put, if it is at war with the interests of society and is in conflict with public morals." Frank Briscoe Co., Inc. v. Travelers Indem. Co., 65 F. Supp. 2d 285, 312 (D.N.J. 1999) (quoting Garlinger v. Garlinger, 322 A.2d 190 (N.J. Ch. Div. 1974) (citation omitted), order modified on other grounds, 347 A.2d 799 (N.J. App. Div.1975)). When considering whether a contract contravenes public policy, the New Jersey

a reasonable period of time are questions of fact. Fablok Mills, Inc. v. Cocker Mach. & Foundry Co., 310 A.2d 491, 494 (N.J. Super. App. Div. 1973); Massari v. Accurate Bushing Co., 85 A.2d 260, 266 (N.J. 1951); Kearney & Trecker Corp. v. Master Engraving Co., Inc., 560 A.2d 1320, 1321 (N.J. Super. L. Div. 1988) (citing Fablok Mills, 310 A.2d at 493-94). Accordingly, to the extent Defendant seeks summary judgment on this ground, it is denied.

Appellate Division has guided courts to consider a number factors including, "the parties' justified expectations, any forfeiture that would result if enforcement were denied, any special public interest in the enforcement of the particular term, the strength of the public policy involved, the extent to which that policy would be impaired or subverted, the seriousness of any misconduct involved and whether it was deliberate, and the connection between the misconduct and the terms." *Saxon Const. & Mgmt. Corp. v. Masterclean of N.C., Inc.*, 641 A.2d 1056, 1059 (N.J. Super. Ct. App. Div. 1994) (citation omitted).

The Third Circuit has also noted the caution required by federal courts when deeming a contract unenforceable on grounds of public policy. See, e.g., Allied Erecting & Dismantling, Co., Inc. v. USX Corp., 249 F.3d 191, 197 (3d Cir. 2001) (overturning district court's decision not to enforce contract because of public policy and noting that "a court must speak for a 'virtual unanimity" when addressing public policy) (citation omitted); see also Wechsler v. Hunt Health Sys., Ltd., 216 F. Supp. 2d 347, 354-55 (S.D.N.Y. 2002) ("[C]ourts must be mindful of the general rule that competent persons shall have the utmost liberty of contracting and that their agreements voluntarily and fairly made shall be held valid and enforced in the courts unless a violation of the law or public policy is clear and certain.") (internal quotations and citations omitted). Given that Defendant only indirectly touches on the factors set forth above, Defendant has left open questions concerning its illegality defense that make summary judgment inappropriate at this time.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> The Court acknowledges that Defendant relies on *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004) and *Ecosse Hospital Products, LTD. v. Illinois*, 69 Ill. Ct. Cl. 107 (2015) to support its argument that the contract at issue here is illegal. Def. Br. at 8–9; Oral Arg. Tr. at 6:23–7:18. However, those cases are inapposite to the present circumstances. Unlike the instant case, which is a private action for breach of contract and related claims, *Lane Labs-USA* involved a government enforcement action, not implicating a contractual dispute between private parties. And further, while a specialized Illinois state court in *Ecosse Hospital* found a contract for the sale of drugs void, that case, concerning the importation of unapproved *foreign*-manufactured drugs, did not address factors weighed by New Jersey courts and others to determine whether an agreement contravenes public policy and is thus unenforceable.

Moreover, in light of the ambiguity of the contract's terms, there are additional questions concerning illegality, including whether the contract, when formed, indeed had an illegal purpose. For example, Defendant has conceded that the mere manufacturing of the drugs at issue may not be illegal. See Oral Arg. Tr. at 49 ("Just manufacturing is not [wrongful]."). Additionally, the record indicates (although the parties dispute the exact facts) that around 2009 Vision began working toward obtaining FDA approval for various drugs at issue, potentially undercutting the clear illegal purpose Defendant asserts. See Def. SMF ¶ 19; Busman Dep. 197:11-16, 198:10-199:12; ECF No. 142-18 (Busman Dep. Ex. 16). And finally, even when a contract is "illegal", "a court may elect to grant some relief despite the unlawful nature of the contract if the party seeking enforcement is less guilty of moral fault than the opposing party." United Realty Corp. v. Green Valley Acres, Inc., II, 792 F.2d 1555, 1558 (11th Cir. 1986); see also Bus. Capital Group, Inc. v. Thai Airways Intl. Pub. Co. Ltd., 2012 WL 13018424, at \*6 (C.D. Cal. Sept. 10, 2012) (noting that "in certain cases illegal contracts may be enforced, ... such as where the defendant is more at fault than the party seeking to enforce the contract"). Yet beyond the assertion that Plaintiff "came to" Defendant and initiated the contractual relationship, Defendant has not sufficiently addressed the issue of fault. Oral Arg. Tr. at 48:8-9. Accordingly, there are multiple unaddressed questions regarding Defendant's illegality defense that counsel against summary judgment. See Anderson, 477 U.S. at 255.

#### **B.** Contract-related Claims (Counts III-VI)

Defendant also moves for summary judgment as to Counts III through VI, namely breach of the implied warranty of merchantability (Count III), breach of the implied warranty of fitness for a particular purpose (Count IV), breach of the implied covenant of good faith and fair dealing (Count V), and unjust enrichment (Count VI). Because these claims either depend on disputed facts relating to the terms of the contract or have disputed facts in their own right, summary

judgment is denied. These questions include, among others, whether the products were unsalable and thus defective and whether the parties contracted over the quality of the drugs. *See Lone Star Indus., Inc. v. Besser Co.*, No. 11-cv-1481, 2013 WL 1655983, at \*4 (E.D. Pa. Apr. 17, 2013) (denying summary judgment as to implied warranty claims where issue of fact existed regarding the scope of the contract). Moreover, because the validity of the breach of the implied covenant of good faith and fair dealing and unjust enrichment claims depend on the terms and scope of the contract, summary judgment is similarly inappropriate. *See Creative Concepts Mfg. Ltd. v. Team Beans LLC*, No. 17-6066, 2018 WL 2002800, at \*4 (D.N.J. Apr. 30, 2018) (breach of implied covenant of good faith requires wrongful conduct "apart from [the] contractual obligations"); . *Estate of Gleiberman v. Hartford Life Ins. Co.*, 94 F. App'x 944, 947 (3d Cir. 2004) ("Claims for unjust enrichment . . . are only supportable when the parties' rights are not governed by a valid, enforceable contract."). Therefore, summary judgment as to Counts III-IV is denied.

# C. Remaining Claims (Counts VII-IX)

In denying Defendant's motion to dismiss, this Court stated that the issues of negligence, fraud and deceit, and deceptive trade practices "may be dealt with more soundly on a developed factual record." ECF No. 117 at 14-15 (quoting *HUMC Opco L.L.C. v. United Benefit Fund*, No. 16-168, 2016 WL 6634878, at \*4 (D.N.J. Nov. 7, 2016)). Defendant renews those contentions in its Motion for summary judgment. *See* Def. Br. at 36. The Court takes them in turn.

#### i. Negligence (Count VII)

Defendant contends that because the alleged loss here is purely economic, the claim sounds in contract, and thus, the UCC is the only analytical framework that can be used to resolve this dispute. *See* Def. Br. at 38. Plaintiff asserts that its negligence claim is based upon a "breach of duty separate and apart from [Defendant's] contractual obligations." Pl. Br. at 30. The Court agrees with Defendant.

"New Jersey courts have unequivocally stated their opposition to tort law's encroachment into the contractual domain." Travelers Indem. Co. v. Dammann & Co., Inc., 594 F.3d 238, 251 (3d Cir. 2010). When determining whether a claim "sounds in contract rather than tort, a court may consider whether the loss was of a nature normally associated with a contract action and whether the relationship between the parties is governed by a lengthy and comprehensive contractual agreement." Silla Jewelry Co., Ltd. v. Sunico L.L.C., 2016 WL 427723, at \*11 (N.J. Super. Ct. Law Div. Feb. 1, 2016) (citing New Mea Constr. Corp. v. Harper, 203 N.J. Super. 486, 494 (N.J. Super. Ct. App. Div. 1985)). In the seminal case Spring Motors Distribs., Inc. v. Ford Motor Co., 98 N.J. 555 (N.J. 1985), the New Jersey Supreme Court articulated the difference between duties rooted in tort and contract law and ultimately concluded that "[a]s among commercial parties in a direct chain of distribution, contract law, expressed here through the UCC, provides the more appropriate system for adjudicating disputes arising from frustrated economic expectations." Id. at 580. This doctrine, titled the economic loss doctrine, "defines the boundary between overlapping theories of tort law and contract law by barring the recovery of purely economic loss in tort, particularly in strict liability and negligence cases." *Travelers*, 594 F.3d at 244 (citations omitted).

The Court finds Plaintiff's negligence claim fails under the economic loss doctrine. Despite Plaintiff's allegation that Defendant had breached its duty—purportedly separate from its contractual obligations—to manufacture and sell the Drug Products "in a manner in compliance with the CGMP, and to reasonably and adequately notify [Plaintiff] in circumstances of its CGMP violations and associated remedial actions," Compl. ¶ 103, Plaintiff's claim for damages, as explained by its damages expert, is largely driven by lost profits. *See* ECF No. 142-32, Ex. GG, Pl. Damages Exp. Rep. at 14-29; *see also* ECF No. 142-31, Pl. Supp. Interrog. Resp. No. 15. Moreover, the parties have acknowledged their extensive contractual relationship, even if the precise terms are disputed. *See Silla Jewelry*, 2016 WL 427723, at \*11. Further, no claim for bodily

injury or property damage is put forth. Since Plaintiff seeks purely economic damages in relation to its negligence claim, the claim sounds in contract rather than tort, and the only remedies available to Plaintiff are those authorized under the UCC. See Spring Motors, 98 N.J. at 580 ("[T]he UCC is generally regarded as the exclusive source for ascertaining when a seller is subject to liability for damages if the claim is based on intangible economic loss not attributable to physical injury to person or harm to a tangible thing other than the defective product itself.") (emphasis in original) (internal citation omitted). Because the economic loss doctrine precludes the negligence claim, Defendant's Motion for summary judgment is granted as to Count VII.

## ii. <u>Deceptive Trade Practices (Count VIII)</u>

Defendant also argues that Plaintiff's "Deceptive Trade Practice" claim is legally non-cognizable as a standalone claim under New Jersey law. Def. Br. at 39. Plaintiff, however, does not offer a substantive argument in reply. *See* Pl. Br. at 30 (asserting only that Defendant has not met its burden and "Vision respectfully submits that disposition of this claim is better addressed during pretrial proceedings rather than pursuant to Rule 56."). The Court agrees with Defendant.

This Court has construed "deceptive trade practice" claims as arising under the NJCFA—not as legally cognizable standalone claims. *See Creditors Relief L.L.C. v. United Debt Settlement L.L.C.*, No. 17-7474, 2019 WL 7288978, at \*13 (D.N.J. Dec. 30, 2019) (dismissing an "unfair and deceptive trade practices" claim as duplicative of plaintiff's NJCFA claim); *Celgene Corp. v. Gupta*, No. 17-5308, 2018 WL 4027032, at \*1 n.1 (D.N.J. Aug. 23, 2018) (construing a claim brought under the non-existent "New Jersey Deceptive Trade Practices Act" as a NJCFA claim); *Mitchell v. Walters*, No. 10-1061, 2010 WL 3614210, at \*5 (D.N.J. Sept. 8, 2010) (stating that New Jersey has not adopted the Uniform Deceptive Trade Practices Act, and thus, construing the claim as one under the NJCFA). Plaintiff has not offered any authority suggesting deceptive trade practice is a legally cognizable standalone claim under New Jersey law. Since Plaintiff's claim

must be construed as one under the NJCFA, and the Court previously determined that Plaintiff has no standing under the NJCFA because Plaintiff is a reseller—and not a consumer—of the Drug Products (*see* ECF No. 117 at 16), it must also grant Defendant's Motion for summary judgment as to Count VIII.

## iii. Fraud and Deceit (Count IX)

Lastly, Defendant contends that this Court "has construed the law of New Jersey to prohibit fraud claims when the 'fraud contemplated by the plaintiff does not seem to be extraneous to the contract, but rather on fraudulent performance of the contract itself." Def. Br. at 38 (quoting *Unifoil Corp. v. Cheque Printers & Encoders Ltd.*, 622 F. Supp. 268, 271 (D.N.J. 1985)). Plaintiff asserts that the record, at a minimum, establishes issues of material fact as to whether Defendant committed fraud. Pl. Br. at 30. The Court again agrees with Defendant.

In *JD James Construction, L.L.C. v. PDP Landscaping, L.L.C.*, 2020 WL 5587439 (N.J. Super. Ct. App. Div. Sep. 18, 2020), the court stated that New Jersey federal courts have recognized "the *fraud in the inducement* exception to the economic loss doctrine," while barring fraud in the performance claims. *Id.* at \*6 (quoting *G & F Graphic*, 18 F. Supp. 3d at 593) (emphasis added). Fraud in the inducement is "a misrepresentation of a statement of intent at the time of contracting, which then induces detrimental reliance on the part of the promisee." *Id.* (quoting *Bracco Diagnostics, Inc. v. Bergen Brunswig Drug Co.*, 226 F. Supp. 2d 557, 563 (D.N.J. 2002)). Here, even when the Court construes all facts and makes all inferences in a light most favorable to Plaintiff, the record is simply devoid of any evidence indicating Plaintiff was fraudulently induced to enter into the contractual relationship. *See Bracco*, 226 F. Supp. 2d at 563. Therefore, since Plaintiff puts forth no allegations or evidence of fraud in the inducement, its fraud claim is barred as well. Defendant's motion for summary judgment is granted as to Count IX.

V. **CONCLUSION** 

For the foregoing reasons, Defendant's Motion for summary judgment is **DENIED** as to

Counts II-VI and GRANTED as to Counts VII-IX. An appropriate Order accompanies this

Opinion.

DATED: September 29, 2022

s/Claire C. Cecchi

CLAIRE C. CECCHI, U.S.D.J.