

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

RIVER'S EDGE PHARMACEUTICALS,)
LLC,)
)
Plaintiff,)
)
v.)
)
GORBEC PHARMACEUTICAL SERVICES,)
INC., and J. MICHAEL GORMAN)
)
Defendants.)
_____)

1:10CV991

MEMORANDUM OPINION

This matter is before the Court on the parties' Motions to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Defendant/Counterclaim Plaintiff Gorbec Pharmaceutical Services, Inc. ("Gorbec") and Defendant J. Michael Gorman¹ ("Gorman") have each filed a Motion to Dismiss [Doc. #56 & #59] the Amended Complaint filed by Plaintiff/Counterclaim Defendant River's Edge Pharmaceuticals, LLC ("River's Edge" or "Plaintiff").² In addition, Plaintiff has filed a Motion to Dismiss [Doc. #70] Gorbec's Amended Counterclaims. The three Motions have been fully briefed and are ready for disposition by the Court.

I. FACTUAL BACKGROUND

This factual background briefly sets forth the allegations as stated in Plaintiff's Amended

¹ Defendant J. Michael Gorman has not yet filed an Answer to the Amended Complaint, and therefore has not filed any counterclaims against Plaintiff at this time.

² Gorbec and Gorman previously filed Motions to Dismiss with respect to Plaintiff's original Complaint, but those Motions to Dismiss were rendered moot by the filing of Plaintiff's Amended Complaint on March 31, 2011.

Complaint and in Gorbec's Amended Counterclaims.³

A. Plaintiff's Allegations and Claims for Relief

Since its establishment in 2003, Plaintiff has engaged in distributing pharmaceutical products “with the mission of providing reasonably priced alternatives to costly ‘name brand’ pharmaceuticals.” (Am. Compl. ¶ 20). Plaintiff began its work with the development and marketing of certain unapproved products, which, according to Plaintiff, the FDA allows companies to market pending a review process known as Drug Efficacy Study Implementation (“DESI”). In 2007, Plaintiff entered into a business relationship with Gorbec to formulate and manufacture several DESI drugs and to formulate and test certain generic drugs and medical devices pursuant to the Abbreviated New Drug Application (“ANDA”) process. Plaintiff alleges that the parties, including Gorbec President and CEO, J. Michael Gorman, discussed and agreed that Gorbec would undertake the ANDA work “for and on behalf of River’s Edge, and at River’s Edge’s expense,” and that Plaintiff, only, would retain all interest in the products, the approvals, and the underlying work product. (Am. Compl. ¶ 27). Plaintiff further alleges that

³ The Court notes that Gorbec has attached certain documents to its Motion to Dismiss, which it contends are central to Plaintiff’s Amended Complaint. The Court further notes that it may consider documents not attached to the Amended Complaint without converting a motion to dismiss into a motion for summary judgment in limited circumstances where such documents are incorporated by reference, are central to the claims, and the authenticity of the documents is not challenged by the plaintiff. See Hall v. Witteman, 569 F. Supp. 2d 1208, 1216 (D. Kan. 2008). However, the Court finds that such review is not necessary for purposes of ruling on any Motion to Dismiss in this case. As such, the Court has not considered the content of the attached documents, but rather addresses each Motion to Dismiss based on the allegations set forth in the Amended Complaint and the Amended Counterclaims, as relevant to Motion being addressed. See McBurney v. Cuccinelli, 616 F.3d 393, 409 (4th Cir. 2010) (noting that the Court “*may*, but is not *required*, to consider” materials outside the pleadings when resolving a motion to dismiss).

the parties verbally agreed that they would eventually memorialize their overall agreement in a writing. The parties nevertheless began their relationship with a series of purchase orders specifying the services to be rendered and the payments to be made by the parties.

Plaintiff alleges that, beginning in 2010, Gorbec made statements to Plaintiff that Gorbec, and not Plaintiff, owned the “know-how, intellectual property, and regulatory approvals River’s Edge hired and paid Gorbec to develop for River’s Edge.” (Am. Compl. ¶¶ 27, 33, 36). Plaintiff further alleges that these statements were made despite the fact that, at all times, Plaintiff claimed such ownership. In addition, Plaintiff alleges that Gorbec stopped work on certain ANDA products and threatened to stop FDA required stability testing on the ANDA products. Furthermore, Plaintiff alleges that Gorbec, through counsel, made statements of its intent to compete with Plaintiff and “refused to provide complete copies of communications with the FDA concerning pending ANDAs for River’s Edges products.” (Am. Compl. ¶¶ 38, 39). Plaintiff alleges that Gorbec’s actions have or will cause harm to Plaintiff and its chances of obtaining approval for its ANDA products. Based on all of its allegations, Plaintiff has filed nine Claims for Relief in this case as follows: (1) First Claim for Relief–Declaratory Relief (against Gorbec); (2) Second Claim for Relief–Breach of Contract (against Gorbec); (3) Third Claim for Relief–Breach of Fiduciary Duty (against Gorbec); (4) Fourth Claim for Relief–Constructive Fraud (against Gorbec and Gorman); (5) Fifth Claim for Relief–Promissory Estoppel (against Gorbec and Gorman); (6) Sixth Claim for Relief–Unjust Enrichment (against Gorbec); (7) Seventh Claim for Relief–Conversion (against Gorbec); (8) Eighth Claim for Relief–Misappropriation of Trade Secrets (against Gorbec); and (9) Ninth Claim for

Relief–Punitive Damages (against Gorbec and Gorman).

B. Gorbec’s Allegations and Amended Counterclaims

Gorbec alleges that it was founded in 2006, “at the urging of Brendan Murphy, the principal of River’s Edge,” and that the two entities began working together in 2007 on both DESI and ANDA drugs. (Am. Countercl. ¶¶ 8, 9, 10, 31). With regard to the DESI drugs, Gorbec alleges that it was “reluctant to manufacture DESI drugs because the FDA in 2006 had begun barring manufacture of DESI drugs.” (Am. Countercl. ¶ 11). However, Gorbec alleges that it agreed to manufacture DESI drugs for Plaintiff based on representations from Plaintiff that it had retained experts who stated that production of such drugs could continue. Gorbec further alleges that it “would not have agreed to manufacture DESI drugs or agreed to continue the manufacture of DESI drugs but for the express representations of River’s Edge that it would be allowed to continue to sell DESI drugs.” (Am. Countercl. ¶ 88). Gorbec manufactured DESI drugs for Plaintiff from 2007 until July of 2010, at which time Gorbec alleges it became aware, via the FDA website, of a warning letter from the FDA ordering Plaintiff to stop selling DESI drugs. Gorbec alleges that Plaintiff had received the letter from the FDA in May of 2010, but did not tell Gorbec about it at that time. As a result, Gorbec alleges that it incurred costs associated with continued manufacturing of DESI drugs between May 2010 and July 2010, for which Gorbec alleges Plaintiff failed to pay in full. In addition, Gorbec alleges, based on information and belief, that Plaintiff transferred DESI manufacturing to another entity to continue producing the drugs in violation of the FDA warning letter. Gorbec alleges that, as a result of the two-month period during which Gorbec continued manufacturing DESI drugs,

Gorbec suffered potential harm to its reputation with the FDA. Furthermore, Gorbec alleges that Plaintiff's alleged conduct in continuing to manufacture DESI drugs with another entity has jeopardized the approval of the ANDA products on which Gorbec has worked.

With regard to Gorbec's ANDA work, Gorbec alleges that it verbally agreed to "work together [with River's Edge] to develop new drugs for FDA approval through the ANDA process and that Gorbec would manufacture any drugs that were eventually approved." (Am. Countercl. ¶ 49). Gorbec alleges that the ANDA work was done pursuant to purchase orders, and that Plaintiff agreed to pay for the work done, including stability testing costs, costs associated with required FDA deficiency work, and "pass through" costs, such as laboratory reagents and equipment. (Am. Countercl. ¶¶ 52, 53). Gorbec also alleges that the parties agreed to enter into a manufacturing agreement whereby Gorbec would manufacture any drugs eventually approved by the FDA. Gorbec alleges that Plaintiff failed to pay some or all of the money owed to Gorbec for the ANDA work and that Plaintiff failed to enter in a manufacturing agreement with Gorbec.

Furthermore, Gorbec alleges an agreement, entered into on October 12, 2010, which "was intended to reconcile existing differences between the parties," related to Gorbec's ANDA work. (Am. Countercl. ¶ 56). In addition, Gorbec alleges the existence of a subsequent separation agreement, entered into on November 30, 2010, wherein the parties agreed to certain terms of separation. Gorbec alleges that Plaintiff failed to meet its obligations under both agreements. Based on all of its allegations, Gorbec has filed six Amended Counterclaims against Plaintiff as follows: (1) First Amended Counterclaim—Breach of Contract—DESI drugs; (2)

Second Amended Counterclaim–Breach of Contract–ANDAs; (3) Third Amended Counterclaim–Unjust Enrichment; (4) Fourth Amended Counterclaim–Negligent Misrepresentation; (5) Fifth Amended Counterclaim–Fraud; and (6) Sixth Amended Counterclaim–Unfair and Deceptive Trade Practices.

II. LEGAL STANDARD

In reviewing Motions to Dismiss for failure to state a claim pursuant to Rule 12(b)(6), the Court must “take the facts in the light most favorable to the [non-moving party],’ but ‘[it] need not accept the legal conclusions drawn from the facts,’ and ‘[it] need not accept as true unwarranted inferences, unreasonable conclusions, or arguments.’” Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008) (quoting Eastern Shore Mkts., Inc. v. J.D. Assocs. Ltd. P’ship, 213 F.3d 175, 180 (4th Cir. 2000)). The Supreme Court, in Ashcroft v. Iqbal, noted that “[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” 556 U.S. 662, 678, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 1974, 167 L. Ed. 2d 929 (2007)). In this regard, the Iqbal Court noted that Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain a “short and plain statement of the claim showing that the pleader is entitled to relief,” but Rule 8 “does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” Id. at 677-78, 678-79, 129 S. Ct. at 1949, 1950. Pleadings containing “labels and conclusions,” “a formulaic recitation of the elements of a cause of action,” or “naked assertion[s]’ devoid of ‘further factual enhancement,’” will not survive a motion to dismiss. Id. at 678, 129 S. Ct. at 1949 (citations omitted).

Rather, “[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. . . . Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” Id. (citations omitted). Thus, dismissal of a complaint is proper where a plaintiff’s factual allegations fail to “produce an inference of liability strong enough to nudge the plaintiff’s claims ‘across the line from conceivable to plausible.’” Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 256 (4th Cir. 2009) (citing Iqbal, 556 U.S. at 683, 129 S. Ct. at 1952 (internal quotation omitted)).

III. DISCUSSION

A. Gorbec’s and Gorman’s Motions to Dismiss the Amended Complaint

Plaintiff raises a total of nine Claims for Relief in its Amended Complaint, eight of which are the subject of Defendants’ Motions to Dismiss in this case. For example, Gorbec moves to dismiss Plaintiff’s Second through Ninth Claims for Relief.⁴ In addition, Gorman moves to dismiss all three claims filed against him: the Fourth Claim for Relief–Constructive Fraud, the Fifth Claim for Relief–Promissory Estoppel, and the Ninth Claim for Relief–Punitive Damages. Each claim will be addressed in turn.

⁴ Plaintiff’s First Claim for Relief seeks declaratory relief against Gorbec regarding ownership of the various products, formulations, production methods, and FDA submissions related to this action. This claim is not the subject of Gorbec’s Motion to Dismiss. As such, discussion of Plaintiff’s claims begins with its Second Claim for Relief–Breach of Contract (against Gorbec).

1. **Plaintiff's Second Claim for Relief–Breach of Contract (against Gorbec)**

Plaintiff, in its Second Claim for Relief, alleges breach of contract against Gorbec. Under North Carolina law, “[t]he elements of a claim for breach of contract are (1) existence of a valid contract and (2) breach of the terms of that contract.” Parker v. Glosson, 182 N.C. App. 229, 232, 641 S.E.2d 735, 737 (2007) (internal quotations omitted). Formation of a valid contract requires “an agreement to which at least two parties manifest an intent to be bound.” Id. In addition, the terms of the contract must be sufficiently definite to be enforceable. See Horton v. Humble Oil & Ref. Co., 255 N.C. 675, 679, 122 S.E.2d 716, 719 (1961).

In support of its claim for breach of contract, Plaintiff alleges that

[i]t was specifically discussed, represented, and agreed by Gorman on behalf of Gorbec that all of the work product developed and approvals obtained by Gorbec for and on behalf of River's Edge, at River's Edge's expense, would belong to River's Edge, and that Gorbec's role would be to assist River's Edge in the development of products for the benefit of River's Edge, with Gorbec having no interest in the products, the approval or the underlying work product.

(Am. Compl. ¶ 27). Plaintiff further alleges that, although the parties intended to reduce this “overall agreement” to a written form eventually, the parties started their relationship by entering into a series of purchase orders “memorializing specific elements of the projects,” such as “specific services to be performed toward various milestones” and “pricing for those services.”

(Am. Compl. ¶ 29). Plaintiff also alleges that the parties entered into a written Pharmaceutical Quality Agreement, which stated, among other things, that “[b]ecause [Plaintiff] owns the regulatory applications for the Products, [Plaintiff] is responsible for all Regulatory Filings.”

(Am. Compl. ¶ 30). Furthermore, Plaintiff alleges that “[n]othing in any of the purchase orders, or in the Pharmaceutical Quality Agreement embodying some aspects of the underlying

agreement, or in any other form conveys to Gorbec the right of ownership or control over either the products River's Edge hired it to formulate or the know-how and related technical information related to those products.” (Am. Compl. ¶ 54). Based on these, and other, allegations, Plaintiff, in its Second Claim for Relief, alleges that “Gorbec breached its agreements with River's Edge by refusing to deliver, or even to disclose, to River's Edge the know-how, intellectual property and regulatory status relating to products formulated for River's Edge.” (Am. Compl. ¶ 56).

In its Motion to Dismiss, Gorbec contends that Plaintiff has failed to allege the existence of any terms in the alleged agreements which would require Gorbec to turn over, or otherwise disclose the claimed “know-how, intellectual property and regulatory status.” Therefore, Gorbec contends that could not be found in breach of terms not alleged in the Amended Complaint. In addition, Gorbec contends that Plaintiff has not alleged any other breach for which relief could be granted, and thus the Court should grant Gorbec's Motion and dismiss Plaintiff's Second Claim for Relief for breach of contract. In Response, Plaintiff contends that it alleges multiple breaches throughout the Amended Complaint including (1) that Gorbec claimed ownership of intellectual property developed for Plaintiff, as part of the parties' agreement, and thereafter attempted to keep that information from Plaintiff, (2) that Gorbec stated its intention to compete with Plaintiff on the ANDA products that Plaintiff hired Gorbec to develop, (3) that Gorbec threatened to stop stability testing work required by the FDA unless Plaintiff agreed to extra-contractual conditions, and (4) that Gorbec did stop work on certain ANDA products submitted to the FDA. As such, Plaintiff contends that it has alleged the existence of valid

contracts between the parties and has further alleged sufficient facts to state a claim for breach of those contracts.

Based on the allegations in the Amended Complaint, making all reasonable inferences in favor of Plaintiff, as the non-moving party, the Court finds that Plaintiff has alleged agreements by the parties which, taking the facts alleged as true, would appear to include terms that require performance by Gorbec in the form of formulating and testing certain DESI and ANDA products, handling submissions to the FDA for ANDA products, and designing, testing, and obtaining FDA pre-market clearance for certain medical devices. (Am. Compl. ¶ 31). The Court further finds that Plaintiff has alleged that Gorbec stopped working on certain ANDA products that it had submitted to the FDA for approval, and threatened to stop work on stability testing unless Plaintiff agreed to extra-contractual conditions. (Am. Compl. ¶ 37). Based on these allegations, the Court concludes that Plaintiff has alleged a plausible claim for breach of contract regarding Gorbec's alleged cessation of performance of ANDA-related work.⁵

⁵ To the extent that Plaintiff alleges that Gorbec threatened to stop conducting stability testing unless Plaintiff agreed to extra-contractual conditions, the Court finds that such a claim may proceed at this time under the theory of anticipatory breach. See Southeast Brunswick Sanitary Dist. v. City of Southport, No. COA09-1369, 2011 WL 340535, at *7 (N.C. Ct. App. Feb. 1, 2011) (unpublished) (“[I]f a party to the contract states that he cannot perform except on some condition which goes outside the terms of his contract then the statement will constitute a repudiation.” (quoting Millis Constr. Co. v. Fairfield Sapphire Valley, Inc., 86 N.C. App. 506, 510-11, 358 S.E.2d 566, 569 (1987))); see also Gupton v. Son-Lan Dev. Co., 205 N.C. App. 133, 139 n.1, 695 S.E.2d 763, 768 n.1 (2010) (noting that the defendant's failure to specifically plead anticipatory breach was not fatal to his claim given the facts alleged). However, the Court notes that it will ultimately be Plaintiff's burden to show that Gorbec's alleged threats amounted to a distinct, unequivocal, and absolute repudiation of the alleged contract in order for Plaintiff to succeed on this anticipatory breach claim. See D.G. II, LLC v. Nix, 712 S.E.2d 335, 340 (N.C. Ct. App. 2011).

However, beyond these limited allegations of breach, the Court finds that Plaintiff has failed otherwise to allege sufficiently definite terms of any other agreement, such that the Court could reasonably infer liability for breach of contract.

Specifically, to the extent that Plaintiff alleges that Gorbec made statements in which it claimed ownership over certain “know-how, intellectual property, and regulatory approvals,” and made additional statements that Gorbec intended to compete with Plaintiff, the Court finds that Plaintiff has failed to allege sufficiently definite terms in any agreement such that Gorbec’s statements alone, even though contrary to Plaintiff’s alleged interest, would constitute a breach of contract in this case. As such, Plaintiff has not alleged a plausible claim for breach of contract based on Gorbec’s alleged statements regarding ownership and intent to compete. Furthermore, to the extent that Plaintiff alleges that Gorbec refused to deliver or disclose to Plaintiff “know-how, intellectual property and regulatory status relating to the products formulated for [Plaintiff],” (Am. Compl. ¶ 56), the Court finds that Plaintiff has failed to allege sufficiently definite terms of any agreement, which would require such disclosure.

Based on the foregoing, the Court will grant in part and deny in part Gorbec’s Motion to Dismiss Plaintiff’s Second Claim for Relief. Specifically, to the extent that Plaintiff alleges a breach based on Gorbec’s statements of ownership or intent to compete, or based on Gorbec’s alleged failure to disclose certain information, the Court concludes that Plaintiff has failed to state a claim for breach of contract. In that regard, Gorbec’s Motion to dismiss will be granted, and Plaintiff shall not be allowed to proceed on these aspects of its claim. However, to the extent that Plaintiff alleges Gorbec’s cessation of ANDA-related work, including alleged threats

to stop conducting stability testing, the Court concludes that Plaintiff has stated a claim for breach of contract. In that regard, Gorbec's Motion to Dismiss will be denied, and Plaintiff may proceed on its claim for breach of contract against Gorbec, as limited herein.

2. Plaintiff's Third Claim for Relief—Breach of Fiduciary Duty (against Gorbec)

In its Third Claim for Relief, Plaintiff alleges breach of fiduciary duty against Gorbec. North Carolina generally recognizes two types of fiduciary relationships: (1) “those that arise from legal relationships such as attorney and client . . . partners, principal and agent . . . and (2) those that exist as a fact, in which there is confidence reposed on one side, and the resulting superiority and influence on the other.” S.N.R. Mgmt. Corp. v. Danube Partners 141 LLC, 189 N.C. App. 601, 613, 659 S.E.2d 442, 451 (2008) (quoting Rhone-Poulenc Agro S.A. v. Monsanto Co., 73 F. Supp. 2d 540, 546 (M.D.N.C. 1999)) (internal quotations omitted). In cases where the parties' relationship is based in contract and pursuant to arms-length bargaining, North Carolina courts will typically only find that a fiduciary relationship exists “when one party figuratively holds all the cards—all the financial power or technical information.” Broussard v. Meineke Discount Muffler Shops, Inc., 155 F.3d 331, 348 (4th Cir.1998).

In the present case, Plaintiff alleges that a fiduciary relationship exists between Plaintiff and Gorbec based on both an agency relationship and a relationship based on confidence and control. With regard to the alleged agency relationship, Plaintiff alleges that Gorbec acted as Plaintiff's agent for purposes of the formulation and testing of ANDA products and for purposes of communicating with the FDA throughout the drug approval process. Plaintiff further alleges that this agency relationship was confirmed by documentation sent to the FDA,

which listed Gorbec as the agent for River's Edge. As such, Plaintiff alleges that Gorbec is bound by fiduciary duties arising out of this agency relationship. In addition, Plaintiff alleges that it "disclosed to Gorbec in confidence the identity of various products," and "relied on Gorbec to act in River's Edge's interest to formulate products that would be approved by the FDA." (Am. Compl. ¶ 61). Furthermore, Plaintiff alleges that Gorbec "has maintained sole control over the materials and technical information needed to achieve River's Edge's marketing objectives." (Am. Compl. ¶ 62). As such, Plaintiff also alleges that Gorbec is bound by fiduciary duties based on the confidential nature of the parties' relationship, and based on Gorbec's total control over necessary information.

Plaintiff further alleges that Gorbec breached its alleged fiduciary duties by refusing to provide Plaintiff with complete copies of communications with the FDA and information regarding pending ANDAs, and by making statements asserting Gorbec's ownership over certain intellectual property claimed by Plaintiff. In addition, as part of its allegations of a breach of fiduciary duty, Plaintiff alleges that conduct that "would breach" Gorbec's alleged fiduciary duties, includes Gorbec's (1) "use of any materials or information developed on behalf of River's Edge for Gorbec's own interest, or for the benefit of any third party," and (2) Gorbec's "unjustified delay in performance of its duties, such as completing required testing, responding to FDA communications, and filing required documentation." (Am. Compl. ¶¶ 64, 65).

In its Motion to Dismiss, Gorbec contends that there is no agency agreement between Plaintiff and Gorbec. Gorbec contends that Plaintiff hired it "to manufacture drugs, perform testing, and negotiate the ANDA process, not to serve as its agent." (Gorbec's Br., [Doc. #57],

at 5). As such, Gorbec contends that no fiduciary duty exists based on any legal relationship. Gorbec further contends that the parties are mutually interdependent businesses that contracted at arms-length, and that North Carolina courts generally do not recognize fiduciary duties in such situations. See Broussard, 155 F.3d at 348. Moreover, Gorbec contends that Plaintiff has failed to sufficiently allege that Gorbec dominated the relationship, such that North Carolina courts would find extra-contractual fiduciary duties in this case. As such, Gorbec contends that no fiduciary relationship exists between Gorbec and Plaintiff in this case, and therefore the Court should dismiss Plaintiff's Third Claim for Relief.

Based on the allegations set forth in the Amended Complaint, making all reasonable inferences in Plaintiff's favor, the Court finds that Plaintiff has sufficiently alleged a fiduciary relationship in this case based both on an alleged agency relationship and on an alleged relationship between the parties with respect to confidence and control. With regard to the alleged agency relationship, Plaintiff has alleged facts to support its claim that Gorbec acted as Plaintiff's agent with regard to interactions with the FDA during the ANDA approval process. Furthermore, although the nature of the relationship between Gorbec and Plaintiff does, in part, involve contractual bargaining, the Court finds that Plaintiff has alleged facts to support its claim that Gorbec controlled the necessary confidential information related to the ANDA process, to Plaintiff's exclusion, and that Plaintiff fully relied on Gorbec to act in Plaintiff's interest during the course of the ANDA process.

With regard to breach of any alleged fiduciary duties in this case, the Court finds that Plaintiff has alleged breach of those duties, but, as described below, the Court will limit the bases

for Plaintiff's claim of breach to only certain alleged conduct. Specifically, the Court finds that Plaintiff has sufficiently stated a claim for breach from the fiduciary duty perspective with regard to Gorbec's alleged conduct of refusing to provide Plaintiff with complete copies of communications with the FDA and information regarding pending ANDAs, and Gorbec's alleged conduct of making statements asserting ownership over certain intellectual property claimed by Plaintiff.⁶ However, to the extent that Plaintiff alleges breach of any alleged fiduciary duties based on threatened conduct, or based on conduct that, *if it occurred, would* result in a breach, the Court finds that such allegations do not sufficiently state a claim for breach of fiduciary duty in this case. For example, Plaintiff alleges that "use of any materials or information developed on behalf of River's Edge for Gorbec's own interest, or for the benefit of any third party," *would breach* the alleged fiduciary duty, but does not allege that Gorbec actually engaged in any such use. In addition, Plaintiff alleges that any unjustified delay in the "performance of [Gorbec's] duties, such as completing required testing, responding to FDA communications, and filing required documentation," *would breach* the alleged fiduciary duty. However, Plaintiff does not allege any actual delay.⁷ The Amended Complaint contains no allegations that Gorbec actually acted on any of the alleged threatened or potential conduct, or that Plaintiff gave up, conferred to Gorbec, or was denied anything as a result of Gorbec's

⁶ The Court notes that, although these allegations did not serve to support Plaintiff's claim for breach of contract, as the Court found no contract terms existed which would bind Gorbec in the manner alleged by Plaintiff, the Court does find that such allegations do support Plaintiff's claim for breach of fiduciary duty, as set forth herein.

⁷ To the extent that Plaintiff alleges any cessation of work on ANDA products, the proper remedy for any such alleged conduct is found in Plaintiff's claim for breach of contract claim, as set forth above.

alleged threatened or potential conduct. As such, the Court concludes that Plaintiff has failed to state a claim for breach of fiduciary duty with regard to the alleged threatened or potential conduct by Gorbec, as described herein.

Based on the foregoing, the Court will grant in part and deny in part Gorbec's Motion to Dismiss Plaintiff's Third Claim for Relief. Specifically, to the extent that Plaintiff alleges breach based on Gorbec's threatened or potential conduct, as set forth herein, the Court concludes that Plaintiff has failed to state a claim for breach of fiduciary duty. In that regard, Gorbec's Motion to dismiss will be granted, and Plaintiff shall not be allowed to proceed on these aspects of its claim. However, to the extent that Plaintiff alleges that Gorbec refused to provide Plaintiff with complete copies of communications with the FDA and information regarding pending ANDAs, and made statements asserting ownership over certain intellectual property claimed by Plaintiff, the Court concludes that Plaintiff has stated a claim for breach of fiduciary duty. In that regard, Gorbec's Motion to Dismiss will be denied, and Plaintiff may proceed on its claim for breach of fiduciary duty against Gorbec, as limited herein.

3. Plaintiff's Fourth Claim for Relief—Constructive Fraud (against Gorbec and Gorman)

In addition to its claim for breach of fiduciary duty against Gorbec, Plaintiff, in its Fourth Claim for Relief, raises a claim for constructive fraud against both Gorbec and Gorman. Under North Carolina law, to survive a motion to dismiss on a claim for constructive fraud, a plaintiff must sufficiently allege (1) a relationship of trust and confidence; (2) that the defendant took advantage of that position of trust and confidence in order to benefit himself; and (3) that the plaintiff was, as a result, injured. White v. Consol. Planning, Inc., 166 N.C. App. 283, 294, 603

S.E.2d 147, 156 (2004). North Carolina courts have noted the similarities between a claim for breach of fiduciary duty and a claim for constructive fraud, noting that “[t]he primary difference . . . is the constructive fraud requirement that the defendant benefit himself.” Clay v. Monroe, 189 N.C. App. 482, 488, 658 S.E.2d 532, 536-37 (2008) (internal quotations omitted). In addition, courts have found that when the “superior party obtains a possible benefit through the alleged abuse of the confidential or fiduciary relationship, the aggrieved party is entitled to a presumption that constructive fraud occurred. . . . This presumption arises not so much because [the fiduciary] has committed a fraud, but [because] he may have done so.” Forbis v. Neal, 361 N.C. 519, 529, 649 S.E.2d 382, 388 (2007) (internal quotations and citations omitted).

With regard to Plaintiff’s claim for constructive fraud against Gorbec, the Court notes that because the Court has already concluded that Plaintiff has stated a claim for breach of fiduciary duty against Gorbec, based, in part, on a relationship of confidence and control, Plaintiff has satisfied the first prong of the constructive fraud analysis. In addition, based on the allegations referenced above, the Court finds that Plaintiff has sufficiently alleged that Gorbec obtained the possible benefits associated with retention and/or use of the ANDA products or underlying work product, based on Gorbec’s alleged conduct of failing to provide complete copies of communications with the FDA and information regarding pending ANDAs, and making statements asserting ownership over certain intellectual property claimed by Plaintiff. Based on the foregoing, the Court concludes that Plaintiff has stated a claim for constructive fraud against Gorbec. As such, the Court will deny Gorbec’s Motion to Dismiss Plaintiff’s Fourth Claim for Relief, and Plaintiff may proceed on its claim for constructive fraud against

Gorbec.

With regard to Plaintiff's claim for constructive fraud against Gorman, the Court notes that Plaintiff does not allege a claim for breach of fiduciary duty against Gorman. As such, the Court must first determine whether Plaintiff has sufficiently alleged a confidential or fiduciary relationship with Gorman. In examining the Amended Complaint, the Court notes that Plaintiff refers to Gorman infrequently, and when Plaintiff does reference alleged conduct by Gorman, Gorman is generally alleged to be acting "on behalf of Gorbec." In fact, in Plaintiff's own Response to Gorman's Motion to Dismiss, wherein Plaintiff spends most of the allotted pages simply reciting, verbatim, paragraphs from the Amended Complaint, Plaintiff notes that "[t]hese specific paragraphs typically refer just to Gorbec, and not specifically to Gorman as an individual." (Pl.'s Resp., [Doc. #72], at 7). Plaintiff further states that "as a legal fiction, the corporate entity cannot act except through its officers and employees," in order to support its claim against Gorman individually. (Pl.'s Resp., [Doc. #72], at 7). However, even taking the limited allegations referencing Gorman as true, the Court finds that Plaintiff has failed to allege a confidential or fiduciary relationship between Plaintiff and Gorman, as an individual. Plaintiff does not allege that Gorman acted as Plaintiff's agent, or otherwise engaged in a legal relationship that would support a fiduciary duty. In addition, Plaintiff has failed to allege that Gorman had control or dominance over the technical information necessary to the ANDA process, as Plaintiff alleges against Gorbec. Furthermore, to the extent that Plaintiff alleges that Gorman acted on behalf of Gorbec, the Court finds that Plaintiff's remedy would be found in its claims against Gorbec, as an entity, and not against Gorman, as an individual.

Therefore, the Court concludes that Plaintiff has failed to state a claim for constructive fraud against Gorman, individually. As such, the Court will grant Gorman's Motion to Dismiss Plaintiff's Fourth Claim for Relief, and Plaintiff's claim for constructive fraud against Gorman will be dismissed.

4. Plaintiff's Fifth Claim for Relief—Promissory Estoppel (against Gorbec and Gorman)

Plaintiff, in its Fifth Claim for Relief, raises a claim against both Gorbec and Gorman for promissory estoppel. However, the Court notes that in its Response to Gorman's Motion to Dismiss, Plaintiff expressly withdrew its promissory estoppel claim. As such, the Court will grant Gorman's Motion to Dismiss Plaintiff's Fifth Claim for Relief, and Plaintiff's claim for promissory estoppel will be dismissed as against Gorman.

With regard to Gorbec, however, it is unclear whether Plaintiff intends to pursue its claim for promissory estoppel. Plaintiff did not expressly withdraw the promissory estoppel claim against Gorbec in Plaintiff's Response to Gorbec's Motion to Dismiss. Rather, Plaintiff did not address the claim in any way. Assuming Plaintiff intends to pursue its claim for promissory estoppel against Gorbec, the Court will address the sufficiency of that claim herein.

In support of its claim for promissory estoppel, Plaintiff alleges that "Gorbec's . . . promises to River's Edge were intended to be and were reasonably relied upon by River's Edge . . . when utilizing Defendants' services and paying Defendants . . . to develop its ANDA products." (Am. Compl. ¶¶ 75, 76). In general, there exists two types of promissory estoppel. Defensive promissory estoppel has been recognized by North Carolina Courts in limited circumstances where there has been an intended abandonment of an existing right by the

promisee, such as a promise by a landlord to waive the written notice requirement under a lease. See Home Elec. Co. of Lenoir, Inc. v. Hall and Underdown Heating and Air Conditioning Co., 86 N.C. App. 540, 543, 358 S.E.2d 539, 541 (1987) (citing Wachovia Bank & Trust Co., N.A. v. Rubish, 306 N.C. 417, 293 S.E.2d 749 (1982)). Some courts also recognize a second form of promissory estoppel known as “affirmative” or “offensive” promissory estoppel, whereby “a promisee attempts to create a contract which would not exist without the application of promissory estoppel.” Dealers Supply Co. v. Cheil Industries, Inc., 348 F. Supp. 2d 579, 587 (M.D.N.C. 2004). However, while some courts will use affirmative or offensive promissory estoppel to supply a missing contract term, and bind the parties, North Carolina courts do not recognize a claim for this type of “offensive” promissory estoppel. Home Elec. Co. of Lenoir, Inc., 86 N.C. App. at 543, 358 S.E.2d at 541.

In this case, Plaintiff does not allege that Gorbec promised to abandon an existing right, which may permit the Court to infer a claim for defensive promissory estoppel. Rather, Plaintiff’s allegations suggest that Gorbec made promises in the absence of a valid contract, on which Plaintiff allegedly relied. As such, to the extent that Plaintiff sets forth a claim for promissory estoppel, the Court categorizes such a claim as “affirmative” or “offensive” promissory estoppel, which North Carolina does not recognize as a claim for relief. Therefore, the Court concludes that Plaintiff has failed to state a claim for promissory estoppel against Gorbec upon which relief can be granted under North Carolina law.

Moreover, even assuming, *arguendo*, that the Court construed Plaintiff’s claim as one for defensive promissory estoppel, the Court finds that, considering all allegations set forth

throughout the Amended Complaint, Plaintiff's claim for promissory estoppel, as alleged, would not meet the threshold requirements under Iqbal. Plaintiff's claim merely recites the elements of promissory estoppel, in that Gorbec allegedly made certain unspecified promises and Plaintiff reasonably relied on those promises. Even taking as true that Gorbec made promises on which Plaintiff reasonably relied, without more information, the Court and Gorbec are left to speculate as to which promises Plaintiff refers and under what circumstances those promises were made. Therefore, as alleged, Plaintiff's claim does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 556 U.S. at 678, 129 S. Ct. at 1949 (citation omitted). Based on the foregoing, the Court will grant Gorbec's Motion to Dismiss Plaintiff's Fifth Claim for Relief, and Plaintiff's claim for promissory estoppel against Gorbec will be dismissed.

5. Plaintiff's Sixth Claim for Relief—Unjust Enrichment (against Gorbec)

Plaintiff also raises a claim for unjust enrichment against Gorbec in its Sixth Claim for Relief. Under North Carolina law, the party claiming unjust enrichment must sufficiently allege that (1) a measurable benefit was conferred on the other party, (2) that party consciously accepted the benefit, and (3) the benefit was not conferred officiously or gratuitously. Primerica Life Ins. Co. v. James Massengill & Sons Constr. Co., 712 S.E.2d 670, 677 (N.C. Ct. App. 2011). "A claim of unjust enrichment is an alternative to a claim based on breach of contract whereby, upon the absence of an actual agreement between the parties, the court implies that a 'quasi-contract' existed and permits a plaintiff to bring an action in restitution to recover the amount of the benefit conferred on the defendant." Volumetrics Med. Imaging, Inc. v. ATL

Ultrasound, Inc., 243 F. Supp. 2d 386, 411 (M.D.N.C. 2003).

In the present case, Plaintiff alleges that it conferred to Gorbec “substantial money and provided the benefits of market research and strategic planning, all of which Gorbec threatens to claim for itself.” (Am. Compl. ¶ 81). Plaintiff further alleges that Gorbec knowingly accepted “these benefits.” (Am. Compl. ¶ 82). In addition, Plaintiff alleges that “[b]ecause of Gorbec’s control over pertinent information, River’s Edge is unable to determine whether or to what extent Gorbec has already begun to carry out its threats,” but “[t]o whatever extent Gorbec retains the benefits at River’s Edge’s expense, [Gorbec] will be unjustly enriched.” (Am. Compl. ¶ 84).

Based on the allegations set forth in the Amended Complaint, the Court finds that Plaintiff has failed to allege the Gorbec has retained any benefit conferred by Plaintiff. Plaintiff merely alleges that Gorbec has threatened to claim certain information or items, but does not allege that Gorbec has actually claimed such information or items. Furthermore, the Court notes that, in Plaintiff’s own words, Plaintiff does not know “whether . . . Gorbec has begun to carry out its threats” to claim anything for itself. (Am. Compl. ¶ 84). Such allegations do not “contain sufficient factual matter, even if accepted as true, to ‘state a claim to relief that is plausible on its face.’” Iqbal, 556 U.S. at 678, 129 S. Ct. at 1949 (citation omitted). Therefore, the Court concludes that Plaintiff has failed to state a claim for unjust enrichment. As such, the Court will grant Gorbec’s Motion to Dismiss Plaintiff’s Sixth Claim for Relief is granted, and Plaintiff’s claim for unjust enrichment against Gorbec will be dismissed.

6. Plaintiff’s Seventh Claim for Relief—Conversion (against Gorbec)

In its Seventh Claim for Relief, Plaintiff raises a claim for conversion against Gorbec. Conversion is defined in North Carolina as “an unauthorized assumption and exercise of the right of ownership over goods or personal chattels belonging to another, to the alteration of their condition to the exclusion of an owner’s rights.” State ex rel. Pilard v. Berninger, 154 N.C. App. 45, 57, 571 S.E.2d 836, 844 (2002) (internal quotations omitted). As such, a party seeking relief for conversion must allege ownership of the property in question and a wrongful deprivation of that property. Id. Furthermore, in cases where the defendant may have come rightfully in possession of the property at some point in time, demand by the owner of the property’s return and refusal by the defendant become necessary elements of the tort. White v. Consol. Planning, Inc., 166 N.C. App. at 310-11, 603 S.E.2d at 165. Moreover, because the “essence of conversion is . . . a wrongful deprivation of [the property] to the owner[,] . . . it is of no importance what subsequent application was made of the converted property, or that defendant derived no benefit from the act.” Berninger, 154 N.C. App. at 57, 571 S.E.2d at 844 (internal quotations omitted).

In its Amended Complaint, Plaintiff alleges ownership of “know-how, intellectual property, and regulatory approvals” developed by Gorbec, for Plaintiff, since 2007. (Am. Compl. ¶ 87). Plaintiff further alleges that Plaintiff demanded that Gorbec provide Plaintiff with the property “embodied and reflected in written form and electronic storage devices,” and that Gorbec refused to do so. (Am. Compl. ¶¶ 87-88, 34). As such, Plaintiff alleges that “Gorbec’s refusal to provide River’s Edge with all physical embodiments of its know-how, intellectual property and regulatory approvals is an unlawful exercise of dominion over River’s Edge’s

property that constitutes conversion.” (Am. Compl. ¶ 89). In its Motion to Dismiss, Gorbec contends that any property it has possessed was possessed legally pursuant to the parties’ agreement. In addition, Gorbec contends that to the extent that Plaintiff alleges that it demanded the return of any specific property, Gorbec contends that it has complied and “has not retained any property that is subject to a demand by River’s Edge.” (Gorbec’s Br., [Doc. #57], at 15-16).

Considering the allegations in the Amended Complaint, the Court notes that, in addition to the requirement that Plaintiff allege the general elements of conversion, Plaintiff must also allege demand and refusal in this case because the facts in Plaintiff’s Amended Complaint supports the notion that Gorbec initially came into possession of the “know-how, intellectual property, and regulatory approvals” as part of its business relationship with Plaintiff. In that regard, the Court first finds that Plaintiff has sufficiently alleged ownership over the “know-how, intellectual property, and regulatory approvals,” developed by Gorbec, for Plaintiff, since 2007. In addition, the Court finds that Plaintiff has sufficiently alleged that it made a demand that Gorbec return the written and electronic forms of the of the property at issue, and that Gorbec subsequently refused.

Based on the foregoing, the Court concludes that Plaintiff has sufficiently alleged the elements of conversion in this case and, therefore, has stated a claim for relief based on conversion. The Court notes that whether, and to what extent, Gorbec may have returned any of the property demanded is a question of fact not properly resolved on a motion to dismiss. Furthermore, the Court notes that, to the extent that Gorbec returned any property in this case,

such return would not necessarily negate the initial act of conversion, as alleged. See Wall v. Colvard, Inc., 268 N.C. 43, 49, 149 S.E.2d 559, 564 (1966) (“After an act of conversion has become complete, an offer to return or restore the property by the wrongdoer will not bar the cause of action for conversion.”). As such, the Court will deny Gorbec’s Motion to Dismiss Plaintiff’s Seventh Claim for Relief, and Plaintiff may proceed on its claim for conversion against Gorbec.

7. Plaintiff’s Eighth Claim for Relief–Misappropriation of Trade Secrets (against Gorbec)

Plaintiff, in its Eighth Claim for Relief, also raises a claim for misappropriation of trade secrets against Gorbec pursuant to the North Carolina Trade Secret Protection Act (“TSPA”).

Under North Carolina law, the TSPA defines a “trade secret” as

business or technical information, including but not limited to a formula, pattern, program, device, compilation of information, method, technique, or process that:

- a. Derives independent actual or potential commercial value from not being generally known or readily ascertainable through independent development or reverse engineering by persons who can obtain economic value from its disclosure or use; and
- b. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

N.C. Gen. Stat. § 66-152. The elements of an action for misappropriation of trade secrets are “(1) [the defendant] knows or should have known of the trade secret; and (2) [the defendant] has had a specific opportunity to acquire it for disclosure or use or has acquired, disclosed, or used it without the express or implied consent or authority of the owner.” N.C. Gen. Stat. § 66-155. To properly plead a claim for misappropriation of trade secrets under the TSPA, “a plaintiff must identify a trade secret with sufficient particularity so as to enable a defendant to

delineate that which he is accused of misappropriating and a court to determine whether misappropriation has or is threatened to occur.” Washburn v. Yadkin Valley Bank & Trust Co., 190 N.C. App. 315, 326, 660 S.E.2d 577, 585 (2008) (internal quotations omitted).

In support of its claim, Plaintiff alleges that it “hired Gorbec to develop know-how and intellectual property exclusively for River’s Edge related to the development of its ANDA products,” (Am. Compl. ¶ 92), and that such “know-how and intellectual property constitutes trade secrets that are owned by River’s Edge.” (Am. Compl. ¶ 94). In addition, Plaintiff alleges that such “know-how and intellectual property” is not commonly known, and that “River’s Edge has taken steps that are reasonable under the circumstances to maintain the secrecy of the know-how and intellectual property.” (Am. Compl. ¶ 93). Plaintiff also alleges that, due to Gorbec’s alleged failure to disclose to Plaintiff the “know-how and intellectual property developed by Gorbec exclusively for River’s Edge,” Plaintiff does not know “exactly what the trade secrets are,” (Am. Compl. ¶ 94), but contends that “*whatever* Gorbec continues to claim ownership of, in relation to the dozens of projects it has undertaken for River’s Edge, is what Gorbec is accused of misappropriating.” (Pl.’s Resp., [Doc. #71], at 18) (emphasis in original). Furthermore, Plaintiff alleges that Gorbec misappropriated the claimed trade secrets “by utilizing the trade secrets for its own benefit, by holding the trade secrets so as to extract additional money from River’s Edge and by threatening to disclose the existence and nature of the trade secrets to others.” (Am. Compl. ¶ 95).

In this case, Plaintiff alleges that it hired Gorbec “to develop know-how and intellectual property exclusively for River’s Edge related to the development of its ANDA products,” and

that such “know-how and intellectual property” constitutes the claimed trade secrets in this case. (Am. Compl. ¶¶ 92, 94). Based on the alleged relationship between the parties, whereby Plaintiff alleges ownership over all know-how and intellectual property associated with the development of the ANDA products by Gorbec and exclusively for Plaintiff, the Court finds that Plaintiff’s identification of the claimed trade secrets, as the know-how and intellectual property related to that ANDA development, enables both Gorbec and the Court to delineate what Gorbec is accused of misappropriating. In addition, the Court finds that Plaintiff has alleged sufficient facts to support its claim that Gorbec misappropriated the claimed trade secrets. Although ultimately, it will be Plaintiff’s initial burden to introduce “substantial evidence” that Gorbec “had a specific opportunity to acquire it for disclosure or use or has acquired, disclosed, or used it without the express or implied consent or authority of the owner,” as required by North Carolina General Statute Section 66-155, the Court concludes that, for purposes of a motion to dismiss, Plaintiff has stated a claim for misappropriation of trade secrets. As such, the Court will deny Gorbec’s Motion to Dismiss Plaintiff’s Eighth Claim for Relief, and Plaintiff may proceed on its claim for misappropriation of trade secrets against Gorbec.

8. Plaintiff’s Ninth Claim for Relief–Punitive Damages (against Gorbec and Gorman)

In its Ninth Claim for Relief, Plaintiff seeks punitive damages against both Gorbec and Gorman. Under North Carolina law, “[p]unitive damages are available, not as an individual cause of action, but as incidental damages to a cause of action.” Collier v. Bryant, 719 S.E.2d 70, 82 (N.C. Ct. App. 2011). In general, courts have held that punitive damages are not recoverable for contract claims, but may be recoverable for tort claims. See Broussard, 155 F.3d

at 346. Specifically, courts have allowed punitive damages for claims alleging constructive fraud, among other tort claims. See Collier, 719 S.E.2d at 82.

With regard to Plaintiff's claim for punitive damages against Gorbec, the Court notes that, based on the standards above, Plaintiff may not seek punitive damages based on its breach of contract claim. However, the Court finds that to the extent that the Court has allowed certain of Plaintiff's tort claims to proceed against Gorbec, the Court will allow Plaintiff's claim for punitive damages to proceed at this time against Gorbec. As such, the Court will deny Gorbec's Motion to Dismiss Plaintiff's Ninth Claim for Relief, and Plaintiff may proceed on its claim for punitive damages against Gorbec, based upon Plaintiff's tort claims that are going forward. The Court notes, however, that Plaintiff carries the ultimate burden of proving the existence of an aggravating factor, namely, fraud, malice, or willful or wanton conduct, by clear and convincing evidence in order to recover punitive damages. N.C. Gen Stat. § 1D-15.

With regard to Plaintiff's claim for punitive damages against Gorman, the Court finds that because the Court has dismissed the only two substantive tort claims against Gorman, that is, Plaintiff's Fourth Claim for Relief for constructive fraud, and Plaintiff's Fifth Claim for Relief for promissory estoppel, there does not exist any remaining claim against Gorman for which Plaintiff could recover punitive damages. As such, the Court will grant Gorman's Motion to Dismiss Plaintiff's Ninth Claim for Relief, and Plaintiff's claim for punitive damages against Gorman will be dismissed.

B. Plaintiff's Motion to Dismiss Gorbec's Amended Counterclaims

As part of its Answer to Plaintiff's Amended Complaint, Gorbec raises six counterclaims against Plaintiff. Each claim will be addressed in turn.

1. **Gorbec's First Amended Counterclaim—Breach of Contract—DESI drugs**

In its First Amended Counterclaim, Gorbec raises a claim for breach of contract related to the parties work with the DESI drugs. As noted above, under North Carolina law, “[t]he elements of a claim for breach of contract are (1) existence of a valid contract and (2) breach of the terms of that contract.” Parker, 182 N.C. App. at 232, 641 S.E.2d at 737 (internal quotations omitted). Formation of a valid contract requires “an agreement to which at least two parties manifest an intent to be bound.” Id. In addition, the terms of the contract must be sufficiently definite to be enforceable. See Horton, 255 N.C. at 679, 122 S.E.2d at 719.

In support of its counterclaim for breach of contract, Gorbec alleges that Plaintiff engaged Gorbec to manufacture DESI drugs beginning in 2007 “as a way of generating cash flow for Gorbec while it developed other projects . . . for River’s Edge.” (Am. Countercl. ¶ 12). Gorbec alleges that manufacture of the DESI drugs was done on a purchase order basis. In addition, Gorbec alleges that the parties agreed that Gorbec would purchase any needed raw materials, “but River’s Edge was ultimately responsible for the costs of those materials” and “River’s Edge agreed to pay for the drugs actually manufactured, or purchase any leftover materials from Gorbec.” (Am. Countercl. ¶ 14). Gorbec alleges that on May 20, 2010, the FDA issued Plaintiff a warning letter “telling [Plaintiff] to cease and desist from manufacturing DESI drugs,” (Am. Countercl. ¶ 18), but that Gorbec did not learn of the warning letter until

it was posted on the FDA website on July 28, 2010. As such, Gorbec alleges that “[f]rom May 20, 2010 until July 28, 2010, Gorbec continued to manufacture DESI drugs at the request of River’s Edge” and “continued to purchase inventory necessary to continue manufacturing the DESI drugs” during that time. (Am. Countercl. ¶ 21).

Gorbec alleges that it stopped manufacturing DESI drugs for Plaintiff on July 29, 2010, due to the FDA warning letter, and further alleges that, at that time, it had approximately \$150,000 worth of inventory that it had purchased for the manufacture of DESI drugs. Gorbec further alleges that it asked Plaintiff to compensate Gorbec for the remaining inventory, but that Plaintiff refused, claiming it had not cancelled any purchase orders. Gorbec alleges that Plaintiff at best only paid Gorbec fifty cents on the dollar for the inventory at issue. Based on this alleged series of events, Gorbec alleges that Plaintiff “breached the agreements to manufacture DESI drugs by failing to perform its obligations . . . including but not limited to its failure to pay, and by breaching the implied covenant of good faith and fair dealing, causing Gorbec damages including . . . the expense incurred in purchasing inventory to the extent not previously paid, as well as the lost revenue due to excess capacity.” (Am. Countercl. ¶ 70).

In its Brief in support of its Motion to Dismiss, Plaintiff first contends that Gorbec unilaterally made the decision to stop production of DESI drugs. As such, Plaintiff contends that Gorbec’s counterclaim does not allege a plausible basis for inferring that Plaintiff “would or did agree to pay Gorbec for materials that were rendered unusable by Gorbec’s own decision to stop manufacturing ‘DESI’ products for River’s Edge.” (Pl.’s Br., [Doc. #73], at 4). However, Plaintiff further contends that, even if there existed an agreement that Plaintiff would

pay costs associated with DESI inventory under these circumstances, such an agreement would have been void from the start due to illegality. Specifically, Plaintiff contends that because DESI drugs are not approved by the FDA, and are therefore “on the market illegally,” the parties could not enter into a valid agreement to produce such DESI drugs. (Pl.’s Br., [Doc. #73], at 4). As such, Plaintiff raises the rather surprising contention that any agreement between the parties related to DESI drugs production is unenforceable, and Gorbec cannot, therefore, state a claim for breach of contract for which relief can be granted. Moreover, Plaintiff contends that even if the alleged agreement is not barred due to illegality, it is barred based on the doctrine of accord and satisfaction. Plaintiff contends that Gorbec’s acceptance of Plaintiff’s offer to pay half of what Gorbec wanted for the inventory at issue resulted in a “compromise agreement.” As such, Plaintiff contends that, that “[t]his compromise agreement, having been fully executed (as alleged in ¶ 26), superseded any ‘general arrangement’ the parties might have had, and precludes Gorbec from now enforcing the ‘general arrangement’.” (Pl.’s Br., [Doc. # 73], at 5). Therefore, Plaintiff contends that the Court should dismiss Gorbec’s First Amended Counterclaim for breach of contract with regard to the DESI drugs.

In its Response, Gorbec contends that the agreement between the parties is not barred due to illegality. Gorbec contends that the FDA guidance regarding DESI drugs, cited by Plaintiff, discusses the discretionary nature of the FDA’s enforcement in stopping DESI production, and notes that the FDA often allows grace periods with regard to cessation of production. As such, Gorbec contends that the agreement to produce DESI drugs is enforceable and that the Amended Counterclaims sufficiently state a claim for breach. With

regard to Plaintiff's contention that the parties' agreement is now barred by the doctrine of accord and satisfaction, Gorbec contends that "the fact that River's Edge paid a portion of the money owed on the DESI drugs does not excuse it from paying the balance owed." (Gorbec's Resp., [Doc. #78], at 6).

In considering Gorbec's First Amended Counterclaim, the Court notes that Plaintiff's contention that the agreement alleged by Gorbec is an illegal contract, and therefore unenforceable, raises an affirmative defense to Gorbec's breach of contract claim. See Orthodontic Ctrs. of America, Inc. v. Hamachi, 151 N.C. App. 133, 135, 564 S.E.2d 573, 575 (2002). Courts may reach the merits of an affirmative defense when ruling on a motion to dismiss only "if all facts necessary to the affirmative defense 'clearly appear[] on the face of the [pleading].'" Goodman v. Praxair, Inc., 494 F.3d 458, 464 (4th Cir. 2007) (quoting Richmond, Fredericksburg & Potomac R.R. v. Forst, 4 F.3d 244, 250 (4th Cir. 1993)). In the present case, Plaintiff appears to contend that production of the DESI drugs at issue is *per se* illegal, based on FDA compliance directives. See Guidance for FDA Staff and Industry: Marketed Unapproved Drugs – Compliance Policy Guide: Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs ("Guidance Manual"), (2011). As such, Plaintiff appears to contend that Gorbec's claim for breach of contract is illegal on its face, simply because it alleges production of DESI drugs, and is therefore subject to dismissal at this stage of the litigation. The Court notes, however, that even the Guidance Manual cited by Plaintiff states that "[s]ome unapproved marketed products are undergoing DESI reviews in which a final determination regarding efficacy has not yet been made. . . . It is the Agency's longstanding policy that products subject

to an ongoing DESI proceeding may remain on the market during the pendency of the proceeding.” (Guidance Manual at 10). In addition, the Guidance Manual distinguishes those products presently undergoing DESI review, which may remain on the market until a final determination is made, and those products subject to completed DESI proceedings, which the FDA considers to be “marketed illegally.” (Guidance Manual at 10-11). Plaintiff, in its Amended Complaint, appears to acknowledge this distinction, at least to some extent, by alleging that “FDA policy has been to permit the marketing of [DESI] products pending a review process.” (Am. Compl. ¶ 19).

In considering the allegations in this case, the Court notes that Gorbec alleges that the parties entered into the agreement to produce DESI drugs in 2007. Furthermore, Gorbec alleges that the FDA issued a letter ordering cessation of the DESI drugs in 2010, at which point Gorbec stopped production. Gorbec does not, however, allege that the FDA had ordered cessation of the DESI drugs at any time prior to 2010. As such, all facts necessary to determine whether contracting to produce the DESI drugs at issue was illegal in 2007 do not clearly appear on the face of Gorbec’s Amended Counterclaims. Therefore, the Court will deny Plaintiff’s Motion to Dismiss Gorbec’s First Amended Counterclaim at this stage of the litigation based on a purported claim of illegality.

With regard to Plaintiff’s contention that Gorbec’s breach of contract claim is barred by the doctrine of accord and satisfaction, Plaintiff again raises an affirmative defense. Under North Carolina law,

[e]stablishing an accord and satisfaction affirmative defense as a matter of law requires evidence that permits no reasonable inference to the contrary and that shows the

“unequivocal” intent of one party to make and the other party to accept a lesser payment in satisfaction and discharge of a larger claim.

Moore v. Frazier, 63 N.C. App. 476, 478–79, 305 S.E.2d 562, 564 (1983). In the present case, the Court finds that the allegations set forth in Gorbec’s Amended Counterclaims do not clearly show that the parties agreed that acceptance of half of the total inventory cost eliminated Gorbec’s right to enforce the alleged original agreement regarding DESI production. Therefore, the Court finds that all facts necessary to determine whether a full accord and satisfaction occurred do not clearly appear on the face of Gorbec’s Amended Counterclaims. As such the Court will deny Plaintiff’s Motion to Dismiss Gorbec’s First Amended Counterclaim at this stage of the litigation based on a purported claim of accord and satisfaction.

Based on the foregoing, the Court concludes that Gorbec has sufficiently alleged that an agreement existed between the parties, with specific terms regarding production of DESI drugs, and payments owed thereunder, and that Plaintiff breached that agreement. In addition, as set forth herein, the Court finds that Gorbec’s First Amended Counterclaim is not barred by any affirmative defenses for purposes of resolving Plaintiff’s Motion to Dismiss. As such, the Court will deny Plaintiff’s Motion to Dismiss Gorbec’s First Amended Counterclaim, and Gorbec may proceed on its counterclaim for breach of contract regarding the DESI drugs.

2. Gorbec’s Second Amended Counterclaim–Breach of Contract–ANDAs

In addition to its counterclaim for breach of contract with regard to the DESI drugs, Gorbec, in its Second Amended Counterclaim, raises a counterclaim for breach of contract with regard to the ANDA drugs. In support of that counterclaim, Gorbec alleges an agreement between the parties, beginning in 2007, whereby the parties “would work together to develop

new drugs for FDA approval through the ANDA process and that Gorbec would manufacture any drugs that were eventually approved.” (Am. Countercl. ¶ 49). Gorbec further alleges that, since 2007, it “has performed the necessary regulatory work with the FDA in an attempt to get the drugs approved,” including required stability testing and continued communication with the FDA. (Am. Countercl. ¶ 31, 39, 45). Gorbec alleges that the parties would agree to quotations for ANDA projects to be paid in installments over a designated period of time. In addition, Gorbec alleges that additional costs often arose in relation to “deficiency” work required by the FDA, and certain “pass-through costs,” such as costs for laboratory reagents and equipment. Gorbec alleges that Plaintiff agreed to pay for these “pass through costs” and any costs associated with the “deficiency” work required by the FDA, but alleges further that Plaintiff either failed to pay for those costs or made payment contingent on certain concessions by Gorbec. In addition, Gorbec alleges that Plaintiff failed to pay for stability testing required by the FDA. Furthermore, Gorbec alleges that, although the parties contemplated that they would enter into a manufacturing agreement, under which Gorbec would manufacture the drugs approved by the FDA, Plaintiff has failed to enter into such an agreement with Gorbec.

Moreover, Gorbec alleges that the parties entered into an agreement on October 12, 2010, whereby the parties agreed that Plaintiff “would make the last payment on each ANDA project, totaling [\$265,901.00], as well as 25% of previous work Gorbec had performed on FDA deficiencies pursuant to ANDA project addenda, totaling approximately [\$90,000.00],” and that Plaintiff would “pay Gorbec for reasonable future expenses in responding to FDA deficiency requests outside the scope of the original quotation.” (Am. Countercl. ¶ 55). Gorbec alleges

that Plaintiff has failed to make the payments contemplated by that agreement. In addition, Gorbec alleges that the parties entered into a separation agreement on November 30, 2010, whereby the parties agreed that Gorbec would file the ANDA for one specific product and would “assist River’s Edge in effecting technology transfers without incurring out of pocket costs.” (Am. Countercl. ¶ 57). Gorbec also alleges that under the November 30, 2010, separation agreement, “the parties agreed that holdback monies would be paid on approval and previous addendum (deficiency) work would be paid at \$.25 per dollar,” and that Plaintiff would assign two ANDAs to Gorbec. (Am. Countercl. ¶ 57). Gorbec alleges that Plaintiff has failed to meet its obligations set forth in the November 30, 2010, separation agreement.

In its Motion to Dismiss, Plaintiff raises factual disputes regarding Plaintiff’s alleged failure to pay Gorbec and Plaintiff’s alleged failure to meet the obligations under the November 30, 2010, separation agreement. In addition, Plaintiff contends that Gorbec’s allegations regarding the alleged October 12, 2010, agreement fail for lack of any alleged consideration. Finally, Plaintiff contends that the agreement by the parties to enter into a manufacturing agreement is merely an agreement to agree, as there are no specific terms of the agreement outlined, such that the Court could find breach.

Based on the foregoing, the Court finds that Gorbec has alleged certain valid agreements between the parties that contain sufficiently definite terms from which the Court could infer liability for breach. Specifically, the Court finds that Gorbec has alleged an agreement between the parties whereby Gorbec would conduct ANDA-related work, and Plaintiff would pay Gorbec for that work and for certain associated costs. The Court further finds that Gorbec has

stated a claim for breach of that contract with regard to Plaintiff's alleged failure to pay for the work done by Gorbec, including, but not limited to, "deficiency" work and stability testing, and Plaintiff's alleged failure to pay "pass through costs." In addition, the Court finds that Gorbec has alleged valid agreements between the parties on October 12, 2010, and November 30, 2010, and has stated a claim for breach of those agreements with regard to Plaintiff's alleged failure to meet its obligations under each agreement, as alleged. To the extent that Plaintiff raises factual disputes with regard to whether it breached any agreements, those matters are not properly before the Court on Plaintiff's Motion to Dismiss, but may be raised at a later stage in these proceedings. In addition, to the extent that Plaintiff contends that the October 12, 2010, agreement fails for lack of consideration, such a contention raises an affirmative defense which is more properly resolved at a later stage in these proceedings. See Deal v. Christenbury, 50 N.C. App. 600, 605, 274 S.E.2d 867, 871 (1981). As such, the Court concludes that Gorbec's has stated a claim for breach of contract with regard to ANDA-related work, as set forth herein.

However, the Court further concludes that Gorbec has failed to state a claim for breach of contract regarding Plaintiff's alleged failure to enter into a manufacturing agreement. Gorbec alleges that, as part of the overall agreement between the parties, the parties *anticipated* that they would eventually enter into a manufacturing agreement. The Court notes, however, that Gorbec does not allege a time by when the parties anticipated that they would enter into any manufacturing agreement. The Court notes that Gorbec does allege that it submitted a proposed manufacturing agreement to Plaintiff in the fall of 2010, which Plaintiff thereafter rejected. However, the Court notes that Gorbec does not allege that Plaintiff, in the fall of

2010, or at any other time, refused outright to *ever* enter into a manufacturing agreement. In addition, the Court notes that Gorbec does not allege that the fall of 2010 marked the passage of the agreed upon period by which the manufacturing agreement must have been entered, such that the Court could infer Plaintiff's refusal to enter into a manufacturing agreement as a breach of the alleged agreement. Furthermore, Gorbec does not allege that Plaintiff granted manufacturing rights of the ANDA drugs at issue to any other party, in violation of any alleged agreement under which Gorbec had a right to eventually manufacture the drugs. Based on the foregoing, the Court concludes that Gorbec has not stated a claim for breach of contract with regard to Plaintiff's alleged failure to enter into a manufacturing agreement.

Therefore, the Court will grant in part and deny in part Plaintiff's Motion to Dismiss Gorbec's Second Amended Counterclaim. Specifically, to the extent that Gorbec alleges breach based on Plaintiff's failure to enter into a manufacturing agreement, the Court concludes that Gorbec has failed to state a claim for breach of contract. In that regard, the Court will grant Plaintiff's Motion to Dismiss, and Gorbec will not be allowed to proceed on this aspect of its counterclaim. However, to the extent that Gorbec alleges breach based on Plaintiff's alleged failure to pay Gorbec for work done in the ANDA process and for associated costs, Plaintiff's alleged failure to meet its obligations alleged under the October 12, 2010, agreement, and Plaintiff's alleged failure to meet its obligations alleged under the November 30, 2010, separation agreement, the Court concludes that Gorbec has stated a claim for breach of contract. In that regard, the Court will deny Plaintiff's Motion to Dismiss, and Gorbec may proceed on its counterclaim for breach of contract, as stated herein.

3. **Gorbec's Third Amended Counterclaim—Unjust Enrichment**

In its Third Amended Counterclaim, Gorbec raises a claim for unjust enrichment. As noted above, under North Carolina law, the party claiming unjust enrichment must sufficiently allege that (1) a measurable benefit was conferred on the other party, (2) that party consciously accepted the benefit, and (3) the benefit was not conferred officiously or gratuitously. Primerica Life Ins. Co., 712 S.E.2d 670, 677 (N.C. Ct. App. 2001). “A claim of unjust enrichment is an alternative to a claim based on breach of contract whereby, upon the absence of an actual agreement between the parties, the court implies that a ‘quasi-contract’ existed and permits a plaintiff to bring an action in restitution to recover the amount of the benefit conferred on the defendant.” Volumetrics Medical Imaging, Inc., 243 F. Supp. 2d at 411. While a party cannot recover under both a claim for breach of contract and a claim for unjust enrichment, a party may pursue alternative claims at the motion to dismiss stage of the litigation. See Park v. American Circuit Breaker Corp., No. 1:06cv00549, 2008 WL 4596234, at *3 (M.D.N.C. Oct. 14, 2008).

In support of its counterclaim for unjust enrichment, Gorbec alleges that Plaintiff accepted non-gratuitous benefits from Gorbec in the form of the DESI drugs inventory, stability testing services for DESI and ANDA drugs, and ANDA deficiency work, for which Plaintiff has failed to fully compensate Gorbec. In its Motion to Dismiss, Plaintiff contends that Gorbec cannot recover under a theory of unjust enrichment because the allegations set forth in the Third Amended Counterclaim are the same as those set forth in Gorbec's breach of contract counterclaims. Gorbec, in response, contends that the unjust enrichment counterclaim is meant to be an alternative to the breach of contract counterclaims, “[s]hould the contracts prove

illusory or otherwise unenforceable.” (Gorbec’s Resp., [Doc. #78], at 10).

Based on the allegations, the Court finds that Gorbec has sufficiently alleged that it conferred to Plaintiff certain non-gratuitous benefits, which Plaintiff accepted in this case. Therefore, the Court concludes that Gorbec has sufficiently alleged a claim for unjust enrichment, as an alternative to its breach of contract counterclaims, such that the counterclaim may proceed at this stage of the litigation. As such, the Court will deny Plaintiff’s Motion to Dismiss Gorbec’s Third Amended Counterclaim, and Gorbec may proceed on its counterclaim for unjust enrichment. The Court notes, however, that Gorbec cannot recover under both contract and unjust enrichment theories, and that the unjust enrichment counterclaim may ultimately be subject to dismissal if evidence shows that a valid and enforceable contracts covers the dispute between the parties.

4. **Gorbec’s Fourth Amended Counterclaim–Negligent Misrepresentation**

In its Fourth Amended Counterclaim, Gorbec raises a counterclaim for negligent misrepresentation. North Carolina has adopted the definition of negligent misrepresentation set forth in the Restatement (Second) of Torts, whereby “[o]ne who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.” Raritan River Steel Co. v. Cherry, Bekaert & Holland, 322 N.C. 200, 209, 367 S.E.2d 609, 615 (1988) (quoting Restatement (Second) of Torts § 552 (1977)). To survive a

motion to dismiss, the party raising the negligent misrepresentation claim must sufficiently allege (1) that it justifiably relied, (2) to its detriment, (3) on information prepared without reasonable care, (4) by one who owed the relying party a duty of care. Simms v. Prudential Life Ins. Co. of America, 140 N.C. App. 529, 532, 537 S.E.2d 237, 240 (2000).

In support of its counterclaim, Gorbec alleges that Plaintiff made certain representations relating to Plaintiff's status with the FDA over the course of their business relationship which "were untrue when made," and on which Gorbec justifiably relied to its detriment. (Am. Countercl. ¶ 93). Specifically, Gorbec alleges that in May of 2007, Plaintiff "retained regulatory experts who had stated that River's Edge could continue to manufacture DESI drugs," and River's Edge relayed that information, and made its own representations to that effect, to Gorbec. (Am. Countercl. ¶ 12). Gorbec further alleges that it was reluctant to manufacture DESI drugs because the FDA had began barring their manufacture in 2006, and that it "would not have agreed to manufacture DESI drugs or agreed to continue the manufacture of DESI drugs but for the express representations of River's Edge that it would be allowed to continue to sell DESI drugs." (Am. Countercl. ¶¶ 11, 89).

Gorbec alleges that the end of DESI manufacturing came in 2010, following issuance of a warning letter from the FDA, which ordered Plaintiff to stop selling DESI drugs and indicated that non-compliance could "be a basis for the withholding of FDA approval for any pending drug applications by [River's Edge]." (Am. Countercl. ¶ 22). Gorbec further alleges that the FDA based its warning on the FDA's 2009 inspection of Plaintiff's facilities during which the FDA found "significant violations of federal law." (Am. Countercl. ¶ 15, 18). Gorbec alleges

that it had asked Plaintiff for the paperwork resulting from the 2009 inspection shortly after its completion, but Plaintiff refused “on the basis of the false assertion that [the paperwork] contained the proprietary information of other manufacturers.” (Am. Countercl. ¶ 17). In addition, Gorbec alleges that the FDA issued the warning letter to Plaintiff in May of 2010, but that Plaintiff did not tell Gorbec about the letter at any time. Rather, Gorbec alleges that it learned of the letter’s existence and content after the FDA posted the letter on its website in July of 2010. Gorbec alleges that, as a result of the order contained in the FDA letter, Gorbec stopped manufacturing DESI drugs, which resulted in harm to Gorbec due to excess inventory costs incurred between May 2010 and July 2010, loss of its source of income to offset ANDA production costs, and potential harm to its reputation with the FDA for continuing DESI production after issuance of the warning letter.

In addition, Gorbec alleges that it justifiably relied on the above “representations and assurances about the viability of its operations under FDA auspices,” with regard to its ANDA work. (Am. Countercl. ¶ 90). Specifically, Gorbec alleges that it agreed to work at a reduced cost based on Plaintiff’s promise that the parties would enter into a manufacturing agreement whereby Gorbec would manufacture drugs eventually approved by the FDA. (Am. Countercl. ¶ 54). Gorbec further alleges, however, that it “would not have agreed to perform work for River’s Edge at a considerable discount if it knew the truth of River’s Edge’s situation and business practices.” (Am. Countercl. ¶ 91). Gorbec alleges that Plaintiff knew that Gorbec would use Plaintiff’s representations as guidance in deciding whether to engage in the business relationship with Plaintiff, and further alleges that Plaintiff made the representations without the

due care owed to Gorbec in the parties' business relationship.

According to Gorbec, the “crux of [its] claim is Plaintiff’s failure to tell the truth about its regulatory status with the FDA.” (Gorbc’s Resp., [Doc. #78], at 11-12). Based on the allegations, the Court notes that Gorbec’s negligent misrepresentation counterclaim includes allegations of both affirmative misrepresentations and failures to disclose certain information related to Plaintiff’s FDA status. With regard to the alleged affirmative misrepresentations related to DESI manufacturing, the Court finds that Gorbec has failed to sufficiently allege that Plaintiff acted without reasonable care in guiding Gorbec in its business dealings, when Plaintiff made or relayed statements in 2007 and 2008 that DESI production could continue. The Court notes that Gorbec concedes that it knew that the FDA had begun barring DESI manufacturing across the industry in 2006, and understood that such manufacturing would not be perpetual. (Am. Countercl. ¶ 11; Gorbec’s Resp., [Doc. #78], at 12). The Court further notes that although Gorbec alleges that the FDA conducted an inspection of Plaintiff’s facilities in 2009, from which violations were ultimately found, Gorbec does not allege that Plaintiff had been subject to any FDA inquiry or inspection regarding DESI production, or any other matter, prior to making the alleged statements in 2007 and 2008. As such, the Court cannot reasonably infer, based on Gorbec’s allegations, that Plaintiff did or should have known that the FDA had a negative impression regarding Plaintiff’s manufacturing of DESI drugs in 2007, such that Plaintiff could be liable for representing to Gorbec that DESI production could continue for a period of time. Therefore, the only alleged misrepresentations that could be inferred to have guided Gorbec in its business dealings were alleged to have been made in 2007 and 2008, prior to any allegation

that there existed a potential regulatory issue between Plaintiff and the FDA. As such, to the extent that Gorbec alleges affirmative misrepresentations in this case, the Court concludes that Gorbec has failed to state a claim for negligent misrepresentation.

In addition, to the extent that Gorbec claims that Plaintiff failed to disclose certain information, such as the existence of the FDA warning letter in 2010, or information regarding the FDA inspection completed in 2009, such a claim would be for negligent omission or concealment, rather than for negligent misrepresentation. This Court has previously found that no such claim currently exists under North Carolina law. See Breeden v. Richmond Cmty. Coll., 171 F.R.D. 189, 202-03 (M.D.N.C. 1997). Therefore, to the extent that Gorbec bases its negligent misrepresentation counterclaim on negligent concealment or omission, as opposed to affirmative misrepresentation, the Court concludes that Gorbec fails to state a claim upon which relief can be granted. As such, the Court will grant Plaintiff's Motion to Dismiss Gorbec's Fourth Amended Counterclaim, and Gorbec's counterclaim for negligent misrepresentation will be dismissed.

5. Gorbec's Fifth Amended Counterclaim—Fraud

Gorbec, in its Fifth Amended Counterclaim, also raises a counterclaim for fraud against Plaintiff based on the same or similar conduct alleged in support of its negligent misrepresentation counterclaim. As with the negligent misrepresentation counterclaim, Gorbec alleges both affirmative representations and fraudulent omissions. With regard to the alleged affirmative fraudulent acts, Gorbec again alleges that Plaintiff made false representations regarding the continuation of DESI production, as set forth above. Gorbec further alleges that

these statements were false when made and were made with the intent to deceive. In addition, Gorbec alleges that Plaintiff made material misrepresentations when it told Gorbec that “if Gorbec performed ANDA work at a reduced cost, Gorbec would receive the manufacturing work for any products eventually approved.” (Am. Countercl. ¶ 101). Gorbec alleges no agreement was ever reached, that Plaintiff’s statement regarding entry into a manufacturing agreement for ANDA drugs was false when made, and that Plaintiff made the statement with the intent to deceive Gorbec and to induce Gorbec to work for a lower price.

With regard to the alleged fraudulent omissions, Gorbec alleges (1) that Plaintiff refused to disclose to Gorbec the paperwork generated pursuant to a 2009 FDA inspection of River’s Edge’s facility, after Gorbec asked for that information; (2) that Plaintiff failed to disclose to Gorbec the May 2010 warning letter from the FDA which ordered River’s Edge to stop DESI work; and (3) that, upon information and belief, Plaintiff failed to inform Gorbec that Plaintiff was organizing Kylemore Pharmaceuticals “in an attempt to circumvent anticipated FDA sanctions against River’s Edge.” (Am. Countercl. ¶ 106).

Under North Carolina law, the essential elements of fraud are: “(1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party.” Forbis v. Neal, 361 N.C. 519, 526-27, 649 S.E.2d 382, 387 (2007) (internal quotations omitted). Such a claim requires a showing that the plaintiff “acted or refrained from acting in a certain manner due to defendant’s representations” and that reliance on the false representations was “justified or reasonable.” Pleasant Valley Promenade v. Lechmere, Inc., 120 N.C. App. 650, 663, 464

S.E.2d 47, 57 (1995). In addition, unlike a claim for negligent misrepresentation, which must be based on only affirmative misrepresentations and not on concealment or nondisclosure, a party can base its claim for fraud on concealment or nondisclosure. See Breeden, 171 F.R.D. at 194. In such cases, the plaintiff “must additionally allege that all or some of the defendants had a duty to disclose material information to him as silence is fraudulent only when there is a duty to speak.” Id. A duty to disclose may arise from the existence of a fiduciary relationship or where “one party has taken affirmative steps to conceal material facts from the other.” Id. at 196.

In considering whether Gorbec has sufficiently alleged a claim of fraud in the present case, the Court also notes that Federal Rule of Civil Procedure 9(b) requires the party alleging fraud “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Specifically, a party must identify the time, place, and contents of the allegedly false statements, the identity of the person making the representation, and what was obtained as a result of the fraudulent misrepresentation. See Breeden, 171 F.R.D. at 195. Moreover,

[i]n order to comply with the pleading requirements of Rule 9(b) with respect to fraud by omission, a plaintiff usually will be required to allege the following with reasonable particularity: (1) the relationship or situation giving rise to the duty to speak, (2) the event or events triggering the duty to speak, and/or the general time period over which the relationship arose and the fraudulent conduct occurred, (3) the general content of the information that was withheld and the reason for its materiality, (4) the identity of those under a duty who failed to make such disclosures, (5) what those defendant(s) gained by withholding information, (6) why plaintiff’s reliance on the omission was both reasonable and detrimental, and (7) the damages proximately flowing from such reliance.

Id. “However, a court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied: ‘(1) that the defendant has been made aware of the particular circumstances for which

[it] will have to prepare a defense at trial, and (2) that plaintiff has substantial pre-discovery evidence of those facts.” Adams v. NVR Homes, Inc., 193 F.R.D. 243, 250 (D. Md. 2000) (quoting Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999)). Finally, “[a]llegations of fraud may be made ‘upon information and belief’ only when the matters are particularly within the defendants’ knowledge, and facts are stated upon which the belief is founded.” Breeden, 171 F.R.D. at 197 (citing Andrews v. Fitzgerald, 823 F. Supp. 356, 375 (M.D.N.C. 1993)).

Based on the allegations in the present case, and the standards set forth in Rule 9, the Court concludes that Gorbec has failed to state a claim for fraud based on the affirmative representations alleged in this case. With regard to Plaintiff’s alleged statements that DESI manufacturing could continue, the Court previously concluded that Gorbec failed to state a claim for negligent misrepresentation based on a failure to allege that Plaintiff acted without reasonable care in making the statements. Based on that conclusion, and the discussion set forth above, the Court further concludes that the same allegations would not support Gorbec’s claim that such statements were made with intent to deceive for purposes of this fraud counterclaim. With regard to Plaintiff’s alleged promise to enter into a manufacturing agreement with Gorbec, the Court finds that Gorbec has failed to allege facts supporting its claim that Plaintiff made this statement with the intent to deceive Gorbec and to induce Gorbec to work for a lower price. The Court notes that Gorbec alleges that the parties engaged in negotiations, some as late as the fall of 2010, regarding the terms of a manufacturing agreement. (Am. Countercl. ¶ 60). As noted in the discussion for Gorbec’s Second Amended Counterclaim, Gorbec does not allege

that Plaintiff indicated it would never enter into a manufacturing agreement, nor does Gorbec allege that Plaintiff entered into a manufacturing agreement with another party. Rather, the Court notes that Gorbec only alleges that the parties anticipated ultimately making an manufacturing agreement, but had yet to set the terms. Based on Gorbec's allegations, the Court cannot reasonably infer that Plaintiff intended to deceive Gorbec when it agreed to eventually enter into a manufacturing agreement with Gorbec. As such, the Court concludes that Gorbec has failed to state a claim for fraud based on affirmative representations, as set out herein.

However, unlike with Gorbec's negligent misrepresentation counterclaim, the Court concludes that, to the extent that Gorbec raises a counterclaim for fraud based on concealment or nondisclosure, Gorbec has stated a claim for relief with regard to Plaintiff's alleged failure to disclose information related to the 2009 FDA inspection and the 2010 FDA warning letter. In so concluding, the Court notes, as stated above, that to state a claim for fraud based on concealment or non-disclosure, Gorbec must first sufficiently allege that Plaintiff had a duty to speak in this case. Based on Gorbec's Amended Counterclaims, the Court finds that Gorbec has alleged sufficient facts to support such a duty. The Court notes that Gorbec alleges a business relationship between Plaintiff and Gorbec based, at least in part, on effectively communicating with the FDA and abiding by FDA requirements for purposes of manufacturing the products involved in this case. Although Gorbec does not allege a fiduciary relationship between the parties, the Court finds that Gorbec does allege facts to support a duty to disclose based on Plaintiff's alleged knowledge of the contents of the paperwork from the 2009 FDA

inspection and the 2010 FDA warning letter issued based on violations found in 2009, which Gorbec alleges Plaintiff knew were material to the business relationship, and knew that Gorbec could not obtain until the FDA made such information public. In addition, the Court finds that Gorbec has sufficiently alleged facts as to why its reliance on the omissions were reasonable and detrimental and as to what Plaintiff allegedly gained by withholding the FDA information.

However, to the extent that Gorbec alleges, based upon information and belief, that Plaintiff “failed to inform Gorbec it was organizing . . . Kylemore Pharmaceuticals, in an attempt to circumvent anticipated FDA sanctions,” (Am. Countercl. ¶ 106), the Court finds that Gorbec has not alleged facts to support its belief. The allegation that Kylemore Pharmaceuticals was formed by Plaintiff shortly after the 2009 FDA inspection of Plaintiff’s facilities is not sufficient for the Court to reasonably infer the purpose alleged upon information and belief, that is, that Plaintiff formed Kylemore Pharmaceuticals to “circumvent anticipated FDA sanctions.”

Based on the foregoing, the Court will grant in part and deny in part Plaintiff’s Motion to Dismiss Gorbec’s Fifth Amended Counterclaim. Specifically, to the extent that Gorbec raises a counterclaim for affirmative acts of fraud based on statements related to continuing DESI products, and to the extent that Gorbec raises a counterclaim for fraud based upon its information or belief of Plaintiff’s basis for forming Kylemore Pharmaceutical, the Court concludes that Gorbec has failed to state a claim upon which relief can be granted. In that regard, the Court will grant Plaintiff’s Motion to Dismiss, and Gorbec will not be allowed to proceed on these aspects of its counterclaim for fraud. However, to the extent that Gorbec alleges fraudulent concealment or nondisclosure based on Plaintiff’s alleged failure to disclose

information related to the 2009 FDA inspection and the 2010 FDA warning letter, the Court concludes that Gorbec has stated a claim for relief. In that regard, the Court will deny Plaintiff's Motion to Dismiss, and Gorbec may proceed on its counterclaim for fraud, as limited herein.

6. Gorbec's Sixth Amended Counterclaim—Unfair and Deceptive Trade Practices

In its Sixth Amended Counterclaim, Gorbec raise a counterclaim for unfair and deceptive trade practices pursuant to North Carolina General Statute § 75-1.1. Under North Carolina law, a party raising a claim for unfair and deceptive trade practices must allege “(1) defendant committed an unfair or deceptive act or practice, (2) the action in question was in or affecting commerce, and (3) the act proximately caused the injury to the plaintiff.” Dalton v. Camp, 353 N.C. 647, 656, 548 S.E.2d 704, 711 (2001). An act or practice is “unfair if it is unethical or unscrupulous, and it is deceptive if it has a tendency to deceive.” Id. “[P]roof of actual deception is not required.” Marshall v. Miller, 302 N.C. 539, 548, 276 S.E.2d 397, 403 (1981).

Gorbec bases its counterclaim for unfair and deceptive trade practices on the same alleged misrepresentations and omissions discussed above as part of Gorbec's counterclaims for negligent misrepresentation and fraud. Gorbec alleges that these misrepresentations and omissions constitute deceptive acts within the meaning of North Carolina General Statute § 75-1.1. To the extent that the Court has already concluded that Gorbec has stated a claim for fraud based on concealment or nondisclosure, the Court further concludes that the factual allegations supporting such a claim also support Gorbec's claim that Plaintiff engaged in conduct that has a tendency to deceive. Cf. Sutton v. Driver, 712 S.E.2d 318, 326 (N.C. Ct. App. 2011) (“Proof

of fraud necessarily constitutes a violation of the prohibition against unfair and deceptive trade practices.” (internal quotations omitted)). Therefore, the Court concludes that Gorbec has stated a claim for unfair and deceptive trade practices. As such, the Court will deny Plaintiff’s Motion to Dismiss Gorbec’s Sixth Amended Counterclaim, and Gorbec may proceed on its counterclaim for unfair and deceptive trade practices.

IV. CONCLUSION

Based on the Foregoing, the Motions to Dismiss are resolved as follows:

With regard to Defendant Gorbec Pharmaceutical Services, Inc.’s Motion to Dismiss [Doc. #56], the Court will grant in part and deny in part Gorbec’s Motion, as set out herein. Specifically, the Court will grant Gorbec’s Motion to Dismiss as to Plaintiff’s Fifth and Sixth Claims for Relief, and, as such, Plaintiff’s Fifth and Sixth Claims for Relief against Gorbec for Promissory Estoppel and Unjust Enrichment will be dismissed. Furthermore, the Court will grant in part and deny in part Gorbec’s Motion to Dismiss as to Plaintiff’s Second and Third Claims for Relief, and, as such, Plaintiff may only proceed with its Second and Third Claims for Relief against Gorbec for Breach of Contract and Breach of Fiduciary Duty, as limited herein. Finally, the Court will deny Gorbec’s Motion to Dismiss as to Plaintiff’s Fourth, Seventh, Eighth, and Ninth Claims for Relief, and, as such, Plaintiff may proceed with its Fourth, Seventh, Eighth, and Ninth Claims for Relief against Gorbec for Constructive Fraud, Conversion, Misappropriation of Trade Secrets, and Punitive Damages.

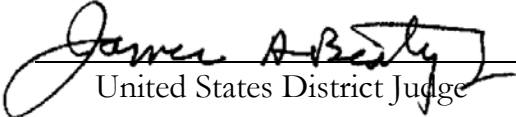
Furthermore, with regard to Defendant J. Michael Gorman’s Motion to Dismiss the Amended Complaint [Doc. #59], the Court will grant Gorman’s Motion to Dismiss as to all

Claims of Relief asserted against Gorman, and all such claims will be dismissed.

Finally, with regard to Plaintiff River's Edge Pharmaceuticals, LLC's Motion to Dismiss Amended Counterclaims [Doc. #70], the Court will grant in part and deny in part Plaintiff's Motion, as set out herein. Specifically, the Court will grant Plaintiff's Motion to Dismiss Gorbec's Fourth Amended Counterclaim and, as such, Gorbec's Fourth Amended Counterclaim for Negligent Misrepresentation will be dismissed. Furthermore, the Court will grant in part and deny in part Plaintiff's Motion to Dismiss Gorbec's Second and Fifth Amended Counterclaims, and, as such, Gorbec may only proceed with its Second and Fifth Amended Counterclaims for Breach of Contract—ANDAs and Fraud, as limited herein. Finally, the Court will deny Plaintiff's Motion to Dismiss Gorbec's First, Third, and Sixth Amended Counterclaims, and, as such, Gorbec may proceed on its First, Third, and Sixth Amended Counterclaims for Breach of Contract—DESI drugs, Unjust Enrichment, and Unfair and Deceptive Trade Practices.

An Order will be filed contemporaneously herewith.

This the 25th day of April, 2012.


United States District Judge