UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRYAN CORPORATION, Plaintiff, v. CHEMWERTH, INC., Defendant.	)	**FILED UNDER SEAL**
CHEMWERTH, INC., Third-Party Plaintiff, v. WALDMAN BIOMEDICAL CONSULTANCY, INC. and DR. ALAN A. WALDMAN, Third-Party Defendants.	)	CIVIL ACTION NO. 12-10446-MLW

REVISED MEMORANDUM OF DECISION AND ORDER ON PARTIES' MOTIONS FOR SUMMARY JUDGMENT

April 2, 2015

DEIN, U.S.M.J.

I. INTRODUCTION

This action arises out of an alleged oral agreement pursuant to which the plaintiff, Bryan Corporation ("Bryan"), agreed to purchase the pharmaceutical ingredient Tobramycin Sulfate ("TS") from the defendant, ChemWerth, Inc. ("ChemWerth"). Bryan alleges that in order to induce it to purchase TS from ChemWerth and to develop

products that could expand ChemWerth's TS market in the United States, ChemWerth falsely represented to Bryan that it would provide certain documents, including what is known as a Drug Master File ("DMF"), that were necessary for Bryan to obtain approval for its TS products from the United States Food and Drug Administration ("FDA"). By its First Amended Complaint for Damages, Bryan has asserted claims against ChemWerth for breach of contract (Count I), breach of the implied covenant of good faith and fair dealing (Count II), promissory estoppel (Count III), negligent misrepresentation (Count IV), fraud (Count V), and violation of Mass. Gen. Laws ch. 93A ("Chapter 93A") (Count VI). Bryan is seeking to recover more than $2 million, which it claims to have lost seeking FDA approval of its TS products in reliance on ChemWerth's allegedly false promises.

ChemWerth denies that the parties entered into an enforceable agreement or that it misled Bryan about its ability to provide necessary documentation, and it has asserted various affirmative defenses, as well as counterclaims against Bryan for a declaration of no contract and a declaration of no fraud. In addition, ChemWerth has filed a third-party complaint against Bryan's long-time consultant, Waldman Biomedical Consultancy, Inc., and its principal, Dr. Alan A. Waldman (collectively, "Waldman"), in which it alleges that Waldman was responsible for any damages that Bryan may have incurred, and that Waldman made misrepresentations to ChemWerth, which resulted in damages to that party as well. By its claims against Waldman, ChemWerth is seeking to hold the third-

party defendants liable for negligent representation (Count I), fraud (Count II), violation of Chapter 93A (Count III), and contribution (Counts IV and V).

The matter is presently before the court on Bryan's motion for partial summary judgment with respect to its claims against ChemWerth for breach of contract, promissory estoppel and negligent misrepresentation (Docket No. 173), and on ChemWerth's cross-motions for summary judgment with respect to its counterclaim of no contract, and to preclude or limit Bryan from collecting damages with respect to its claim for promissory estoppel. (Docket Nos. 175 & 177). It is also before the court on Waldman's motion for summary judgment with respect to all of ChemWerth's claims against it. (Docket No. 171). The parties have consented to the Magistrate Judge's final jurisdiction pursuant to 28 U.S.C. § 636(c) for purposes of these motions. For all the reasons described below, it is hereby ORDERED as follows:

A. "Plaintiff Bryan Corporation's Motion for Partial Summary Judgment" (Docket No. 173) is DENIED.

B. "ChemWerth's Motion for Summary Judgment of No Contract" (Docket No. 175) is ALLOWED.

C. "ChemWerth's Motion for Summary Judgment Dismissing or Limiting Damages on Bryan Corp.'s Promissory Estoppel Claim" (Docket No. 177) is ALLOWED.

D. "Third-Party Defendants Waldman Biomedical Consultancy, Inc. and Dr. Alan Waldman's Motion for Summary Judgment" (Docket No. 171) is ALLOWED IN PART and DENIED IN PART. Specifically, the motion is allowed to the extent ChemWerth's claims arise out of statements regarding Bryan's $5.5 million claim for damages. However, the motion is otherwise denied.

II. STATEMENT OF FACTS[1]

Scope of the Record

In connection with the pending motions, the parties have filed approximately 75 exhibits, and have submitted statements pursuant to Local Rule 56.1 containing hundreds of paragraphs of asserted facts. In addition, ChemWerth has disputed nearly all of Bryan's and Waldman's facts, at least in part, and each of the parties has objected to its opponent's characterization of the evidence. Consequently, this court has not attempted

[1] The facts set forth below in this court's Statement of Facts are derived from the following materials submitted by the parties in connection with the pending motions for summary judgment: (1) Plaintiff Bryan Corporation's Statement of Material Facts as to Which There is No Genuine Issue ("BF") (Docket No. 180); (2) the Statement of Material Facts Not in Dispute in Support of ChemWerth's Motion for Summary Judgment of No Contract and ChemWerth's Motion for Summary Judgment Dismissing or Limiting Damages on Bryan Corp.'s Promissory Estoppel Claim ("CF") (Docket No. 183); (3) the exhibits attached to the Declaration of Bojuan Deng ("CW Ex. __") (Docket No. 184); (4) Third-Party Defendants Waldman Biomedical Consultancy, Inc. and Dr. Alan Waldman's Statement of Material Facts as to Which They Contend There is No Genuine Issue to be Tried Under Local Rule 56.1 ("WF"), and the exhibits attached thereto ("Wa Ex. __") (Docket No. 186); (5) ChemWerth's Response to Bryan Corporation's Rule 56.1 Statement Concerning Bryan Corporation's Motion for Partial Summary Judgment ("CRBF") (Docket No. 215); (6) ChemWerth's Statement of Additional Material Facts Precluding Bryan Corp.'s Motion for Partial Summary Judgment ("CAF"), which is set forth beginning on page 40 of its response to Bryan's statement pursuant to Local Rule 56.1 (Docket No. 215); (7) ChemWerth's Response to Waldman Biomedical Consultancy Inc.'s and Dr. Alan Waldman's Local Rule 56.1 Statement of Material Facts ("CRWF") (Docket No. 216-1); (8) ChemWerth's Statement of Additional Material Facts Precluding Waldman's Motion for Summary Judgment ("CAF2"), which is set forth beginning on page 68 of its response to Waldman's statement pursuant to Local Rule 56.1 (Docket No. 216-1); (9) the exhibits attached to the Declaration of Alyson J. DiLena in Support of ChemWerth's Oppositions to Bryan Corp.'s and Waldman's Motions for Summary Judgment ("CW Supp. Ex. __") (Docket No. 217); (10) Plaintiff Bryan Corporation's Response to ChemWerth, Inc.'s Statement of Material Facts Not in Dispute ("BR"), and the exhibits attached thereto ("Br. Ex. __") (Docket No. 219); (11) the exhibits attached to the Declaration of Alyson J. DiLena in Support of ChemWerth's Reply to Bryan Corp.'s Opposition to ChemWerth's Motions for Summary Judgment ("CW 2d Supp. Ex. __") (Docket No. 224); and (12) the exhibits attached to Waldman's Reply Memorandum ("Wa. Supp. Ex. __") (Docket No. 221).

to describe all of the facts or to provide details of all of the issues in dispute. The following Statement of Facts reflects this court's effort to focus on the facts necessary to describe the critical issues in this case, and to understand this court's rulings on the parties' motions for summary judgment. To the extent any of the parties' factual assertions, or their responses to another party's factual assertions, merely reflect the arguments of counsel or are not supported by the underlying record, this court has not credited them. See Change the Climate, Inc. v. Mass. Bay Transp. Auth., 202 F.R.D. 43, 47-53 (D. Mass. 2001) (denying cross-motions for summary judgment where parties filed "argumentative rather than factual" statements of material undisputed facts containing "non-factual assertions" rather than "assertions of historical facts"); L.R. 56.1 (requiring party opposing summary judgment to "include a concise statement of material facts of record as to which it is contended that there exists a genuine issue to be tried, with page references to affidavits, depositions and other documentation"). However, this court has carefully considered all of the parties' submissions in order to determine which matters are and are not genuinely in dispute.

The Parties

The plaintiff, Bryan, is a Massachusetts company that was founded in 1985 and provides high quality medical devices and innovative pharmaceutical products to the global medical community. (CF ¶¶ 1-2, 4; Am. Compl. (Docket No. 76) ¶ 8). Due to the nature of Bryan's business, it is subject to regulation by the United States FDA. (CF ¶ 5). This litigation arises out of Bryan's effort to develop and obtain FDA approval of

products using TS active pharmaceutical ingredient ("API"), a chemical that may be used in antibiotic formulations. (See Am. Compl. ¶ 13; WF ¶ 9; CRWF ¶ 9).

Third-party defendant, Waldman Biomedical Consultancy, Inc., is a New York company that was founded in 1988 by third-party defendant Dr. Alan A. Waldman, who serves as the company's President. (CF ¶¶ 6-8; CW Ex. L at 12). Throughout the time period that is relevant to this action, Waldman worked as a consultant to Bryan in connection with the plaintiff's effort to develop pharmaceutical products using TS API. (CF ¶ 9). In its capacity as Bryan's consultant, Waldman had responsibility for the plaintiff's TS project, including responsibility for communicating with ChemWerth regarding the procurement of TS API. (CF ¶ 9; CW Supp. Ex. L at WAL_001738).

The defendant, ChemWerth, is a Connecticut company that advertises itself as a "full-service drug development business" with expertise in regulatory issues and 25 years of experience "developing API's for generic & proprietary pharmaceutical customers in a timely manner." (CF ¶ 10; CW Ex. FF at WAL_008463-64). As part of its business, ChemWerth purchases APIs from pharmaceutical manufacturers, and resells them in various markets. (CF ¶ 11; BR ¶ 11). It also assists companies in assembling DMFs, and works with API manufacturers in China and elsewhere to obtain the information necessary to compile DMFs and to file them with the FDA. (See WF ¶ 5; CRWF ¶¶ 4-5). There is no dispute that ChemWerth agreed to obtain TS API from a Chinese pharmaceutical manufacturer known as Chongqing Daxin Company Limited, Inc. ("Daxin"), and to resell it to Bryan for use in its TS applications. (See CW Ex. O). At issue is whether

ChemWerth also agreed to obtain and file a DMF, and whether it should be held liable for its failure to do so.

A DMF, and in particular a Type II DMF at issue here, includes information regarding the manufacture of an API. (WF ¶ 2; CRWF ¶ 2). The FDA requires that information from a DMF be disclosed in connection with its review of a new drug application ("NDA") or an abbreviated new drug application ("ANDA"). (WF ¶ 3; CRWF ¶ 3). Bryan alleges that ChemWerth promised to obtain DMF materials for the TS API that it sold to the plaintiff, and to file those materials with the FDA. (Am. Compl. ¶ 16). It further alleges that ChemWerth's failure to follow through on its promise caused Bryan to waste nearly $2.1 million in pursuing FDA approval, damages which it is seeking to recoup in this litigation. (See id. ¶¶ 1, 16, 65, 88-89, 101-02).

ChemWerth's Relationship with Daxin

ChemWerth has had an agency agreement with Daxin since the mid-1990s pursuant to which the defendant serves as Daxin's exclusive agent and distributor for Tobramycin base. (CAF ¶ 175; WF ¶ 6; CRWF ¶ 6). ChemWerth also assisted Daxin with the assembly of a DMF for its Tobramycin base. (CRWF ¶ 6). That DMF has been filed with the United States FDA. (Id.).

As part of its responsibilities with respect to Daxin's Tobramycin base, Chem-Werth produces annual reports, communicates with the FDA on behalf of Daxin, and performs regular audits of Daxin's drug manufacturing facility. (WF ¶ 7; CRWF ¶ 7). Peter Werth, ChemWerth's CEO, estimates that the defendant has conducted 30 to 50

such audits during the course of the companies' relationship. (CF ¶ 13; CRWF ¶ 7). In addition, ChemWerth assisted Daxin in preparing its facility for an FDA inspection in 2005. (CRWF ¶ 8). However, there is no dispute that ChemWerth has never had an exclusive agency agreement with Daxin for Tobramycin Sulfate, and that TS API has never been included on the defendant's list of products. (CAF ¶¶ 176-77). It is also undisputed that Daxin has no DMF available for its TS API. (See CF ¶ 25; BR ¶ 25; CAF2 ¶ 175; Wa Ex. NN). Among the issues in this litigation is whether ChemWerth was obligated to obtain a DMF for the TS API.

The Parties' Initial Contacts

The record reveals that the first communications between the parties took place in 2005. In December of that year, Waldman contacted ChemWerth to inquire about procuring TS for Bryan, and ChemWerth's Senior Vice President for Sales informed Waldman that the defendant could obtain the material from Daxin. (See CW Exs. O & P). In particular, ChemWerth informed Waldman that "[w]e currently have 7 customers that [have] filed ANDA's and NDA's using Chongqing Daxin Tobramycin, marketed products require Sterile dosage forms. They use the Tobramycin Base, add Sulfuric Acid in their formulation." (CW Ex. O). It also provided Waldman with a price quote for "Tobramycin Base – $3,600/kg (DMF material)" and "Tobramycin Sulphate – $2,500/kg (non-DMF material)," and informed Waldman that ChemWerth had a staff of 20 employees in Shanghai who could arrange for an audit of Daxin's manufacturing facility. (Id.).

On August 9, 2006, Waldman contacted ChemWerth, and informed the defendant that its client, Bryan, was committed to "the manufacture and introduction of [TS] and other antibiotics into the US market." (Wa Ex. I). Waldman also asked ChemWerth to

> confirm, *taking into account that we do not necessarily need a DMF on file at this point* and can help with the FDA filings, the availability of Tobramycin Sulfate (preferably) or Tobramycin base (less preferred), and indicate:
>
> a. the price/kg for the product, and how this varies by size of the order
> b. how soon samples (up to about 250 gm) could be made available for analysis [and]
> c. how soon 5-10 kg from up to 3 different lots could be made available for purchase[.]

(Id. (emphasis added)). In a subsequent email dated August 11, 2006, Dr. Waldman reminded ChemWerth of its prior bid of "Tobramycin Base – $3,600/kg (DMF material)" and "Tobramycin Sulfate – $2,500/kg (non-DMF material)[.]" (CW Ex. DD). He specifically acknowledged that ChemWerth's bid "recognizes the lower level of Tobramycin actually in the Tobramycin Sulfate product" than in the Tobramycin base. (Id.).

ChemWerth confirmed its ability to procure the materials and sell them to Bryan for the stated prices. (Id.). However, it explained that the material it purchased from the manufacturer would be measured in kilograms of activity ("kgA"). (Id.). Based on the prices that it had quoted to Waldman, ChemWerth calculated a cost of approximately $3,960 per kgA for the Tobramycin Base, and a price of $3,625 per kgA for the TS. (Id.). In September 2006, Bryan placed an order for 0.720 kg of TS API from ChemWerth at a

unit price of $2,500 per kilogram (or $3,625 per kgA). (CF ¶ 47; CW Ex. T at BC584-86). ChemWerth supplied the product, identified as Lot Nos. 060805-060807, in or around October 2006, and Bryan paid the defendant $1,800 for that material. (CF ¶¶ 47-48; CW Ex. T at BC583-86).

Waldman's November 2006 Audit of Daxin

The parties arranged for Waldman to conduct an audit of Daxin in late November 2006. (CF ¶ 27; BR ¶ 27; CW Ex. R). Waldman and Bryan contend that an oral agreement was reached with ChemWerth during this audit. For ChemWerth's part, it contends that no agreement was reached then. The relevant facts are as follows.

Prior to the audit, ChemWerth sent an email to Dr. Waldman informing him that Li Lixin, who was identified as the Senior Manager of Manufacture Regulatory Affairs and an Associate Researcher for Chemwerth, China, would be accompanying him on the audit "as your translator[,]" and that Dr. Waldman could "handle any logistical details concerning the audit with Mrs. Li Lixin[.]" (CW Ex. R). In its email, ChemWerth also informed Dr. Waldman that "we typically do not mix business discussions with GMP[2] audits since a member of the [ChemWerth] US sales team will not be present and business issues on the customer side are handled through sales; Not directly with the plants." (Id.). Accordingly, ChemWerth indicated that no one would be present to

[2] "GMP" refers to "Good Manufacturing Practices."

negotiate the terms of any purchase and sale agreement, and that it had no intention of addressing the substance of any potential business deal during the course of the audit.

ChemWerth's view that business issues would not be discussed during the audit is further illustrated in an email exchange between Ms. Lixin and ChemWerth employee Marco D'Urso before the date of the audit. Therein, Ms. Lixin expressed concern about the lack of a formal agreement between ChemWerth and Daxin with respect to sales and distribution of Daxin's TS, and stated that she had no information about such matters as TS manufacturing, records or validation. (Wa Ex. J at 1). In response to Ms. Lixin's concerns, Mr. D'Urso stated in relevant part as follows:

> Dear Mrs. Li – We spoke to the auditor today. He will be looking at Toby Base ... He will also be briefly looking at Toby Sulfate. Basically, just how the production would change from Base to Sulfate and other general issues. He would not need sterile Toby Sulfate so sterility is not a concern for him. He also knows we do not have a DMF for Toby Sulfate. I recommend just showing him Daxin's general quality systems and let him look at some Toby Base ... documentation. Give him a brief description of Toby Sulfate but do not provide him too much information on it. Keep it general.
>
> He also now knows not to discuss business issues at the audit. If he asks to look at other factories, just tell him [no]. We already explained that he is only to audit Daxin....

(Id.).[3] Thus, it was ChemWerth's stated intention that neither party was to discuss the details of an agreement during the visit to the plant.

[3] Waldman points to this email as evidence that ChemWerth was hiding information during the audit. (Wa Mem. (Docket No. 172) at 8). ChemWerth denies any implication that it was concealing information from Waldman or Bryan. (See CRWF ¶ 13).

The audit of Daxin's manufacturing facility took place on November 29-30, 2006. (Wa. Ex. K at 2). The individuals who were present during the audit included Dr. Waldman and the plaintiff's CEO, Bryan Abrano; Ms. Lixin and Katherine Zhang, who was identified as a Regulatory Affairs Senior Associate for Chemwerth Pharmaceutical Technology, Shanghai Co., Ltd.;[4] and six employees of Daxin, including two of its Assistant General Managers, its Quality Assurance and Quality Control Managers, the Director of Daxin's Tobramycin workshop, and the company's GMP Senior Manager. (Id.; CW Ex. L at 78; CW Ex. CC). During the audit, Waldman and Bryan were given a slide presentation regarding Daxin, which described the manufacturer's production of "Tobramycin" and identified that substance as one of the company's "Main APIs." (See WF ¶ 15; CRWF ¶ 15; CW Supp. Ex. M at BC37-BC38, BC55-BC60). As part of the presentation, Waldman and Bryan were shown a slide that read, "[d]ocuments relating to manufacturing, quality management, material control, equipment, personnel, hygiene, sales, self-inspection, etc. are all available and [established] according to GMP." (Wa Ex. L). In addition, they were informed that "[a]ctivities conducted [by Daxin] in

[4] The parties dispute whether Ms. Lixin and Ms. Zhang had the authority to bind Chem-Werth to the terms of an agreement with Bryan. ChemWerth insists that neither individual was an employee of ChemWerth, Inc., the defendant named in this lawsuit, and that they attended the audit only in their capacities as "translators." (See CRWF ¶¶ 16-19). Bryan, on the other hand, contends that Ms. Lixin and Ms. Zhang held themselves out to Bryan and Waldman as representatives of the defendant with authority to speak on the company's behalf. (See BR ¶¶ 16-17; 19-20; Pl. Reply Mem. (Docket No. 220) at 5). It further argues that ChemWerth waived lack of authority as a defense to Bryan's contract claims by failing to raise it as an affirmative defense in its answer to Bryan's complaint. (Pl. Reply Mem. at 5). However, this court finds that it is not necessary to resolve this dispute because, even assuming they had authority, the parties did not reach an agreement on materials terms.

purchasing of raw material, storage, manufacturing, testing, checking, releasing, marketing and personnel training are all in accordance with the requirement of [current Good Manufacturing Practices ('c-GMP')] of [the] SFDA[.]" (CW Supp. Ex. M at BC66). Notably, however, the slide presentation did not indicate that such activities were conducted pursuant to the practices approved by the United States (as opposed to Shanghai) FDA. (See CW Supp. Ex. M at BC37-68). Nor did it make any specific references to Daxin's production of TS API. (See id.).

Dr. Waldman claims that during the audit he also received a presentation regarding ChemWerth's agency relationship with Daxin, from which he learned that ChemWerth was the exclusive distributor of Daxin products, including both Tobramycin and TS API. (Wa. Ex. G at 90-91). According to Dr. Waldman, he was further informed that ChemWerth guaranteed the quality of the materials produced by the manufacturing plants in China, and would ensure the availability of all documentation necessary to support the use of Daxin's products in the United States. (Id. at 91). In addition, Dr. Waldman was told that ChemWerth had filed numerous DMFs, and would have no problem filing a DMF for Daxin's TS as well. (Id.). Dr. Waldman cannot identify the individual who made these statements, and he cannot point to any written material reflecting the substance of the presentation. (See id. at 90-92). Nevertheless, ChemWerth has not presented any specific evidence to refute Dr. Waldman's version of events.

Mr. Abrano claims that similar representations were made during the audit by either Ms. Lixin or Ms. Zhang. (Wa Ex. F at 195-96). According to Mr. Abrano,

ChemWerth's representative promised that if Bryan agreed to purchase TS API through ChemWerth, the defendant would obtain and file with the FDA all of the documentation necessary to obtain regulatory approval of its products. (Id.). ChemWerth denies that it made any such promises or representations during the Daxin audit. (CRBF ¶ 20). It insists that Ms. Lixin and Ms. Zhang attended the audit as translators, and had no authority to bind the defendant with respect to any business issues. (Id.). It also notes that there is no documentary evidence supporting Mr. Abrano's account of the conversation. (See CRBF ¶ 20). Again, however, ChemWerth has presented no specific facts to refute Mr. Abrano's account of the conversation.

On November 30, 2006, following completion of the audit, Ms. Lixin prepared an audit summary, which she distributed to various ChemWerth personnel, including personnel located in the United States. (Wa Ex. K). Therein, Ms. Lixin listed the individuals who participated in the audit, briefly described the presentations that were made and the activities that occurred prior to and during the audit, and summarized the results of Bryan's and Waldman's visit. (Id.). With respect to the parties' pre-audit presentations, Ms. Lixin stated in relevant part as follows:

> As a business chain, Bryan has license of distribution, while waldman responsible regulatory filing and quality verifying. Then, they need to find supplier, manufacturer and test unit to get final drug products.
>
> They have licensed Tobramycin sulfate in two forms: Powder and liquids. Liquids can be used as injectable (40mg/2ml), and powder can be injectable too if dissolve. These usages will be covered in ANDA application. Another important and specific usage of powder

> is Bone Cement, since couldn't provide effective data to prove its efficiency, it is used in operation mostly and they try to file NDA for this specific usage[.]
>
> Besides Tobramycin sulfate, they are looking for Amikacin sulfate and vancomycin sulfate.
>
> Before formal audit, Li lixin gave a brief introduction about CW, and focused on CW/Sha function.

(Id. at 3). She then described the events that occurred during Waldman's tour of the facility. (Id.) Thus, as Ms. Lixin stated,

> [b]asically, this audit is very different from common supplier verification which focuses on quality system. Considering the FDA and SFDA inspection history, Dr. Alan believes their system is ok. So, his focus is product itself.
>
> H[e] started from equipment, checked equipment history, material of equipment, IQ/OQ/PQ, calibration, process validation and several SOPs related. Second day, Dr. Alan toured workshop, QC and final product warehouse. He tried to review process very detail in workshop, which Daxin reminded Dr. Alan during the audit, they couldn't reply every point he asked for the process confidential. Dr. Alan accepts and checked process based on flow chart generally. After touring, Dr. Alan picked three batch records of Tobramycin sulfate (060805-060807), go through one batch from beginning to end and then reviewed others from stultify to end. One release test records are reviewed thoroughly.

(Id.). Finally, Ms. Lixin reported that both Waldman and Bryan "are satisf[ied] with Daxin's system, daxin's people. And comfortable for Tobramycin sulfate quality. Several minor observations/suggestions are raised which Dr. Alan thinks no one couldn't be corrected . . . And both of them think the facility is acceptable and can be Tobramycin sulfate supplier." (Id. at 4).

Communications Regarding the Purchase and Sale of TS

On December 1, 2006, Dr. Waldman sent an email to ChemWerth's National Account Manager in which he reported that "the results of the recent visit and audit at Daxin confirmed the acceptability of this site and of its products for use by Bryan Corporation." (WF ¶ 23; CRWF ¶ 23). He also reported that Bryan was "ready to order [TS] materials for use in trial production lots[,]" and he requested information regarding "the minimum size of a lot that can be ordered by Bryan . . . and made under GMP in the current facility[,]" as well as on the time that would be required to provide the TS. (Wa Ex. N at 1). In response to Dr. Waldman's email, ChemWerth's National Account Manager acknowledged the success of the audit, confirmed that Daxin was a "good factory[,]" and asked for information about the amount of material that Bryan would require. (Id. at 3). Dr. Waldman replied that Bryan was prepared to purchase about 5-10 kg immediately for use in the initial test lots, and that "once we have the initial lots made, we will almost immediately be submitting an ANDA, which we have every reason to believe will have a rapid turnaround[.]" (Id. at 2). Dr. Waldman further informed ChemWerth that Bryan "will be planning clinical trials for additional claims, and an eventual NDA[,]" and that he anticipated an initial need for TS in the 35-100 kg range once they were ready to build the first larger commercial lots. (Id.).

On December 19, 2006, Bryan placed an order for 14.22 kg of TS API from ChemWerth at a unit price of $2,500/kg (or $3,625 per kgA). (CF ¶ 49; CW Ex. T at BC590-91; see also CW Ex. DD at BC519). ChemWerth delivered the product,

identified as Lot Nos. 070101-070103, in January 2007. (CF ¶ 50; CW Ex. T at BC579-80). Bryan paid ChemWerth $35,550 for that order. (CF ¶ 49).

The parties continued to communicate regarding the supply of TS API. In early July 2007, after discovering that Daxin TS API Lot No. 070103 had a high bioburden result upon testing, Dr. Waldman wrote to ChemWerth and asked whether "Daxin would expect all of the materials in hand to fail the bacterial specifications[.]" (See CF ¶ 56; BR ¶ 56; CW Ex. Z at 1). ChemWerth responded that the material at issue met the specifications that Daxin had for release. (CW Ex. Z at BC479). It also explained that "[m]aterial intended for oral [use] is handled differently tha[n] injectable material. Your material was intended to be oral. Our injectable material is almost sterile." (Id. (emphasis omitted).

On July 13, 2007, Dr. Waldman sent an email to ChemWerth in which he apologized "for what has clearly been a misunderstanding of our requirements[,]" and explained that "[w]e require Tobramycin Sulfate supplied to be of injectable quality." Significantly, Dr. Waldman makes no mention of any contract terms, but rather seems to acknowledge that Bryan's needs were still being clarified. (CW Ex. GG at BC477).

In his communication, Dr. Waldman also asked ChemWerth to clarify what was meant by the "oral" use of Tobramycin. (Id.). In its reply to Dr. Waldman's correspondence dated July 17, 2007, ChemWerth stated as follows:

> At this time we really need to set up a conference call to discuss what your marketing and regulatory intentions are.

> Our main product is Tobramycin Base which is injectable DMF material.
>
> We have Tobramycin Sulfate because the manufacturer and [ChemWerth] developed it for the domestic Chinese market many years ago (hence the oral grade – non DMF).
>
> We have the expertise to make injectable Tob sulfate and what we can do is run 3 Process validation batches (PVB) to ensure we meet your requirements. Remember this is not a product we routinely manufacture. To commit to running the PVB, we need to know what the marketing projections are so we can determine the viability of the project and design the proper batch size necessary to meet your needs. This is especially important if you use this material for the filling of your exhibit batch and you later require a DMF.

(Id.; WF ¶ 31; CRWF ¶ 31). The parties agree that process validation batches ("PVBs") consist of consecutive batches of material that are manufactured by one manufacturing process and meet the same level or specification, and that one purpose of a PVB is to demonstrate whether a manufacturer has a repeatable manufacturing process. (WF ¶ 32; CRWF ¶ 32). However, the parties dispute what was meant by the term "non-DMF" material. According to Waldman and Bryan, the parties meant only that there was no DMF material on file at that particular point in time. (See BF ¶ 33; WF ¶ 33). Chem-Werth disagrees, and contends that it was using that term to refer to a lower quality of material than DMF grade API. (See CRWF ¶ 33; CW Supp. Ex. G at 55-56). Again, significantly, as of July 2007, there was no mention of contract requirements but rather a continuing dialogue between the parties.

In response to the defendant's July 17, 2007 communication, Dr. Waldman sent another email to ChemWerth in which he emphasized Bryan's intent "to bring [TS] to

market in both liquid and powder forms," and its need for "injectable grade materials." (Wa Ex. P). In addition, Dr. Waldman informed the defendant that

> [w]e anticipate, once the drug is approved, sales of over 100 kg equivalent per year during the first year or so, and higher levels thereafter.
>
> While we will be happy to discuss this further, we hope the above provides the basic information you and your colleagues need to commit to the preparation of PVB materials.
>
> *With regard to the DMF, we understand your concerns, but would feel comfortable referencing the current Tobramycin one and submitting the ANDA/NDA with the extra steps, so a new DMF is not an absolute requirement.*

(Id. (emphasis added)). Thus, as of about mid-July 2007, Dr. Waldman and Bryan were not requiring a DMF for TS API, but rather, were indicating that the existing DMF for Tobramycin Base could suffice.

The next communication between the parties occurred on July 19, 2007. At that time, ChemWerth contacted Dr. Waldman, and informed him of the importance to Chem-Werth of putting a supply agreement in place. (CW Ex. V). Dr. Waldman responded that he appreciated ChemWerth's position, and he asked the defendant to provide him with a template for such an agreement. (Id.). Dr. Waldman also requested information "regarding the timing and requirements for performance of appropriate validation of manufacture of injectable quality [TS]." (Id.). Later that day, ChemWerth sent another email to Dr. Waldman in which it requested "a purchase order for your 2 x 5kgs so we can keep the momentum going on this project." (Id.). ChemWerth further informed

Dr. Waldman that "[y]our specs for this material are set[,]" that it had instructed Daxin "to schedule manufacturing of 3 x 10kg process validation batches[,]" and that it would provide Waldman with information on timing as soon as possible. (Id.). With respect to the supply agreement, ChemWerth inquired whether the agreement would be between ChemWerth and Waldman, or whether it should include Bryan as well. (Id.). Dr. Waldman replied that the defendant should "[p]rovide a supply agreement template that includes both myself, and Bryan Corporation as the prime purchaser[.]" (Id.).

The Draft Supply Agreement

On July 25, 2007, ChemWerth provided Waldman with a draft Supply Agreement, which consisted of 19 pages and included signature lines for ChemWerth, Bryan and Waldman Biomedical Consultancy, Inc. (CF ¶ 35; CW Ex. U ("Supply Agreement")). The proposed Agreement contemplated that ChemWerth would sell and deliver TS API to Waldman/Bryan, and that Waldman/Bryan would purchase at least 50% of their annual TS requirements from ChemWerth. (See Supply Agreement at Art. 2.0). It also contemplated that the TS would be manufactured by Daxin in accordance with specifications that were to be listed in a separate attachment to the Agreement, and that the price of the material would be "$3,625 USD per KgA for a minimum of 450 Kilograms of Activity per year." (Id. at Art. 1.0-3.0 & Exs. A-B thereto). This was the same price that ChemWerth had quoted to Waldman in its original proposal for the sale of non-DMF TS material. (See CW Ex. DD at BC519). However, if Bryan's annual demand were to drop

below the minimum of 450 KgA per year, the price of the material would be $3,850 per KgA, and would be billed retroactively. (Id. at Ex. B).

The draft Supply Agreement included an effective date of July 19, 2007 and an initial term of three years. (CF ¶¶ 41-42). It also included provisions addressing such matters as delivery and inspection of the TS product, renewal following expiration of the initial term, rights of termination, rights of inspection, confidentiality, warranties and indemnification, among others. (Id. ¶¶ 43-44; BR ¶ 44; see also Supply Agreement). In addition, the draft Agreement provided that "[ChemWerth] has a contract with Chonqing Daxin Limited Inc. . . . where [ChemWerth] is assigned the exclusive agent for the development and marketing of TOBRAMYCIN SULFATE." (Supply Agreement at 1).

Article 7.0 of the draft Supply Agreement addressed the parties' proposed rights and responsibilities with respect to "Regulatory Matters." In particular, it provided that

> CHEMWERTH warrants and represents to WALDMAN/BRYAN that CHONGQING DAXIN has filed a drug master file (DMF) with the FDA and shall respond to any plant deficiencies or manufacturing problems called to [DAXIN'S] attention, by the FDA. [DAXIN] shall maintain at all times during the term of this Agreement an FDA approved manufacturing plant in which it will manufacture TOBRAMYCIN SULFATE for WALDMAN/BRYAN in accordance with all applicable regulations of the FDA and current Good Manufacturing Practices.

(Supply Agreement ¶ 7.2). It further provided that ChemWerth would warrant "that TOBRAMYCIN SULFATE delivered to WALDMAN/BRYAN shall conform to PRODUCT SPECIFICATIONS and shall be manufactured in a FDA approved facility in accordance to [DMF] and in accordance with current GMP's." (Id. ¶ 8.2). The term

"DMF" was defined in the draft Agreement to mean "the file maintained by the U.S. Food and Drug Administration, which contains information submitted by [Daxin] with respect to *TOBRAMYCIN SULFATE*, its composition, manufacture, and packaging." (Id. ¶ 1.4). ChemWerth informed Waldman that it typically spends $250,000 to arrange for the filing of a DMF. (CF ¶ 26; BR ¶ 26).

ChemWerth's CEO, Peter Werth, reviewed the draft Supply Agreement before it was sent to Waldman. (CW Supp. Ex. A at 81). Although Dr. Werth knew that ChemWerth had no exclusive agency agreement with Daxin for the purchase and sale of Daxin's TS API, he claims that the defendant would have been able to enter into such an arrangement if the parties had executed the Supply Agreement. (Id. at 82). It is undisputed that the parties never executed, or even attempted to negotiate, a final Supply Agreement. (See CF ¶¶ 36-38; BR ¶¶ 36-38).

Bryan's Final Purchase of TS from ChemWerth

Despite the fact that no written agreement was signed, the parties continued to communicate regarding the purchase and sale of TS API. On or about July 31, 2007, Bryan placed an order for 6.36 kg of TS API from ChemWerth at a unit price of $2,500/kg (or $3,625 per kgA). (CW Ex. T at BC589). ChemWerth delivered that material, identified as Lot Nos. 070801-070803, in September 2007, and Bryan paid ChemWerth $15,900 with respect to that order. (CF ¶ 52; CW Ex. T at BC588). It is undisputed that this was the last shipment of TS that Bryan received from ChemWerth, and that the plaintiff placed no further orders. (See WF ¶ 47; CRWF ¶ 47; see also CW

Ex. T at BC579-91). Accordingly, the record establishes that Bryan purchased a total of 21.300 kg of TS through ChemWerth, for which it paid ChemWerth $53,250. (See CW Ex. T at BC579-91).

On August 22, 2007, ChemWerth wrote to Dr. Waldman, and informed him that "[t]he PVBs can be completed and available to ship by the third week in September. This material is designed to meet the quality requirements of Bryan Corp. Batch sizes will be 3 x 10kg." (WF ¶ 41; Wa Ex. S). The record establishes that PVBs must be included in a DMF, and that no ANDA or NDA application will be approved by the FDA without them. (See BF ¶ 43; CRBF ¶ 43). However, it is not clear from the record whether Bryan ever ordered PVBs, or whether ChemWerth ever suggested that it was shipping PVBs.

Bryan claims that it ordered PVB material on July 31, 2007, when it placed the order for 6.36 kg of TS API, and that ChemWerth misled it into believing that it had sent PVBs in September 2007, when, in fact, it had not done so. (See BF ¶¶ 42-44). Chem-Werth disputes that Bryan ever ordered the PVBs, and points to the fact that Bryan never ordered anything close to 3 x 10 kg of TS material. (See CRBF ¶¶ 42, 44). ChemWerth also disputes that it ever purported to deliver PVBs. (See id. ¶¶ 42-43). In light of the parties' disputes, these issues will need to be resolved by a finder of fact at trial.

ChemWerth's Efforts to Obtain a DMF for TS API

As detailed above, as of July 2007, Dr. Waldman had informed ChemWerth that "a new DMF is not an absolute requirement" (Wa Ex. P), and ChemWerth had proposed a Supply Agreement that was never discussed or signed. With the exception of ChemWerth's August 22, 2007 communication to Dr. Waldman regarding the availability of PVBs, there is no evidence of further communications between the parties during the remainder of 2007 or the first four months of 2008. In 2008, there were new personnel involved at ChemWerth, and suddenly there were communications between ChemWerth and Daxin reflecting an (unsuccessful) attempt to have Daxin commit to producing a DMF for TS API, and between ChemWerth and Dr. Waldman reflecting ChemWerth's efforts to obtain a DMF. There is no explanation in the record for this shift. Dr. Waldman and Bryan point to these communications as evidence that there was a prior existing contract obligating ChemWerth to produce a DMF. For its part, ChemWerth argues that these communications merely reflect its voluntary efforts to assist Bryan in obtaining a DMF. As detailed below, this court finds that while there is insufficient evidence of an agreement on material terms so as to support the existence of a contract, these communications in 2008 and thereafter may support a finding of negligent misrepresentation.

Specifically, in May 2008, ChemWerth's newly appointed senior associate for regulatory affairs, Maria LaChance, informed Daxin that Waldman and Bryan were

seeking DMF information for TS API. (Wa Ex. W at 2). In an email to Daxin dated May 16, 2008, Ms. LaChance wrote in relevant part as follows:

> Waldman/Bryan is asking for a LOA and Open Section of the Tobi Sulfate DMF. I noticed in the bi-weekly report there is a note about problems between Daxin and the customer. I am not sure what issues are going on. Please provide me with an update for where we stand with this product.

(Id.).

On May 20, 2008, Ms. LaChance was informed that there was some "concern" regarding Daxin's ability to prepare a DMF, but that Daxin could provide ChemWerth with the requested material in about two or three months if the parties could resolve an outstanding "business issue". (Id.). According to ChemWerth's CEO, Dr. Werth, the "business issue" arose from the fact that ChemWerth did not have a written contract with Bryan pursuant to which Bryan would commit to purchase TS API from ChemWerth. (CW Supp. Ex. A at 89-90). However, there is no evidence that ChemWerth discussed the need for a written agreement with Waldman and/or Bryan at this time, or that it made any effort to negotiate the terms of a supply contract with them. Those discussions seem to have ended with ChemWerth's sending of the draft Supply Agreement in July 2007.[5] Moreover, ChemWerth's internal communications indicate that the unresolved "business

[5] The record does not support ChemWerth's repeated assertion that after 2007, it "informed Bryan Corp. that it could not proceed with the TS project until it had a supply agreement in place with Bryan Corp." (See CRWF ¶¶ 82-91). The evidence cited by ChemWerth indicates that the only discussions regarding a written contract between the parties occurred in July 2007 in connection with ChemWerth's request for a supply agreement and its transmittal of a draft agreement. (See CW Supp. Ex. K at CHEMWERTH000523-25; CW Supp. Ex. A at 89-91).

issue" with Daxin concerned ChemWerth's failure to consummate an agency agreement with Daxin regarding sales of its TS API rather than Waldman's and Bryan's failure to enter into a written contract with ChemWerth. (See Wa Ex. Z at 1-2; Wa Ex. BB at 1-2).

In May 2008, at about the same time as ChemWerth was attempting to obtain DMF information from Daxin, Dr. Waldman spoke with the ChemWerth's National Account Manager, and was told that ChemWerth was planning to pick up the DMF from the manufacturer in three months. (Wa Ex. G at 229). There is no indication that ChemWerth mentioned any outstanding "business issue" to Dr. Waldman. (See id. at 229-31). Nor is there evidence that ChemWerth sought any type of written agreement from either Waldman or Bryan. (See id.).

Subsequently, on June 11, 2008, Dr. Waldman provided ChemWerth with projections of Bryan's future TS requirements. (Wa Ex. X). As Dr. Waldman wrote in an email to ChemWerth, "[w]e now envision the following . . . ANDA submission for routine intravenous product is still on track for July . . . with an estimated approval late this year, start of next, with an annual usage of [TS] for our product . . . of about 30-50 kg/year[.]" (Id.). He also stated that Bryan anticipated an "NDA submission for novel and protected application in late-first, early-second quarter 2009, with an annual usage of [TS] . . . of about 400-600 kg/year." (Id.). There is no dispute, however, that Bryan never finalized or filed an NDA. (See CRWF ¶ 54; CW Supp. Ex. H at 80-81). Moreover, ChemWerth has presented evidence showing that the NDA project never even advanced beyond the planning stage. (CW Supp. Ex. H at 80-81). Thus, although

ChemWerth understood that the estimates of Bryan's TS requirements were contingent upon FDA approval of the plaintiff's applications, and that no approval would occur without a DMF on file (see WF ¶ 55; CRWF ¶ 55; Wa Ex. A at 207), it contends that the projections were misleading because there was no prospect for sales "of about 400-600 kg/year."

ChemWerth forwarded Dr. Waldman's projections to Daxin, and asked it to arrange for the release of DMF documents to ChemWerth. (Wa Ex. X). In addition, ChemWerth asked Daxin to sign a new agreement under which ChemWerth would become the exclusive agent with respect to the sale and distribution of Daxin's TS API. (See id.). However, Daxin remained unwilling to execute an agency agreement or to release the necessary documentation to the defendant. (See, e.g., Wa Ex. Z at 1).

The record reveals that Bryan did not file its TS applications in 2008 or 2009 as Dr. Waldman had anticipated, and that the parties continued to discuss the procurement of a TS DMF. (See, e.g., WF ¶¶ 74-75; CRWF ¶¶ 74-75; Wa Ex. G at 230). During the course of their communications, ChemWerth informed Dr. Waldman that it was "working hard on getting all of the DMF preparations" for the TS, and assured him that DMF material necessary to support Bryan's applications would be filed with the FDA. (See Wa Ex. G at 229-30; Wa Ex. Y; WF ¶ 75; CRWF ¶ 75). Significantly, however, ChemWerth did not reveal the fact that it had been unable to obtain an agency agreement with Daxin with respect to TS API, or the fact that Daxin was refusing to provide the TS DMF information without such an agreement in place. (See Wa Ex. G at 231; Wa Ex. Z

at 1-2; Wa Ex. AA; Wa Ex. BB at 1-2; WF ¶¶ 70, 73; CRWF ¶¶ 70, 73). Thus, while the evidence shows that ChemWerth continued to negotiate with the manufacturer in an effort to resolve these issues and obtain the information necessary to support Bryan's TS applications, it failed to inform the opposing parties that no DMF was forthcoming. (See Wa Ex. BB at 1; WF ¶¶ 70, 73, 77; CRWF ¶¶ 70, 73, 77).

Bryan's ANDA Filing

On about March 17, 2010, Dr. Waldman notified ChemWerth that Bryan had filed an ANDA with the United States FDA. (Wa Ex. DD at 3). He also informed the defendant that the following language was included in the application:

> Following is an authorization letter from Chemwerth granting the FDA authority to review DMF 13774 for Tobramycin USP, non-sterile bulk drug substance manufactured by ChongQing DaXin Pharmaceuticals Co., Ltd on behalf of Bryan Corporation. Chemwerth is currently submitting a DMF for Tobramycin Sulfate, USP and will provide an authorization letter granting the FDA authority to review this DMF on behalf of Bryan Corporation as soon as a number has been assigned to the submission.

(Id. at 2). At the time ChemWerth received this information, it was still attempting to resolve its dispute with Daxin. (See Wa Ex. EE; CW Supp. Ex. B at 103, 128). Nevertheless, it confirmed that "[w]e will work on the API DMF parts accordingly and keep you updated on any progress." (See Wa Ex. GG at 1).

Throughout the spring and into the summer of 2010, ChemWerth assured Dr. Waldman that it was working with the manufacturer to file a DMF for TS API, and that it expected to file the information in the near future. (See WF ¶¶ 84, 86, 88; CRWF

¶¶ 84, 86, 88). In reality, however, ChemWerth was still experiencing resistance from Daxin. Thus, as Dr. Werth stated in an internal email dated June 24, 2010,

> ChemWerth/Daxin is committed to file a [TS] DMF, which is in both companies interest to significantly increase the tobramycin sales. Maria has not received the required information and is of the opinion that Daxin is not cooperating and may not be doing the work necessary to collect the data for Chemwerth to file the DMF. Please review Maria's e-mails and the situation with Sunny. Once you have a clear picture then discuss the issues with Daxin. We need a definitive plan and timing to complete the plan. So we can have truthful and meaningful conversations with our customers. It is hard to explain the long delay in getting the information and lack of cooperation from the factory.

(Wa Ex. II at 3). Still, ChemWerth did not discuss these issues with Bryan or Dr. Waldman. (See WF ¶¶ 98-99; CRWF ¶¶ 98-99).

The FDA's Response to Bryan's ANDA

In June 2010, Bryan received a letter (the "Refusal to Receive letter") from the FDA in which the agency stated that it had given the ANDA a preliminary review, and had determined "that it [was] not sufficiently complete to merit a critical technical review." (Wa Ex. SS at 1). The FDA explained that its refusal to receive Bryan's application was due to 33 separate deficiencies, which it listed in the letter and which the parties' experts agree is a high number of deficiencies. (Id. at 1-3; CW Supp. Ex. E at 59-60; CW Supp. Ex. F at 207). Notably, however, the FDA did not list the absence of a TS DMF as one of the deficiencies, although it did note that "an ANDA cannot be accepted for filing until all the supporting DMFs have been submitted to the agency." (Wa Ex. SS at 2-3). The FDA instructed Bryan that it would need to amend its applica-

tion to correct all of the deficiencies or withdraw its application from consideration. (Id. at 3-4). While the parties agree that Bryan had no chance of obtaining FDA approval of an amended application without the information that would have been included in a TS DMF, they dispute whether Waldman and Bryan could have corrected the deficiencies that were listed in the Refusal to Receive letter. (See WF ¶¶ 108-09, BF ¶¶ 108-09; CRWF ¶ 108; CRBF ¶ 108; CAF2 ¶¶ 173, 178-79; CW Supp. Ex. E at Ex. 1 ¶¶ 99, 235-65). Accordingly, they dispute whether ChemWerth's failure to obtain a DMF made any practical difference to Bryan's prospects for FDA approval of its ANDA.

ChemWerth was not shown a copy of the Refusal to Receive letter, and was unaware of its contents prior to the instant litigation. (CW Supp. Ex. G at 14). Thus, it had no knowledge that the FDA had identified 33 deficiencies as the basis for its refusal to receive Bryan's application. Rather, Dr. Waldman informed ChemWerth that the defendant's failure to submit a TS DMF had "[held] up the final acceptance and review of [Bryan's] ANDA application." (CAF2 ¶ 166). Consequently, ChemWerth was led to believe that its failure to obtain a DMF was the only real obstacle to approval, and it remained committed to finding a solution. (See Wa Ex. RR at 1).

Final Communications Between the Parties

Dr. Waldman continued to press ChemWerth regarding the submission of a DMF for TS API, but ChemWerth was still unable to obtain the necessary information from Daxin. (See Wa Exs. JJ, KK & LL). On January 8, 2011, Dr. Werth wrote an email to Jeff Bauer, the President of ChemWerth, in which he described a visit that one of Chem-

Werth's employees had made to Daxin's facility in August 2010. (See Wa Ex. NN; CAF2 ¶ 143). As Dr. Werth stated in relevant part:

> We have a delicate situation with Dr. Waldman/Bryan[] concerning tobramycin sulfate ... CQ Daxin has informed Yaping that they have no cGMP acceptable facility to add the necessary equipment to manufacture FDA approvable tobramycin sulfate. Yaping has visited the facility and confirms that CQ Daxin is telling the truth. CQ Daxin will cooperate and sell us DMF tobramycin if we can find an FDA approved facility to convert to sulfate. This will be an expensive proposition and will add significantly to the selling prices of tobramycin sulfate.

(Wa Ex. NN). Thus, according to the record, ChemWerth discovered that Daxin had no ability to generate a TS DMF.

On March 11, 2011, Mr. Bauer notified Dr. Waldman that ChemWerth was "having difficulty securing the documentation from our factory CQ Daxin[,]" and that it intended to "recreate the process to produce the Sulfate salt at one of its Joint Venture partners in China." (Wa Ex. PP at 1). He also stated that the proposed transfer process would take about 4-5 months, and that ChemWerth was "committed to getting this done and assisting Bryan[] to file its dossiers and garnering approval." (Id.). In other words, Mr. Bauer admitted that ChemWerth would not be able to obtain a TS DMF from Daxin, but that it remained committed to pursuing the information from another manufacturer. According to ChemWerth, it spent hundreds of thousands of dollars seeking a TS DMF from an alternative source after it discovered that Daxin lacked the ability to produce DMF grade TS API. (CAF2 ¶ 175). It further claims that it would not have made such an

effort or incurred those expenses if it had known the real reasons for the FDA's refusal to receive Bryan's ANDA application. (See id.).

After considering ChemWerth's proposal and speaking about it to the FDA, Waldman and Bryan declined to pursue it. (See CW Supp. Ex. C at 259-60). Thus, on May 5, 2011, Dr. Waldman notified ChemWerth that he and Bryan were "not confident that your approach is appropriate under FDA protocols and regulations[.]" (CW Supp. Ex. K at CHEMWERTH001923). He also informed ChemWerth that its proposal "does not address the damages Bryan Corporation already has and will incur as a result of this situation[,]" and he indicated that Bryan expected to "be made whole for its many expenses and losses in time and opportunity, estimated . . . as a minimum of $5,500,000." (Id.).

ChemWerth rejected Bryan's demand for damages, noting that "[t]here is no business contract in place upon which to base any damages claims." (Id. at CHEM-WERTH001925). It also reiterated its commitment to assist Bryan in the completion of its product development. (Id.). However, the parties did not resolve their dispute, and on March 9, 2012, Bryan filed the instant lawsuit. By its claims, Bryan is seeking approximately $2.1 million in damages against ChemWerth.

Additional factual details relevant to this court's analysis are described below where appropriate.

III. ANALYSIS – BRYAN'S AND CHEMWERTH'S CROSS-MOTIONS FOR SUMMARY JUDGMENT

Bryan has filed a motion for partial summary judgment on its claims against ChemWerth for breach of contract (Count I), promissory estoppel (Count III) and negligent misrepresentation (Count IV). In addition, ChemWerth has filed two motions for summary judgment on Bryan's contract and promissory estoppel claims. By its first motion, ChemWerth contends that it is entitled to judgment as a matter of law on Bryan's claims for breach of contract and breach of the implied covenant of good faith and fair dealing (Count II) because the parties never entered into a legally enforceable contract. By its second motion, ChemWerth is seeking a ruling "precluding or limiting Bryan . . . from collecting damages on Count III, its promissory estoppel claim, . . . entirely or at least after July 2007 when ChemWerth provided a Draft Supply Agreement to Bryan Corp." (Docket No. 177). For all the reasons described below, summary judgment shall be entered for ChemWerth on Counts I-III of Bryan's complaint. Because there are disputed issues of material fact with respect to Bryan's claim for negligent misrepresentation, the plaintiff's motion for summary judgment will be denied with respect to Count IV.

A. Summary Judgment Standard of Review

"The role of summary judgment is 'to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial.'" PC Interiors, Ltd. v. J. Tucci Constr. Co., 794 F. Supp. 2d 274, 275 (D. Mass. 2011) (quoting Mesnick v. Gen. Elec.

Co., 950 F.2d 816, 822 (1st Cir. 1991)) (additional citations omitted). The burden is upon the moving party to show, based upon the discovery and disclosure materials on file, and any affidavits, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[A]n issue is 'genuine' if it 'may reasonably be resolved in favor of either party.'" Vineberg v. Bissonnette, 548 F.3d 50, 56 (1st Cir. 2008) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 48 (1st Cir. 1990)). "A fact is 'material' only if it possesses the capacity to sway the outcome of the litigation under the applicable law." Id. (quotations, punctuation and citations omitted).

"Once the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue." PC Interiors, Ltd., 794 F. Supp. 2d at 275. The opposing party can avoid summary judgment only by providing properly supported evidence of disputed material facts. LeBlanc v. Great Am. Ins. Co., 6 F.3d 836, 841 (1st Cir. 1993). Accordingly, "the nonmoving party 'may not rest upon mere allegation or denials of his pleading[,]'" but must set forth specific facts showing that there is a genuine issue for trial. Id. (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256, 106 S. Ct. 2505, 2514, 91 L. Ed. 2d 202 (1986)).

"Cross-motions for summary judgment do not alter the basic Rule 56 standard, but rather simply require [the court] to determine whether either of the parties deserves judgment as a matter of law on facts that are not disputed." Adria Int'l Group, Inc. v. Ferre Dev., Inc., 241 F.3d 103, 107 (1st Cir. 2001). "'When facing cross-motions for summary judgment, a court must rule on each motion independently, deciding in each instance

whether the moving party has met its burden under Rule 56.'" Peck v. City of Boston, 750 F. Supp. 2d 308, 313 (D. Mass. 2010) (quoting Dan Barclay, Inc. v. Stewart & Stevenson Servs., Inc., 761 F. Supp. 194, 197-98 (D. Mass. 1991)). Applying this standard in the instant case compels the conclusion that Bryan's motion for summary judgment should be denied and that ChemWerth's motions for summary judgment should be allowed.

B. Counts I & II: Bryan's Contract Claims

Bryan's contract claims are premised upon its contention that a binding agreement was reached by the parties during the audit of Daxin in 2006, and was confirmed by the parties' subsequent actions and communications. (See Pl. Mem. (Docket No. 179) at 5-6). Thus, in support of its motion for summary judgment on its claim for breach of contract, Bryan contends that in 2006 it entered into an enforceable agreement with ChemWerth under which the parties "agreed that, if Bryan Corp. purchased TS API from ChemWerth and used that TS in Bryan Corp.'s FDA applications, then ChemWerth would provide the DMF that Bryan Corp. needed for FDA approval."[6] (Id. at 5). It further contends that

[6] While this court finds that the parties failed to reach an enforceable contract under the terms asserted by Bryan, the plaintiff's description of the parties' alleged agreement is far too narrow under any possible view of the evidence because it ignores the parties' mutual assumption that any agreement would involve the purchase and sale of TS, not only for use in Bryan's FDA applications, but also for use in Bryan's FDA approved products. (See, e.g., Waldman Ex. P at 1; Waldman Ex. X). That assumption was expressed most directly by ChemWerth in its draft Supply Agreement, and by Waldman when he provided ChemWerth with projections of Bryan's ongoing TS requirements, but it is implied throughout the parties' course of dealing. Therefore, this court finds that Bryan's theory regarding the terms of the parties' alleged agreement lacks any support in the record on summary judgment.

ChemWerth breached that agreement by failing to obtain a DMF, and that Bryan suffered $2,096,000 in damages as a result of ChemWerth's breach. (Id.). ChemWerth's principal challenge to Bryan's breach of contract claim, as well as to its claim for breach of the implied covenant of good faith and fair dealing, is that no binding agreement was ever reached. This court agrees that Bryan has failed to present sufficient facts to establish the existence of an enforceable contract, and that ChemWerth is entitled to summary judgment on Counts I and II of Bryan's complaint, as well as on its counterclaim for a declaration of no contract.

Governing Legal Principles

"To recover damages in a breach of contract claim, the plaintiff must prove the existence of a valid binding agreement, the defendant's breach thereof, and damages resulting from the breach." Mass Cash Register, Inc. v. Comtrex Sys. Corp., 901 F. Supp. 404, 415 (D. Mass. 1995). Consequently, a plaintiff claiming breach of contract has "the burden of proving the existence of a contract." Moore v. La-Z-Boy, Inc., 639 F. Supp. 2d 136, 140 (D. Mass. 2009). Similarly, a party claiming breach of the implied covenant of good faith and fair dealing "must show that there existed an enforceable contract between the two parties." Christensen v. Kingston Sch. Comm., 360 F. Supp. 2d 212, 226 (D. Mass. (2005) (quoting Learning Express, Inc. v. Ray-Matt Enters., Inc., 74 F. Supp. 2d 79, 84 (1999)) (additional citations omitted). This is because the implied covenant of good faith and fair dealing arises out of an understanding between parties to a contract "that neither party shall do anything that will have the effect of destroying or injuring the right

of the other party to receive the fruits of the contract." Tufankjian v. Rockland Trust Co., 57 Mass. App. Ct. 173, 177, 782 N.E.2d 1, 5 (2003) (quoting Anthony's Pier Four, Inc. v. HBC Assocs., 411 Mass. 451, 471-72, 583 N.E.2d 806, 820 (1991)). "Whether a purported contract contains the necessary elements for enforceability is (ordinarily) a question of law reserved for the court." Moore, 639 F. Supp. 2d at 140.

ChemWerth argues that Bryan cannot establish the existence of an enforceable contract because it cannot show that the parties reached agreement on essential terms, that there was consideration for ChemWerth's alleged promise to supply a DMF, or that there was mutual assent to be bound. (Def. Opp. Mem. (Docket No. 214) at 6-10). This court finds that the parties' lack of mutual assent and their failure to agree on essential details of a contractual arrangement warrant a ruling in favor of the defendant.[7]

"It is black letter law that for a contract to exist, there must be a 'meeting of the minds.'" Adelson v. Hananel, 641 F. Supp. 2d 64, 83 (D. Mass. 2009) (quoting Fraser & Wise, P.C. v. Primarily Primates, Inc., 966 F. Supp. 63, 76 (D. Mass. 1996)). Accordingly,

> [p]arties do not become contractually bound until they mutually assent to bind themselves to an agreement. Courts determine that mutual assent, not on the basis of what goes on inside the parties' heads, but rather on the basis of what they say and do.... Parties can

[7] Bryan argues that ChemWerth waived its lack of consideration defense by not raising it as an affirmative defense in its Answer, and that the record demonstrates the presence of adequate consideration for ChemWerth's promises. (Pl. Opp. Mem. (Docket No. 218) at 10-11). In light of this court's conclusion that Bryan cannot demonstrate mutual assent or an agreement on essential terms, it is unnecessary to address the parties' arguments regarding consideration.

> agree on every term in a contract, yet not be bound until they sign a written agreement, if they so indicate.

Mass Cash Register, Inc., 901 F. Supp. at 416 (quoting Salem Laundry Co. v. N.E. Teamsters & Trucking Indus. Pension Fund, 829 F.2d 278, 280 (1st Cir. 1987)).

In addition, "[t]here must be agreement on the essential terms of the transaction in order that the nature and extent of the parties' obligations can be determined and, hence, enforced." Adelson, 641 F. Supp. 2d at 83 (quoting Novel Iron Works, Inc. v. Wexler Constr. Co., Inc., 26 Mass. App. Ct. 401, 408, 528 N.E.2d 142, 146 (1988)). "'It is not required that all terms of the agreement be precisely specified, and the presence of undefined or unspecified terms will not necessarily preclude the formation of a contract.'" Moore, 639 F. Supp. 2d at 140-41 (quoting Situation Mgmt. Sys., Inc. v. Malouf, Inc., 430 Mass. 875, 878, 724 N.E.2d 699, 703 (2000)). "However, the parties must 'have progressed beyond the stage of imperfect negotiation.'" Id. at 141 (quoting Situation Mgmt. Sys., Inc., 430 Mass. at 878, 724 N.E.2d at 703) (additional quotations and citation omitted). "A lack of definiteness in an agreement might be based on a lack of specificity regarding the time of performance, price to be paid, work to be done, or property to be transferred." Armstrong v. Rohm & Haas Co., Inc., 349 F. Supp. 2d 71, 78 (D. Mass. 2004). "In determining whether such an agreement is nonetheless enforceable, courts should ask whether the parties intended to contract with one another and there is a reasonably certain basis for providing an appropriate remedy." Id. In the instant case, the record

demonstrates that there was no meeting of the minds on the essential terms of a contract, and that any agreement remained too indefinite to constitute a legally enforceable contract.

The Failure to Reach an Agreement

As described above, Bryan contends that the parties entered into a contract under which they agreed that if Bryan purchased TS API from ChemWerth and used it in its applications to the FDA, ChemWerth would obtain and file a TS DMF. (See Pl. Reply Mem. (Docket No. 220) at 6). It further contends that under the terms of the agreement, the plaintiff would pay ChemWerth at a rate of $2,500 per kg, or $3,625 per kgA. (Id.). However, the undisputed facts fail to support Bryan's assertion that ChemWerth agreed to these terms, or otherwise manifested an intent to be bound. Moreover, the undisputed evidence establishes that the parties failed to reach an agreement on other material terms as well.

In support of its claim that a binding agreement was reached, Bryan relies primarily upon representations that were allegedly made by ChemWerth's representatives during the November 2006 audit of Daxin's manufacturing facility in China. (See Pl. Mem. at 2-3; BF ¶ 20). According to the evidence submitted by the plaintiff, one of ChemWerth's regulatory affairs representatives, Li Lixin or Katherine Zhang, "promised and represented to Bryan Corp. that, if Bryan Corp. purchased TS API through ChemWerth, then ChemWerth would obtain and file with FDA the necessary documentation, regarding the manufacture, testing and characteristics of the TS API." (BF ¶ 20; Wa Ex. F at 195-96). However, the record demonstrates that ChemWerth had no intent to be bound by any such

representations, and that this was made clear to Bryan. In particular, it is undisputed that ChemWerth informed Dr. Waldman that Ms. Lixin would be accompanying him on the audit in her capacity as a "translator," and was only available to handle "logistical details." (CW Ex. R at BC1357). It also explained that ChemWerth's approach was not to mix business discussions with audits, and that no one with responsibility for handling business matters would be present during the visit to Daxin. (Id.). Therefore, the undisputed evidence establishes that ChemWerth had no intention of negotiating, much less entering into, a binding agreement with the plaintiff during the course of the audit, and it unambiguously conveyed as much in its communications with Bryan's consultant.

The record also belies Bryan's assertion that the parties reached an agreement at any time as to the price and quantity of the TS material that Bryan would purchase from ChemWerth. As an initial matter, there is no evidence that the parties discussed or even mentioned these matters at the audit. Nor is there any dispute that the price ChemWerth quoted in its bid for the sale of TS API was for "non-DMF material" which, in Dr. Waldman's words, "recognize[d] the lower level of Tobramycin . . . in the Tobramycin Sulfate product." (CW Ex. O; CW Ex. DD). Although ChemWerth eventually produced a draft Supply Agreement in which it proposed a price of $3,625 per kgA for DMF TS API – the same price that it had previously quoted for non-DMF material – its latter proposal contemplated certain quantity commitments from Bryan. Under the terms of the draft Supply Agreement, Bryan would have been required to purchase 50% of its annual TS requirements from ChemWerth, and to pay a unit price of $3,850 per kgA rather than

$3,625 per kgA if its annual demand were to fall below 450 kgA. (Supply Agreement at 1 & Ex. B thereto). These facts, as well as the fact that the parties failed to finalize a written agreement or even discuss the substance of ChemWerth's supply agreement proposal, confirm the defendant's assertion that there was no mutual assent on even the most basic parameters of a contractual agreement.

Bryan suggests that ChemWerth's actions in selling TS to Bryan for $3,625 per kgA were consistent with an intent to be bound by the terms of the alleged oral agreement. (See Pl. Reply Mem. at 6). Again, however, the undisputed facts undermine Bryan's assertion. As the plaintiff discovered after testing revealed a high bioburden in some of the material that Bryan had purchased from ChemWerth, the TS that Bryan purchased was "oral grade -- non DMF" material. (See CW Ex. GG). Accordingly, Dr. Waldman apologized "for what [was] clearly . . . a misunderstanding" of Bryan's requirements, and explained that the plaintiff was seeking injectable quality TS. (Id.). While ChemWerth subsequently offered to run 3 PVB batches in order to ensure that it would be able to meet the quality requirements for the injectable material (see WF ¶ 41; Wa Ex. S), there is no evidence of further discussions confirming ChemWerth's ability to satisfy Bryan's TS-related needs. Therefore, the record fails to show that the parties were able to "progress[ ] beyond the stage of imperfect negotiation" to reach agreement on the nature and quality of the product at issue in their discussions. Moore, 639 F. Supp. 2d at 141 (quoting Situation Mgmt. Sys., Inc., 430 Mass. at 878, 724 N.E.2d at 703) (additional quotations and citation omitted).

Significantly, the evidence demonstrates that at least as late as the summer of 2007, the parties had not even reached a definitive agreement regarding Bryan's need for a DMF. Thus, in July 2007, after the parties discovered the misunderstanding regarding the quality of the material Bryan was seeking, Dr. Waldman informed the defendant that Bryan would feel comfortable referencing the DMF for Tobramycin base in its applications to the FDA, and submitting its applications with "the extra steps[.]" (Wa Ex. P). He further stated that "a new DMF" for the TS API was "not an absolute requirement." (Id.). Accordingly, the terms of any contractual agreement remained far from clear.

In addition to failing to reach an agreement as to the basic terms of product identification, price and quantity of the TS API, the record also establishes that the parties never agreed on terms regularly incorporated into supply agreements of the type which would normally govern arrangements such as that contemplated by Bryan. For example, although proposed by ChemWerth in the draft Supply Agreement, the undisputed facts establish that Bryan never discussed, much less agreed to, terms on issues such as duration, termination, options for renewal, delivery and inspection of the TS.[8] "While in some cases, it is appropriate for the court to supply a missing term negotiated by the parties, but mistakenly omitted from their agreement, it may do so only when the terms of

[8] The fact that ChemWerth addressed all of the outstanding matters in its proposed draft Supply Agreement provides further evidence that it had no intent to be bound prior to a resolution of all of these types of terms. See Mass Cash Register, Inc., 901 F. Supp. at 416 ("language looking to execution of a final written contract justifies a strong inference that significant items on the agenda of the transaction are still open, and hence, that the parties do not intend to be bound." (quotations, citation and alteration omitted)).

the contract are otherwise unambiguous." Moore, 639 F. Supp. 2d at 141. In the instant case, the court cannot reasonably supply the missing provisions "without writing a contract for the parties which they themselves did not make." Id. (citation omitted). Thus, as the court stated in Moore,

> "[t]he difficulty here is that the [agreement] sued on is silent as to material matters important in its interpretation for the ascertainment of the obligations of the parties and the evidence of the circumstances surrounding its making is not such as to permit by inference the supplying of the lack. Many of the essential terms necessarily involved in the proposed undertaking are not set forth and without them no enforceable contract is shown.

Id. (quoting Geo. W. Wilcox, Inc. v. Shell E. Petroleum Prods., Inc., 283 Mass. 383, 390, 186 N.E. 562, 565 (1933)).

Finally, Bryan's contention that ChemWerth "confirmed" the existence of a contract beginning in the spring of 2008, when it informed Bryan of its efforts to obtain a DMF, is unavailing. (Pl. Mem. at 5-6). None of these communications fill in the material terms necessary to form a contract. At most, ChemWerth (mis)represented its ability to produce a DMF for TS API whenever the DMF was required for Bryan's applications to the FDA. While this may be sufficient to state a claim for negligent misrepresentation as discussed below, it is insufficient to fill in the terms necessary to obligate ChemWerth to sell, and Bryan to buy, DMF TS.

In sum, the undisputed material facts establish that the parties did not reach an agreement as to the material terms of a contract, and that their discussions were too indefinite to create a legally enforceable contract. Consequently, ChemWerth is entitled

to summary judgment on Bryan's breach of contract claims (Count I). Since the implied covenant of good faith and fair dealing only exists in connection with a contract, ChemWerth is entitled to summary judgment on this claim (Count II) as well.

C. Count III: Bryan's Claim for Promissory Estoppel

Bryan has alleged, as an alternative to its breach of contract claim, that it is entitled to damages from ChemWerth on the basis of promissory estoppel. In order to prevail on such a claim under Massachusetts law, the plaintiff must prove the following elements:

> that (1) defendant made a promise which he should reasonably expect to induce action or forbearance of a definite and substantial character on the part of the promisee, (2) the promise does induce such action or forbearance, and (3) injustice can be avoided only [by] enforcement of the promise.

Armstrong, 349 F. Supp. 2d at 82. Both Bryan and ChemWerth have moved for summary judgment on this claim. This court finds that the record warrants a ruling in favor of the defendant.

Under Massachusetts law, "an action based on reliance is equivalent to a contract action, and the party bringing such an action must prove all the necessary elements of a contract other than consideration." Id. (quoting R.I. Hosp. Trust Nat'l Bank v. Varadian, 419 Mass. 841, 850, 647 N.E.2d 1174, 1179 (1995)). See also Dixon v. Wells Fargo Bank, N.A., 798 F. Supp. 2d 336, 340 (D. Mass. 2011) (same). "Thus as with a claim for breach of contract, in order to establish the existence of an enforceable promise under promissory estoppel, the plaintiff must show that the defendants' promise included enough essential terms so that a contract including them would be capable of being enforced."

Armstrong, 349 F. Supp. 2d at 82 (quotations, citations and alterations omitted). "Inchoate negotiations are no better basis for reliance than for an action on the purported contract as such." Coll v. PB Diagnostic Sys., Inc., 50 F.3d 1115, 1124 (1st Cir. 1995) (quoting Hall v. Horizon House Microwave, Inc., 24 Mass. App. Ct. 84, 94, 506 N.E.2d 178, 184 (1987)). "To impose rights and duties at 'the stage of imperfect negotiation' would be to interfere with the liberty to contract -- or not to contract." Dixon, 798 F. Supp. 2d at 341 (citing Lafayette Place Assocs. v. Boston Redev. Auth., 427 Mass. 509, 517, 694 N.E.2d 820, 826 (1998)) (internal quotations omitted). In the instant case, since, as detailed above, the parties had not agreed on the essential terms of a contract, the claim for promissory estoppel must fail as well.

The issue whether the representations made by ChemWerth beginning in 2008 to the effect that it would obtain a DMF from Daxin supports a claim of promissory estoppel is a closer question. As the District Judge (Young, J.) recognized in Dixon, while "the courts of Massachusetts have yet to formally embrace promissory estoppel as more than a consideration substitute[,]" the Massachusetts courts have also adopted the broader statement of promissory estoppel found in the Restatement (Second) of Contracts § 90, which provides that "[a] promise which the promisor should reasonably expect to induce action or forbearance on the part of the promisee or a third person and which does induce such action or forbearance is binding if injustice can be avoided only by enforcement of the promise." Dixon, 798 F. Supp. 2d at 343, and cases cited. Under the Restatement, the promise does not have to be as comprehensive in scope as it would be to support the

existence of a contract. Rather, reliance on "indefinite promises" may be sufficient. Id. at 343-44, and cases cited. "Typically, where the Massachusetts courts have applied the doctrine of promissory estoppel to enforce an otherwise unenforceable promise, there has been a pattern of conduct by one side which has dangled the other side on a string." Id. at 344 (internal quotation omitted).

An argument can be made that beginning in about May 2008, ChemWerth lured Bryan into believing that it would obtain the DMF and that Bryan relied on those promises in deciding to continue with its FDA applications.[9] However, this court does not need to decide whether such a scenario would fit within the parameters of promissory estoppel as defined by the Restatement, even assuming such a theory would be entertained by the Massachusetts courts. See id. at 346 ("As the cases reveal, where, like here, the promisor opportunistically has strung along the promisee, the imposition of liability despite the preliminary stage of the negotiations produces the most equitable result."). Even under the Restatement, a promise is found by the courts to be binding "only if injustice can be avoided by its enforcement." Id. As detailed below, Bryan may recover its reliance damages under a theory of negligent misrepresentation if the factfinder determines the

[9] Notably, under this analysis, Bryan's reliance damages would begin in 2008, not end at that point as ChemWerth argues. ChemWerth argues that by the time it sent the draft Supply Agreement in July 2007 Bryan should have known that ChemWerth was not yet obligated to get the DMF, and, therefore, that any promissory estoppel damages should end at that time. This argument, however, ignores the undisputed fact that in July 2007 Dr. Waldman told ChemWerth that a new DMF might not be necessary, but in May 2008 and thereafter ChemWerth nevertheless represented that it would obtain the DMF. It is Bryan's reliance on these later representations that may be actionable.

facts in its favor. This court does not need to expand the theory of promissory estoppel beyond the parameters generally recognized by the Massachusetts courts in order for Bryan to have a viable theory of recovery. Therefore, summary judgment on Bryan's promissory estoppel claim (Count III) shall enter in favor of ChemWerth.[10]

D. Count IV: Bryan's Claim for Negligent Misrepresentation

Finally, Bryan has moved for summary judgment on its claim against ChemWerth for negligent misrepresentation. In order to prevail on such a claim, Bryan must establish that the defendant:

> (1) in the course of its business, (2) supplied false information for the guidance of others (3) in their business transactions, (4) causing and resulting in pecuniary loss to those others (5) by their justifiable reliance upon the information, and (6) that it failed to exercise reasonable care or competence in obtaining or communicating the information.

Cummings v. HPG Int'l, Inc., 244 F.3d 16, 24 (1st Cir. 2001). Bryan contends that it is entitled to judgment as a matter of law on this claim because "[t]here is no genuine issue of material fact that ChemWerth repeatedly misrepresented to Bryan Corp. that Chem-Werth was Daxin's exclusive agent, that ChemWerth would provide the DMF, and that ChemWerth was delivering [PVBs] to Bryan Corp." (Pl. Mem. at 9). This court finds that Bryan's motion must be denied because the facts material to these claims are in dispute.

[10] In light of this ruling, this court will not address ChemWerth's remaining challenges to Bryan's promissory estoppel claim.

As described above, the record reveals the existence of disputed facts relating to Bryan's claim that ChemWerth made misrepresentations regarding the delivery of PVBs. In particular, the parties dispute whether Bryan ever ordered such material from Chem-Werth. (See BF ¶¶ 42-44; CRBF ¶¶ 42-44). They also dispute whether ChemWerth said anything or did anything to lead Bryan and Waldman into believing that it was delivering PVBs to Bryan when in fact it had not done so. (See id.). Consequently, Bryan cannot show that it is entitled to judgment as a matter of law on this claim.

With respect to Bryan's claims that ChemWerth misrepresented its relationship to Daxin and its ability to obtain a DMF, this court finds that while Bryan has stated a claim for relief, there are questions of fact which preclude summary judgment in favor of the plaintiff. To the extent Bryan is relying upon statements that were made by ChemWerth's representatives during the audit in November 2006, a reasonable factfinder could conclude that Bryan's reliance on those statements was unjustified in light of the explicit disclaimers made by ChemWerth prior to the audit. Similarly, a reasonable jury could conclude, based on ChemWerth's communications to Dr. Waldman prior to the audit, that ChemWerth used reasonable care to ensure that Bryan did not rely on any representations of a business nature that may have been made by Ms. Lixin or Ms. Zhang during the course of the audit. Thus, this court cannot find that ChemWerth was negligent as a matter of law in connection with representations made at the audit.

To the extent Bryan is relying upon subsequent statements that ChemWerth made regarding its agency relationship with Daxin and its commitment to provide a DMF, this

court finds that there are disputed issues of fact on these claims, in particular with respect to Bryan's alleged reliance and damages. For instance, it is undisputed that ChemWerth's draft Supply Agreement provided, inaccurately, that ChemWerth had a contract with Daxin under which it had been "assigned the exclusive agent for the development and marketing of [TS,]" and that ChemWerth would arrange for the filing of a TS DMF. (See Supply Agreement at 1, ¶ 7.2). However, a reasonable factfinder could conclude from the fact that the parties never negotiated or signed the Agreement that Bryan did not rely and/or was not justified in relying on any of the representations contained therein. Moreover, there is evidence that a jury may credit to the effect that ChemWerth would have executed such a contract with Daxin if Bryan had signed the Supply Agreement.

It is undisputed that during the time period from the spring of 2008 to March 2011, ChemWerth repeatedly assured Waldman that it would obtain and file a TS DMF while failing to disclose the lack of an agency agreement with Daxin for the sale and distribution of TS API, or the fact that Daxin was unwilling to provide a DMF without such an agreement in place. (See, e.g., Wa Ex. G at 229-31; Wa Ex. W; Wa Ex. Y at 2; Wa Ex. Z at 1; WF ¶¶ 70, 73; BF ¶¶ 70, 73; CRWF ¶¶ 70, 73; CRBF ¶¶ 70, 73). However, the question whether Bryan did rely and/or reasonably relied on any such representations will have to be decided by a factfinder. Bryan's last purchase of TS from ChemWerth occurred in July 2007, and there is no evidence that Bryan attempted to make any purchases after that. Moreover, ChemWerth honestly represented that it did not have the DMF, yet Bryan elected to file the ANDA in any event. Accordingly, the record creates an issue of

fact as to whether Bryan relied on any of ChemWerth's statements. "Massachusetts courts have expressed a strong preference that reliance, in the context of negligent misrepresentation claims, be determined by a jury, and not on summary judgment, 'unless the undisputed facts are so clear as to permit only one conclusion.'" First Marblehead Corp. v. House, 473 F.3d 1, 11 (1st Cir. 2006) (quoting Nota Constr. Corp. v. Keyes Assocs., 45 Mass. App. Ct. 15, 20, 694 N.E.2d 401, 405 (1998)). In light of the uncertainties presented in this case, the question whether Bryan reasonably relied on ChemWerth's statements should be resolved by a jury at trial.

In addition to the question of reliance, issues of fact remain as to whether any of ChemWerth's statements caused the plaintiff to suffer pecuniary loss. As an initial matter, it is undisputed that Bryan never submitted an NDA to the FDA, and the defendant has presented facts which, if accepted as true, show that the NDA project never advanced beyond the planning stage. (See CRWF ¶ 54; CW Supp. Ex. H at 80-81). Therefore, it is unclear whether the losses that Bryan suffered in connection with that project were caused by any of ChemWerth's alleged misstatements or omissions. With respect to Bryan's ANDA, the record establishes that the FDA refused to accept that application due to 33 separate deficiencies, which did not specifically include the absence of a TS DMF. (See Wa Ex. SS at 1-3). Although the parties agree that Bryan could not have obtained FDA approval without such a DMF, they disagree as to whether it would have been possible for Bryan to correct each of the listed deficiencies. (See WF ¶¶ 108-09; BF ¶¶ 108-09; CRWF ¶ 108; CRBR ¶ 108; CAF2 ¶¶ 173, 178-79; CW Supp. Ex. E at Ex. 1 ¶¶ 99, 136,

235-65). Accordingly, there is a genuine issue of material fact as to whether the alleged misrepresentations caused any of the plaintiff's damages or whether Bryan's inability to win approval of its ANDA was caused by Bryan's and Waldman's own failings. For this reason as well, Bryan's motion for summary judgment on Count IV of its complaint is denied.

IV. ANALYSIS– WALDMAN'S MOTION FOR SUMMARY JUDGMENT

Waldman has moved for summary judgment on ChemWerth's third-party claims for negligent representation (Count I), fraud (Count II), violation of Chapter 93A (Count III), and contribution as a result of Waldman's negligent and fraudulent representations to Bryan (Counts IV & V). By its motion, Waldman argues that there is no evidentiary support for these claims, and that certain claims are not actionable because they are untimely. For the reasons detailed below, Waldman's motion is allowed with respect to one of the five representations alleged in support of ChemWerth's claims for fraud and negligent representation. However, the motion is otherwise denied.

A. Counts I & II: Misrepresentation Claims

ChemWerth's claims for fraud and negligent representation are based upon Waldman's statements regarding (1) the acceptability of Daxin's TS API for use in Bryan's FDA applications; (2) the quantities of TS that Bryan expected to purchase; (3) the timing of and necessity for the DMF submission; (4) the reasons listed by the FDA in its Refusal to Receive letter; and (5) Bryan's claim that it incurred $5.5 million in

damages. (See Wa Mem. (Docket No. 172) at 5-6). Under Massachusetts law, a claim for fraud, like a claim for negligent misrepresentation, requires a showing that the alleged wrongdoer made a false statement of material fact, and that the party asserting the claim reasonably relied upon that statement to his detriment. See Rodi v. S. N.E. Sch. of Law, 389 F.3d 5, 13 (1st Cir. 2004) (describing claim for fraudulent misrepresentation); Cumis Ins. Soc'y, Inc. v. BJ's Wholesale Club, Inc., 455 Mass. 458, 471-72, 918 N.E.2d 36, 47-48 (2009) (describing claims for fraud and negligent misrepresentation). Waldman contends that the record lacks sufficient facts to satisfy either of these requirements, and that ChemWerth's claims with respect to three of the challenged statements are barred by the statute of limitations. While this court agrees that Waldman is entitled to summary judgment to the extent ChemWerth's claims are based on statements regarding the amount of Bryan's alleged damages, the motion is otherwise denied with respect to Counts I and II of ChemWerth's third-party complaint.

Acceptability of Daxin's TS

The first alleged misrepresentation is Dr. Waldman's statement, contained in his December 1, 2006 email to ChemWerth's National Account Manager, confirming "the acceptability" of Daxin's site and its products "for use by Bryan Corporation." (See WF ¶ 23; Wa Ex. N). Waldman argues that this statement is not actionable because nothing in the email was false. (See Wa Mem. at 9). Specifically, Waldman argues that while "Waldman, Bryan Corp. and ChemWerth *all* knew that Daxin did not possess a DMF for TS in November 2006[,]" Waldman did not know "that Daxin could *never* supply a DMF

for TS and that Daxin, therefore, could and would only supply 'non-DMF TS material' now and in the future." (Wa Reply Mem. (Docket No. 221) at 3-4). Thus, Waldman argues, when it represented that Daxin's facility was acceptable, it did so based on the understanding that DMF TS material could be manufactured there in the future, and, so, the representation was not false.

This court finds that the record contains enough evidence, which when viewed in the light most favorable to ChemWerth, could support a reasonable finding that Waldman's statement was untrue. While Waldman claims that ChemWerth knew about the need for DMF TS from the outset, this is strenuously denied by ChemWerth and there is record support for both sides. (See Wa Mem. at 10 (testimony establishes that "ChemWerth and Daxin knew at the time of the [audit] that Bryan Corp. intended to use the TS for an ANDA and NDA filed with the FDA, which required a DMF"); CW Ex. O (prior to the audit, ChemWerth informed Waldman that Daxin only manufactured "non-DMF" TS API)). There is evidence that Waldman represented to ChemWerth that it had not yet determined as of November 2006 whether DMF TS would be needed for Bryan. (See Wa Ex. I; Wa Ex. J). If a jury finds that Waldman secretly knew that a DMF would be needed for the TS, and failed to disclose this fact to ChemWerth, then Waldman's representation that Daxin's facility was acceptable despite its lack of capability to manufacture DMF TS could be found to be knowingly false when made. Moreover, a jury could find that ChemWerth, knowing that Daxin did not manufacture DMF TS, and believing that DMF TS was not needed by Bryan, reasonably relied on Waldman's representation in deciding

to continue with the project. This is sufficient to state a claim of negligent misrepresentation.

Waldman also argues that any claim arising from its statement regarding the acceptability of Daxin's TS is barred by the three-year statute of limitations set forth in Mass Gen. Laws ch. 260, § 2A. (Wa Mem. at 11). That statute provides in relevant part that "actions of tort . . . shall be commenced only within three years next after the cause of action accrues." Because ChemWerth's third-party complaint was not filed until September 24, 2012, more than three years after the date of Dr. Waldman's December 1, 2006 email, Waldman argues that any claim arising out of that email is untimely. (Id. at 11-12). This court disagrees.

"The Massachusetts discovery rule applies to tort actions" such as actions for fraud and negligent misrepresentation. Loguidice v. Metro. Life Ins. Co., 336 F.3d 1, 6 (1st Cir. 2003). As the First Circuit has explained,

> [t]he rule "operates to toll a limitations period until a prospective plaintiff learns or should have learned that he has been injured, [and] may arise in three circumstances: where a misrepresentation concerns a fact that was 'inherently unknowable' to the injured party, where a wrongdoer breached some duty of disclosure, or where a wrongdoer concealed the existence of a cause of action through some affirmative act done with the intent to deceive."

Id. (quoting Patsos v. First Albany Corp., 433 Mass. 323, 328, 741 N.E.2d 841, 846 (2001)). ChemWerth argues that it did not become aware of the alleged misrepresentation regarding the acceptability of Daxin's facility until its employee visited that facility in August 2010 and discovered that Daxin could not manufacture TS in accordance with

c-GMP. (See CW Opp. Mem. (Docket No. 216) at 15; Wa Ex. NN). Therefore, it contends that its claim is timely.

Waldman insists that ChemWerth's effort to invoke the discovery rule is unavailing because it knew on the date of Dr. Waldman's December 1, 2006 email "that it was withholding material information from Waldman and Bryan Corp. that would have affected their decision to give ChemWerth authorization to proceed," and because it knew from its twenty-year relationship with Daxin whether Daxin could meet Bryan's needs. (Wa Mem. at 12; see also Wa Reply Mem. at 11). However, as detailed above, the fact-finder will need to determine the hotly contested factual issues concerning when Bryan determined that it needed a new TS DMF, and when this requirement was conveyed to ChemWerth. Without that information, it is impossible to determine when the statute of limitations begins to run on this claim.

Estimated Quantities of TS

The next alleged misrepresentation concerns Dr. Waldman's email to the defendant, dated June 11, 2008, in which Dr. Waldman estimated the quantity of TS that Bryan would need following approval of its ANDA and NDA applications. Therein, Dr. Waldman stated that Bryan would need "about 30-50 kg/year" of TS for its ANDA product and "about 400-600 kg/year" for its NDA product. (Wa Ex. X). Waldman contends that ChemWerth cannot prove that these estimates were false. Specifically, as Waldman reasons:

> ChemWerth conceded during its deposition that Bryan Corp.'s estimated purchases were premised upon Bryan Corp. first obtaining FDA approval for the ANDA and NDA. Bryan Corp., however, never obtained the FDA's approval, because ChemWerth failed to procure a DMF. Thus, Bryan Corp. could not purchase 30-50kg/year of TS for the ANDA product and 400-600 kg/year of TS for the NDA product, because *ChemWerth* failed to do its part, *i.e.* procure a DMF. Thus, ChemWerth cannot credibly claim that Bryan Corp. would not have purchased 30-50 kg/year of the ANDA product and 400-600 kg/year for the NDA product had ChemWerth first procured a DMF as it was required to do.

(Wa Mem. at 13) (internal citations and footnote omitted).

This court finds that Waldman's argument is premised upon a misunderstanding of ChemWerth's claim. The issue is not whether Bryan could commit to the projected purchases. Rather the issue is whether Waldman misrepresented its potential purchases in order to induce ChemWerth to seek a DMF and incur the costs associated with doing so. As ChemWerth alleged in its complaint,

> 79. Waldman knew and should have known that ChemWerth would be induced to engage in the task of obtaining DMF documentation from Daxin in support of Bryan Corp.'s ANDA and NDA submissions, as Waldman requested, because an annual purchase of 400-600 kg of TS would be significant to ChemWerth, as compared to the 21 kg TS purchase that Bryan Corp. had previously placed.
>
> 80. Not knowing that Waldman's projections for the amount of Bryan Corp. TS API were false . . . ChemWerth spent a significant amount of time and financial investment from 2008 to 2011 attempting to establish an agency relationship with Daxin and obtaining documentation from Daxin for filing a DMF with FDA.

(CW Am. Compl. (Docket No. 91) ¶¶ 79-80). Thus, ChemWerth claims that it would not have pursued a DMF and suffered damages if Waldman had not misled it about the volume of potential sales.

The record contains sufficient evidence to support ChemWerth's claim that Waldman's estimates were made, at a minimum, with reckless disregard for their truth or falsity. For instance, there is no dispute that Bryan never completed or filed an NDA application, and the record contains evidence to show that the project never even progressed beyond the planning stage. (See CRWF ¶ 54; CW Supp. Ex. H at 80-81). A reasonable factfinder could conclude from these facts that Waldman's estimates were baseless. In addition, as this court has already determined, the record contains adequate evidence for a jury to conclude that Waldman knew or should have known that Daxin lacked the ability to manufacture injectable quality TS API, which would withstand scrutiny by the United States FDA. For this reason as well, a reasonable jury could find that Waldman's statements of intent to purchase the TS API of the quality which Daxin could manufacture were false. It may be, as Waldman suggests, that a jury will reject such evidence and determine that ChemWerth was responsible for the failure of Bryan's applications. On summary judgment, however, the evidence must be viewed in the light most favorable to the non-moving party, which in this case is ChemWerth.

Waldman argues that even if ChemWerth can establish falsity, it cannot demonstrate reasonable reliance on Waldman's estimates because the evidence shows that ChemWerth was seeking a DMF well before it received those estimates. (Wa Mem. at

13). However, as detailed above, through July 2007, Bryan had not unequivocally stated its need for a TS DMF. While ChemWerth spoke to Daxin about obtaining a DMF for TS API in May 2008, the month before Waldman conveyed its estimates to ChemWerth (Wa Ex. W), a factfinder could conclude that ChemWerth was still trying to determine the scope of Bryan's needs at that time. This would be consistent with the fact that the draft Supply Agreement remained unexecuted as of that time. A reasonable factfinder could infer that ChemWerth would not have persisted in its subsequent lengthy efforts to obtain a DMF, and would not have continued to incur the costs of doing so, if it had not received some level of assurance that its efforts would be worthwhile. The question of Chem-Werth's reliance on Waldman's estimates must await a determination by the finder of fact.

Finally, Waldman argues that this claim too is barred by the three-year statute of limitations. (Wa Mem. at 14). However, there is no indication that ChemWerth knew or should have known in 2008, or at any time outside the limitations period, that Waldman's estimates were false or that it was harmed by Waldman's statements. Therefore, Waldman's motion for summary judgment will not be allowed on this basis.

Timing of and Necessity for the DMF Submission

As described above, ChemWerth is seeking to hold Waldman liable for alleged misrepresentations relating to the timing of and necessity for the submission of a TS DMF. These claims are based on: (1) the email dated August 6, 2006, in which Waldman asked ChemWerth to "confirm, *taking into account that we do not necessarily need a DMF on file at this point* and can help with the FDA filings, the availability of Tobramycin Sulfate

(preferably) or Tobramycin base (less preferred)"; and (2) the email that Dr. Waldman sent to ChemWerth in July 2007, in which he stated that Bryan "would feel comfortable referencing the current Tobramycin [DMF] and submitting the ANDA/NDA with the extra steps, *so a new DMF is not an absolute requirement*. (Wa Ex. I; Wa Ex. P (emphasis added)). ChemWerth contends that these statements constitute misrepresentations because Waldman knew that Bryan needed a TS DMF in order to obtain FDA approval of its ANDA and NDA applications, and the statements suggest that no such information was necessary. (See CW Opp. Mem. at 17-18). Waldman, on the other hand, argues that ChemWerth's corporate representative abandoned these claims during his testimony pursuant to Fed. R. Civ. P. 30(b)(6), and that ChemWerth cannot establish the falsity of the statements or its reliance thereon. (Wa Mem. at 15-16; Wa Reply Mem. at 15). In addition, it argues that these claims are barred by the applicable statute of limitations. (Wa Mem. at 16 n.9).

As an initial matter, this court finds that the deposition testimony cited by Waldman does not rise to the level of a waiver of a properly pleaded claim. At most, it constitutes a lay witness's lack of familiarity with the details contained in legal filings. See Rose v. Regan, 344 Mass. 223, 229, 181 N.E.2d 796, 800 (1962) ("[w]aiver is the intentional relinquishment of a known right"), and authorities cited. Waldman's argument that these communications do not contain untrue statements must fail for the reasons discussed above with respect to the suitability of the Daxin facility. A jury will have to determine the contested facts relating to when Waldman and ChemWerth knew about the need for a

TS DMF, and when that was disclosed to ChemWerth. For the same reasons as discussed above, the question whether ChemWerth relied on these statements in deciding to continue with the project will need to await further development at trial. Finally, the discovery rule precludes a finding that this claim is time-barred. Therefore, Waldman's motion for summary judgment on these claims is denied.

The FDA's Refusal to Receive Letter

Waldman is also seeking summary judgment on ChemWerth's claim that Waldman made misrepresentations regarding the substance of the FDA's Refusal to Receive letter. Waldman argues that this claim is not actionable because ChemWerth is attempting to allege a misrepresentation claim on Bryan's behalf rather than on its own behalf. (Wa Mem. at 16). In addition, Waldman contends that ChemWerth cannot establish the falsity of the challenged statements or that Bryan relied on them to its detriment. (Id. at 17-18).

This court finds that Waldman's first argument is based upon a misreading of ChemWerth's claim. Although ChemWerth's complaint does allege that Waldman made misrepresentations to Bryan about the contents of the FDA letter, it also alleges that Waldman mischaracterized the contents of the FDA letter in its communications with ChemWerth by informing the defendant that the "FDA had refused to accept Bryan Corp.'s ANDA because ChemWerth did not submit a DMF for Daxin's TS API." (CW Am. Compl. ¶ 85). Furthermore, the complaint alleges that ChemWerth had to rely on Waldman's description of the letter because it had no access to the FDA's communications with Bryan. (Id. ¶ 88). ChemWerth has confirmed, in its opposition to the motion

for summary judgment, that it is seeking recovery on its own behalf, not on Bryan's behalf, based on Waldman's statement to ChemWerth. (CW Opp. Mem. at 18).

This court finds that there is adequate evidence in the record on summary judgment to support ChemWerth's claim. As described above, the FDA's Refusal to Receive letter listed 33 separate deficiencies as the basis for the agency's refusal to accept Bryan's ANDA, and none of them mentioned the absence of a TS DMF. (Wa Ex. SS at 1-3). Nevertheless, according to the evidence presented by ChemWerth, Dr. Waldman informed the defendant that final acceptance and review of the ANDA was "held up" by Chem-Werth's failure to submit a TS DMF. (CAF2 ¶ 166). ChemWerth has also presented facts by which a reasonable jury could determine that the defendant continued to incur significant costs in an effort to procure a DMF, in reliance on Waldman's representation that it was at fault for the FDA's refusal to receive the application. (See CAF2 ¶ 175; CW Supp. Ex. G at 232-38). Therefore, the motion for summary judgment must be denied with respect to this claim.

Waldman's effort to show that its statement to ChemWerth was not misleading is insufficient to warrant summary judgment in its favor. Thus, Waldman contends that its statement was accurate because there is no dispute that FDA approval of Bryan's ANDA could not occur in the absence of a TS DMF. (See Wa Reply Mem. at 16). This argument ignores the issue as to whether a DMF would have made any difference to Bryan's prospects for approval of its application. ChemWerth's expert has opined that Bryan could not have obtained approval because, among other things, it failed to order enough

TS API to meet FDA requirements for its exhibit batches, it used a TS API lot with high bioburden outside acceptable limits, and it chose the wrong quality TS API for formulating Bryan's product. (See CW Supp. Ex. E at Ex. 1 ¶¶ 99, 237, 262). Such evidence, if believed, would show that ChemWerth was not responsible for the failure of Bryan's ANDA, and that Waldman's characterization of the Refusal to Receive letter was misleading.

Bryan's Damages

Finally, ChemWerth takes issue with Waldman's May 2011 statement that Bryan had suffered damages, including expenses and losses in time and opportunity, of at least $5.5 million. However, Waldman argues that ChemWerth cannot rely on this statement to prove its claims for fraud and negligent representation because its estimate of Bryan's damages was not false, and because ChemWerth has failed to show how it relied on the statement to its detriment. (Wa Mem. at 18). This court finds that Waldman is entitled to judgment as a matter of law on this claim.

In support of its assertion that Waldman's $5.5 million damages estimate was false, ChemWerth argues as follows:

> Waldman knew how much Bryan Corp. spent developing its TS products because it was solely and completely responsible for the TS project. In fact, Bryan Corp. relied on Waldman's calculations to bring its lawsuit seeking recovery of an alleged $2.1 million. In light of the considerable difference in the two alleged damages amounts (even if lost profits are considered) and his personal knowledge of the actual cost, Waldman's estimate was knowingly false.

(CW Opp. Mem. at 20 (internal citations omitted)). Thus, ChemWerth reasons that the $5.5 million figure must have been false because Bryan is seeking only $2.1 million in this lawsuit. However, the fact that Bryan lowered its damages estimate for purposes of litigation says nothing about the veracity of Waldman's earlier estimate. There are many strategic and practical reasons why a plaintiff may choose to pursue only some of its damages in litigation, and ChemWerth has not pointed to any evidence, such as receipts, billing records, or a cost analysis, to support its assertion that the $5.5 million figure was untrue. A party opposing summary judgment must set forth specific facts in order to establish the existence of a genuine issue for trial. See LeBlanc, 6 F.3d at 841. ChemWerth's speculative assertion is insufficient to withstand Waldman's motion.

Even if ChemWerth were able to establish the falsity of Waldman's estimate, it would not be able to demonstrate its reasonable reliance on the challenged statement. ChemWerth argues that it incurred significant costs attempting to obtain a TS DMF because it was unaware that Waldman's estimate was false. (CW Opp. Mem. at 20-21). However, it has failed to explain, much less present evidence to show, how it would have acted differently if Waldman had used the $2.1 million estimate rather than the $5.5 million estimate. For this reason as well, Waldman's motion for summary judgment is allowed with respect to this aspect of ChemWerth's misrepresentation claims.

B. Count III: Alleged Violations of Chapter 93A

In Count III of its Third-Party Complaint, ChemWerth claims that Waldman's misrepresentations constituted unfair and deceptive acts and practices, in violation of Chapter 93A. Waldman argues that ChemWerth cannot prevail on this claim because it has failed to show that any of Waldman's statements were false or that it reasonably relied on those statements to its detriment. (Wa Mem. at 20-21). It also argues that the 93A claim is time-barred because the alleged misrepresentations occurred more than four years prior to the filing of ChemWerth's complaint. (Id. at 21). Under Massachusetts law, both fraudulent and negligent misrepresentations can support a claim under Chapter 93A. See Rodi, 389 F.3d at 20 ("a fraudulent misrepresentation, actionable at common law, often can form the basis for a Chapter 93A claim"); Marram v. Kobrick Offshore Fund, Ltd., 442 Mass. 43, 62, 809 N.E.2d 1017, 1032 (2004) ("a negligent misrepresentation may be so extreme or egregious as to constitute a violation of G.L. c. 93A, § 11"). Moreover, the discovery rule applies not only to tort claims, but to claims under Chapter 93A as well. Loguidice, 336 F.3d at 6. Because ChemWerth has established a trialworthy issue on at least some of its misrepresentation claims, and has raised a question of fact as to when it knew or should have known that it suffered harm, Waldman's motion for summary judgment will be denied with respect to Count III of ChemWerth's third-party complaint.

C. Counts IV and V: Claims for Contribution

Finally, Waldman is seeking summary judgment on ChemWerth's claims for contribution. By those claims, ChemWerth alleges that any damages incurred by Bryan in this case were caused, in whole or in part, by Waldman's actions. While the parties have each put forth various theories as to the basis (or lack thereof) of ChemWerth's alleged liability to Bryan, given the disputed facts concerning Waldman's knowledge of Daxin's capabilities, as well as Waldman's expectations regarding the need for a TS DMF, summary judgment is inappropriate on ChemWerth's claim for contribution. Further analysis of each argument raised by the parties is unnecessary.

Under Mass. Gen. Laws ch. 231B, "contribution is allowed between joint tort-feasors who cause another, by reason of their wrongdoing, to incur injury or damage." Elias v. Unisys Corp., 410 Mass. 479, 482, 573 N.E.2d 946, 948 (1991). Thus, in order to prevail on a claim for contribution, "the party seeking contribution must show that the potential contributor is directly liable to the tort plaintiff." Panagakos v. Walsh, 434 Mass. 353, 354-55, 749 N.E.2d 670, 671 (2001). However, joint tortfeasors are not required to be liable under the same legal theory in order for contribution to apply. "There is ample authority for the proposition that contribution is appropriate between persons who are liable jointly in tort for the same injuries, even if they are liable on different theories of tort liability." Wolfe v. Ford Motor Co., 386 Mass. 95, 100, 434 N.E.2d 1008, 1011 (1982).

While the exact contours of Waldman's responsibilities are in dispute, there is evidence in the record from which a jury could find that Waldman, in its capacity as Bryan's consultant, had complete responsibility for the plaintiff's TS project. (CW Supp. Ex. L at WAL_001738; see also CW Ex. R at BC1357). In fact, Mr. Abrano testified that Bryan did not have the expertise to select an API provider, so he would have had to rely entirely on Waldman's recommendations in that regard. (CW Supp. Ex. C at 155-56). If a jury so finds, the jury may also find that Waldman did not clearly explain Bryan's needs to ChemWerth, and did not appropriately evaluate Daxin's manufacturing capabilities. Moreover, a jury may find that Waldman made misrepresentations to ChemWerth, which caused misunderstandings and the eventual failure of the project, as well as to Bryan concerning the reasons the project was not progressing favorably. Under such circumstances, both ChemWerth and Waldman may be liable to Bryan, and ChemWerth may be entitled to contribution. Clearer definition of the parties' roles and responsibilities is necessary before a definitive ruling on ChemWerth's contribution claim can be made. Summary judgment is not appropriate at this time.

V. CONCLUSION

For all the reasons detailed herein, it is hereby ORDERED as follows:

A. "Plaintiff Bryan Corporation's Motion for Partial Summary Judgment" (Docket No. 173) is DENIED.

B. "ChemWerth's Motion for Summary Judgment of No Contract" (Docket No. 175) is ALLOWED.

C. "ChemWerth's Motion for Summary Judgment Dismissing or Limiting Damages on Bryan Corp.'s Promissory Estoppel Claim" (Docket No. 177) is ALLOWED.

D. "Third-Party Defendants Waldman Biomedical Consultancy, Inc. and Dr. Alan Waldman's Motion for Summary Judgment" (Docket No. 171) is ALLOWED IN PART and DENIED IN PART as described in detail herein.

/ s / Judith Gail Dein
Judith Gail Dein
U.S. Magistrate Judge