UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRYAN CORPORATION	)	
	)	
Plaintiff,	)	
v.	)	CIVIL ACTION
	)	NO. 12-10446-MLW
CHEMWERTH, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OF DECISION AND ORDER ON THIRD-PARTY DEFENDANT'S MOTION TO DISMISS AND DEFENDANT'S MOTION FOR LEAVE TO FILE AMENDED THIRD-PARTY COMPLAINT

July 8, 2013

DEIN, U.S.M.J.

I. INTRODUCTION

This action arises out of an 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 claims 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 required by the United States Food and Drug Administration ("FDA") so that Bryan could obtain FDA approval of its TS products. Bryan has asserted claims against the defendant for breach of contract (Count I), breach of 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 (Count VI).

The defendant ChemWerth filed a third-party complaint against Waldman Biomedical Consultancy, Inc. and its principal, Dr. Alan A. Waldman (unless otherwise indicated, collectively, "Waldman"), who had served as Bryan's consultant in the transaction with ChemWerth, alleging that Waldman was liable in whole or in part for any damages Bryan may have suffered. The original third-party complaint (Docket No. 28) contained claims for contribution and/or indemnity for all or any portion of the amounts for which ChemWerth may be adjudged liable to Bryan. (Docket No. 28 at p. 23, ¶ 72). Waldman responded with a motion to dismiss the third-party complaint in its entirety pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. (Docket No. 41). That motion is a subject of this decision.

In response to the motion to dismiss, ChemWerth filed a motion for leave to file an amended third-party complaint (Docket No. 51), which motion is also the subject of this decision.[1] In the proposed amended third-party complaint,[2] ChemWerth purports to state claims of negligent representation (Count I), fraud (Count II), violation of Mass. Gen. Laws ch. 93A (Count III), and contribution as a result of Waldman's negligent representation (Count IV) and fraudulent representation (Count V). ChemWerth has dropped

[1] The parties have consented to the Magistrate Judge's final jurisdiction pursuant to 28 U.S.C. § 636(c) for purposes of these two pending motions. (Docket No. 83).

[2] A copy of the proposed amended third-party complaint is attached to the Declaration of Bojuan Deng, Esq. (Docket No. 53) as Ex. A.

its claim for indemnification. Waldman has opposed the motion to amend on the grounds that the proposed amendment is futile, as the proposed amended third-party complaint still fails to state a claim. See Waldman Opp. (Docket No. 58).

As detailed herein, Waldman's opposition to ChemWerth's motion for leave to amend is based on too restrictive a reading of the proposed third-party complaint. ChemWerth is entitled to explore more fully its allegations through discovery. Therefore, ChemWerth's "Motion for Leave to File Amended Third-Party Complaint" (Docket No. 51) is ALLOWED. The "Third-Party Defendant's Motion to Dismiss" ChemWerth's original third-party complaint (Docket No. 41) is DENIED AS MOOT.

II. STATEMENT OF FACTS

Bryan's Claims Against ChemWerth

The following summary of Bryan's claims is helpful to put ChemWerth's claims against Waldman in context. According to Bryan, it "provides high quality medical devices and innovative pharmaceuticals to the global medical community." Bryan Compl. (Docket No. 1) ¶ 8. In 2006, Bryan was interested in developing new products or uses of TS that could receive FDA approval. Id. ¶ 13. ChemWerth held itself out as an agent for Chinese pharmaceutical ingredient manufacturers, and described itself "as having substantial expertise in ensuring that the manufacturers it represents in China produce pharmaceutical ingredients and documentation that meet FDA requirements." Id. ¶ 11. Bryan contacted ChemWerth in connection with its plan to develop products with TS. Id. ¶ 14. ChemWerth allegedly represented that it would obtain and file with the

FDA the documentation necessary to show that the TS manufactured in China by Chongqing Daxin Company Limited, Inc. ("Daxin") met FDA standards. Id. ¶¶ 15-16. ChemWerth's failure to obtain such documentation forms the basis of Bryan's complaint. See id. ¶ 1. Bryan summarizes its claim as follows:

> 1. This action arises from Defendant ChemWerth's fraud, misrepresentation and other misconduct in connection with the sale of a pharmaceutical ingredient (Tobramycin Sulfate) to Plaintiff Bryan Corp. To induce Plaintiff to buy Tobramycin Sulfate from ChemWerth and to develop products that could expand ChemWerth's Tobramycin Sulfate market in the United States, ChemWerth represented and promised to Plaintiff that ChemWerth would provide certain documents regarding the Tobramycin Sulfate that Plaintiff required to obtain FDA approval of Plaintiff's Tobramycin Sulfate products.
>
> 2. ChemWerth's representations and promises were false, and ChemWerth knew or should have known that it would not and could not provide the necessary documents. Ultimately, ChemWerth did not provide the documents, and suggested that Bryan Corp. could cure the problem through misleading filings with FDA. Bryan Corp. refused to participate in such a scheme, and has lost millions of dollars that it spent seeking FDA approval of Tobramycin Sulfate products in reliance on ChemWerth's promises and representations.

Id. ¶¶ 1-2. Waldman has asserted in connection with the instant motions that "Waldman was Bryan Corp.'s consultant, and was just as mislead and deceived by ChemWerth and Daxin's misrepresentations." Waldman Opp. at 2.

ChemWerth's Claims Against Waldman[3]

ChemWerth denies liability to Bryan, and contends that Waldman is liable for any and all damages Bryan allegedly suffered. According to ChemWerth, Waldman Biomedical is a New York company, and Dr. Waldman is its president. Proposed Third-Party Complaint ("TPCompl.") ¶¶ 2-4. Waldman served as consultants to Bryan in its development of TS products during the period at issue in this litigation, December 2005 through March 2012, as well as Bryan's agent in regulatory matters. Id. ¶¶ 12-13. Waldman's expertise is detailed in its website, which provides that Waldman Biomedical "offers every aspect of bringing a product from strategic definition through production, processing and testing, to regulatory approval, licensure and distribution." Id. at ¶ 10. The company provides "consulting and support" in connection with "compliance with QSR, GMP and ISO standards," "qualification and validation of facilities and operations," "creation of regulatory strategies," "all aspects of product and plant registration, including, creation and conduct of clinical trials, creation and filings of all necessary documents, preparation for FDA inspections." Id. ¶ 11. Bryan paid Waldman Biomedical approximately $1.35 million dollars out of the alleged approximately $2.1 million

[3] Waldman opposed ChemWerth's motion to amend its third-party complaint on the grounds that it is futile. Where, as here, "leave to amend is sought before discovery is complete and neither party has moved for summary judgment, the accuracy of the 'futility' label is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6)." Hatch v. Dep't for Children, Youth & Their Families, 274 F.3d 12, 19 (1st Cir. 2001). Under Fed. R. Civ. P. 12(b)(6), the court must accept as true all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences. See Cooperman v. Individual Inc., 171 F.3d 43, 46 (1st Cir. 1999).

dollars spent developing Bryan's TS products, and Waldman was very involved in every aspect of Bryan's transaction with ChemWerth. Id. ¶¶ 14-16.

On December 5, 2005, Bryan and Waldman contacted ChemWerth to purchase Tobramycin Sulfate Active Pharmaceutical Ingredient ("TS" or "TS API") manufactured by Daxin for use in new TS drug products being developed by Bryan. Id. ¶ 17. Bryan was interested in obtaining TS from Daxin because since December 2005, Daxin has held an FDA approved drug master file ("DMF") for Tobramycin Base. Id. ¶ 18. According to ChemWerth, however, Daxin did not have an FDA approved DMF for TS API, nor did it have a Good Manufacturing Practices ("GMP") facility to manufacture TS API. Id. ¶¶ 19-20. Without a GMP facility to manufacture TS API, Daxin could not obtain an FDA approved DMF for TS API. Id. ¶ 21. According to ChemWerth, at the outset of the parties' relationship in December 2005, ChemWerth informed Waldman that Daxin could supply only non-DMF quality TS API. Id. ¶ 25.

From September to October 2006, Waldman purchased three lots of test samples of Daxin TS API. Id. ¶ 23. On November 29-30, 2006, Waldman conducted a two-day on-site audit of Daxin's facility to observe the manufacture of TS API. Id. It was only after the purchase of test samples and the audit that Bryan agreed to use Daxin as the API supplier for Bryan's TS products in December 2006. Id. ChemWerth contends that "Waldman knew and should have known, from correspondence with ChemWerth, from handling the test samples, and from conducting the Audit, that Daxin did not have an FDA approved DMF for TS API and that Daxin also lacked the capacity to manufacture

TS API in a GMP facility." Id. ¶¶ 24, 36. Moreover, according to ChemWerth, "[f]rom about December 2005 to about July 2007, Waldman never advised ChemWerth that DMF quality TS API would be needed for Bryan Corp.'s TS drug products." Id. ¶ 28.

ChemWerth alleges that despite learning during the audit that Daxin did not have the capability to manufacture GMP compliant TS, Waldman failed to so inform Bryan. Id. ¶¶ 43, 46. Moreover, Waldman sent Ms. Flynn of ChemWerth an email on December 1, 2006, informing her that "We are pleased to be able to report 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." Id. ¶ 43. Chemwerth contends that this representation was knowingly false when made. Id. ¶ 44. Specifically, ChemWerth alleges that "[a]s a consultant in the pharmaceutical industry and one admittedly having knowledge regarding 'compliance with GMP' and FDA documentation, Waldman knew or should have known the falsity of his representation concerning the acceptability of the Daxin TS when he made the representation on December 1, 2006." Id. ¶ 45 (internal punctuation and citation omitted). In reliance on Waldman's (mis)representation, ChemWerth supplied, and Bryan purchased, approximately 21 kilograms of the Daxin TS API (non-DMF material) for approximately $53,000. Id. ¶¶ 47-48.

Although "Waldman knew or should have known that Daxin would not make the significant investment to obtain an FDA approvable DMF for its TS based on a purchase of only about $53,000 by Bryan Corp.," in July 2007, Waldman nevertheless approached ChemWerth requesting that ChemWerth obtain a DMF for the Daxin TS API. Id. ¶¶ 51-

53. Waldman was expressly informed "that there had to be sufficient quantities of TS purchased to justify the significant cost of the validation process." Id. ¶ 55. Dr. Waldman requested that ChemWerth draft a proposed Supply Agreement committing Bryan to purchase at least 450 kilograms of the Daxin TS per year in exchange for ChemWerth providing DMF quality TS to Bryan. Id. ¶¶ 58, 60. ChemWerth complied with this request and drafted the Supply Agreement, but it was never signed and Bryan never purchased more than the initial 21 kilogram purchase of TS API. Id. ¶¶ 59-62.

According to ChemWerth, Waldman knew, as early as July 2007, that the Daxin TS API had failed a bioburden test, which indicated that the TS API was not manufactured under GMP conditions, and therefore would not pass FDA's test for obtaining a DMF. Id. ¶¶ 63-66. However, Waldman failed to report this test result to Bryan. Id. ¶¶ 69-70. Moreover, Waldman used the same failed sample to prepare Bryan's TS drug products for FDA approval despite knowing that TS products which used the Daxin TS API would not be accepted by the FDA. Id. ¶¶ 67-68. As a result, Bryan continued to invest in the development of TS drug products in reliance on Waldman's representation about the acceptability of the Daxin TS API. Id. ¶ 71. Moreover, during the period July 2007 through March 2011, "Waldman continued to mislead ChemWerth along regarding the projected large quantities of the Daxin TS API that Bryan Corp. was planning to order in order to induce ChemWerth to collect documentation from Daxin that could, possibly, be used to file a DMF for the TS API sold to Bryan Corp." Id. ¶ 72. Since Waldman allegedly knew that the FDA would not accept Bryan's TS products, which used the

Daxin TS API, and knew that Daxin could not produce necessary documentation for an FDA approved DMF because it manufactured its TS in a non-GMP facility, "the representations to ChemWerth by Dr. Waldman regarding projected purchases of TS API were false." Id. ¶¶ 74-77. Nevertheless, in reliance on these projected purchases, ChemWerth was "induced to engage in the task of obtaining DMF documentation from Daxin in support of Bryan Corp.'s ANDA and NDA submissions[.]" Id. ¶¶ 78-79. ChemWerth was harmed by this reliance since it "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." Id. ¶ 80.

According to ChemWerth, Waldman misled Bryan as to the reasons that the FDA refused to accept Bryan Corp.'s application concerning the TS products in an attempt to blame ChemWerth. Id. ¶ 81. Although Waldman represented that it was the failure of ChemWerth or Daxin to submit a DMF for Daxin's TS API that was the principal reason for the FDA rejecting its application, this was not true. Id. ¶¶ 81-87, 110-11. However, ChemWerth could not challenge Waldman's misrepresentations because it did not have access to Bryan's application or to the FDA's Refusal To File ("RTF") letter which listed 33 problems with the application. Id. ¶¶ 81, 88. ChemWerth alleges that Bryan relied on Waldman's misrepresentations about ChemWerth's liability in deciding to bring suit against ChemWerth, and sent ChemWerth a draft complaint for millions of dollars in damages. Id. ¶¶ 85-91.

ChemWerth alleges that in reliance on Waldman's misrepresentations that it was the cause of the FDA's decision, and the misrepresentations in Bryan's draft complaint in which Bryan claimed that it had been seriously harmed as a result of ChemWerth's actions, ChemWerth spent hundreds of thousands of dollars trying to obtain a DMF for the TS API. Id. ¶¶ 89-94. In addition, ChemWerth contends that it proposed an alternative plan to substitute TS API prepared by another manufacturer, which plan ChemWerth contends was lawful and would work. Id. ¶¶ 95-101. However, Waldman advised Bryan not to approve the plan and Bryan followed Waldman's advice. Id. ¶ 104. ChemWerth contends that Bryan's failure to mitigate its alleged injury was caused by Waldman, and that "[b]ecause of Waldman's misrepresentations, ChemWerth has been injured by spending hundreds of thousands of dollars attempting to obtain DMF documentation for FDA filing and by trying to mitigate the alleged injury to Bryan Corp. which was not even proximately caused by ChemWerth." Id. ¶¶ 107-08. For its part, by blaming ChemWerth, Waldman ignored the fact that it was Waldman's actions that caused the FDA refusal to accept Bryan's application. Id. ¶¶ 113-18. Thus, "Bryan Corp.'s injury, if any, was contributed to by Waldman." Id. ¶ 115.

In sum, ChemWerth alleges "that Waldman is liable to ChemWerth because Waldman made material representations to ChemWerth regarding, among other things, (1) Daxin's manufacturing capabilities as of the time of the Audit, (2) the acceptability of the Daxin TS for use in Bryan Corp.'s products, and (3) the proximate cause for FDA's RTF[.]" Id. ¶ 119. In reliance on these representations, ChemWerth spent "considerable

sums of money in an attempt to collect documentation from Daxin for FDA approval and to mitigate the alleged injury to Bryan Corp. which was not even proximately caused by Chem Werth[.]" Id. ¶¶ 125, 133. ChemWerth contends that it has been injured at least in the amount of $250,000.00. Id.

In addition, ChemWerth alleges that it is entitled to contribution from Waldman because Waldman made misrepresentations to "both Bryan Corp. and ChemWerth regarding, among other things, (1) Daxin's manufacturing capabilities as of the time of the Audit and (2) the acceptability of the Daxin TS for use in Bryan Corp.'s products[.]" Id. ¶ 119. Bryan relied on these misrepresentations and "purchased the Daxin TS API for use in Bryan Corp.'s TS products, invested in Bryan Corp.'s TS products made with the TS API that had failed to pass a bioburden test, and failed to mitigate its alleged injury." Id. 147, 156. Since, if Bryan was injured, its injuries were caused, in whole or in part by Waldman, ChemWerth is seeking contribution from Waldman. Id. ¶¶ 148-50, 157-159.

Additional facts will be provided below where appropriate.

III. ANALYSIS

A. Standard of Review[4]

1. Motion to Dismiss/Amend

[4] ChemWerth contends that it did not need leave of court to amend the complaint under Fed. R. Civ. P. 15(a)(1), although it did seek judicial consent in an abundance of caution. Regardless, since Waldman's opposition to the motion to amend raises the same issues as would be raised by a motion to dismiss an amended third-party complaint, this court will address the merits of Waldman's challenge to the sufficiency of the third-party complaint in the context of its opposition to the motion to amend.

Leave to amend under Fed. R. Civ. P. 15(a)(2) is to be "'freely given when justice so requires' absent an adequate basis to deny amendment such as futility, bad faith, undue delay or a dilatory motive." Transwitch Corp. v. Galazar Networks, Inc., 377 F. Supp. 2d 284, 290 (D. Mass. 2004) (quotations and citations omitted), and cases cited. Waldman has challenged the proposed amendment only on the grounds of futility, so that is the only grounds which will be addressed. Waldman contends that the proposed third-party complaint fails to state a claim upon which relief can be granted. When faced with such a claim, dismissal is only appropriate if the pleadings, so viewed, fail to support "'a plausible entitlement to relief.'" Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559, 127 S. Ct. 1955, 1967, 167 L. Ed. 2d 929 (2007)).

Two underlying principles must guide the court's assessment as to the adequacy of the pleadings to support a claim for relief. Maldonado v. Fontanes, 568 F.3d 263, 268 (1st Cir. 2009). "'First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.' Such conclusory statements are 'not entitled to the assumption of truth.'" Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678-79, 129 S. Ct. 1937, 1949-50, 173 L. Ed. 2d 868 (2009)) (internal citations omitted). "'Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.'" Id. (quoting Iqbal, 556 U.S. 679, 129 S. Ct. at 1950). "This second principle recognizes that the court's assessment of the

pleadings is 'context-specific,' requiring 'the reviewing court to draw on its judicial experience and common sense.' '[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not show[n] – that the pleader is entitled to relief.'" Id. (quoting Iqbal, 556 U.S. 679, 129 S. Ct. at 1950) (internal quotations and citation omitted; alterations in original).

2. Negligent Misrepresentation and Fraud

ChemWerth contends that Waldman is liable for negligent misrepresentation (Count I) and fraud (Count II). "'To prevail on a claim of fraudulent misrepresentation under Massachusetts law, the plaintiff must show that the defendant made a false representation of a material fact with knowledge of its falsity for the purpose of inducing the plaintiff to act thereon, and that the plaintiff reasonably relied upon the representation as true and acted upon it to his damage.'" Pearce v. Duchesneau Group, Inc., 392 F. Supp. 2d 63, 72-73 (D. Mass. 2005) (quoting Eureka Broadband Corp. v. Wentworth Leasing Corp., 400 F.3d 62, 68 (1st Cir. 2005) (additional citations omitted). "Under Massachusetts law, it is 'sufficient to show proof of a statement made, as of the party's own knowledge, which is false, provided the thing stated is not merely a matter of opinion, estimate, or judgment, but is susceptible of actual knowledge; actual intent to deceive on the part of the defendants need not be shown.'" Id. at 73 (quoting Russell v. Cooley Dickinson Hosp., Inc., 437 Mass. 443, 458-59, 772 N.E.2d 1054, 1066 (2002)). Moreover, "[a] statement, though couched in terms of opinion, may constitute a statement of fact if it may reasonably be understood by the reader or listener as implying the

existence of facts that justify the statement (or, at least, the non-existence of any facts incompatible with it)." Rodi v. S. N.E. Sch. of Law, 389 F.3d 5, 14 (1st Cir. 2004), and cases cited.

To prove negligent misrepresentation in Massachusetts, the plaintiff must allege that the defendant "(1) in the course of his 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 on the information, and that he (6) failed to exercise reasonable care or competence in obtaining or communicating the information." Braunstein v. McCabe, 571 F.3d 108, 126 (1st Cir. 2009) (quotation and citation omitted). "A claim of negligent misrepresentation is ordinarily one for the jury, unless the undisputed facts are so clear as to permit only one conclusion." In re TJX Cos. Retail Sec. Breach Litig., 524 F. Supp. 2d 83, 91 (D. Mass. 2007) (internal quotation and citation omitted).

As a general statement, a civil complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). For that reason, "[g]reat specificity is ordinarily not required to survive a Rule 12(b)(6) motion." Garita Hotel Ltd. P'ship v. Ponce Fed. Bank, F.S.B., 958 F.2d 15, 17 (1st Cir.1992). However, an exception to this general rule is codified in Fed. R. Civ. P. 9(b), which provides a heightened pleading standard for fraud claims. See N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale, 567 F.3d 8, 13 (1st Cir. 2009) ("Rule 9(b)'s heightened pleading standard applies to state law fraud claims asserted in

federal court."). Thus, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

"This heightened pleading standard is satisfied by an averment of the who, what, where, and when of the allegedly false or fraudulent representation." Rodi, 389 F.3d at 15 (internal quotation omitted). The First Circuit has further noted that "the specificity requirement extends only to the particulars of the allegedly misleading statement itself." Id. (citing Educadores Puertorriquenos en Accion v. Hernandez, 367 F.3d 61, 66 (1st Cir. 2004)). "The other elements of fraud, such as intent and knowledge, may be averred in general terms." Id. Nevertheless, the complaint must "also identif[y] the basis for inferring scienter." Cardinale, 567 F.3d at 13.

Applying these principles to the instant case compels the conclusion that Waldman's claim of futility must fail.

B. Claims of Misrepresentation

Each of Waldman's objections will be addressed in turn. As a general statement, however, underlying Waldman's challenge to all of the claims of misrepresentation is its contention that ChemWerth knew and understood that it was responsible for providing a product that met FDA approval. While this is consistent with Bryan's position, and may (or may not) be established through discovery, it ignores critical allegations made by ChemWerth in its third-party complaint. Thus, it is ChemWerth's position that it informed Waldman that Daxin could not provide product that met FDA approval, and that

Waldman understood that Daxin could not undertake the work necessary to undertake any validation process needed for FDA approval without a firm purchase commitment, which was never forthcoming. It is not for this court to decide at this stage whose version of events is more credible. Viewing the third-party complaint as a whole, and in the light most favorable to ChemWerth, its pleading withstands Waldman's futility challenge.

1. Falsity of Statements

Waldman argues that ChemWerth has failed to establish either that Waldman made false statements to ChemWerth or that Waldman knew or should have known that its statements were false when made. This court disagrees.

The first alleged misrepresentation was Waldman's assertion in December 2006, after its audit of Daxin, that Daxin's site and product were "acceptable" for use by Bryan. Waldman Opp. at 7 (citing TPCompl. ¶ 43). Waldman contends that there is no allegation that this representation was false when made because "in 2006 there was no reason for Waldman to believe that Daxin could not demonstrate to the FDA that its TS [like its previously approved Tobramycin Base] was also appropriately made and tested. More importantly, even if it were true that Daxin could never satisfy FDA requirements, ChemWerth does not allege that Waldman knew this to be so in 2006 when he made the representation." Id.

This argument ignores several critical pleadings. For example, ChemWerth alleges that it informed Waldman as early as December 2005 that Daxin could supply only non-DMF quality TS API. TPCompl. ¶ 25. ChemWerth has alleged further that

based on its correspondence, and Waldman's audit, Waldman knew that Daxin did not have an FDA approved DMF for TS API "and that Daxin also lacked the capacity to manufacture TS API in a GMP facility." Id. ¶¶ 24, 36. Thus, if Waldman believed in 2006 (contrary to its alleged statements to ChemWerth) "that DMF quality TS API would be needed for Bryan Corp.'s TS drug product[,]" ChemWerth has alleged sufficient facts to establish that Waldman's representation that the Daxin facility was "acceptable" for Bryan's purposes was knowingly false when made in December 2006. See id. ¶ 28; see also ¶¶ 43-44 (affirmatively alleging representation false when made).

Waldman next argues that the allegation that "Waldman falsely represented the quantities of TS that he and/or Bryan Corp. might purchase from Daxin through ChemWerth in the future, is not an actionable misrepresentation." Waldman Opp. at 8. In fact, ChemWerth does not cite to this representation as a basis of its misrepresentation claim. See, e.g., TPCompl. ¶ 119. Assuming, however, that ChemWerth does intend this alleged statement to be the basis for its tort claims, this court cannot rule as a matter of law at this juncture that the statement is not actionable.

Waldman argues:

> As an initial matter, any such representation was speculative, and the supply agreement was never finalized and executed.... Moreover, all of the parties were aware that Waldman's assertion that Bryan Corp. would purchase large quantities of TS was conditioned on Bryan Corp. first getting FDA approval for the sale of new TS products. After all, the draft Supply Agreement explicitly placed the responsibility of ensuring that Daxin filed a DMF with the FDA on ChemWerth (*see* ATPC at ¶ 60). If the FDA had approved Bryan

> Corp.'s application, Waldman's predictions may well have been achieved.

Waldman Opp. at 8.

This argument misconstrues ChemWerth's claim. A liberal reading of the complaint establishes that ChemWerth's contention is not simply that Waldman did not presently intend to purchase a specific quantity of FDA approved TS in the future. Rather, the allegation is that Waldman misrepresented its present intention to have the Supply Agreement executed presently, which would commit Bryan to making significant purchases after FDA approval was received, so as to give Daxin the assurances it needed to undertake the validation process. This is a sufficient allegation of present intent to constitute an actionable misrepresentation.

ChemWerth has alleged that Waldman "knew or should have known that Daxin would not make the significant investment to obtain an FDA approvable DMF for its TS" unless there were going to be "sufficient quantities of TS purchased to justify the significant cost of the validation process." TPCompl. ¶¶ 51, 55; see also id. ¶ 57 ("ChemWerth was concerned that Bryan Corp. would be bound to purchase commercially significant quantities of TS API before ChemWerth undertook the burden and expense of undertaking the validation process."). ChemWerth drafted the Supply Agreement, at Waldman's request, so as to commit Bryan to sufficient purchase amounts of TS after FDA approval was received to make the validation process viable. Id. ¶¶ 57-60. Based on the belief that Bryan was going to execute the Supply Agreement, ChemWerth

expended considerable time and money pursuing Daxin to undertake the validation process. Id. ¶¶ 78-80. However, it is ChemWerth's contention that Waldman did not intend to have Bryan sign the Supply Agreement and commit to purchasing the TS and give Daxin the assurances it needed to invest in the validation process. See id. ¶ 72. These allegations are sufficient to state a claim based on an actionable misrepresentation of present intent.

Finally, Waldman challenges ChemWerth's contention that Waldman misrepresented the reason the FDA denied Bryan's application. As Waldman alleges, "[i]n paragraph 83 of the proposed Amended Third-Party Complaint, ChemWerth itself alleges that Daxin's failure to submit necessary documentation to the FDA was, indeed, one of the reasons expressly listed by the FDA for its refusal to accept Bryan Corp.'s ANDA." Waldman Opp. at 8-9. Therefore, its representation that ChemWerth had caused the FDA's rejection was not false. However, ChemWerth also alleged that Waldman knew that ChemWerth had provided the necessary documentation referenced in the FDA letter to Waldman in 2010. TPCompl. ¶ 84. The implication is that the FDA's request for such information was easily remedied and could not be a valid reason for the rejection of Bryan's application. Nevertheless, Waldman blamed ChemWerth for the FDA decision. Id. ¶ 85. Since the court must accept the allegations as true, ChemWerth has sufficiently pleaded that Waldman knew that its representation that ChemWerth caused the FDA rejection was false when made.

2. Reasonable Reliance

Waldman next argues that ChemWerth's reliance on Waldman's alleged false statements was neither reasonable nor justified. However, this court cannot conclude that ChemWerth's reliance was unreasonable as a matter of law.

Waldman first argues that "ChemWerth's allegation that it relied on Waldman's 'representations about the projected purchases of Bryan Corp. is nonsensical'" because "it is clear that all parties understood that Bryan Corp.'s future purchases of Daxin's TS were contingent on the FDA approving Bryan Corp.'s application." Waldman Opp. at 9. However, as detailed above, ChemWerth contends that it relied on Waldman's representation that there would be a present commitment to make sufficient purchases in the future to justify Daxin investing in the validation process. This is not inconsistent with an understanding that purchases would not be consummated until after FDA approval.

Waldman also argues that ChemWerth "cannot allege that it relied on statements by Waldman regarding Daxin's ability to provide TS that would meet FDA requirements" since ChemWerth had the relationship with Daxin, not Waldman. Waldman Opp. at 9-10. However, it is not unreasonable on the face of the third-party complaint for ChemWerth to have relied on Waldman's assessment of Daxin after Waldman itself audited Daxin's facility and communicated directly with Daxin. Thus, Waldman has not established that ChemWerth has not pleaded reliance as a matter of law.

3. <u>Pecuniary Loss</u>

Waldman also alleges that ChemWerth has failed to establish that it suffered any damage as a result of Waldman's alleged misrepresentations. However, ChemWerth did allege that it expended approximately $250,000 in working to gather DMF information from Daxin in reliance on Waldman's (mis)representation that Bryan would commit to making purchases of sufficient magnitude to make the validation efforts economically feasible, among other things. See, e.g., TPCompl. ¶¶ 125-27. Whether or not Waldman finds this assertion credible, it is sufficient to withstand a motion to dismiss.

For these reasons, Waldman's challenge to ChemWerth's claims of fraud and misrepresentation must fail.

C. Mass. Gen. Laws ch. 93A

Waldman has moved to dismiss ChemWerth's claim under Mass. Gen. Laws ch. 93A on the grounds that the conduct alleged, even if actionable, does not rise to the level of unfair and deceptive acts or practices under chapter 93A. While the question is a close one, it is more appropriate to allow further development of the record on this issue as well.

As detailed above, ChemWerth has stated misrepresentation claims. It is undisputed that even negligent misrepresentations may rise to the level of an unfair or deceptive act or practice. Marram v. Kobrick Offshore Fund, Ltd., 442 Mass. 43, 62, 809 N.E.2d 1017, 1033 (2004). Moreover, ChemWerth has asserted a theory that Waldman wrongfully induced ChemWerth to continue its development efforts with Daxin, knowing that the efforts would be futile. In addition, ChemWerth has alleged that Waldman

wrongfully blamed ChemWerth for the FDA rejection, not only thereby inducing Chem-Werth to shoulder the blame, but also diverting Bryan from investigating Waldman's own failures. Since "it cannot be said conclusively at this early stage of the proceedings that such statements [and conduct] are unactionable[,]" ChemWerth will be permitted to include its 93A claim in its amended third-party complaint. Id. at 62, 809 N.E.2d at 1033. "In a G.L. c. 93A claim, the existence of unfair or deceptive acts ordinarily must be determined from the circumstances of each claim[.]" Id. at 61, 809 N.E.2d at 1032. The chapter 93A claim is not futile as a matter of law.

D. Contribution

Waldman contends that ChemWerth's proposed contribution claims are futile because ChemWerth has failed to sufficiently allege that Waldman is directly liable to Bryan for fraudulent or negligent misrepresentation. Waldman Opp. at 13. Because the third-party complaint is sufficient, at this stage, to allege that Waldman is liable directly to Bryan in tort, ChemWerth will be permitted to add its contribution claims to its amended third-party complaint.

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). "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). Finally, "[i]n order to state a claim for contribution from a joint tortfeasor, 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).

In the instant case, Waldman challenges ChemWerth's allegation that, "upon information and belief," Waldman also misrepresented to Bryan, as it had to ChemWerth, that Daxin's site and products were acceptable for Bryan's purposes. See Waldman Opp. at 13 (citing TPCompl. ¶ 46). Specifically, Waldman contends that ChemWerth has no factual basis for its belief that the representation was ever made to Bryan. However, in light of the fact that Waldman was Bryan's consultant, Waldman conducted its site visit and audit of Daxin on behalf of Bryan, Waldman represented to ChemWerth that Daxin's site and products were acceptable and, as ChemWerth has alleged, it knew that Waldman communicated with Bryan regarding its visit to the facility, see Waldman Opp. at 14 n.3, there is sufficient basis for ChemWerth to allege, upon information and belief, that Waldman made the same report to Bryan about the acceptability of the Daxin facility and product.

Waldman also contends that ChemWerth has not alleged that Waldman knew in December 2006, when it allegedly made the representation about the sufficiency of Daxin's site and product, that it was false. This is the same argument that was addressed above in connection with Waldman's representation to ChemWerth and the argument fails for the same reason. Since it is alleged that Waldman knew from the audit and

correspondence that Daxin could only produce non-DMF TS API, that Daxin lacked the capacity to manufacture TS API in a GMP facility, and that Bryan required DMF quality TS API, then Waldman's representation that the Daxin site and facility were acceptable for Bryan's purposes could be found to have been knowingly false when made.

Finally, Waldman takes strong exception to ChemWerth's allegation that Waldman "mischaracterized to Bryan Corp. the reason that FDA refused to accept Bryan Corp.'s ANDA[,]" pointing out that since ChemWerth has also alleged that Waldman sent Bryan an email reciting all 33 reasons the FDA identified for its refusal, Waldman "clearly did not mislead Bryan Corp. about the basis for the FDA's denial of the new drug application." Waldman Opp. at 14-15 (citing TPCompl. ¶¶ 81, 83). However, ChemWerth also alleged that Bryan has sued ChemWerth on the grounds that ChemWerth's and Daxin's failure to provide acceptable TS API was the basis for the FDA's denial, despite the fact that this was not the reason given by the FDA in its letter. See, e.g., TPCompl. ¶ 82. Moreover, ChemWerth has alleged that to the extent the FDA referred to Daxin's TS API in its letter, it was only to require a document which Waldman knew it had already received from ChemWerth. Id. ¶¶ 83-84. ChemWerth has alleged that Waldman participated in Bryan's efforts to blame ChemWerth for the failure to obtain FDA approval. Id. ¶¶ 89-90. If, as ChemWerth has alleged, the FDA did not reject Bryan's application because of the Daxin TS API, yet Bryan, with Waldman's participation, has brought a lawsuit blaming Daxin's failure to provide FDA approved TS API as the reason for the FDA's rejection of Bryan's application, there is ample support

in the record at this stage to support ChemWerth's assertion that Waldman mislead Bryan about the reason for the FDA rejection.

In sum, ChemWerth has sufficiently alleged that Waldman made misrepresentations directly to Bryan to support ChemWerth's claim for contribution against Waldman as a joint tortfeasor.

IV. ORDER

For all the reasons detailed herein, ChemWerth's "Motion for Leave to File Amended Third-Party Complaint" (Docket No. 51) is ALLOWED. The "Third-Party Defendant's Motion to Dismiss" ChemWerth's original third-party complaint (Docket No. 41) is DENIED AS MOOT.

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