

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  
PLAINTIFF’S MOTION TO DISMISS AND TO STRIKE**

December 9, 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).

ChemWerth denies any liability in this matter and has asserted various affirmative defenses and counterclaims. Of present relevance, ChemWerth has asserted as its Fifth Affirmative Defense that the plaintiff's claims are barred by the doctrine of unclean hands, and in its Third Counterclaim that Bryan violated Mass. Gen. Laws ch. 93A. This matter is presently before the court on "Plaintiff Bryan Corp.'s Motion to Dismiss and to Strike" (Docket No. 82), pursuant to which Bryan is seeking to strike the Fifth Affirmative Defense pursuant to Fed. R. Civ. P. 12(f)(2), and to dismiss the Third Counterclaim for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). The parties have consented to the Magistrate Judge's final jurisdiction pursuant to 28 U.S.C. § 636(c) for purposes of this motion.

For all the reasons detailed herein, the motion is ALLOWED.

## **II. ANALYSIS**

### **A. Standard of Review**

Fed. R. Civ. P. 12(f) allows a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." A motion to strike "offers the primary opportunity for a plaintiff to object to affirmative defenses" and "is governed by the same standards as a motion to dismiss filed pursuant to Fed. R. Civ. P. 12(b)(6)." In re Gabapentin Patent Litig., 648 F. Supp. 2d 641, 647 (D.N.J. 2009), and cases cited. Therefore, 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). Here, the facts applicable to the unclean hands defense are found in the Fifth Affirmative Defense (“FAD”) included in ChemWerth’s Answer (Docket No. 80 at 23-24) and attached exhibits, and in ChemWerth’s Counterclaims (Docket No. 80 at 26, et seq.) (“Counterclaim”).

In connection with the motion to strike the affirmative defense and motion to dismiss the counterclaim, dismissal is only appropriate if the pleadings 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. at 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).

Applying these principles compels the conclusion that Bryan’s motion be allowed.

**B. Statement of Facts – Unclean Hands**

The facts relevant to the pending motion to strike the affirmative defense of unclean hands are as follows. Bryan’s former president was a gentleman named Frank Abrano. In December 2007, Bryan pleaded guilty in the United States District Court, District of Massachusetts, to a three count Information involving criminal conduct which occurred between 1997 and 2000. (See FAD, Ex. B at 1). This was before Bryan’s first contact with ChemWerth in 2005. (See Counterclaim ¶ 18). Count 1 involved the interstate shipment of misbranded drugs – specifically sterile “bulk talc” powder, Product #1690. Count 2 involved the interstate shipment of adulterated devices – specifically barium sulfate. The third Count involved obstruction of an agency proceeding. Bryan was fined \$4,514,700.00 plus a special assessment fee of \$650.00, and was subject to a one year term of probation. See United States v. Bryan Corp., 1:07-CR-10353-RWZ at Docket No. 9.

In 2008, Frank Abrano pleaded guilty to one count of mail fraud in the United States District Court, District of Massachusetts in connection with the sale of Product #1690. He was sentenced to one year and one day imprisonment, and ordered to pay a \$1

million fine, which was satisfied. See United States v. Frank Abrano, 1:07-CR-10229-WGY at Docket No. 34, 46. In connection with his plea, Mr. Abrano admitted that between March 1997 and September 5, 2000, he engaged in a scheme to defraud hospitals. Id. at Docket No. 34, p. 13.

In addition to these facts, ChemWerth has alleged the following in connection with its Fifth Affirmative Defense:

As a result of its criminal conduct, Bryan Corp. is under heightened scrutiny by FDA. Bryan Corp.'s ANDA review and approval is adversely affected by its criminal record. As such Plaintiff's claims, including those for damages, are barred by the doctrine of unclean hands.

(FAD at 24). No additional facts are alleged.

**C. Analysis – Unclean Hands Defense**

Unclean hands is an equitable remedy that allows a court to refuse to aid “one tainted with inequity or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant.” Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814, 65 S. Ct. 993, 997, 89 L. Ed. 1381 (1945). “Its purpose is to prevent a party from benefiting by his dishonesty.” Fisher v. Fisher, 349 Mass. 675, 677, 212 N.E.2d 222, 224 (1965). “In order to deny relief to a party because of inequitable conduct, the conduct at issue must directly affect the claim being brought.” Amerada Hess Corp. v. Garabedian, 416 Mass. 149, 156, 617 N.E.2d 630, 634 (1993). See also Fidelity Mgmt & Research Co. v. Ostrander, 40 Mass. App. Ct. 195, 200, 662 N.E.2d 699, 704 (1996) (“[W]hile ‘equity does not demand that

its suitors shall have led blameless lives’ . . . as to other matters, it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue.” (quoting Precision Instrument Mfg. Co., 324 U.S. at 814–815, 65 S. Ct. at 997)). Thus, the defense does not apply “merely because [a party] has sinned in the past; his wrongdoing must have been related directly to the present situation to justify his being barred.” Santagate v. Tower, 64 Mass. App. Ct. 324, 335, 833 N.E.2d 171, 180 (2005) (internal quotation and citation omitted).

None of the criminal behavior which forms the basis of the claim of unclean hands relates to the conduct at issue in this litigation. Frank Abrano was not involved in the ChemWerth/Bryan transaction. In fact, it does not appear that he was involved with Bryan at all during the time relevant to this litigation. The criminal charges raised by ChemWerth relate to conduct involving products which are not at issue in the instant litigation. The criminal charges have nothing to do with TS, or with ChemWerth’s or Bryan’s attempts to obtain approval for TS products.

To the extent that ChemWerth has alleged that Bryan’s prior record affected the FDA’s consideration of the TS application, it has not supported such a conclusion with any facts at all. In its counterclaim, ChemWerth admits that its conclusory allegation is made only “on information and belief.” (See Counterclaim ¶ 131 (“on information and belief, part of the reason that Bryan Corp.’s ANDA may not have been accepted is due to Bryan Corp.’s own criminal acts, which include previously defrauding FDA.”)) Conclusory allegations of wrongdoing, without more, are insufficient to state a claim.

Maldonado, 568 F.3d at 268. Since Bryan’s prior criminal record is unrelated to the events raised in this case, the unclean hands defense shall be stricken.<sup>1</sup>

**D. Statement of Facts – 93A Counterclaim**

ChemWerth’s Third Counterclaim, brought pursuant to Mass. Gen. Laws ch. 93A, is based on Bryan’s alleged scheme to defraud the FDA. Thus, ChemWerth has alleged that Bryan attempted to defraud the FDA by knowingly applying for FDA approval of a drug product made out of non-compliant TS API. (Counterclaim ¶ 153). Such conduct, “upon information and belief,” was part of Bryan’s “plan to corrupting endeavor (sic) to influence, obstruct, and impede an agency (*i.e.*, FDA).” (Id. ¶ 154). Further, ChemWerth has alleged, “upon information and belief,” that Bryan “planned to use ChemWerth as a pawn [in] its plan to corruptly obtain FDA approval of its drug product.” (Id. ¶ 155).

The remaining allegations are as follows:

156. Bryan Corp. knowingly induced ChemWerth to attempt to obtain documentation for filing a DMF for TS API, in an attempt to defraud FDA into believing that the DMF would match with the TS API (non-DMF material) used in the drug product described in Bryan Corp.’s ANDA that it submitted to FDA for approval.

157. Bryan Corp. engaged in extreme and egregious behavior in its dealings with ChemWerth.

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<sup>1</sup> In light of this conclusion, this court will not address either whether the doctrine of unclean hands is a defense only to legal claims, or whether Bryan’s complaint, which includes a count for promissory estoppel, should be considered as being limited to legal, as opposed to equitable, claims. See Saggese v. Kelley, 445 Mass. 434, 444, 837 N.E.2d 699, 706 (2005) (the principle of unclean hands “is an equitable principle, and generally has no application to an action at law for breach of contract.”).

158. Bryan Corp.'s conduct with respect to ChemWerth was unscrupulous, intolerable, and unethical.

159. Bryan Corp.'s acts are unfair competition and violate Mass. Gen. L. CH. 93 A Section 2. "(a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

160. ChemWerth is entitled to a declaration of fraud against Bryan Corp. under Mass. Gen. L. CH. 93 A Section 2(a) and an award of damages for its losses incurred in the amount of at least \$250,000.

(Emphasis added). ChemWerth has not explained either the basis for its \$250,000 damage claim, or how obtaining documentation for filing a DMF for TS API would be fraudulent as to the FDA, especially since the FDA was allegedly seeking TS with a DMF. ChemWerth also has not alleged that its relationship with the FDA was harmed in any way.

ChemWerth asserts that its counterclaim should be read more broadly than a scheme to defraud the FDA. Specifically, ChemWerth argues that the court should consider the allegations contained in the "facts" section of its counterclaims and conclude that its 93A claim is based on its contention that Bryan made various misrepresentations during the course of the parties' business relationship. (See ChemWerth's Opp. (Docket No. 94) at 8-10). Even ignoring the fact that fraud must be pleaded with particularity, see Fed. R. Civ. P. 9(b), ChemWerth has not asserted a specific counterclaim for fraud or misrepresentation. Nor do all misrepresentations constitute unfair or deceptive acts or practices under 93A. Baker v. Goldman Sachs & Co., No. 09-10053-PBS, 10-10932-PBS, 2013 WL 4780962, at \*2 (D. Mass. Sept. 4, 2013) ("ordinary negligent



misrepresentations” do not violate ch. 93A, as negligence alone is not enough) (collecting cases). See also Marram v. Kobrick Offshore Fund, Ltd., 442 Mass. 43, 62, 809 N.E. 2d 1017, 1032 (2004) (recognizing that “a negligent misrepresentation may be so extreme or egregious as to constitute a violation of G.L. c. 93A, § 11”). It would stretch the Counterclaim beyond recognition to say that ChemWerth’s 93A claim was premised on a string of unidentified misrepresentations made throughout the course of the parties’ relationship. Rather, a fair reading of the Counterclaim is that ChemWerth contends that Bryan engaged in unfair and deceptive acts and practices by attempting to defraud the FDA, and that ChemWerth objects to the fact that Bryan attempted to induce it to obtain documentation which Bryan intended to submit to the FDA. For the reasons detailed below, ChemWerth has failed to state a claim under ch. 93A.<sup>2</sup>

**E. Analysis – 93A Claim**

Mass. Gen. Laws ch. 93A prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Mass. Gen. Laws ch. 93A, § 2(a). Pursuant to § 11:

Any person who engages in the conduct of any trade or commerce  
and who suffers any loss of money or property, real or personal, as a

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<sup>2</sup> The fact that this court has found that ChemWerth has asserted a claim under ch. 93A against Dr. Waldman is not inconsistent with this conclusion. In its Third-Part Complaint against Dr. Waldman ChemWerth asserted a specific claim for fraud and misrepresentation, and identified specific statements on which it was basing its claim. Also, ChemWerth’s claim against Dr. Waldman did not relate to statements allegedly made to the FDA, but rather to Bryan with whom ChemWerth had a direct business relationship. (See Docket No. 89 (Memorandum of Decision and Order on Third-Party Defendant’s Motion to Dismiss)).

result of the use or employment by another person who engages in any trade or commerce of an unfair method of competition or an unfair or deceptive act or practice declared unlawful by section two ... may, as hereinafter provided, bring an action.

Mass. Gen. Laws ch. 93A, § 11. The statute ““was designed to encourage more equitable behavior in the marketplace and impose liability on persons seeking to profit from unfair practices.”” Arthur D. Little, Inc. v. Dooyang Corp., 147 F.3d 47, 55 (1st Cir. 1998) (quoting Linkage Corp. v. Trs. of Boston Univ., 425 Mass. 1, 25, 679 N.E.2d 191, 208 (1997) (citation, internal quotation marks and alterations omitted)). While the statute does not specifically define the prohibited conduct, it is generally recognized that “[a] practice is unfair if it is within the penumbra of some common-law, statutory, or other established concept of unfairness; is immoral, unethical, oppressive, or unscrupulous; and causes substantial injury to other businessmen.” Linkage Corp., 425 Mass. at 27, 676 N.E.2d at 209 (citation, internal quotation marks and alterations omitted). “[T]he existence of unfair or deceptive acts ordinarily must be determined from the circumstances of each claim.” Marram, 442 Mass. at 61, 809 N.E.2d at 1032 (internal citations omitted).

Bryan has alleged that the 93A counterclaim should be dismissed on four grounds: (1) ChemWerth has not alleged that Bryan was engaged in “trade or commerce” as defined in ch. 93A; (2) ChemWerth has no standing to raise this claim because it does not allege that Bryan engaged in any unfair or deceptive acts or practices with respect to ChemWerth, only the FDA; (3) ChemWerth does not allege that Bryan’s scheme to

defraud the FDA caused any loss of money or property to ChemWerth; and (4) the claim is implausible on its face. For the reasons detailed herein, the motion to dismiss is allowed.

### **Trade or Commerce**

Mass. Gen. Laws ch. 93A, § 1 provides that “trade” or “commerce” “shall include the advertising, the offering for sale, rent or lease, the sale, rent, lease or distribution of any services . . . .” Bryan argues that because it did not engage in any of these activities, it did not engage in “trade or commerce.” This argument is without merit.

The statutory definition of “trade and commerce” “is open-ended to a considerable degree because, although it states certain activities that are included, it does not exclude other activities.” Riseman v. Orion Research Inc., 394 Mass. 311, 313, 475 N.E.2d 398, 399 (1985). Therefore, the fact that Bryan did not engage in any of the listed activities is not dispositive of whether ch. 93A applies.

“Under Massachusetts law, whether ch. 93A applies to an ‘interaction between two parties requires a dual inquiry: first, the court assesses whether the interaction is ‘commercial’ in nature, and second, it evaluates whether the parties were both engaged in ‘trade or commerce,’ and therefore acting in a ‘business context.’” State Resources Corp. v. The Architectural Team, Inc., 433 F.3d 73, 84 (1st Cir. 2005) (quoting Linkage Corp., 425 Mass. at 22-23, 679 N.E.2d at 206-07). “An interaction is not commercial in nature if it is a ‘purely private’ intra-enterprise interaction[.]” Id. That is not the situation here,

and Bryan's interactions, be it with the FDA, Dr. Waldman and/or ChemWerth, were not private in nature. Thus, the first prong of the 93A analysis has been satisfied.

Bryan also satisfies the second inquiry. Determining "whether a party is engaging in trade or commerce by acting in a business context 'depends on a number of factors including: 'the nature of the transaction, the character of the parties involved, and [their] activities . . . and whether the transaction [was] motivated by business or personal reasons.'" McDermott v. Marcus, Errico, Emmer & Brooks, P.C., CIV.A. 09-10159-MBB, 2013 WL 4539071, at \*6 (D. Mass. Aug. 26, 2013) (quoting Peabody N.E., Inc. v. Town of Marshfield, 426 Mass. 436, 689 N.E.2d 774, 778 & n.6 (Mass.1998)). Here, a consideration of all these factors compels the conclusion that Bryan's activities occurred in the context of trade or commerce. There was nothing "personal" about its efforts to obtain FDA approval of its TS products. Therefore, ch. 93A applies to Bryan's conduct.

### **Standing**

Bryan alleges that ChemWerth lacks standing to bring the 93A claim because the claim is based on an alleged scheme to defraud the FDA, not ChemWerth. To have standing to assert a claim under ch. 93A § 11, a party must simply be engaged in the conduct of trade or commerce, and, as detailed above, ChemWerth meets this requirement. See City of Boston v. Aetna Life Ins. Co., 399 Mass. 569, 575, 506 N.E.2d 106, 110 (1987). Bryan's claim that ChemWerth has not suffered any loss of money or property, or that Bryan did nothing wrong, "have no significance" as to the standing of ChemWerth to assert a 93A claim. Id. at 574-75, 506 N.E.2d at 109-110. Those "are

issues concerning the existence of a claim, but they do not concern standing.” Id. at 575, 506 N.E.2d at 110. Therefore, Bryan’s challenge to the 93A claim based on lack of standing must fail.

### **Absence of Loss of Money or Property**

To sustain a claim under ch. 93A, the plaintiff must establish that it suffered a loss of money or property which stems from the ch. 93A misconduct. RGJ Assoc., Inc. v. Stainsafe, Inc., 338 F. Supp. 2d 215, 237 (D. Mass. 2004), and cases cited. In the instant case, while ChemWerth has alleged a loss of \$250,000, it has failed to allege how that loss was causally related to Bryan’s conduct in allegedly seeking to defraud the FDA. It has not explained the basis of its alleged loss at all, and a conclusory allegation of harm is insufficient to sustain a claim. Moreover, the allegations of the counterclaim are to the effect that ChemWerth put effort into its (unsuccessful) effort to obtain DMF documentation from Daxin for the TS. (Counterclaim ¶ 106). Since the alleged fraud was that Bryan was trying to defraud the FDA into believing that the TS API had DMF documentation (see Counterclaim ¶ 156), it is unclear how ChemWerth’s efforts to obtain DMF documentation could be in furtherance of any fraud. Since ChemWerth has failed to allege that Bryan’s fraudulent conduct vis-à-vis the FDA caused ChemWerth injury, the 93A counterclaim must be dismissed. RSA Media, Inc. v. AK Media Group, Inc., 260 F.3d 10, 16 (1st Cir. 2001) (“causation remains a necessary element of a successful 93A claim.”).

### **Sufficiency of the Pleading**

Bryan argues that the 93A claim must be dismissed because it does not pass the “common sense” test in that Bryan would not have engaged in a multi-year effort to obtain FDA approval that it knew it could not obtain. ChemWerth argues that given Bryan’s history of fraud on the FDA, it makes sense that Bryan would continue to engage in fraudulent behavior. This court does not have to reach this issue.

The allegations of the counterclaim, even most liberally construed, do not allege conduct that rises to the level of a 93A violation. As detailed above, in addition to failing to allege a causal connection between its alleged harm and the allegedly fraudulent scheme, ChemWerth has not identified with any specificity the alleged misrepresentations on which it is relying in support of its 93A claim. To the extent that ChemWerth is basing its claim on Bryan’s efforts to induce ChemWerth to obtain documents to submit to the FDA, the conduct is not sufficiently egregious to rise to the level of a 93A violation. Since ChemWerth has not alleged any facts showing that Bryan “was in any way unfair, unethical or unscrupulous” vis-à-vis ChemWerth, its contention that Bryan is liable under ch. 93A must fail. See Wellesley Hills Realty Trust v. Mobil Oil Corp., 747 F. Supp. 93, 103 (D. Mass. 1990) (conclusory allegations of unfair acts or practices insufficient to state a claim under 93A). For this reason as well, ChemWerth’s 93A counterclaim must be dismissed.

### **III. ORDER**

For all the reasons detailed herein, Bryan's motion to dismiss the affirmative defense of unclean hands and the counterclaim under Mass. Gen. Laws ch. 93A (Docket No. 82) is ALLOWED.

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