

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

AMERITOX, LTD.,

Plaintiff,

v.

Case No.: 8:11-cv-775-T-24-TBM

MILLENNIUM LABORATORIES, INC.,

Defendant.

ORDER

This cause comes before the Court on two motions: (1) Millennium Laboratories, Inc.'s Motion for Summary Judgment (Doc. No. 328), which Ameritox, Ltd. opposes (Doc. No. S-366); and (2) Ameritox's Motion to Strike (Doc. No. 356), which Millennium opposes (Doc. No. 372). As explained below, Millennium's motion for summary judgment is granted in part, denied in part, and deferred in part. Ameritox's motion to strike is denied.

I. Standard of Review

Summary judgment is appropriate "if the movant shows 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). The Court must draw all inferences from the evidence in the light most favorable to the non-movant and resolve all reasonable doubts in that party's favor. See Porter v. Ray, 461 F.3d 1315, 1320 (11th Cir. 2006)(citation omitted). The moving party bears the initial burden of showing the Court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial. See id. (citation omitted). When a moving party has discharged its burden, the non-moving party must then go beyond the pleadings, and by its own

affidavits, or by depositions, answers to interrogatories, and admissions on file, designate specific facts showing there is a genuine issue for trial. See id. (citation omitted).

II. Background

Ameritox and Millennium are clinical laboratories that screen urine specimens for the presence of drugs. They are competitors in the industry and have been engaged in extensive litigation for several years.

Currently, Ameritox has seven claims pending against Millennium: (1) Lanham Act - false advertising (Count I), (2) violation of Florida's Deceptive and Unfair Trade Practices Act (Counts II and III), (3) unfair competition under California law (Count IV), (4) unfair competition under New Hampshire law (Count V), (5) common law tortious interference with business relationships in Arizona, Florida, California, New Hampshire, Tennessee, and Texas (Count VI), and (6) common law unfair competition in Arizona, Florida, New Hampshire, and Texas (Count VII).¹ (Doc. No. 92). In response, Millennium has the following counterclaims pending against Ameritox: (1) violation of Florida's Deceptive and Unfair Trade Practices Act (Count I), (2) violation of California's Unfair Competition Law (Count II), (3) violation of New York's Consumer Protection from Deceptive Acts and Practices Law (Count V),² (4) common law unfair competition in Florida, Texas, and Washington (Count VI), and (5) common law tortious interference with business relationships in Florida, California, New York, Tennessee,

¹The Court dismissed Ameritox's common law unfair competition claim to the extent that it was based on unfair competition in California and Tennessee. (Doc. No. 132).

²This claim has been limited by this Court's order on Ameritox's Motion to Dismiss. (Doc. No. 178).

Texas, Washington, and Oregon (Count VII).³ (Doc. No. 133). Relevant to this motion are Ameritox's claims that Millennium violated the Lanham Act and engaged in tortious interference and unfair competition.

A. Lanham Act Claim

Ameritox's Lanham Act false advertising claim is based on the following seven alleged representations: (1) the billing letter representation, (2) the press release, (3) the billing manual, (4) the gross revenue chart, (5) the encouragement regarding billing modifiers, (6) the encouragement regarding testing, and (7) the representations that certain business practices were legal.⁴ Below is a brief summary of each alleged representation.⁵

First, Millennium allegedly sent billing letters to physicians to distribute to patients stating a policy: (1) not to collect the difference between the amount Millennium billed for its services and the amount the patients' insurance companies agreed to pay, and (2) not to require patients to pay deductible or co-pays. (Doc. No. S-366, Ex. B, ¶ 4, 15; Doc. No. 359-30, ¶ 8-10). Ameritox alleges that these advertisements were false, deceptive, and misleading to three classes of patients: those enrolled in Medicare who are not required to pay any co-pay or deductible; those enrolled in Florida Medicaid who are required to pay only a \$1 co-payment; and those

³Millennium has withdrawn its counterclaim for violation of Texas' Deceptive Trade Practices Act - Consumer Protection Act, which was contained in Count IV. (Doc. No. 157). The Court has dismissed Millennium's counterclaim for a violation of California's Unfair Practices Act, which was contained in Count III. (Doc. No. 178).

⁴Ameritox is no longer pursuing an eighth representation regarding the alleged promotion of fractional ownership arrangements. (Doc. No. S-366, p. 12, n.10).

⁵The parties do not include a description of many of these representations in their summary judgment briefs, and the Court refers to its order on Millennium's motion to dismiss for a description of representations #2 through #6. (Doc. No. 132).

enrolled in private insurance programs that include the services that Millennium provides within a patient's annual deductible. Therefore, Ameritox alleges that: (1) Millennium advertised an illusory benefit to Medicare patients; and (2) because waiving these payments is illegal under Medicare, Medicaid, and under some states' laws, Millennium garnered business by falsely representing to potential customers that these actions were proper. (Doc. No. S-366, Ex. B, ¶ 15).

Second, Millennium allegedly created a press release advocating for Medicare to reimburse physicians at a higher rate for drug screening and representing that Millennium had no vested interest in advocating for this change. However, Ameritox asserts that presenting the press release from a purportedly neutral standpoint is misleading, because Millennium's business model depends upon generating as much revenue as possible for healthcare providers, so long as they agree to contract with Millennium. Thus, Ameritox contends that Millennium is falsely representing its motive as altruistic and that such a misrepresentation would induce healthcare providers to choose Millennium as their laboratory.

Third, Millennium allegedly gave billing manuals to physicians using its services that included unnecessary, duplicative, and improperly coded billing methods. Ameritox contends that the billing manual deceptively represented that Millennium's billing scheme was proper.

Fourth, Millennium allegedly created a gross revenue chart that promoted an improper billing practice whereby physicians could bill Medicare multiple times for screening a single urine sample for multiple classes of drugs. Ameritox contends that this constitutes false advertising because the chart deceptively implied that Millennium's billing and coding method was proper and could be instituted in good faith.

Fifth, Millennium allegedly encouraged physicians to un-bundle global fees for urine drug screen testing by utilizing billing modifiers. Ameritox contends that these representations deceived healthcare providers into believing that Millennium's revenue-generating schemes were proper.

Sixth, Millennium allegedly encouraged physicians to reduce the number of individual component point-of-care ("POC") tests performed in the physician's office, but to send the samples to Millennium for more expensive comprehensive testing that would be billed to third party payers.

Seventh, Millennium allegedly stated and implied that certain business practices (giving products and services to physicians at below-market prices) were legal when, according to Ameritox, they are not. Specifically, Ameritox contends that these business practices include: (1) providing free POC testing cups ("POCT cups"), (2) providing free assistance for obtaining CLIA waivers, and (3) offering chemical analyzers at preferential pricing. (Doc. No. S-366, Ex. A, ¶ 2).

Ameritox challenges Millennium's provision of free POCT cups, which contain POC test strips inside the cups that detect the presence of certain drugs in the patient's urine and provide immediate preliminary results to the doctors while the patient is in the doctor's office. The doctors receiving the free POCT cups from Millennium execute "Cup Agreements" in which they agree that: (1) they will not bill their patients (or their insurance companies) for the POC tests; (2) they will not use the free POCT cups for any reason other than to collect the urine samples, obtain the preliminary results, and then transport the urine samples to Millennium for confirmatory testing; and (3) they will work with Millennium to account for the cups to ensure

that none of the cups are used for billable POC testing. The Cup Agreements contain the following statement: “To ensure compliance with requirements imposed by the federal ‘Stark’ physician self-referral and anti-kickback laws, we cannot provide these specimen collection cups to your practice without charge unless they are used for collecting and transporting specimens for testing by our laboratory.” (Doc. No. 330-6)(emphasis in original).

Millennium entered into approximately 1,000 Cup Agreements. (Doc. No. S-366, Ex. NN, p. 50-51) Millennium’s sales representatives told doctors that the Cup Agreements were legal. (Doc. No. S-366, Ex. A, ¶ 15; Doc. No. S-366, Ex. B, ¶ 10). Millennium was able to convert accounts from Ameritox to Millennium as a result of the Cup Agreements. (Doc. No. S-366, Ex. B, ¶ 13).

Ameritox also challenges Millennium’s provision of assistance for obtaining CLIA waivers. In order to conduct POC testing, physicians must obtain a certificate of waiver under the Clinical Laboratory Improvement Amendments (“CLIA”). Millennium offered physicians assistance with obtaining the CLIA waiver and stated that the physician would be charged \$50 for this service. (Doc. No. S-366, Ex. H). The form that physicians filled out to obtain Millennium’s assistance stated: “Compliance with applicable laws and regulations is important to us and to you and we believe your acknowledgment below serves to protect both parties. Pursuant to federal laws and regulations, . . . Millennium cannot provide services to your practice unless we agree in advance and your practice pays fair market value. (Doc. No. S-366, Ex. H).

Millennium assisted approximately 200 physicians obtain CLIA waivers. (Doc. No. 328-

39, ¶ 5). However, Millennium did not enforce the collection of the \$50 fee until after this lawsuit was filed. (Doc. No. S-366, Ex. B, ¶ 18; Doc. No. S-366, Ex. K; Doc. No. S-366, Ex. Q; Doc. No. 359-30, ¶ 11). Millennium was able to convert accounts from Ameritox to Millennium as a result of the CLIA waiver assistance. (Doc. No. S-366, Ex. A, ¶ 6; Doc. No. S-366, Ex. B, ¶ 17).

Ameritox also challenges Millennium's offers of chemical analyzers at preferential pricing. Millennium made arrangements with third-parties to offer analyzers at below-market pricing to Millennium's customers, and these offers were communicated to Millennium's customers by Millennium's sales representatives. (Doc. No. S-366, Ex. A, ¶ 8-12; Doc. No. S-366, Ex. A: Ex. B1; Doc. No. S-366, Ex. B, ¶ 20-22; Doc. No. S-366, Ex. R; Doc. No. S-366, Ex. U; Doc. No. 359-30, ¶ 12; Doc. No. S-366, Ex. HH; Doc. No. S-366, Ex. LL). Millennium's sales representatives told doctors that the arrangements were legal. (Doc. No. S-366, Ex. A, ¶ 9-10; Doc. No. S-366, Ex. B, ¶ 4, 20).

B. Tortious Interference and Unfair Competition Claims

Ameritox also asserts claims for tortious interference and unfair competition. The alleged representations and business practices described above provide the basis for Ameritox's tortious interference and unfair competition claims.

III. Motion for Summary Judgment

Millennium moves for summary judgment on Ameritox's Lanham Act, tortious interference, and unfair competition claims. In support of its motion, Millennium makes the following arguments: (1) Ameritox cannot establish Lanham Act liability; (2) Ameritox's attempt to obtain Lanham Act damages or disgorgement fails; (3) Ameritox's tortious

interference and unfair competition claims fail; and (4) Ameritox's claims are barred by its own unclean hands. Accordingly, the Court will address each argument.

A. Lanham Act Liability

Millennium argues that Ameritox cannot establish Lanham Act liability for false advertising in violation of 15 U.S.C. § 1125(a). Section 43(a) of the Lanham Act provides in relevant part:

Any person who . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C.A. § 1125(a)(1)(B). Furthermore, a successful false advertising claim under the Lanham Act must establish:

(1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented product or service affects interstate commerce; and (5) the movant has been-or is likely to be-injured as a result of the false advertising.

Hickson Corp. v. N. Crossarm Co., Inc., 357 F.3d 1256, 1260 (11th Cir. 2004). Millennium makes several arguments with respect to its contention that Ameritox cannot establish Lanham Act liability, and the Court will address each argument below.

1. Cup Agreements

Ameritox contends that the Cup Agreements are violations of the Anti-Kickback Statute ("AKS") and/or the Stark Law. Millennium argues that its representations regarding the legality of its Cup Agreements cannot provide a basis for a Lanham Act claim, because the arrangement described in the Cup Agreements has not been held to be illegal by a court or agency of

competent jurisdiction. As this Court stated in its order on Millennium's motion to dismiss:

Statements by laypersons that purport to interpret the meaning of a statute or regulation are opinion statements, and not statements of fact, unless "a court or agency of competent jurisdiction" has clearly and unambiguously ruled on the matter. [Gen. Cigar Holdings, Inc. v. Altadis, S.A., 205 F. Supp. 2d 1335, 1357 (S.D. Fla. 2002)](citing Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co., 173 F.3d 725, 731 (9th Cir. 1999)). Additionally, "the proper inquiry is whether the law was unambiguous at the time [the] alleged misstatements were made." Dial A Car, Inc. v. Transp., Inc., 82 F.3d 484, 489 (D.C. Cir. 1996).

(Doc. No. 132, p. 17).

The Court agrees with Millennium on this issue. As the Court explained in connection with Ameritox's motion for summary judgment, there is no clear case law on this issue. The only relevant authority comes from Florida's Agency for Health Care Administration ("AHCA"). In June of 2012, Millennium received a letter from AHCA regarding its provision of free POCT cups, which AHCA asserted was a kickback for patient referrals. (Doc No. 328-36). The AHCA letter required Millennium to respond with its plan of correction, and Millennium responded in June of 2012 that the provision of free POCT cups was not a kickback because the doctors agreed not to bill for the POC testing. (Doc. No. 328-36). By early October of 2012, Millennium did not receive any response from AHCA, and on October 9, 2012, Millennium called AHCA to find out AHCA's response to Millennium's plan. (Doc. No. 328-36). The AHCA representative stated that it had received Millennium's plan and that Millennium should proceed with the assumption that the plan had been accepted by AHCA in the absence of further communication indicating otherwise. (Doc. No. 328-36). Millennium has not received any further communications from AHCA. (Doc. No. 328-36).

Accordingly, because a court or agency of competent jurisdiction has not clearly and

unambiguously ruled on the matter of the legality of the Cup Agreements, the Court agrees with Millennium that its representations regarding the legality of the Cup Agreements cannot be the basis for a Lanham Act false advertising claim. Accordingly, the Court grants summary judgment to Millennium on this issue.

2. Chemical Analyzers

Next, Millennium argues that there is no evidence that it offered chemical analyzers at below market rates to its customers; instead, the chemical analyzers were provided by third-parties. The Court rejects this argument, as Ameritox has presented evidence that Millennium sought out the third-party vendors, negotiated preferential pricing for Millennium customers, and would benefit from the transactions between the third-party vendors and the customers. Accordingly, the Court denies Millennium summary judgment on this issue.

3. Representations Regarding Billing and CLIA Waiver Assistance

Next, Millennium argues that its billing representations⁶ are not actionable, because the method of billing it described was legal prior to April of 2010. The Court is unable to analyze this argument, because the parties did not sufficiently identify the specific billing representations that were made or show how such billing practices were proper or improper. For example, Ameritox has provided evidence that Millennium's sales representatives would tell customers: (1) how the customers and Millennium could both bill for testing the same urine specimen; and

⁶The three billing representations at issue are: (1) the billing manuals that included unnecessary, duplicative, and improperly coded billing methods, (2) the gross revenue chart that promoted an improper billing practice whereby physicians could bill Medicare multiple times for screening a single urine sample for multiple classes of drugs, and (3) Millennium's encouragement of physicians to un-bundle global fees for urine drug screen testing by utilizing billing modifiers.

(2) how the customers could bill multiple units of CPT 80101QW. (Doc. No. 359-30, ¶ 6-7).

However, neither party has addressed the specifics of these billing practices or addressed their propriety. Accordingly, the Court denies Millennium's motion for summary judgment on this issue.

Millennium also argues that its marketing of its assistance for obtaining CLIA waivers was not improper, because it told doctors that in order to comply with federal law, it would have to charge them fair market value (\$50) for its services. Ameritox responds that Millennium did not enforce the collection of the \$50 fee until after this lawsuit was filed. (Doc. No. S-366, Ex. B, ¶ 18; Doc. No. S-366, Ex. K; Doc. No. S-366, Ex. Q; Doc. No. 359-30, ¶ 11). Thus, according to Ameritox, Millennium falsely represented the legality of providing its assistance for obtaining CLIA waivers, because Millennium essentially provided the service for free.

The Court concludes that Ameritox's argument is flawed to the extent that there is no allegation that Millennium advertised that it could provide assistance in obtaining a CLIA waiver for free; Millennium advertised that it could do so in exchange for \$50. Thus, Millennium did not falsely advertise the legality of providing its assistance for \$50, and as such, Ameritox's Lanham Act claim based on Millennium's representations regarding CLIA waiver assistance fails. Accordingly, the Court grants Millennium's motion for summary judgment to the extent that Ameritox's Lanham Act claim is based on Millennium's advertising its provision of assistance in obtaining a CLIA waiver. However, Ameritox can still pursue Millennium's *conduct of not collecting* the \$50 fee via its unfair competition claims based on its argument that Millennium improperly provided CLIA waiver assistance for free.

4. Commercial Advertising or Promotion

Next, Millennium argues that Ameritox cannot identify any representations that Millennium made about the legality of the chemical analyzer arrangements, nor can Ameritox identify how and to whom the representations were made.⁷ This argument has no merit, as Ameritox has made such identifications. Ameritox has provided evidence that: (1) Millennium made arrangements with third-parties to offer analyzers at below-market pricing to Millennium's customers, and these offers were communicated to Millennium's customers by Millennium's sales representatives (Doc. No. S-366, Ex. A, ¶ 8-12; Doc. No. S-366, Ex. A: Ex. B1; Doc. No. S-366, Ex. B, ¶ 20-22; Doc. No. S-366, Ex. R; Doc. No. S-366, Ex. U; Doc. No. 359-30, ¶ 12; Doc. No. S-366, Ex. HH; Doc. No. S-366, Ex. LL); and (2) Millennium's sales representatives told doctors that the arrangements were legal (Doc. No. S-366, Ex. A, ¶ 9-10; Doc. No. S-366, Ex. B, ¶ 4, 20).

Millennium also argues that Ameritox has not shown that the gross revenue chart at issue in this case was authenticated as a Millennium document or that it was sufficiently disseminated. Ameritox responds that Millennium has not shown that no genuine issues of fact exist regarding authentication and dissemination, and as the moving party, the burden is on Millennium to show the absence of a genuine issue of fact. The Court agrees with Ameritox. Accordingly, the Court denies Millennium's motion for summary judgment on these issues.

⁷Millennium made this same argument with respect to the Cup Agreements and the CLIA waiver assistance, but the Court has already granted Millennium's motion for summary judgment to the extent Ameritox's Lanham Act claim is based on the Cup Agreements and the CLIA waiver assistance.

5. Abandoned Representations

Next, Millennium makes a one-sentence argument, with no citation to authority, that Ameritox has abandoned its pursuit of Millennium's billing letter representation, Millennium's press release, and Millennium's encouragement regarding testing, because Ameritox does not have any expert testimony regarding damages from such representations. Ameritox responds that expert testimony is not required to prove damages and that it is also seeking injunctive relief with respect to those representations. Given Millennium's failure to provide sufficient argument or authority, the Court denies Millennium's motion on the issue.

B. Lanham Act Damages and Disgorgement

Next, Millennium argues that Ameritox's attempt to obtain Lanham Act damages or disgorgement fails because Ameritox cannot establish that the alleged false advertising caused an injury. As previously stated, a successful false advertising claim under the 15 U.S.C. § 1125(a) of the Lanham Act must establish:

- (1) the advertisements of the opposing party were false or misleading;
- (2) the advertisements deceived, or had the capacity to deceive, consumers;
- (3) the deception had a material effect on purchasing decisions;
- (4) the misrepresented product or service affects interstate commerce; and
- (5) the movant has been-or is likely to be-injured as a result of the false advertising.

Hickson, 357 F.3d at 1260. Once those elements are established, 15 U.S.C. § 1117(a) provides the following regarding the plaintiff's recovery:

[T]he plaintiff shall be entitled . . . , subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action. The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter

judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case. Such sum in either of the above circumstances shall constitute compensation and not a penalty. The court in exceptional cases may award reasonable attorney fees to the prevailing party.

15 U.S.C. § 1117(a). Thus, Ameritox’s potential recovery could include both its own damages and disgorgement of Millennium’s profits, as discussed below.

1. Damages

In order to recover damages, Ameritox must establish that it has been injured by the alleged false advertising. See Trilink Saw Chain, LLC v. Blount, Inc., 583 F. Supp.2d 1293, 1320 (N.D. Ga. 2008). As explained by the Trilink court:

[In order to establish an injury from the false advertising,] the plaintiff must demonstrate that the false advertisement actually deceived or misled consumers, which in turn caused injury to the plaintiff. However, “the court must ensure that the record adequately supports all items of damages claimed and establishes a causal link between the damages and the defendant's conduct, lest the award become speculative or violate [Lanham Act] section 35(a)'s prohibition against punishment.”

Courts have noted that “marketplace damages and actual confusion are notoriously difficult and expensive to prove.” Thus, many courts—including the Eleventh Circuit—routinely presume that literally false advertising actually deceives consumers. Moreover, a growing number of courts have also adopted a presumption, in cases where money damages are sought, that willfully deceptive, comparative advertisements cause financial injury to the party whose product the advertisement targets.

Id. (internal citations omitted). Thus, based on Trilink, to the extent that the challenged representations are shown to be literally false, there is a presumption of actual deception.

However, because none of the challenged representations involve comparative advertisements (i.e., representations comparing Millennium to Ameritox), there will not be a presumption of causation.

Millennium contends that Ameritox cannot show that Ameritox suffered any actual damages as a result of its alleged false advertising. Ameritox's response largely focuses on Millennium's representations regarding its Cup Agreements and CLIA assistance, both of which this Court has held cannot support a Lanham Act false advertising claim. Furthermore, Ameritox points to the fact that Ameritox began missing its financial projections in 2011 while Millennium was exceeding its projections, which Ameritox contends coincides with the explosion of the Cup Agreements at that time. Again, the Cup Agreements cannot be the basis for Ameritox's Lanham Act claim. Additionally, causation of actual damages cannot be shown simply by evidence that Ameritox began missing its financial projections in 2011 while Millennium was exceeding its projections. A change in the parties' sales positions without a showing that the change was caused by a specific advertising representation is not sufficient evidence of causation. See 3M Innovative Properties Co. v. Dupont Dow Elastomers LLC, 361 F. Supp.2d 958, 973 (D. Minn. 2005); Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc., 829 F. Supp.2d 802, 816 (D. Minn. 2011). This is because such evidence does not account for customer purchasing decisions that were made for reasons other than the challenged advertising. See 3M, 361 F. Supp.2d at 973.

Ameritox also relies on an analysis of its customers' proffered reasons for switching to Millennium. However, Ameritox does not provide any evidence directly from the customers themselves. As such, the analysis of its customers' proffered reasons for switching is tainted by

hearsay, as the customers' statements are hearsay. See Air Turbine Technology, Inc. v. Atlas Copco AB, 295 F. Supp.2d 1334, 1344-45 (S.D. Fla. 2003).

Finally, Ameritox relies on the opinions of its expert, Dr. Robin Cantor, to provide evidence of causation. However, via a separate motion, Millennium has moved to exclude the opinion of Dr. Cantor. (Doc. No. 334). The Court intends to hold a hearing on the motion to exclude the opinion of Dr. Cantor, and the Court will address this portion of Millennium's summary judgment motion at that time. Accordingly, the Court defers ruling on whether Ameritox can prove causation, and consequently, its entitlement to damages.

2. Disgorgement of Profits

Ameritox also seeks disgorgement of Millennium's profits. Ameritox does not need to show actual damages in order to obtain a disgorgement of Millennium's profits resulting from its alleged false advertising. See Burger King Corp. v. Mason, 855 F.2d 779, 781 (11th Cir. 1988). "[A]n accounting of defendant's profits is appropriate where: (1) the defendant's conduct was willful and deliberate, (2) the defendant was unjustly enriched, or (3) it is necessary to deter future conduct." Optimum Technologies, Inc. v. Home Depot U.S.A., Inc., 217 Fed. Appx. 899, 902 (11th Cir. 2007).

The Eleventh Circuit has not spoken on the specific issue of the method for proving profits for false advertising claims, but other courts have. For example, in Rexall Sundown, Inc. v. Perrigo Co., 707 F. Supp.2d 357 (E.D.N.Y. 2010), the court stated:

[The defendant] argued that, under § 1117(a), [the plaintiff] bore the burden of establishing what portion of [the defendant's] profits were due to the allegedly false [advertising], as opposed to other aspects of the packaging and promotion of the [defendant's] products. [The plaintiff] disagreed and argued that it was only required to prove [the defendant's] sales and that [the defendant] had to establish any

apportionment. . . . [T]he Court agrees with [the plaintiff].

Both the plain text of the statute and case law support the proposition that, when a plaintiff seeks a defendant's profits in a Lanham Act false advertising case, the plaintiff must establish only the defendant's sales of the product at issue; the defendant bears the burden of showing all costs and deductions, including any portion of sales that was not due to the allegedly false advertising.

The Court's analysis begins with the plain text of the statute at issue, Section 35(a) of the Lanham Act, 15 U.S.C. § 1117(a). That statute provides, in relevant part, that “[i]n assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed.” By its plain terms then, the statute requires the plaintiff to prove “sales only.” It does not say that it is plaintiff's burden to prove, for example, “sales due to the false advertising” or “sales due to the violative conduct.”

Id. at 359 (internal citations omitted). Relying on Rexall, another court stated:

The Court finds the reasoning in Rexall Sundown to be persuasive. To be entitled to recover profits, [the plaintiff] must only prove [the defendant's] sales of the allegedly falsely advertised products. If [the defendant] fails to prove the sales not due to the allegedly violative conduct, [the plaintiff] may be entitled to all of [the defendant's] profits from the allegedly falsely advertised products—subject only to the principles of equity.

[The plaintiff] has sufficient evidence of a likelihood of injury caused by [the defendant's] allegedly false advertising. [The plaintiff's] damages expert presented evidence of [the defendant's] sales of and profits from the allegedly violative products. . . . [The plaintiff] has presented sufficient evidence to allow a recovery of [the defendant's] profits.

Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc., 829 F. Supp.2d 802, 819 (D. Minn. 2011).

While Millennium may argue that such a method of proving profits could provide a windfall to Ameritox, the Court notes three things: First, as noted by the court in Rexall:

“[I]f the defendant can apportion its profits, then the plaintiff is given the appropriate amount and not a windfall. If the defendant cannot

apportion its profits, equity supports the view that, having already been held liable for [violating the Lanham Act], it is the defendant who should suffer the consequences of its own failure to apportion its profits.”

Rexall, 707 F. Supp.2d at 361, n.2 (quoting David S. Almeling, The Infringement–Plus–Equity Model: A Better Way to Award Monetary Relief in Trademark Cases, 14 J. Intell. Prop. L. 205, 224–25 (2007)).

Second, Ameritox still would have to prove causation (i.e., that the false advertising caused injury), and Ameritox would still have to prove the sales of the allegedly falsely advertised products. See Aviva, 829 F. Supp.2d at 819; Rexall, 707 F. Supp.2d at 362 (noting the distinction between proving causation and apportioning profits).

Third, this method is consistent with the Eleventh Circuit’s statement regarding determining an appropriate remedy under § 1117(a):

The Lanham Act . . . confers broad discretion upon the district court to fashion the assessment of damages “according to the circumstances of the case,” 15 U.S.C.A. § 1117, and it is the character of the conduct surrounding the [violation] that is relevant. Thus, it is the district court’s assessment of the particular conduct involved that governs the exercise of its discretion in fixing an appropriate remedy. The district court has the statutory authority to “enter judgment for such sum as the court shall find to be just, according to the circumstances of the case.” 15 U.S.C.A. § 1117. . . . “[A]ll monetary awards under Section 1117 are ‘subject to the principles of equity,’ [and] . . . no hard and fast rules dictate the form or quantum of relief.”

Burger King, 855 F.2d at 782-83.

In its motion for summary judgment, Millennium argues that Ameritox cannot obtain the remedy of disgorgement, because Ameritox has not proven that the false advertising caused an injury. As previously stated with respect to the expert opinion of Dr. Cantor regarding causation,

the Court will address this portion of the Millennium's summary judgment motion when the Court holds its hearing on Millennium's motion to exclude the opinion of Dr. Cantor. Accordingly, the Court defers ruling on whether Ameritox can prove causation, and consequently, its entitlement to Millennium's profits.

C. Tortious Interference and Unfair Competition Claims

Next, Millennium argues that Ameritox's tortious interference and unfair competition claims fail. In support of this contention, Millennium asserts four arguments, which the Court will address in turn.

First, Millennium argues that because the representations at issue do not support a Lanham Act claim, they cannot support a tortious interference or unfair competition claim. The Court has found that Ameritox cannot assert Lanham Act false advertising claims based on Millennium's Cup Agreements or CLIA waiver assistance.

To the extent that Millennium makes the argument that the CLIA waiver assistance *representation* cannot support a tortious interference or unfair competition claim, the Court grants Millennium's motion. However, the Court notes that it has stated that Ameritox may pursue a claim regarding Millennium's *conduct* after making the CLIA waiver assistance representation; specifically, Millennium's failure to collect the \$50 CLIA waiver assistance fee. As such, to the extent of Millennium's conduct in failing to collect the \$50 CLIA waiver assistance fee, the Court rejects Millennium's argument that such conduct cannot form the basis of a tortious interference or unfair competition claim.

Likewise, with respect to the Cup Agreements, Ameritox is challenging the underlying

conduct of providing free POCT cups. As such, the Court's conclusion that Ameritox cannot pursue a Lanham Act claim based on Millennium's representations regarding the provision of free POCT cups does not bar Ameritox from pursuing a claim based on Millennium's conduct.

Second, Millennium argues that conduct that the Court has found not to be illegal under the Stark Law or AKS cannot provide a basis for a tortious interference or unfair competition claim. Ameritox responds that "illegal" conduct is not required for these claims, as deceptive conduct could support tortious interference and unfair competition claims. Thus, Ameritox argues that even if Millennium shows an ambiguity under the Stark Law or AKS with respect to its conduct, Ameritox can still pursue its tortious interference and unfair competition claims regarding such conduct.

The Court notes that it has deferred ruling on Ameritox's motion for partial summary judgment regarding the legality of the Cup Agreements under the AKS and Stark Law. Therefore, the Court will also defer ruling on Millennium's argument that if the Cup Agreements are found not to violate the AKS and Stark Law, whether the Cup Agreements could still provide a basis for an unfair competition or tortious interference claim. The Court will address this issue at the hearing that the Court sets with respect to Ameritox's motion for partial summary judgment.

Third, Millennium argues that Ameritox's tortious interference and unfair competition claims fail because Ameritox cannot show that it was damaged by the conduct. Millennium points out the lack of evidence directly from any doctors showing that they chose Millennium due to any of the challenged practices. As previously stated with respect to Ameritox's evidence of causation regarding its Lanham Act claim, the Court will hold a hearing on the issue of

damages arising from Ameritox's tortious interference and unfair competition claims.

Fourth, Millennium argues that Ameritox cannot seek the remedy of disgorgement of Millennium's profits in connection with its tortious interference and unfair competition claims.⁸ In support of this argument, Millennium simply cites to one case applying Texas law that concluded that disgorgement of profits is not a proper remedy for a tortious interference claim.⁹ See Marcus, Stonewall & Beye Government Securities, Inc. v. Jefferson Investment Corp., 797 F.2d 227, 231-32 (5th Cir. 1986). However, the court in Marcus stated that because the jury was able to determine the amount of the plaintiff's loss, the court did not need to determine whether Texas courts would allow recovery based on the defendant's profits when the plaintiff's loss was not readily ascertainable. See id. at 231 n.5. Furthermore, Ameritox cites a case applying Texas law that concluded that the plaintiff was entitled to the defendant's profits in connection with a tortious interference claim where the plaintiff's lost profits were not readily ascertainable. See Sandare Chemical Co., Inc. v. WAKO International, Inc., 820 S.W.2d 21, 23 (Tx. App. 1991). Additionally, Ameritox cites a case applying Florida law that concluded that the plaintiff was entitled to an accounting of the defendant's profits with respect to its unfair competition claim.¹⁰ See Spray-Bilt, Inc. v. Ingersoll-Rand World Trade, Ltd., 350 F.2d 99, 108 (5th Cir. 1965).

Based on the parties' briefing, the Court concludes that disgorgement of profits is an

⁸The tortious interference claims are brought under the laws of Arizona, Florida, California, New Hampshire, Tennessee, and Texas. The unfair competition claims are brought under the laws of Arizona, Florida, New Hampshire, and Texas.

⁹In footnotes, Millennium cites to two other cases applying the laws of jurisdictions not implicated in this case.

¹⁰In a footnote, Ameritox cites other cases that discuss that disgorgement of profits is an appropriate remedy under the Lanham Act.

available remedy for a tortious interference claim under Texas law and for an unfair competition claim under Florida law. The parties, however, have failed to cite sufficient case law from each state to support their arguments regarding the remedy of disgorgement of profits in connection with tortious interference and unfair competition claims under the other state laws, and the Court is not inclined to do their work for them. When the parties complete their pretrial statement, they are directed to include a section regarding the available remedies for each claim with citations to relevant case law to support their assertions.

Additionally, Millennium argues that even if disgorgement of profits is an available remedy when the plaintiff's lost profits are not readily ascertainable, disgorgement is not an appropriate remedy in this case, because Plaintiff has identified its lost profits through the expert opinion of Dr. Cantor. However, because there is a pending motion to exclude Dr. Cantor's opinion, the Court defers ruling on this argument at this time and will address it in connection with the hearing on Millennium's motion to exclude Dr. Cantor's opinion.

D. Unclean Hands

Next, Millennium argues that Ameritox's claims are barred by its own unclean hands. Both parties cite to Calloway v. Partners National Health Plans, 986 F.2d 446 (11th Cir. 1993), for the elements of the equitable defense of unclean hands. In Calloway, the court stated:

For a defendant to successfully avail itself of the doctrine of unclean hands, it must satisfy two requirements. First, the defendant must demonstrate that the plaintiff's wrongdoing is directly related to the claim against which it is asserted. Second, even if directly related, the plaintiff's wrongdoing does not bar relief unless the defendant can show that it was personally injured by her conduct.

Id. at 450-51 (internal citations omitted).

Millennium bases its unclean hands argument on the following conduct allegedly committed by Ameritox: (1) Ameritox advertises the money that can be made from POC testing by the doctors, (2) Ameritox refers customers to the same vendors for chemical analyzers and those customers receive the same price as Millennium's customers, (3) Ameritox provides billing and coding information for its customers. In response, Ameritox argues that Millennium was not injured by the alleged conduct, because Millennium has not asserted counterclaims against Ameritox for such conduct or otherwise shown how it was injured by Ameritox's alleged conduct.

The parties each devoted two pages to this argument and have not sufficiently fleshed out the factual allegations or briefed the legal issue. Accordingly, the Court concludes that this issue is not ripe for summary judgment, and as such, the Court denies Millennium's motion on this issue.

IV. Motion to Strike

Ameritox moves to strike various declarations that Millennium submitted to the Court in support of its motion for summary judgment. The Court, however, did not rely on any of the declarations, with the exception of the declaration of Robert West regarding the AHCA investigation. As such, the Court denies the motion as moot to the extent that it is based on the declarations of anyone other than West.

The basis for the motion to strike West's declaration is that Millennium did not identify West in its Rule 26 disclosures. Federal Rule of Civil Procedure 37(c)(1) provides: "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a

trial, unless the failure was substantially justified or is harmless.” The burden is on Millennium to show that the failure to disclose was substantially justified or harmless. See Mitchell v. Ford Motor Co., 318 Fed. Appx. 821, 824 (11th Cir. 2009).

Millennium responds that West’s declaration (Doc. No. 328-36) should not be stricken, because West was identified 263 times in documents produced to Ameritox¹¹ (Doc. No. 327-28, ¶ 8) and Ameritox’s counsel questioned Millennium’s president, Howard Appel, at length regarding an email that Appel sent to West (Doc. No. 372-4; Doc. No. 372-16). Accordingly, Millennium argues that West was made known to Ameritox during the discovery process and Ameritox is not prejudiced by the Court’s consideration of West’s declaration.

Upon consideration, the Court concludes that the failure to disclose West was harmless and Ameritox was not prejudiced. In his declaration, West describes the AHCA’s investigation regarding Millennium’s provision of free POCT cups. Most of the information relied on by the Court came from the documents sent from and submitted to AHCA, and Ameritox has not argued that the documents, themselves, are not admissible. The only evidence directly from West that the Court relied on relates to his conversations with AHCA after Millennium’s response to AHCA that its provision of free POCT cups was not a kickback. Specifically, West states: (1) by October of 2012, Millennium did not receive any response from AHCA, and on October 9, 2012, Millennium called AHCA to find out AHCA’s response to Millennium’s plan; (2) the AHCA representative stated that it had received Millennium’s plan and that Millennium should proceed with the assumption that the plan had been accepted by AHCA in the absence of further communication indicating otherwise; and (3) Millennium has not received any further

¹¹Examples of a few of such documents can be found at Doc. No. 372-10 through 372-14.

communications from AHCA. Even if the Court were to strike West's direct testimony, the Court would still be persuaded that AHCA implicitly accepted and approved of Millennium's response given the absence of any evidence of any penalty issued by AHCA against Millennium. Accordingly, the Court denies Ameritox's motion to strike West's declaration.

V. Conclusion

Based on the above, it is ORDERED AND ADJUDGED that:

(1) Millennium Laboratories, Inc.'s Motion for Summary Judgment (Doc. No. 328) is

GRANTED IN PART, DENIED IN PART, and DEFERRED IN PART:

- (a) The motion is **GRANTED** to the extent that Millennium moves for summary judgment on the Lanham Act false advertising claim based on the Cup Agreements and the CLIA waiver assistance; the motion is **DENIED** to the extent that the Lanham Act claim is based on other representations.
- (b) The Court **DEFERS** ruling on the issues of causation, damages, and disgorgement of Millennium's profits with respect to the Lanham Act claim, tortious interference, and unfair competition claims. Additionally, the Court **DEFERS** ruling on the issue of whether the Cup Agreements can provide a basis for an unfair competition or tortious interference claim if the Court concludes that the Cup Agreements do not violate the AKS and Stark Law.

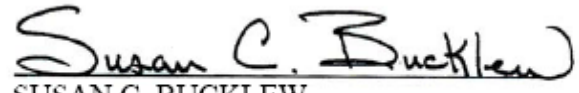
(2) Ameritox's Motion to Strike (Doc. No. 356) is **DENIED**.

(3) The Court will, by separate order, set oral argument on this motion to the extent

that the Court deferred ruling on the issues identified above.

- (4) When the parties complete the pretrial statement, they are directed to include a section regarding the available remedies for each claim with citations to relevant case law to support their assertions.

DONE AND ORDERED at Tampa, Florida, this 14th day of April, 2014.


SUSAN C. BUCKLEW
United States District Judge

Copies to: All parties and Counsel of Record