

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.

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ORDER

This cause comes before the Court on Ameritox, Ltd.'s Motion for Partial Summary Judgment. (Doc. No. 337-1). Millennium Laboratories, Inc. opposes the motion. (Doc. No. S-365). As explained below, the motion is denied in part and deferred in part.

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, Texas, Washington, and Oregon (Count VII).³ (Doc. No. 133).

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).

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

Relevant to this motion are Ameritox's claims that Millennium violated the Lanham Act and engaged in unfair competition based on Millennium's provision of free point-of-care ("POC") testing cups ("POCT cups") to doctors. The free POCT cups 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 agree not to bill for the POC testing. Alternatively, doctors can purchase POC test strips and/or POCT cups from Millennium or other suppliers and then bill the patient for the POC testing.

At issue in the instant case is Millennium's provision of free POCT cups to doctors who 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. (Doc. No. 337-6). Ameritox contends that the provision of free POCT cups violates that Anti-Kickback Statute ("AKS") and/or the Stark Law. Millennium does not dispute that it gives doctors free POCT cups, but it argues that such conduct, under the facts of this case, does not violate the AKS or Stark Law. If such conduct is found to violate the AKS or Stark Law, then Ameritox contends that such conduct provides the basis for liability under Ameritox's Lanham Act and unfair competition claims in Counts I through VII.

Also relevant to this motion are Millennium's unfair competition counterclaims based on

Practices Act, which was contained in Count III. (Doc. No. 178).

three types of conduct. First, Millennium contends that Ameritox entered into prohibited, sham space-lease arrangements with doctors. Millennium contends that Ameritox would lease small amounts of space in doctors' offices and pay the doctors rent for such space. Millennium contends that the leases were not commercially reasonable, the "rent" constituted unlawful remuneration, and the leases would not be entered into absent the doctors referring their urine testing work to Ameritox.

Second, Millennium contends that Ameritox gave doctors free computers to use to carry out their daily office tasks. Millennium contends that these free computers were an unlawful kickback.

Third, Millennium contends that Ameritox purposefully withholds information from their sales representatives regarding Ameritox's in-network or out-of-network provider status. As a result, Millennium contends that the sales representatives erroneously imply to doctors that Ameritox is an in-network provider when it is not. Millennium contends that this practice influences doctors' purchasing behavior, because in-network provider status is a significant driver of lab selection. Therefore, Millennium contends that Ameritox receives referrals for testing that it would not otherwise receive had the doctors known of Ameritox's out-of-network status.

III. Motion for Partial Summary Judgment

Ameritox moves for partial summary judgment on four issues: (1) whether Millennium's provision of free POCT cups to doctors violates the AKS (42 U.S.C. § 1320a-7b(b)(2)) and/or the Stark Law (42 U.S.C. § 1395nn); (2) whether Ameritox entered into challenged space-lease arrangements in Florida, New York, Washington, and/or Oregon; (3) whether Ameritox gave

doctors free computers to use without restriction; and (4) whether Ameritox's sales representatives implied to doctors that Ameritox was an in-network provider when it was not. Accordingly, the Court will address each issue.

A. POCT Cups

Ameritox argues that it is entitled to summary judgment on its contentions that Millennium's provision of free POCT cups to doctors: (1) is a compensation arrangement that violates the Stark Law, and (2) is improper remuneration that violates the AKS.⁴ Accordingly, the Court will address both arguments.

1. Stark Law

The Stark Law prohibits doctors from referring their Medicare and Medicaid patients to business entities with which the doctors have a financial relationship. See U.S. v. Halifax Hospital Medical Center, 2014 WL 68603, at *2 (M.D. Fla. Jan. 8, 2014); 42 U.S.C. § 1395nn(a)(1)(A). One example of a financial relationship is a compensation arrangement. 42 U.S.C. § 1395nn(a)(2)(B). With certain exceptions, a compensation arrangement is an arrangement involving any remuneration—directly or indirectly, overtly or covertly, in cash or in kind—between a doctor and the entity. 42 U.S.C. § 1395nn(h)(1). Thus, the Stark Law prohibits doctors who have a compensation arrangement with an entity from making referrals of Medicare or Medicaid patients for clinical laboratory services to that entity. See Halifax, 2014 WL 68603, at *9; U.S. ex rel. Osheroff v. Tenet Healthcare Corp., 2013 WL 1289260, at *1 (S.D. Fla. Mar.

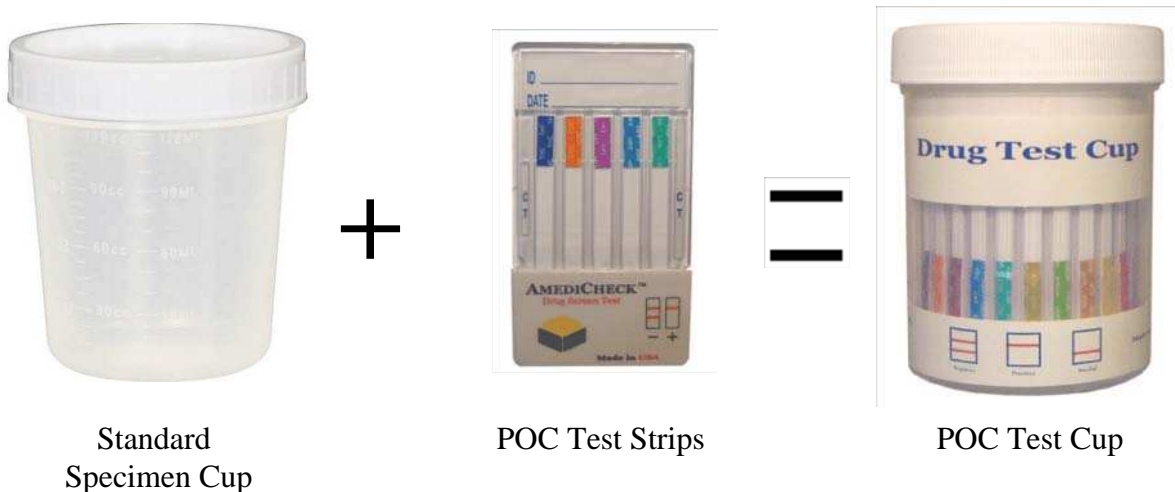
⁴Neither the Stark Law nor the AKS provides a private right of action, and as such, Ameritox is using the alleged violation of the Stark Law and AKS as the basis for its Lanham Act and unfair competition claims. See U.S. v. Halifax Hospital Medical Center, 2014 WL 68603, at *4, *4 n.2 (M.D. Fla. Jan. 8, 2014); U.S. ex rel. Osheroff v. Tenet Healthcare Corp., 2013 WL 1289260, at *1 (S.D. Fla. Mar. 27, 2013).

27, 2013); 42 U.S.C. § 1395nn(a)(1)(A); 42 U.S.C. § 1395nn(a)(2)(B); 42 U.S.C. § 1395nn(h)(6).

Remuneration is defined under the statute as “includ[ing] any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. § 1395nn(h)(1)(B). One exception to the broad definition of remuneration is the provision of items that are used solely to collect, transport, process, or store specimens for the entity providing the item. 42 U.S.C.

§ 1395nn(h)(1)(C)(ii)(I). Another exception to the broad definition of remuneration is the provision of items that are used solely to communicate the results of tests for the entity providing the item. 42 U.S.C. § 1395nn(h)(1)(C)(ii)(II). In this case, the parties dispute whether Millennium’s provision of free POCT cups falls within these exceptions to the broad definition of remuneration.

The parties do not dispute that the provision of a free standard clear plastic receptacle (“standard specimen cup”) falls within the exception to the broad definition of remuneration, because its sole purpose is collect, store, and transport a urine specimen. Likewise, the parties do not dispute that the provision of free POC test strips would not fall within the exception, as the strips are not used solely to collect, transport, process, or store specimens for the entity providing the test strips. However, a POCT cup combines a standard specimen cup with test strips that can immediately detect the presence or absence of drugs in a urine sample:



The parties dispute whether the provision of free POCT cups—which are used to: (1) collect, transport, process, and store urine specimens, and (2) provide immediate preliminary test results to the doctor regarding the presence or absence of drugs in the patient’s urine prior to Millennium’s confirmatory testing—violates the Stark Law or comes within its exceptions for items used solely to collect, transport, process, or store specimens for the entity providing the item. Millennium argues that the POCT cups fall within the exceptions because the POCT cups are used solely for the purposes outlined in the exceptions: (1) to *collect, store, and transport* urine for confirmatory tests performed by Millennium, (2) to *process* the urine to generate a preliminary result as a step to getting final confirmatory test results from Millennium, and (3) to *communicate* the preliminary results.

Additionally, Millennium argues that because it requires that doctors who are given free POCT cups cannot bill the patients or their insurance for the POC testing, Millennium has not given the doctors anything of financial value, and as such, it has not violated the Stark Law. Millennium de-emphasizes the value provided by the POCT cups’ immediate preliminary results by characterizing it the following way:

The purpose for the test strips in these cups is to provide a possible deterrent for patients who may consider deviating from their prescribed regimen; any unexpected preliminary results can trigger a conversation with the patient while still at the office. It also allows the health care provider to write a short (3-5 day) prescription with some confidence until more comprehensive test results are received from the clinical laboratory.

(Doc. No. 328-36, p. 10). Thus, Millennium emphasizes that the POCT cups' immediate preliminary results advance patient care and do not involve any *financial* benefit to the doctors.

Ameritox, on the other hand, focuses on three primary arguments: (1) the POCT cups' immediate preliminary results provide a value that the doctor would not have if standard specimen cups were used; (2) doctors receive a financial benefit from the POCT cups in the form of cost savings due to the doctors not having to buy the POCT cups in order to get immediate preliminary results; and (3) Millennium only provided free POCT cups to doctors whose practices were profitable accounts for Millennium. (Doc. No. 330-8). Millennium disputes these arguments.

First, as previously stated, Millennium de-emphasizes the value provided by the POCT cups' immediate preliminary results and emphasizes that the immediate preliminary results advance patient care. Furthermore, Millennium argues that preliminary positive results should not be relied on, as the information packet that comes with the POCT cups states that a urine sample that produces a preliminary positive result should be sent to a certified laboratory for confirmatory testing. (Doc. No. 357-9, p. 4 of 7). Also, a preliminary negative result communicates only that the concentration of the specific drug is not present within the prescribed detection amount. (Doc. No. 357-9, p. 4 of 7).

Second, Millennium disputes that doctors receive a financial benefit from the POCT cups

in the form of cost savings due to the doctors not having to buy the POCT cups in order to get immediate preliminary results. Specifically, Millennium points out two things: (1) POCT cups are not a required expense that doctors must incur, because the doctor could just send urine specimens to labs for testing; and (2) the doctors are not billing for the POC testing, so there are no expenses being saved. Stated differently, if doctors *choose* to do POC testing, they have two options: (1) use Millennium's free POCT cups and not bill for the POC test, or (2) buy POC testing supplies and bill for the POC test. Since doctors likely bill for the POC testing at an amount greater than the amount of the POC testing, doctors give up the ability to make money on the POC tests by using Millennium's free POCT cups.⁵

Third, Millennium points to record evidence to dispute Ameritox's assertion that Millennium only provided free POCT cups to doctors whose practices were profitable accounts for Millennium. (Doc. No. 357-2, p. 345). Millennium argues that profitability is not considered with respect to the provision of free POCT cups. (Doc. No. 357-2, p. 345).

The parties agree that there is no case law specifically addressing whether the provision of free POCT cups falls within the exceptions to the definition of remuneration when the doctors receiving the free POCT cups agree not to bill for the POC testing. 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 alleged deficiencies at two of its laboratories. (Doc No. 328-36). One of the alleged deficiencies related to the provision of free POCT cups, and AHCA asserted that the free POCT cups were a kickback for patient referrals. (Doc No.

⁵Millennium points out that the POCT cups can be purchased for a few dollars, and the Medicare rate for reimbursement is approximately \$20. (Doc. No. 328-43, p.12 of 18; Doc. No. 328-17, p.60 of 106).

328-36). The AHCA letter required Millennium to respond with its plan of correction, and Millennium responded with the following in June of 2012:

With respect to Facility 1, the free cups provided to this physician's office are used solely for the purpose of collecting, processing, storing and transporting specimens to the laboratory as permitted by AHCA rule 59A-7.020(14)(c).⁶ Indeed, Millennium worked closely with the manufacturer to design this specific cup to prevent leakage during transportation of the specimen to Millennium. These particular cups also incorporate technology embedded inside the cup itself to enable a user to perform certain limited tests (should the user choose to do so) in addition to the collection, storage and transportation of the specimen.

The purpose for the test strips in these cups is to provide a possible deterrent for patients who may consider deviating from their prescribed regimen; any unexpected preliminary results can trigger a conversation with the patient while still at the office. It also allows the health care provider to write a short (3-5 day) prescription with some confidence until more comprehensive test results are received from the clinical laboratory. (Note that Millennium Clinical Supply also has available other supplies and test strips that physicians' offices are able to purchase at fair market value.)

It is important to note that the health care providers receive no financial benefit by being provided this form of collection and transportation cup. Prior to receiving these cups, the physician's office is required by Millennium to sign an agreement which certifies that they will not bill any patient or payers for the limited range of tests that can be performed in these types of cups, and Millennium routinely verifies that no such billings have been submitted by the physician's office to third party insurers through a comprehensive internal audit program. Accordingly, no violations of AHCA rules have occurred at Facility 1 because nothing of value has been provided to the physician's office except for a free collection, storage and transportation cup as permitted under AHCA rule 59A-7.020(14)(c).

⁶Pursuant to AHCA rule 59A-7.020(14)(c), AHCA recognizes an exception to the definition of a kickback for “items, devices or supplies that are for the sole purpose of” (1) “[c]ollecting, processing, storing and transporting specimens to the laboratory;” or (2) “communicating laboratory tests or results . . . between the physician . . . and the laboratory.”

Plan of correction: Millennium will conduct education sessions for its staff to reinforce the requirements of AHCA' rule 59A-7.020(14) that allows labs to provide free items, devices or supplies so long as they are used only for collecting, processing, storing and transporting specimens to the laboratory. Millennium staff periodically will remind physicians' offices of these limitations, and Millennium will continue its policy of routinely conducting random audits of the physicians' billing practices to verify that no physicians' office is billing for any tests that might have been performed with cups provided by Millennium.

(Doc. No. 328-36).

By early October of 2012, Millennium had not received 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 of correction 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).

Thus, Millennium argues that AHCA's failure to take further action in response to Millennium's provision of free POCT cups is evidence that Millennium's provision of POCT cups meets AHCA's exception to the definition of a kickback, which is almost identical to the Stark Law's exceptions to the definition of remuneration. As such, Millennium argues that its provision of the free POCT cups does not violate the Stark Law.

The Court finds Millennium's argument to be persuasive but not dispositive given the lack of relevant case law. Therefore, the Court will defer ruling and set the matter for a hearing on the issue of whether Millennium's provision of free POCT cups violates the Stark Law. At

the hearing, the parties should be prepared to address: (1) whether Millennium’s provision of the POCT cups fall within the exceptions to the definition of remuneration; and (2) if not, whether the issue of whether the POCT cups constitute remuneration is a question of fact (i.e., whether the doctors, in fact, received anything of value via Millennium’s provision of free POCT cups⁷) or whether it is a question of law (i.e., whether, as a matter of law, the provision of free POCT cups can be considered remuneration, given that the doctors did not receive any *financial* value from the free POCT cups⁸).

2. AKS

The AKS prohibits healthcare providers from knowingly and willfully offering to pay any remuneration—directly or indirectly, overtly or covertly, in cash or in kind—to induce a doctor to refer a patient for services covered under Medicare or Medicaid. See Tenet, 2013 WL 1289260, at *1; 42 U.S.C. § 1320a-7b(b)(2). The civil counterpart of the AKS defines remuneration as including “transfers of items or services for free or for other than fair market value.” 42 U.S.C. § 1320a-7a(i)(6). Unlike the Stark Law, the AKS does not contain exceptions to the broad definition of remuneration for items: (1) used solely to collect, transport, process, or store specimens for the entity providing the item, or (2) used solely to order or communicate the results of tests or procedures for the entity providing the item. As such, the parties dispute

⁷The parties dispute whether the free POCT cups’ immediate preliminary results provides a value to the doctors or whether the immediate preliminary results simply benefit the patient through enhanced patient care.

⁸ Millennium argues that the doctors do not receive any *financial* value from the free POCT cups, because: (1) the doctors make no money from the provision of free POCT cups because they cannot bill for the POC testing; and (2) the free POCT cups do not result in cost savings for the doctors, because the doctors are not required to do POC testing (and thus, they are not required to purchase POCT cups).

whether Millennium's provision of free POCT cups falls within the broad definition of remuneration under the AKS.

The parties agree that there is no case law specifically addressing whether the provision of free POCT cups violates the AKS. Given the lack of case law and the analysis set forth above with regards to the Stark Law, the Court finds oral argument on this issue would be helpful. Thus, the issues that remain are: (1) whether remuneration under the AKS includes the value provided by the free POCT cups' immediate preliminary results or whether the immediate preliminary results simply benefit the patient through enhanced patient care; and (2) if the provision of free POCT cups does not violate the Stark Law due to its exceptions to the definition of remuneration, whether/how that affects the analysis of whether a violation of the AKS has occurred.

B. Space-Lease Arrangements

Next, Ameritox argues that there is no evidence that it entered into any space-lease arrangements in Florida, New York, Washington, and/or Oregon. As such, Ameritox argues that to the extent that Millennium's counterclaims in Counts I, V, VI, and VII are based on the contention that it did enter into such arrangements in those states, Ameritox is entitled to summary judgment.

In support of its motion, Ameritox cites to two exhibits in the record. First, Ameritox cites to its First Supplemental Response to Interrogatory Number 1 to support its assertion that it did not have any space-lease arrangements in Florida after December 31, 2007. (Doc. No. 330-36). Additionally, Ameritox relies on a chart describing leases (Doc. No. 330-35), but no context is provided regarding what the chart was created in response to and whether/how the chart is

admissible. Stated differently, there is no evidence that the chart lists all of Ameritox's post-2007 leases in the states of Florida, New York, Washington, and/or Oregon. In fact, the document states that the "File Name" is "CA FL NY TN TX WA - Leases Jan 08 to Sep 12.xlsx"; thus, it does not even appear to address leases in Oregon. Therefore, based on Ameritox's motion and the evidence cited in support, Ameritox has only pointed to evidence that it did not have any space-lease arrangements in Florida after December 31, 2007.

In response, Millennium points to emails from Ameritox acknowledging a space-lease arrangement in South Florida. (Doc. No. S-365, Ex. 15). Accordingly, there is a genuine issue of disputed fact regarding whether Ameritox entered into any space-lease arrangements in Florida post-2007, which precludes summary judgment on this issue.

Likewise, Ameritox did not meet its burden of showing the Court, by reference to materials on file, that there is no evidence of space-lease arrangements in New York, Washington, and/or Oregon. For example, it did not submit an affidavit stating that it did not enter into any such arrangements in New York, Washington, and/or Oregon. Instead, it made such an argument in its motion and cited to an unclear, arguably inadmissible Excel chart as support. As a result, summary judgment must be denied on this issue as well.⁹

C. Free Computers

Next, Ameritox argues that there is no evidence that it gave doctors free computers to use to carry out their daily office tasks. Instead, Ameritox implies that it gives doctors free laptops to

⁹The Court notes, however, that Millennium also failed to point to any evidence that showed that Ameritox had any space-lease arrangements in New York, Washington, and/or Oregon. However, because the burden is on Ameritox, as the party moving for summary judgment, the Court finds that Millennium's failure to point to evidence to support its claims is not fatal at this juncture.

use solely for accessing Ameritox's systems in order to upload patient data and to view laboratory test results.

Ameritox appears to argue that providing free laptops to doctors to use solely for accessing Ameritox's systems in order to upload patient data and to view laboratory test results is permissible under an exception to the Stark Law. The exception permits laboratories to provide devices "that are used solely to . . . order or communicate the results of tests or procedures." 42 U.S.C. § 1395nn(h)(1)(C)(ii). As such, Ameritox argues that to the extent that Millennium's counterclaims in Counts I through VII are based on the contention that it gave doctors free computers to use to carry out their daily office tasks, Ameritox is entitled to summary judgment.

Ameritox, however, does not point to any evidence to support its argument, such as submitting an affidavit that states that it only provided free laptops to doctors to use solely for accessing Ameritox's systems in order to upload patient data and to view laboratory test results. As a result, Ameritox did not meet its 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. Therefore, Ameritox is not entitled to summary judgment on this issue.¹⁰

D. In-Network Status

Next, Ameritox argues that there is no evidence that its sales representatives implied to

¹⁰The Court notes, however, that Millennium also failed to point to any evidence that showed that Ameritox did, in fact, provide computers for doctors' unlimited use. Instead, Millennium points to evidence that doctors were given computers—a fact that does not appear to be in dispute—but does not address whether the use of the computers was limited to accessing Ameritox's systems in order to upload patient data and to view laboratory test results. (Doc. No. S-365, Ex. 25). However, because the burden is on Ameritox, as the party moving for summary judgment, the Court finds that Millennium's failure to point to evidence to support its claims is not fatal at this juncture.

doctors that it was as in-network provider when it was not. As such, Ameritox argues that to the extent that Millennium's counterclaims in Counts I through VII are based on the contention that it falsely represented its in-network status, Ameritox is entitled to summary judgment.

Ameritox, however, does not point to any evidence to support its argument, such as submitting an affidavit that states that its sales representatives never implied to doctors that it was as in-network provider when it was not. As a result, Ameritox did not meet its 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. Furthermore, the Court notes that Millennium has pointed to an email which appears to support Millennium's contention that Ameritox's sales representatives have told doctors that Ameritox was in network when it was not. (Doc. No. S-365, Ex. 26). Accordingly, Ameritox is not entitled to summary judgment on this issue.

IV. Conclusion

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

- (1) Ameritox's Motion for Partial Summary Judgment (Doc. No. 337-1) is **DEFERRED IN PART AND DENIED IN PART**: The Court **DENIES** summary judgment to the extent that Ameritox seeks summary judgment with respect to the space lease agreements, computers, and in-network status claims. The Court **DEFERS** ruling on the motion to the extent that Ameritox seeks summary judgment regarding the Stark Law and the AKS.
- (2) The Court will, by separate order, set oral argument on this motion to the extent that Ameritox seeks summary judgment regarding the Stark Law and the AKS. At the hearing, the parties should be prepared to address: (1) whether Millennium's

provision of the POCT cups fall within the Stark Law's exceptions to the definition of remuneration; and (2) if not, whether the issue of whether the POCT cups constitute remuneration under the Stark Law is a question of fact for the jury or whether it is a question of law for the Court. Likewise, the parties should be prepared to address: (1) whether remuneration under the AKS includes the value provided by the free POCT cups' immediate preliminary results or whether the immediate preliminary results simply benefit the patient through enhanced patient care; and (2) if the provision of free POCT cups does not violate the Stark Law due to its exceptions to the definition of remuneration, whether/how that affects the analysis of whether a violation of the AKS has occurred.

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