

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
SENIOR JUDGE WALKER D. MILLER

Civil Action No. 07-cv-01460-WDM-MEH

UNITED STATES OF AMERICA, *ex rel.*, MARY JO PFEIFER,

Plaintiff

v.

ELA MEDICAL, INC.,
SORIN GROUP USA, INC.,
SORIN GROUP,
SORIN GROUP, S.p.A.,
DR. A. THOMAS GARCIA,
ADVANCED CARDIAC SPECIALISTS CHARTERED,
DR. ROBERT SIEGEL,
DR. ASHKOK GARG,
DR. STEPHEN BLUMBERG,
DR. URI BEN-ZUR,
DR. MARK SEIFERT,
DR. WILLIAM STUCK,
DR. JOHN R. DYLEWSKI, and
DOES 1-20,

Defendants.

ORDER ON MOTIONS TO DISMISS

Miller, J.

This matter is before me on Defendants Ela Medical, Inc., Sorin Group USA, Inc., Sorin Group, and Sorin S.p.A.'s Motion to Dismiss Relator's Complaint (Docket No. 57), Defendants Advanced Cardiac Specialists Chartered, Dr. Stephen Blumberg, Dr. William Stuck, and Dr. John R. Dylewski's Motion to Dismiss Relator's Complaint (Docket No. 62), Defendant Dr. Uri Ben-Zur's Motion to Dismiss (Docket No. 68), Dr. Mark Seifert's Motion to Dismiss (Docket No. 116), and Dr. Ashkok Garg's Motion to

Dismiss (Docket No. 125). Pursuant to Rule 10(c) of the Federal Rules of Civil Procedure, Defendants Advanced Cardiac Specialists Chartered, Blumberg, Stuck, Dylewski, Ben-Zur, and Seifert also join (Docket Nos. 62, 68, 116 and 125) and incorporate by reference the legal arguments and exhibits submitted by Defendants Ela Medical, Inc., Sorin Group USA, Inc., Sorin Group, and Sorin S.p.A. in their Motion to Dismiss Relator's Complaint. A. Tomas Garcia joins and incorporates by reference all Defendants' Motions to Dismiss (Doc. No. 134). Upon review of the motions, as well as the responses and replies thereto, I conclude that oral argument is not required. For the reasons that follow, the motions are granted in part and denied in part.

BACKGROUND

This a False Claims Act ("FCA") case alleging kickbacks and other wrongdoing by Ela Medical, Inc. ("EMI"), and Sorin Group USA, Inc., Sorin Group, and Sorin S.p.A. (collectively, "Sorin Entities") and the physicians named above. Defendants assert that Relator Pfeifer's claims are barred because Tania Lee filed an FCA claim in the Southern District of Florida against EMI and Dr. Dylewski before Relator Pfeifer filed her complaint in this court, that she took her claims from publicly disclosed information and that she is not the original source and that she failed to plead the alleged fraud with sufficient particularity.

Defendant EMI manufactures and sells medical devices for the treatment of heart disease. Compl. (Docket No. 1) ¶¶ 23, 31. Sorin Entities are EMI's parent corporations. Compl. ¶¶ 6-8, 23.¹

¹ "Sorin Group" is not a business entity. See unrebutted Declaration of Thomas F. Carlucci, Paragraph 1, n.1, attached as Exhibit F to Defendants' EMI *et al* Motion to

Tania Lee (“Relator Lee”) is a cardio-vascular technician and a former employee of EMI. (Lee Compl. ¶ 5, Ex. C to Def. EMI’s Mot. to Dismiss Relator’s Compl.) Relator Lee worked for EMI from 2003 through 2005 as a Technical Services Representative. *Id.* On May 15, 2006, Relator Lee brought a *qui tam* suit in the United States District Court in the Southern District of Florida against a number of defendants alleging violations of the False Claims Act, 31 U.S.C. § 3729 (“FCA”). Lee Compl. (Docket No. 57-4). Specifically, Relator Lee’s complaint names Defendant EMI and Dr. Dylewski as defendants and states that two of the cardiologist defendants referred patients to Defendant Dylewski for implantation of EMI devices. Lee Compl. ¶¶ 52-53. Other than Defendants EMI and Dylewski, Relator Lee’s complaint does not list any other Defendants from the present action.

Relator Lee’s Claims

Relator Lee’s complaint alleges that, “[w]orking through independent sales representatives, [EMI] created an elaborate scheme to compensate cardiac surgeons for the use of [EMI] pacemakers and defibrillators.” Lee Compl. ¶ 38. This scheme, according to Relator Lee, was accomplished by EMI encouraging cardiologists to refer their patients to specific cardiac surgeons and implanting physicians. Upon these surgeons’ and physicians’ referrals, the cardiologists received monitors and ambulatory equipment manufactured by EMI at reduced prices and on unusually favorable terms. *Id.* ¶¶ 38-38(a).

These doctors’ patients wore the provided equipment for twenty-four hours and,

Dismiss (Doc. No. 57-7). It appears to be a trade name or a reference to defendants Sorin Group USA and Sorin S.p.A., collectively.

unknown to the patients, the equipment transmitted monitoring information to the cardiologists' offices. The monitoring information was later submitted to EMI. *Id.* ¶¶ 38(a)-(b). Medicare reimbursed the cardiologists for the monitoring and diagnostic examinations of the patients. *Id.* at ¶ 38(a).

Relator Lee alleged that the cardiologists who referred patients to the specific cardiac surgeons and implanting physicians were compensated by EMI for participating in the monitoring program, paying them an average of \$1,200 per study. *Id.* at ¶ 38(b). Additionally, Relator Lee alleged that cardiologists who referred patients to these specific cardiac surgeons and implanting physicians would, on one day every month, host "clinics" for patients with existing pacemakers manufactured by any vendor to come to their offices to have their pacemakers checked. *Id.* at ¶ 38(c). During these clinics, Relator Lee would go to the cardiologists' offices and examine the patients' pacemakers, regardless of the manufacturer, to determine whether the batteries needed to be replaced. *Id.*

If a battery needed replacement, the cardiologist would refer the patient to one of the specific implanting surgeons to replace the existing pacemaker with an EMI pacemaker, and the cardiologist would bill Medicare for the cost of the test performed by Relator Lee. *Id.* at ¶¶ 38(c)(ii)-(iv). Relator Lee's complaint also alleges that the cardiologists who referred patients to the specific cardiac surgeons and implanting physicians, as well as the surgeons and physicians themselves, "were sent on [EMI]-sponsored and paid for trips," to places including Colorado, Milan, Rio de Janeiro, and Argentina.

Relator Pfeifer's Claims

Plaintiff/Relator Mary Jo Pfeifer ("Relator Pfeifer") was the Director of Finance and Operations by EMI from February 2004 until March 2006. See Compl. ¶ 22. On July 11, 2007, Relator Pfeifer filed the present action in this Court, alleging violations of the FCA. Compl. Relator Pfeifer's allegations are based on her experience while employed for EMI, as well as information she received from other EMI employees during the term of her employment. Compl. ¶ 22.

Relator Pfeifer alleges that "EMI made a practice of paying physicians and/or their closely held corporations, fees for using EMI products." *Id.* at ¶ 24. According to Relator Pfeifer, these kickback payments made to physicians for using EMI's products were disguised as "training fees," for training EMI representatives or other physicians, evidenced in part by the execution of "training contracts" between EMI and the physicians. Execution of the contracts were followed by substantial increases in the usage of EMI's products by the physicians. Decreases in the usage of EMI's products occurred after the expiration or termination of the training contracts. Compl. ¶ 24.

Relator Pfeifer claims these actions were in violation of the so-called "anti-kickback statute," 42 U.S.C. §1320a-7b, and the Stark Act, 42 U.S.C. § 1395. Compl. ¶ 34. Relator Pfeifer also asserts that "[t]he nature of EMI's products, devices for treatment of heart disease, is such that they are used primarily in elderly patients, patients who are on Medicare and Medicaid. Accordingly, Medicare and Medicaid pay a substantial amount of EMI's income." *Id.* at ¶ 31.

Relator Pfeifer finally alleges that Defendants violated the FCA when EMI paid, and the other Defendants received, training fees, entertainment, and other benefits in

exchange for using EMI's products, and then "submitt[ed] claims to the United States Government for reimbursement based upon representations that Defendants complied with applicable law in presenting the claims." Compl. ¶¶ 30, 39, 40.

Although Relator Pfeifer's claim is premised on violations of the anti-kickback statute, 42 U.S.C. § 1320a-7b, as well as violations of the Stark Act, 42 U.S.C. § 1395, the only relief requested by Relator Pfeifer arises under the FCA, 31 U.S.C. § 3729. Specifically, Relator Pfeifer requests an order requiring Defendants to cease and desist from violating the False Claims Act; pay compensatory damages to the United States in an amount equal to three times the amount of damages the United States has sustained for each violation of the FCA; pay a civil penalty of \$10,000.00 per false claim; pay the costs of this action pursuant to 31 U.S.C. § 3729(a); pay all of Relator Pfeifer's costs and expenses, including attorneys' fees and court costs, pursuant to 31 U.S.C. § 3730(d)(1); and pay the maximum relief allowed to Relator Pfeifer pursuant to 31 U.S.C. § 3730(d)(1). Compl. ¶¶ 10-11.

Defendants raise four arguments in their motions to dismiss. All of them claim, directly or by incorporation by reference, that I cannot exercise subject matter jurisdiction over this action. They assert that Relator Pfeifer's claims should be dismissed pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure, pursuant to the FCA's first-to-file bar, 31 U.S.C. § 3730(b)(5), and the FCA's public disclosure bar and original source provisions, 31 U.S.C. § 3730(e)(4)(A). Additionally, Defendants claim that Relator's claims should be dismissed because they are not pled with sufficient particularity, as required under Fed. R. Civ. P. 9(b). Sorin Entities also contend that Relator's complaint fails to state any claim against them.

Finally, Dr. Seifert also claims insufficient service of process pursuant to Fed. R. Civ. P. 12(b)(5).

STANDARD OF REVIEW

A motion to dismiss is properly granted when a complaint provides no “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action Factual allegations must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). A complaint must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted if it does not plead “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 570. “[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action.” *Id.* at 555 (quoting 5 C. Wright & A. Miller, *Federal Practice and Procedure* § 1216, at 235-36 (3d ed. 2004)). The court must accept as true all well-pleaded facts and construe all reasonable allegations in the light most favorable to the plaintiff. *United States v. Colo. Supreme Court*, 87 F.3d 1161, 1164 (10th Cir. 1996).

“The plausibility standard is not akin to a ‘probability requirement,’” but the allegations must “permit the court to infer more than the mere possibility of misconduct.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” *Id.* (quoting *Twombly*). Under *Iqbal*, a court considering a motion to dismiss may first identify allegations that are no more than conclusions, and therefore not entitled to the assumption of truth. *Id.* at 1950. “While legal conclusions can provide the framework of a complaint, they must be supported by

factual allegations.” *Id.* Then, the court may examine the well-pleaded factual allegations and determine, assuming their veracity, “whether they plausibly give rise to an entitlement to relief.” *Id.*

A number of Defendants’ motions to dismiss are premised on Rule 12(b)(1) of the Federal Rules of Civil Procedure, asking this Court to dismiss Relator Pfeifer’s claims for lack of subject matter jurisdiction. “Since federal courts are courts of limited jurisdiction, we presume no jurisdiction exists absent a showing of proof by the party asserting federal jurisdiction.” *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 551 (10th Cir. 1992) (hereinafter, “*Precision*”). Accordingly, Relator Pfeifer, “the party invoking federal jurisdiction in this case, must allege in [her] pleading the facts essential to show jurisdiction, and must support those facts by competent proof.” *Id.* (internal quotations omitted). “If jurisdiction is challenged, the burden is on the party claiming jurisdiction to show it by a preponderance of the evidence.” *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1160 (10th Cir. 1999) (hereinafter, *Hafter*). “[A] court is required to convert a Rule 12(b)(1) motion to dismiss into a Rule 12(b)(6) motion or a Rule 56 summary judgment motion when resolution of the jurisdictional question is intertwined with the merits of the case,” which occurs when “subject matter jurisdiction is dependent on the same statute which provides the substantive claim in the case.” *Holt v. United States*, 46 F.3d 1000, 1003 (10th Cir. 1995).

Under the FCA, subject matter jurisdiction is dependent on the same statute which provides the substantive claim in the case, thereby requiring treatment of a Rule 12(b)(1) motion as a Rule 12(b)(6) motion or a Rule 56 summary judgment motion.

Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1278 n.1 (10th Cir. 2004) (finding that the jurisdictional question under the FCA's first-to-file bar is intertwined with the merits of the case); *United States ex rel. Fine v. MK-Ferguson Co.*, 99 F.3d 1538, 1543 (10th Cir. 1996) (holding that the jurisdictional question under the FCA's public disclosure bar arises out of the same statute that creates the cause of action) (hereinafter, "MK-Ferguson").

However, Rule 12(d) of the Federal Rules of Civil Procedure provides:

Result of Presenting Matters Outside the Pleadings. If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given reasonable opportunity to present all the material that is pertinent to the motion.

Fed. R. Civ. P. 12(d). "Notice to the parties is required to prevent unfair surprise when a judge converts a 12(b)(6) motion into a Rule 56 motion." *Arnold v. Air Midwest, Inc.*, 100 F.3d 857, 859 n.2 (10th Cir. 1996). "The court cannot convert a motion to dismiss to a motion for summary judgment without notice, unless the opposing party has responded to the movant's attempt to convert the motion by filing his own affidavits." *Ketchum v. Cruz*, 961 F.2d 916, 919 (10th Cir. 1992). "[W]hen a party submits material beyond the pleadings in support of or opposing a motion to dismiss, the prior action on the part of the part[y] puts [her] on notice that the judge may treat the motion as a Rule 56 motion." *Arnold*, 100 F.3d at 859 n.2 (quoting *Wheeler v. Hurdman*, 825 F.2d 257, 260 (10th Cir. 1987), *cert. denied*, 484 U.S. 986 (1987)).

I note that Relator Pfeifer responded with her own affidavits and requested further discovery to adequately respond regarding whether her claims are barred by the

public disclosure bar, which request I deny.² Defendants did not submit any further affidavits with their replies. Accordingly, I conclude that all Defendants had adequate notice that I would consider the motions under Fed. R. Civ. P. 56. Therefore, I will apply the standard for summary judgment rather than a motion to dismiss to the extent that the parties have presented information outside the pleadings. Otherwise, I will apply the standard of review applied for motions made pursuant to Fed. R. Civ. P. 12(b)(6).

Summary judgment is appropriate when there is no genuine issue as to any

² Local Rule 7.1(c) prohibits moving on a separate matter from the original motion in a response or reply and no motion is pending before the clerk on this issue. Nevertheless, I will address the request under Rule 56(f).

Unless dilatory or lacking in merit, a motion pursuant to Rule 56(f) should be liberally treated. *Comm. for First Amend. v. Campbell*, 962 F.2d 1517, 1522 (10th Cir. 1992) (citing James W. Moore & Jeremy C. Wicker, *Moore's Federal Practice* ¶ 56.24 (1988)). An affidavit furnished by the nonmovant must explain why facts precluding summary judgment cannot be presented, however. *Id.* (citing *Pasternak v. Lear Petroleum Exploration, Inc.*, 790 F.2d 828, 832 (10th Cir.1986) and 10A Charles A. Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice & Procedure* § 2740 at 530 (1983)). The nonmovant must identify the probable facts that are not available without further discovery and the steps that she has taken to obtain the facts. *Id.* (citing 6 *Moore's Federal Practice* ¶ 56.24). She must also explain "how additional time will enable [her] to rebut movant's allegations of no genuine issue of fact." *Id.* (quoting *Meyer v. Dans un Jardin, S.A.*, 816 F.2d 533, 537 (10th Cir.1987)). "Advocacy by counsel does not suffice for evidence or fact in the Rule 56(f) context." *Comm. for First Amend.*, 962 F.2d at 1522 (citing *Radich v. Goode*, 886 F.2d 1391, 1395 (3rd Cir.1989)).

Relator Pfeifer's counsel, Mr. Rayment, submitted an affidavit setting forth reasons for which discovery was needed. His affidavit does not meet the Tenth Circuit standard set forth in *Comm. for First Amend.*, *supra*, to allow additional discovery, however. It does not explain why facts precluding summary judgment cannot be presented or the steps that Relator Pfeiffer has taken to obtain the facts. *Comm. for First Amend.*, 962 F.2d at 1522 (citing 6 *Moore's Federal Practice* ¶ 56.24). He has not explained "how additional time will enable [Relator Pfeifer] to rebut movant's allegations of no genuine issue of fact," either. Therefore, I do not order a continuance to enable affidavits to be obtained, depositions to be taken, or other discovery to be undertaken.

material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. A factual issue is genuine if “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986). “When applying this standard, we view the evidence and draw all reasonable inferences therefrom in the light most favorable to the nonmoving party.” *Sierra Club v. El Paso Gold Mines, Inc.*, 421 F.3d 1133, 1146 (10th Cir. 2005) (quoting *Simms v. Okla. ex rel. Dep't of Mental Health & Substance Abuse Servs.*, 165 F.3d 1321, 1326 (10th Cir.1999)).

The movant bears the initial burden of making a *prima facie* demonstration of the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664 (10th Cir. 1998) (citing *Celotex*, 477 U.S. at 323). In so doing, a movant who will not bear the burden of persuasion at trial need not negate the nonmovant's claim. See *Celotex*, 477 U.S. at 325. He may make his *prima facie* demonstration simply by pointing out to the court a lack of evidence for the nonmovant on an essential element of the nonmovant's claim. See *id.*

If the movant carries this initial burden, the nonmovant that would bear the burden of persuasion at trial may not simply rest upon its pleadings; the burden shifts to the nonmovant to go beyond the pleadings and “set forth specific facts” that would be admissible in evidence in the event of trial from which a rational trier of fact could find for the nonmovant. Fed. R. Civ. P. 56(e).

DISCUSSION

1. First-to-File Bar

I first address Defendants' arguments that I lack subject matter jurisdiction over this matter, under the FCA's first-to-file bar and the public disclosure and original source provisions. Congress has directed the courts to follow a two-step inquiry when a relator files a *qui tam* action. First, I must ask whether the relator's action is "based upon" a prior public disclosure of the defendant's alleged wrongdoing. *United States ex rel Boothe v. Sun Healthcare Group, Inc.*, 496 F.3d 1169, 1173 (10th Cir. 2007) (citing 31 U.S.C. § 3730(e)(4)(A)) (hereinafter, "*Boothe*"). Second, if the action is based upon a prior public disclosure, I must then ask whether the relator was the "original source of the information." *Id.* If the relator is not the "original source," I must dismiss the action for lack of subject matter jurisdiction. *Id.* "In other words, if the fraud upon the government has already come to light, . . . [I have] the power to hear only *qui tam* actions from the relator who originally exposed the deception, not those from subsequent relators who may try to copycat and capitalize on the original source's efforts." *Id.* I must "assess jurisdiction on a claim-by-claim basis," and determine whether bars to subject matter jurisdiction apply "to each reasonably discrete claim of fraud." *Id.* at 1176.

In considering the FCA's first-to-file bar, a court need only consider the allegations in the present complaint and the allegations of the complaint in the prior action, thereby permitting treatment of the motion as one under Rule 12(b)(6). *See id.* at 1174. This alleviates the necessity of treating the motion as one for summary judgment because the court is entitled to take judicial notice of its own files and records and other facts that are a matter of public record, including a complaint in a prior action. *Grynberg*

v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1278 n.1 (10th Cir. 2004). Accordingly, I treat Defendants' motions to dismiss for lack of subject matter jurisdiction based on the FCA's first-to-file bar as motions to dismiss pursuant to Rule 12(b)(6), considering only Relator Lee's complaint (Docket No. 57) and Relator Pfeifer's Complaint (Docket No. 1).

The FCA's first-to-file bar provides, "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). *Precision* defines "based upon" as "supported by" and held that the it encompasses actions "even partly based upon prior public disclosures." See *Boothe* 496 F.3d at 1173 (citing *Precision*, 971 F.2d at 522)).

"This provision is a jurisdictional limit on the courts' power to hear certain duplicative *qui tam* suits." *Grynberg*, 390 F.3d at 1278. The purpose of the first-to-file bar is to weed out parasitic claims and create an incentive for relators with valuable information to file quickly. *In re Natural Gas Royalties Qui Tam Litigation* ("CO2 Appeals"), 566 F.3d 956, 961 (10th Cir. 2009). Furthermore, once one relator has filed a *qui tam* suit, the purpose behind allowing such suits has been satisfied because duplicative claims do nothing to further assist the government, as the first *qui tam* claim puts the government on notice of the essential facts of the fraudulent scheme such that it can discover related frauds. *Grynberg*, 390 F.3d at 1279 (citing *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)).

"[W]hether a *qui tam* action is a 'related action based on the facts underlying the pending action,'" is determined by using an "'essential claim' or 'same material

elements' standard." *CO2 Appeals*, 566 F.3d at 962 (citing *Grynberg*, 390 F.3d at 1279). Under this standard, "so long as a subsequent complaint raises the same or a related claim based in significant measure on the core fact or general conduct relied upon in the first *qui tam* action, the . . . first-to-file bar applies." *Id.* Subsequent suits that "do no more than assert the same material elements of fraud," even if they "are able to marshal additional factual support for the claim," are barred by the first-to-file bar. *Id.*

In determining whether the first-to-file bar acts to foreclose a subsequent *qui tam* action, courts are to look at the facts as they existed at the time the subsequent action was brought. *Id.* (citing *Smith v. Sperling*, 354 U.S. 91, 93 n.1 (1957)). Changes in the prior action after the date that the subsequent action was brought—including amendments, new or different claims, and settlement of the matter—are not relevant to whether the subsequent action is a "related action based on the facts underlying the pending action."³ *Grynberg*, 390 F.3d at 1279 n.2.

The identity of the defendant is a material element of a fraud claim and consequently, the first-to-file bar does not prevent subsequent *qui tam* suits alleging the same material elements of fraud against different defendants. *CO2 Appeals*, 566 F.3d at 962. Rather, in order for a subsequent *qui tam* claim to be barred under the first-to-file bar, it must be asserted against the same defendants as was the prior claim. *Id.*

³ Although the parties, in their briefs, mention subsequent changes that have occurred in Lee's action, I do not take those into account here. Rather, I consider the facts as they existed on July 11, 2007, the date on which Relator Pfeifer's action was brought.

Defendants EMI and Dr. Dylewski were named as defendants in Relator Lee's previous *qui tam* claim. Furthermore, although the Sorin Entities were not named as defendants in Relator Lee's claim, according to Relator Pfeifer's complaint, they are EMI's parent corporations (Compl. ¶¶ 6-8, 23), which might "require deviation[] from the general requirement that claims must share common defendants in order to trigger the first-to-file bar." *CO2 Appeals*, 566 F.3d at 962. Pursuant to the holding in *CO2 Appeals*, Defendants EMI, Dr. Dylewski, and the Sorin Defendants are the only Defendants who could potentially have the claims against them dismissed on this basis.

Relator Pfeifer claims that the defendants falsely certified claims to the United States government. "The FCA recognizes two types of actionable claims—factually false claims and legally false claims." *United States v. Conner*, 543 F.3d 1211, 1217 (10th Cir. 2008). A factually false claim involves a relator showing "that the government payee has submitted 'an incorrect description of goods or services never provided.'" *Id.* (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)). A legally false claim, otherwise known as a false certification claim, in contrast, is one in which a relator alleges "that the defendant has 'certifie[d] compliance with a statute or regulation as a *condition* to government payment,' yet knowingly failed to comply with such statute or regulation." *Id.* (quoting *Mikes*, 274 F.3d at 697) (emphasis in original).

"[L]egally false certification claims can rest on one of two theories—express false certification, and implied false certification." *Id.* The express false certification theory applies when a government payee "'falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.'" *Id.* (quoting *Mikes*, 274 F.3d at 698). Under the implied false certification theory, "courts do

not look at the contractor's actual statements; rather, the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *Id.* at 1218. Complete identity of the allegations is not necessary to invoke the first-to-file bar. *Grynberg*, 390 F.3d at 1279.

I now turn to the similarities and differences between Relator Pfeifer's claims and Relator Lee's claims to determine if they raise the same material elements of fraud. Relator Pfeifer's claim appears to be a false certification claim, alleging legally false claims. She states that Defendants violated the [FCA] when EMI paid and the other Defendants received the training fees, trips, entertainment, and other benefits, and then "submitt[ed] claims to the United States Government for reimbursement based upon representations that Defendants complied with applicable law in presenting the claims." Compl. ¶¶ 39, 40. Furthermore, Relator Pfeifer's statement that Defendants made "representations that Defendants complied with applicable law in presenting the claims" (Compl. ¶¶ 39, 40) appears to demonstrate that Relator Pfeifer's claim relies on the express false certification theory. Relator Lee's claim appears to be a false certification and a false statement claim, as well. Lee Compl. ¶ 1. Thus, Relator Pfeifer's *qui tam* complaint raises the same essential claim as Relator Lee's. See *CO2*. My analysis does not end here, however. I must look at the core facts and general conduct on which each relator relies. See *CO2 Appeals*, 566 F.3d at 962.

The alleged wrongdoings occurred during overlapping time periods. Relator Lee's claim encompasses activities that occurred between 2003 and 2005 (Lee Compl. Part III, ¶ 5), whereas Relator Pfeifer's claim encompasses activities that occurred

between 2004 and 2006. Pfeifer Compl. ¶ 22. Similarities in the time periods covered by the claims and the theory relied upon cannot suffice to bar Relator Pfeifer's claim under the first-to-file bar, however. To so hold would mean that any claims alleging false certification in the relevant time period would be barred, regardless of whether the facts underlying the false certifications were at all related. Rather, the subsequent claim must assert the same material elements of fraud as the prior claim.

Relator Lee's claim alleged that cardiologists, cardiac surgeons, and implanting physicians who assisted in EMI's alleged scheme were sent on EMI-paid trips and were reimbursed by EMI for expenses incurred on other personal and unrelated trips. Lee Compl. ¶ 38(d). Similarly, Relator Pfeifer's complaint alleges that "EMI paid for entertainment and travel of physicians who purchased EMI's products." Compl. ¶ 30. These two claims not only both allege fraudulent activity, but allege the same material elements constituting the fraudulent activity. Accordingly, as Relator Pfeifer appears to admit, this claim is based on the facts underlying Relator Lee's claim (Rel.'s Response to Defs.' Mot. to Dismiss ¶ 22, Docket No. 84). Relator Pfeifer's apparent concession that her claim of kickbacks in the form of entertainment and travel is similar to Relator Lee's allegations and is highly damaging to this element of her claim. Therefore, Relator Pfeifer's claims alleging EMI kickbacks embodied as EMI-paid trips and reimbursements EMI for expenses incurred on other personal and unrelated travel are barred under the FCA's first-to-file bar as to EMI, Sorin Entities and Dr. Dylewski.

For the remaining claims, the factual bases of the two relators' claims are distinct. Relator Lee alleged that the defendants violated the FCA by engaging in an elaborate scheme that compensated cardiologists, cardiac surgeons, and implantation

physicians for using EMI products by way of the patient monitoring program and one-day-per month clinics in the cardiologists' offices.

On the other hand, Relator Pfeifer alleges the scheme compensated doctors for entering into training agreements which ostensibly required physicians to provide training in exchange for the receipt of training fees paid by EMI, where no training was ever provided. Compl. at ¶¶ 25, 26, 27. After entering the training contracts, however, Defendant physicians and surgeons' use of EMI products increased. After the contracts terminated, a decrease in their use of the EMI products occurred. *See id.*

Consequently, Relator Pfeifer's claims based on training contracts are not barred as to any Defendant pursuant to the FCA's first-to-file bar. All Defendants are subject to jurisdiction for the training contract scheme.

2. Public Disclosure and Original Source Provisions

Defendants also move for dismissal for lack of subject matter jurisdiction under the FCA's public disclosure bar and original source provisions. 31 U.S.C. § 3730(e)(4)(A). In considering a motion to dismiss for lack of subject matter jurisdiction under the public disclosure bar, I must necessarily consider more than just the allegations in Relator Pfeifer's complaint. I must also consider the public disclosure at issue. I can also consider any documents referred to in the complaint that are central to the claim, as long as the parties do not dispute the documents' authenticity. *Alvarado v. KOB-TV, LLC*, 493 F.3d 1210, 1215 (10th Cir. 2007) (quoting *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002)).

In this case, the public disclosures at issue are two *New York Times* articles, to which Relator Pfeifer does not refer in her complaint. Defendant Ben-Zur claims that

the *New York Times* articles are subject to judicial notice under Rule 201(b) of the Federal Rule of Evidence, and that I can therefore treat Defendants' motions to dismiss for lack of subject matter jurisdiction under the FCA's public disclosure bar as motions to dismiss under Rule 12(b)(6). (Def. Ben-Zur's Reply in Support of Mot. to Dismiss at 4, n.2 (Docket No. 98). However, as support for this proposition, Defendant Ben-Zur cites only to a district court opinion from the Western District of Texas, *United States ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 673, 680-81 (W.D. Tex. 2006). *Id.* Although the court in *Lam* did take judicial notice of newspaper articles in evaluating the applicability of the FCA's public disclosure bar, the court also stated that it was treating the motion as one for summary judgment. *Lam*, 481 F. Supp. 2d at 678 ("A challenge under the public disclosure bar is treated as a motion for summary judgment because it is intertwined with the merits of the case."). Accordingly, *Lam* does not stand for the proposition that I can consider newspaper articles in reviewing Defendants' motions without converting them into motions for summary judgment, nor am I aware of any authority that allows me to do so.

The *New York Times* articles report that an administrative subpoena served on EMI by the inspector general of the Department of Health and Human Services, "sought any documents related to 'arrangements, clinical studies, provision of monitoring equipment and services and other agreements by which the company may have provided benefits to persons in a position to recommend purchase of devices.'" Barry Meier, *Federal Officials Scrutinizing Company Payments to Doctors*, *New York Times*, Sept. 22, 2006. The article also recalls that there was an on-going investigation of the "biggest makers of heart devices—Medtronic, St. Jude and Guidant—to determine if

they provided doctors with excessive payments to enroll patients in postmarketing studies of their devices as a way of increasing sales. . . . [and] that an inquiry into [EMI] focusing on, among other things, financial relationships between the company and doctors in the Miami area, including physicians who were enrolling patients in postmarketing trials.” *Id.*

The *New York Times* articles center around investigations of postmarketing trials by EMI and its largest competitors. *See id.*; *see also*, Barry Meier, *Small Maker of Heart Devices is Said to be Focus of Inquiry*, *New York Times*, March 25, 2006. The article specifies that the government was investigating EMI’s activities in the Miami area, including physicians who were enrolling patients in postmarketing trials. *Id.*

The articles do not provide substantially similar information as to the allegations in Relator Pfeifer’s Complaint. *See Maxwell v. Kerr-McGee Oil and Gas Corp.*, 540 F.3d 1180 (10th Cir. 2008). Neither article mentions EMI’s medical training agreements that Relator contends were EMI’s means of increasing sales. *See id.*; *see also*, Compl. at ¶¶ 24, 27, 28, 29. Relator Pfeifer has alleged facts showing how and when she obtained her direct and independent knowledge of the allegedly fraudulent training contract scheme. Although one might prefer more particularity, they are sufficient to overcome a motion for summary judgment at this stage of the case.

Even if the *New York Times* articles had mentioned the training agreements, the public disclosure bar provides an exception in the event that “the person bringing the action is an original source of the information.” *See CO2 Appeal*, 566 F.3d at 961 (citing 31 U.S.C. § 3730(e)(4)(A)). The relator must be the original source of the

information on which her allegations are based. See *Rockwell Int'l Corp v. United States*, 549 U.S. 457, 470 (2007).

In order to qualify as an “original source of the information,” a relator must be “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.” 31 U.S.C. § 3730(e)(4)(B); see also, *Boothe*, 496 F.3d at 1174 (The words “original source” mean the “‘original source’ of the information on which [relator] bases her allegation” and not “the ‘original source’ of the information on which the publicly disclosed allegations that triggered the public disclosure bar are based.” *Id.*). Relator “must allege specific facts—as opposed to mere conclusions—showing exactly how and when . . . she obtained direct and independent knowledge of the fraudulent acts alleged in the complaint. . . .” *Natural Gas Royalties*, 562 F.3d at 1043-44 (quoting *Hafter*, 190 F.3d at 1162).

“Secondhand information, speculation, background information, or collateral research do not satisfy a relator’s burden. . . .” *Id.* at 1043-44. Tenth Circuit authority teaches that knowledge is “direct and independent” if it is “marked by the absence of an intervening agency,” and “unmediated by anything but the relator's own labor.” *MK-Ferguson Co.*, 99 F.3d at 1547. Independent knowledge is not secondhand. Instead, “a relator must demonstrate that he discovered the information on which the allegations are based through his own efforts and not by the labors of others, and that the information was not derivative of the information of others.” *CO2 Appeals* (citing *Hafter*, 190 F.3d at 1162); see also, *United States ex rel. Stinson, Lyons, Gerlin &*

Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1160 (3d Cir.1991) (A relator's background information or unique expertise allowing him to understand the significance of publicly disclosed allegations and transactions is insufficient to establish original source.).

Relator Pfeifer claims that she “is an original source individual with direct and independent knowledge of the information set forth herein, and has voluntarily provided the information to the government pursuant to 31 U.S.C. § 3730(e)(4)(B).” Compl.

¶ 19. She supports this conclusion by affirming that she had not seen the *New York Times* articles prior to filing the *qui tam* action. See Pfeifer Affidavit attached as Ex. 1 to Relator’s Response (Docket No. 84-2) at ¶¶ 8–9. As Director of Finance and Operations at EMI, Pfeifer “received reports concerning the payment of funds to doctors and medical service entities controlled by doctors who did business with [EMI].” Pfeifer Affidavit ¶ 2, Compl. ¶ 22. “Included amongst the reports and documents . . . were contracts entered into between [EMI] and various physicians who purchased or arranged for hospitals to purchase . . . products manufactured and sold by [EMI] . . . Cobe, Sorin, SpA, and Sorin Group.” *Id.* ¶ 3, Compl. ¶ 23. She reports that, “In a July, 2004, budget meeting for EMI, Rodger Stewart, EMI’s President asked the question[,] ‘How much are we paying in training fees and how much business are we getting for it?’” *Id.* ¶ 5 and Compl. ¶ 28. Relator Pfeifer also attests that she gave “a statement of substantially all material evidence and information related to her complaint” to the Attorney General of the United States and the United States Attorney for the District of Colorado prior to July 11, 2007. *Id.* ¶ 6.

Thus, there is sufficient evidence to show that Relator Pfeifer is the original source of the facts from which her claims arise. Therefore, the Motion for Summary Judgment on the first-to-file bar and original source doctrine shall be granted as to EMI and Dr. Dylewski insofar as it pertains to kickbacks in the form of entertainment and travel. The Motion for Summary Judgment on the first-to-file bar and the public disclosure and original source provisions shall be denied as to all Defendants insofar as it pertains to the training contracts.

3. Rule 9(b) Particularity

Defendants argue that Relator Pfeifer's claims against them should be dismissed because she failed to plead claims of fraud with the particularity required by Rule 9(b). Fed. R. Civ. P. 9(b) ("In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other conditions of mind of a person may be averred generally.") False Claims Act ("FCA") claims, which involve averments of fraud, are held to the heightened standard of Rule 9(b). See *United States ex rel. Lacy v. New Horizons, Inc.*, 348 Fed. Appx. 421, 424, 2009 WL 3241299, 2 (10th Cir. 2009) (quoting *United States ex rel. Karvelas v. Melrose- Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004)). In reviewing a dismissal pursuant to Rule 9(b) for failure to plead fraud with particularity, I must confine my analysis to the text of the Complaint, accepting as true all well-pleaded facts as distinguished from conclusory allegations. *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726 (10th Cir. 2006). I view those facts in the light most favorable to Relator Pfeifer as the non-moving party. *Id.*

The Tenth Circuit requires that a complaint alleging fraud must “set forth the time, place, and contents of the false representation, the identity of the party making the false statements, and the consequences thereof.” *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1236 (10th Cir. 2000) (quoting *Lawrence Nat’l. Bank v. Edmonds (In re Edmonds)*, 924 F.2d 176, 180 (10th Cir. 1991)(internal quotations omitted)). The purpose of this requirement is to give defendants fair notice of a plaintiff’s claims against them and the factual grounds upon which they are based. *Id.* at 1236–37. Specifically, at a minimum, this requires that a plaintiff set forth the “who, what, when, where and how of the alleged fraud.” *Ex rel. Sikkenga*, 472 F.3d at 727–28.

The Tenth Circuit has held that generalized statements are insufficient. In *Koch*, for example, the court held that a time frame of twenty-four years was not sufficiently precise, nor did the following paragraph provide sufficient particularity:

[D]efendants planned and acted to conceal the true value of shares of stock in Koch Industries from plaintiffs and the other selling shareholders and carried out a scheme designed to understate the existence, extent and value of property and assets owned directly or beneficially by Koch Industries by failing to disclose the existence, location, ownership, condition and true value of assets and property, including but not limited to, oil and gas reserves, acreage, prospects and properties, oil and gas production and planned development of oil and gas properties owned or acquired prior to June 10, 1983.

Id. at 1236.

In *United States v. Cheng*, 184 F.R.D. 399 (D.N.M. 1988) the court rejected the following as conclusory:

the sum total of the information alleged in the Complaint regarding the purported fraud is the statement that Dr. Cheng “submitted fraudulent leave slips or failed to submit leave slips for hours he was absent from his duty

station and still received a pay check.” Complaint ¶ 9. The Court can hardly imagine a more “conclusory” allegation of fraud. The Government has failed to provide even a vague description of the content of the fraudulent statements and has provided no grounds from which this Court might infer what about those statements is false. What does it mean to “submit fraudulent leave slips”? Did Dr. Cheng affirmatively state that he was entitled to leave when he was not? Did Dr. Cheng affirmatively state that he was at work hours when he was not? Or, did Dr. Cheng simply fail to request all of the time off which he took, and how would this failure translate into a false statement? What did Dr. Cheng say, when did he say it, and how was it false? The Complaint does not provide the Court with any basis for answering these questions.

Id. at 402.

In applying these standards, I begin with Sorin Entities. Relator Pfeifer’s complaint names EMI, Sorin Group USA, Inc., Sorin Group, and Sorin S.p.A. as defendants. She asserts that EMI is a Delaware corporation owned and controlled by Cobe (n/k/a Sorin Group USA, Inc.) (Compl. ¶ 6) and that Cobe is a Delaware corporation, which is owned and controlled by Sorin S.p.A., an Italian corporation. See Compl. ¶ 7. Taking Relator Pfeifer’s allegations as true, I find that the companies are related.

That EMI and the Sorin Entities are related is not sufficient to make EMI’s affiliated companies liable under the FCA, however. Relator Pfeifer’s allegations do not identify any specific acts taken by the Sorin entities. “Being a parent corporation of a subsidiary that commits an FCA violation, without some degree of participation by the parent in the claims process, is not enough to support a claim against the parent for the subsidiary’s FCA violation.’ Relator must be able to demonstrate either that [the defendant] is liable under a veil piercing or alter ego theory, or that it is directly liable for

its own role in the submission of false claims.” *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 60 (D.D.C. 2007) (quoting *United States ex rel. Tillson v. Lockheed Martin Corp.*, 2004 WL 2403114, *33, 2004 U.S. Dist. LEXIS 22246 at *107 (W.D. Ky. 2004)); see also, *United States ex rel Fent v. L-3 Commc’ns Aero Tech., LLC*, 2007 WL 3485395 at *3 (N.D. Okla.). “A court can pierce the veil between the parent and subsidiary only where the parent ‘so dominated the subsidiary corporation as to negate its separate personality.’” *Hockett*, 498 F. Supp. 2d at 60 (quoting *AGS Int’l Servs. S.A. v. Newmont USA Ltd.*, 346 F.Supp.2d 64, 89 (D.D.C. 2004)). “Except in unusual circumstances, courts will not disregard the separate identities of a parent and its subsidiary, even a wholly-owned subsidiary.” *Id.* (quoting *Secs. Indus. Ass’n v. Fed. Home Loan Bank Bd.*, 588 F. Supp. 749, 754 (D.D.C. 1984)).

The Complaint does not assert that the corporate veil of the Sorin Entities should be pierced. It does not assert that Sorin Entities exercised such control over EMI that it had become their mere instrumentality, nor does it assert any of the factors that would evidence the lack of a separate existence between parent and subsidiary such as, commonality of officers and directors; an improper financial relationship between the parent and EMI; failure to maintain separate books, records, and offices; or that the property used by one is used by the other as its own. See, e.g., *Hockett*, 498 F. Supp. 2d at 60; see also, 45 *AmJur Proof of Facts* 1 § 15 (citing Krendl & Krendl, *Piercing the Corporate Veil: Focusing the Inquiry*, 55 *Denver L.J.* 1 (1978)).

Relator Pfeifer asserts that “[t]he actions of EMI as set forth herein were undertaken for the benefit of Cobe [Sorin Group USA, Inc.], Sorin S.p.A., and the Sorin

Group and at the direction of Cobe, Sorin S.p.A. and the Sorin Group.” *Id.* at ¶ 8. In the claim, she refers to “Defendants,” without specifying any particular actors. She does not define the term “EMI” as including the Sorin Entities.

Relator Pfeifer’s allegations are insufficient to pierce the corporate veil, as required by the FCA. Even accepting Relator Pfeifer’s allegations as true and construing them in the light most favorable to her, the allegations are insufficient to withstand Sorin Entities’ motion to be dismissed as defendants. Therefore, the Sorin Entities shall be dismissed for failure to plead with sufficient particularity as required by Fed. R. Civ. P. 9(b).

As to the remaining Defendants, Relator Pfeifer gives sufficient factual information to provide certain of the defendants with fair notice of the factual grounds on which her claims are based. She provides the who, what, when, where and how of the transactions of EMI and Dr. Garcia (Compl. ¶ 25); Advanced Cardiac Specialists and Drs. Siegel and Garg (Compl. ¶ 26); and Dr. Blumberg (Compl. ¶ 27), naming the time frame of the relationship, the amounts of each contract, and the quantities of EMI product purchased by each physician or practice during the term of the contracts. Thus, the Complaint against EMI, and Drs. Garcia, Siegel, Garg, and Blumberg and Advanced Cardiac Specialists cannot be dismissed on the basis of failure to plead with sufficient particularity pursuant to Fed. R. Civ. P. 9(b).

In contrast, Relator Pfeifer supplies no detail concerning Drs. Ben-Zur, Seifert, Stuck, and Dylewski’s dealings with EMI. See Compl. ¶¶ 13, 14, 15, and 16. In failing to supply any specific averments concerning these Defendants, she does not answer

the questions who, what, when, where, and how. Thus, under Fed. R. Civ. P. 9(b), Relator Pfeifer does not plead fraud with sufficient detail to maintain the FCA claim against these individuals. Therefore, Drs. Ben-Zur, Seifert, Stuck, and Dylewski shall be dismissed.

Accordingly, it is ORDERED:

1. Defendants Ela Medical, Inc., Sorin Group USA, Inc., Sorin Group, and Sorin S.p.A.'s Motion to Dismiss Relator's Complaint (Docket No. 57), Defendants Advanced Cardiac Specialists Chartered, Dr. Stephen Blumberg, Dr. William Stuck, and Dr. John R. Dylewski's Motion to Dismiss Relator's Complaint (Docket No. 62), Defendant Dr. Uri Ben-Zur's Motion to Dismiss (Docket No. 68), Dr. Mark Seifert's Motion to Dismiss (Docket No. 116), and Dr. Ashkok Garg's Motion to Dismiss (Docket No. 125), and Dr. A. Tomas Garcia's Motion to Dismiss (Docket No. 134) are granted in part and denied in part as follows:
 - a. Relator Pfeiffer's claims, based upon expenses incurred for entertainment and personal and unrelated travel are dismissed with prejudice under the first-to-file bar as to all Defendants;
 - b. claims based on training contracts remain pending against Defendants Ela Medical, Inc., Advanced Cardiac Specialists Chartered, Dr. Blumberg, Dr. Garcia, Dr. Seigel, and Dr. Garg;

- c. claims against Defendants Sorin Group USA, Inc., Sorin Group, Sorin S.p.A., Dr. Ben-Zur, Dr. Seifert, Dr. Stuck, and Dr. Dylewski are dismissed without prejudice;
2. Defendants Sorin Group USA, Inc., Sorin Group, Sorin S.p.A., Dr. Ben-Zur, Dr. Seifert, Dr. Stuck, and Dr. Dylewski may have their costs;
3. Defendant Dr. Seifert's Motion to Dismiss as it pertains to insufficient service of process (Docket No. 116) is denied as moot.

DATED at Denver, Colorado, on March 31, 2010.

BY THE COURT:

s/ Walker D. Miller

Walker D. Miller
United States Senior District Judge