512 F.Supp.2d 1158
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United States District Court,
N.D. Illinois,
Eastern Division.
UNITED STATES of America ex rel. Katy **KENNEDY** and Frank A. Matos, The State of Illinois ex rel. Katy **Kennedy** and Frank A. Matos, and Katy **Kennedy**, individually, Plaintiffs,
v.
AVENTIS PHARMACEUTICALS, INC., and Pharmanetics, Inc., Defendants.

No. 03 C 2750.
Sept. 13, 2007.

Background: Former sales representatives brought qui tam action on behalf of the United States and the State of Illinois against pharmaceutical and drug development companies alleging they engaged in a scheme to market a prescription drug for off-label uses resulting in doctors submitting fraudulent reimbursement claims to the government in violation of the False Claims Act (FCA). One sales representative also brought claim against pharmaceutical company alleging retaliation under FCA and state law. Companies moved to dismiss.

Holdings: The District Court, Matthew F. Kennelly, J., held that:
(1) sales representatives' lawsuit did not "depend essentially" on publicly disclosed information, as would require application of FCA's public disclosure bar;
(2) sales representatives met heightened pleading requirements for fraud; and
(3) sales representative claiming retaliation did not engage in conduct protected by the FCA.

Motions granted in part and denied in part.

West Headnotes

[1] United States 393 122

393 United States
393VIII Claims Against United States
393k120 Making or Presentation of False Claims and Other Offenses Relating to Claims
393k122 k. Penalties and Actions Therefor. Most Cited Cases

The public disclosure bar disallowing certain qui tam actions under the False Claims Act (FCA), is not to be excessively construed, and its application is evaluated within the context of Congress's intent to increase incentives for the exposure of fraud. 31 U.S.C.A. § 3730(e)(4).

[2] United States 393 122

393 United States
393VIII Claims Against United States
393k120 Making or Presentation of False Claims and Other Offenses Relating to Claims
393k122 k. Penalties and Actions Therefor. Most Cited Cases

A court lacks jurisdiction to hear a qui tam action, under the False Claims Act (FCA), if the allegations made by the relator have been "publicly disclosed" and the lawsuit is "based upon" that publicly disclosed information, unless the relator is an "original source" of the information. 31 U.S.C.A. § 3730(e)(4).

[3] Federal Courts 170B 33

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk29 Objections to Jurisdiction, Determination and Waiver
170Bk33 k. Affidavits and Evidence in General. Most Cited Cases

A court is not restricted to the jurisdictional contentions asserted in the complaint, but may use other evidence that has been submitted to determine whether it has subject matter jurisdiction. Fed.Rules Civ.Proc.Rule 12(b)(1), 28 U.S.C.A.

[4] Federal Courts 170B 33

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk29 Objections to Jurisdiction, Determination and Waiver
170Bk33 k. Affidavits and Evidence in General. Most Cited Cases

Federal Courts 170B 34

170B Federal Courts
170BI Jurisdiction and Powers in General
170BI(A) In General
170Bk29 Objections to Jurisdiction, Determination and Waiver
170Bk34 k. Presumptions and Burden of Proof. Most Cited Cases

The party asserting jurisdiction, in response to a motion to dismiss for lack of subject matter jurisdiction, has the burden of proof, and the court is free to weigh the evidence to determine whether jurisdiction has been established. Fed.Rules Civ.Proc.Rule 12(b)(1), 28 U.S.C.A.

[5] United States 393 122

393 United States
393VIII Claims Against United States
393k120 Making or Presentation of False Claims and Other Offenses Relating to Claims
393k122 k. Penalties and Actions Therefor. Most Cited Cases

A "public disclosure" exists, as required to bar certain qui tam actions under the False Claims Act (FCA), when the critical elements exposing the transaction as fraudulent are placed in the public domain. 31 U.S.C.A. § 3730(e)(4)(A).

[6] United States 393 122

393 United States
393VIII Claims Against United States
393k120 Making or Presentation of False Claims and Other Offenses Relating to Claims
393k122 k. Penalties and Actions Therefor. Most Cited Cases

Former sales representatives' qui tam action brought against pharmaceutical and drug development companies alleging they engaged in a scheme to market a prescription drug for off-label uses resulting in doctors submitting fraudulent reimbursement claims to the government in violation of False Claims Act (FCA) did not "depend essentially" on publicly disclosed information pled in amended complaint, as would require application of public disclosure bar, disallowing certain qui tam actions under FCA, even though amended complaint included public information regarding alleged off-label marketing, where complaint also included allegations that had not been publicly disclosed. 31 U.S.C.A. § 3730(e)(4)(A).

[7] United States 393 122

393 United States
393VIII Claims Against United States
393k120 Making or Presentation of False Claims and Other Offenses Relating to Claims
393k122 k. Penalties and Actions Therefor. Most Cited Cases

A lawsuit is "based on" a public disclosure, as required to bar certain qui tam actions under the False Claims Act (FCA), when it both depends essentially upon publicly disclosed information and is actually derived from such information. 31 U.S.C.A. § 3730(e)(4)(A).

[8] Federal Civil Procedure 170A 636

170A Federal Civil Procedure
170AVII Pleadings and Motions
170AVII(A) Pleadings in General
170Ak633 Certainty, Definiteness and Particularity
170Ak636 k. Fraud, Mistake and Condition of Mind. Most Cited Cases

Former sales representatives bringing qui tam action against pharmaceutical and drug developing companies met heightened pleading requirements for fraud provided by rule, in alleging companies engaged in off-label marketing of a prescription

drug resulting in doctors submitting fraudulent reimbursement claims to the government in violation of False Claims Act (FCA), even though specific facts regarding particular claims were not likely within representatives' reach; representatives drew a reasonable inference that claims for reimbursement regarding off-label use of the drug were submitted to the government for payment, given the significant proportion of medical care in country financed by medicare and medicaid. 31 U.S.C.A. § 3729 et seq.; Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.

[9] Federal Civil Procedure 170A 636

170A Federal Civil Procedure
170AVII Pleadings and Motions
170AVII(A) Pleadings in General
170Ak633 Certainty, Definiteness and Particularity
170Ak636 k. Fraud, Mistake and Condition of Mind. Most Cited Cases

Heightened pleading requirement provided by rule for fraud generally requires a qui tam plaintiff, bringing a claim under the False Claims Act (FCA), to do more than merely charge that the defendants engaged in fraudulent schemes and then conclusively assert that fraudulent claims were submitted to the government; rather, the plaintiff typically must come forward with evidence linking the allegations of fraud to an actual false claim for payment. 31 U.S.C.A. § 3729 et seq.; Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.

[10] Federal Civil Procedure 170A 636

170A Federal Civil Procedure
170AVII Pleadings and Motions
170AVII(A) Pleadings in General
170Ak633 Certainty, Definiteness and Particularity
170Ak636 k. Fraud, Mistake and Condition of Mind. Most Cited Cases

Heightened pleading requirements for fraud provided by rule are relaxed when the plaintiff lacks access to all facts necessary to detail his claim. Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.

[11] Federal Civil Procedure 170A 636

170A Federal Civil Procedure
170AVII Pleadings and Motions
170AVII(A) Pleadings in General
170Ak633 Certainty, Definiteness and Particularity
170Ak636 k. Fraud, Mistake and Condition of Mind. Most Cited Cases

Heightened pleading requirements provided by rule for fraud can be fulfilled by pleading facts on information and belief if they are facts inaccessible to the plaintiff, in which event he has to plead the grounds for his suspicions. Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.

[12] Labor and Employment 231H 778

231H Labor and Employment
231HVIII Adverse Employment Action
231HVIII(A) In General
231Hk775 Reporting or Opposing Wrongdoing; Criticism and “Whistleblowing”
231Hk778 k. Protected Activities. Most Cited Cases

Former sales representative bringing qui tam action against her former company did not engage in conduct protected by the False Claims Act (FCA), as required to support her claim for retaliation against company, by complaining to superiors regarding the inappropriate use of company funds, the creation of false entertainment invoices, and the off-label promotion of a prescription drug; sales representatives' actions provided no indication that she informed company that she suspected the company was defrauding the government or that she was pursuing or assisting in making an FCA claim. 31 U.S.C.A. § 3730(h); S.H.A. 740 ILCS 175/4(g).

***1160** AUSA, United States Attorney's Office (NDIL), Michael Charles Rosenblat, Michael C. Rosenblat, P.C., Clinton A. Krislov, Kenneth Todd Goldstein, Krislov & Associates, Ltd., Office of the Attorney General, State of Illinois General Law

Bureau, Chicago, IL, for Plaintiffs.

Scott R. Lassar, Jaime L.M. Jones, Sidley Austin LLP, Michael Irving Leonard, Meckler, Bulger & Tilson, Chicago, IL, Stephen C. Payne, Sidley Austin LLP, Washington, DC, Benjamin N. Thompson, Jennifer M. Miller, Wyrick Robbins Yates & Ponton LLP, Raleigh, NC, for Defendants.

1161 *MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge.

Relators Katy Kennedy and Frank Matos bring this *qui tam*[FN1] action on behalf of the United States and the State of Illinois under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (FCA), and the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1 *et seq.* (IWRPA), against Aventis Pharmaceuticals, Inc. and PharmaNetics, Inc. Kennedy also brings a claim on her own behalf against Aventis, claiming retaliation under the FCA and IWRPA. Aventis and PharmaNetics have moved to dismiss relators' amended complaint pursuant to Federal Rules of Civil Procedure 8(a), 9(b), 12(b)(1) and 12(b)(6). For the following reasons, the Court denies PharmaNetics's motion and grants in part and denies in part Aventis's motion.

> FN1. *Qui tam* is short for *qui tam pro domino rege quam pro se ipso in hac parte sequitur* ("who brings the action for the King as well as for himself.") *United States ex rel. Mathews v. Bank of Farmington,* 166 F.3d 853, 857 (7th Cir.1999).

Facts

When considering a motion to dismiss a complaint, the Court accepts the plaintiff's allegations as true. *Thompson v. Ill. Dep't of Prof'l Reg.,* 300 F.3d 750, 753 (7th Cir.2002).

Kennedy and Matos are former Aventis sales representatives. While at Aventis, Kennedy and Matos promoted the prescription drug Lovenox, an anticoagulant prescribed by physicians almost exclusively for inpatient hospital care. Lovenox is approved by the Food and Drug Administration (FDA) for seven indications. These indications are prophylaxis of deep vein thrombosis in patients undergoing abdominal surgery; prophylaxis of deep vein thrombosis in patients undergoing hip replacement surgery; prophylaxis of deep vein thrombosis in patients undergoing knee replacement surgery; prophylaxis of deep vein thrombosis in patients who are at risk for thromboemobolic complications due to severely restricted mobility; prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin; inpatient treatment of acute deep vein thrombosis with or without pulmonary embolism, when administered in conjunction with warfarin sodium; and the outpatient treatment of acute deep vein thrombosis without pulmonary embolism when administered in conjunction with warfarin sodium.

Relators allege that Aventis engaged in a scheme to market Lovenox for off-label uses that resulted in doctors submitting fraudulent reimbursement claims to the government. They allege that in August 2000, Aventis entered into an agreement with PharmaNetics pursuant to which PharmaNetics developed a test, called the ENOX test, to detect the anticoagulant effects of Lovenox on patients with unstable angina. Relators allege that the purpose of the test was to overcome objections from interventional cardiologists who were unwilling to perform interventional procedures, such as cardiac catheterization, on patients with unstable angina who were receiving Lovenox. Lovenox has not been approved by the FDA for use in the catheterization laboratory on patients with unstable angina. Aventis informed its sales associates about the test and told them that a brochure they had been provided "should help you to discuss management of patients on [Lovenox] who may transition to the cath lab. The Enox test card is now available and can be used to help give skeptical physicians the evidence they need to feel confident using [Lovenox] in this scenario." Amend. Compl. ¶ 46. On ***1162** April 18, 2000, PharmaNetics issued a

press release, approved by Aventis, which stated that "the ability to monitor [Lovenox] in potential new areas of study such as Percutaneous Coronary Intervention [PCI] ... has been an increasingly important issue. We believe that by providing access to a rapid test for [Lovenox], we will strengthen the drug's leadership position, facilitate administration in acute-care settings and help physicians manage difficult sub-sets of patients." *Id.* ¶ 44. Relators allege that Lovenox is not approved for PCI or acute-care settings.

Relators allege that on August 10, 2001, Matos received a copy of an e-mail concerning renal dosing for Lovenox, which was given to a medical center in Elk Grove Village, Illinois. The FDA has not approved Lovenox for renal patients. Relators further allege that in May 2002, an Aventis district manager instructed a subordinate to make a binder containing off-label information. The Aventis manager provided the binder to a sales associate to help market Lovenox for off-label uses. The binder contains eight sections: trauma, general surgery, stroke, neurosurgery, spinal cord injuries, obstetrician/gynecology/pediatrics, heparin induced thrombocytopenia, and other. The FDA has not approved Lovenox to treat any of these conditions.

In May 2002, Matos informed senior Aventis personnel in the legal and human resources departments that unapproved and off-label clinical studies were being distributed by Aventis. Also in May 2002, another Aventis employee gave Kennedy a Lovenox dosing guideline booklet. On February 4, 2003, Kennedy visited Resurrection Hospital in Park Ridge, Illinois and saw approximately 150 of the booklets. The booklets contained dosing guidelines for special patient populations for which Lovenox had not been approved by the FDA.

At the January 2003 Lovenox national sales meeting, participants were given clinical workshop materials on the off-label use of Lovenox in the catheterization lab and unapproved intravenous dosing. The sales force also was shown a slide presentation that stated that Lovenox is "therapeutic within 30 minutes." During a sales practice session in May 2003, however, the director of marketing for Lovenox told Kennedy and Matos that therapeutic levels are reached in sixty to ninety minutes.

In March 2003, Aventis conducted advanced training at Northwestern Memorial Hospital in Chicago. A significant amount of the training took place in the catheterization lab, though Lovenox is not approved for use with catheterization procedures. Aventis also provided its Lovenox sales team with articles containing off-label indications for Lovenox. Relators contend that Aventis provided these articles to the sales force to assist them in selling Lovenox for off-label purposes.

In November 2003, PharmaNetics filed a lawsuit against Aventis arising out of their agreement to develop and market the ENOX test card. In the suit, PharmaNetics alleged that "although [Lovenox] is not approved for PCI [,] Aventis nonetheless has engaged in off-label promotion of its drug for PCI." Amend. Compl. ¶ 49. PharmaNetics also alleged that Aventis engaged in false advertising regarding Lovenox's efficacy and whether physicians needed to routinely monitor the effects of the drug on heart patients.

Relators allege that Aventis encouraged its Lovenox sales representatives to provide items of value to physicians, pharmacists, and others in order to induce health care providers to purchase Lovenox. They also contend that Aventis paid excessive fees to speakers to encourage their continued use and promotion of Lovenox and provided unrestricted grants to ***1163** healthcare organizations to promote the off-label use of Lovenox.

Kennedy also alleges that she suffered retaliation for reporting alleged internal financial irregularities to management. In May 2002, she received a message from her supervisor, Joe Levato, directing her to spend the remaining funds in her expense account by July 1, 2002. He advised Kennedy to spend the funds on events that would occur after July 1 and that she should create false entertainment

invoices and submit them for reimbursement. Kennedy asked Levato whether the practice would violate internal company controls. Kennedy contends that Levato threatened, harassed, and in other ways discriminated against her as a result of her questions. In August 2002, Kennedy reported her concerns to the human resources department. She also informed the director of human resources of the off-label promotion and marketing of Lovenox. Kennedy contends that she was "threatened, harassed, retaliated and discriminated against" for reporting the financial irregularities and off-label marketing. Amend. Compl. ¶ 59. Kennedy contends that due to the harassment, in February 2004 she was forced to resign.

The docket reflects that relators met with representatives from the government on April 17, 2003. *See* United States' Motion for Extension of Time to Consider Election to Intervene, filed June 17, 2003 (docket no. 9). On April 24, 2003, relators filed their original complaint. Relators state in their response to defendants' motions that they provided additional documents and information to the government regarding the alleged fraud on several occasions between June 2003 and July 2006. On May 14, 2004, relators filed an amended complaint. The government ultimately declined to intervene in the case.

Discussion

1. Submission of false claims

The FCA imposes civil liability on "[a]ny person" who "knowingly presents, or causes to be presented, to ... the United States ... a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a). It is the government's "primary litigative tool for combating fraud." *United States ex rel. Kelly v. Boeing Co.,* 9 F.3d 743, 745 (9th Cir.1993). The United States may bring an FCA action itself, or a private party may initiate the suit under the FCA's *qui tam* provisions. *See* 31 U.S.C. § 3730(a) & (b)(1).

Kennedy and Matos allege that Aventis and PharmaNetics violated the FCA and parallel state statutes by promoting and marketing off-label uses of Lovenox, which they allege caused healthcare providers to present false claims to the United States government and the State of Illinois for reimbursement.[FN2] Defendants' alleged fraud can be summarized as follows. Aventis's off-label marketing constituted false or fraudulent statements to doctors. Many doctors would not have prescribed Lovenox but for defendants' fraudulent statements. Ordinarily, the government does not reimburse costs associated with off-label uses of drugs. Therefore, each claim for reimbursement for an off-label use of Lovenox submitted to the government by a healthcare provider is a direct result of defendants' alleged fraud.

> FN2. Case law regarding the FCA is also applicable to the IWRPA. *See Humphrey v. Franklin-Williamson Human Servs., Inc.,* 189 F.Supp.2d 862, 867 (S.D.Ill.2002); *Scachitti v. UBS Finan. Serv.,* 215 Ill.2d 484, 507, 294 Ill.Dec. 594, 831 N.E.2d 544, 557 (2005).

[1][2] Defendants contend that relators' *qui tam* action must be dismissed pursuant to Rule 12(b)(1) because of the so-called public disclosure bar. Congress ***1164** established the public disclosure bar to disallow certain *qui tam* actions:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4). The jurisdictional bar "is not to be excessively construed," and its application is evaluated within the context of Congress's intent to increase incentives for the exposure of fraud. *Mathews,* 166 F.3d at 858. A court lacks jur-

isdiction to hear a *qui tam* action if the allegations made by the relator have been "publicly disclosed" and the lawsuit is "based upon" that publicly disclosed information, unless the relator is an "original source" of the information. *Rockwell Int'l Corp. v. United States,* ---U.S. ----, ---- - ----, 127 S.Ct. 1397, 1405-06, 167 L.Ed.2d 190 (2007) (court lacks jurisdiction over a *qui tam* action in which the information underlying plaintiff's claims were publicly disclosed unless plaintiff is an original source).

[3][4] When deciding a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a court must accept the factual allegations made in the complaint as true and construe reasonable inferences in favor of the non-movant. *Rueth v. EPA,* 13 F.3d 227, 229 (7th Cir.1993). A court is not, however, restricted to the jurisdictional contentions asserted in the complaint but may use other evidence that has been submitted to determine whether it has subject matter jurisdiction. *Ezekiel v. Michel,* 66 F.3d 894, 897 (7th Cir.1995). The party asserting jurisdiction has the burden of proof, and the Court is free to weigh the evidence to determine whether jurisdiction has been established. *United Phosphorus Ltd. v. Angus Chem. Co.,* 322 F.3d 942, 946 (7th Cir.2003).

Defendants argue that Kennedy and Matos cannot pursue their claims because the relevant allegations were publicly disclosed, their allegations are based upon the publicly disclosed information, and Kennedy and Matos were not original sources of the information.

a. Public disclosure

[5] A public disclosure exists under § 3730(e)(4)(A) "when the critical elements exposing the transaction as fraudulent are placed in the public domain." *United States ex rel. Feingold v. AdminaStar Federal, Inc.,* 324 F.3d 492, 495 (7th Cir.2003). In this case, many facts regarding the alleged off-label marketing of Lovenox were placed in the public domain. For example, as early as April 2000, information was in the public domain regarding the agreement between Aventis and PharmaNetics to develop the ENOX test. The 2000 press release specifically refers to the use of Lovenox in PCI patients. An August 29, 2002 press release quotes PharmaNetics's principal investigator, Dr. David Moliterno, as saying "[i]t is great to finally have a quick reliable method for detecting the extent of anticoagulation provided by [Lovenox]. This should help bridge the gap between upstream anticoagulation for unstable angina and procedural anticoagulation during percutaneous coronary intervention." Jones Aff., Ex. 7. The press release also said that the test "should facilitate [the use of Lovenox] in ... patients transitioning to the cath lab." *Id.*

An October 11, 2002 press release by PharmaNetics states that "patients who are initiated on [Lovenox] are transferred ***1165** to the cardiac intervention lab for angioplasty or other revascularization procedures. The cardiologist today has no means to determine the level of anticoagulation the patient has when on [Lovenox]. Thus, the patient is often taken off [Lovenox] and put on heparin in order to better manage the anticoagulation status." *Id.,* Ex. 9.

An October 17, 2002 press release states that "[f]or patients who are initiated on [Lovenox] then transferred to the cardiac intervention lab for angioplasty or other revascularization procedures, the intervention cardiologist may desire a simple and timely test to determine whether the patient is adequately anticoagulated prior to the procedure." *Id.,* Ex. 8.

In November 2002, PharmaNetics issued a press release stating that a recent test "reinforce[d] the safety of PCI among patients receiving [Lovenox], yet provide[d] meaningful guidance before initiating PCI....". *Id.,* Ex. 11. The press release also stated that the ENOX test "is the missing link cardiologists have needed to effectively and safely replace heparin with [Lovenox] during coronary intervention ... [and] provides the interventional cardiologist with a tool to more confidently use [

Lovenox] in this patient population." *Id.* The defendants continued to issue press releases like these through April 2003.

In addition to these public disclosures, in November 2003, PharmaNetics filed suit against Aventis, asserting (among other things) claims under the Lanham Act regarding Aventis's marketing of Lovenox. PharmaNetics's complaint alleged that Aventis's marketing campaign constituted false advertising because it described Lovenox as requiring no routine monitoring. The complaint also alleged that "although [Lovenox] is not approved for PCI, Aventis nonetheless has engaged in off-label promotion of its drug for PCI, as demonstrated, for example, by Aventis' Lovenox advertisements in invasive cardiology publications such as 'Cath Lab Digest' and 'The Journal of Invasive Cardiology.' " Jones Aff., Ex. 2 ¶ 33.

It is not clear, however, whether these disclosures are the "critical elements" exposing the alleged fraud. *See Feingold,* 324 F.3d at 495. The disclosures do not, for example, touch upon the alleged false claims doctors submitted to Medicare and Medicaid as a result of the off-label marketing. Whether false claims were submitted is critical to the alleged fraud, because without the submission of such claims there has been no fraud on the government. As relators point out, the press releases do not describe the fraud relators allege. The press releases are public statements by the companies announcing a business development; they do not hint that the defendants are engaged in a fraud on the government. The parties have not cited, and the Court has been unable to locate, Seventh Circuit case law addressing whether a transaction is publicly disclosed when some of the facts from which a fraud might be inferred are placed in the public domain, but other significant facts are missing. There is no doubt, however, that facts described in defendants' press releases, the Aventis/PharmaNetics lawsuit, and relators' complaint overlap. Therefore, for purposes of resolving defendants' motions, the Court will assume that a public disclosure exists within the meaning of § 3730(e)(4)(A).

b. "Based upon" the public disclosure

[6][7] A lawsuit is based on a public disclosure when it "both depends essentially upon publicly disclosed information and is actually derived from such information." *Id.* at 496 (quoting *Mathews,* 166 F.3d at 864). Many of relators' allegations are drawn directly from the publicly disclosed information. For example, relators allege ***1166** that on April 18, 2000, defendants issued a press release describing their development of the ENOX test. Amend. Compl. ¶ 44. They further allege that on October 17, 2002, Aventis and PharmaNetics issued a press release regarding the ENOX test stating that the test "is intended to provide interventional cardiologists with the means of detecting the anticoagulant effects of [Lovenox] in patients prior to [PCI]." *Id.* ¶ 45. Other allegations in the complaint regarding the ENOX test are drawn directly from PharmaNetics's lawsuit against Aventis in which it made the same allegation as relators do here-that Aventis engaged in off-label promotion of Lovenox for PCI. *See id.* ¶¶ 46, 48, 49, 50. Thus, there is no doubt that many of relators' allegations are based on the publicly disclosed information.

Relators do, however, include other allegations in their amended complaint that are not based on publicly disclosed information. For example, they include allegations regarding internal sales meetings during which Aventis management told sales representatives to market Lovenox for off-label uses. *See, e.g.,* Amend. Compl. ¶¶ 29, 31, 32, 35. Similarly, they allege that Aventis paid "kickbacks" to healthcare workers to induce them to use and promote Lovenox for off-label uses. *Id.* ¶¶ 36-42. There is no indication that any of this information was publicly disclosed.

The majority of the circuit courts apply the standard "that a qui tam action is 'based upon' a public disclosure when the supporting allegations are the same as those that have been publicly disclosed ... regardless of where the relator obtained his information." *See Mathews,* 166 F.3d at 864

(citing cases from other circuits). The Seventh Circuit, however, has expressly rejected this standard. Instead, the court has adopted the Fourth Circuit's position in *United States ex rel. Siller v. Becton Dickinson & Co.,* 21 F.3d 1339, 1347-48 (4th Cir.1994), that "[a] lawsuit is based upon public[ly] disclose[d information] when it both depends essentially upon publicly disclosed information and is actually derived from such information." *Feingold,* 324 F.3d at 497; *Mathews,* 166 F.3d at 863. *See also United States ex rel. Fowler v. Caremark RX, L.L.C.,* 496 F.3d 730, 737-38 (7th Cir.2007). The Court therefore must examine whether relators' suit "depends essentially upon" the publicly disclosed information, or to put it another way, whether the lawsuit can stand without such information.[FN3]

> FN3. The Court need not consider the second part of the *Feingold- Mathews* test-whether the suit is "actually derived from" publicly disclosed information-because defendants' argument fails on the first part of the test.

Relators' amended complaint undeniably includes a good deal of public information regarding alleged off-label marketing, particularly Aventis's press releases. Their claims still hold up, however, even if the Court disregards that information. For example, relators allege that Aventis personnel sent Matos an e-mail regarding renal dosing for Lovenox, which was given to a medical center, even though the FDA had not approved Lovenox for renal patients. Amend. Compl. ¶ 25. Relators allege that in May 2002, an Aventis manager instructed a subordinate to create a binder of off-label product information to be used by the sales team to conduct off-label marketing of Lovenox. *Id.* ¶ 26. They allege that in May 2002, a Lovenox dosing booklet made by Aventis was given to Kennedy, who thereafter saw 150 of the books at a local hospital. The FDA had not approved Lovenox for the special patient populations indicated in the booklet. *Id.* ¶ 28. None of these allegations have been publicly disclosed. Relators also allege that

> ***1167** [d]efendants fraudulently induced physicians to write prescriptions for off-label uses by false and fraudulent misrepresentations regarding Lovenox ... [t]he fraud surrounding the efforts of Defendants to cause doctors to write prescriptions for Lovenox for unapproved uses was for the purpose of obtaining government payments. The initial fraudulent marketing of Lovenox for off-label uses was a step in Defendants' ultimate goal of obtaining payments from the Governments.

Id. ¶ 52. These allegations likewise are not claimed to have been publicly disclosed.

For these reasons, the Court concludes that the relators' lawsuit does not "depend[ ] essentially" on the publicly disclosed information pled in the amended complaint. *Feingold,* 324 F.3d at 497. Relators' claims therefore survive the public disclosure bar. The Court thus need not decide whether relators are an "original source" of the information under § 3730(e)(4).

c. Rule 9(b)

[8][9] Because the FCA is an anti-fraud statute, relators' amended complaint must meet the heightened pleading requirements of Rule 9(b). *United States ex rel. Gross v. AIDS Research Alliance-Chicago,* 415 F.3d 601, 604 (7th Cir.2005). Rule 9(b) states that "the circumstances constituting fraud ... shall be stated with particularity." Fed.R.Civ.P. 9(b). Moreover, Rule 9(b) generally requires a *qui tam* plaintiff to do more than merely charge that the defendants engaged in fraudulent schemes and then conclusively assert that fraudulent claims were submitted to the government. *See United States ex rel. Garst v. Lockheed-Martin Corp.,* 328 F.3d 374, 378 (7th Cir.2003). Rather, the relator typically must come forward with evidence linking the allegations of fraud to an actual false claim for payment. *Id.*

[10][11] It is well established, however, that the requirements of Rule 9(b) are relaxed when the plaintiff lacks access to all facts necessary to detail

his claim. *Corley v. Rosewood Care Ctr., Inc.,* 142 F.3d 1041, 1051 (7th Cir.1998). *See also Emery v. Am. Gen. Fin., Inc.,* 134 F.3d 1321, 1323 (7th Cir.1998) (Rule 9(b) is relaxed when plaintiff shows that "further particulars of the alleged fraud could not have been obtained without discovery."). Such a situation is more likely to arise when, as in this case, the relators' claims are based on fraud allegedly committed against third parties. In addition, Rule 9(b)'s requirements can be fulfilled by pleading facts on information and belief if they are "facts inaccessible to the plaintiff, in which event he [has] to plead the grounds for his suspicions." *Bankers Trust Co. v. Old Republic Ins. Co.,* 959 F.2d 677, 684 (7th Cir.1992). That is precisely the case here. Relators have alleged with particularity facts regarding defendants' alleged off-label marketing. Specific facts, however, regarding particular claims were and are not likely within relators' reach. Given the significant proportion of medical care in this country that is financed by Medicare and Medicaid, relators have drawn a reasonable inference that claims for reimbursement regarding off-label uses of Lovenox were submitted to the federal government or the State of Illinois for payment. For these reasons, dismissal at this stage under Rule 9(b) would be inappropriate. The Court therefore denies defendants' motions to dismiss counts 1 through 6 of relators' amended complaint.

2. Whistleblower protection

[12] Aventis has moved to dismiss Kennedy's retaliation claim under the FCA ***1168** and IWRPA pursuant to Rule 12(b)(6). A complaint "need only 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.' " *Erickson v. Pardus,* --- U.S. ----, ----, 127 S.Ct. 2197, 2200, 167 L.Ed.2d 1081 (2007) (*per curiam*) (quoting *Bell Atlantic Corp. v. Twombly,* --- U.S. ----, ----, 127 S.Ct. 1955, 1964, 167 L.Ed.2d 929 (2007)). When ruling on a motion to dismiss for failure to state a claim, a judge "must accept as true all of the factual allegations contained in the complaint." *Bell Atlantic,* 127 S.Ct. at 1964.

To state a claim for retaliation under the FCA, Kennedy must allege that she was engaged in conduct protected under the FCA. Protected conduct includes "lawful acts done by the employee ... in furtherance of an [FCA or IWRPA action], including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section." 31 U.S.C. § 3730(h); 740 ILCS 175/4(g). Moreover, Kennedy must allege that her statements to her superiors put the company on notice that she was preparing to bring a suit under the FCA. *See Brandon v. Anesthesia & Pain Mgmt. Assocs., Ltd.,* 277 F.3d 936, 944-45 (7th Cir.2002); *see also Luckey v. Baxter Healthcare Corp.,* 183 F.3d 730, 733 (7th Cir.1999); *see also U.S. ex rel. Hopper v. Anton,* 91 F.3d 1261, 1270 (9th Cir.1996).

Kennedy alleges that Aventis threatened, harassed, retaliated, and discriminated against her because she complained to her superiors regarding the inappropriate use of company funds, the creation of false entertainment invoices, and the off-label promotion of Lovenox. Amend. Compl. ¶¶ 53-63. The allegations regarding improper use of company funds and the creation of false entertainment invoices do not support a FCA retaliation claim, as there is no indication in her complaint that these practices resulted in fraud on the government.

Kennedy's allegations that she complained to her superiors regarding alleged off-label marketing and promotion also are insufficient to support a retaliation claim as currently alleged. It is not enough that Kennedy complained to her employers regarding the alleged off-label marketing. As the Seventh Circuit said in *Brandon,*

> [Relator] had never explicitly told the shareholders that he believed they were violating the FCA and had never threatened to bring a *qui tam* action. He never threatened to report their conduct to the government until after he was discharged.... [Relator] was simply trying to convince the shareholders to comply with the Medicare billing regulations. Such conduct is usually not protected by the FCA.... Additionally, such

conduct usually does not put an employer on notice of potential FCA litigation. *See United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1523 (10th Cir.1996) (Plaintiff's conduct in advising her superiors of non-compliance with Medicaid program requirements did not suggest to employer that she intended to bring an FCA action.).

Brandon, 277 F.3d at 945. *See also Hopper,* 91 F.3d at 1270 ("[Relator] never gave any indication she was investigating the School District for defrauding the federal government. [Relator's supervisor] may have engaged in retaliation for her activities, but the record does not show any connection to the FCA."). Though Kennedy may have complained about off-label marketing, there is no indication in her complaint that she informed her employers that she suspected that Aventis was defrauding the government or that she was pursuing or assisting in making an FCA claim. For this reason, her retaliation ***1169** claims fail to state a claim under the FCA or IWRPA. The Court therefore grants Aventis's motion to dismiss counts 7 and 8 of the amended complaint pursuant to Rule 12(b)(6) . Kennedy has leave to file an amended version of these claims within fourteen days of this order.

Conclusion

For the foregoing reasons, the Court denies PharmaNetics's motion to dismiss [docket no. 57] and grants in part and denies in part Aventis' motion to dismiss [docket no. 60]. Counts 7 and 8 of Kennedy's amended complaint are dismissed for failure to state a claim. Kennedy has until September 26, 2007 to file an amended version of counts 7 and 8. Aventis's motion that the Court take judicial notice of certain facts [docket no. 65] is denied as moot. To the extent that relators' response to Aventis's notice of supplemental authority [docket no. 76] could be construed as a motion to strike, it is denied as moot. The case is set for a status hearing on October 2, 2007 at 9:30 a.m. to set a discovery schedule. Any stay of discovery previously imposed is lifted. The Clerk is directed to terminate motions 49, 54, 62, and 66.

N.D.Ill.,2007.
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