UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OFAMERICA, ex rel. FRANK SOLIS,

Plaintiffs,

v.

MILLENNIUM PHARMACEUTICALS, INC., SCHERING-PLOUGH CORP., and MERCK & CO.,

Defendants.

No. 2:09-cv-03010-MCE-EFB

MEMORANDUM AND ORDER

This lawsuit was originally filed under seal on November 4, 2009, pursuant to the qui tam provisions of the Federal False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA"), against Defendants, who are pharmaceutical companies, include Millennium Pharmaceuticals, Inc., Schering-Plough Corp., and Merck and Co. ("Defendants" unless otherwise indicated). The so-called "Relator" Plaintiff, Frank Solis, a former sales employee who at various points worked for all three Defendants ("Relator" or "Plaintiff") claims that the companies fraudulently marketed and/or promoted the use of two drugs, Integrilin and Avelox, for so called "off label" uses not approved by the Food and Drug Administration.[1] In so doing, according to Relator, Defendants "caused" physicians to

[1] Off label use of a drug occurs when it is used either for a purpose not approved by the FDA, of

improperly prescribe the drugs and, consequently, to submit false claims to Medicare, Medicaid and TRICARE (United States Military Healthcare) for federal reimbursement, which the government allegedly paid without knowing the claims were ineligible. Following a three-year investigation, the United States and all twenty-four states named in the initial complaint chose not to intervene, and Relator's Complaint was subsequently unsealed on December 20, 2012.

In response to Motions to Dismiss previously filed on behalf of each of the Defendants, Relator filed a First Amended Complaint ("FAC") on June 27, 2013. The viability of Plaintiff's FAC was then also attacked through three separate motions. Defendants Schering-Plough Corp. ("Schering-Plough") and Merck & Co. ("Merck") filed a joint Motion to Dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1)[2] on grounds that Relator's complaint was barred by the FCA's so called "public disclosure" bar. Defendant Millenium Pharmaceuticals, Inc. ("Millenium") subsequently joined in that motion. Additionally, two other motions, one filed jointly by Schering-Plough and Merck and the other by Millenium, argued that the various causes of action pled in the FAC are substantively deficient in contravention of Rule 12(b)(6). By Memorandum and Order filed March 26, 2014, this Court granted Defendants' Rule 12(b)(1) motion on grounds that Relator's "combination use" allegations were precluded under the FCA's s-called "public disclosure" bar precluding suits whose allegations have already been disclosed. Because Relator's FAC contained other allegations beyond combination use, however, including assertions pertaining to a completely different drug, Avelox, as well as allegations of fraud, improper billing, and impermissible kickbacks, the Court permitted Relator to file a Second Amended Complaint ("SAC") omitting the combination use allegations.[3]

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where non-indicated dosing regimens for the drug are promoted.

[2] All further references to "Rule" or "Rules" are to the Federal Rules of Civil Procedure unless noted otherwise.

[3] Because the Rule 12(b)(6) motions challenged the sufficiency of the FAC's allegations at a point when the question of the Court's jurisdiction over this qui tam action had not yet been determined, and

Relator's SAC was filed on April 5, 2014, and that amended pleading is the subject of yet another motion, this time offered by Defendant Millenium alone, that challenges the court's jurisdiction under Rule 12(b)(1) as to any claims asserted against Millenium. As set forth below, that Motion is GRANTED. Because the Court concludes that it has no jurisdiction over Relator's claims against Millenium in this matter, Millenium's concurrently filed Motions to Dismiss under Rule 12(b)(6), and to strike under Rule 12(c), are DENIED as moot.[4]

BACKGROUND

Integrilin is a drug that helps reduce blood clots and thereby helps to prevent heart attacks and death in patients suffering from acute coronary syndrome ("ACS"). ACS is an umbrella term covering a variety of diseases related to clotting in the coronary arteries that supply blood to the heart muscle, including unstable angina ("UA"), mild heart attacks known as non-ST–segment elevation myocardial infarctions ("NSTEMI"), and more severe heart attacks called ST-segment elevation myocardial infarctions ("STEMI"). Avelox, on the other hand, is an antibiotic approved by the Food and Drug Administration ("FDA") for treating adult patients with infections caused by a few susceptible strains of microorganisms.[5]

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since the parameters of a SAC without the combination use allegations would likely be far different than its predecessor, the Court denied those motions without prejudice to being renewed following submission of the SAC.

[4] Having determined that oral argument would not be of material assistance, the Court ordered this matter submitted on the briefing. See E.D. Cal. Local Rule 230(g).

[5] While Relator contends that Millenium was involved in the promotion of Integrilin between 2002 and 2005, Millenium had no similar role with respect to Avelox, the other drug implicated by Relator's lawsuit. The SAC makes it clear that only Schering and Merck were involved in marketing, selling, and distributing Avelox. SAC, ¶ 2. Consequently, since the "combination use" allegations have already been dismissed, Millenium's role in marketing Integrilin is the only remaining claim against Millenium at this juncture of the proceedings, and the only factor that need be considered in determining whether the Court has jurisdiction over Millenium.

With respect to Integrilin, FDA approval was first obtained in May 1998 by a company named COR Therapeutics, Inc. ("COR"), which thereafter promoted the drug along with Defendant Schering-Plough. In February of 2002, Defendant Millennium acquired COR and thereby obtained the right to co-promote Integrilin. In September of 2005, Defendant Millennium transferred its right to market Integrilin within the United States to Defendant Schering-Plough, thereby relinquishing any responsibility for the drug after a period of less than four years. Schering-Plough later merged with Merck in November of 2009 to form a new company, also known as Merck.

The allegations incorporated within Relator's initial complaint included contentions that Defendants, including Millenium, facilitated the presentation of false reimbursement claims by doctors and hospitals. According to Relator, Defendants promoted the prescription of Integrilin in particular, in combination with other drugs, without properly disclosing the dangers implicit in such combinations. As already stated, those allegations have already been adjudicated in Defendants' previous Rule 12(b)(1) Motion to Dismiss. Relator's SAC, however, also alleges other allegedly improper uses of Integrilin, including its early use for STEMI patients, despite the fact that such early use is "extremely dangerous, off-label and fraudulent." SAC, ¶ 5, 11. Relator further claims that Defendants violated the so-called Anti-Kickback Statute ("AKS"), which prohibits a drug company from knowingly and willfully offering or paying remuneration to purchase goods or services for which payment may be made by a federal healthcare program. See 42 U.S.C. § 1320a-7b(b). Relator alleges that Defendants violated the AKS by "funnel[ing] millions of dollars" in grants, honoraria, and meals to physicians in order to induce Integrilin prescriptions and to drive "off label" sales, all in violation of the AKS. See SAC, ¶ 6-7, 151-55.

Relator Solis was an Integrilin sales representative for Millennium covering the Los Angeles area between July 2003 and September of 2005. At that time he transitioned to employment for Schering-Plough. Then, in November of 2009, after the

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Schering/Merck merger, he became a Merck sales representative. Relator was terminated by Merck on March 9, 2010.

Plaintiff's SAC alleges causes of action for federal false claims based on the AKS (Counts One and Two), false claims for causing the submission of off-label billings (Count Three and Four), and false claims for the fraudulent promotion of Integrilin (Count Five). Plaintiff's claims are all rooted in the federal FCA, but additional causes of action based on corresponding state law statutory provisions are also made on behalf of both California (Count Seven) and 27 other states (Counts Eight through Thirty Four). While the Second and Fourth Claims are pled against Schering-Plough alone, the remaining claims are asserted against all named Defendants, including Millenium.

As indicated above, with respect to Relator's claims that Defendants promoted "combination use" of Integrilin along with other drugs, this Court has already found those allegations to be foreclosed by the FCA's "public disclosure" bar. Unless a relator can show he qualified as an "original source" of the disclosure, that bar strips courts of jurisdiction over qui tam actions where the allegations or transactions underlying the claimed fraud have already been "publicly disclosed." 31 U.S.C. § 3730(e)(4)(A) (2006). The Court based its finding that the public disclosure bar applied on the fact that key allegations made in Relator's complaint had already disclosed three years before the filing of this action in a state court case filed in South Carolina.

Now, through the present motion, Millenium asserts that any remaining claims levied against it were previously disclosed in five separate federal lawsuits filed between February and July of 2007 in Pennsylvania, Massachusetts and Florida. Those claims include allegations that Millenium schemed and conspired to induce healthcare providers to use Integrilin through activities ranging from the funding of grants, speakers, honoraria, and meals, all designed to promote the drug and encourage the submission of false claims to the government. Because the previous federal actions identified similar forms of kickbacks, including lavish entertainment, questionable speaker fees or

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honorariums, and phony grants, Millenium claims that Relator's attempt to levy substantially the same allegations in this matter is foreclosed.

STANDARD

Federal courts are courts of limited jurisdiction, and are presumptively without jurisdiction over civil actions. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994). The burden of establishing the contrary rests upon the party asserting jurisdiction. Id. Because subject matter jurisdiction involves a court's power to hear a case, it can never be forfeited or waived. United States v. Cotton, 535 U.S. 625, 630 (2002). Accordingly, lack of subject matter jurisdiction may be raised by either party at any point during the litigation, through a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1). Arbaugh v. Y&H Corp., 546 U.S. 500, 506 (2006); see also Int'l Union of Operating Eng'rs v. Cnty. of Plumas, 559 F.3d 1041, 1043-44 (9th Cir. 2009). Lack of subject matter jurisdiction may also be raised by the district court sua sponte. Ruhrgas AG v. Marathon Oil Co., 526 U.S. 574, 583 (1999). Indeed, "courts have an independent obligation to determine whether subject matter jurisdiction exists, even in the absence of a challenge from any party." Id.; see Fed. R. Civ. P. 12(h)(3) (requiring the court to dismiss the action if subject matter jurisdiction is lacking). There are two types of motions to dismiss for lack of subject matter jurisdiction: a facial attack, and a factual attack. Thornhill Publ'g Co. v. Gen. Tel. & Elec. Corp., 594 F.2d 730, 733 (9th Cir. 1979). Thus, a party may either make an attack on the allegations of jurisdiction contained in the nonmoving party's complaint, or may challenge the existence of subject matter jurisdiction in fact, despite the formal sufficiency of the pleadings. Id.

When a party makes a facial attack on a complaint, the attack is unaccompanied by supporting evidence, and it challenges jurisdiction based solely on the pleadings. Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004). If the motion to dismiss constitutes a facial attack, the Court must consider the factual allegations of the

complaint to be true, and determine whether they establish subject matter jurisdiction. Savage v. Glendale High Union Sch. Dist. No. 205, 343 F.3d 1036, 1039 n.1 (9th Cir. 2003). In the case of a facial attack, the motion to dismiss is granted only if the nonmoving party fails to allege an element necessary for subject matter jurisdiction. Id. However, in the case of a facial attack, district courts "may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment." Safe Air for Everyone, 373 F.3d at 1039.

In the case of a factual attack, "no presumptive truthfulness attaches to plaintiff's allegations." Thornill, 594 F.2d at 733 (internal citation omitted). The party opposing the motion has the burden of proving that subject matter jurisdiction does exist, and must present any necessary evidence to satisfy this burden. St. Clair v. City of Chico, 880 F.2d 199, 201 (9th Cir. 1989). If the plaintiff's allegations of jurisdictional facts are challenged by the adversary in the appropriate manner, the plaintiff cannot rest on the mere assertion that factual issues may exist. Trentacosta v. Frontier Pac. Aircraft Ind., Inc., 813 F.2d 1553, 1558 (9th Cir. 1987) (quoting Exch. Nat'l Bank of Chi. v. Touche Ross & Co., 544 F.2d 1126, 1131 (2d Cir. 1976)). Furthermore, the district court may review any evidence necessary, including affidavits and testimony, in order to determine whether subject matter jurisdiction exists. McCarthy v. United States, 850 F.2d 558, 560 (9th Cir. 1988); Thornhill, 594 F.2d at 733. If the nonmoving party fails to meet its burden and the court determines that it lacks subject matter jurisdiction, the court must dismiss the action. Fed. R. Civ. P. 12(h)(3).

A court granting a motion to dismiss a complaint must then decide whether to grant leave to amend. Leave to amend should be "freely given" where there is no "undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment . . . ." Foman v. Davis, 371 U.S. 178, 182 (1962); Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003) (listing the Foman factors as those to be considered when deciding whether to grant leave to amend). Not all of these factors

merit equal weight. Rather, "the consideration of prejudice to the opposing party . . . carries the greatest weight." Id. (citing DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 185 (9th Cir. 1987)). Dismissal without leave to amend is proper only if it is clear that "the complaint could not be saved by any amendment." Intri-Plex Techs. v. Crest Group, Inc., 499 F.3d 1048, 1056 (9th Cir. 2007) (citing In re Daou Sys., Inc., 411 F.3d 1006, 1013 (9th Cir. 2005); Ascon Props., Inc. v. Mobil Oil Co., 866 F.2d 1149, 1160 (9th Cir. 1989) ("Leave need not be granted where the amendment of the complaint . . . constitutes an exercise in futility . . . .")).

ANALYSIS

A. The "Public Disclosure" Bar: Initial Considerations

If a public disclosure has occurred and the Relator cannot qualify as an "original source" of the false claim allegations, this Court lacks jurisdiction under the FCA over the previously disclosed allegations. See Rockwell Int'l Corp. v. United States, 549 U.S. U.S. 457,472-73 (2007; United States ex rel. Meyer v. Horizon Health Corp., 565 F.3d 1195, 1199 (9th Cir. 2009). The resulting "public disclosure" bar seeks to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" in which "opportunistic plaintiffs who have no significant information to contribute of their own" seek to collect a share of the government's recovery. Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 295 (2010).

By its Memorandum and Order filed March 26, 2014 in this matter (ECF No. 105), this Court determined that the statutory bar, in effect at the time Relator's initial complaint was filed on November 4, 2009, governs. As amended in 2006, that public disclosure bar precludes jurisdiction over a qui tam action "based upon" previously disclosed allegations, unless the party bringing the action qualifies as an "original source of the information already disclosed:

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> **No court shall have jurisdiction over an [FCA qui tam] action . . . 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 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)(A) (2006) (emphasis added).

The 2006 statute goes on to define the term "original source" as follows:

> For purposes of this paragraph, "original source" means 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.

Id. at § 3730(e)(4)(B).

With these statutory provisions in mind, the Court next analyzes whether the allegations made by the federal case previously filed in 2007 are sufficient to constitute a public disclosure. If they are, then Plaintiff can avoid the jurisdictional bar only upon a showing that he is an "original source" as defined by the statute and case law. A-1 Ambulance Ser., Inc. v. California, 202 F.3d 1238, 1243 (9th Cir. 2000) (under two part test court need only address the original source issue if it first determines a prior public disclosure has occurred). Relator bears the burden of establishing that he qualified as an original source. See United States v. Alcan Elec. & Eng'g, Inc., 197 F.3d 1014, 1018 (9th Cir. 1999) (holding that a relator bears the burden of establishing subject matter jurisdiction, including whether he is an "original source" under the statute).

Turning first to the initial question of disclosure itself, in order to determine whether the requisite dissemination has occurred, the court must make "two distinct but related determinations." A-1 Ambulance Serv., 202 F.3d at 1243. First, it must "decide whether the public disclosure originated in one of the sources enumerated in the statute." Id. If so, then the court must then decide "whether the disclosure consisted of the allegations or transactions giving rise to the relator's claims. . . ." Id.

The 2006 version of the statute unquestionably applies to actions filed in federal court like the six 2007 lawsuits cited by Millenium, so the initial determination as to whether the allegations originated from a source enumerated within the statute can easily be answered in the affirmative.

The second prong creates more difficulty. In order to constitute public disclosure, "the publicly disclosed facts need not be identical with, but only substantially similar to, the relator's allegations," U.S. ex rel. Meyer v. Horizon Health Corp., 565 F.3d 1195, 1199, (9th Cir. 2009), and need not be accompanied by "an explicit allegation of fraud." Hagood v. Sonoma Cnty. Water Agency, 81 F.3d 1465, 1473 (9th Cir. 1996). All that is required for a public disclosure is that the "material elements" of the underlying "transaction" be disclosed in the public forum. A-1 Ambulance Serv., 202 F.3d at 1243. In order to be preclusive, disclosure need not necessarily be comprehensive, but must only contain "enough information to enable the government to pursue an investigation." Alcan Elec., 197 F.3d at 1019.

Since prior public disclosures need not be identical with a Relator's subsequent allegations to trigger the public disclosure bar, it follows that the standard for applying the bar is not an onerous one. See Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S. Ct. 1885, 1891-92 (2011) (admonishing courts against construing the public disclosure bar too narrowly); Hagood, 81 F.3d at 1476 n.18 (9th Cir. 1996) (characterizing "based upon" test as a "quick trigger"). Indeed, courts construe the "based upon" language of 31 U.S.C. § 3730(e)(4)(A) liberally to prevent the "flourishing of parasitic suits" that Congress sought to curtail with the public disclosure bar. United States ex rel. Biddle v. Bd. of Trs. of Stanford Univ, 161 F.3d 533, 537-40 (9th Cir. 1998). Public disclosures that contain substantially similar allegations or transactions to those later levied by a Relator suffice. Meyer, 565 F.3d at 1199; United States ex rel. Boothe v. Sun Healthcare Group, Inc., 496 F.3d 1169, 1174 (10th Cir. 2007) (dismissing where "the essence" of FCA claim was contained in "a prior public disclosure.").

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B. Prior Federal Lawsuits Identify the Same Alleged Kickbacks Identified by Relator in this Proceeding

Relator herein alleges that Millenium participated in a scheme and conspiracy to induce healthcare providers to use Integrilin through various means. According to the SAC, the activities employed in that regard included funding grants (SAC, ¶¶ 6,7), paying speaker fees (Id. at ¶¶ 6, 7, 82-83, 99, 102, 104, 121,133-34), providing honoraria (Id. at ¶ ¶ 7, 82, 104-106), furnishing meals (Id. at ¶¶ 7, 14, 82, 91, 100, 102, 104-13, 116, 133-34) and funding preceptorships and advisory boards (Id. at ¶ 99). Relator alleges that these activities violated both the FCA and the AKS.

Examination of the five federal cases cited by Millenium shows markedly similar allegations with respect to the promotion of Integrilin. In a federal complaint filed in Pennsylvania on February 16, 2007, Plaintiffs alleged that Millenium had "co-promoted Integrilin" with Schering since 1998 (Def.'s Request for Judicial Notice ("RJN"), Ex. 1 at ¶¶ 37-38) and that Schering and its "co-conspirators" had engaged in a scheme to "defraud" by causing Integrilin (along with other "Subject Drugs") to be prescribed "due to kickbacks, bribes and payment or provision of illegal remuneration or other inducements." Id. at ¶¶ 177-80; see also id. at ¶ 2 (defining "Subject Drugs" as including Integrilin). The complaint went on to specifically reference both the FCA and the AKS (id. at ¶¶ 10, 13-16). It alleged kickbacks that ran afoul of both Medicare, Medicaid, and TRICARE program regulations (id. at ¶¶ 13-16), alleged that defendants' conspiracy included an intent to "violate federal and state laws and to defraud" (id. at ¶ 178), and described thirteen forms of kickbacks, including "lavish entertainment," "phony speaker fees a/k/a 'honorariums,'" "phony grants," "phony preceptorships," and "[u]sing 'advisory board meetings' as inducements." Id. at ¶ 4.

Second, a federal complaint filed in Massachusetts roughly two months later, on April 4, 2007, contained similar allegations. There, plaintiffs also alleged that Millenium had "co-promoted Integrilin with Schering since 1998 (RJN Ex. 2 at ¶ 31), and that the companies co-conspired to "defraud" by causing Integrilin, along with other "Subject

Drugs," to be "prescribed . . . due to kickbacks, bribes and payment of provision of illegal remuneration or other inducements." Id. at ¶ 90; see also id. at n.1 (defining "Subject Drugs as including Integrilin"). According to the Massachusetts complaint, the conspirators "discussed and agreed" to "offer" kickbacks to "further proper sales of these Subject Drugs for both indicated and off-label uses" to obtain "additional revenues and profits from the illegal promotion and sale." Id. at ¶ 94(a); see also id. at ¶ 75(c) (alleging that "kickbacks, bribes and/or other payments or provision of illegal remuneration or inducements [were provided] to induce physicians and other healthcare providers" to prescribe the drugs).

Essentially identical allegations were repeated in two more federal complaints filed in Massachusetts on April 27, 2007, and May 10, 2007, respectively. RJN Exs 3, 4. Then, on July 3, 2007, yet another plaintiff, this time in Florida, filed a federal complaint alleging that Millenium had "co-promoted Integrilin" with Schering since 1998 (RJN Ex. 5 at ¶¶ 28-29). That complaint, similar to its predecessors, alleged that the companies "engaged in a continuing conspiracy and/or concerted action to violate federal and state laws and to defraud" by causing physicians to prescribe Integrilin (and other "Subject Drugs") due to "kickbacks, bribes and payment or provision of illegal remuneration or other inducements." Id. at ¶ 87. The purported kickback scheme took multiple forms, including "phony speaker fees paid for by honorariums" (id. at ¶ 33), "phony grants" (id. at ¶ 34), "lavish entertainment and excessive gift-giving" in connection with investigator and speaker meetings. Id. at ¶ 36.

Relator's opposition to the sufficiency of the prior allegations rests exclusively with the proposition that since the allegations of the prior lawsuit relate to a group of "Subject Drugs," the allegations are not specific enough to constitute a public disclosure as to Integrilin itself. Relator does not dispute, however, that the prior lawsuits specifically include Integrilin as one of the seven "Subject Drugs" at issue in those lawsuits. Instead, Relator claims only that such "generic" allegations are insufficient to put the government on notice about a particular scheme to investigate, since allegations relating to multiple

drugs simultaneously cannot suffice.[6] As Millenium points out, however, Relator offers no legal support for its proposition in this regard, and the Court concludes that Relator's argument runs counter to the principles underlying the FCA. As stated above, applicable case law makes it clear that the standard for assessing whether facts have already been disclosed is a liberal one. Prior allegations need only be similar to those subsequently advanced by a Relator; they need not be identical. Meyer, 565 F.3d at 1199. Significantly too, as enumerated earlier in this Memorandum and Order, the Supreme Court made it abundantly clear in Schindler, that the public disclosure bar is properly construed as "wide reaching" and having a broad meaning" and should consequently not be interpreted narrowly. Schindler, 131 S. Ct. at 1891-92. The fact that the prior 2007 complaints at issue here used the term "Subject Drugs" to avoid repeating the names of seven drugs—one of which was Integrilin—hundreds of times does not make the allegations any less compelling given the broad interpretation that mandated by applicable case law. Consequently this Court finds that the prior allegations of Integrilin being included within a list of "Subject Drugs" subject to remarkably similar allegations of kickbacks and "off market" use is more than enough to constitute prior disclosures.

The Court therefore concludes that the allegations in any one of the five 2007 cases were sufficient to support a governmental investigation into allegedly improper marketing schemes and alleged kickbacks provided by Millenium as the co-promoter of Integrilin. When viewed collectively, however, such a determination is inescapable.

C. The Prior Federal Lawsuits Also Allege Similar Off-Label Use

Relator fares no better with respect to his additional allegations that Millenium caused the submission of false claims by "presenting physicians with false information about off-label uses of Integrilin and encouraging physicians to prescribe Integrilin for such uses and procure the drug for such uses which were not approved by the FDA or any relevant drug compendium." SAC, ¶ 157. According to Relator, such improper

[6] Relator asserts that the only marketing allegation made with regard to Integrilin alone (as opposed to Integrilin included within the enumerated "Subject Drugs") rests with the provision of free samples of Integrilin, an allegation not made in the prior 2007 lawsuits.

promotion "caused physicians and facilities to submit numerous bills for Integrilin that were ineligible for reimbursement under Medicaid, Medicare, and TRICARE because the drug [was] used for an off-label use." Id.; see also id. at ¶ 163 (Defendants, including Millenium, made "false and fraudulent representations "to physicians that Integrilin was safe and effective for use in off-label patient populations.").

Comparing these allegations to the prior 2007 federal complaints, we again see striking parallels. The Pennsylvania action, filed February 16, 2007, alleges that Millennium, along with Schering, promoted Integrilin (and other "Subject Drugs") for "non-indicated/unapproved or 'off-label' uses." Id. at ¶ 3; see also id. at ¶ 2 (defining "Subject Drugs" as including Integrilin). The complaint went on to allege that the purported conspirators, including both Schering and Millenium, created a ""fraudulent scheme" to derive "huge profits from their illegal and improper promotions of these Subject Drugs for off label uses . . . ." Id. at ¶ 182(a). Moreover, the federal complaint filed in Massachusetts on April 4, 2007, similarly identified wrongful prescriptions of Subject Drugs, including Integrilin, "for off-label uses that were not approved by the FCA and were not scientifically proven to be safe, efficacious, effective, or useful for the conditions for which such Subject Drugs were prescribed, administered or otherwise provided." RJN Ex. 2 at ¶ 91. The same off-label allegations were levied in the other two Massachusetts complaints filed on April 27, 2007, and May 10, 2007, RJN Ex. 3; at ¶ 2; RJN ex. 4 at ¶ 2. Moreover, with regard to the July 3, 2007, Florida lawsuit, the plaintiff in that case contended that Millenium, along with Schering, engaged in a "conspiracy and/or concerted action to defraud" by causing Integrilin to be prescribed (along with other "Subject Drugs) "for off label uses that were not approved by the FDA and were not scientifically proven to be safe, efficacious, effective or useful. RJN Ex. 5 at ¶ 88. All of these allegations are substantially similar to those alleged by Relator herein.

Therefore, with respect to both Relator's kickback and off-label use allegations, the Court finds the present complaint is "based upon" public disclosures previously made

in a statutorily enumerated source, here the five 2007 complaints filed in federal court. 31 U.S.C. § 3730(e)(4)(A) (2006).

D. Relator Cannot Qualify as an Original Source

Relator can still establish subject matter jurisdiction, however, if he can show he qualified as an "original source" for his kickback and off-label FCA claims against Millenium. Id. Ninth Circuit law makes it clear that in order "[t]o qualify as an original source, a relator must show that he or she [1] has direct and independent knowledge of the information on which the allegations are based, [2] voluntarily provided the information to the government before filing his or her qui tam action, and [3] had a hand in the public disclosure of allegations that are a part of . . . [the] suit." Meyer, 565 F.3d at 1201 (citing U.S. ex rel. Lujan v. Hughes Aircraft Co., 162 F.3d 1027, 1033 (9th Cir. 1998)). Although only the first two requirements are explicitly set forth in the statute (the 2006 version of 31 U.S.C. § 3730(e)(4)(B)), the Ninth Circuit has found the third and final prerequisite to be an "additional requirement" implicit in the statutory scheme. United States v. Johnson Controls, Inc., 457 F.3d 1009, 1013 (9th Cir. 2006) (citing Wang ex rel. U.S. v. FMC Corp., 975 F.2d 1412, 1418 (9th Cir. 1992)).

The Wang court underscores the need to impose the third requirement by explaining that if "someone republishes an allegation that already has been disclosed, he cannot bring a qui tam suit, even if he had 'direct and independent knowledge of the fraud. He is no 'whistleblower.' A 'whistleblower' sounds the alarm; he does not echo it." Wang, 975 F.2d at 1419.

Although it appears that given Relator's position as a salesmen for Defendants he may well have direct and independent knowledge of the subject matter of the allegedly fraudulent claims, and while Relator claims he did provide the information to the government before filing his suit, it looks uncontroverted that he had nothing to do with the initial public disclosure made in the five federal lawsuits filed in 2007, some two years before Relator filed the present qui tam action in 2009. Relator has presented no evidence that he "had a hand" in the prior 2007 litigation. To demonstrate such

involvement, Relator "must have directly or indirectly been a source to the entity that publicly disclosed the allegations on which [the] suit was based." Wang, 975 F.2d at 1418 (quoting United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 16 (2nd Cir. 1990)). As Millenium notes, Relator was not a plaintiff in any of the prior lawsuits that alleged kickbacks and off-label promotion to increase Integrilin sales, and was not mentioned as a source of information in any of the complaints. Not surprisingly, Relator makes no attempt to connect himself with the public disclosures made in that case, a shortcoming which prevents him from qualifying as an "original source" that would permit him to maintain this qui tam suit with respect to the kickback and off-label allegations he asserts.

In sum, then, Millenium has demonstrated that the gravamen of Relator's remaining claims against it were already publicly disclosed in the prior 2007 federal lawsuits. Because Relator has not met his burden of proof in showing that he was an original source of those allegations, the public disclosure bar applies and prevents Relator from maintaining any of the three causes of actions rooted in the federal FCA and asserted against Millenium. In addition, although Relator goes on to assert some additional claims predicated on the false claims laws of some 28 states, because those claims also hinge on the same false claim analysis set forth above, they too fail as against Millenium. Moreover, even were the state law claims to have some viability apart from the merits of the federal FCA claims alleged against Millenium, which the Court believes they do not, in the absence of any predicate federal claim the Court declines to exercise supplemental jurisdiction over the state law claims against Millenium in any event. See Gorstein v. World Savings Bank, 110 F. App'x 9, 10-11 (9th Cir. 2004) (district court has discretion to decline to exercise supplemental jurisdiction).

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CONCLUSION

For all the reasons stated above, Defendant Millenium's Motion to Dismiss, ECF No. 114, is GRANTED. Because the Court does not believe that the jurisdictional infirmities of Relator's claims against Millenium can be rectified through further amendment, no additional leave to amend will be permitted. Finally, since the Court concludes that it lacks jurisdiction over Relator's claims against Millenium in the first instance, Millenium's alternative motions challenging the substance of Relator's claims are moot. Plaintiff's Motion to Dismiss (ECF No. 116) and Motion to Strike (ECF No. 117) are accordingly DENIED on that basis.

IT IS SO ORDERED.

Dated: March 25, 2015

MORRISON C. ENGLAND, JR, CHIEF JUDGE
UNITED STATES DISTRICT COURT