UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, 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") The 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. In so doing, according to Relator, Defendants "caused" physicians to improperly prescribe the drugs and in so doing 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 for reimbursement. 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 filed on behalf of each of the Defendants, Relator filed his First Amended Complaint ("FAC") on June 27, 2013.

Presently before the Court are three motions attacking the viability of Plaintiff's FAC. Defendants Schering-Plough and Merck have filed a joint Motion to Dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1)[1] on grounds that Relator's complaint is barred by the FCA's so called "public disclosure" bar.[2] Alternatively, all three Defendants contend that the allegations of the Relator's FAC fail to state a viable claim against them in any event. They have filed two additional motions to that effect, one presented jointly by Schering-Plough and by Merck, and the other submitted on behalf of Millennium. Those Motions argue that that the various causes of action pled in the FAC are substantively deficient in contravention of Rule 12(b)(6) and, further, that the FAC's allegations of fraud are not pled with sufficient particularity under Rule 9(b).

As set forth below, Defendants' Motion under Rule 12(b)(1) will be granted. The remaining Motions will, however, be denied without prejudice at this time.

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

[2] While Millennium did not initially file its own 12(b)(1) motion, ostensibly on grounds that it did not believe the allegations of the FAC underlying the jurisdictional motion were directed towards Millennium, once it became clear during the course of the briefing on this motion that that was not the case, Millennium moved to join the Rule 12(b)(1) Motion filed by Schering-Plough and by Merck. See Millennium's Mot., ECF No. 80 at 12, n.5. Because the arguments posed by the Motion apply equally to Millennium, and since there is no difference between Millennium's position with respect to the jurisdictional issue and that of Schering-Plough and Merck, the Court will deem the Rule 12(b)(1) motion to have been brought on behalf of all three Defendants.

BACKGROUND

Integrilin 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 that covers 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").

Food and Drug Administration ("FDA") approval for Integrilin use 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 later merged with Merck in November of 2009 to form a new company, Defendant Merck & Co.

Relator contends that Defendants facilitated the presentation of false reimbursement claims by doctors and hospitals by promoting the prescription of Integrilin in particular, in combination with other drugs,[3] without properly disclosing the dangers implicit in such combinations. Plaintiff further alleges other allegedly improper uses of Integrilin, including its early use for STEMI patients. Relator also 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-7(b)(2)(B). Relator alleges that Defendants violated the AKS by

[3] Both tenecteplase and heparin were specifically targeted by the FAC as some of the drugs used in combination with Integrilin, along with other anti-platelets, anti-coagulants, and other GPIIb/IIIa inhibitors. See FAC ¶¶ 50, 52, 54-55, 57

"funnel[ing] millions of dollars" in grants, honoraria, and meals to physicians in order to induce prescribing and to drive "off label" sales (in contravention of FDA approval), all in violation of the AKS. See FAC, ¶ 6-7, 153-57.

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

The FAC now at issue alleges causes of action for false claims based on the AKS, false claims for causing the submission of off-label billings, and false claims for the fraudulent promotion of Integrilin. There are additional claims made with respect to another drug, Avelox. 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 31 different states.

With respect to Plaintiff's claims that Defendants promoted "combination use" of Integrilin along with other drugs, Defendants claim that allegation is foreclosed by the FCA's "public disclosure" bar. That bar strips courts of jurisdiction over qui tam actions where the allegations or transactions underlying the claimed fraud have already been "publicly disclosed," unless a relator can show he qualified as an "original source" of the disclosure. 31 U.S.C. § 3730(e)(4)(A) (2006). Defendants allege that key allegations made in Relator's complaint were already disclosed three years before the filing of this action in a state court case filed in South Carolina. That case, entitled Bentley v. Med. Univ. of S.C., et al., 2006-CP-3164, 2006,[4] was filed following the death of a patient who died after receiving Integrilin in combination with other drugs, specifically tenecteplase and heparin.

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[4] A copy of the Complaint filed in Bentley on August 14, 2006, is attached as Exhibit 1 to Defs.' Rule 12(b)(1) Motion (ECF No. 84). The case will be referred to as "Bentley" throughout the remainder of this Memorandum and Order.

Plaintiff in the Bentley case alleged that Millennium and Schering Plough,[5] who were both named as Defendants, were negligent for failing to warn physicians of the dangers in using the drugs together, and for marketing the drug for use in combination with tenecteplase and heparin. Given the similarity of the underlying allegations made in Bentley and those levied in the present case with regard to such combination use, Defendants assert that the "public disclosure" bar precludes such allegations from being litigated here.

STANDARD

A. Rule 12(b)(1)

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

[5] Merck and Co. is not named as a Defendant in Bentley, apparently because Merck's interest in the drug did not begin until after it merged with Schering-Plough in 2009, as stated above.

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. n 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).

B. Rule 12(b)(6)

On a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), all allegations of material fact must be accepted as true and construed in the light most favorable to the nonmoving party. Cahill v. Liberty Mut. Ins. Co., 80 F.3d 336,337-38 (9th Cir. 1996). Rule 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). A complaint attacked by a Rule 12(b)(6) motion to dismiss does not require detailed factual allegations. However, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. (internal citations and quotations omitted). A court is not required to accept as true a "legal conclusion couched as a factual allegation." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1950 (2009) (quoting Twombly, 550 U.S. at 555). "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555 (citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1216 (3d ed. 2004) (stating that the pleading must contain something more than "a statement of facts that merely creates a suspicion [of] a legally cognizable right of action.")).

Furthermore, "Rule 8(a)(2) . . . requires a showing, rather than a blanket assertion, of entitlement to relief." Twombly, 550 U.S. at 556 n.3 (internal citations and quotations omitted). Thus, "[w]ithout some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirements of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests." Id. (citing 5 Charles Alan Wright & Arthur R. Miller, supra, at § 1202). A pleading must contain "only enough facts to state a claim to relief that is plausible on its face." Id. at 570. If the "plaintiffs . . . have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." Id. However, "[a] well-pleaded complaint may proceed

even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" Id. at 556 (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)).

C. Leave to Amend

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

The "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).

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As indicated above, if public disclosure has occurred and Relator cannot qualify as an "original source" of the false claim allegations, this Court lacks jurisdiction over the previously disclosed allegations.

Defendants urge the Court to apply the public disclosure bar in effect at the time Relator's initial complaint was filed on November 4, 2009. As amended in 2006, that bar provides as follows:

> **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). In 2010, the FCA was amended to limit the bar to federal proceedings, which in the present case would exempt the allegations of the South Carolina Bentley case from constituting a public disclosure bar since that case was filed in state court.

Therefore, before the Court even examines the allegations of Bentley, it must first determine if indeed the 2010 version of the FCA, as opposed to its 2006 predecessor, applies. Obviously, if the 2010 version is operative, the Bentley case cannot form the predicate disclosure.

Relator's contention that the 2010 amendments to the FCA should retroactively apply is incorrect. First, the Supreme Court, in Graham, notes that the 2010 amendments contain no mention of retroactivity, which would be necessary in order to

apply the 2010 statute to cases already pending like Relator's action herein. Graham, 559 U.S. at 283 n.1. Because making the statutory bar less stringent by limiting its application to federal disclosures would result in more plaintiffs able to sue, the 2010 amendment creates a substantive change in the law. As such, the amendment is presumed not to apply retroactively to conduct occurring before its passage. See Hughes Aircraft Co. v. U.S. ex rel. Schumer, 520 U.S. 939, 946-47 (1997).

The fact that Relator here amended his complaint after the statute was amended does not change this result. Where a relator seeks to amend his qui tam complaint, the applicable version of the public disclosure bar remains the one in effect when the original complaint was filed. U.S. ex rel. Doe v. Staples, Inc., 932 F.Supp.2d 34, 39 n.1. (D.D.C. 2013). This is not surprising given the general rule that an amended complaint is deemed to relate back to the date of its original filing. Martell v. Trilogy, Ltd., 872 F.2d 322, 323 (9th Cir. 1989).

Having determined that the 2006 statute should apply, the Court next analyzes whether the allegations of the South Carolina Bentley case are sufficient to constitute a public disclosure. If they are, then Plaintiff can avoid the jurisdictional bar only if he can show 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.

Under the 2006 version of the FCA, it is clear that a state "criminal, civil or administrative hearing" may qualify as a disclosure. Graham County, 559 U.S. at 286, 290. This encompasses disclosures in state court. U.S. ex rel. Green v. Northrop Corp., 59 F.3d 953, 966-67 (9th Cir. 1985), and extends to both a state complaint itself as well as any filings or other materials disclosed in the course of state court litigation. Alcan Elec., 197 F.3d at 1020. Because the disclosures in Bentley were made in the context of a complaint filed in state court, the first prong of the requisite two-part test for determining disclosure is unquestionably satisfied. 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.

Defendants maintain that Relator's claims about the "combination use" of Integrilin with other drugs was already disclosed in the Bentley lawsuit. Relator's FAC alleges, among other things, that Defendants promoted the use of Integrilin in combination with thrombolytic agents and heparin. According to the FAC:

> [U]nsafe and inappropriate combination uses of Integrilin are widely known to lead to bleeding. Bleeding risk is the primary safety concern with Integrilin, and in numerous medical studies the bleeding risk increased when Integrilin was given in combination with other anti-platelets, anti-coagulants, and other GPIIb/IIIa inhibitors. Schering's fraudulent strategy included the promotion [of] Integrilin for "early use" or "upstream" in STEMI patients – what is otherwise known in the scientific literature as "Facilitated PCI". Facilitated PCI is

> the pretreatment of patients with a GP IIb/IIIa inhibitor and/or a thrombolytic agent before being diagnosed, indicated, or transferred for PCI. However, promotion of combination use, or "combo use" as the sales rep called it, of Integrilin, especially prediagnosis, was never appropriate: it was extremely dangerous, off-label, and fraudulent.

FAC, ¶ 5.

According to Relator, publicly available studies looked at the combination of Integrilin along with tenecteplase, a thrombolytic agent, and the anti-coagulant heparin, and identified increased bleeding risk. FAC, ¶¶ 50, 52-55, 57. In the Bentley complaint, filed August 14, 2006, more than three years before the institution of the present lawsuit, the plaintiff alleged that:

> Millenium and Schering-Plough were negligent in the. . . marketing, advertising and sale of Integrilin in at least the following respects:
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> > a) in failing to adequately warn physicians who would prescribe the drug of its danger of causing intracranial bleeds;
> >
> > b) in failing to adequately warn physicians who would prescribe the drugs of the dangers of using it in combination with tenecteplase and heparin; [and]
> >
> > c) in marketing the drug for use in combination with tenecteplase and heparin.

Bentley Complaint, Ex. 1 to Defs.' Mot., ¶ 24.

The FAC in this matter, at 145 pages, obviously contains far more detail than the 6-page complaint in Bentley. The FAC contains allegations, for example, of the numbers of instances where combination use of the drugs affected various individuals (such as the number of people who experienced death, congestive heart failure, major bleeding, and severe and moderate bleeding, for example, see FAC ¶50). Nonetheless, at least as far as the drug combination itself is concerned, Defendants allege that Bentley sufficiently disclosed the material elements of the claims in that regard advanced by the FAC. According to Defendants, the core allegation of Bentley's combination use allegations are the same as Relator advances herein; namely, that Defendants

marketed Integrilin for use in combination with other drugs, including a thrombolytic agent, tenecteplase, and an anti-coagulant, heparin, and failed to adequately warn doctors of the risk of bleeding associated with such combined use.

Given the fact that the allegations need not be the same, or presented in the same detail, to qualify as a public disclosure under the applicable case law, the Court agrees with Defendants that the Bentley case does qualify as a disclosure for purposes of Relator's "combination use" allegations in this FCA case. See U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 655 (D.C. Cir. 1994) ("a qui tam action cannot be sustained where all the material elements of the fraudulent transaction are already in the public domain [even when] the qui tam relator comes forward with additional evidence incriminating the defendant."). Even Relator appears to concede the weakness of his position by initially arguing that no public disclosure occurred solely on grounds that the 2010 amendment, with its requirement that the disclosure be in a federal as opposed to state proceeding, applies. Otherwise, all Relator says is that the Bentley complaint still should not qualify because it alleged only that defendants acted negligently in the marketing of Integrilin as opposed to more specific "fraudulent" allegations made within the FAC . Given the fact, however, as discussed above, that specific allegations of fraud are not necessary as long as the allegations are substantially similar, the Court does not find that distinction persuasive. Bentley sufficiently disclosed the same core elements of the claims made in Plaintiff's FAC with respect to drug combinations.

This is not the end of the inquiry, however, since as stated above a relator can still pursue a qui tam claim, even once a public disclosure has occurred, provided that he or she qualifies as an "original source" under the terms of the statute. 31 U.S.C. § 3730(e)(4)(A).

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 Solis' 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 Solis 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 in Bentley, and therefore cannot qualify as an original source. There is no indication that Relator Solis had anything to do with the Bentley litigation. All Relator says is that the language of the 2010 amendments changes any inferred third requirement, a position which makes no difference since it is the 2006 version of the statute that applies. Other than that distinction, Relator concedes that the Ninth Circuit requires, at least under the prior 2006 version of the statute, that the Relator have a hand in the public disclosure. See Relator's Opp'n, ECF No. 89 at 6 n.2. Here, as Defendants point out, the FAC contains no allegations that Relator promoted, or witnessed anyone else, promoting Integrilin in combination with other drugs. Since the Bentley litigation was filed on August 14, 2006, it makes sense that Relator had nothing to do with the public disclosure of the combination use allegations in Bentley.

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 combination use allegations.

Plaintiff's combination use claim, however, does not encompass the entirety of his lawsuit, which, as stated above, contains allegations pertaining to another completely different drug, Avelox, as well as allegations of fraud in promoting and marketing Integrilin, claims that Defendants caused the submission of improper off-label bills to Medicaid, Medicare and TRICARE, and assertions that Defendants illegally paid kickbacks to facilitate additional sales of Integrilin and/or Avelox. The combination use allegations that the Court finds Plaintiff cannot maintain in the present qui tam action extend across the various Counts pled in the FAC, and are substantially intertwined with the extensive factual narrative contained within the FAC's 145 pages. Defendants represented at the time of the oral argument in this matter, held on November 14, 2013, that the combination use allegations permeated at least 23 paragraphs of the factual allegations contained within the FAC, as well as unspecified portions of three of the five Counts pled as FCA violations. The Court's examination of the subject paragraphs indicates that it is by no means uniformly clear whether all or just portions of those paragraphs pertain to the foreclosed combination use. Additionally, by bringing their jurisdictional motion as a Motion to Dismiss rather than a Motion to Strike, it would be improper for the Court to strike particular paragraphs and/or other portions of the FAC in any event. The only prudent course of action, given the fact that the Court is granting Defendants' Motion to Dismiss, is to direct Plaintiff to file a Second Amended Complaint ("SAC") that eliminates the combination use allegations. Given the fact that those allegations without question figured prominently in Plaintiff's FAC, a very different SAC could in fact be forthcoming.

This brings us to the second and third motions submitted by Defendants, which as stated above are substantive challenges to the sufficiency of Plaintiff's FAC under

Rule 12(b)(6) and Rule 9(b). Both motions are similar and to a large extent ask that the Court dismiss, at the pleading stage, allegations which, at least on initial review, would appear to raise numerous issues of disputed fact not amenable to disposition at this time In addition, the Court believes that deciding these motions in the context of a pleading which may substantially change would be an inefficient use of this Court's limited resources since serial motions to dismiss could result, an outcome which may be avoided through further clarification of the pleadings in the wake of this Memorandum and Order.

The Court further notes that Defendants' substantive motions appear to violate the Court's prohibition against briefs or other papers filed in excess of twenty (20) pages. See ECF No. 43, ¶ 8. Although the Points and Authorities filed in support of the Motions to Dismiss filed by Schering Plough/Merck and by Millennium weigh in at exactly 20 pages each, both Motions attack state law equivalents of the federal FCA for 26 states in Schering-Plough/Merck's case and 27 states with regard to Millennium. While the points and authorities for both Motions devote less than a page to these state law claims, they each attach lengthy appendices in a skeletal, table format that summarizes their objections to the state claims. Deciding a motion to dismiss on the basis of such tables would not only be inadequate, it also is improper. Moreover, filing ten page, single-spaced appendices in order to avoid the Court's page limitation for motions in advance of the issuance of a Pretrial Scheduling Order violates the spirit, if not the explicit terms, of the Court's clearly-stated page limitations, particularly since the record shows no evidence that either Defendant submitted any request to exceed those limitations given the nature extent of the involved claims. Consequently, the Court declines to rule on the substantive motions to dismiss for that reason as well. Those motions will be denied, without prejudice, to being renewed following submission of Plaintiff's SAC.

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CONCLUSION

For all the reasons stated above, Defendants' Motion to Dismiss, ECF No. 84, is GRANTED with respect to Defendants Schering-Plough, Merck, and Millennium. Plaintiff is directed to file a Second Amended Complaint not later than twenty (20) days after this Memorandum and Order is electronically filed. Defendants' Motions to Dismiss, ECF Nos. 80 and 82, brought pursuant to Rule 12(b)(6) and 9(b), are DENIED, without prejudice, to being renewed once Plaintiff has filed his Second Amended Complaint.

IT IS SO ORDERED.

Dated: March 25, 2014

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